QATAR UNIVERSITY

COLLEGE OF PHARMACY

EVALUATION OF THE PHARMACOVIGILANCE SYSTEM IN QATAR: A MIXED METHOD STUDY ON STRUCTURE PROCESS, AND OUTCOME

BY

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ABSTRACT

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Title: Evaluation of the Pharmacovigilance System in Qatar: A Mixed Method Study on Structure, Process and Outcome

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Introduction: It is evident that pharmacovigilance (PV) centers are the entities required to ensure medication safety and protect public health from drug-related morbidity and mortality. In many developing countries PV systems are mostly immature or non-existent. In Qatar, a centralized PV center does not exist. Therefore, this research aimed to conduct a comprehensive system assessment by evaluating the current state of PV in Qatar in order to establish a baseline understanding of PV situation and to identify weaknesses and improvement opportunities for PV.

Methodology: This mixed-method case study (i.e., concurrent) provided multiple case evaluation for: a) in-depth subnational PV systems case evaluation, b) comparative case analysis, and c) evaluation of the overall national PV system. Quantitative approach included a cross-sectional descriptive study utilizing the World Health Organization (WHO) PV indicators (i.e., structure, process, and outcome). It included the Ministry of Public Health (MOPH); public sector; private sector; academic institutions; pharmaceutical industry. Descriptive statistics were used to describe systems' performance based on a scoring scheme. Qualitative approaches included semi-structured interviews, document review and field observation. Deductive content analysis was used to analyze qualitative data.

Additionally, the WHO minimum requirements for a functional PV system were employed in the evaluation.

Findings: The WHO five minimum requirements for an operational PV system are not available in Qatar. The overall national PV system achieved a good total system performance status. Most subnational PV systems obtained good total system performance. The MOPH system revealed weak performance status. However, MOPH plans to establish a medication safety program and patient safety reporting system. The highest scores were for structural indicators with most subnational PV systems demonstrating excellent performance. MOPH structural shortfalls included the lack of PV specific legislation, national reporting system, and a dedicated budget for PV. Process indicators revealed good performance status for the public and private sectors. However, existing PV processes are mostly at an early stage of advancement. Outcome indicators showed the weakest performance across the subnational PV systems.

Conclusion: Subnational PV systems strengthening is required to address the identified challenges to effective PV and performance disparities between systems. The overall performance of the country needs to be improved following a system-based approach. It is recommended to: 1) improve PV prioritization in the regulatory, practice and academic agendas; 2) establish effective PV structures, especially PV specific legislation and PV center; 3) target efforts to improve and coordinate PV between national stakeholders; 4) build the national PV system capacity to meet the minimum requirements of WHO. Finally, future research can focus on aspects related to the governance of the PV system and the feasibility of establishing the proposed PV center organizational structure.

DEDICATION

This thesis is dedicated to my family my most treasured gift. It is especially dedicated to my father and mother for their unlimited support and unmatched love. Finally, I am blessed to have amazing siblings, my two brothers and three sisters who have made my life a joyful one.

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"In the Name of Allah, the Most Beneficent, the Most Merciful".

Alhamdulillah for blessing me, guiding me, and for protecting me through this stage of my life.

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ABBREVIATION

ADRs	Adverse Drug Reactions
EMA	European Medicine Agency
GCC	Gulf Cooperation Council
HMC	Hamad Medical Corporation
IPAT	Indicator-Based Pharmacovigilance Assessment Tool
MAHs	Marketing Authorization Holders
MENA	Middle East and North Africa
MMR	Mixed-Method Research
MOPH	Ministry of Public Health
MSH	Management Sciences for Health
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Systems
PHCC	Primary Healthcare Corporation
PHP	Public Health Program
PV	Pharmacovigilance
PV KPIs	Pharmacovigilance Key Performance Indicators
WHO	World Health Organization
UMC	Uppsala Monitoring Centre
USAID	United States Agency for International Development

CHAPTER I: INTRODUCTION

This chapter will introduce the pharmacovigilance field with an emphasis on pharmacovigilance systems and the assessment of such systems. This chapter will demonstrate the concepts behind the planned assessment of the pharmacovigilance system in a Middle Eastern country (i.e., Qatar). It will identify the guiding evaluative framework (i.e., the World Health Organization pharmacovigilance indicators) and the employed research approach (i.e., mixed-methods research). In addition, it will present the problem statement, research rationale, aim and objectives, and study contribution.

1. Background

1.1. Pharmacovigilance

According to the World Health Organization (WHO), pharmacovigilance (PV) is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems" (1). The WHO is a specialized agency established in 1948 for global cooperation in and improvement of public health conditions. The agency falls under the United Nations, and one of its main mandates is to promote the achievement and/or realization of "the highest possible level of health" for the world population at the international level (2).

A series of milestone events shaped the development of drug safety and PV as a distinct scientific discipline (1, 3-6). However, conforming to the WHO interpretation, the official beginning for PV as a science and practice can be traced back to 1961. In 1961, the thalidomide tragedy resulted in thousands of incidences of phocomelia, a congenital malformation that occurred in the infants of pregnant females who were exposed to the drug (1, 7). As a prompt response to the thalidomide tragedy, the World Health Assembly proposed the concept of a global joint project designed for the early

identification of possible occurrences similar to the thalidomide tragedy (7, 8). Later, in 1968, the program was named the WHO Programme for International Drug Monitoring (PIDM). The program was established to serve as a holistic system for the collection of adverse drug reaction (ADR) reports at the international level (9).

The tragedy highlighted the importance of the safety claims produced by pharmaceutical companies being followed up by systematic approaches to validate the information provided in drug safety profiles in the preauthorization stage. Additionally, it highlighted the need for systematic approaches to the collection, assessment, and communication of information on ADRs and other unidentified safety issues during the mass exposure of various populations to medicines that have been tested and found to be safe, efficacious, and of good quality in specifically designed preclinical and clinical studies (1, 4, 5, 7).

At present, the scope of PV covers aspects relevant to ADRs, medication errors, drug-drug interactions, lack of effectiveness of drug products, substandard medications, misuse of medicines, and counterfeit medicines (10). Additionally, contemporary PV is concerned with vigilance regarding various products such as modern medicines, vaccines, traditional medicines, biosimilars, and medical devices (7, 11).

1.2. Pharmacovigilance Systems at the Global Level

In the course of the growth of the PV field, PV systems have been established to perform the necessary PV and drug surveillance activities (10). These systems are the cornerstone for the legal monitoring of authorized medicinal product safety and the oversight responsibility for drug risk-benefit analysis in a country. PV systems are the entities required to safeguard public health and medication safety in a country (12-15). Essentially, they are the basis of the structures, processes and outcomes required to allow effective and prompt detection, collation, and evaluation of adverse events

resulting from the use of medicinal products. Accordingly, they aid in decision making about safety issues, risk communication, and risk management applied in all sectors of a health care system (10, 11). According to the directive of the European Economic Community, a PV system is defined as “a system [that is] used to collect information useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, and to evaluate such information scientifically” (16).

At the international level, the PIDM represents a focal point for member countries to work together in the reporting and analysis of international data on ADRs and signal identification from the collated individual case safety report (ICSR) databases of member countries. The PIDM network consists of the following main actors: a) the WHO headquarters in Geneva, which is concerned with policy issues; b) the Uppsala Monitoring Centre (UMC) in Sweden, which oversees the operational and scientific aspects; and c) member country national PV centers, which are responsible for reporting national data to the international database (i.e., VigiBase) (1, 11).

The number of countries with a specific PV program increased from 10 in 1970 to 136 in 2019, which is promising for the concept of therapeutic product safety surveillance. In the Arab world, 10 countries are full members, and 7 countries are associate members. Associate members do not contribute data to VigiBase (17). With the increased number of national PV centers contributing to the global arena of PV, there is a need to evaluate the functionality and performance of those systems to ensure that their contributions to global PV data and practices are positive and effective (11, 18, 19).

In various countries, the PV system or the activities performed by the system can suffer from deficiencies that affect medication safety, public health, the efficient use of available national resources, and compliance with internationally recognized

standards of public health and safety (20, 21). A questionnaire-based analysis of 55 developing countries indicated that PV system gaps and challenges were related to the slow and ineffective development of PV. Shortfalls were encountered in the establishment of organized PV systems, regulatory frameworks, and governance, as well as in the necessary coordination with international PV actors (e.g., the UMC and WHO) (21). Similarly, an expert review on PV systems in developing countries pinpointed the need to develop more effective regulatory frameworks and legislation specific to the country context. It also highlighted the importance of coordination with global PV professional bodies. In doing so, PV systems will be effectively supported, and their advancement and sustainability will be made feasible (20).

1.3. Pharmacovigilance Systems in the Arab Countries

Recently, PV has been recognized as an important component of the healthcare system among Arab countries. This increased interest has resulted in the development of PV with respect to regulations, concepts, and activities (22, 23). For instance, in 2015, the Arab guideline for PV was developed by the Higher Technical Committee for Medicine under The Arab League (24).

In Arab countries with well-structured PV systems (e.g., Morocco, Jordan, and Egypt), many achievements in PV have been highlighted (23). For instance, Morocco was acknowledged by the first Eastern Mediterranean Region/Arab Countries Meeting of Pharmacovigilance to be a good model for other Arab countries that are striving to build their PV capacity and improve their PV activities. Additionally, Morocco is contributing to the international PV system, as it is one of the collaborating centers of the WHO (23).

Despite the continuous development of PV in the Arab world, the PV system scenario is heterogeneous with respect to the existing structures, processes and achieved

outcomes (25). Such discrepancies in system capacity and maturity have resulted in challenges for many Arab countries, including challenges for committed countries in implementing a successful PV program, establishing a dedicated national PV center, or managing and maintaining a sustainable PV program (25-27).

A study by Qato using official PV key performance indicators (KPIs) to assess PV systems indicated that only 75% of the countries reported the availability of a dedicated workplace for PV, and only one-third of the countries reported the allocation of a specific budget for PV activities. Hence, the low performance of some PV systems in the Arab region is not surprising given the limitations (25). Additionally, in some countries, PV activities suffer from the fragmentation and duplication of stakeholders' efforts, which can be highly detrimental for countries with unstable political systems or financial issues (26).

The literature pertinent to PV in the Arab region has highlighted the importance and need to understand the PV scenario of each country, as Arab region countries are heterogeneous not only with respect to their PV system maturity and performance but also in their developmental, economic, social, political, and cultural characteristics. Therefore, understanding each country's situation will highlight many of the factors that can affect PV system and will help to explain some of the deficiencies affecting the development or implementation of a national PV system (25-28).

2. Research Focus

2.1. Pharmacovigilance System Assessment

The literature has discussed the assessment of PV systems and the development of PV systems in different geographical contexts (10, 11, 29-31). The PV system assessment requires the use of validated PV KPIs for an objective system assessment based on structural, process, and outcome criteria. Evidence collected from studies

utilizing PV KPIs developed by international professional bodies such as the WHO and the Strengthening Pharmaceutical Systems (SPS) Program allows the development of strategic and operational recommendations and can help in the identification of limitations in the systems based on structure, process, and outcome criteria (10, 11, 32).

When evaluating PV systems and where relevant, national PV stakeholders' contributions, as well as objective PV KPIs, should be considered as early as possible to ensure that the PV system evaluation is executed in a systematic and comprehensive manner. The quality of a context-based system evaluation is made more purposeful through national PV stakeholder views and perceptions and is strongly dependent on the nature of the PV challenges present in the country. This information can be used to evaluate the appropriateness of national PV processes and identify solutions to PV challenges (10, 11, 18, 32).

2.2. Pharmacovigilance System in Qatar

The state of Qatar is located in the Arabian Peninsula on the Persian Gulf in the region of the Middle East and North Africa (MENA). Qatar has one of the largest economies in the world, with an estimated population of 2.7 million and a gross domestic product (GDP) of 191 billion USD in 2018, which makes it a high-income country (33). Qatar has experienced tremendous advances in the field of healthcare. In 2014, it had an annual healthcare GDP budget of $3071 per capita, one of the highest among the countries in the Arab region (34). Expatriates constitute 80% of the population and are the major workforce in the country (35).

In the context of Qatar, in 2012, a study by Wilbur indicated the need to establish a national PV center to serve the needs of the population (36). Furthermore, a number of deficiencies were reported in the Qatari Healthcare System, including the absence of an integrated regulatory framework to manage health institutions and

professionals, the lack of a national drug policy, the underprovision of education and training pertinent to medication safety, issues in reporting ADRs and medication safety issues, and a less-than-optimal rate of ADR reporting compared to that in other countries (27, 36, 37).

According to Al Hail et al., the Qatar public sector, namely Hamad Medical Corporation (HMC), has its own ADR reporting form, and PV is considered well structured (38). However, public sector PV activities focus mainly on ADR reporting, which is considered one of the older methods for PV data collection (11, 30). Furthermore, pharmacists at private healthcare institutions have reported problems with the availability of reporting forms (36). Similarly, a survey among community pharmacists in Qatar indicated that the unavailability of reporting forms is a factor that can undermine ADR reporting practices in Qatar (37).

Moreover, concerns have been raised over the underreporting of ADRs among pharmacists in the public sector. Assessment of the knowledge, attitudes, and practices of ADR reporting revealed that the majority had positive attitudes toward ADR reporting. However, 60% of pharmacists reported that they had reported no ADRs during a one-year period. Additionally, a lack of knowledge of ADRs among pharmacists was linked to the underreporting problem (38).

Consequently, there is a need to understand the current status of PV in Qatar since there is no specific PV center to coordinate PV at the national level.

3. Problem Statement

International organizations aimed at the continuous improvement and development of PV, including the WHO and SPS, have concluded that a PV system assessment is an essential step toward establishing a successful and sustainable PV system (10, 11, 32).

According to the WHO, the status of PV in countries around the world is an area of major concern because governments often do not support PV systems. Many factors can lead governments to neglect PV or consider it a nonpriority. For instance, in developing countries or countries with weak PV systems, the resources required to improve, establish, and sustain PV are often limited or mobilized to serve other areas, such as the treatment of prevalent ailments. Furthermore, the human resources needed to provide PV services can be deficient in terms of the number of personnel and/or expertise level. Second, many countries rely on developed nations' safety data, and government and healthcare professionals often incorrectly assume that drugs that have been on the market for many years are entirely safe. Third, the concept of collecting PV data such as ADRs, medication errors, and quality issues can be perceived as a fault in the system by various stakeholders, including government officials, healthcare professionals, patients, and society in general (1, 39).

PV as a concept is considered to be at an early stage of development in Qatar, even though the basic PV practice of ADR reporting is included in the public sector system (36, 38). This sector has indicated the underreporting of ADRs as a challenge for PV (38). This underreporting can be detrimental to the success of PV in Qatar (27, 36, 37). In addition, Al Hail et al. reported a lack of interest, lack of accountability, fear of reporting consequences, false belief in the absolute safety of marketed drugs, and judgment bias as contributing factors to underreporting (38).

As mentioned above, Qatar has no dedicated national program or center for PV. Therefore, the country is an associate member of the PIDM. Associate member countries do not contribute to the global ICSR repository (25-27). Therefore, information on the safety profile of medicines used in the population remains unclear (e.g., genetic factors effect on drug therapy). This information is important for

international PV practices and could be used to alter the safety profiles or manufacturing practices of certain medications used in the population (1).

Currently, there is no national reporting system to manage ADR reports or any other drug-related issues. The unavailability of an official unified reporting system and reports presents a major challenge for the PV system in Qatar (27, 36, 37). For instance, the fate of submitted reports and their subsequent evaluation for healthcare professionals practicing in Qatar is unclear (36, 37). These challenges and the need to ensure medication safety and patient safety can be addressed by: 1) understanding the existing challenges and success factors for PV in Qatar, 2) strengthening the current subnational and national PV systems, and 3) establishing a well-structured national PV center or program and ensuring its sustainability (10).

Barriers encountered in the Qatar healthcare system and the factors influencing PV concepts and practices in the country are worth investigating, as they will be the first step toward developing feasible recommendations to improve PV in Qatar and to develop future plans to implement a national PV program or center for the management of medication safety, quality, and effectiveness in the country (10). Moreover, none of the PV system assessment studies conducted in the Arab world including the state of Qatar evaluated the PV system following a full system-based approach of structure, process, and outcomes components with the complete utilization of validated internationally recognized tools (i.e., PV KPIs).

The current PV status at various levels of the Qatar healthcare system is an area worth investigating in order to improve the national PV situation. The areas of importance include: 1) the status of the national PV system with respect to structures, processes, and achieved outcomes; 2) the current good PV practices followed in the country; 3) the challenges facing the PV system and affecting its development; and 4)

national stakeholders' views on PV system improvement and the idea of a centralized PV system. Therefore, it is essential to understand the current situation in Qatar and how it can be improved to comply with the internationally recognized requirements for a functional PV system defined by the WHO and other international PV organizations, e.g., the SPS program (10, 11, 32, 40).

4. Study Rational

Medication safety issues can impose an additional burden on the healthcare system (41). In the literature, ADRs are a well-documented cause of mortality and morbidity in addition to the cost in terms of losing trust in the health care system. Additionally, ADRs can lead to additional costs related to hospital admissions, the prolongation of hospital stays, and the need for additional therapeutic interventions (42-44). In a meta-analysis study, ADRs were associated with more than 100 thousand deaths in the United States (U.S.) making ADRs the fourth to sixth leading cause of mortality in 1994 (42). A recent systematic review evaluated the economic impact of preventable ADRs in Western countries. The review found that the cost implications of preventable ADRs were between €2,851 and €9,015 in the inpatient setting and between €174 and €8,515 in the outpatient setting (44). In addition, a major study in the United Kingdom (UK) found that ADRs were associated with a longer hospitalization period, with an annual cost of up to € 706 million (45). Similarly, a major report by the U.S. Institute of Medicine reported the deaths of approximately 98 thousand individuals annually due to medication errors and found that treating injury resulting from medication error can have an annual cost of up to 29 billion U.S. dollars (41). Consequently, medication safety issues and ADRs are significant elements in healthcare system expenditures, and cost-saving benefits are associated with their early detection and prevention. Therefore, PV is an integral part of any healthcare system

that aims to reduce the burden of drug product-related morbidity and mortality (1, 10, 41).

The continuous growth and scope expansion of PV have been accompanied by challenges that impose burdens on PV systems at the strategic and operational levels (46). The SPS program has indicated that challenges affect PV system abilities to perform effectively and efficiently (10). Irrespective of the organizational structure and the developmental stage of a PV system, it faces a set of challenges. Additionally, regional differences require PV systems to identify a suitable approach to address contextual challenges, as a uniform approach may not be appropriate for all PV systems. Since the PV system is a subset of the healthcare system in a country, it is affected by some factors that affect the capacity of the PV system to achieve the desired outcomes (10, 11, 18, 32, 46, 47).

To this end, the quality and evaluation of PV systems are important areas that have been recently discussed in the literature (10, 11, 18, 30, 32, 47). It has been stated that predefined measures (i.e., PV KPIs) are necessary to understand the effectiveness, performance, and adequacy of systems to achieve their objectives. Furthermore, the evaluation of systems can directly inform the concerned parties about the potential areas that require improvements or corrective actions, as the sources of the PV system underperformance will then be understood and can be addressed accordingly. This is essential in countries where PV systems are continuously challenged, and their effectiveness in safeguarding medication safety is not deemed satisfactory. Therefore, carrying out evaluation studies on PV systems is necessary to ensure patient safety in a country. Determining the strategic, structural, and operational grounds of such a unique system requires systematic and comprehensive system analysis (10, 11, 18, 30, 32, 47).

Consequently, there is a need to evaluate the current PV situation in Qatar since

a specific PV system does not exist and the PV situation has not been comprehensively assessed using validated PV KPIs before. In the literature, only a few validated PV KPIs (e.g., the WHO PV indicators) exist for a comprehensive PV and medicine safety system assessment. Such PV KPIs permit a comprehensive evaluation with respect to structure, processes, and outcomes to detect the existing opportunities and deficiencies in order to develop, enhance or even monitor PV and medicine safety systems (11, 18, 32). To the best of our knowledge, the present study will be the first in Qatar to use the WHO PV indicators for the purpose of a critical evaluation of the PV system. Finally, it is important to emphasize that there is no centralized PV center and a focal point in Qatar. Therefore, this research will use the knowledge of the available experts operating in the Qatar healthcare system in the specific area of PV.

4.1. Research Aim and Objectives

4.1.1. The Overall Aim

This research aimed to conduct a comprehensive system assessment by evaluating the current state of the existing PV and medicine safety systems in Qatar with reference to the WHO PV indicators. Therefore, this study aimed to assess the state of PV at the subnational levels of Qatar's healthcare system. The study was extended to distinct levels of the Qatar healthcare system to obtain a better understanding of various stakeholders' views and subnational PV systems status, including PV system performance, challenges, strengths, and opportunities. In doing so, it determined the feasibility of identifying and generating recommendations to enhance the PV situation of Qatar.

4.1.2. Objectives

The PV system analysis aimed to fulfill the following objectives:

I. Evaluate the baseline PV situation using the WHO PV indicators. These recently developed PV KPIs allowed the measurement and assessment of the current PV system structures, processes, and outcomes achieved in the context of medicine and patient safety in Qatar.

II. Compare the current PV situation in Qatar to the minimum recognized international standards for a functional PV system determined by the WHO.

III. Identify the potential strengths, opportunities, and limitations that can affect the development of the PV system as well as the establishment and sustainability of a specific PV center.

IV. Advocate feasible recommendations aimed at different stakeholders for the improvement of the PV situation as well as the creation and continuity of a well-functioning PV system specific to Qatar's needs.

5. Research Methodology

The literature on research methodologies suggests that to obtain a comprehensive understanding of research problems and to overcome the limitations inherent to either the qualitative or quantitative approach alone, researchers can employ a mixed-methods research (MMR) approach (48, 49). The area of PV system assessment is no exception. PV systems assessment can be a comprehensive process of inquiry in which the qualitative and quantitative approaches can facilitate the assessment process and provide a means to negotiate the expected national goals and outcomes (50-52). In this light, MMR can be time and resource consuming, but there is growing evidence that MMR, if well designed, can be worth the investment because it enables researchers to gain a complete understanding by conducting both the qualitative

and quantitative methods. Because each method alone would provide only a partial view of a PV system (11, 49).

This study aimed to conduct a comprehensive PV and medication safety system assessment employing an MMR case study design. According to Creswell and Clark, it is “a type of mixed methods study in which the quantitative and qualitative data collection, results, and integration are used to provide in depth evidence for a case(s) or develop cases for comparative analysis”. Within this complex design, the convergent core design was applied. It is a type of MMR design in which qualitative and quantitative data are collected concurrently, analyzed in parallel, and combined to provide a full understanding of the research problem (49). In this study, quantitative data were used to compare the performance of the national and subnational PV systems (i.e., the studied cases) to the WHO PV indicators, the latest assessment tool for PV systems. These PV KPIs represent the functionality and sophistication of the PV system and can aid in the development of strategic and operational recommendations to improve the PV system as well as to determine the measures required to achieve a fully operational system. Previous studies as well as the PV KPIs developed by the SPS program were used to complement the WHO PV indicators, including a few recommended PV KPIs thresholds used to obtain information not covered by the WHO PV indicators and the adaptation of a scoring system since the WHO PV indicators do not have one. The qualitative data obtained in the semistructured interviews on the subject of PV with national PV stakeholders from various sectors were used to provide a context-based system evaluation that was strongly dependent on the stakeholders' views and perceptions of the limitations, strengths, and opportunities present in the country. In addition, document review and field observation were employed to obtain qualitative information. The reason for collecting both qualitative and quantitative data

was to obtain a more comprehensive understanding of and deeper insight into the PV system in Qatar as well as to overcome the limitations inherent in using either the qualitative or quantitative approach alone (49, 53).

6. Study Contribution

As an introduction to this important topic in Qatar, this research included collecting, analyzing and compiling information on the aforementioned subject on the basis of the gathered available and accessible data. With the coordination of my advisor (Professor Mohamed Izham Mohamed Ibrahim, Ph.D.), this thesis is arranged to meet the requirements of the Master of Science (MSc) degree of Qatar University. The research describes various methods in the evaluation of PV systems. A detailed discussion of the findings of the study and its conclusions focuses on PV system requirements and their improvement. The available data are utilized at various levels of the healthcare system, mainly the healthcare regulatory bodies, public sector, private sector, pharmaceutical industry sector, academic institutions, and governmental health-related organizations.

Different stakeholders, including administrators in the Qatari healthcare system, can benefit from this system analysis. For instance, administrators at the Ministry of Public Health (MOPH), HMC, Primary Health Care Corporation (PHCC) and other sites can utilize the results and propose recommendations to implement and/or develop policies, regulations, activities, and programs aimed at improving public health and ensuring medication safety. In addition, the findings highlight some key aspects of the Qatar National Health Strategy, including the preparedness of the healthcare system and the development of a comprehensive healthcare system that takes into consideration the needs of the whole population (54). The following issues could be targeted:

I. Governmental bodies and healthcare institutions can improve the medication use process and ensure patient safety through the development, provision, and monitoring of specific policies, processes, and norms related to PV.

II. Providing an a priori assessment is the foundation of the establishment of a national PV center that can play an active role in the PV field at the national and international levels.

III. A sense of ownership and accountability among stakeholders in the decision-making process regarding PV and the coordinated practices of PV should be encouraged.

IV. Awareness of the need for a platform that encourages collaboration among academic, regulatory, and healthcare institutions through research and other activities that are valuable in addressing the current gaps and important aspects related to medication safety, efficient use of resources, decision-making processes, and system capacity building should be increased.

V. Legal structures and guidelines for PV practices based on the evidence available in the WHO PV indicator manual and the current literature should be proposed.

VI. The importance of launching a national medicine policy in Qatar to enforce the aspects of good PV practices should be highlighted since there is currently no such policy.

VII. Improvements of the national data management systems or sharing networks for postmarketing surveillance activities, medication safety, medication errors, therapeutic guidelines, and system quality that are currently available and used in Qatar should be recommended to create valuable datasets for future utilization (e.g., research and development purposes).

VIII. The current gaps in PV practices should be communicated to the relevant authorities to be addressed for further improvements in the healthcare system to comply with international standards.

7. Thesis Outline

I. Chapter II, Literature review: This chapter will cover the literature pertinent to the history and criteria of PV system assessment and the concept of using different methodologies and PV KPIs. Additionally, it will identify the study guiding evaluative framework (i.e., the WHO PV indicators) and the planned research methodology.

II. Chapter III, Methodology: This chapter will elaborate on the measures required to address the specific research problem at different levels, starting from reflecting on the employed research paradigm, followed by a description of the methodological approach, research design, and the specific qualitative and quantitative procedures for data collection, analysis, and interpretation.

III. Chapter IV, Results: This chapter will concentrate on establishing the documented results required to address the specific research objectives including integrated results of the WHO PV indicators and qualitative research approaches. These results will be reported by subnational stakeholder level as well as at the overall Qatar system level.

IV. Chapter V, Discussion and Conclusion: This chapter will include the interpretation of the study findings and their significance in the context of the research aim and specific objectives. Moreover, it will discuss the study findings to compare the national PV situation with other studies, standards and best practices from the literature. Additionally, it will present the limitations

associated with the design and conduct of this study. Finally, it will provide the recommendations and conclusions.

CHAPTER II: LITERATURE REVIEW

This chapter will provide an overview of the literature concerning the pharmacovigilance (PV) discipline as a whole as well as the research foci on PV systems and the assessment of such systems. First, the concept of PV and PV systems around the globe will be delineated. Then, the literature using various methods and tools for PV system assessment will be discussed. This will be followed by a gap analysis of the PV situation in the Arab countries, with an emphasis on the PV situation in Qatar. To this end, the selected research methodology and the developed conceptual framework will be used as a guiding framework to realize the research aim.

1. Pharmacovigilance

International standards require that any drug to be released in the market must follow a specific system that ensures the efficacy and safety of the drug in preclinical testing and clinical trial testing. However, the thalidomide tragedy, in 1961, was the trigger for the publication of "International Drug Monitoring: The Role of National Centres." This document fostered international awareness of the need for a specific system to identify drug safety issues at the postmarketing stage as well as awareness of the potential adverse effects of drugs considered to be safe in the premarketing stage. This document provided the input of subject matter experts around the globe and was guided by the WHO (4, 5, 8). After the realization of the need for continuous monitoring of released products, the idea of a system for postmarketing surveillance and/or PV was officially introduced and became a global standard system. (1, 13, 54). In 1968, the holistic system for the collection of ADR reports at the international level was officially named the WHO PIDM (9).

The term "pharmacovigilance" was officially introduced in the 1970s by a group

of French researchers to identify the scientific field of concern about drug safety (55). PV can be referred to as drug safety, postmarketing surveillance, drug surveillance, or drug monitoring (56). The key terminology utilized in PV is defined differently by various authors and organizations. The main definitions used within this research are based on the WHO and UMC frameworks as well as the European Medicines Agency (EMA) when stated (15, 57, 58).

PV is concerned with the systematic processes of the collection, collation, and analysis of reports of suspected ADRs as well as signal identification of suspected ADRs. It is also concerned with communicating safety information to PV stakeholders and the general public (11, 12, 15). Further, per the European Union (EU) PV system, PV can involve the decision-making process with respect to medication safety issues, a proactive risk management process, and an audit of PV processes as well as the associated outcomes (13).

At the global level, the UMC is one of the collaborating centers within the WHO PIDM and is responsible for the development of the PV discipline and the technologies employed for drug safety. The UMC has also played a vital role in the development of the operational activities of PV, such as the management and maintenance of VigiBase, a repository database for collecting international ICSRs. There are four other WHO collaborating centers in the global PV network. The other centers are located in Norway, Morocco, the Netherlands, and India (59, 60)

In addition to the establishment of the global PV network and the PIDM specifically, the safety issues that have emerged throughout the history of pharmaceutical products have fostered the adoption of various countermeasures and targeted efforts by international organizations and national regulatory bodies around the globe. These efforts have taken the form of programs, projects, and targeted

initiatives, such as the creation of standards for postmarketing drug surveillance to ensure effective PV (1, 56). For instance, a very early initiative in response to the thalidomide tragedy was the creation of reporting schemes for suspected safety issues in the UK. The yellow cards scheme, which was developed in 1964 to capture information regarding ADRs, to date remains in place to serve UK healthcare professionals and the public (61). More recently, the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action was initiated in European nations in November 2013. SCOPE is aimed at strengthening the European PV network, improving the operational PV capabilities, and expanding collaborative work by national European medicines regulators. The project has resulted in the development of guidance and has provided training on the fundamental aspects of PV, and it has resulted in the development of some publicly available tools and templates to support PV practices (62). Such PV initiatives are continuously evolving as the medical community's awareness and interest in PV as a discipline have increased through the continuous growth of this discipline and its potential contributions to the medical community (5).

One of the strengths of PV as a discipline is the heterogeneity of the parties concerned and interested in the whole therapeutic product life cycle (5, 18, 63, 64). For more than 70 years, the PV discipline has shown promising growth with respect to global efforts to streamline and standardize PV through the development of specific parameters, methods, tools, terminologies, and infrastructural concepts to enable PV and to facilitate information sharing among various parties involved in it (5, 18, 63, 64). The importance of communication between PV parties has been further endorsed by the publication of the Erice Declaration, which has placed additional emphasis on the need for effective communications on medication safety among the various parties (65).

A constellation of various parties, namely, the UMC, national regulatory agencies, national PV centers, other reputable agencies such as the Food and Drug Administration (U.S. FDA), and the EMA has created a holistic and formal system for the global management of pharmaceutical product safety issues. In addition, it has been highlighted that in addition to the initial efforts by the WHO and the abovementioned key players, further efforts from national PV systems are essential to enhance PV global cooperation (1, 18, 59, 66). The active engagement of individual countries in global cooperation is a fundamental aspect of contemporary PV to identify and mitigate drug safety issues and to continuously shape and develop the global PV system. In fact, global data and knowledge sharing can play a major role in investigating and mitigating drug safety issues and in empowering healthcare professionals and the general public (18).

National PV centers (i.e., PV systems) have been established in many countries to ensure that a systematic process is followed to guarantee drug safety in the country. Postmarketing surveillance and/or PV requires that systems and structures be in place to undertake the required functions. To establish an effective PV center, specific criteria should be followed. This process is almost harmonized, as many global parties (e.g., the WHO and SPS program) have shaped the criteria for countries to create a purposeful plan for building an effective PV center. An organized PV center requires the effective build-up of the formal capacities that are required for effective, efficient, and sustainable functionality and development. This depends mainly on the functions of the legal framework and PV policies, which will define the system and roles. Building these capacities also entails the proper management and monitoring of medications and other health-related products. These functions will become feasible with the proper utilization of workforce and infrastructure. The latter will be aided by the effective

utilization of services and equipment. All the aforementioned components, if managed well and benefiting from proper coordination, will ensure effective capacity building (10, 11, 13, 40, 67-69).

Traditionally, national PV systems have been based mainly on passive PV approaches. Spontaneous reporting of ADRs, case series reports, and summary reports are examples of passive surveillance activities in which the eligible reporters are only encouraged to report medical product safety issues, and no specified active measures are undertaken to detect and act on ADRs or other safety issues. Passive surveillance is dependent mainly on the submission of spontaneous reports from various PV stakeholders such as the pharmaceutical industry, marketing authorization holders (MAHs), healthcare professionals, and, less commonly, patients. Those reports are mainly voluntarily reported; however, some countries mandate this form of reporting. However, more recently, active PV has gained ground in the developed countries, and active approaches are now utilized, e.g., through epidemiological and PV studies such as cohort event monitoring, intensive monitoring, and targeted reporting (10, 11, 30, 68, 70). For a PV system to be considered a comprehensive entity for PV-related activities, it must cover both passive and active approaches. An all-encompassing system will aid in the processes of identifying medication safety issues, establishing mechanisms for the communication of safety information to the target audience, nurturing collaboration and coordination at the national and global levels, and fully integrating PV-related activities at all levels of the healthcare system (11, 68, 70).

Few countries have the resources required to initiate active surveillance as the prevailing approach for PV (10, 18, 29, 31). Countries with limited resources or rich countries with weak PV systems (i.e., developing countries) (71) rely on the more common passive method or appropriate data from other developed systems in which

both aforementioned types of PV activities are implemented as a way of communicating knowledge on the subject. Developed countries with well-established PV systems rely on both active and passive surveillance, as it is believed that the two forms provide complementary yet divergent approaches in terms of sensitivity and robustness, with an overarching aim of collecting a more comprehensive risk-benefit profile of available medicines (10, 18, 29, 31).

2. Pharmacovigilance Systems in the Developing Countries

In the past two decades, there has been considerable growth in the awareness of improving safety mechanisms among developing countries to ensure patient safety. This involves attention to improving PV practices and establishing national PV programs. Many developing countries have succeeded in becoming full members or associate members of the PIDM (20, 71, 72). Additionally, as shown in the UMC recent data, there has been encouraging substantial growth in developing countries reporting input to VigiBase, as reporting increased from 6.7% to 12.5% between 2011 and 2017 (72). Nevertheless, developing countries often fail to successfully implement PV in the national healthcare system (20, 21, 72, 73). As described by Al Elshafie et al., developing countries are lagging in their awareness of PV systems and PV policies (73). This has been clearly reflected in the low numbers of ADR reports from developing countries received by the UMC in comparison to those received from developed nations (72). To illustrate, an analysis of VigiBase reports found that low-income countries, even those that had mass administration of medication and prevalent disease, had lower reporting rates than developed countries (74). Ampadu et al. reported that while the number of African countries entering the WHO PIDM grew, the reporting rate growth remained lower than 1% (75).

De Abajo indicated that to date, spontaneous reporting is the main and possibly

the sole tool used to collect PV data in many developing countries. The author related this dependence to the simple and economical nature of spontaneous reporting (76). However, Giezen et al. noted that the use of such concepts in a PV system makes the system outdated (77). Notably, Rodrigues and Khan reported that the shift from the prevalent method of spontaneous reporting to active approaches can put pressure on a PV system (78). This shift can be especially challenging for less developed PV systems or systems based on outdated PV methods (77, 78).

Another challenge in spontaneous reporting among developing countries is the quality of the submitted reports (79). For instance, a study by Bandekar et al. aimed at evaluating ADR reporting forms, including quality, in various countries found that developing countries performed poorly with regard to the standard quality baseline of reporting forms; for example, Pakistan scored 6 of 18 possible points, and Sub-Saharan African countries scored 12. According to Rachlis et al., the unsatisfactory quality of reports as well as the lack of essential data that prevents further investigation is a challenge for PV systems (80). Likewise, Pan indicated that the availability of high-quality information is essential for PV systems (46). In developing countries, PV processes such as causality assessment and signal investigation can be unfeasible without solid data (21, 46, 79). In addition, Bandekar et al. concluded that there is a need for global guidelines on reporting forms to ensure that individual countries' contributions to the WHO global database are appropriate (79).

As mentioned in the section on global PV systems, PV systems are established based on a hierarchical structure that starts at the global level, with the WHO PIDM and the UMC, and extends to national PV centers and subnational PV centers (e.g., regional centers) in individual countries (19, 81). In developing countries, the unavailability of dedicated PV centers, as well as the lack of subnational centers, was

confirmed by Olsson et al. and Isah et al. The authors related the shortage of PV centers to the dearth of monetary and nonmonetary assistance, namely, government support, human resources, infrastructure, capacity building initiatives, and PV methodologies (21, 82). A major study by the SPS program of 46 African countries reported that 26% of the countries had no dedicated PV center, and of the sample, almost 90% had a nonfunctional systems (31). Similarly, a study covering five Asian countries reported that no more than 50% of the assessed health facilities had a functional system (29).

Regarding PV legislation in their analysis of 55 countries, Olsson et al. reported that developing countries' PV systems are burdened by a lack of PV legislation or challenged by ineffective PV legislation. Olsson et al. noted that there is a need for better legislation for proper coordination of PV systems (21). Similarly, PV studies in developing countries have suggested that 59% of African countries lack national policies on the subject of PV or medication safety (31) and that fewer than 60% of Asian countries' health facilities have guidelines or standard operating procedures (SOPs) that address PV (29).

Additionally, the authors attributed the successful operation of PV systems to the acquisition of and proper allocation of resources. Resources include monetary and nonmonetary (e.g., technological infrastructure, human resources, public participation) assistance (20, 46, 82, 83). For instance, it has been reported that the effective management of existing resources for the operation of a system is one of the most crucial factors in the success of a PV system (83, 84). Isah et al. asserted that PV systems operate within a limited budget and that this scenario is more prominent in developing countries, as many countries suffer from political or social challenges, forcing them to target their limited resources and efforts toward prominent challenges such as war and poverty. This investment often does not include PV implementation,

and PV is not a priority within the healthcare system (82). Similarly, a survey conducted in 2016 by Suwankesawong et al. indicated that Association of Southeast Asian Nation (ASEAN) countries reported the lack of resources as one of the main challenges affecting the development of PV systems (85). Olsson et al. reported that a common challenge for developing countries is the lack of technical capacity (20, 21). Shortcomings in the skills, knowledge, and experience required for PV are interfering with the efficient operation of PV systems as well as the developmental capacity of PV systems (10, 20, 21, 46).

As mentioned above, public participation (e.g., of patients and consumers) is one of the important resource elements for successful PV operation, as these participants are considered key stakeholders in contemporary PV (1, 46, 78). In developing countries, public participation and involvement are minimal (21, 46, 86), Additionally, it has been reported that in developing nations, there is a lack of trust in the healthcare system (87). This issue is especially challenging, as there is a reported lack of trust among the general public, even in developed nations, regarding drug safety systems and the pharmaceutical industry (88). Therefore, building effective relationships with consumers is necessary within the context of developing nations.

According to Palaian, the failure of PV implementation in developing countries occurs in various stages, as described below (72):

I. National level: PV systems can lack the commitment of regulatory authorities or the health ministry e.g., omissions in PV policy provisions.

II. Institutional level: PV programs remain uninstitutionalized, and PV programs often fail to receive support from the leadership or management of an institute.

III. Individual level: PV system implementation and subsequent success often depend on the efforts of few enthusiastic and dedicated individuals. This reliance on a few individuals, often without the necessary monetary and nonmonetary assistance, can lead to failure to realize PV goals.

To conclude, Pan remarked that international efforts need to be targeted toward the subject of strengthening PV systems in countries where PV systems are overburdened or simply do not exist. In addition, it is important to evaluate the outcomes of growing PV systems (46).

3. Pharmacovigilance Systems Evaluation

Over the years, PV as a science has developed to include sophisticated structures and processes, and its scope has expanded due to the efforts of international organizations and the global PV network. At the heart of those efforts is the establishment of PV systems as entities required to ensure medication safety and protect public health. Despite the surging advancement of PV, the need to develop objective metrics for PV system assessment, evaluation, and monitoring was realized not long ago. However, because monitoring the safety, quality, and effectiveness of medications has been a focus of PV around the globe, the development of PV systems has been accompanied by the development of tools to assess those systems. In the field of PV, there have been few initiatives by international organizations and professional groups to develop objective measures (i.e., PV KPIs) to assess the performance and adequacy of PV systems. Those PV KPIs have been established as validated tools to evaluate the performance of PV systems on the way to identifying areas that need proper investment to improve PV systems in terms of performance and capacity (18, 32, 47).

3.1. Pharmacovigilance Indicators History and Development: A Permeable to International Efforts

In 2006, the Fraunhofer survey, the European Community System of Pharmacovigilance Assessment, was one of the early initiatives to comprehensively assess PV systems and propose some useful metrics to serve as PV KPIs in the European context. The survey report provided details on the suggested success factors as well as the PV KPIs required for a robust PV system. The system assessment included the EMA, EU member states' medicines agencies, MAHs, and other stakeholders. The assessment focused on aspects related to the legal framework, technical and human resources, stakeholder coordination and/or cooperation, PV data collection, safety studies, quality management, PV data management (e.g., systems and databases), signal detection, PV data assessment, decision-making processes, and the communication and implementation of actions. It found that any legal framework helps harmonize the work and makes regular action more effective, but at the same time, managing such a framework can be complicated because of the differences between the various authorities involved that make it difficult to oversee the existing guidelines. It also alluded to the frequently difficult communication between agencies of varying quality and with different standards. Moreover, a portion of the work was duplicated among different agencies. In addition, the lack of safety studies and related data was a substantial hurdle at the time, and most databases were insufficient to manage the necessary data. Additionally, the decision-making process was delayed beyond an acceptable time, and experts from abroad were suggested to be beneficial if they were available and managed correctly. The Fraunhofer survey concluded that for a successful and more robust system, there was a need to review the different sources of PV data used, review and streamline the decision-making process, systematically examine

communications and the implemented actions, ensure the accountability of MAHs in complying with the legal obligations, identify and correct system weaknesses, and perform continuous audits to ensure the realization of PV targets (e.g., impact values) (89). Subsequent to the Fraunhofer survey, other international efforts have resulted in the development of comprehensive PV KPIs for PV systems (18).

First, in 2009, was the effort by the European Society for Quality in Health Care, Office for Quality Indicators. A set of indicators was developed with the aim of serving as a tool to monitor patient safety quality problems (90). Those indicators, although not specific to PV, covered aspects relevant to PV, including medication errors and culture. Because the indicators are not specific to PV, they are not utilized as an assessment tool in this research.

Second, in 2009, "The Management Sciences for Health (MSH) – U.S. Agency for International Development (USAID) Indicator-based Pharmacovigilance Assessment Tool" (IPAT) was developed to assess PV systems on the basis of a system-based approach to structure, processes, and outcomes. The SPS program published a manual for this PV indicator tool, which was designed for implementation in developing countries. There are two main PV KPIs: core categories (n=26) and supplementary categories (n=17), and each indicator category is intended to cover a group of essential component of PV, specifically, a) "Policy, law, and regulation"; b) "System, structure, and stakeholder coordination"; c) "Signal generation and data management"; d) "Risk assessment and evaluation"; and e) "Risk management and communication". The IPAT has a scoring scheme based on the ability of the PV system to meet the threshold of functionality for each indicator. If an indicator is available or reaches the standard threshold of functionality, the indicator score is entered as "2" for core and "1" for supplementary; if the standard threshold is not attained, a score of "0"

will be recorded. This tool has high validity and wide applicability in the context of developing countries, where systems are at an early stage of development. The IPAT implementation will be discussed further in this chapter since the tool will be used to complement the main assessment PV KPIs: the WHO PV indicators. This involves including a few recommended thresholds of IPAT, inquiring about information that is not covered by the WHO PV indicators, and adapting the IPAT scoring system (32).

Third, Kshirsagar et al. published a paper in 2010 with the aim of providing a set of desirable features for objective PV KPIs specially tailored to PV system assessment. Those PV KPIs were used to compare PV system performance in the U.S. and in Africa to demonstrate the potential applicability and usefulness of the selected indicators in PV systems at varying stages of development. The authors concluded that irrespective of the PV system stage of advancement, continuous monitoring and evaluation are required to ensure that the system achieves the target outcomes of PV (47).

Fourth and finally, in 2015, the WHO developed PV KPIs as a tool to evaluate a PV system's capacity, performance, and ability to fulfill its objectives. The indicators measure the aforementioned aspects based on structure, process, and outcome criteria. This tool will be utilized in the evaluation of the PV system in Qatar given its high validity, reliability, and applicability and because it is the most recent PV KPIs developed. The WHO PV indicators will be reviewed in more detail in this chapter (11).

In addition, the literature has reported the existence of checklists used for regulatory assessment. However, the metrics used do not provide a comprehensive assessment. Some PV inspections rely on the use of metrics to evaluate the systems. However, these metrics have often been developed for use in MAH systems, and many other PV stakeholders are often excluded. Moreover, countries can establish their own

performance metrics. For instance, in France, the French healthcare system established PV KPIs for the routine evaluation of its PV system as well as for national health facilities (18, 91). Similarly, countries such as Belgium, Canada, and Portugal follow the same practice of evaluating their systems based on country-specific criteria that may depend on published or unpublished metrics (30). Nevertheless, this chapter will not discuss the application of those measures since the most predominantly used, comprehensive, and validated PV KPIs are the IPAT and the WHO PV indicators, both of which offer the opportunity to evaluate different systems, including regulatory bodies and other subnational PV systems, within the context of developing countries and/or developing PV systems (18).

4. World Health Organization Pharmacovigilance Indicators

The main research tool, the WHO PV KPIs, is considered the latest PV systems assessment tool, it was developed after years of continuous development by the WHO, the professionl organization responsible for the PIDM, which covers almost 90% of the global population (11, 59).

The WHO PV indicators manual is a validated and standardized tool that is available on the WHO website (11). The idea of the WHO PV indicators was first discussed in 2007 during a meeting of Pharmacovigilance Sans Frontiers that involved PV experts from African countries and was supported by the WHO and the UMC, the main PV partners at the global level. Accordingly, a consensual approach was followed to develop a set of objective measures to assess PV systems (11, 92). Afterward, the initial set of PV KPIs was utilized in a systematic assessment of PV systems, with a focus on the elements of structure, processes, and outcomes. In addition to the consensual approach, the process of identifying PV KPIs was reliant on other established WHO indicator methodologies (11), the “Australian Therapeutic Indicator

Schema" (18), and key findings from a major questionnaire-based study on PV systems covering 55 countries (21). This was followed by further selection and categorization of the PV KPIs (93). To validate the final PV KPIs set, many PV experts were involved, and in 2015, the WHO PV indicators were made publicly available on the WHO website (11).

According to the WHO manual, the PV KPIs are "specific objective measures that allow the evaluation of the baseline, situation and progress in a system and the assessment of services and interventions". It "measures the input, processes, outputs, outcomes, and impact of development projects, programs or policies related to health systems and services….on how well a PV programme is achieving its objectives" (11) The WHO PV indicators are designed to be reproducible and have been successfully adapted in various countries. The selected WHO PV indicators, when used as an assessment tool, can provide simple measures for the compliance of PV systems with the expected PV WHO framework. The PV KPIs are specific and can be used to detect and interpret recognizable gaps in a PV system or simply to explore and outline the current structures, the process of PV systems, and the PV system's impact on the healthcare system (11, 18).

PV KPIs are classified based on a system-based approach to: a) Structural indicators: indicators selected to recognize and evaluate the PV structures required for a visible and standard-compliant PV system; b) Process: indicators selected to assess the breadth and depth of PV functionalities, e.g., activities relevant to the collection, collation, analysis, and evaluation of PV data, including ADRs; c) Impact or outcome indicators: indicators selected to measure the consequences as outcomes for the development and effect of PV activities to ensure patients' safety as a key objective; d) Public health program (PHP) indicators: indicators selected to assess the PV system

situation at the program level; and e) Background information: indicators selected to outline the demographics, the pharmaceutical sector, and much other relevant information on the country or site being assessed (11).

4.1. World Health Organization Pharmacovigilance Indicators Implementation

Table 1 below highlight the international studies that have utilized WHO PV indicators for a PV system assessment. Some studies have been conducted in the Arab world; therefore, they will be discussed under the Arab world section.

Some of the below mentioned studies' limitations will be addressed by developing a scoring system, utilizing all of the WHO PV indicator categories, including various stakeholders across the healthcare system to ensure better representation of the national PV scenario, and utilizing the qualitative research approach to ensure a comprehensive collection of context-specific data. This will be described in detail in the current study section of this chapter.

Table 1. Characteristics of the included literature on the subject World Health Organization (WHO) pharmacovigilance (PV) indicators implementation

Author and date	Background and/or objective	Methods	Findings	Review
Opadeyi et al. (2018)	A study on PV status in six tertiary hospitals with the aim of improving the PV situation in the south-south zone of Nigeria (94).	• The WHO PV core indicators were adapted, phrased, and employed in the assessment. • The sample was randomly selected.	• The sample reported the presence of a PV department. However, only three systems could be considered appropriately functional. • The main challenges identified in the hospital setting were the unavailability of ADR reporting forms in some hospitals, underreporting problems (e.g., only one institution reported submitting reports to the national PV center), and poor documentation systems and PV data practices. • The authors described the need to strengthen PV systems with a special emphasis on the need to institutionalize PV as a first step toward improving PV in hospital settings.	• The limitations of the study included the small number of included hospitals and the fact that the study did not include other levels of the healthcare system, e.g., regulatory bodies, the pharmaceutical industry, and academic institutions. • Limitations inherent to the WHO PV indicators when used in survey design. For instance, it was reported that the actual details and system functions were not reflected by the dichotomous response provided by the structural indicators. Additionally, challenges of the successful implementation of outcome indicators were reported. • The authors reported the need to develop a scoring scheme to enable system weaknesses to be demonstrated in numerical terms, since the WHO PV indicators do not yet have a scoring system.
Shin et al. (2019)	A study in 15 Asia-Pacific region countries to evaluate the	• The authors used a modified WHO PV indicator questionnaire to	• Based on the recorded data, disparity exist between systems. For instance, for process indicators, the source of the ADR reports differed between	• The limitations of the study can be attributed to the survey design using emails, as it can be affected by response bias or arbitrary interpretation.

Author and date	Background and/or objective	Methods	Findings	Review
	structure, process, and outcome components of the PV system and to understand PV regulatory differences between countries (95).	assess the systems using an email survey with questions and subquestions. • The authors developed a simple scoring system that recorded responses as “no/not applicable” or “yes” (i.e., categorical variable).	countries. In addition, for outcome indicators, the U.S. was reported to be a very active country in terms of active PV efforts. • In conclusion, the authors recommended global harmonization, which can include guidelines harmonization, as an essential step toward PV improvement.	• The WHO PV indicators were not used comprehensively (i.e., the full set of indicators was not used). Therefore, the ability to benchmark the PV systems against the standardized WHO requirements is inadequate. • The study is limited because it represents only the regulatory body system performance and adequacy, whereas the level of PV implementation across the different levels of the healthcare systems remains unclear, and no opportunities will be available to compare subnational PV situations, e.g., private sector performance. • Nevertheless, the authors achieved expert agreement on the development of the study questionnaire. • This study contributed by increasing our understanding of the differences in regulatory PV and the effect on the PV system functionality observed between the surveyed countries. • Moreover, harmonization as a final recommendation is highly valuable, given that it will be executed strategically to benefit different systems by improving PV at the national and global levels.

Author and date	Background and/or objective	Methods	Findings	Review
Ejekam et al. (2017)	A study conducted in Nigeria to evaluate the PV system in three selected national PHPs (96).	• A cross-sectional descriptive study employed the WHO PV indicators namely, PHP indicators. • The study used interviews with national PV key informants to collect the required information on the national programs' PV system structures, processes, and outcomes.	• The main structures required for PV activities were available; however, the system lacked optimal implementation of PV. For instance, underreporting ADRs and poor documentation of PV data were affecting the PHP systems. • In addition to the aforementioned limitations, financial resources and human resources were deemed common issues in the authors' thematic analysis.	• It was not feasible to examine the study in detail to obtain information on the values and detailed results, as only the abstract of this study was available.

5. Minimum Requirements of the World Health Organization

For countries seeking to improve their PV systems, the WHO minimum requirements for PV were defined as the first standard by the WHO (2010) for countries to use as the measuring criteria for their systems (i.e., PV center, ADR or PV advisory committee, spontaneous reporting system. national database, ADR reporting form, and communication strategy). These requirements are the lowest acceptable quality level that ensures that a PV system exists and can function properly (40). Those requirements will be used in this research as an assessment guide to identify the minimum capacity of a functional PV compared to the WHO PV indicators that assess the complete all of the PV system components. Table 2 below highlights the international studies that have utilized WHO minimum requirements for a PV system assessment.

Table 2. Characteristics of the included literature on the subject World Health Organization (WHO) minimum requirements implementation

Author and date	Background and/or objective	Methods	Findings	Review
Maigetter et al. (2015)	The authors studied the PV system in Uganda, South Africa, and India and compared them to the minimum requirements for PV systems by the WHO (97).	• Data collection for this research involved conducting multiple interviews as well as a literature review (i.e., gap analysis). • After analyzing the data, the authors compared their findings with the WHO requirements.	• Maigetter et al. concluded that the countries examined need more funding so that the PV activities could be coordinated and sustained according to the WHO requirements. • The authors emphasized the need for a systematic approach so that PV practices and facilities could be regularly monitored and evaluated.	• The authors noted a limitation in the WHO guidance, as one full-time staff member was deemed inadequate for running a PV center. This review also contained the remark that one full-time staff member would not be able to handle emergency cases that require immediate action.
Suwankesawong et al. (2016)	The authors studied the PV landscape in the ASEAN countries and identified the challenges that these systems face (85).	• The authors utilized the WHO minimum requirements to assess each country. • In addition to the assessment of the minimum requirements, the authors determined a few PV KPIs related to the PV process, namely, the number of ICSRs, signal detection and management, and	• The authors indicated that Malaysia, Singapore, Thailand, and Indonesia met and/or exceeded the minimum requirements, while the remaining countries did not. • The authors concluded that an advisory committee should provide technical assistance to strengthen the PV systems. • Additionally, an effective communication strategy between the different entities was considered essential in strengthening PV systems.	• This study developed the following scoring scheme for the minimum requirements: “no” (0), “yes” (1), and “unclear answer” (0.5). This scoring system enabled the quantification of data to compare countries, and the addition of a score (0.5) for ambiguous response implies that the authors attempted to deliver a fair evaluation across the sample.

Author and date	Background and/or objective	Methods	Findings	Review
		sending reports to the global database.		
McEwen et al. (2016)	In a current opinion published in the Drug Safety journal, McEwen et al. presented the case of Pacific Island countries and their ability to meet the five minimum requirements (98).	• Not provided.	• The authors indicated that most of these countries did not have the capacity or resources to meet the requirements and that PV is ineffective in a setting of such limited resources. • Therefore, the authors proposed that for small countries with very limited capacity, external support is needed and that targeting the quality of medications should be a priority before attempting to build the capacity to impose the five WHO requirements on an operational system.	• The review emphasized the authors' remark on the need for external support to understand a country's situation when it fails to meet the lowest required standards of operation. Understanding the challenges and prioritization based on the national context would be even more crucial in such cases compared to striving to establish a standard that may not solve context-specific situations. • A limitation is that the assessment methodology was not described since this was not a research article.

6. Indicator-based Pharmacovigilance Assessment Tool Implementation

To date, the IPAT has been successfully utilized in more than 50 countries. The international efforts to apply the IPAT will be presented in Table 3. The PV effort in the below-mentioned countries has been reported as the consequence of empirical research and a review of the relevant literature. This is a signpost of the necessity of evaluating the PV system in each unique context to identify the best fit for the purpose of a solution aimed at the advancement of PV and PV systems at the national and international levels.

Table 3. Characteristics of the included literature on the subject Indicator-based Pharmacovigilance Assessment Tool (IPAT) implementation

Author and date	Background and/or objective	Methods	Findings	Review
The SPS program (2011)	Forty-six countries located in Sub-Saharan Africa were evaluated by the SPS program to fill the gap in the PV scenario, including identifying context-based challenges, success factors, and recommendations (31).	• The methodology included a survey of the literature, mail surveys, and in-depth situational analyses of 9 selected countries. • The countries' PV system performance and capacities were evaluated using the IPAT.	• The impact of challenges on PV system capacity was very clear, as 87% of the countries failed to have a functional PV system. • The main challenges reported were the absence of medication safety policies (59%) and the absence of a policy for adverse event monitoring (70%). In addition, the document mentioned the lack of an organized PV center (26%) and a dedicated advisory committee on medication safety (61%).	• The methodology and findings were included in a document posted on the WHO website. • For this research, the previously published studies' methodological best practices will be utilized, and findings from the major works (e.g., challenges and recommendations) will be included in the supplementary assessment questions related to the WHO PV indicators. This will facilitate the collection of supplementary data when the stakeholders do not satisfy the WHO PV indicator standards.
The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program (2013)	SIAPS Program conducted an analysis of the PV systems of 5 Asian countries (Bangladesh, the Philippines, Thailand, Nepal, and Cambodia) (29).	• The methods used were a review of the literature pertinent to the PV systems and regulatory frameworks in the selected countries followed by an in-depth single-country assessment using the IPAT. • Then, based on the results of the in-depth assessment, a comparative analysis of the countries was performed.	• The findings provided information on the variations in the PV systems as well as the challenges faced by each system. • The study indicated that the statutory provisions available to define PV and medication safety vary between countries. For instance, even though both the Philippines and Cambodia have legal mandates for pharmaceutical industry reporting, only the Philippines has a legally binding mandate for the industry to conduct postmarketing surveillance of its products. • The identified areas of system weakness were similar to those in Africa, as less	

Author and date	Background and/or objective	Methods	Findings	Review
			than half of the health facilities surveyed reported the existence of a functional PV center or unit. In addition, only 50% had established a drug and therapeutics committee to provide support as well as advice on medication safety and PV. • The study concluded with a call for international efforts to strengthen PV systems and safeguard patients' safety in Asian countries	
Nwokike and Joshi (2009)	A diagnostic system analysis of the existing PV system in Rwanda as part of the SPS program work in developing nations (99).	• The authors used structured interviews following the IPAT assessment questions. • Additionally, they reviewed the national documents and interviewed key informants.	• The study gave information on the national system capacity, including the relevant national departments and 16 health facilities. • Based on the recorded data, including the "SWOT analysis," the national PV scenario could be improved by strengthening the legal provisions and approving required PV and medication safety-specific legislation, establishing a center for PV and drug information under a regulatory body, establishing a national PV committee, and strengthening the pharmacy and therapeutics committees at the health facility level.	• The study described the usefulness of the IPAT as a diagnostic tool that can be used for the routine monitoring of systems. • This research will also employ the SWOT analysis framework.
Lebega et al. (2012)	Lebega et al. conducted a comprehensive assessment to	• The authors collected evidence based on interviews with national	• At that time, the findings were considered the highest results achieved for PV system performance, with an	• Limitation and possibility of error because the study relied

Author and date	Background and/or objective	Methods	Findings	Review
	benchmark the performance of Ukraine's healthcare system by including different levels of national PV systems, such as academia and the healthcare industry (100).	stakeholders as well as a literature survey pertinent to PV and medication safety in Ukraine.	overall result exceeding the performance of 40 countries. • The authors provided information on weaknesses affecting the system related to medical device surveillance, national PV implementation, and active PV or surveillance activities. • Therefore, it was recommended that the aforementioned weaknesses be resolved through a robust legislative base, targeted solutions, and national coordination and cooperation.	on the data collector interpretation when transforming qualitative findings into quantitative forms. Additionally, the study did not verify the provided responses. • Lower-level health facilities were not included affecting the study generalizability.
Kabore et al. (2013)	The authors evaluated the PV system in Burkina Faso to identify possible areas of improvement and used the IPAT as the means of data collection (101).	• The IPAT was the mean for data collection. • The interviewed Key informants were selected by convenience sampling.	• Based on their results, PV-specific guidelines were lacking, and the coordination of stakeholders was insufficient. • Kabore et al. also provided suggestions to help implement and design pertinent activities to improve PV in the country.	• The sample was limited in number, and the study did not include some healthcare sectors e.g. private sector. • The study included a high number of respondents from a pharmacy background (i.e., 75%).
Allabi and Nwokike (2014)	A situational analysis of the Benin PV system conducted in 2009. The system analysis was deemed necessary after the	• The IPAT tool was employed in the system assessment. • The quantitative approach included semistructured interviews with national stakeholders, including	• The authors recommended that PV be improved in the country by establishing a national PV center, forming a PV committee, building human resource capacities (e.g., providing training, utilizing university students), and	• The study took both quantitative and qualitative approaches, each of which delivered a unique understanding of the PV situation.

Author and date	Background and/or objective	Methods	Findings	Review
	increased accessibility of antimalarial medications due to changes in the malaria control policy (50).	practicing healthcare professionals, drug representatives, and representatives of the pharmaceutical industry, to assess their knowledge, attitude and practices related to ADRs. • The qualitative approach included conducting a focus group discussion with national regulatory officials of Benin to obtain their views on the measures required to improve PV in the country	ensuring strong links among national stakeholders.	• The recognized strength of the study is its use of various methods, each of which targeted a component of the system, e.g., the reporters (e.g., healthcare professionals) and the data analyzers (e.g., the regulatory body), as well as the system itself (using the validated indicator tool). • Additionally, the study allowed the authors to conduct a SWOT analysis to inform the development of the recommendations.
Abiri and Johnson (2019)	The authors aimed to provide information on the PV functionality status of the national stakeholders since the country (i.e., Sierra Leone) had officially become a member of the PIDM (52).	• A descriptive cross-sectional study conducted in 2016 using the IPAT on the PV systems of various national stakeholders (i.e., the regulatory body, PHPs, and medical facilities) in Sierra Leone. • The study included 14 respondents from various sites, namely, the national	• When a threshold of 60% was set to categorize system performance, the recorded data showed that the regulatory body was able to reach and exceed the target threshold, but the other stakeholders' systems did not satisfy the criteria, and the PV systems clearly required further strengthening.	• However, some limitations were related to the reliance on the convenience sampling method and the small number of study sites. • Additionally, the study had the commonly encountered issue of reliance on the key

Author and date	Background and/or objective	Methods	Findings	Review
		regulatory body, 3 teaching hospitals and 3 regional referral health facilities, and 6 PHPs.		informants' information and assertions. • In addition, the identified gap was that the threshold of overall functionality (i.e., 60%) was subjectively set with no evidence from IPAT and no consideration of statistical targets, e.g., performance based on a quartile range.
Nwokike and Eghan (2010)	Nwokike and Eghan, representing the SPS program, conducted a comprehensive situational analysis at the request of the regulatory body in Ghana (51).	• Using multiple methods including semistructured interviews with national key informants and document review.	• The main shortfalls were the lack of statutory provisions on PV, the lack of a mechanism to coordinate among stakeholders, and the lack of a dedicated budget for PV. • Additionally, the process and outcome domains required to attain a well-functioning system were deficient. • Accordingly, the authors recommended revising the existing legal provisions, developing PV guidelines, establishing a postmarketing directorate under the regulatory body, improving cooperation and coordination among national stakeholders, and implementing or enhancing PV activities, e.g., spontaneous reporting.	• The authors discussed the PV situation across the different levels of the Ghana health system and how it could be improved to ensure the safety of health products. However, the limited number of the included representative sample can affect the generalizability.

Author and date	Background and/or objective	Methods	Findings	Review
			• In addition, at the health facilities level, they recommended measures to improve the contribution of drug and therapeutics committees to PV-related activities. • Finally, the authors recommended prioritizing areas worth targeting through medication safety research to improve PV.	

7. Other Research Methodologies to Assess Pharmacovigilance Systems

In addition to the use of PV KPIs and guidance documents to assess PV system capacity, other forms of research can deliver insight into PV systems or an aspect of those systems. These can include but are not limited to PV review articles, qualitative studies, and policy assessments.

Narrative reviews or expert opinions on the PV situation can be performed for a single country or across several countries (20, 26, 102-105). These assessments are performed by conducting a literature survey that often includes published scholarly articles, governmental documents, and governmental websites to determine the current standing of PV systems. Although they can be affected by the limitations of selection bias, the quality of the content included, and the methodology used to extract the relevant literature, reviews have been used to describe PV in many countries. For instance, Olson et al. described the PV landscape in developing countries through an expert review that is commonly cited because it discusses the challenges affecting developing countries' capacity to improve PV (20). Additionally, Gupta et al. compared PV regulations among four countries to identify areas that required improvement and provided recommendations, e.g., the need for harmonization (106). In addition, reviews can include a discussion of a country's PV system. For instance, Zhang et al. described the PV scenario in China in a leading article published in Drug Safety (81). This approach will not be utilized alone, as it does not rely on evidence-based tools or methodology for PV system assessment.

Qualitative research often focuses on aspects selected for study through an exhaustive qualitative methodology, such as country case studies and in-depth interviews with key informants (107). Such initiatives require time, are limited in their generalizability, and/or can be influenced by the researcher role; however, they can

deliver a wealth of details on the components required for a functional PV system (108). For instance, Ampadu et al. conducted qualitative semistructured interviews to investigate how different categories of resources and relations with concerned PV parties can affect unsuccessful and successful PV activities in 18 African countries (109). Similarly, Moscou et al. used qualitative semistructured interviews and document reviews to compare active surveillance approaches and the use of postmarketing evidence in the decision-making process between North American and European regulatory agencies (110). Qualitative research will not be utilized alone, as the PV KPIs provide a more objective, comprehensive, and validated assessment methodology that covers all the PV system components: structure, process, and outcome.

Anantachoti and Kaewpanukrungsi used various approaches to collect qualitative and quantitative data as a means of evaluating the Thai national PV center performance. The authors used interviews, field observations, and document reviews to collate data on a set of selected questions and PV KPIs. Content analysis was used for the analysis of the qualitative data, and descriptive statistics was used for the quantitative data. The recorded data were reviewed by PV experts as a mean of data triangulation, clarification, and validation. The use of several approaches offered an in-depth understanding of the current PV system performance. However, a limitation to consider was that the assessment did not utilize an internationally validated PV KPIs such as the IPAT or WHO PV indicators (111).

8. A Gap Analysis of Pharmacovigilance System Assessment in the Arab World and Qatar

8.1. Overview of Pharmacovigilance Challenges in the Arab World

After the introduction of the Arab PV guidelines, many Arab countries significantly improved their PV systems to comply with the guidelines. However, to date, some Arab countries still face challenges in establishing the basic foundation of PV activities; therefore, it may require years to successfully implement, sustain, and further develop the full scope of PV. The challenges facing the Arab region and less developed PV systems in the region may negatively impact drug safety and patient safety. Additionally, in many settings, PV activities suffer from fragmentation and the duplication of stakeholder efforts, which can be highly detrimental to countries with unstable political systems or financial issues (25-28). For instance, despite the efforts of the Yemen PV center, the Yemen PV system still suffers from the consequences of political instability, including an immature PV system that is currently operating under a shortage of basic structures and funds (26). Further, many nations are in the burgeoning stage of PV, as reflected in achieving less than the desired PV outcomes (25). Findings in the region indicate that there is a need to develop PV through collaborative efforts (i.e., national, regional, and international efforts), mobilization of resources, targeting efforts to address governance, policy and pragmatic challenges, and educational efforts targeting various stakeholders (25-28).

8.2. Pharmacovigilance System Assessment in the Arab World

Table 4 below highlights the research foci that have been conducted on the subject PV system assessment in the Arab world.

Table 4. Characteristics of the included literature on the subject pharmacovigilance (PV) system assessment in the Arab world

Author and date	Background and/or objective	Methods	Findings	Review
Wilbur, K. (2013)	Wilbur used survey methods to assess the PV situation in thirteen Middle Eastern countries (27).	• The survey questions were adapted from the 2008 "UMC Assessment of Country Pharmacovigilance Situation Questionnaire".	• Wilbur estimated that up to 50 million of the Arabic-speaking population (e.g., Qatar) lacked a national PV center. • Additionally, even among 11 of the responding countries, challenges related to financial and human resources were affecting the PV systems. • Wilbur recommended exploring regional collaboration mechanisms and information technology to improve PV.	• The limitations of the research were associated with the email survey method, which is entirely dependent on the provided responses, as responses can be limited in their reliability. For instance, in cases with no evidence of the existence of the selected parameters or cases, the situation in nonresponding countries remained ambiguous. Additionally, surveys sent to officials may be delegated to less relevant PV key informants, which can affect the quality and accuracy of the received information. • However, the survey offered insight into PV and was the first to assess the PV situation in the Middle East.
The Uppsala report (2015)	The report included an assessment of the WHO PV indicators structural components of the Oman PV system by Almaskari (112).	• The author conducted a survey to gather information on the structural complement of the regulatory body system of Oman. • This was followed by a comparison of Oman's performance	• The assessment and subsequent comparison allowed the exploration of system weaknesses. • It was found that Oman's system performance on core structural indicators was 35% compared with 70% in the Netherlands and 75% in Ireland. • The author concluded that in addition to the recommended implementation of the	• A limitation to note is the sole reliance on the structural components of the WHO PV indicators; further studies in Oman should include all of the system components to identify the structures available to attain a satisfactory level of operational capacity.

Author and date	Background and/or objective	Methods	Findings	Review
		as a developing nation to that of the regulatory bodies and systems of other developed nations, namely, Ireland and the Netherlands.	measures required to improve the Oman PV system, continuous monitoring of the system using validated tools as well as benchmark comparisons would be necessary to ensure the attainment of a functional and contemporary system in the country..	• Additionally, the survey method can be influenced by response bias and/or arbitrary interpretation. • However, based on the recorded data, the study was the first to utilize the WHO structural PV indicators and compare the situation with that of other benchmark countries.
Qato, D. (2018)	In 2015, Qato used survey methods to describe the state of PV systems in 20 Arabic and Eastern Mediterranean countries (25).	• Cross-sectional survey methods. • In this study, the IPAT and WHO PV indicators were used to assess the performance of each country, represented by its regulatory authority or the national PV center. • The author selected a few PV KPIs from each tool to assess the countries (i.e., 10 structure, 10 processes, and 7 outcomes). • A simple scoring scheme was developed	• Based on the recorded data, the countries with higher overall system performance status were Egypt, Morocco, and Jordan, while those with the lowest performance were Libya and Lebanon. • Additionally, of the 20 countries that completed the internet survey, 4, e.g., Qatar, reported the lack of a dedicated PV program or center. • Qato found varying differences in the performance of the PV systems in the studied countries and recommended prioritizing PV within the countries' healthcare systems. This can be achieved by increasing the budgetary allocation for PV implementation, addressing policy gaps, implementing educational interventions and fostering regional coordination to realize common goals and achieving a good PV standing that meets international standards	• A limitation to consider is the use of a few PV KPIs from each tool, as none of the tools were implemented comprehensively. • Additionally, the use of email surveys can generate results that are possibly influenced by response bias and/or arbitrary interpretation.

Author and date	Background and/or objective	Methods	Findings	Review
		in which positive responses received a score of "1" or "2" based on the indicator selected, while nonresponses received a score of "0".		
Elsidig et al. (2018)	Elsidig et al. assessed the PV system in Sudan using the structural and process PV KPIs of the WHO PV indicators (113).	• The study used the interview method to assess the three available PV centers in Sudan (i.e., 1 national and 2 subnational). • In addition, the study included school healthcare curriculums across Sudan.	• Elsidig et al. found that the national PV center is well structured, with available accommodation and national legislation as well as national ADR reports for the general public and healthcare professionals. • In healthcare schools, PV is incorporated into programs for graduate and undergraduate students of pharmacy schools, but dentistry schools do not provide theoretical education on PV. • However, challenges were reported in relation to the resources required for operational centers, including irregular budgetary allocations as well as inadequate human resources (i.e., only 2 pharmacists). Regarding the process of reporting, Elisidig et al. reported that the report management process is not clearly defined. • The authors concluded that the observed poor status of PV is attributable to	• Finally, the authors did not address the outcome PV KPIs domain, which could shed light on the impact on the PV activities that are currently available in Sudan (e.g., the effect on clinical and financial outcomes). • It was not feasible to examine the study in detail to obtain information on the values and detailed results, as only the abstract of this study was available.

Author and date	Background and/or objective	Methods	Findings	Review
			unstable funding for PV and the inadequate inclusion of PV in academic curricula	
Hamid, A. and Mohamed Ibrahim (2017)	A systematic scoping review was conducted by Hamid, A., and Mohamed Ibrahim (i.e., a research team) to explore the state of governance and PV in the MENA region (28).	• The scoping review used a pharmacogovernance (PG) framework that consisted of domains with specific definitions to evaluate and explore the available challenges, strengths, and opportunities for PV and effective PG in the region.	• Based on the information provided, the review indicated challenges that affected effective PV and PG, including limitations in the policies, laws and regulations; insufficient resource allocation and availability; deficiencies in transparency and accountability between various stakeholders; and limited participation and inclusion of the general public. • The authors stated, "The key to a robust PV system is the development and enforcement of comprehensive regulations that engage all stakeholders effectively to ensure a culture of patient safety that is built on the principles of transparency, accountability, and equity."	• Although the review provided an explicit methodology, it remained limited in the data provided, which were restricted by the inclusion criteria (e.g., only studies published in Arabic and English). • Additionally, the review provided an understanding at the regional level, not at the specific country level. This was addressed in the review, as it identified the need for research based on empirical data to understand the observed variances between the PV systems in the region, and it recommended utilizing qualitative and/or mixed-methods research to study the PV and pharmacogovernance situation in the national context.
Al Shammari et al. (2019)	Al Shammari et al. provided a narrative review of the research foci for the PV situation in 22 Arab countries (26).	• The authors used the available literature to discuss the PV system in each country, including challenges and strengths.	• In the Qatar context, it is worth noting that Al Shammari et al. reported that the Gulf Cooperation Council (GCC) countries, namely, Qatar, Kuwait, United Arab Emirates, Oman, Bahrain, and Saudi Arabia, have the privilege of GCC membership, which offers them better opportunities, including the acquisition of	• All those factors, if utilized strategically, can create many success factors to establish a well-structured system or to maintain the sustainability and efficiency of already existing PV systems.

Author and date	Background and/or objective	Methods	Findings	Review
			the capacity and support needed to establish a PV system. • In GCC countries, such programs have the privilege of receiving governmental support and are considered wealthy countries.	• Regarding the quality of using review papers to provide insight into PV systems, this review is limited, as no methodology for conducting the review was provided. • Additionally, narrative reviews cannot provide the real-world data that are required to characterize and measure PV system capacity and functionality.

8.3. The State of Pharmacovigilance in Qatar

Only PV research efforts and literature related specifically to Qatar will be discussed, as it is the study's scope of interest. Empirical research on the PV situation in Qatar was described in 3 articles by Wilbur and the aforementioned cross-sectional survey by Qato (25, 27, 36, 37). The latter was limited in its ability to provide an in-depth, context-dependent evaluation because it did not comprehensively use the international PV assessment tools (i.e., utilize all PV KPIs for a full system evaluation) (25). Regarding Wilbur's studies, first, Qatar was included in the assessment of the PV situation in 13 Arabic-speaking countries (26). Second, Wilbur used survey methods in 2012 to assess PV practices among pharmacists in hospital settings (36), and survey methods in 2013 to assess the knowledge, attitudes, and practices of ADR reporting in the community pharmacy sector in Qatar (37). Through survey methods, Wilbur identified challenges to effective PV related to the lack of a national PV program and the lack of a unified reporting system, including the availability of a national ADR form. However, these studies are limited in their ability to provide details on the factors that influence PV from a system perspective, including the exact pattern of interaction between national systems and stakeholders, the national capacity to establish a central PV entity, and other details on the exact functionality of the Qatar system. Further, the studies focused on pharmacists as a professional group, so details on the challenges and perspectives of other healthcare professionals remain ambiguous. Hence, per the IPAT and WHO PV indicators, the rate of reporting can be measured for each healthcare professionals group since PV is a responsibility shared by any individual concerned about medication and patient safety. Similarly, a commentary by Al Hail et al. was published in 2018 to describe the current PV practices, which were mainly passive surveillance and ADR reporting, in the public sector of Qatar. The authors identified

challenges related to underreporting and lack of awareness of PV (38). Therefore, the system performance on other PV activities, e.g., signal identification and active surveillance, require further investigation. Additionally, Al Hail et al. commented on an internal survey to assess knowledge, attitudes, and practices that focused on pharmacists as a professional group; thus, details on this subject matter (i.e., the reporting of various HCPs) can also be investigated through the use of PV KPIs (e.g., the WHO PV indicator coded P2).

Finally, and most importantly, none of the studies conducted in the Arab world and/or Qatar evaluated the PV system following a full system-based approach of structure, processes, and outcomes that completely utilized the validated, internationally recognized PV KPIs. Additionally, the Qatar PV studies were conducted in 2012, 2013, and 2015, and the national situation is likely to have changed since this period. Therefore, there is a need for research that considers qualitative and quantitative information on PV system structures, processes, and outcomes. In addition, there is a need to examine the usefulness of using PV KPIs in a comprehensive manner in a single-country context (i.e., the situation of Qatar).

9. The Current Study

According to our knowledge, this is the first mixed-methods study in the Arab world or the MENA region to cover the full WHO PV indicators manual, including all three indicator domains, structure, processes, and outcomes, as well as the main indicator core and complementary PV KPIs. In addition, it is the first study to assess the PV and medication safety system in Qatar following a comprehensive system-based approach using various internationally recognized tools and research procedures, including the WHO PV indicators, the minimum WHO requirements for a functional PV system, and the input of various national PV stakeholders.

The current study will consider the following issues from the literature. First, a scoring system was developed for the WHO PV indicators, considering the statistical targets to be the threshold of functionality and/or performance capacity (i.e., performance based on a quartile range). Second, the WHO minimum requirements (2010) were used to provide a simple and minimal guide to assess and improve PV. Third, the IPAT PV KPIs were utilized to inquire about PV recommendations and the use of recommended IPAT thresholds for the PV KPIs, e.g., the reporting rate for a functional system. Fourth, multiple stakeholders were involved in the PV system assessment for better comprehensive coverage and a representative evaluation e.g., representatives of the pharmaceutical industry and academic institutions. Fifth, emerging methods of research and analysis (i.e., MMR) were used. Sixth, an analysis of PV system strengths, weaknesses, and opportunities was conducted. Seventh, an organizational structure for a proposed national PV center was developed. The aforementioned points offer an opportunity to develop solutions and recommendations to improve the PV situation in Qatar.

9.1. Conceptual Framework

9.1.1. The Objective of the Study Conceptual Framework

Figure 1 was developed to guide the research process for a robust evaluation of the existing PV and medicine safety system in Qatar, including answering the supplementary assessment questions and generating recommendations.

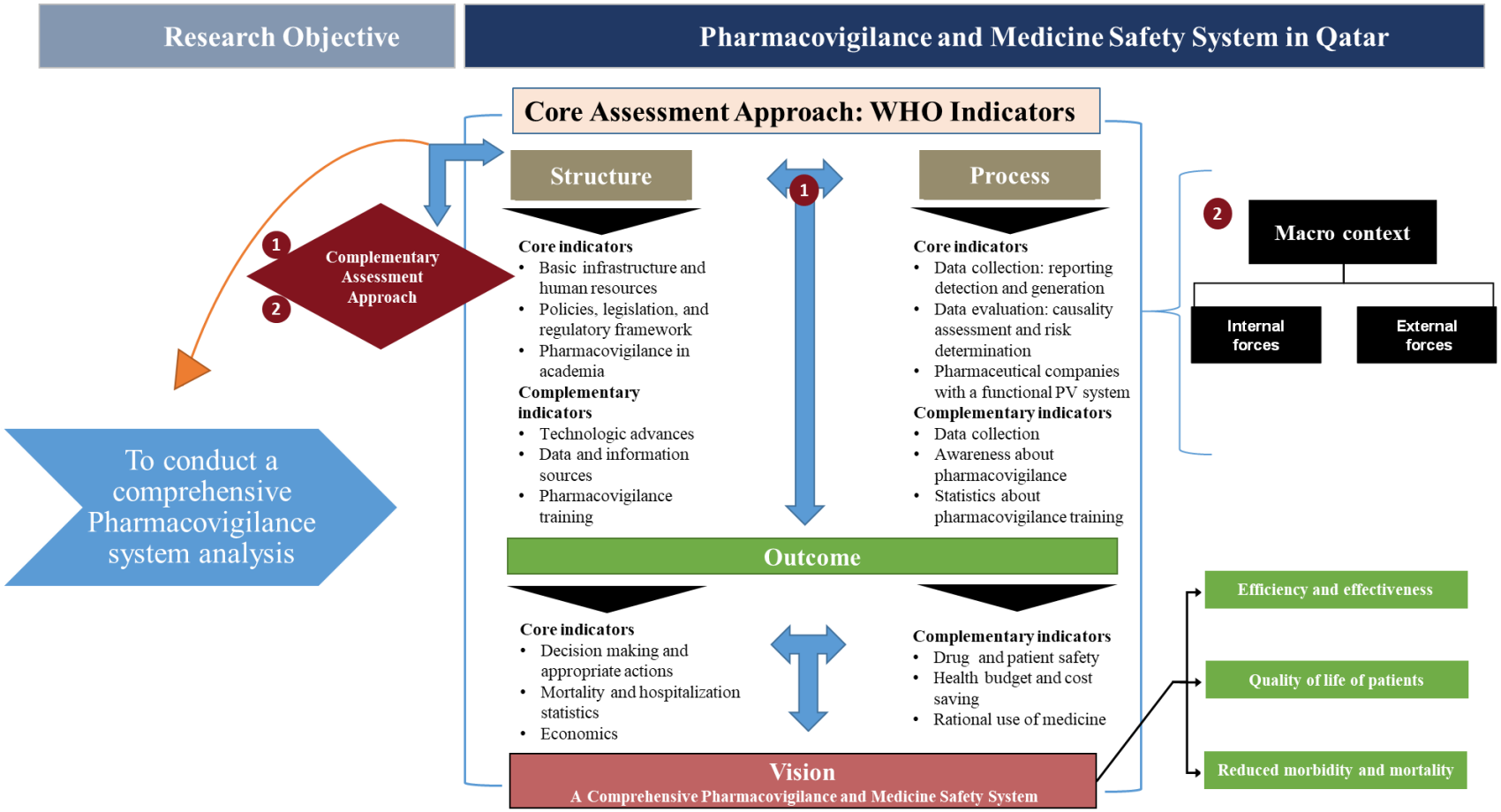

Figure 1. The pharmacovigilance system assessment conceptual model

9.1.2. Method for Developing the Conceptual Model

First, the literature review shaped the development of the model and placed the model within the context of the meaning and importance of a PV and medicine safety system and its impact on patient and pharmaceutical product safety. This includes 1) PV as a discipline; 2) Factors (i.e., internal and external) influencing PV; 3) the PV system and its importance; 4) PV KPIs and the selection of WHO PV indicators; 5) Studies evaluating PV systems in other countries; and 6) The impact of PV and PV systems on the safety of pharmaceutical products, patients, and the public.

Second, well-established frameworks were identified, including the distinct concepts of assessment approach, structure, process, outcomes, purpose, and the macrocontext. To develop the model, the conceptual models from the existing literature, namely, the Handler et al. framework (2008) (114) and the SPS program PV framework (10), were used to build a comprehensive model.

9.1.3. The Framework Content

Below is the current study conceptual framework content:

I. Context: Qatar healthcare sector PV and medicine safety system.

II. Macrocontext: Represents the environment directly or indirectly influencing the institutionalization and functionality of the PV system. It encompasses several factors. First are internal influences such as 1) Political, social, and economic influences; 2) The extent of the demand and need of the Qatar population; and 3) Social values and preferences with respect to the medicine safety system. Second are external forces, which affect the system functionality (e.g., the nature of PV actors' relationships).

III. Structure, processes, and outcomes: Per the WHO PV indicators (i.e., core and complementary).

IV. System assessment approach: First, the core assessment approach, uses the validated instrument, the WHO PV indicators. Second, the complementary assessment approach, uses the qualitative method.

V. Purpose or objective of the study: To conduct a comprehensive PV system analysis of Qatar.

VI. Vision: In the future, a comprehensive PV and medicine safety system will be established to 1) Ensure efficiency and effectiveness; 2) Improve the quality of life of patients; and 3) Reduce morbidity and mortality.

9.2. Research Question

"What are the most important measures to improve the pharmacovigilance system in Qatar based on the WHO PV framework?" This question will be answered in the discussion chapter (section 4) in the form of recommendations following the structure, process, and outcome PV KPIs. Those recommendations will be aimed at different national PV stakeholders in Qatar.

CHAPTER III: METHODOLOGY

In Qatar, a centralized and comprehensive pharmacovigilance (PV) system does not exist, and the slow advancement of PV in Qatar has been reported in different studies concerning the regulatory and practice aspects of PV. Therefore, empirical data are required to obtain an in-depth understanding of the PV situation in Qatar. This study aimed to conduct a comprehensive PV and medication safety system assessment, including exploring the opportunities available for effective PV as well as the important measures required for the improvement of PV and the development of a centralized PV system. This chapter will elaborate on the measures required to address the specific research problem at different levels, first reflecting on the employed research paradigm and then describing the methodological approach, research design, and specific quantitative and qualitative procedures for data collection, analysis, and interpretation.

1. Topic Selection

As an emerging economy seeking to enhance practices in the country's healthcare infrastructure, the state of Qatar is currently experiencing surging advancement in the field of medication safety. This study is intended to describe the status of the knowledge, reporting, experiences, systems, and framework structures of PV in Qatar. The primary investigator's interest is in PV, and the literature search indicated that a gap was observed throughout earlier studies conducted by Wilbur, who found that there is no national PV center and that such a center is needed in Qatar (27, 36, 37). Therefore, this study aimed to assess the baseline situation to understand the gaps that could affect the establishment of such an entity. Accordingly, a search for evidence-based literature was conducted to address the research problem and assess the PV situation in Qatar. It was found that the WHO has published an PV KPI s assessment

tool that is designed for a comprehensive evaluation of the PV system structure, processes, and outcome. However, because a PV system does not exist, and the indicator tool would be difficult to implement, it was decided to utilize the knowledge of available experts as well as their views on PV. Therefore, in-depth MMR was conducted to address this problem. Refer to (Chapter II) for details.

2. Research Paradigm

First, the researchers need to select a research paradigm for their study. There are several paradigm worldviews (i.e., research paradigm) available for researchers to position their current study within a set of assumptions and beliefs that directly informs subsequent levels of the research process, including the methodological approach adopted and the specific methods and techniques used to collect, analyze, and interpret data (108, 115, 116). Morgan (117) along with Tashakkori and Teddlie (48) conveyed that the pragmatism worldview can be used as a philosophical basis to support MMR. The pragmatism worldview is widely accepted as the philosophical foundation for MMR, in which the researcher focuses on the research problem and then attempts to acquire knowledge on the problem utilizing pluralistic approaches. In pragmatism, researchers value the subjective and objective meaning involved in solving the research problem. Therefore, in pragmatism, researchers can utilize both qualitative and quantitative approaches in a single study, and they may abandon the dichotomy of worldviews, research approaches, and concepts of reality in order to prioritize the research question or problem as the most important concept and the guide to their philosophies and methods. As a result, the use of the pragmatism paradigm and MMR approach is suitable for the current study, as both qualitative and quantitative approaches will be used to address the specific research problem (48, 53).

3. Research Proposal

A thesis proposal was prepared under the supervision of the main supervisor. It detailed the goals and process of the research, and it was presented to the student supervisory committee. The research proposal was approved with no additional changes suggested to the structure and methodology.

4. Background Research: Desk Work

Previously published research was utilized to develop the methodology while avoiding systematic gaps and weaknesses, and the study considered benchmarks to be the best research practice, e.g., complying with evidence-based PV KPIs and including a representative sample. Additionally, previous work was included in the design of the data collection instruments, specifically the semistructured interview guide that aided in inquiring about gaps (e.g., weak regulatory frameworks, governance of systems, and patient reporting) reported previously in the literature or best practices (e.g., causality assessment and signal management processes) that have been implemented in other countries of the world. Additionally, previous studies helped in addressing the feasibility of some recommendations addressed in the literature (e.g., establishing a PV center in an academic university). Finally, previous work enabled the researchers to outline the PV systems of some benchmark countries, such as Morocco or the European countries, on which Qatar could model a national PV center. Refer to (Chapter II) for details.

5. Pharmacovigilance Key Performance Indicators

Monitoring the safety of medications has been a focus of PV in many countries around the world. PV development has been accompanied by the development of PV systems and tools to assess those systems. In the field of PV, there have been few initiatives to develop objective measures (i.e., PV KPIs) to assess the performance and

adequacy of PV systems. The two most commonly used PV KPIs are the WHO PV indicators and IPAT. These PV KPIs will serve as the researchers' validated tools to evaluate the performance of PV systems in the process of identifying areas that need proper investment to improve PV systems in terms of performance and adequacy. However, the IPAT tool was used only to identify supplementary information, e.g., the threshold of reporting rates, the threshold of individuals receiving training, examples of risk mitigation activities, and the regulatory framework of the PV system. The main indicator tool that was formally used to evaluate the PV system is the WHO PV indicators. Refer to (Chapter II) for details

6. Ethical Considerations

Ethical approval was obtained from the Institutional Review Board (IRB) at Qatar University (QU) (Research Ethics Approval No. is QU-IRB 826-E/17), Primary Healthcare Corporation (PHCC) ethics committee (Research Section, Clinical Affairs Department, Approval Number PHCC/IEC/1710/036), and the Medical Research Centre (MRC) at Hamad Medical Corporation (HMC) (Protocol No. MRC-01-17-069). In addition, a support letter was granted by QU. Consent forms were appropriately developed to ensure compliance with legal and ethical research regulations that cover information collection through interviewing key informants and, where applicable, review of official documents at each data level. A consent form was developed in both Arabic and English and submitted to all the relevant ethical committees. The PHCC research participant information sheet on the study was included with the consent forms. All the aforementioned ethics-related documents are presented in Appendix A, (from M1 to M3).

7. Introduction Letters and Forms to National Pharmacovigilance Stakeholders

After ethical approval was obtained, official invitation letters and emails were sent to the stakeholders and/or target population to obtain their consent to participate in this research and to obtain the relevant information and data prior to starting the data analysis of this research. The generic introduction letter is presented in Appendix A, (M4). Along with the invitation letters, the approved study instruments, the approved proposal, and ethical permission forms were distributed to the target population and stakeholders. This was necessary to provide the participants with enough time to understand and prepare for the interviews and to save copies for their records. The distribution of these materials was through email, and printed copies were provided when conducting the face-to-face interviews and/or beforehand on request. The stakeholders' responses to the invitation came at different times and will be mentioned in the study timeline section.

8.Methodological Approach

On the basis of the MMR design, the baseline PV situation was evaluated by adapting a mixed-methods case study design (convergent core design). The MMR case study design was employed to provide a comprehensive multiple case evaluation for: a) in-depth case evaluation of subnational PV systems, b) comparative case analysis across subnational PV systems, c) and evaluation for the overall national PV system. In the convergent core design, the two types of data were collected at the same time with equal weighting for the priority of collection. Mixing took place in the stage of data collection, data analysis, and interpretation of the findings. The approach allowed the researchers to build a strong foundation of data to assess the PV and medicine safety system and to integrate and interpret the two types of data for a comprehensive discussion of the research problem as indicated below in Figure 2. Furthermore, it is

used to benefit from the strengths and reduce the limitations inherent to the quantitative and qualitative methods. (49, 118).

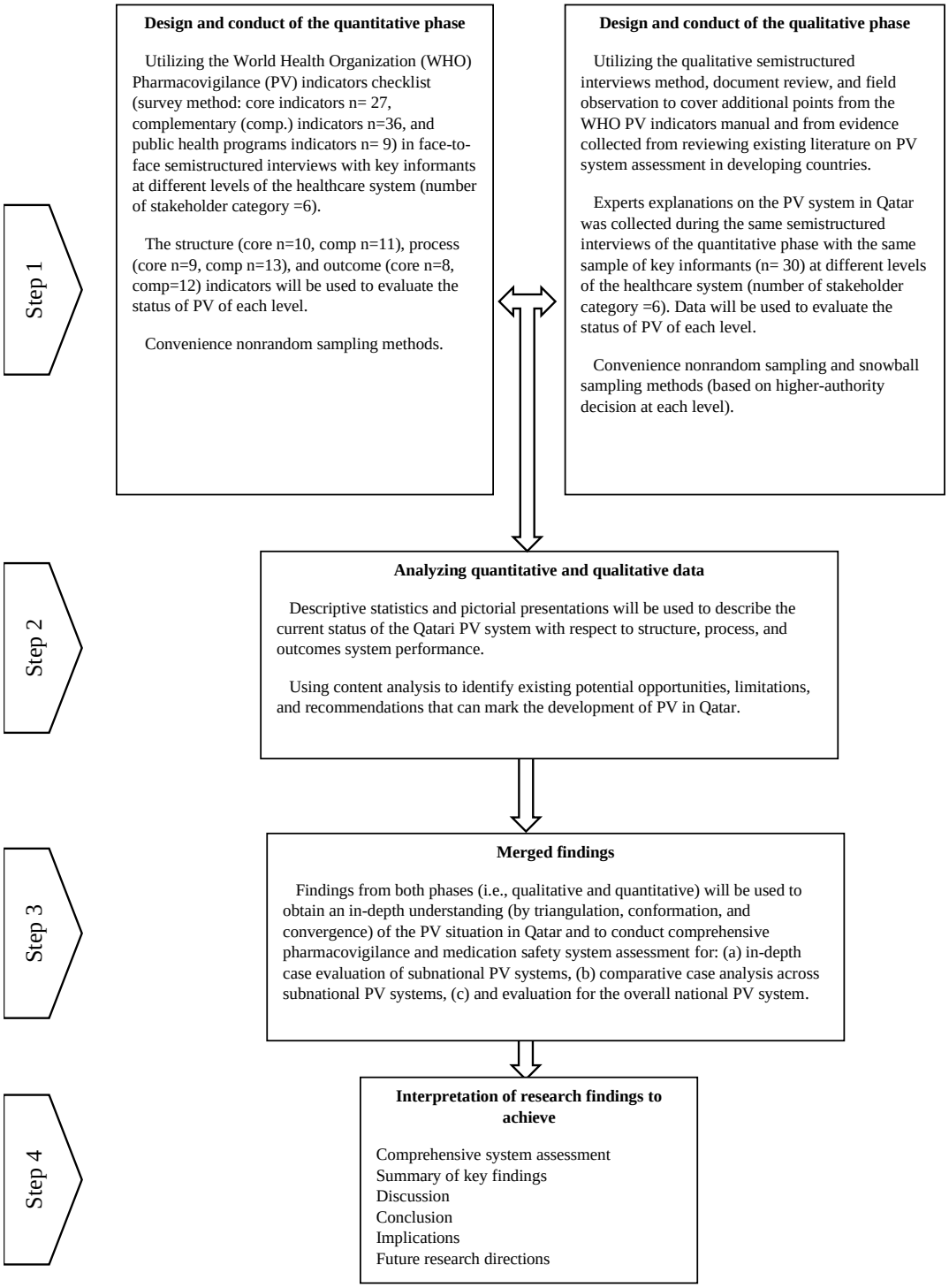

Figure 2. Concurrent mixed-methods case study flow diagram

A case study allows researchers to inquire about and observe the characteristics of a case (e.g., program, event, activity, process). This design is popular in evaluation studies because it allows researchers to conduct an in-depth analysis of a case that is circumscribed by time (i.e., one year), and many methods can be used to collect all the relevant data for that case (118) and/or to generate cases for comparative analysis (49). This design is frequently used in MMR (119). For this mixed-methods study, the case design is a multiple case study design (e.g., MOPH as a case of the PV system situation and HMC as a separate case) with a naturalistic structure (i.e., as a flexible design in the sequence it follows, as a flexible design in the size of the sample, and as a design to study cause and effect that is not experimental in nature) (119).

The case study design aimed for a deeper understanding of the compliance provisions in each stakeholder's PV system, including the deficiencies in the implemented structures, processes, and procedures as measured by the WHO PV indicators. The design was utilized to assess the performance, status, and capacity of such elements of PV systems as the techniques and practices of PV and whether they showed a degree of compliance with international standards. Additionally, it enabled the researchers to understand the level of awareness regarding PV provisions (118) and to cover the thesis objectives. Furthermore, a case study design was used in a systematic qualitative assessment of the PV system. This qualitative approach respects individual meaning in providing an understanding of the complexity of a situation or research problem (119). Individual meaning and situational system analysis are important, as PV systems are influenced by the political, financial, technological, and financial status of the country. For example, developing countries' PV systems are an area of research interest due to continuous changes in the societal, behavioral, and political aspects of PV systems (10, 20, 21).

Following the convergent design enabled the research to employ quantitative and qualitative data to address the national context, as requested in the WHO framework (11), since both forms of data would be converged, triangulated, and corroborated to obtain results on a single topic. This study used qualitative and quantitative methods on the same sample of key informants in a single-phase study (i.e., at the same time). The rationale for the convergent design is to acquire complementary data that are different in nature to address the same topic with a deeper level of meaning and understanding. The immense amount of detail merged with the statistical results helped in constructing, validating, and synthesizing both quantitative and qualitative outcomes to develop a complete understanding at multiple levels within the national and subnational PV systems. The final outcome can be used to direct future interventions and research in relation to the national PV system (49).

9. Quantitative Phase

9.1. Instrumentation: World Health Organization Pharmacovigilance Indicators

The WHO PV indicators manual is a validated and standardized tool that is available on the WHO website. The WHO indicators were selected for the purpose of the Qatar PV system evaluation because the PV KPIs were designed to be reproducible and have been successfully adopted in various countries. The selected PV KPIs were used as an assessment tool to provide simple measures for the compliance of PV systems with the expected PV WHO framework. The WHO indicators were used as the basis for the semistructured interviews and all other system assessment concepts. Each indicator was used to assess an objective that the national and subnational PV systems must meet. The results would serve as a baseline benchmark to enable future

comparisons and possibly to evaluate trends. The results were generated as counts or numerical values that quantitatively described specific aspects of PV stakeholders' system compliance with WHO standards (11).

The WHO PV indicator manual encompasses a ready-to-use checklist, presented in Appendix A, (M5), that was developed for use as a data collection tool. This data collection tool was adapted and utilized to collect all relevant data that address each specific indicator. It is important to emphasize that there is no centralized PV system in Qatar. Nonetheless, the study used the knowledge of the available experts in the area of PV in Qatar. The PV indicator checklist was shared with the key research informants and was adapted (i.e., changed) only by substituting the name of the organization or data collection site surveyed for the term PV center. For example, the words "pharmacovigilance center" were changed to "Medication Safety and Quality Center in HMC". Furthermore, the survey asked about each indicator in relation to the relevant study sites only; for example, the MOPH relevant indicator set was slightly different from the service delivery organization set. The WHO PV indicator manual has a specific section for identifying all the relevant stakeholder systems or data collection sites for each indicator. Table M6 in Appendix A provides the relevant and nonrelevant PV KPIs at each study site.

9.2. Survey Design

In this research, the survey design as a quantitative design was based on the WHO PV indicators questionnaire. The survey design followed a standard format to provide a numerical description of the trends, perceptions, and attitudes of a population through selecting and studying a representative sample to produce an outcome that can be generalized or aid in drawing inferences for the population (118).

Many benefits can be achieved from a standard survey design. Information can be obtained from different stakeholders representing a specific population. Surveys can obtain the data used to describe the sample composition. Additionally, surveys can be useful for assessing variables that need to be comprehensively described with respect to number and type. Surveys can be easy to develop and administer. Nevertheless, the results of surveys are in the form of compliance-level estimates rather than exact measurements (118, 120). In this research, a sample of national stakeholder PV systems were surveyed (i.e., a cross-sectional survey) to obtain baseline data on PV system performance that could provide an estimate for national PV system compliance. Another drawback of the survey method is that it is not possible to obtain bulky and large-scale information on a phenomenon. The nature of surveys that depend on a study sample response can create a bias, for instance, lack of response of key participants or uncertain accuracy of information provided, that affects the ability to generalize the results. Response bias can also have a degree of intentional misreporting; for example, in some cases, the respondents' attempts to hide inappropriate or misimplemented practices imposed difficulty in assessing the compliance of the PV system with the WHO PV indicators (118, 120). The data collection was conducted during face-to-face interviews with one or more key informants at each data collection site. Although face-to-face interviews are time-consuming and can be expensive compared to internet or phone surveys, they help ensure data availability for each indicator. MMR including Face-to-face interviews methods offer the opportunity to validate the findings through direct interaction with the key informants since documents can be sought, and the process can be observed where applicable (118). Moreover, additional data collection forms were used and were intended to be completed during the face-to-fac meeting. Details will be described in the qualitative phase instrumentation section (i.e., 10.6.).

9.3. Study Setting

Qatar is located in the Arabian Peninsula on the Persian Gulf (or Arabian gulf) in the MENA region (121). The system analysis covers mostly representative study sites at the national level that are responsible for PV and medicine safety in the Qatar healthcare system. For this study, each sector represents a data collection level and each site is a unique case study. The following sites were assessed:

I. Regulatory body: Ministry of Public Health or the Supreme Council of Health.
II. Public sector: 1) Hamad Medical Corporation and 2) Primary Health Care Corporation.
III. Private sector: 1) Health facilities or organizations; and 2) Community pharmacies.
IV. Pharmaceutical industry.
V. Higher academic education institutions.
VI. Public health program: Mental Health Strategy case.

Data collection involved various departments or units at each study site, covering the main stakeholders where the PV-relevant department was the focus of the conducted survey (e.g., Pharmacy Department, Drug and Therapeutics Committee, Quality Department, etc.).

9.4. Population and Sample

The target population is PV and medication safety systems (6 levels of the healthcare system; a total of 18 case studies) and potential stakeholders involved in ensuring medication safety and improving public health through participation in different activities, processes, and/or programs at their institutions. Table 5 explains the criteria of selection of national PV systems and representative stakeholders from each

level.

Table 5. Criteria for selecting target study sites

Data collection level	Justification for inclusion
MOPH PV system	MOPH is the regulatory body for Qatar's national healthcare system and is responsible for legislation and policy setting, regulation and management, priority setting, providing advice and planning, and providing healthcare services. Consequently, MOPH is considered the current national-level PV system and was one of the primary sources of data for this study.
HMC PV system	HMC offers healthcare services in the public sector and is considered the primary provider of healthcare services in Qatar. HMC hospitals treat individuals with common or specific needs, including cancer or cardiovascular disease patients, and it delivers care for different patient groups, such as women and children. Thus, HMC is considered a primary source of national PV data, including ADR reporting.
PHCC PV system	Since the establishment of the PHCC in 2012, the primary healthcare centers have been the providers of primary healthcare services in Qatar. Given the accessibility of the 25 centers located in all regions of Qatar, specifically the northern, western, and central regions, the corporation plays an important role in ensuring medication safety for the Qatar population and is considered a rich data source on PV and medication safety.
Private sector: healthcare institutions	The healthcare system in Qatar is extended to include the private sector, where healthcare services are provided mainly as paid services. The study targeted the PV system of different private health institutions (i.e., private hospitals, private healthcare organizations, and semigovernmental hospitals). Each is considered a unique case and a potential source of PV data.
Private sector: community pharmacies	The community pharmacy is the first contact point for many patients. Given their accessibility, their current capacity and performance in contributing to PV at the national level is worth investigation. The assessment of the PV system at the community pharmacy level included chain pharmacy groups and independent pharmacies. Each is considered a unique case and a potential source of PV data.
Pharmaceutical industry	The pharmaceutical industry represents recent improvements in the Qatari pharmaceutical sector. The national pharmaceutical industry in Qatar is in the business of manufacturing generic medications. Thus, the performance and status of PV at the national pharmaceutical industry level is of great importance to this study. The reason is that the literature on WHO PV indicators has reported that the collection of details on the industry is required if users aim to assess the complete system.
Mental health strategy	The WHO Public Health Program indicators require the assessment of governmental programs designed to protect public health;

Data collection level	Justification for inclusion
	therefore, the researchers approached governmental organizations that are concerned with the public health of various patient groups or medication classifications.
Academic Institutions	Academic institutions are one of the core structural indicators (i.e., CST8) required for a comprehensive evaluation of systems. Incorporating PV into the curriculum across different healthcare programs is essential for this study.

The present study employed nonprobability sampling techniques, specifically the purposive and snowball sampling techniques (122). First, the study selected a group of respondents with predetermined characteristics. The first contact point or the initial authority at each site were as follows:

I. MOPH: Pharmacy and Drug Control Department.

II. Academic institutions: dean or associate dean.

III. Pharmaceutical industry: CEO or general manager.

IV. PHCC: ethics committee.

V. HMC: executive pharmacy director at the corporate level.

VI. Private sector: human resources department, medical director or research or pharmacy department, based on the study site.

VII. Public healthcare programs: program coordinators and the MOPH (one key informant).

Then, the snowball sampling method was applied. In this technique, the first contact point referred the researcher to other members who could serve as potential key informants to provide the necessary contributions to the study. At times, the initial contact point was the eligible key informant who participated as a sample to provide information. Many advantages were achieved by following this sampling technique. This sampling method allows researchers to access and recruit samples from a

population (i.e., higher-level authority and administrative teams) that is not easily accessible under normal circumstances. Furthermore, the sample size can be increased to allow the researcher to gather more in-depth and comprehensive data required for the study and thus to achieve the desired outcomes (i.e., comprehensive coverage of the WHO PV indicators). The participants recruited included experts in the field who directed the researcher to other experts until all relevant data or the best possible information was obtained (122, 123). Based on the WHO PV indicators, manual data were obtained from different sources, including stakeholders, databases, records, documents, and surveys specific to each study site. The candidate study sites were accessed, and information was obtained from representative members and experts at each institution. The study included 30 candidate representatives who were members of a department or unit that had relevant information and documents for the system analysis. The process of data collection was coordinated with the key informants working at each study site or institution (11). The ultimate key informant selection and the number of key informants representing each site were determined by the institutional authority or initial informant approached through the purposive and snowball sampling methods to avoid any constraints (e.g., legal, logistical, or ethical) or other key informant availability issues. Eligible members from various departments or units were approached to obtain their consent to participate in the study.

No specific sample size was determined a priori, as this study employed the MMR principals to allow a comprehensive analysis of the availability and current status of PV systems in Qatar. Therefore, extensive data collection was required, and convenience sampling was used to ensure the attainment of a representative number of study sites and key stakeholders working at each site (i.e., 30 key informants or candidate representatives) (118). It is worth noting that based on Creswell's work, a

sample size of 5 to 25 individuals is acceptable in qualitative research (124). Finally, stakeholders who were approached but did not agree to participate, along with their justifications, are presented in Appendix A, (M7).

9.5. Data Collection Process

The WHO PV indicator set was not pilot-tested, as it is a well-established tool, and the WHO methodology has been used previously in several countries. For a critical evaluation of the PV system, all the relevant information was collected through semistructured interviews. The identified key informant from each study site who provided informed consent was interviewed using the semistructured interview method (duration from 30 minutes to 3 hours). Moreover, when necessary, multiple interviews were undertaken with the same key informants; these arrangements were organized through the study participants. The interviews included questions about the PV KPIs specified in the WHO PV manual such as the activities held at each site and the actual implementation of any PV-related activities. Regarding the qualitative counterpart that will be mentioned in detail under the relevant section, additional feedback was sought, including any opinions or recommendations relevant to PV and medicine safety that were not highlighted in the ready-to-use WHO PV indicator checklist.

Since this study is a single-phase MMR that involves the same stakeholders in both a case study design and a survey method design, further elaboration on the exact steps followed will be included in the qualitative part of the methodology section to comply with the detailed discourse nature of case studies (125).

9.6. Timeline

Research was conducted in Doha city and the surrounding areas. Data collection initiation at each stakeholder level was based on the granting of ethical approval. The

study started in early November 2017 after ethical approval was received from QU. The PV system analysis timeframe was extended due to delays and/or lack of response from some stakeholders despite conducting several site visits, requesting a response by phone, and sending e-mail requests to the committed stakeholders' representatives. Meeting dates and frequencies were determined by the stakeholders. Finally, the PV system analysis ended in July 2019 even though some stakeholders still had not provided the requested information. Table M8 in Appendix A describes the stakeholder level, ethical approval receipt, date of the first visit for obtaining consent to participate, and meeting dates and frequencies.

10. Qualitative Phase

10.1. Study Setting

For the setting, refer to section 9.3. in the Quantitative Phase.

10.2. Population and Sample

For the population and sample, refer to section 9.4. in the Quantitative Phase.

10.3. Timeline

For the timeline, as it is a single-phase study, refer to section 9.6 in the Quantitative Phase.

10.4. Instrumentation

The qualitative part of this study involved the use of instruments that were used as tools to measure the phenomena of interest and to guide the data collection process (118). The instruments included the WHO indicator checklist; semistructured interview protocols, one general and one based on the study site; and the instrument created by the researcher. The first tool was the WHO indicator ready-to-use checklist, as described previously, which is presented in Appendix A, (M5). Then, the

semistructured interview protocol, which included quires in the form of additional points, including follow-up points on the limitations and details for each indicator, was extracted from the WHO PV indicator manual, including closed-ended and open-ended questions, and is presented in Appendix A, (M9) (11). The researcher created an additional semistructured interview protocol to collect additional information following a system-based approach; it is presented in Appendix A, (M10). This helped in collecting information relevant to the strengths, weaknesses, opportunities, and recommendations for improvements to the PV system. This content was covered after covering the WHO PV indicators and the additional qualitative assessment for each indicator; if a subject had been mentioned previously during the discussion, it was not included (1, 10, 29). This instrument was developed for the service delivery level, the pharmaceutical industry level, and the academic institution level. Finally, the researcher-created instrument that collected information on the study participants and served as an observational protocol to collect all relevant information observed or mentioned during the semistructured interview is presented in Appendix A, (M11) (118). This survey collected information on the stakeholders and the data collection site. The survey was specifically designed to collect information relevant to the interview, the study site, and the research participant, including the date of the field visit, data collection level, name of the institution, name of the key informant, designation of the key informant, contact information, documents used and year of issue, topic discussed, and additional notes. This survey was used only to facilitate follow-up with the stakeholder and the system he/she represented, and its confidential content will not be published to ensure the anonymity of the research participants and the study site regulations. These data collection tools were all used during the same semistructured interviews.

10.5. Data C ollection Process

The data collection process was mentioned briefly in the Quantitative Phase section. This section will elaborate further on the qualitative nature of this study. Data were collected through the following procedures:

10.5.1. Semistructured Interviews

Semistructured interviews were the main method of data collection, as mentioned in the quantitative phase. According to Kvale, as a data collection procedure, the semistructured interview is intended to elicit the in-depth meanings that the interviewees ascribe to a specific topic (126). Face-to-face semistructured interviews were the most suitable type for this study, allowing the collection of in-depth information and facilitating discussion using both closed-ended and open-ended questions (127). Thus, the study was able to collect the required information on all the objectives, from the first objective of evaluating the PV system performance to determining whether the national PV system complied with the standards of a functional PV system established by the WHO (11, 40), to the collection of stakeholders' views and opinions on the current strengths, limitations, and opportunities of the baseline PV situation and recommendations for how it can be improved.

10.5.2. Document Reviews

Electronic or paper-based documents, manuals, reports, and publications were reviewed at each study site. Documents identified through the field visit were sought from the key informants or directors at each study site. For example, the ADR reporting forms, the ADR policies in some organizations, the KPIs of organizations, and the terms of reference of the department concerned with PV were shared. Such documents were not published or shared as agreed upon and with respect to the legal requirements at

each site. The documents helped ensure the validity of responses as well as confirm data availability (118).

10.5.3. Field Observation

Some of the data collected were a result of close observation of some processes, for example, the use of electronic reporting systems, the databases created and how information is inputted, the approach to access the organization policy. Field observations allowed validating the participants' responses and obtaining an in-depth understanding of the actual environment PV (118).

10.6. Data Recording Procedure

10.6.1. Semistructured Interview Structure

The semistructured interviews started by collecting all the relevant information about the key informants and the data collection site. Then, the WHO indicators and the supplementary questions for the PV KPIs were discussed in parallel, which allowed the researcher to gather the quantitative and qualitative data concurrently Appendix A, (M9). Then, the researcher-created instrument, which contained open-ended questions following a system-based approach to seek an in-depth understanding of the current strengths, weaknesses, opportunities, and recommendations of the interviewees, was presented. The key informants were asked to comment at the level of their system, the interface of their PV system with other subnational systems, and the national level represented by the regulatory authority (i.e., MOPH) system. This allowed the researcher to generate data concerning the status and implementation of PV in the healthcare system that were relevant to the individual institutional context as well as the country context. The interviews were conducted in Arabic or English, depending on the preference of the key informant. These interviews were conducted until the data

collection reached the saturation point.

10.6.2. Validation of Interview Guide

All data collection forms and the interview guide were reviewed by the research supervisor, who has expertise in the field of PV social and administrative pharmacy, and research methodology. Furthermore, although there was no pilot testing, the created data collection instrument that followed a system-based approach was utilized by the primary supervisor in an interview, and no changes to the structure or content were requested. Finally, the data collection tools and all the documents relevant to the study were reviewed by the ethics committees at QU-IRB, PHCC, and the MRC at HMC and, when applicable, by the private hospitals' research sections.

10.6.3. Transcribing

The semistructured interviews were audio-recorded using two recording tools and then transcribed. Translation was performed for the interviews conducted in both Arabic and English. The translation quality was not evaluated for two reasons. First, per the ethical requirements of the study, only the primary investigator and the primary supervisor were allowed to access the audio records and interview scripts. Second, the primary supervisor is not an Arabic speaker. The translated interview transcriptions were shared with the key informants (i.e., in the HMC case study), and no changes were made and/or requested.

10.7. Role of the Researcher

According to Creswell and Plano, MMR involves the researcher role on the quantitative (i.e., as the investigator who follows systematic procedures aimed at reducing bias and threats to the validity of the research) and qualitative (i.e., as the inquirer who can shape the findings and their interpretation through prior experience or

personal background) approaches. Accordingly, the role of the researcher was included in both approaches throughout all stages of the study from planning to data collection, data analysis, and interpretation (49, 118). The researcher has no conflict of interest or affiliation with the stakeholders' systems or the key informants, which gives the study an advantage. Additionally, the systematic steps, e.g., relying on the higher authority at each level to select the participants, that were followed for each case study helped in limiting the potential bias that the researcher might bring to the data provided. However, the researcher role in inquiring about recommendations, challenges or strengths could influence the study results, as they were affected by the previously published literature and interactions with previous stakeholder systems, especially when the participants raised comments that the researcher pursued to investigate their occurrence in other settings.

11. Variables: Outcome Measures

For the quantitative phase, the study aimed to address objective number one: "Evaluate the baseline PV situation using the WHO PV indicators". Based on the WHO PV indicator checklist presented in Appendix A, (M5), the quantitative phase addressed the following set of PV KPIs:

I. Twenty-seven core PV KPIs (i.e., 10 structure, 9 process, and 8 impact/outcome indicators).
II. Thirty-six complementary PV KPIs (i.e., 11 structure, 13 process, and 12 impact/outcome indicators).
III. Nine PV KPIs for PHPs.
IV. Eleven indicators for the background information were not provided by any of the stakeholders. This omission was acceptable because the anonymity of the study sites was maintained.

The following operational definitions were used for the study variables that were assessed in the quantitative and qualitative phases (11):

I. Core indicators: Objective measures that are important, highly relevant, and useful to characterize PV. The ability of the PV system to perform well in the core indicators is a requirement for a PV system to be considered functional or performing at a satisfactory level.

II. Complementary indicators: Objective measures that are considered additional, useful and relevant to characterize the PV situation in the assessed setting in further detail. The ability of the PV system to perform well in the complementary indicators is a requirement for a PV system to be considered a sophisticated system. However, complementary indicators need not be used in all cases.

III. Structural indicators: A selected set of indicators to assess the availability of key structures, infrastructures, mechanisms, and systems for PV in a specific setting, the availability of which can provide visibility for PV.

IV. Process indicators: A selected set of indicators to directly or indirectly assess the operational aspects of the PV system, including dynamic and interactive mechanisms and the activities performed by the system. The ability of the system to perform well can result in outcomes that can be used for further interventions and corrective actions.

V. Outcome indicators: A selected set of indicators to assess the final outcomes as long-term or short-term effects or results of PV activities. The measured results and trends can be used for healthcare planning and the development of interventions, as the ability of the system to meet the final objectives of a fully operational PV system will be benchmarked.

VI. Public health program indicators: Nine selected indicators that cover the spectrum of structural (i.e., setup of the system), process (i.e., system operation), and outcome (e.g., early detection of harm) indicators that are relevant to the PHP setting.

In addition, to address objective number two, the current national PV system (represented by the MOPH system) was assessed for its compliance with the five minimum recognized international requirements determined by the WHO for a functional national PV system (i.e., a PV center, ADR or PV advisory committee, spontaneous reporting system. national database, ADR reporting form, and communication strategy) (40).

12. Data Analysis

Mixed-methods research design requires rigorous analysis, as both qualitative and quantitative data are analyzed to provide a comprehensive understanding of the research problem (118).

12.1. Quantitative Phase

For the quantitative phase, all data required for the completion of the WHO PV indicator assessment checklist were analyzed by descriptive statistics using the Microsoft Excel Program. First, a database was created in the form of an Excel spreadsheet for each data collection level (e.g., PHCC), and a single spreadsheet was created for all stakeholders. The content of each database was based on a component of the WHO PV indicators manual. Furthermore, data or responses to each indicator, both qualitative and quantitative, were entered in the databases; that is, if an indicator was available or had reached the standard threshold of functionality, the indicator score was entered based on the indicator category, whereas if the standard threshold was not attained, a score of 0 was recorded. Based on the study scoring scheme, the parameters

that were not provided shall be granted less than a complete score or a zero score for fair consideration of the other competent stakeholders in this research. The exact scoring system was as follows:

I. Core PV KPIs (*) score: (2) Yes, fully satisfactory; (1) Yes, partially satisfactory (2); (0) No, not satisfactory, missing data, no values, not applicable, or not clear; and (-) Not relevant for the stakeholder in this evaluation of PV system performance with WHO PV indicators.

II. Complementary PV KPIs (*) score: (1) Yes; (0.5) Score for indicators with two parts or more, e.g., A and B (if A, the answer is No Score (0.5), and vice versa for B); and (-) Not relevant for the stakeholder in this evaluation of PV system performance with WHO PV indicators.

The scoring system was adapted based on the IPAT tool with a modification to include the "Yes, partially satisfactory" score. The IPAT scoring system uses only satisfactory and not satisfactory. No formal reliability testing was performed; however, the scoring system was developed based on discussion and agreement with the primary supervisor. Additionally, the scores obtained for each stakeholder system were discussed in meetings with the primary supervisor and the supervisory committee, including the detailed purpose of each indicator, the stakeholder ability to satisfy the criteria of each indicator and issues with missing values, inadequate information, and no proof of evidence of the required PV KPIs. Furthermore, the scoring system received the approval of all ethics committees with no additional changes suggested.

Descriptive statistics, including percentages and means, were considered appropriate to describe the observed trends. No further statistical tests or analyses were carried out, and only the percentages and means were used to represent or indicate the status of the PV system and its performance in Qatar. Table 6 represents an example of

how values were calculated and presented. The target performance range is described as percentages based on quartiles (Q1: 25%, Q2: 50%, and Q3: 75%) (128):

I. Excellent performance 75-100%

II. Good performance 50-74.9%

III. Average performance 25-49.9%

IV. Poor performance 0-24.9%

Table 6. Examples of pharmacovigilance (PV) system performance and capacity results measured by the WHO PV indicators

CORE STRUCTURAL INDICATORS				
Code	**Assessment questions (main)**	**Response**	**Score**	**Assessment (qualitative)**
CST1	"Is there a pharmacovigilance centre, department or unit with a standard accommodation?"	Yes, no specific PV department	(1)	Applicable but not a specific department for PV.
Total core structural indicators score	Out of x [x*2=(x)] is [(100%)] relevant indicators the obtained score is [(x) = 0.0%]		(x)	

In addition, graphical representations, namely, bar charts, radar charts, and creative charts, were used to demonstrate and compare the results for each indicator category and each system and for the comparative analysis of systems.

This type of statistical analysis and graphical representations helped to address objective one of this thesis by presenting the evaluation findings for each subnational PV system, the overall system performance in Qatar and the comparative analysis of

the systems.

The number of key informants representing each data collection site will be described in text format at the beginning of the results chapter. Additionally, the departments or units that they represent will be noted. However, no names or designations will be made available, as this study aims to preserve the confidentiality of the respondents, per the ethical requirements of each study site.

12.2. Qualitative Phase

Content analysis is a systematic and objective research method used for the description and quantification of a phenomenon. It is used to enhance the understandability of data, as a large volume of text is distilled into words, categories or concepts, and phrases. This aids researchers in presenting new insights and making valid inferences relevant to their context (129-131). In this research, the term category will be used to present data since it is a term commonly used in the literature (132).

As a research method, content analysis can be challenged, as it is a simple technique that is not based on thorough statistical analysis. Additionally, the method has been criticized because even researchers with limited analytical abilities can attain simple results (132, 133). Nevertheless, the method has been used successfully in the literature for the analysis of the PV system (50, 110), as it offers the benefits of being a content-sensitive and flexible method with respect to research design (129, 134). Additionally, the case study design will aid in developing an understanding of the PV situation in Qatar because this method enables researchers to develop their understanding and identify critical issues (130, 132), as it is concerned with context, consequence, meanings, and intentions (135).

There are two approaches to conducting a content analysis on data, namely, the inductive and deductive approaches. For this study, deductive content analysis was

used. Deductive content analysis is “used when the structure of analysis is operationalized on the basis of previous knowledge” (132). This applies to this study because it aimed to evaluate PV systems and the related concepts that have well-established definitions in the relevant literature. The evaluation will rely on the use of the WHO PV indicators, which were developed on the basis of the PV system components of structure, processes, and outcomes. Additionally, the PV field is characterized by specific standardized definitions, terminology, concepts, and practices; therefore, it is most suitable to follow the deductive content analysis in this study by complying with the current practice. Accordingly, the study utilized the previous knowledge on PV systems and PV systems assessment methodology to conduct deductive content analysis following a system-based approach. Additionally, the study accounted for additional observed codes and categories that were applicable and relevant. Therefore, following the deductive content analysis method, a matrix of analysis was developed with predetermined codes and categories that represent the PV system model defined by the WHO framework (131). Subsequently, the data presented in the interview scripts were assessed and coded according to their correspondence to the developed unstructured or unconstrained categorization matrix (132, 136) (Table 7).

Table 7. Unconstrained categorization matrix

Main Category *	Category **	Codes**
Challenges Strengths Opportunities Recommendations	Structure indicators	Based on the core indicators: • Pharmacovigilance center/department • Policy, legislation or guidelines • Healthcare system regulatory authority (i.e., MOPH) • Financial provisions • Human resources • Adverse drug reaction reporting form • Report management process for reporting collection analysis and databases • Pharmacovigilance education • Pharmacovigilance information communication • Pharmacovigilance advisory committee Based on the complementary indicators: • Computerization of pharmacovigilance e.g., a computerized case report management system • Sources for data and information • Communication facilities • Essential medicine list • Laboratory for pharmacovigilance • Standard treatment guidelines • Pharmacovigilance training, e.g., courses and tools
	Process indicators	Based on the core indicators: • Reporting rate • Feedback and responsiveness, e.g., feedback on ADR reporting • Causality assessment • Quality of reports • Sending reports to the regulatory body • Pharmaceutical companies' functionality • Active surveillance activities Based on the complementary indicators: • Patient awareness of adverse drug reactions and pharmacovigilance • Healthcare provider awareness of adverse drug reactions and pharmacovigilance • Risk management strategies and process

Main Category *	Category **	Codes**
		• Periodic safety update reports
	Outcome indicators	Based on the core indicators: • Signals, e.g., identification and evaluation of signals • Regulatory actions • Clinical outcomes, e.g., medicine-related hospital admissions, medicine-related deaths, extension of hospital stays • Financial outcomes, e.g., cost in monetary units Based on the complementary indicators: • Preventable adverse drug reactions • Congenital malformations • Counterfeit and substandard medications
	Additional: system-based approach***	• Systems structure and networking o Organizational structure o Duplication, overlap or omission o Stakeholders coordination • Leadership and management o PV as a Priority o Expertise o Decision making • Culture o Accreditation and performance management o Ethics o Just or blame-free culture

*Based on the study objectives.
**Based on the WHO indicators for pharmacovigilance.
*** Additional categories that emerged during the content analysis process (some were mentioned only once but were accounted for in the results section due to their importance).

The deductive content analysis of the qualitative data in the form of recommendations and other text-based concepts obtained during the interviews and/or

the examination of the documents allowed a better and more detailed understanding of and reflection on the WHO PV indicator checklist. Such a combination allowed a comprehensive assessment of the PV and medicine safety system. The following sequence was followed for a valid assessment of the qualitative information: a) Data reduction: selection of all relevant information to be summarized, employing the unconstrained categorization matrix; b) Data display: representation of the findings using an organized comprehensive approach employing the predetermined coding process that included categories as appropriate (Table 7); and c) Conclusion drawing: drawing a solid conclusion based on summarizing the findings to address the specific concepts of situational PV system analysis. No sophisticated software was used for coding; instead, the analysis relied on hand-coding printed scripts. Table M12 in Appendix A presents a few examples of the coding process. The examples provided are from different stakeholders and different levels of the healthcare system, namely, the national level and the private and public sectors as well as academia. The results of this analysis will be presented in the results chapter as a general text-based qualitative assessment as well as in the tables showing the qualitative assessment of each indicator category to complement the results of the quantitative analysis. The results section will not include direct quotations, per the request of the key informants.

13. Validity

The steps mentioned below were followed to enhance the validity of the research findings. These measures are based on the work of Creswell (118):

I. Triangulation of data sources: The study used many methods and sources to gather qualitative and quantitative data, including semistructured interviews, document review, and field observations.

II. Peer debriefing: The findings from each data collection site and for the whole study were discussed in detail with the primary supervisor as well as the supervisory committee.

III. Participant checks (i.e., member check): The key informants were offered the opportunity to validate the findings at their level, so they were involved in the process based on their preference. Some, e.g., HMC, requested that the full interview script be provided; others, e.g., private health organizations, requested tabulated results; and others requested a final report and discussion to validate the findings. For example, the MOPH requested a one-hour meeting and an 8-page report discussing the findings. This meeting involved the primary supervisor and covered the MOPH case as well as the country PV situation. Other stakeholders made no requests, so no measures were taken to provide them with such information.

IV. Potential biases: The study clarified potential biases for the study in the role of the researcher as well as the section limitations, e.g., response bias. These are presented in the discussion chapter.

V. The use of rich description to present the findings: In the results section, the study will present the case studies with details; specifically, the MOPH findings are presented following a rich text format. This allowed many details on the qualitative components, such as the codes, to be shared. This process will provide readers with a more realistic picture.

VI. Presenting discrepant information: in the results section, some discrepancies reported across PV subnational systems and by different stakeholders will be shared.

VII. Data collection: A long period was allowed for the data collection stage, especially for cases in which stakeholders requested many meetings.

14. Reliability

The following steps were followed to improve the reliability of the findings (118, 125): 1) details including date and time, sample or key informant information, and the study site where the interviews took place were included in the records of the interviews; 2) evidence on the procedure (e.g., the interview questions, content analysis with examples of some parts of the transcript, and results tables), was provided; 3) the accuracy of the transcripts was ensured; and 4) the unconstrained categorization coding matrix, scoring system, and data collection instruments were agreed upon with the primary supervisor.

15. A Summary for the Mixed Methods Study

This mixed-methods study is summarized as follows:

I. The study started by identifying the national and subnational PV systems as well as the higher authority at each site who was the most suitable informant for facilitating the conduct of this research. The priority list was based on the stakeholder's level of importance in the country's PV system implementation.

II. The research team applied for ethical approval and obtained it to comply with the QU and stakeholder system specified research processes and guidelines.

III. The researcher approached each stakeholder in the priority list to obtain the approval of higher-level administration or management and started the study

by conducting a single interview or a series of semistructured interviews regarding the PV system with the department or unit to enable the collection of all the required data.

IV. During the initial phase, the researcher shared, via email invitation, the full research proposal, data collection tools, main WHO PV indicators manual, ethics-related documents, and support letters. Additionally, the researcher visited and conducted initial meetings with the relevant key informants to explore the purpose of the given research, the process it would follow, and the nature and goals of the data collection and determined the roles the key informants could play in gathering the required data.

V. The researcher started visiting the selected stakeholders after a prescheduled interview time frame was agreed upon with the key informant and a meeting agenda was established. The researcher started the qualitative (open-ended) and quantitative (close-ended) aspects of the data collection concurrently to determine the status in terms of the compliance, implementation, and situation of the PV system in relation to the WHO framework.

VI. The process of data collection was performed through semistructured interviews in which information was gathered during face-to-face discussions. Further, information not available or accessible during the interviews was followed up through e-mail communication.

VII. Some data and information were not addressed by the interviewed representatives due to the ethical regulations and internal policies of the concerned stakeholder system; in these cases, the evaluation and scoring were

identified within the assessment tables (e.g., data are available, but no values are reported for the given PV KPIs). In addition, it is worth noting that some information was not addressed by some stakeholders despite several phone call reminders as well as e-mail reminders; therefore, the scores for the specific missing data were assessed by the scoring system as partial performance or zero depending on the case and whether the indicator had been satisfactorily addressed during the meeting.

VIII. The quantitative and qualitative data for the listed WHO PV indicators as well as the supplementary information received from each key informant were assessed concurrently as applicable or relevant. The gathered data were analyzed for the final results and scores that are presented in the tables, graphical presentations, and text.

CHAPTER IV: RESULTS

This chapter presents the findings from the qualitative and quantitative data collected about PV and medication safety system assessment and improvements. This mixed-methods study will present a comprehensive PV and medication safety system assessment to provide a full understanding of the Qatar PV system at various levels of the healthcare system. In this study, the performance of the PV system was measured in terms of compliance with the WHO PV indicators (structure, process, and outcome indicators). The results of the PV KPIs represent the functionality and sophistication of the PV system and can aid in developing strategic and operational recommendations to improve the PV system as well as determining the measures required to achieve a fully operational system. The qualitative data will be used to provide a context-based system evaluation that is strongly dependent on stakeholders' views and perceptions of the limitations, strengths, and opportunities present in the country. Additionally, qualitative data will be used to supplement the WHO PV indicator assessment. The reason for utilizing a MMR approach is to obtain a more comprehensive understanding and deeper insight into the PV system in Qatar and to overcome the limitations inherent to using the qualitative or quantitative approach alone. The results will be presented in the following sequence in order to respond to the research objectives:

I. Evaluate the baseline PV situation using the WHO PV indicators.

II. Compare Qatar's current national PV system to the minimum requirements of the WHO for a functional national PV system.

III. Identify the potential opportunities, strengths, and limitations to address the level of development of the PV system as well as the establishment and sustainability of a specific PV center.

1. Evaluation of the Baseline Pharmacovigilance Situation Using the WHO Pharmacovigilance Indicators

The results of the comprehensive evaluation of the PV system in Qatar are presented in this section as a selected case analysis as well as a comparative analysis among PV systems, including those at the national level (MOPH, regulatory body system), in the public sector (including HMC and PHCC), in private healthcare facilities and service delivery organizations (including private healthcare institutions and community pharmacies), in the local pharmaceutical industry, in PHPs (i.e., MHS), and in academic institutions. Each stakeholder performance level will be closely assessed in relation to the WHO PV structure, process, and outcome PV KPIs. For the indicator scores and calculation values, refer to Table R1a and Excel spreadsheet R1b in Appendix B.

The sample of key informants included physicians, nurses, pharmacists, and other healthcare-related backgrounds. The total number of participants was 30 individuals at different data collection levels:

I. MOPH: five people.

II. HMC: four people.

III. PHCC: seven people.

IV. Private sector institution 1: one person.

V. Private sector institution 2: one person.

VI. Private sector institution 3: one person.

VII. Private sector institution 4: two people.

VIII. Private sector healthcare group: three people.

IX. Private sector chain pharmacy group: one person.

X. Private sector independent pharmacy: one person.

XI. MHS: one person.

XII. Pharmaceutical industry: one person.

XIII. Qatar University College of Pharmacy: two people.

XIV. Qatar University College of Medicine: one person.

XV. Qatar University College of Health Sciences: one person (not a face-to-face interview but only email response, which was acceptable because there is only one indicator, CST8, for universities).

XVI. College of the North Atlantic: one person.

XVII. Weill Cornell College of Medicine: one person.

XVIII. University of Calgary: one person.

1.1. Ministry of Public Health (MOPH)/National Level

The study assessed the PV system at the MOPH level, which was represented by 5 members from the Department of Pharmacy and Drug Control and the Department of Quality and Patient Safety (HQPS).

1.1.1. Total Performance of the MOPH Pharmacovigilance System

According to the assessment findings, the total score for the three PV structure, process, and outcome domains was 19.5 (23.8%; actual performance status) out of an allowed cumulative score of 82 (100%; desired performance status). The compliance of the MOPH PV system with the WHO PV indicators was highest for the structural indicator score of 12.5 (40.3%) and lowest for the outcome indicator score of 2 (9.1%). Figure 3 and Figure 4 represent the performance of the MOPH PV system based on the

measured compliance with the WHO PV indicators. As a result of the low performance on many of the indicators, the MOPH case will be presented following a qualitative text format. The full details on the MOPH system performance for each indicator can be found in the Appendices in table format, namely, Table R2 in Appendix B on the core indicators and Table R3 in Appendix B on the complementary indicators.

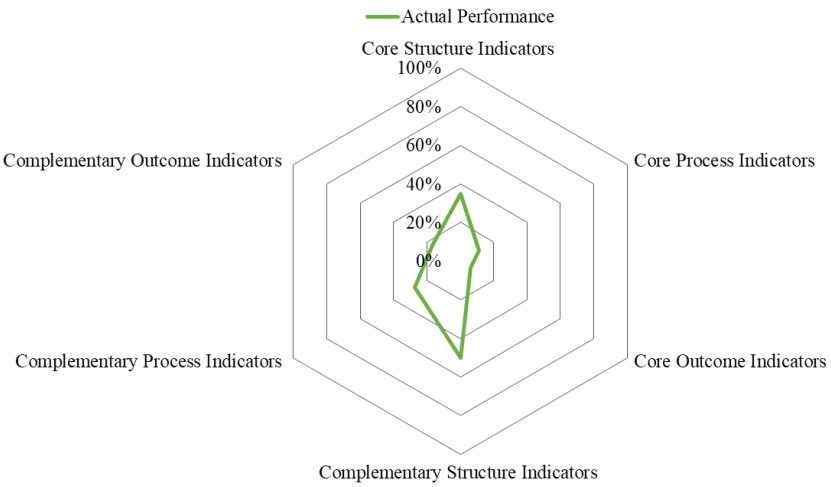

Figure 3. National pharmacovigilance system performance at the MOPH level (presented as percentages)

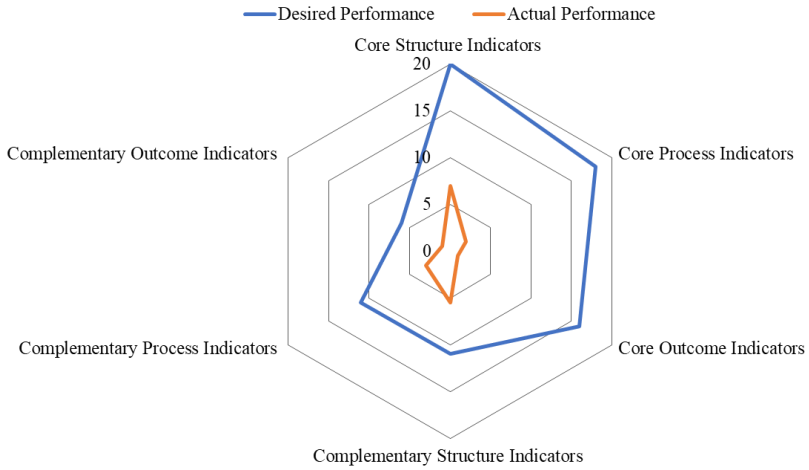

Figure 4. National pharmacovigilance system performance at the MOPH level (presented as scores)

1.1.2. Structural Indicators Performance

The performance of the MOPH PV system as measured by the core structural indicators was 7 out of an allowed score of 20 (35%). The MOPH PV setup has not demonstrated the availability of the core PV structures, such as an independent PV center (i.e., CST1), a national policy or guidelines for PV (i.e., CST2), and a national ADR reporting form (i.e., CST6), required for a functional PV system in the WHO PV indicator manual; refer to Table R2 in Appendix B. The MOPH performed higher in the complementary structural indicators, achieving a score of 5.5 out of an allowed score of 11 (50%). The MOPH reported having data sources on drug safety information for daily PV activities, and data from stringent regulatory authorities in the U.S., Europe, and Australia are used to ensure that PV requirements are followed in the country.

The regulatory framework for the Pharmacy and Drug Control Department includes guidelines for medicinal product registration, MAHs, manufacturing premises, and pharmaceutical premises. According to the MOPH, there is no specific statutory provision for PV and no specific national PV policy or guidelines (i.e., CST2). However, Qatar is a member of the GCC countries, which have well-established guidelines for drug registration, including PV.

Moreover, the pharmaceutical law of Qatar covers aspects of medication safety, but the specific term PV is not employed. The current law does not cover the full scope of passive and active PV activities. Since the current law is relatively old, it is well enforced and well implemented by the Department of Pharmacy and Drug Control. Furthermore, the current law does not provide details on PV information sharing or transparency issues. Regarding the effectiveness of the current law for medication safety and patient safety, it was reported that it is not entirely effective, as it is not

comprehensive to cover the scope of PV (i.e., regulatory and practice PV). Additionally, Qatar does not have a national medicine policy to ensure medication safety.

The MOPH reported that there is a lack of efficiency because to date, there has been no improvement in national PV actions. Therefore, according to the MOPH, unless there is an appropriate law and bylaw that forces various national stakeholders to take action regarding PV, they will not perform those functions as required.

Furthermore, MOPH has submitted a draft for an updated pharmacy law, or "Pharmacy Act". The draft includes many aspects that were not covered in the previous law, such as regulations for medical devices, manufacturing facilities, herbal products, and food supplements. The new law will include PV and medication safety as part of drug registration and pharmaceutical practices in the country.

The reported functionality of the national PV system for the external pharmaceutical industry and service delivery healthcare institutions diverged and did not align with the expected performance required at the national level. According to the MOPH, the PV system is considered functional in relation to the pharmaceutical industry and international stakeholders. However, the current PV system from the national stakeholders' side can be considered nonfunctional. For instance, regarding the roles and responsibilities of stakeholders concerning medicine safety, it is required by law that MAHs and the local agent should declare any quality or safety issue to the MOPH, as represented by the Pharmacy and Drug Control Department, and such issues must be reported within a specific timeline. However, for healthcare professionals, there is no legally binding requirement for reporters in the law; instead, they are merely advised to report medication safety issues.

At the national level, the ethical standards for healthcare professionals that are required to improve PV were considered appropriate from the perspective of the

MOPH. The MOPH reported that ethics has a high profile in the country, but there is still a need to combine it with a specific law or specific guidelines. If there is no law that forces or guides healthcare professionals to perform PV actions, then the situation will not be appropriate.

Within the MOPH, there is no specific PV department (i.e., CST1). Rather, PV activities are incorporated into daily activities. Additionally, there is no allocated budget for PV, as there is no independent or segregated body responsible for PV, thus the current budget for covering medication safety activities does not directly reflect PV functions. It was reported that the budget is sufficient for the current operation of the system. However, to establish a national PV center, a dedicated budget must be properly allocated.

The MOPH reported the absence of a national database for PV data management (i.e., CST7), and a limited number of relevant case reports have been received (i.e., fewer than 10 reports were received from Qatar Petroleum in 2017). The national reports received by the MOPH in recent years were relatively poor in quality and did not allow for a proper causality assessment. No new ADR cases were received, and most of the received reports were well established or mentioned in the leaflet.

Currently, there is no public reporting form (i.e., CST6) for medication safety issues. However, the MOPH has a health website, and members of the public can register their complaints, inquiries, and requests with the Governmental Health Communication Center (GHCC) by filling out a form. The GHCC falls under the Public Relations Department and is directly under the minister, indicating that public complaints are taken seriously.

The MOPH key informants commented on the possibility that in the future, a specific form for ADR reporting may be created for use by the general public. They

stated that this will not be an easy initiative because Qatar has a diverse population; thus, many languages may be required to develop the national form, and cultural adaptation may be difficult. Consequently, the public contribution to reporting could continue to be very limited.

The MOPH informants reported that they support public reporting in general and that in the patient safety reporting system that they are considering implementing, at some stage, the MOPH will look into giving the public access so that patients can directly report data, such as an incident, complaint or alert.

Regarding the possibility of having a specific ADR form that is available to the general public, the MOPH informants reported that public reporting should be performed in a simple and open manner to suit the level of the public, as it must accommodate all levels of the community and not discourage people from reporting. They reported that the MOPH wants to make the reporting system patient-centered and that ADR forms can restrict the public desire to provide information.

The HQPS informants reported that currently, they do not have a process in place to ensure that they follow up on PV and medication safety (i.e., CST7). They reported that currently, the MOPH is still in the planning stage regarding medication safety. There is an intended plan to develop a medication safety program. The program is not specific to PV, but its basic elements depend on the "WHO Global Patient Safety Challenge on Medication Safety", which aims to "reduce severe, avoidable medication-related harm by 50% in the next five years". Although the MOPH is at an early stage, it has made a commitment by signing the WHO pledge; currently, it is in the process of developing an action plan and engaging with national stakeholders.

The HQPS informants reported that there is another future project under the title of the National Patient Safety Reporting System (i.e., CST7). This reporting system

includes reporting on ADRs and medication errors in general. This project is separate, but it acts as a medication safety program. Part of the agenda for this program is to be able to interface with existing systems in hospitals or other healthcare facilities and automatically transfer data to the national system. The HQPS future plan is to have a general reporting system, and part of this reporting system will include ADRs—specifically, an ADR reporting form. However, the HQPS is not aware of the items that will be covered under this ADR report. The plan includes a proper classification system, but the HQPS is not fully aware of the content of this system. Furthermore, it was reported that developing a reporting form will be based partly on stakeholder engagement, so a team will be engaging with the various sectors to develop the ADR form based on evidence-based published literature.

Previously, any issue received from the external pharmaceutical industry was communicated through the licensing department. Currently, the MOPH communicates this information to the Qatar Council for Health Care Professionals (QCHP), where it is publicized in a circular (i.e., CST9) with instructions and guidelines for clinicians on how to submit reports or how to act in cases of that specific medication.

At present, there is no specific and/or organized PV or medicine safety advisory committee (i.e., CST10). Therefore, it was noted that in the future, having a functional committee will serve the needs of the country. For instance, to guard patient safety and the interests of MAHs, such a committee would enable the country to avoid potential conflicts of interest. It has been recommended that the best system models, such as that of Morocco, be used as appropriate benchmarks for improvement. If such a committee is established, it could be affiliated with the MOPH or an academic university. Additionally, it has been recommended that the advisory committee be made up of diverse experts, including 1) Academicians who have good access to reputable sources

of information and who can take a strong leadership role; 2) Regulators from the MOPH, who can provide input by following benchmarks and examining different regulatory agencies; and 3) Healthcare practitioners such as physicians who can also support the advisory committee.

The tools that the MOPH uses to communicate with national stakeholders and within the ministry about PV and medication safety are mainly its website and emails (i.e., CST9 and ST3). Furthermore, the MOPH uses the mobile application Qatar National Formulary to list all ADR precautions and other safety concerns. However, a challenge was reported when the drug information services that were previously available as part of the structure of the Directorate of Pharmacy were deorganized and ceased functioning. The MOPH considers drug information services and PV services to be important aspects that must be in place in the near future.

Additionally, the MOPH key informants made a note of a favorable initiative for PV education in creating or establishing an ADR newsletter (i.e., CST9). A newsletter would serve as a good way to communicate with confidence with physicians to increase their awareness of the PV system and specific ADRs reported in the country. Therefore, the newsletter could ultimately lead to developing desirable behaviors and would offer a good communication tool, as reporters would have the privilege of being acknowledged for their reporting of ADRs. For instance, their efforts could be described within the organization and perhaps at the national level.

Currently, the MOPH is not very active in providing training at the national level (i.e., ST9 and ST10), apart from vaccine training, which is well implemented. However, it was reported that the MOPH has enough capacity to provide training to address the limited awareness of other stakeholders.

One of the major weaknesses reported in the current PV system is

communication, which has a very low profile. Additionally, the pace of policymaker steps and actions was considered slow. In addition, the patients and the general public make minimal contributions to the PV system. Therefore, it was noted that to improve communication, there is a need for awareness and legislation to force stakeholders, mainly healthcare professionals, to take part in PV functions.

1.1.3. Process Indicators Performance

The assessment indicated that of a total possible process indicator score (i.e., core and complementary indicators) of 29, the MOPH achieved a score of 5 (17.2%). The MOPH reported a positive response only for core process indicator number eight (i.e., CP8), which includes the number of pharmaceutical companies registered with fully functional PV systems. For other process indicators, the MOPH does not have the main PV structures in place; therefore, the national PV system has limited capacity to meet the performance requirements of the process indicators.

According to the MOPH key informants, the underreporting issue in Qatar is expected to continue owing to the lack of an appropriate documentation system and national ADR reporting form. However, they reported that underreporting was a challenge even when the previous national reporting form was available. The MOPH created the previous form and made it available online as part of the Qatar National Formulary, but because of certain legislative issues related to patient data security, the MOPH did not continue to use the form. In addition, with respect to establishing a national database to receive direct reports from different stakeholders, the MOPH reported that there is a large project called the eHealth Strategy. This is expected to offer an opportunity to implement such a data management system for ADR reporting and PV. The eHealth Strategy is expected to connect the public and healthcare stakeholders and providers, starting with health insurance payers, public hospitals, and

policymakers. In addition, training courses will be provided through eHealth.

Coordination with stakeholders at the international level, for example, the WHO PIDM, is deemed a strength for the country. The MOPH has a good relationship with the UMC, and it has already been successful as an associate member. The MOPH has received the privilege of accessing the international system that is designed to receive reports. The MOPH considers this privilege a sign of strong collaboration and coordination since the UMC is a well-reputed organization that is pushing the country to become a full member. Consequently, it has been recommended that the country act to develop a national PV system, establish a PV center, hire the required staff, and start submitting reports to the UMC. On the other hand, national coordination among all stakeholders is a major challenge for PV because there is no proper coordination. The MOPH informants, namely, those from the Pharmacy and Drug Control Department, reported that they are informed at a very late stage about the medication safety and PV initiatives of other departments within the MOPH, such as the HQPS, or other stakeholders, such as the HMC. National stakeholders develop initiatives, but there is no proper coordination. Additionally, the MOPH informants reported that there is no national platform to enable PV activities. Furthermore, individual projects or activities are not linked or known to the national system of the MOPH. For example, any clinical trial or research projects will not be known until they are published in journals or otherwise included in the literature.

The MOPH informants reported that national stakeholders' accountability is deficient because the current healthcare system cannot be further improved without a national PV system. Additionally, they reported that there is an issue with transparency in data sharing among stakeholders despite Qatar being a small country. For instance, the eHealth Strategy project has been delayed for many years because of restrictions

and resistance, even from governmental hospitals and institutions, to sharing data.

On the subject of reporting by community pharmacies, the MOPH reported that if reporters have good knowledge and are ambitious, they can report and communicate to the MOPH even in the absence of a national reporting form. The MOPH reported that equity is sustained, and people can take the lead and behave accordingly. This was noted because the community pharmacies ought to be able to respond to the challenges that can affect their reporting, including their restricted resources, work style, interests, and scope, which is mainly commercial.

When addressing the capacity for evidence-based causality assessment, signal investigation and other forms of PV data analysis, it was recommended that awareness and training be mandatory, as such processes require expertise in all elements of healthcare. Although 90% of the HCPs in Qatar are expatriates, and some of them come from countries where PV is well established and known, there is still a need for training and awareness because most of them did not have PV and ADR reporting as their main job functions. Therefore, it was recommended that awareness be improved among HCPs, and in the stakeholder system PV could be included in the performance appraisals of staff at the organizational level.

For active surveillance activities (i.e., CP9), the MOPH did not report any examples of studies that have been conducted, such as cohort event monitoring or phase 4 clinical trials at the national level. Additionally, the MOPH does not have the capacity to conduct such studies. Collaboration on such studies between the MOPH and other sectors was deemed a potential idea. In the future, the MOPH will be ready to collaborate with other sectors and to allow some staff members to support these collaborations. However, because active surveillance activities are very expensive and require considerable technical knowledge, and most pharmaceutical companies can

perform them successfully, it was reported that it is best to rely on third parties and pharmaceutical companies. In addition, the MOPH utilizes the outcome of international active surveillance studies, specifically, data received from clinical trial studies. The MOPH considers clinical trials to be the most rigorous sources with valuable results; therefore, it will take action based on the data reported in these studies if there is a new medication or if there is a change in a specific product. In addition, unless the pharmaceutical companies submit clinical trial data, MOPH does not consider taking action.

The MOPH is not aware of any current national initiatives on clinical trials. In Qatar, clinical trials are a function of the medical research centers (e.g., within HMC or Weil Cornell University), where the trials receive approval. Most of the centers perform either phase 3 or phase 4 trials, especially postmarket surveillance studies. However, the MOPH informants reported that a major challenge for the country is that a specific policy or law that covers the PV training for and conduct of clinical trials is not available, which could present a great risk. Additionally, the HQPS reported that the private sector is allowed to conduct clinical studies (including on human subjects), according to the Research Division of MOPH, which is responsible for the ethical involvement of humans in research and for establishing research policies in Qatar. Therefore, healthcare institutions can apply to conduct such studies, but they must follow a certain process and fulfill all the requirements of the MOPH.

The MOPH requires risk management plans for all drug products in the registration process. Additionally, for risk management practices at the national level, the MOPH follows specific guidelines, and the informants reported that those guidelines should provide an appropriate risk management plan. The local pharmaceutical companies also provide the MOPH with information as part of

benchmarking and technology transfer.

Concerning the evaluation of the benefit-risk ratio, the Pharmacy and Drug Control Department reported that at the current level, it does not have the capacity to conduct such activities because decisions on the risk-benefit ratio reflect the use of medication in practice, which is not an easy task, requires expertise and may require a specific committee.

1.1.4. Outcome/Impact Indicators Performance

The lowest-performing domain for the MOPH was outcome indicators. For core outcome indicators, the MOPH obtained a score of 1 out of a possible total score of 16 (6.3%). For complementary outcome indicators, the MOPH reported one positive response for O4, indicating that less than 1% of medications in Qatar are counterfeit/substandard, as there are stringent regulations, and Qatar procures medications only from reputable sources and mainly procures branded medications (Table R3: Appendix B).

For signal evaluation (i.e., CO1), the MOPH informants commented that there is a lack of awareness about the signal evaluation process, including the use of the relevant tools and methods. Therefore, currently, no signals are generated at the national level. Additionally, the MOPH reported that the signal evaluation process requires great effort from most stakeholders, which can include improving the reporting rates and quality of documentation at the PV practice level.

For decision-making and regulatory actions (i.e., CO2), the MOPH relies on benchmarks from other countries with stringent regulatory agencies because the national reports that it receives sometimes do not align with global data; thus, the MOPH cannot immediately take regulatory action based on those reports. The Registration Section Committee is responsible for taking regulatory actions to

withdraw, suspend or simply continue the use of a medication.

With respect to MOPH responsiveness, the informants reported that the responsiveness to drug safety issues is good; in such cases, there will be very fast action and a decision to address the issue. However, because a PV system is not in place, the MOPH informants reported that such actions are not documented, well monitored or evaluated for the short-term and long-term impacts, as they would be in an appropriate PV system that monitors, documents, evaluates, and communicates PV actions. Additionally, they reported that an inappropriate review process takes place between receiving a report and initiating feedback or taking an action. Therefore, it was recommended that in the future, the review process, including specific timelines, be included in the country regulations. For example, the MOPH reviews Qatar Petroleum reports immediately, but there is no such policy or system for sending feedback; MOPH only appreciates the efforts of the reporters and encourages them to continue submitting reports.

For the identification of medication safety issues from external sources, MOPH regularly uses MedWatch, the UMC website, the EMA, updates from the Therapeutic Goods Administration (TGA) of Australia, the WHO newsletter, and other ADR newsletters. Additionally, the MOPH relies on GCC countries' information, as Qatar is strongly socially connected to the GCC, and the MOPH receives some of those countries' feedback and communications. However, the MOPH informants reported that there is no systematic approach or standardized process in place to process safety alerts from outside sources, although such processing is among the routine functions of the MOPH system.

In an example of actions that were taken based on outside sources, different sources mentioned that there was an increased utilization of Victoza; the MOPH

enacted a strict regulation that the medication could not be dispensed without an appropriate prescription. In another example, the MOPH found that loperamide was being improperly used, so it took a current regulatory action to restrict the use of loperamide. The MOPH reported that key informants at the MOPH revise and review by seeking benchmark countries before initiating regulatory actions at the national level. For instance, in one case, a drug was withdrawn from the market by the EMA and other countries in the region, such as the GCC countries. However, the MOPH concluded that Qatar would not take similar action after reviewing the situation and consulting with experts. Later in that particular case, the EMA notified the company, and the product continued to be used safely.

The MOPH informants reported that a maximum of 1 to 2 days is the usual time lag between receiving a report of an external safety issue and taking regulatory action or communicating it at the national level. In addition, if there are any delays in taking action, the reason is that the MOPH does not have a clear picture. However, the MOPH reported a problem with how such information is received, as the route of communication among MOPH departments is very time-consuming, and the process can be slow.

Regarding national data, the HQPS reported that service delivery organizations do not report hospital admission data (i.e., CO3). Additionally, the HQPS reported that deaths due to medication errors are not reported by service delivery organizations and that such data could be found as part of the morbidity and mortality data (i.e., CO5). In addition, the HQPS reported that capturing these data will be part of the future reporting system plan.

Additionally, according to health economists in MOPH, regarding the financial aspects of the system relevant to core outcome indicators 6, 7, and 8, as well as

complementary outcome indicators 7 and 8, this information is currently not available in the MOPH, but it is very important and worthy of collection. This is especially true of indicator number 7, which is considered feasible, but good planning for the methodology is needed.

1.2. Public Sector Level

1.2.1. Public Sector Part 1: Hamad Medical Corporation (HMC)

The study assessed the PV system at HMC, which was represented by 4 key informants from the Medication Safety and Quality Center (MSQC) and HMC Pharmacy Department.

1.2.1.1. Total Performance of the HMC Pharmacovigilance System

According to the assessment findings, the total score for the three PV structural, process, and outcome indicator domains was 45.5 out of a possible cumulative score of 70 (65%). The compliance of the HMC PV system with the WHO PV indicator manual was highest for the structural indicators, with a score of 20.5 (82%), and lowest for the outcome indicators, with a score of 9 (39.1%). Figure 5 and Figure 6 represent the performance of the HMC PV system based on the measured compliance of the system with the WHO PV indicators. As a result of the good performance on many of the indicators, the MOPH case will be presented in table format with full details on the HMC PV system performance for each indicator.

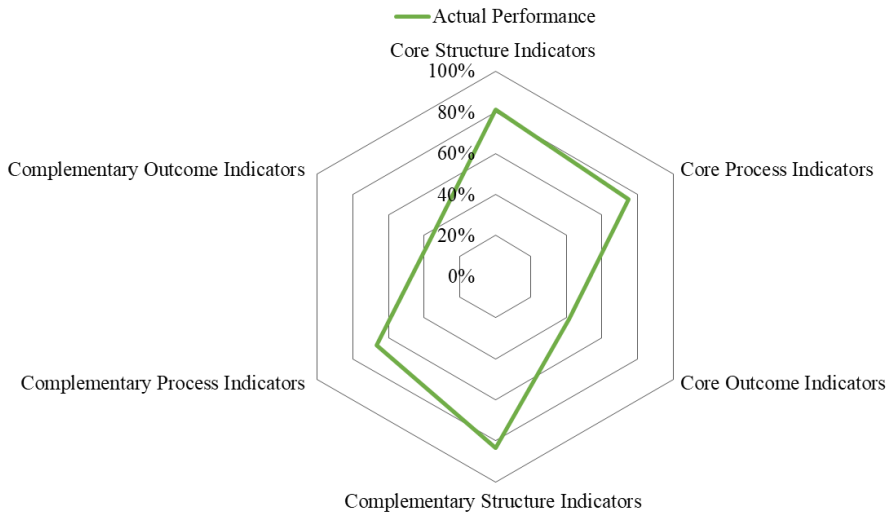

Figure 5. HMC pharmacovigilance system performance (presented as percentages)

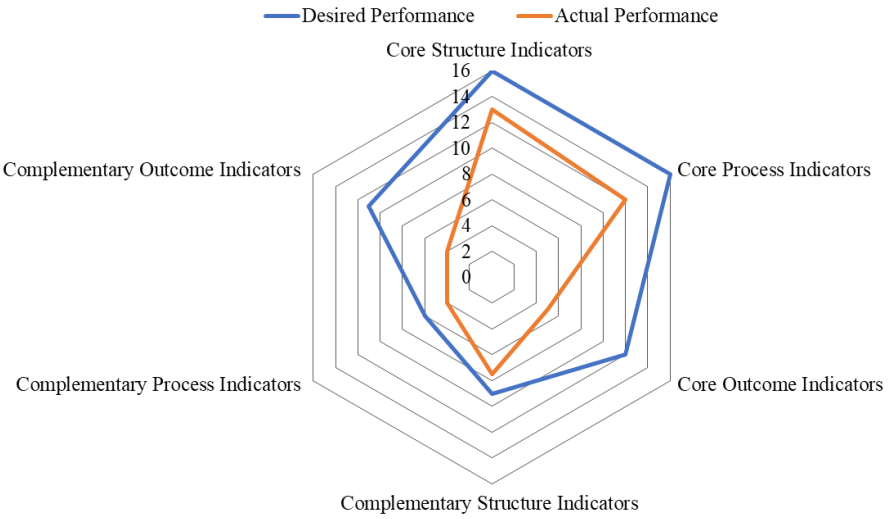

Figure 6. HMC pharmacovigilance system performance (presented as scores)

1.2.1.2. Structural Indicators Performance

The tables illustrate the performance of the HMC system in 8 relevant core indicators (Table 8) and 9 relevant complementary indicators (Table R4: Appendix B), and a qualitative assessment accompanies each indicator. The performance of the HMC PV system measured by the core structural indicators achieved a score of 13 out of a possible score of 16 (81.3%). Similarly, the HMC system performed well in

complementary structural indicators, with a score of 7.5 out of a possible score of 9 (83.3%). Notably, the overall scores, as well as the core and complementary structural indicator scores, indicate an excellent system performance (i.e., target quartile range Q3: 75% to 100%).

HMC established the Medication Safety and Quality Center (MSQC), The MSQC is the unit responsible for PV (i.e., CST1), and it is overseen by the HMC pharmacy executive director. The MSQC plays an important role in the HMC PV system and has direct contact with the Pharmacy Department, the primary department responsible for pharmaceutical products in HMC.

The evaluation indicated that HMC has all the basic core PV structures required for a functional PV system under the WHO PV indicators, except for CST4, as no specific budget is allocated for PV (Table 8). The assessment showed that HMC has existing policies that cover the entire scope of PV (i.e., CST2), including the active and passive aspects of PV, but these policies covers mainly voluntary reporting and passive activities. Furthermore, each indicator has a policy document; for example, ADRs as an indicator have a specific policy document. HMC reported the existence of reporting forms used by healthcare providers and one form for patients. However, no reports were received from patients between 2018 and 2019.

It was reported that while establishing the MSQC, human resource provision was a challenge (i.e., CST5). The need for expert staff was added to the strategy as "the inclusion of medication safety officer". The MSQC has adapted well to this challenge by working with part-time members from 12 HMC hospitals; currently, it considers its efforts a success.

Currently, the executive director of pharmacy is working to develop a center for PV. HMC reported that there is a need to contact the MOPH before this step because

this PV center will represent Qatar at the international level. In addition, if there will be a national PV center under HMC, then HMC should receive the approval of the regulatory body in the initial stage.

1.2.1.3. Process Indicators Performance

The assessment found that of a total allowed process indicator score of 22, the HMC PV system achieved 16 (72.7%). The HMC key informants reported a positive response (i.e., a score of 2 or 1) for all relevant core process indicators (Table 8).

With respect to core PV process requirements, HMC has an internal system for the collation and analysis of PV data. The MSQC receives reports from the 12 hospitals under HMC. The MSQC medication safety officers are responsible for performing trend analysis, signal investigation, and other data analysis. Concerning the strength and growth of the HMC database, the informants conveyed that the reporting rate is increasing gradually each year by an average of 10 to 15%.

After the establishment of the MSQC, the Pharmacy Department reported that the total number of ADR reports at the HMC corporate level was 1599 by the end of December 2017 and more than 700 between 2018 and 2019. Although there has been an increase in the rate of reporting, underreporting remains a challenge for the HMC PV system, as the trends include reporting mainly by the pharmacists.

Table 8 highlights the information relevant to PV communication. It was reported that if important or significant information was identified after multiple reviews of the received reports, the MSQC would release it to the pharmacy executive director, who would present it to the Corporate Pharmacy and Therapeutic Committee (CP&TC), the Drug Supply Unit or the national regulatory body.

Although HMC has limited capacity to meet the performance requirements of active surveillance activities (i.e., CP9), there are plans for active PV, and this subject

has been taken into consideration by the relevant key informants (Table 8).

For the complementary process indicators, the assessment found that HMC achieved a score of 4 out of a total possible score of 6 (66.7%) (Table R4: Appendix B). It was reported that the MSQC does not have data on the average number of reports per total number of healthcare providers; however, the majority of reports are from pharmacists, representing almost 80% of the total reports.

1.2.1.4. Outcome/Impact Indicators Performance

The lowest-performing domain for the HMC PV system was the outcome indicators. For the core outcome indicators, HMC obtained a score of 5 out of a possible total score of 12 (41.7%) (Table 8).

There are plans for economic studies, but the MSQC has not yet conducted such studies. According to the Pharmacy Department, there is one ongoing study about clinical interventions of pharmacists and their impact on the cost and length of stay; however, the study is still in process, and the results have not yet been calculated.

HMC reported that data on the average cost of medicine-related hospitalization exist and can be found through the HMC administration. The administration is conducting studies and has information on the patient cost according to the specialty of the department, but this process does not occur under the Pharmacy Department or the MSQC (i.e., a value was not provided).

Out of 11 relevant complementary outcome indicators, the obtained score was 4 (36.4%). According to the MSQC, the percentage of preventable ADRs in 2018 was 5% for all HMC hospitals. In addition, the number of patients affected by a medication error over the previous three years was 0.16 per thousand admissions (Table R4: Appendix B).

Table 8. Hamad Medical Corporation (HMC) pharmacovigilance (PV) system performance and capacity results measured by the WHO core PV indicators

Code	Response	Score *	Assessment (Qualitative)
CORE STRUCTURAL INDICATORS			
CST1	Yes.	(2)	• Applicable but no specific PV department. • HMC has the Medication Safety & Quality Center (MSQC), which is the unit responsible for PV. • The MSQC has indicators relevant to PV, such as ADRs and medication errors. • The executive director of pharmacy is working to develop a center for PV; it was reported that for a national PV center to be under HMC, it should receive approval at the initial stage.
CST2	Yes.	(2)	• HMC has policies that cover the whole scope of PV, including active and passive aspects, but it covers mainly voluntary reporting and passive activities. • Each indicator has a policy; for example, there is a policy for ADRs and a policy for medication errors. • The body responsible for ensuring that the policy is enforced and implemented is the Pharmacy Department, and the process is performed by the executive director of the Pharmacy Department.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget for PV.	(0)	• Although there is no specific budget allocated for PV the MSQC has a sufficient budget for its activities. • The executive director of pharmacy supports educational intervention (e.g., courses and workshops) and other aspects requested by the MSQC.
CST5	Yes.	(1)	• The MSQC encompasses a committee with the executive director of the Pharmacy Department as the chair. The committee is also made up of the director who is head of the center and is a medication safety officer and a member from each HMC hospital. • It was reported that all members work part time for the MSQC and full time at HMC. It was recommended that the center have full-time staff, as is the case in advanced PV systems. • It was reported that while establishing the MSQC, human resources were a challenge, and the need for expert staff was added to the strategy as “the inclusion of medication safety officers”.
CST6	Yes.	(2)	

Code	Response	Score *	Assessment (Qualitative)
			• HMC reported the existence of reporting forms used by healthcare providers and one form for patients. • Regarding healthcare professional reporting forms, HMC has a specific form for ADRs and a form for medication errors. In addition, the HCP reporting form has a free text area where the reporter can report cases of therapeutic ineffectiveness; suspected misuse of, abuse of or dependence on medications; and other medication-related problems. • HMC reported that suspected counterfeit or substandard medicine is extremely rare because HMC and the MOPH have control over medications and do not allow falsified medications to enter the Qatar pharmaceutical sector. • No reports were received from patients in 2018 and 2019. The patient reporting form is available in the pharmacy and the patient units, as patients who are willing to report must approach a healthcare provider and tell him/her about their willingness to report. The pharmacist will then help the patient complete the report.
CST7	Yes.	(2)	• The executive director of the pharmacy keeps two databases, one at the facility level and the other at the corporate level. The databases are in the form of Excel spreadsheets that are used for the management of reported data. • The report management process in the MSQC involves the evidence-based causality assessment conducted by medication safety officers, which includes the use of evidence-based tools such as the Naranjo scales. The scope of the data analysis involves the assessment of causality, severity, and preventability. • When the Pharmacy Department, specifically the MSQC unit, encounters a significant issue, it issues a newsletter or alert and tries to present data, usually as a proposition in the annual report or at a conference.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• The Pharmacy Department publishes a monthly newsletter or an alert to provide information and notify the HCPs about medication safety issues and the required form of action. • The existing HMC policies provide guidance on communication and the pathway of information, such as the flow of information and timelines. In addition, the current activities of the Pharmacy

Code	Response	Score *	Assessment (Qualitative)
			Department involve informing HCPs about any warnings from international organizations through the newsletters. • A specific policy document developed as a disaster plan provides guidance on communication during crises or emergencies.
CST10	Yes.	(2)	• The Corporate Pharmacy and Therapeutics Committee (CP&TC) is the expert committee in HMC. It is accessible and provides advice on medication safety and PV-related issues in a timely manner. • The members of the CP&TC (20 total) are physicians with a higher level of expertise (medical directors) from different specialties, and not all of them are experts in PV. Therefore, the burden will be on the Pharmacy Department to provide them with all the information required to make the necessary decisions. • In the HMC policies, the minimum number of CP&TC meetings is four per year. However, the committee meets routinely to address medication safety issues; currently, it meets on an almost monthly basis.
Total Score		(13)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(13) = 81.3%]
CORE PROCESS INDICATORS			
CP1	1599 reports.	(2)	• After the establishment of the MSQC, the Pharmacy Department reported that the total number of ADR reports at the HMC corporate level was 1599 between January 2016 and December 2017. • Although the Pharmacy Department reported an increase in the rate of reporting, underreporting remains a challenge for the MSQC. The reporting increment was from pharmacists only. • The MSQC reported that there is a need to address the quality of documented reports, as some reporters provided inadequate information; this issue was discussed with the CP&TC.
	CP1a: not relevant.	(-)	• Not relevant.
CP2	2300 reports for the previous 3 years.	(2)	• 2300 reports over the previous three years. • The strength and size of the database are increasing, as the reporting rate is increasing gradually by an average of 10 to 15%, but the trend includes mainly reporting by pharmacists. The nursing staff is underreporting, so the MSQC has suggested a possibility of including reporting in nurses' performance evaluations.

Code	Response	Score *	Assessment (Qualitative)
CP3	100%.	(2)	• All reports must be analyzed and acknowledged in the same month.
CP4	100%.	(2)	• The Pharmacy Department requests that the MSQC conduct an assessment for each report. • The analysis is performed by the medication safety officer. All the information is sent to and recorded by the MSQC. Then, second round of review is conducted with hospital coordinators as well as drug information specialists to confirm the data, investigate cases further, and consolidate the reports from all HMC hospitals.
CP5	No percentage provided.	(1)	• Only sever or new reports will be sent to the MOPH. • HMC indicated that in the past, data have been sent to the MOPH, but the MOPH did not respond or give feedback to HMC. • HMC has started sending reports to the WHO, especially for important cases. • 70% are complete and of good quality, and 30% have missing information. • HMC promotes the concept of a blame-free culture and provides training to its healthcare professionals.
CP6	No percentage provided.	(1)	• The clinical pharmacist must report this issue using a different reporting form; trends are recorded in a separate database. • HMC has very few reports on therapeutic ineffectiveness because the clinical pharmacists play an active role in drug therapy management. • HMC does not have a detailed report that distinguishes between therapeutic and pharmaceutical factors.
CP7	No percentage provided.	(1)	• Most cases are reported cases of near misses; trends are recorded in a separate database.
CP8	Not relevant.	(-)	• Not relevant.
CP9	No active surveillance studies. However,	(1)	• In the future, HMC plans to conduct active surveillance studies. HMC is currently in the initial phase and has not determined the type of study, but it has plans for active PV. • HMC targets specific drugs, e.g., the ondansetron study. • HMC has studies relevant to medication utilization and medication errors.

Code	Response	Score *	Assessment (Qualitative)
	HMC has initiatives.		
Total Score		(12)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(12) = 75%]

Code	Response	Score *	Assessment (Qualitative)
CORE OUTCOME/IMPACT INDICATOR			
CO1	Yes.	(2)	• The MSQC raises such cases at the corporate level to confirm the information. HMC indicated that the current staff does not have a great experience with signal detection, as the staff has not encountered many cases, and the established system is relatively new. • HMC has published studies on two cases in which a patient had a side effect, but the side effect was not documented. First, for labetalol, an antihypertensive agent, HMC encountered cases in which patients who took the medication suffered from contractions. HMC contacted the WHO and published the research. The second case concerned esomeprazole.
CO2	Not relevant.	(-)	• Not relevant. • HMC sometimes translates drug leaflets, e.g., from French. • HMC uses information from the FDA or EMA.
CO3	No cases reported.	(1)	• HMC is in the process of writing a proposal to evaluate admission due to adverse drug events, but it will be for one facility and not across HMC. • These data will be documented in the file, but HMC does not have a number of reports of such cases. • Underreporting and the possibility of cases remaining undiagnosed could be challenges. In addition, it is not easy to link the outcome to the drugs. • Most HMC reports are voluntary. However, HMC is working on developing clinical surveillance with the Cerner system to capture some triggers for specific drugs. • Clinical pharmacy professionals are not available in the emergency department, so HMC does not have these data. If clinical pharmacy professionals were active in the emergency department, they may be able to collect these data. However, due to the shortages in the clinics, such data cannot be obtained.

Code	Response	Score *	Assessment (Qualitative)
CO4	No cases reported.	(1)	• HMC does not have these data.
CO5	Not relevant.	(-)	• Not relevant.
CO6	No, HMC does not have this data.	(0)	• HMC does not have these data.
CO7	No, HMC does not have these data.	(0)	• HMC does not have these data. HMC has international data only. HMC members are writing a proposal for this subject to capture data retrospectively.
CO8	Data were not provided.	(1)	• HMC has these data. The administration is conducting studies and knows the patient costs according to the specialty of the responsible department, but this information is not under the Pharmacy Department or the MSQC.
Total Score		(5)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators, the obtained score was [(5) = 41.7%]

(*) Score: (2) Yes, fully satisfactory; (1) Yes, partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, and not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

1.2.2. Public Sector Part 2: Primary Healthcare Corporation (PHCC)

The study assessed the PV system of PHCC, which was represented by 7 members from the Medication Management Section, Risk Management Section, Clinical Information Systems Team, and Health Information Management Team.

1.2.2.1. Total Performance of the PHCC Pharmacovigilance System

According to the assessment findings, the total score for the three PV structure, process, and outcome domains was 38.5 out of a total possible cumulative score of 54 (71.3%). The compliance of the PHCC PV system with the WHO PV indicator manual was highest for structural indicators, with a score of 20.5 (82%), and lowest for the outcome indicators, with a score of 4 (57.1%). Figure 7 and Figure 8 represent the performance of the PHCC PV system based on the measured compliance of the system with the core and complementary WHO PV indicators. As a result of the good performance on many of the indicators, the PHCC case will be presented following a table format with full details on the PV system performance for each indicator. The tables illustrate the performance of the PV system in the relevant core indicators (Table 9) and relevant complementary indicators (Table R5: Appendix B) as well as the qualitative assessment accompanying each indicator.

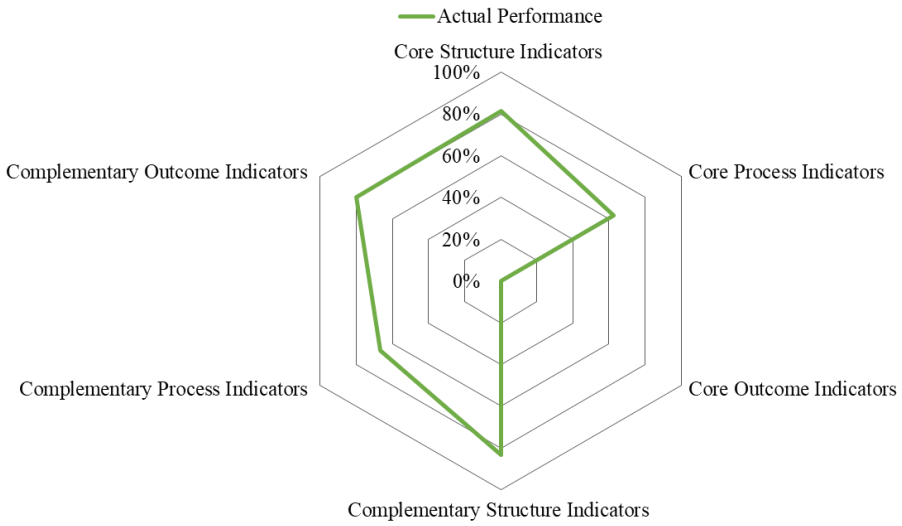

Figure 7. PHCC pharmacovigilance system performance (presented as percentages)

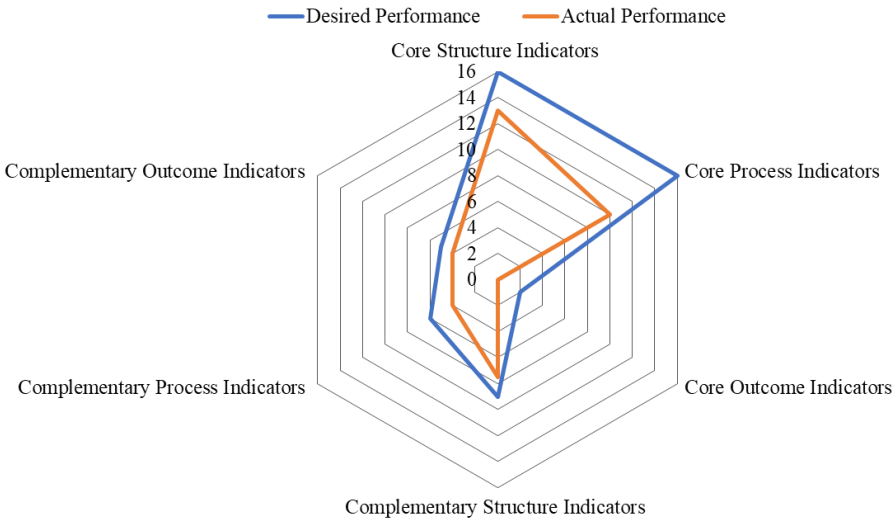

Figure 8. PHCC pharmacovigilance system performance (presented as scores)

1.2.2.2. Structural Indicators Performance

The tables illustrate the performance of the PHCC system in 8 relevant core indicators (Table 9) and 9 relevant complementary indicators (Table R5: Appendix B). The performance of the PHCC PV system as measured by the core structural indicators was 13 out of a possible score of 16 (81.3%). Similarly, the PHCC PV system performed well in the complementary structural indicator assessment, as it achieved a

score of 7.5 out of a possible score of 9 (83.3%). Notably, the achieved total structural scores, as well as the core and complementary structural indicator scores, indicate excellent system performance in this category (i.e., target Q3: 75% to 100%).

This finding highlights the fact that PHCC has key PV system structures. Although not specific for PV, the Medication Management Section is concerned with medication safety activities, including ADR reporting (i.e., CST1). PHCC has no specific PV policy or guideline but rather has a range of policies that focus on medication safety (i.e., CST2) and are implemented and regularly updated, e.g., the policy on ADR reporting. The CST7 assessment found that PHCC has two automated systems for routine PV activities. The electronic Datix and Cerner systems will store all the reports received. Furthermore, the Datix systems will enable PV information communication and feedback across the 25 centers. The Health Information Management Team records all the data from the reports and the interventions that are available for all patients in all PHCC centers. This enables a search for all PV activities that happened as well as all the ADR reporting that occurred in the main centers to generate a full report.

The Pharmacy and Therapeutics Committee is a multidisciplinary committee with 10 members, including physicians, nurses, and pharmacists. The committee is responsible for providing advice on medication safety and PV at the corporate level (i.e., CST10). Furthermore, PV data are essential to PHCC guideline development (i.e., ST8). The guidelines committee, which includes more than 14 consultants, will use PV data obtained at the national level and/or from international sources of information to develop the clinical guidelines used in primary care.

1.2.2.3. Process Indicators Performance

The assessment indicated that out of a total allowed process indicator score of 22, the PHCC PV system achieved 14 (63.6%). PHCC reported a positive response for all relevant core process indicators except for CP9, which requires a number of active PV activities. It was reported that the Risk Management Team is performing passive surveillance activities through incident reporting only. For the complementary process indicators, the assessment found that PHCC achieved a score of 4 out of a total possible score of 6 (66.7%) (Table R5: Appendix B).

With respect to core PV process requirements, PHCC has an internal system for the collation and analysis of PV data. The Datix system counted 50 reported ADR cases (i.e., CP1) for 2017. Many healthcare professionals are willing to report, as reporting is part of their monthly key performance indicators. Additionally, PHCC conducts continuous professional development programs to educate healthcare professionals on reporting, but to date, some of the received reports have had a degree of irrelevancy or deficiency (i.e., CP5). Some healthcare professionals lack knowledge of ADRs, and some fail to differentiate between ADRs and side effects. An event can be reported as an ADR, but when subjected to review, it will not be classified as an ADR. Some healthcare professionals report ADRs, but they do not provide the full information required for further analysis. PHCC does not conduct causality assessment (i.e., CP4). The Risk Management Team of PHCC performs systematic system analysis, but none has been performed for ADR cases. The Risk Management Team has experts with knowledge of statistical methods. The systematic system analysis will be based on the severity and recurrence of the received reports.

According to PHCC, the national PV system of Qatar is not performing as expected; thus, the MOPH currently receives ADR reports only on vaccines.

Additionally, there is no well-defined system for reporting at the national level. Therefore, it was reported that there is a need to improve and activate PV as a centralized system at the national level.

1.2.2.4. Outcome/Impact Indicators Performance

The lowest-performing domain for the PHCC PV system was that for outcome indicators, especially for core indicators (Figures 7 and 8). For core outcome indicators, PHCC obtained a score of 0 out of a possible total score of 2 (Table 9). Out of 5 relevant complementary outcome indicators, the obtained score was 4 (80%). PHCC reported that the assessment of the percentage of preventable ADRs (i.e., O1) is not available (Table R5: Appendix B).

Table 9. Primary Healthcare Corporation (PHCC) pharmacovigilance (PV) system performance and capacity results measured by WHO core PV indicators

Code	Response	Score *	Assessment (Qualitative)
CORE STRUCTURAL INDICATORS			
CST1	Yes, but no specific PV department.	(1)	• Applicable, but no specific department for PV. PHCC has a Medication Management Section that is concerned with medication safety activities, including ADR reporting.
CST2	Yes.	(2)	• Range of policies that focus on medication safety e.g., ADR reporting. The policies are regularly updated. • The regulatory framework covers operations, clinical affairs, and quality.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget for PV.	(0)	• No separate dedicated budget for PV. The budget for PV is included in the operation of the Medication Management Section. The current budget is sufficient.
CST5	Yes.	(2)	• Sufficient; many staff members have master's degrees, PharmD degrees, diplomas, and certification by the American board of pharmacotherapy. • PHCC will require more expertise in PV as they are opening new centers.
CST6	Yes.	(2)	• Cerner and Datix system reporting forms. The form provides a field for medication errors and reporting suspected misuse, abuse, or dependence on medicine. • The form does not have a specific field for suspected counterfeit or substandard medicine or therapeutic ineffectiveness. The pharmaceutical products in Qatar are of good quality and effective. However, if a medication is damaged, has reached the expiration date, or needs to be recalled, it can be reported. • No form available for public reporting. Members of the public can report their concerns as complaints.
CST7	Yes.	(2)	• The electronic Datix and Cerner systems will store all the reports received. • A comprehensive assessment of reported cases is conducted by the Pharmacy Department. Followed by a systematic system evaluation through the Quality Department, followed by Quality Department feedback and communication of actions. • The Health Information Management Team records all the data from the reports and the interventions that are available for all patients in all PHCC centers. This enables a search for all

Code	Response	Score *	Assessment (Qualitative)
			PV activities that happened as well as all ADR reporting that occurred in the main centers to generate a full report.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• The reporting Datix software system is used for PV information communication. The Datix system is available to all PHCC centers. • There is no newsletter for PV specifically, but there is for the Medication Management Section as a whole. • For information communication to the general public, PHCC has many patient leaflets and brochures but not specifically on ADR. PHCC has brochures on antibiotics and missuse of medication in general.
CST10	Yes.	(2)	• The Pharmacy and Therapeutic Committee is a multidisciplinary committee with 10 members, including physicians, nurses, and pharmacists. The committee meets on a regular basis, once per month.
Total Score		(13)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(13) = 81.3%]
CORE PROCESS INDICATORS			
CP1	Yes.	(2)	• In the Datix system, there were 50 reported ADR cases for 2017. • ADR reports are reported in the Cerner and Datix systems. Usually, the ADRs reported in Cerner will be a subset of the Datix system. However, not all ADR reported in the Datix system will be documented in the Cerner system. Ideally, they should be, but this is not always the case. • Healthcare professionals are willing to report, as reporting is part of their monthly key performance indicators. In addition, PHCC conducts continuous professional development programs. Thus, the healthcare professionals report, but their reports can have a degree of irrelevancy. • Some healthcare professionals report ADRs but do not provide the full information required for further analysis. • Some healthcare professionals lack knowledge of ADRs, and some fail to differentiate between ADRs and side effects. Therefore, an event can be reported as an ADR, but when subjected to review, it will not be classified as an ADR. • The Risk Management Section has several projects on quality improvement and reporting of ADRs is one of the projects.
	CP1a: Not relevant.	(-)	

Code	Response	Score *	Assessment (Qualitative)
CP2	The value was not provided.	(1)	• Data were not provided. However, the data can be extracted. • The Risk Management Team is responsible for studying all incidents reported, including the trends and relevant calculations. PHCC relies on risk management analysis.
CP3	100%.	(2)	• The Datix system allows PHCC staff to communicate and provide feedback on the same system. • Based on the type of incident, feedback will be provided through the Datix system, and the system will send an alert. For moderate to high-risk incidents, it is mandatory to provide feedback and a course of action to follow, and an email will be sent to all involved stakeholders selected from the Datix system (within 24-48 hrs.). For minor risk incidents, PHCC usually uses verbal phone communication and different interventions. • ADR reports receive feedback, but other low-risk incidents are investigated, and recommendations are provided.
CP4	No; PHCC does not do causality assessment.	(1)	• PHCC does not perform causality assessment. The Risk Management Team of PHCC performs systematic system analysis, and none was done for ADR cases. • The Risk Management Team has experts with knowledge of statistical methods. Systematic system analysis is based on the severity and recurrence of events.
CP5	No value provided.	(1)	• No value was provided for medication-related reports, but for vaccine ADR reports, it is 100%. • It was reported that the national PV system of Qatar is not performing as expected; thus, the MOPH receives ADR reports only on vaccines. In addition, there is no well-defined system for reporting at the national level. The Qatar National Formulary electronic application had a section for ADR reporting, but the license has expired and was not renewed, thus since February 2017, there has been no form for reporting cases. Therefore, there is a need to improve and activate PV as a centralized system at the national level.
	CP5a: Not relevant.	(-)	
CP6	PHCC has the data, but they are not calculated.	(1)	• PHCC does have this category in the Datix system, but it is not calculated. Additionally, factors contributing to therapeutic ineffectiveness are documented in the Datix system. Cases are detected by pharmacists, and they enter reports into the system. • Data are reported regarding dosage but not medication, hence PHCC does not consider the medication involved, as it has been reported that medications in the Qatar pharmaceutical market are of good quality and are effective. Therefore, the cases reported are related mainly to therapeutic causes and subclinical dosages.
CP7	Yes.	(2)	• Percentages were not provided. Values were provided for incidents (n= 1191) and near misses (n=802).

Code	Response	Score *	Assessment (Qualitative)
			• It was reported that the culture of reporting and positive disclosure can be further improved in PHCC.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• The PHCC Risk Management Team conducts passive surveillance activities through incident reporting only. In addition, the pharmacy supply management monitors for damaged medications.
Total Score		(10)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(10) = 62.5%]
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CORE OUTCOME/IMPACT INDICATOR			
CO1	None.	(0)	• PHCC relies on external sources of data (e.g., an FDA notice on Avandia) and the MOPH only.
CO2	Not relevant.	(-)	• Not relevant. • PHCC has internal initiatives. For example, PHCC reacted to the announcement of the WHO on antimicrobial resistance. A policy was developed, and recommendations were added to the PHCC drug formulary. In addition, PHCC restricted the prescriptions to certain healthcare professionals. This procedure will go through the National Stewardship Program.
CO3	Not relevant.	(-)	• Not relevant to primary care. Cases of drug-related problems such as allergies are referred to the HMC.
CO4	Not relevant.	(-)	• Not relevant.
CO5	Not relevant.	(-)	• Not relevant.
CO6	Not relevant.	(-)	• Not relevant.
CO7	Not relevant.	(-)	• Not relevant.
CO8	Not relevant.	(-)	• Not relevant.
Total Score		(0)	Out of 1 [1*2= (2)] is [(100%)] relevant indicators, the obtained score was [(0) = 0%]

(*) Score: (2) Yes, fully satisfactory; (1) Yes, partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, and not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

1.3. Private Sector Level

1.3.1. Private Sector: Healthcare Institutions

The study assessed the PV system at 5 private health institutions (i.e., 3 private hospitals, one private healthcare organization, and one semigovernmental hospital). The sample of participants included 1 to 3 members from each health institution. This thesis will use the term Hospital to describe the health institutions, e.g., Hospital A.

1.3.1.1. Total Performance of the Private Sector Health Institution Pharmacovigilance Systems

The total possible score for the three PV structural, process, and outcome domains was 68 (100%). The mean total performance score for the 5 hospitals was 39.7, with a range from 33.5 for Hospital D to 44 for Hospital C (Table 10). To comply with the thesis page limit, the complete results for the 5 healthcare institutions will be presented in the appendix in table format with full details on the healthcare institutions' PV system performance for each indicator (Table R6 to Table R15: Appendix B). Although the health organizations have some deficiencies in their performance, all have functioning PV systems, and 4 hospitals achieved the target of good PV system performance (Table 10).

Table 10. Total pharmacovigilance system performance of private sector healthcare institutions

Hospital Code	**Total Performance Score (percentage)**	**Target Performance Range***
Hospital A	42 (61.8%)	Good

Hospital Code	Total Performance Score (percentage)	Target Performance Range*
Hospital B	39.5 (58.1%)	Good
Hospital C	44 (64.7%)	Good
Hospital D	33.5 (49.3%)	Average
Hospital E	39.5 (58.1%)	Good

*Target performance range (based on quartiles Q1: 25%, Q2: 50%, Q3: 75%): Excellent performance 75-100%, good performance 50-74.9%, average performance 25-49.9%, and poor performance 0-24.9%).

Figure 9 and Figure 10 represent the actual performance of PV for the healthcare institutions in the main core and complementary indicators compared to the desired performance score measured by the WHO PV indicators, namely, structure, process, and outcome indicators. As illustrated, there are noticeable differences between healthcare institutions' performance. Overall, the performance on structural indicators was comparable in that all health institutions have achieved many of the core structures required for a functional PV system at the organizational level. For example, Hospital A achieved the highest score, 13 out of a possible total core structural indicator score of 16. On the other hand, the lowest performance of the PV system was in outcome indicators. Out of a possible score of 12, the mean score of core outcome indicators for the 5 hospitals was 2.4, with a range from 0 for Hospital A to 5 for Hospital B. The

health institutions' score for core process indicators was between 13 for Hospital A and 9 for Hospital D. For the aforementioned values, refer to Table R16 in Appendix B.

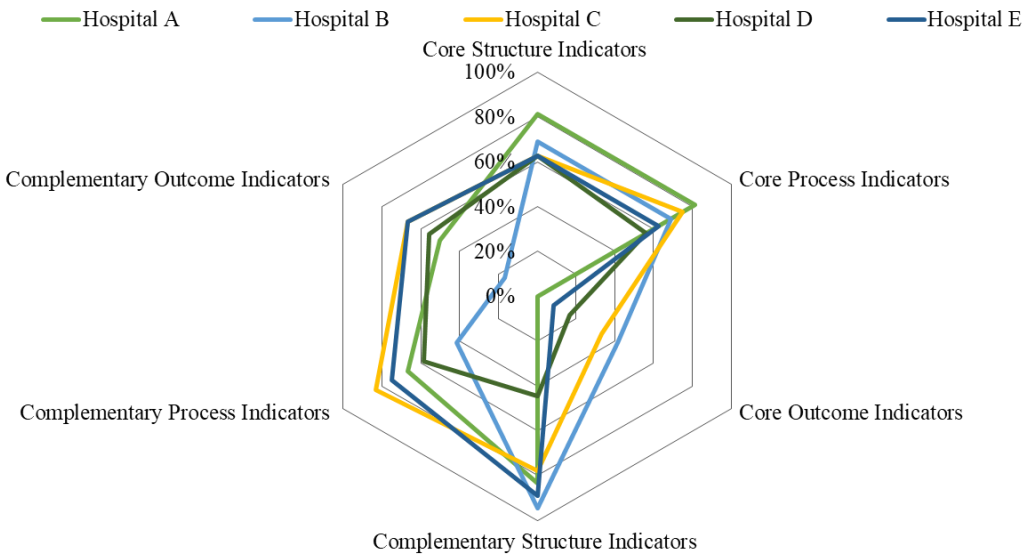

Figure 9. Private healthcare institutions pharmacovigilance system performance (presented as percentages)

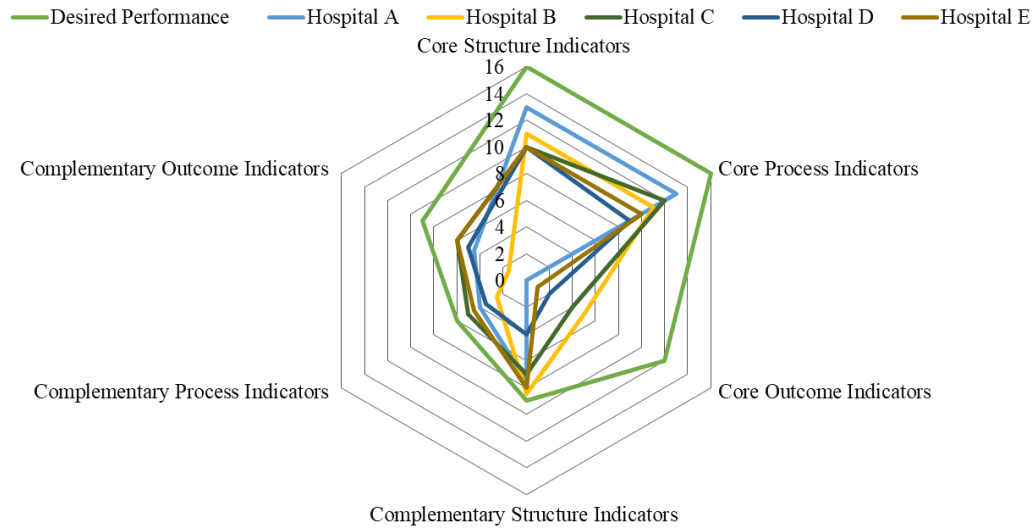

Figure 10. Private health institutions pharmacovigilance system performance (presented as scores)

1.3.1.2. Structural Indicators Performance

The assessment found that although there is no specific PV policy or guidelines (i.e., CST2), all the healthcare facilities have policies and guidelines that cover many elements relevant to PV, e.g., medication errors and ADRs. The key informants reported that a national PV guideline or policy document will be essential to ensure that all private sector institutions follow the standards and expectations set by the MOPH. Additionally, all 5 healthcare institutions had internal structures to enable PV at the organizational level. This includes the availability of a network or single department (i.e., CST1) responsible for PV activities, including the collation and analysis of and feedback on PV data (i.e., CST7). The departments responsible for PV among the research sample were usually the Quality Department, Pharmacy and Therapeutics Committee, and Pharmacy Department.

The results highlighted that PV structures and processes are usually coordinated at the organizational level. None of the healthcare institutions had a dedicated budget for PV or medication safety activities (i.e., CST4). In addition, all the healthcare facilities reported the existence of a report management process (i.e., CST7) that includes the availability of electronic or paper-based reporting forms (i.e., CST6) and a database for PV-related functions. Only one hospital (i.e., Hospital B) reported the availability of a reporting form designed for patient reporting.

For PV information communication, all the healthcare facilities had a structure in place for communication and feedback on PV and medication safety, which in some cases included website portals and newsletters (i.e., CST9). For sharing information with the public, although no PV training sessions were conducted, the healthcare facilities reported many initiatives for public outreach through TV media, radio talks, and social media, and one hospital reported visiting schools to raise awareness of

antibiotics and antimicrobial resistance among students. Healthcare facilities reported the need for a national contact point to address PV and to offer drug information services.

Many healthcare institutions have initiatives to improve the efficiency of their PV and medication safety systems, including the utilization of PV and medicine safety data from internal and external sources to inform the development of their clinical guidelines (i.e., ST8), clinical practices, formulary updates (i.e., ST7), and educational interventions (i.e., ST9).

1.3.1.3. Process Indicators Performance

All the health institutions have procedures in place to ensure the completeness of submitted reports (i.e., CP5). For instance, Hospital B reported that the clinical pharmacist directly communicates with healthcare providers and patients to ensure that all the relevant information required for evidence-based causality assessment (i.e., CST 4) is satisfactorily provided. Furthermore, among the sample, patients' files were the most common source for ensuring the completion of reports.

Many of the health institution key informants reported that they rely on external reputable sources, such as other regulatory bodies' websites, to obtain valid information on PV and include it in routine clinical practice. For example, at the organizational level, Hospital C members check the FDA website and other official websites to follow up on aspects that can be addressed at the hospital level, including any warnings or instructions not provided by the MOPH. For example, no measures were taken or instructions reported for fluoroquinolones from the MOPH, but these issues were mentioned on the FDA website, and the information was published in the hospital monthly newsletter to inform clinicians.

Two hospitals, namely, Hospital A and Hospital C, reported preparations to

purchase an electronic report management system to improve their current report management process. All the healthcare institutions reported initiatives at the organizational level to improve reporting rates. For instance, Hospital E reported that to improve the reporting rates and culture, the hospital leadership is involved. The hospital does leadership rounds, as leadership involvement will assure healthcare providers that there will be no penalties. Additionally, Hospital E conducted a patient safety culture survey for the staff, and based on the results, the line managers were instructed to assure staff that they would not be penalized; the hospital often reviews incentive potency. Similarly, Hospital B indicated that its reporting rate improved after some initiatives, including a) the clinical pharmacist was assigned to be involved in educational campaigns for the healthcare practitioners; b) reporting forms were distributed in the hospital to be accessible to the healthcare practitioners; c) the clinical pharmacists collaborate and are in close communication with healthcare practitioners and can assist them in reporting; d) healthcare providers were encouraged to report; and e) the hospital acknowledges every report and sends a thank-you letter to each reporter.

Currently, not all healthcare institutions submit ADR reports to the MOPH, as ADR data are not requested by the MOPH (i.e., CP5a). However, information that has an impact will be communicated to the Pharmacy and Drug Control Department of the MOPH. All the healthcare institutions send their medication error data to the MOPH as key performance indicator requirements of the health service performance agreement between the MOPH and hospitals. The compiled and approved reports are sent to the HQPS on a monthly or quarterly basis.

The key informants from the private sector reported that awareness of active PV is not uniform or consistent among healthcare professionals (i.e., CP9), and there is a lack of understanding of active PV studies. The factors that enable private hospitals to

participate in such studies include, first, such studies being mandated by the MOPH. Since active PV is not in alignment with the scope and nature of the work of the private sector, it is very difficult for private organizations to engage in these activities because they do not generate revenue. Second, a policy at the national level to cover active PV would be helpful. Third, incentives should be provided for organizations to conduct active surveillance, including MOPH support by providing expertise in PV and statistical analysis.

1.3.1.4. Outcome/Impact Indicators Performance

All the healthcare institutions have a process in place to assess reports received about medication-related issues, but due to the limited number of ADR reports, activities such as signal identification and evaluation (i.e., CO1) are not feasible. However, it was reported that an expert in PV, if available, can not only provide technical guidance but also contribute to PV policy development at the organizational level.

For the outcome indicators related to financial outcomes (e.g., CO3, CO4, CO7) and clinical outcomes (e.g., CO6, CO8), it was reported that it is difficult to quantify such data, as the private sector does not have the required resources in terms of human, financial, and technical resources to collect and analyze data. Additionally, the private sector key informants reported that such PV KPIs do not align with the scope of the services provided, which are considered low risk. In addition, they reported that private sector institutions are focused more on treatment than prevention, which is better performed at the national level (i.e., MOPH). However, some institutions acknowledged that in terms of cost, such PV KPIs are beneficial for realizing profit margins, discovering areas that require attention and further investment, or understanding a health institution's position compared to that of others.

1.3.2. Private Sector: Community Pharmacies

The assessment of the PV system at the community pharmacies level included one chain pharmacy group and one independent (single branch, 24-hour service) pharmacy. The sample of participants included 1 key informant from each pharmacy. This thesis will use the code Pharmacy to describe community pharmacies, e.g., Pharmacy A. The assessment findings will be presented in table format with full details on the PV system performance for each indicator.

The tables illustrate the performance of the PV system in the relevant core indicators (Table 11 and Table 12) and relevant complementary indicators (Tables R17 and Table R18: Appendix B) as well as the qualitative assessment accompanying each indicator. According to the system assessment relevant indicators, the total possible cumulative score for the three PV structure, process, and outcome domains was 42 (100%). In addition, it is important to note that the core outcome indicators are not relevant to the community pharmacies level. The compliance of the community pharmacies PV system with the WHO PV indicator manual was highest for structural indicators, with a score of 14 (60.9%) for Pharmacy A and a score of 4.5 (19.6%) for Pharmacy B. Regarding the core structural indicators performance, Pharmacy A achieved a score of 9 out of 16 (56.3%), while Pharmacy B achieved a score of 1 out of 16 (6.3%). In addition, the lowest-performing indicator category for Pharmacy A was the outcome indicators, with a score of 4 (57.1%). In contrast, the lowest-performing indicator category for Pharmacy B was the process indicators, with a score of 1 (8.3%).

Figure 11 and Figure 12 represent the performance of the community pharmacies PV system based on the measured compliance of the system with the WHO PV indicators for core and complementary indicators. The observed inequality in

systems performance is expected since Pharmacy A is a chain pharmacy, while Pharmacy B is a single branch or independent pharmacy.

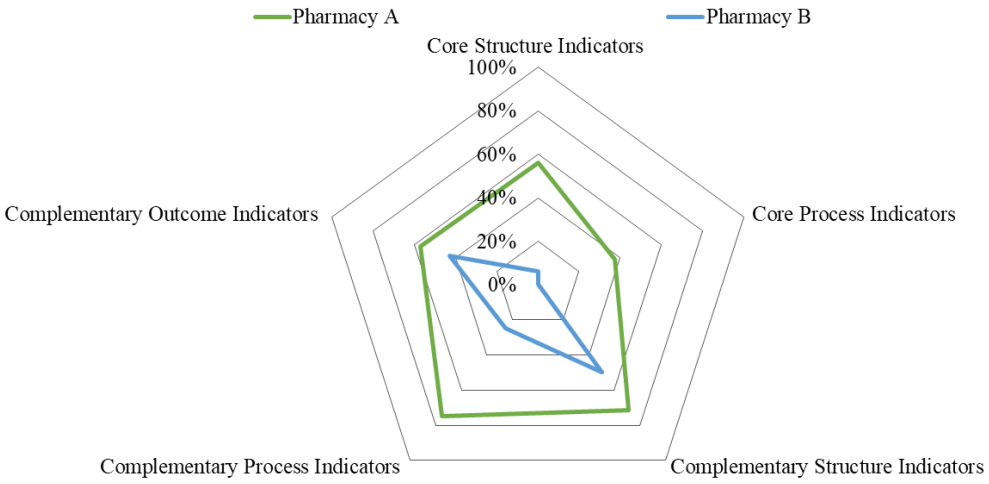

Figure 11. Community pharmacies pharmacovigilance system performance (presented as percentages)

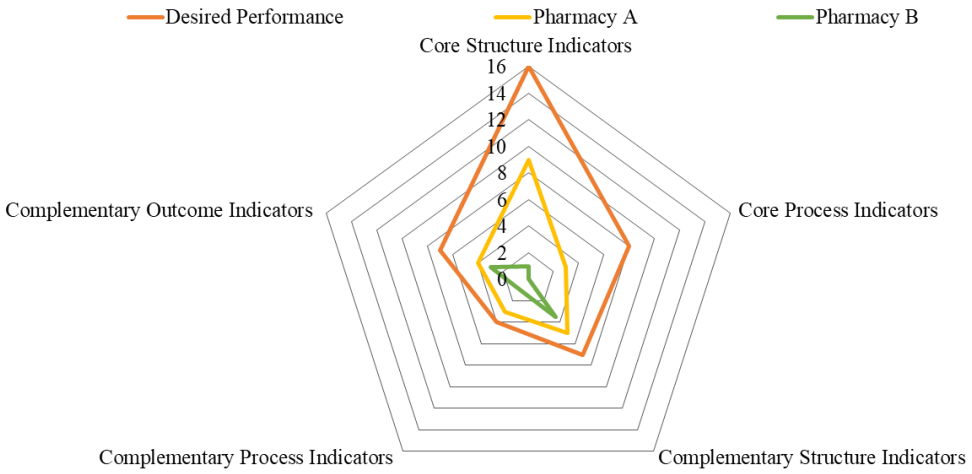

Figure 12. Community pharmacies pharmacovigilance system performance (presented as scores)

Table 11. Community pharmacy "A" pharmacovigilance (PV) system performance and capacity results measured by WHO core PV indicators

Code	Response	Score *	Assessment (Qualitative)
CORE STRUCTURAL INDICATORS			
CST1	No.	(1)	• There is no specific PV department for the chain pharmacy group, but the Academic Committee is responsible for medication safety and PV-related activities e.g., report management, training, and education. • There are clear instructions to follow for all affiliated chain pharmacists to report to the responsible person on the Academic Committee in case of any unwanted or adverse side effects reported by patients directly to pharmacists.
CST2	No.	(0)	• There is no statutory provision within the pharmacy group or even at the national level. • There are no clear national instructions on PV for community pharmacies. • The PV functionality of the pharmacy group is not at the highest level of professional conduct, but there is a crude way of performing activities. However, currently, many community pharmacists have not been trained in PV and do not understand the concept of PV. Therefore, the community pharmacy sector is still on basic grounds regarding PV.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No.	(0)	• There is no exact budget allocated for PV, but the pharmacy group has a budget allocation for academic projects, for example, for developing academies within the organization. This includes a possible future PV related study. • It was reported that if the group focuses on PV, the budget provisions could be approved by the organization provided it returns some benefits in the form of better performance by the pharmacists and pharmacies.
CST5	Yes.	(2)	• The human resources are sufficient. • PV is not included in the job description of the pharmacist, but it is part of the commitment by the pharmacists as healthcare professionals. • The pharmacy group has master's degree holders and PharmD degree holders. In addition, the pharmacy group provides the pharmacists with training programs or offers the opportunity to attend special seminars conducted by the MOPH. • The employees have specific requirements for continuous professional development (CPD), and the group continuously monitors whether the employees are attending the CPD programs.

Code	Response	Score *	Assessment (Qualitative)
CST6	No.	(0)	• The group plans to develop an internal reporting form. • The pharmacists will declare and capture information on a group of incidents but not on individual cases, such as incidents happening within a short time span with a particular drug as well as severe cases. • Incidents captured or encountered are rare. In Qatar, there is underreporting from patients, as it is possible that patients are not able to identify ADRs or that patients are not being educated about adverse effects to medications. • Qatar's legal framework allows the pharmaceutical sector to be free of counterfeit medications. In addition, pharmacists are bound by law to report such cases to the MOPH. In chain pharmacies, it is almost impossible for a counterfeit medication to be purchased because they have a centralized system for purchasing medications. • A patient reporting system is available on the MOPH webpage, but public awareness of it is questionable. • There is no internal reporting form for the public; the pharmacy group receives cases only as complaints. • For public reporting in the future, the group is committed to helping patients, but for this change to be made, a change should be realized in the organizational and social levels.
CST7	Yes.	(2)	• The current functionality of the system that the pharmacy group uses is not at the highest professional level; there is a raw method of collecting information. Reporting is mostly for the group's internal purposes. • The pharmacy group may contact the company to ask for an explanation and, based on the explanation, will decide whether the drug will be taken off the shelf or continue to be used. Sometimes the group has a discussion with a physician, even if the case was a known ADR. • There is no database system, but the group collates data using an Excel spreadsheet. In addition, if there is regular reporting, they will immediately notify the company. • Underreporting by patients can sometimes occur because the patient feels that the reporting will be used against the physician. Thus, patients often deliberately do not report cases. This makes the process of information collection difficult, as the patients do not provide the required details. In addition, it is a challenge that when recording in the database, there is much missing information, such as patient age and medication history.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• The pharmacy group has a newsletter published approximately once per week with the most relevant information for the practice. This newsletter is circulated to all the pharmacists. This initiative gives the

Code	Response	Score *	Assessment (Qualitative)
			pharmacists more confidence in practicing and is used as a refresher for past information. It has a positive influence on the pharmacists and on their practice. • The pharmacy group has network and communication systems. Communication can be through emails, web page, and WhatsApp. • The pharmacy group webpage has a section for members of the public to send complaints or any kind of reporting they desire. Information relevant to PV and medication safety is not published on the website since it is a public domain.
CST10	Yes.	(2)	• The Academic Committee consists of seven individuals, all pharmacists, with a level of education ranging from a PharmaD degree to a bachelor's degree.
Total Score		(9)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(9) = 56.3%]
CORE PROCESS INDICATORS			
CP1	No.	(0)	• In 2017, one case was reported: a side effect, celecoxib and edema. • Many pharmacists are willing to report, but there is a need for training for a more professional way of understanding PV-related activities as well as the proper way to report ADRs. • Regarding the reporting culture, it was reported that it can be difficult to report in the community pharmacy, as pharmacists play many roles, and PV happens to be a lower-priority part of their role that sometimes can be missed and in some cases PV data can be underreported. • It was reported that reporting has a positive impact on the professional behavior and performance of the staff. The pharmacists feel that they have done something as a part of the pharmacy profession. This could have a positive influence on pharmacist counseling systems, such as asking additional questions. • It was reported that there is a general tendency in the medical field to believe that the responsibility of ADR education and ADR reporting rests on pharmacists only. This should not be the case; it should be a step-by-step process and should start with physicians.
	CP1a: Not relevant.	(-)	
CP2	No value provided.	(1)	• In 2017, 14 reports were received, but they were not specific to ADRs. The database was created six years ago. • It was reported that the number of reports has increased, but regarding the severe cases, the numbers are almost stagnant. A few severe conditions or emergency cases were encountered.

Code	Response	Score *	Assessment (Qualitative)
			• The pharmacy group has a monthly meeting of all the pharmacists. Training sessions are conducted in which the pharmacists are reminded of their professional duties. Some of those discussions are about how PV can be incorporated into the pharmacy group in the future.
CP3	100%.	(2)	• Verbal feedback for each report. • Feedback depends on case-by-case prioritization based on the severity of the reported case. • Feedback is issued mostly within 48 hrs.
CP4	Not relevant.	(-)	• A basic assessment is performed by the pharmacist. • Most of the reports do not have full information, e.g., cases when the medication was purchased from a different place, such as the PHCC or from HMC hospitals. • Questions on medication-related issues might come to the community pharmacy if it is the closest source. • The probable information received from very few patients after the pharmacist refers them to the hospital or the emergency department is that this case occurred because of the medication or because the doctor changed the medication.
CP5	No.	(0)	• No reports were submitted to the MOPH. • If a medication-related issue is repeatedly encountered within the pharmacy group, the group will report and try to prevent this medication from being sold in its pharmacies. This will be reported to the manufacturer. However, the group does not report directly to the MOPH since there is no PV center, and the MOPH does not have a system that requires reporting of cases directly.
	CP5a: Not relevant.	(-)	
CP6	Not relevant.	(-)	• It was reported that there are cases of therapeutic ineffectiveness, but there is a thin line between an incorrect diagnosis and therapeutic ineffectiveness, and most community pharmacists do not have access to the basic necessities, such as the required assessment tools, to determine a final judgement. • Cases of therapeutic ineffectiveness and contributing factors are not documented.
CP7	Not relevant.	(-)	• Not relevant.
CP8	Not relevant.	(-)	• Not relevant.
CP9	Not relevant.	(-)	• Not relevant.

Code	Response	Score *	Assessment (Qualitative)
			• Research activity in collaboration with Qatar University includes a review of prescriptions only.
Total Score		(3)	Out of 4 [4*2= (8)] is [(100%)] relevant indicators, the obtained score was [(3) = 37.5%]
CORE OUTCOME/IMPACT INDICATOR			
CO1	Not relevant.	(-)	• They receive incidents from external sources (i.e., an incident happened outside the organization practice), and the pharmacy group shares information with all the pharmacists. • The primary reporting occurs at the pharmacies, but for external incidents, the group sends a general alert through its system to notify the practicing pharmacists to be aware of the possibility of encountering this event.
CO2	Not relevant.	(-)	• Withdrawal policies and other regulatory actions are taken by the MOPH. The pharmacy group's role is to inform the staff and follow the directions of the MOPH. The MOPH has a system, and possibly once or twice per month, it provides circulars or safety warnings. • It was reported that medicines registered in Qatar are approved by the GCC, where it takes two to three years to obtain approval for a medication. In addition, medicines registered in Qatar have FDA approval. Therefore, medications in Qatar are of high quality and effectiveness. • Internal alerts to pharmacists about the cautious use of a particular drug happened 8-9 times in 2017.
CO3	Not relevant.	(-)	• Not relevant.
CO4	Not relevant.	(-)	• Not relevant.
CO5	Not relevant.	(-)	• Not relevant.
CO6	Not relevant.	(-)	• Not relevant.
CO7	Not relevant.	(-)	• Not relevant.
CO8	Not relevant.	(-)	• Not relevant.
Total Score		(-)	Core outcome indicators are not relevant.

(*) Score: (2) Yes. fully satisfactory; (1) Yes. partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, and not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table 12. Community pharmacy "B" pharmacovigilance (PV) system performance and capacity results measured by WHO core PV indicators

Code	Response	Score *	Assessment (Qualitative)
CORE STRUCTURAL INDICATORS			
CST1	No.	(0)	• Single-branch pharmacy with 24-hour operation. • It was reported that ADR reporting is beneficial. as the MOPH can collect data about adverse effects and other issues related to the medications.
CST2	No.	(0)	• The pharmacy has an internal policy for medication damage and expiration-date issues. • The pharmacy follows the MOPH guidance about the medication, e.g., registration for antibiotics, corticosteroids, and antidepressants. • There are no national guidelines for PV, but the MOPH issues circulars that the pharmacy receives from time to time. • The MOPH circulars are considered clear and almost specific regarding medication safety, but sometimes, there is a misunderstanding of some points; for example, the circulars sometimes cover a variety of medications that fall into one group. • The circulars do not cover all aspects that are required for the pharmacist to practice PV and medication safety related activities. • The circulars do not reach the pharmacy regularly Sometimes the pharmacy hears about a circular from other parties. The MOPH sends the circulars by mail, and they sometimes do not reach the pharmacy on time, e.g., a circular will sometimes take two to three months to arrive. • The MOPH performs regular inspections a maximum of three times per year.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No.	(0)	• The pharmacy does not have a specific budget. • The pharmacy stated that the challenge is not with the budget itself. The challenge is in awareness of PV, as only if the pharmacist is aware of PV and cares about his patients will he/she counsel them about the adverse effects and advise them to avoid them.
CST5	Yes. Sufficient.	(1)	• No specific person is responsible for PV or medication safety activities. The total number of staff is 5 pharmacists. • The current pharmacy staff members have a minimum of eight years of experience. In addition, the pharmacists have good communication and good information, but some of the staff consider information sharing a personal effort that is not related to the organization.

Code	Response	Score *	Assessment (Qualitative)
			• The pharmacy hopes there will be PV training at the national level. In addition, it hopes that reporting will be voluntary and not mandatory because the pharmacists sometimes cannot obtain the required information from the customer. It was reported that patients often do not have time and do not want to have more communication with the pharmacist.
CST6	No.	(0)	• There are no specific reporting forms or documents to collect such data except for items that will be removed from the shelves. • It was reported that the unavailability of national reporting forms can impose many challenges in the practice. For example, for atropine spray, although side effects that cause the patient to be addicted are not a serious issue, the pharmacy currently finds them very severe. The pharmacy does not have any reporting method or tool to provide the MOPH with this information. The pharmacy reported that it has never had this communication with the MOPH, and the pharmacy hopes to have a system of this nature in the future. • Reporting forms for the public are not available. The pharmacy reported that although public reporting is beneficial, it would not be easy to have such a form completed, as people are busy and do not have time to fill out forms. In addition, the majority of Qatar's population are foreigners so the pharmacist may not have adequate experience in languages to communicate with all patients.
CST7	No.	(0)	• There is no process in place, and the pharmacy does not have reports; however, the pharmacists can communicate between them if there is an issue.
CST8	Not relevant.	(-)	• Not relevant.
CST9	No.	(0)	• The pharmacists communicate through email and a WhatsApp group. • It was reported that it will be important to have a national website that provides PV related information. In addition, communication by email between the pharmacy and a responsible key person who can addressing requests for information would be helpful. • It was reported that at the pharmacy level, it is not easy to have a newsletter or a small board to disseminate PV information because medication safety is an extensive aspect and thus this will be not feasible. • The pharmacists have internet access, but the staff uses mobile devices more than the computer due to connection problems. However, in general, the pharmacy can afford access to websites, e.g., Medscape, for information.

Code	Response	Score *	Assessment (Qualitative)
CST10	No.	(0)	• None, because the pharmacy is not a chain pharmacy. • It was reported that the pharmacy cannot say that it is important to have an expert person or group in PV, although this could be applicable in a chain of pharmacies.
Total Score		(1)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(1) = 6.3%]
CORE PROCESS INDICATORS			
CP1	No.	(0)	• The pharmacy does not have these data. • The pharmacists are of the opinion that when a case is encountered, they will report it. Three out of five will be aware of PV related definitions. If there is a chance for those who are interested in PV to have a national website to report and communicate with a responsible person, this would help the pharmacists improve their knowledge by obtaining complete information about the adverse effects of some drugs. Additionally, reporting can be added to the required credit hours for continuous professional development as an incentive. • It was reported that financial incentives are not important for increasing reporting.
	CP1a: Not relevant.	(-)	
CP2	None.	(0)	• There is no database.
CP3	None.	(0)	• None.
CP4	Not relevant.	(-)	• Not relevant.
CP5	No reports sent to the MOPH.	(0)	• The MOPH does not have a key person for the pharmacy to communicate with and request information to support the pharmacists. • The pharmacy has an employee in the office who is responsible for following up on the circulars, and he/she will send them to the pharmacists. To improve the process of communication, a website, email, or specific person within the MOPH who is responsible for this would be helpful.
CP5	Not relevant.	(-)	• Not relevant.
CP6	Not relevant.	(-)	• Not relevant.
CP7	Not relevant.	(-)	• Not relevant.
CP8	Not relevant.	(-)	• Not relevant.
CP9	Not relevant.	(-)	• Not relevant.

Code	Response	Score *	Assessment (Qualitative)
Total Score		(0)	Out of 4 [4*2= (8)] is [(100%)] relevant indicators, the obtained score was [(0) = 0%]

(*) Score: (2) Yes, fully satisfactory; (1) Yes, partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, and not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

1.4. The Pharmaceutical Industry Level

The assessment of the PV system at the pharmaceutical industry level included one pharmaceutical company.

According to the assessment findings, the total score for the three PV structure, process, and outcome domains was 34 out of a possible cumulative score of 50 (68%). The compliance of the pharmaceutical company PV system with the WHO PV indicators was highest for the structural indicators, with a score of 21 (91.3%), and lowest for the process indicators, with a score of 9.5 (45.2%). Figure 13 and Figure 14 represent the performance of the pharmaceutical company PV system based on the measured compliance with the WHO PV indicators. The pharmaceutical company case will be presented in table format with full details on the PV system performance for each indicator category. The tables illustrate the performance of the PV system in relevant core indicators (Table 13) and relevant complementary indicators (Table R19: Appendix B) as well as the qualitative assessment accompanying each indicator.

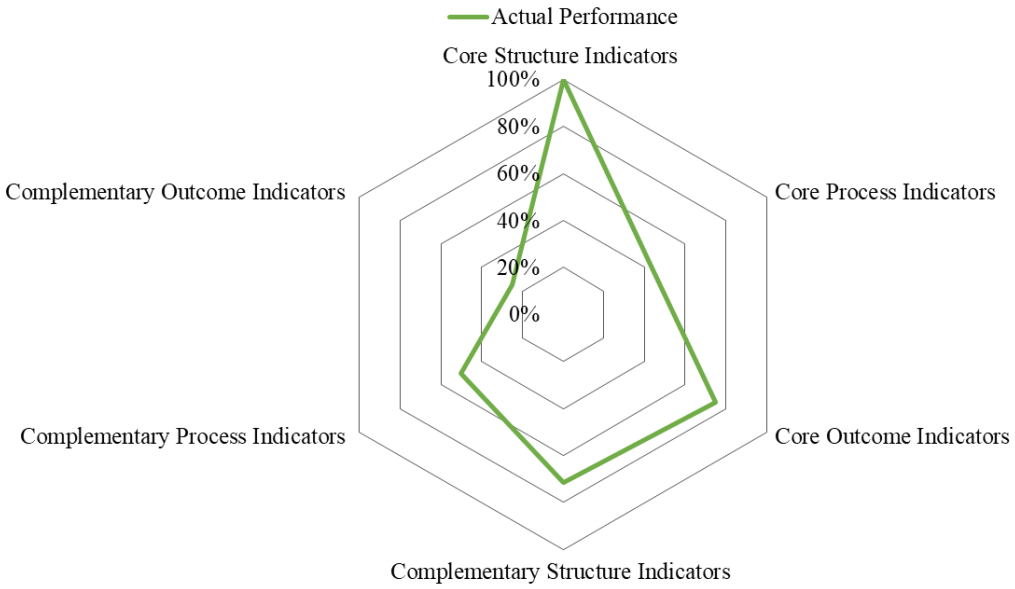

Figure 13. Pharmaceutical industry pharmacovigilance system performance (presented as percentages)

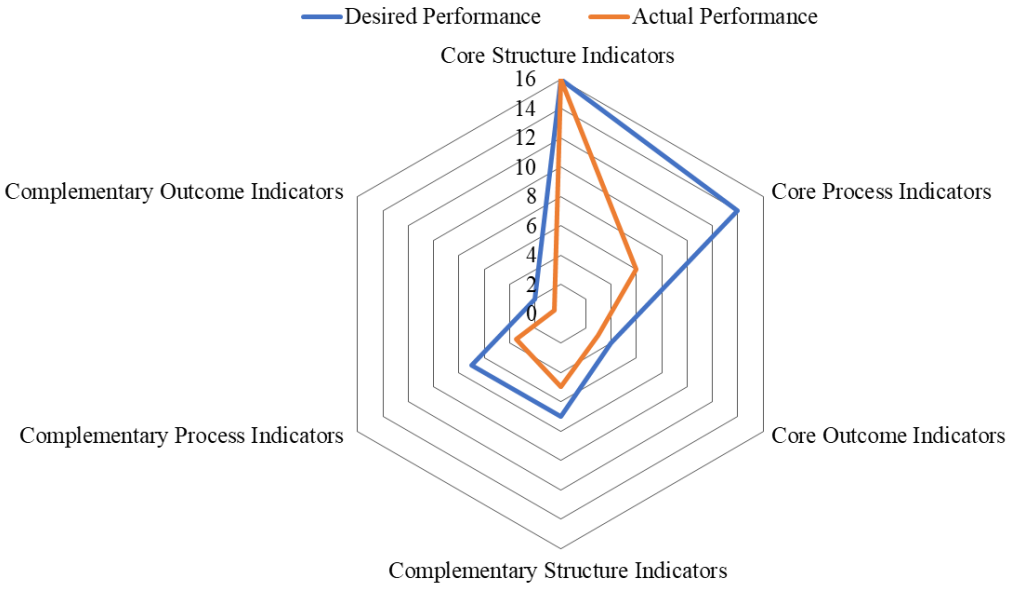

Figure 14. Pharmaceutical industry pharmacovigilance system performance (presented as scores)

The assessment found that the company adheres to the GCC legislation and guidelines (i.e., CST2). Additionally, the MOPH requirements are followed and

included in the governance framework of the company. The company reported that it changes its procedures and structures to ensure that it adheres to the requirements set by the regulatory body, the MOPH. For instance, the MOPH requested a modification in the ADR form, and the company modified it accordingly. The assessment found that standard operating procedures that include PV-related functions exist. Additionally, based on the MOPH requirements, the company is required to communicate with stakeholders using soft copies or hard copies when requested. In addition, it is mandated that it report any reported ADRs or other issues related to the company products to the MOPH.

The company manufactures generic drugs, and such products have preexisting data. Therefore, it reported that there are no major or critical issues with its products, but some critical products (e.g., paracetamol, antibiotics, lidocaine) require evaluation of product safety and efficacy and how to manage the product in post-marketing experiences. Additionally, the company is producing intravenous (IV) products such as normal saline and dextrose, and such IV products do not require risk management plans.

The Regulatory Affairs and Pharmacovigilance Department is the department responsible for PV and post-marketing surveillance activities (i.e., CST1). It was mentioned that the PV system stage of the development complies with the GCC guidelines and the MOPH requirements; hence, the company considers its PV system functional.

The assessment found that the current human resources (i.e., CST5) are sufficient to cover PV activities. Furthermore, job descriptions include PV, and the current staff receives training related to PV. There is a defined procedure for training based on the GCC guidelines. The company representative reported that the department has four members and a manager, and all members work to ensure the fulfillment of

their responsibilities. Additionally, the company representative reported that an annual budget for PV (i.e., CST4) exists and is considered sufficient. The exact budget allocation is based on request, and the management decides accordingly.

For routine PV communication (i.e., CST9) the company has a 24/7 working number to receive any complaint or to address any information request. Additionally, its web portal can be used to report any problem or to communicate information. In addition, email communication is employed in routine and emergency cases.

A quality management system exists for any problem apart from what is mentioned in the leaflet; in these cases, the company will process the complaint. For the assessment process of a report (i.e., CST7), a form will be filled out and sent to the Quality Assurance Team for evaluation. After the team reaches a conclusion, the form will be transmitted to the general manager for approval. Although no critical safety reports have been received, the company reported that there is a proper system for such incidents. The company representative reported the existence of an Excel spreadsheet database. According to the quality assurance standard operating procedures, the company must issue feedback on received reports or complaints within 15 days.

The company had not received any ADR reports or critical cases related to its products (i.e., CP1). Therefore, the company was not involved in signal identification and evaluation (i.e., CO1) at the national level. The company obtains PV information, including regulatory actions (i.e., CP2) from the national regulatory authority, GCC countries, and other regulatory bodies.

Table 13. Pharmaceutical industry pharmacovigilance (PV) system performance and capacity results measured by WHO core PV indicators

Code	Response	Score *	Assessment (Qualitative)
CORE STRUCTURAL INDICATORS			
CST1	Yes.	(2)	• The Regulatory Affairs and Pharmacovigilance Department. • It was mentioned that the PV system functionality complies with GCC guidelines and the MOPH requirements; hence, the company considers the system functional. • The company manufactures generic products, and such products have preexisting data from the pharmacopeia. The company produces IV solutions such as normal saline and dextrose. The company also produces some critical care products (e.g., paracetamol, antibiotics, lidocaine) that require evaluations of product safety and efficacy and how to manage the product in post-marketing experience.
CST2	Yes.	(2)	• The Gulf Cooperation Council (GCC) legislation and guidelines are followed. The company follows the GCC guidelines and requirements in evaluating the safety of the products. The MOPH requirements and guidelines are also followed.
CST3	Not relevant.	(-)	• Not relevant.
CST4	Yes.	(2)	• It was reported that an annual budget for PV exists and is sufficient. The exact budget allocation is based on request, and the management processes the request and provides resources.
CST5	Yes.	(2)	• The current human resources are sufficient to cover PV activities. • The Regulatory Affairs and Pharmacovigilance Department consists of four members and one manager. All the members are full-time staff. • The job descriptions include PV, and details are submitted before product registration, as per the GCC guidelines. The staff receives training related to PV, and there is a defined procedure for training.
CST6	Yes.	(2)	• ADR reporting forms and standard operating procedures (SOPs) are available. • The ADR form can be used to report cases of medication errors, counterfeit and substandard medications, therapeutic ineffectiveness, abuse and misuse. The report format includes a checklist and a full-text area. The ADR report format complies with the GCC guidelines. • The report forms are available as a soft copy, and the company has a separate server that is fully integrated into the system. • Reporting by the public can be on the same form; there is no specific form for the public.

Code	Response	Score *	Assessment (Qualitative)
CST7	Yes; a process and database exist.	(2)	• A quality management system exists. If any problem apart from what is mentioned in the leaflet (ADRs) or summary of product characteristics is reported, the company processes the report or any complaint. However, to date, it has not received any critical complaints on its products. • For report assessment, a form will be filled out and sent to the Quality Assurance Team for evaluation. After the team reaches a conclusion, it is transmitted for approval to the general manager.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• It was reported that a strategy for communication exists. • Within the company, there is an FTP server that allows information sharing across departments. • For routine PV communication, the company has a 24/7 working marketing number to receive any complaint. The reporting forms can also be filled out to communicate any complaints. The company web portal can be used to report any problem and for information communication. • For emergency communication with external parties, all the concerned departments will contribute, depending on the situation or the case. • The company has a summary of product characteristics and product leaflets in English and Arabic that can be used to review all relevant information on their products.
CST10	Yes.	(2)	• Internally, the Regulatory Affairs and PV Department is responsible for providing information. • The company has a large workforce; different departments all work as a team, and each section head is involved (24 total). Diverse professional backgrounds exist, such as pharmacists, biopharmaceutical technology experts, chemists, microbiologists, nurses, and physicians. General meetings are held every 2 weeks and depending on the situation. • The Pharmacy and Drug Control Department (MOPH) is responsible for providing advice on PV at the national level.
Total Score		(16)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators, the obtained score was [(16) =100%]
CORE PROCESS INDICATORS			
CP1	No cases.	(1)	• The company did not receive any ADR cases. • The company always updates its database and utilizes and follows information from the national regulatory authority or GCC regulatory authorities.
	CP1a: Not relevant.	(-)	

Code	Response	Score *	Assessment (Qualitative)
CP2	One case.	(1)	• Only one case of ciprofloxacin rash occurred; this case was mentioned in a leaflet and reported a number of years before.
CP3	No cases.	(1)	• The company reported that this indicator is nonapplicable, as no cases were received. • The company has a proper system for analysis and feedback. The company indicated the presence of a strategy, and the incidents or complaints are documented using Excel spreadsheets. The documentation must include details on the complaint number, the details of the complaint, the action plan, and how to prevent the occurrence in the future. The company must make a full investigation and take action. Per the SOPs for quality assurance (QA), the timeline to issue feedback is 15 days.
CP4	No cases.	(1)	• The company reported that no cases were received, so no assessment was done. • The SOPs have details on the procedure. This entails proper documentation to ensure compliance with standards.
CP5	No cases.	(0)	• The company reported that no cases were received, so it did not send reports to the MOPH. • The MOPH requires the company to report postmarket issues of its products. • The products are registered with the MOPH, so the products comply with the MOPH requirements for safety and quality. In the future, if a case occurs, the company will check the drug leaflet and summary of product characteristics. If the data are already documented, the case will not be considered from the company; for any other situation, the company will process the case, and the product issue will be subjected to proper investigation.
	CP5a: Not relevant.	(-)	• Not relevant.
CP6	No cases.	(-)	• The products comply with the MOPH requirements and have been subjected to previous analysis in the MOPH quality control laboratory. Therefore, the company had not encountered such cases.
CP7	Not relevant.	(-)	• Not relevant.
CP8	100%.	(2)	• It was mentioned that the PV system functionality complies with the GCC guidelines and the MOPH requirements; hence, the company considers the system functional.
CP9	None.	(0)	• The company reported that it does not have to start active PV from its side, as it is in the business of generic manufacturing only. Bioequivalence studies are enough for its products, and such studies are done in the MOPH laboratory. • The company follows the pharmacopeia, mainly the USP or BP.

Code	Response	Score *	Assessment (Qualitative)
			• In the future, for drugs that are critical, the company may make such efforts if they are part of the MOPH requirements.
Total Score		(6)	Out of 7 [7*2= (14)] is [(100%)] relevant indicators, the obtained score was [(6) = 42.9%]
CORE OUTCOME/IMPACT INDICATOR			
CO1	No cases.	(1)	• The company reported that no cases were received. External data from national and international regulatory bodies were used. • The company complies with GCC guidelines regarding signal generation.
CO2	Yes.	(2)	• The company utilizes both internal and external data from GCC countries and others, including Jordan, Lebanon, and Oman. • Internal cases were requested from the company: the total number of regulatory actions was approximately 500, including 1) renewal variation as well as new products; 2) 200 product label changes/variations; 3) no actions on safety warnings about medicines or drug withdrawal issues to HCPs; and 4) restrictions on the use of paracetamol, for which the company made a flyer to include dose requirements for neonates. This issue was reported in Europe, and the company changed the information on its product and communicated it to its customers.
CO3	Not relevant.	(-)	• Not relevant.
CO4	Not relevant.	(-)	• Not relevant.
CO5	Not relevant.	(-)	• Not relevant.
CO6	Not relevant.	(-)	• Not relevant.
CO7	Not relevant.	(-)	• Not relevant.
CO8	Not relevant.	(-)	• Not relevant.
Total Score		(3)	Out of 2 [2*2= (4)] is [(100%)] relevant indicators, the obtained score was [(3) = 75%]

(*) Score: (2) Yes, fully satisfactory; (1) Yes, partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, and not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

1.5. Public Health Programs Level

The study assessed the PV system of the Mental Health Strategy (MHS), which was represented by one member. The WHO PHP indicators were employed to facilitate the discussion on the subject of PV implementation in the MHS, but as the level is not that of an actual PHP, the results will be presented qualitatively, and no scores will be used to represent the performance (Table 14).

Table 14. Pharmacovigilance (PV) implementation within the Mental Health Strategy (MHS)

Indicator Main Concepts	**Mental Health Strategy Status**
PV activities within the program	The MHS has PV and medication activities within its functions: • The members of the MHS meet with different national stakeholders and request data from them. • There is no database for PV or reports. • The MHS analyzes data and shares them with stakeholders. • The MHS processes information from external sources. • The MHS has audits for monitoring purposes.
Guidelines or protocols that address elements of PV	A specific section on medication safety, pages 43 and 48 (document National Mental Health Strategy Impact Evaluation-2015).
Standard ADR reporting form	• There is no available ADR reporting form. • A standardized national form was deemed useful and was recommended. • The MHS reported that one of the key challenges to PV is that the process of reporting is not centralized in the MOPH.
Availability of records or information on medication errors, product quality, and treatment failures	Not available.

1.6. Higher Academic Institutions Level

The study assessed the incorporation of PV into the curriculum of various higher academic institutions (i.e., CST8), which were represented by one member from each institution and two members from QU-College of Pharmacy. The key representative members were interviewed during face-to-face meetings except for the key informant of the College of Health Sciences at QU, who provided a response via email. The CST8 description in the WHO PV indicator manual was employed to facilitate the discussion on the subject of incorporating PV into the academic programs of various healthcare professions. The score for academia will be incorporated into the national level of the MOPH. The results will be presented qualitatively, and no scores will be used to represent each university (Table 15).

Table 15. Pharmacovigilance (PV) incorporation into the curriculum of national higher academic institutions

Candidate Institution	**PV Incorporation into the Curriculum**
Weill Cornell Medical College	√ Regulatory and practice PV.
College of North Atlantic – School of Health Sciences	√ Regulatory and practice PV.
University of Calgary	√ PV and medication safety.
Qatar University • College of Medicine • College of Pharmacy • College of Health Sciences	• √ College of Medicine incorporates it across the curriculum. • √ College of Pharmacy incorporates it across the curriculum based on the WHO safety curriculum. It includes the scope of regulatory and practice PV. • X College of Health Sciences does not include it in the curriculum.

√: PV is integrated into the curriculum.
X: Pharmacovigilance is not integrated into the curriculum.

Key findings from Academic Institutions:

I. There is a need for a national PV center.

II. A national independent PV center could be created under an academic institution.

III. Experts from academia could provide valuable input into a national PV center.

IV. Collaboration with the regulatory body and the PV center will enable effective and effective PV practice. For example, the MOPH can delegate the responsibility for data analysis, research activities, or information provision to experts from academia.

V. Establishing a PV center under an academic institution could improve the reputation and accreditation opportunities of the presenting institution.

VI. Students could benefit from potential research opportunities in the field of PV.

VII. The country could utilize graduate students to build the internal capacity for the national PV system.

VIII. Although PV was not included as a separate course in any of the included study samples, the basic elements of PV and medication safety were effectively implemented in the course work, problem-based learning activities, objective structured clinical examination exams, and interprofessional experiences.

IX. PV is included mainly in undergraduate programs. For instance, QU-College of Pharmacy for a minimum of two credit hours, based on estimates.

X. The students are aware of PV terminology and basic elements, such as ADR reports, and practice PV during their rotations in the public sector.

XI. Undergraduate students are not capable of engaging effectively in advanced PV activities such as causality assessment and signal identification.

XII. There is little focus on the regulatory aspects of PV, and when included, it will cover mainly external regulatory systems, e.g., the QU-College of Pharmacy teaches students about the Canadian perspective.

XIII. The establishment of a PV center in any academic institution will require effective planning and allocation of human and financial resources.

1.7. Comparative Analysis of Qatar Pharmacovigilance Systems Performance and the Baseline National Pharmacovigilance Situation

The following section will provide an assessment of the current baseline PV situation employing pictorial illustrations:

1.7.1. Comparative Analysis and Evaluation of the Baseline Situation (Part 1)

Figure 15 illustrates the overall or cumulative performance of the subnational PV systems in the three PV structure, process, and outcome indicator domains.

Overall, all subnational PV systems achieved good total PV system performance, and the percentages reached the target good performance range (i.e., 50%-74.9%). However, with the exception of the MOPH, the total PV system performance was weak (23.8%). The highest-performing PV system at the subnational level was the PHCC PV system, with a total cumulative score of 71.3%. It is important to note that the HMC system performed lower on some indicators because HMC (Table 8) did not provide the requested missing information. Nevertheless, none of the stakeholders' PV systems fall into the range of excellent performance, (i.e., 75%-100%).

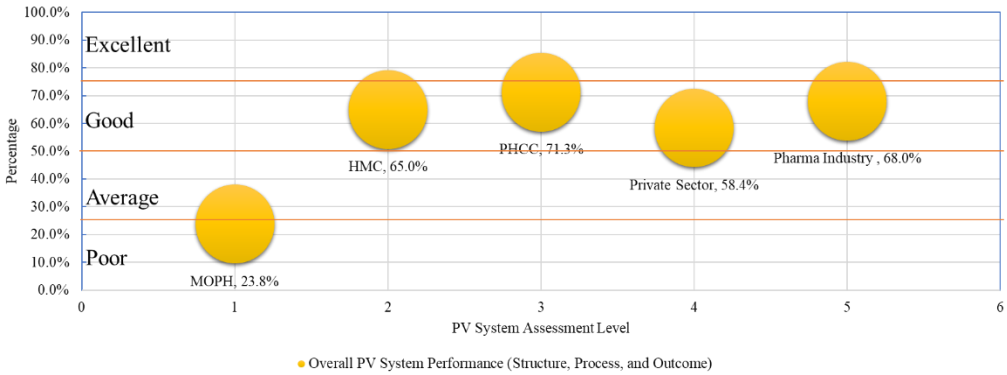

Figure 15. Comparative analysis of the total pharmacovigilance (PV) system performance of Qatar PV stakeholder systems using the WHO PV indicators (Part 1)

1.7.2. Comparative Analysis and Evaluation of the Baseline Situation (Part 2)

The bar chart (Figure 16) provides an analysis of the baseline PV system performance as percentages, including the overall performance of the subnational PV systems as well as the performance of the three PV indicator domains, structure, process, and outcome indicators at each stakeholder level.

The structural indicators had the highest scores among the three indicator domains, with three of the five PV systems assessed as having excellent performance. The performance in the outcome indicators was significantly low, with the MOPH achieving poor performance status (0%-24.9%) and HMC, the pharmaceutical industry, and the private sector achieving average performance status (25%-49.9%). The process indicator performance showed higher status for some stakeholders since their PV system activities were successful in meeting the indicator requirements of a functional PV system. For instance, performance status exceeding 50% was recorded for HMC, PHCC, and the private sector.

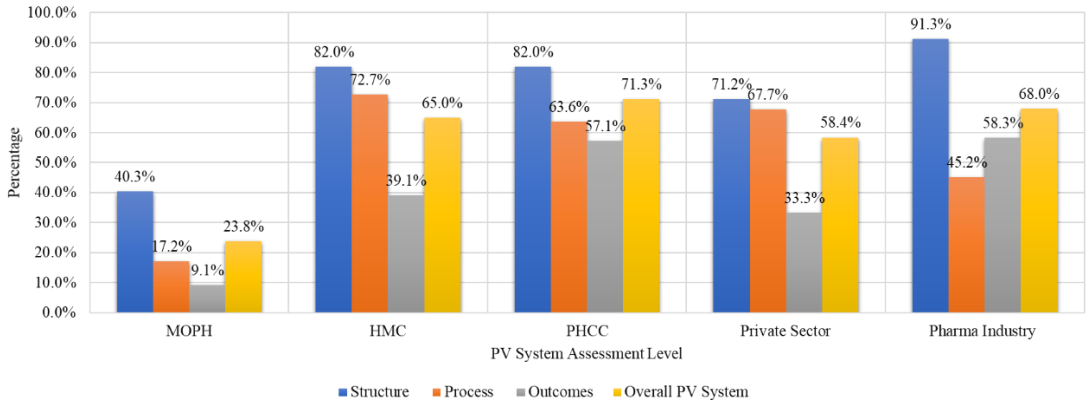

Figure 16. Comparative analysis and evaluation of the baseline situation of Qatar pharmacovigilance (PV) stakeholder systems using the WHO PV indicators (Part 2)

1.7.3. Comparative Analysis and Evaluation of the Baseline Situation (Part 3)

Figure 17 represents the actual performance of the PV subnational systems using scores within the main structure, process, and outcome indicator domains as well as the overall cumulative scores.

The country's PV system performance (i.e., overall national system) was calculated by determining the mean value for the actual performance of the structure, process, and outcome indicators for each stakeholder; refer to Table R1a and Excel spreadsheet R1a in Appendix B for the values and calculations. The calculation of the overall national system excluded the community pharmacy sector, as the sector does not have many relevant WHO PV indicators; thus, adding it may result in an inappropriate representation of the national performance. For the overall performance of the country (i.e., overall national system), the scores of the structure, process, and outcome indicators were 18.46, 11.88, and 5.1, respectively.

As illustrated, there are noticeable differences between subnational systems' performance. Generally, the performance on structural indicators was comparable in

that all subnational systems achieved some of the PV structures required for a functional PV system in the WHO framework. For example, the pharmaceutical industry achieved the highest score of 21 for the structural indicators score because it has a dedicated department for PV and a dedicated budget for PV, as opposed to other stakeholders with internal systems that undertake PV activities but do not have a dedicated department or specific parameters for PV. On the other hand, the lowest performance of the subnational PV systems was in outcome indicators. Figure 17 shows that the performance on outcome indicators was lowest for the MOPH system, with a score of 2, and highest for the HMC system, with a score of 9. Finally, for the process indicators, the scores ranged between 16 for HMC and 5 for the MOPH.

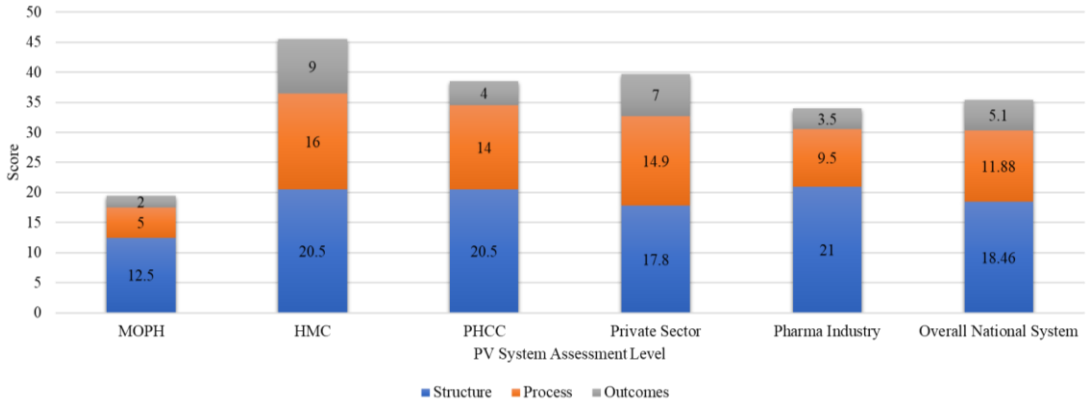

Figure 17. Comparative analysis and evaluation of the baseline situation of Qatar pharmacovigilance (PV) stakeholder systems using the WHO PV indicators (part 3)

1.7.4. Comparative Analysis and Evaluation of the Baseline Situation (Part 4)

Figure 18 is an illustration of the national country situation calculated from the actual and desired means for the country/national PV system portrayed in the previous

bar chart (Figure 17).

Figure 18 highlights a good performance on structural indicators (71.6%). In contrast, it clearly shows that at the national level, the system performance had a considerable challenge in meeting the WHO requirements for the process (51.2%) and outcome (32.3%) indicators. Comparing the actual national situation to the expected system performance based on the WHO framework and the target quartile range revealed a deficient performance in the process and outcome indicators. This weak performance conveys that there are limitations that affect the systems' ability to reach the desired performance for basic PV process and system outcomes requirements. Specifically, the holistic situation for the national PV system displayed considerable limitations in achieving the requirements for the outcome indicators. Finally, the national PV system in operation provides 54.7 % of its total expected performance status.

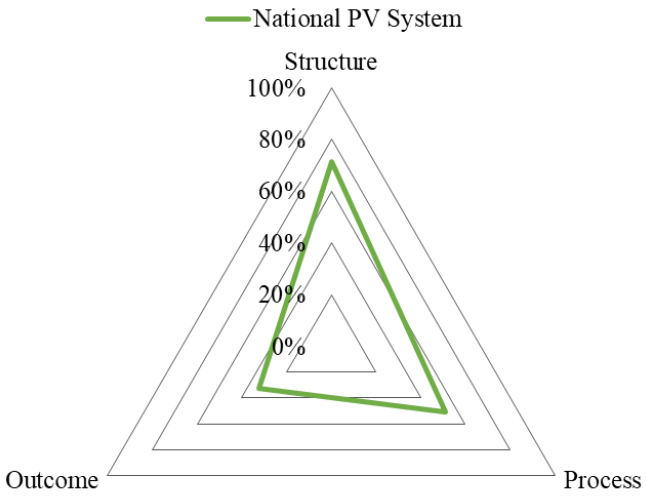

Figure 18. Evaluation of the baseline Qatar pharmacovigilance (PV) system situation using the WHO PV indicators (presented as percentages)

2. Evaluation of Qatar's Current National Pharmacovigilance System Based on the Minimum Requirements of the WHO

To address the second objective of this thesis, Table 16 was created to highlight the compliance of the current national PV system (represented by the MOPH system) with the minimum recognized international requirements determined by the WHO for a functional national PV system. The MOPH level is considered the national PV system for Qatar, as the MOPH is responsible for the management and regulation of Qatar's healthcare system.

Table 16. Evaluation of Qatar's current national pharmacovigilance (PV) system based on the minimum requirements of the WHO for a functional national PV system

Requirement	Parameters	Compliance Status	Qatar National PV System Compliance*
National PV center	• Central workplace. • Human resources, minimum one full-time staff. • Financial resources, basic regular funding. • Clear mandates. • Defined structures. • Defined responsibilities. • International collaboration with the WHO PIDM.	Not fulfilled.	No specific PV department, but PV activities are incorporated into the daily activities of the MOPH. The MOPH hopes that Qatar can become a full member after it prepares a national PV center.
A national spontaneous reporting system	• Reporting system. • A national individual case safety report form, i.e., an ADR reporting form.	Not fulfilled.	The MOPH indicated that the underreporting issue in Qatar is expected to continue without the existence of national ADR reporting forms and a national reporting system.

Requirement	Parameters	Compliance Status	Qatar National PV System Compliance*
National database	National database.	Not fulfilled.	The MOPH reported that currently, there is no national database for PV data management.
National ADR or PV advisory committee	Advisory committee able to provide advice and technical assistance on active and passive PV activities.	Not fulfilled.	There is no specific PV or medicine safety advisory committee. Therefore, according to the MOPH informants, in the future, having a functional committee will serve the needs of the country.
Communication strategy	• Strategy for routine communication. • Strategy for crises communication.	Not fulfilled.	No specific communication and transparency strategies to ensure national stakeholder involvement in the field of PV. However, there is a National Health and Disaster Preparedness Committee that conducts regular meetings that include national stakeholders.

*Qualitative assessment based on MOPH key informant remarks.

3. Highlights of the Strengths, Opportunities, and Weaknesses of the National Pharmacovigilance System

This section presents the results related to objective number 3 for this thesis, that is, identifying potential strengths, opportunities, and limitations that can mark the development of the current PV system as well as the establishment of a specific PV center. The results are based on the evaluation of the PV system at different levels of the healthcare system. Procedures to assess the PV system, using the WHO PV indicators as well as the views and perceptions of numerous stakeholders on the current situation, were employed to identify the challenges and strengths facing PV in Qatar.

3.1. Strengths

This section will be divided into system-based, structural, process, and outcome strengths:

3.1.1. System-Based Strengths

I. Most stakeholders at the subnational level showed strong interest in PV and hoped that the MOPH would inform them about its expectations and collaborate with them to discuss opportunities for strengthening PV, as the MOPH was considered to be the main stakeholder in protecting health and ensuring drug safety.

II. The WHO is leveraging support and collaborative opportunities for PV with the MOPH.

III. Leadership and management involvement were reported at the organizational level as a factor to improve the safety culture and medication safety.

IV. The public and private sectors are utilizing safety culture surveys to understand healthcare professionals' views on the culture of safety, and the outcome is being utilized to improve the system.

V. Accreditation and performance management have made many improvements in the PV systems of public and private sector health institutions. These standards have led to improvements and increased the compliance of systems with internationally recognized standards, including PV-related concepts.

VI. Public sector system connections through the Cerner system have made the networking simple and the sharing of data a clear task for HMC and PHCC.

VII. The public sector, namely, HMC and PHCC, has good communication on some projects. In addition, these institutions share protocols of primary care.

VIII. Some PHCC members are available at the HMC corporate level, e.g., they meet monthly on the CP&TC.

IX. A private hospital reported that HMC provides peer-review support and collaborates with it when it needs experts on PV and medication safety who are not available at its level.

3.1.2. Structural Indicator Strengths

I. Qatar is a member of the GCC countries, and the GCC countries have well-established guidelines for drug registration, including PV.

II. MAHs are required to report safety data to comply with the national pharmaceutical law and MOPH requirements.

III. Most stakeholder PV systems reported the existence of a formal system that covers PV as part of its duties and/or a policy document that includes components of PV, e.g., ADR reporting.

IV. The pharmaceutical industry reported a budget specifically earmarked for PV-related activities, and it reported a specific department specifically dedicated to PV, with staff members who specialize in the field.

V. Most stakeholders have guidelines in place to manage drug safety and PV at the organizational level.

VI. Most stakeholders have developed reporting forms that include a specific form for ADR reporting or a general form for reporting incidents.

VII. PV is included in medical, pharmacy, and nursing curricula.

VIII. On the MOPH website is the GHCC, where members of the public can register their complaints, inquiries, and requests by filling out a form.

IX. In-service education and training on drug safety and basic PV activities are provided by some stakeholders. Some stakeholders, e.g., PHCC, mandate this as a key part of performance evaluations.

X. The MOPH is active in providing training on vaccines at the national level. In addition, vaccine vigilance follows a very structured system, and specific forms are available for reporting ADRs and other vaccine-related issues.

XI. HMC established the MSQC, which plays an important role in the HMC PV system; it was founded under the Pharmacy Department in HMC.

XII. The MSQC has adapted well to the challenge of lack of human resources by working with part-time members from 12 HMC hospitals; currently, it considers its efforts a success. The need for expert staff was added to the corporation strategy.

XIII. HMC is targeting its efforts towards improving healthcare professionals' understanding of internal policies.

XIV. HMC is making efforts to improve medication safety through its educational activities, including seminars and workshops at the national level, e.g., community pharmacy involvement.

XV. Public and private sector design and updates of internal policies follow formalized and appropriate systems.

XVI. The budget was deemed sufficient by many stakeholders for the current operation of the system (i.e., the situation does not meet the requirements for expansion).

XVII. The MOPH communicates external drug safety information to the QCHP, which creates circulars with instructions and guidelines for clinicians on how to act in cases of specific medications.

3.1.3. Process and Outcome Indicator Strengths

I. The MOPH recognizes the need for PV and considers aspects of postmarket surveillance and PV to be important parts of the medication management process.

II. HMC reported efforts to conduct medication safety studies as well as active surveillance activities.

III. Most stakeholders reported the presence of PV and medication-related activities that include the use of evidence-based approaches and tools at the organizational level.

IV. Most stakeholders reported the use of internal mechanisms to follow up on reports and drug safety issues at the organizational level.

V. For decision making and regulatory actions, the MOPH relies on benchmarks from other countries with stringent regulatory authorities, e.g., the FDA and EMA.

VI. The private and public sector reported initiatives to include external drug safety warnings or information from their internal decision-making and/or feedback processes.

3.2. Opportunities

This section will be divided into system-based, structure, process, and outcome opportunities:

3.2.1. System-Based Opportunities

I. There is stakeholder awareness and positive perceptions of the need for a national PV system to cover the country's needs.

II. Some stakeholders are willing to coordinate efforts with the MOPH and HMC to improve PV and medication safety at the national level.

III. MOPH reported a valuable opportunity, as the UMC is encouraging the country to become a full member.

IV. Collaboration between QU and the pharmaceutical industry was reported as a potential network for coordinating PV activities.

3.2.2. Structural Indicator Opportunities

I. The MOPH has submitted a draft for an updated pharmacy law, or "Pharmacy Act". The draft includes many aspects that did not exist in the previous law, and it will include PV and medication safety as part of the registration and as part of clinical practice in the country.

II. Qatar is an associate member of the WHO PIDM.

III. The MOPH reported that public reporting is supported in general and that the patient safety reporting system that it is considering implementing includes a plan that at some stage, access may be granted so that patients will be able to report data themselves, whether for an incident or a complaint.

IV. The HQPS reported that there is an intended plan for a medication safety program. The program is not specific to PV, but the basic elements of the program depend on the WHO Global Patient Safety Challenge on Medication Safety. The MOPH signed the pledge of the WHO, and it is now in the process of taking it further to develop an action plan and engage with national stakeholders.

V. The HQPS reported that there is another future project, the National Patient Safety Reporting System, that will include reporting on ADR and medication errors.

VI. The MOPH reported that documents related to patient safety and spontaneous reporting of ADRs were currently in development. In particular, the new action plans include several activities to strengthen the system, such as the establishment of a data collection system (including data collection tools) to collect information from various stakeholders.

VII. Universities reported that they have experts in the field and can provide input into PV either by directly hosting the national PV system or collaborating with the MOPH PV system. Additionally, graduate and undergraduate students could provide input into the national PV system through research activities.

3.2.3. Process and Outcome Indicators Opportunities

I. Most stakeholders are leveraging opportunities to increase their reporting rates as well as the system capacity to monitor drug safety. For example, private health institutions plan to implement an electronic reporting management system such as the Datix system.

II. The MOPH has a good relationship with the UMC, and it has already been successful in becoming an associate member. Hence, the MOPH has been granted the privilege of accessing the international system that is designed to submit reports.

III. The potential introduction of clinical coding in the national healthcare system could aid in facilitating the process of the WHO PV outcome indicator measurement and evaluation.

IV. HMC is planning to more robustly introduce the concept of economic studies into the current system. This could aid in measuring the outcome of the HMC PV system activities.

3.3. Challenges and Weaknesses

This section will be divided into system-based, structure, process, and outcome challenges:

3.3.1. System-Based Challenges

I. According to the stakeholders, the national PV system's current capacity to monitor and ensure the safe use of medication is not in a desirable state.

II. The private sector reported that there is limited capacity, so the system will focus its efforts on healthcare treatment needs rather than on prevention.

III. Throughout the several interviews conducted, the informants reported that there is no formal or structured system for the interface of various systems across the country, so there is no formal relationship among national PV stakeholders.

IV. A national communication strategy (including crisis communication) does not exist. Additionally, a national emergency plan for higher academic institutions does not exist.

V. There is no formal communication strategy between the departments of the MOPH or between the MOPH and other stakeholders in the country.

VI. According to the MOPH, the governance of the system can impose challenges through overregulation, creating many restrictions, delayed communication and/or feedback.

VII. The eHealth strategy project has been delayed for many years because of restrictions.

VIII. There is resistance to sharing data even among governmental hospitals and institutions.

IX. It was reported that there can be overlap and mixed responsibilities between HMC and PHCC, and miscommunication can occur between the tertiary and primary care healthcare systems.

X. PV is a low priority within the healthcare system agenda for some stakeholders e.g., some private sector stakeholders.

3.3.2. Structural Indicator Challenges

I. There is no document defining a national policy on PV to enable the implementation and enforcement of PV activities in the country.

II. The current law is very old and does not provide comprehensive coverage for active and passive PV activities.

III. The current law does not provide details on PV information sharing or transparency issues.

IV. There is no specific policy or law to cover PV training and the conduct of clinical trials, which could constitute a very large risk.

V. Qatar does not have a national medicine policy that includes medication safety.

VI. For healthcare professionals, there is no legally binding requirement in the current law that mandates reporting; instead, they are advised to report medication safety issues.

VII. There is no national PV center, and there is no functional information and technology infrastructure, including the lack of a national database as well as an ADR form to collect and analyze data from healthcare professionals and the public.

VIII. A formal system for spontaneous reporting is not available for some stakeholders, e.g., community pharmacies.

IX. There is a lack of expert staff devoted to drug safety activities. The dearth of highly qualified PV professionals can be attributed to the lack of advanced training initiatives and limited funding to support in-service training.

X. The budget constraints within which some of the stakeholders, e.g., those in the private sector, operate can affect the acquisition of the structures and infrastructure required for PV activities.

XI. Neither MOPH department concerned with drug safety had the required structure to take full responsibility for PV. Neither department has a database for the collation and analysis of data.

XII. The results identified some of the barriers to reporting ADRs in the country, including fear of punitive measures, lack of education and training on the subject for healthcare professional, barriers in the availability of reporting forms, the perception that reporting is not appreciated, low prioritization of PV, and a lack of public education on issues of drug safety.

XIII. A few key informants from the private sector reported that the MOPH website does not provide ease of use when extracting information, and it does not specify a MOPH expectation for the private sector concerning PV.

XIV. At present, there is no specific PV or medicine safety advisory committee, drug information center, or medical court in the country.

XV. A challenge was reported in that the drug information services that were available in the Qatar National Formulary mobile application (e.g., listing all ADR precautions and other safety concerns) have been deorganized, and ADR reporting through the application is no longer available.

XVI. The MOPH created a reporting form that was previously available online as part of the Qatar National Formulary, but because of legislative issues related to patient data security, the MOPH did not continue with it.

XVII. According to the MOPH informants, many healthcare professionals working in Qatar do not have PV and ADR reporting as their main job function.

3.3.3. Process Indicators Challenges

I. Although HMC and some private hospitals performed satisfactorily in the survey, there is still much room for improvement. In particular, the issue of the underreporting of ADRs continues to be raised in PV systems.

II. Currently, there is a lack of national educational efforts that target healthcare providers in the private sector, e.g., community pharmacies, on the subject of PV.

III. A lack of coordination and accountability among the disparate stakeholders leads to duplicated, fragmented, or overlooked efforts. For example, the MOPH reported that there are several isolated and uncoordinated PV activities at the national level.

IV. Underreporting of ADRs has been identified as a key barrier to the effective functioning of the PV system at the international (UMC database), national (MOPH), and subnational level (e.g., HMC, PHCC).

V. There is no organized national system to analyze data on drug safety, which leads to the inability to utilize and benefit from national reports.

VI. Public and private health institutions do not constantly track and consolidate data on therapeutic ineffectiveness, medicine-related admissions, cost, and budget impact data.

VII. The ability to collect national data that could be used to inform the decision-making process as well as the development of national treatment guidelines is limited.

VIII. There are limitations in the process of continuous monitoring of drug quality in the country for drugs coming from abroad (i.e., through the airport) or sold through social media.

IX. The country does not have regulations to control the purchase and trade of drugs over social media.

X. The quality of the national ADR reports received by the MOPH was considered minimal, which prevents a proper causality assessment.

XI. Some healthcare professionals in the private and public sectors can have a limited ability to fill out complete and high-quality report forms, and their ability to detect actual ADR cases can be inadequate.

XII. One of the major weaknesses in the current PV system is PV communication, as it is a low priority among national stakeholders.

XIII. According to the MOPH policymakers, PV steps and actions are considered slow paced.

XIV. The MOPH reported that patients and the general public make minimal contributions to the PV system, and they are not involved in PV decision making or the PV policy-setting process. This was linked to limited awareness, time constraints, and cultural and linguistic diversity.

XV. The MOPH reported a problem with how drug safety information is received and processed, as the route of communication between MOPH departments is tedious, and the process can be slow.

XVI. The key informants reported that awareness of active PV is not very uniform or consistent among healthcare professionals, and there is a lack of understanding of active PV activities and/or studies.

XVII. It was reported that active PV is not aligned with the scope and nature of the work of the private sector. Additionally, it is difficult for private organizations to engage in these activities because they do not generate any revenue.

XVIII. The private and public sectors reported challenges, as the patients do not report or provide feedback on their medication use experience. The MOPH reported this as well.

XIX. There is a communication gap between the pharmaceutical industry and the private and public sectors. To illustrate, the pharmaceutical industry indicated that no safety issue reports on their products had been received. However, the public sector and one private hospital reported an issue with the products, which had been communicated to the MOPH.

XX. Academic institutions' inclusion of PV in their curricula can be minimal, and only a few credit hours (e.g., 2 credit hours) are provided throughout a whole program period.

3.3.4. Outcome Indicator Challenges

I. Concerning the evaluation of the benefit-risk ratio, the Pharmacy and Drug Control Department reported that at the current level, it does not have enough capacity to conduct such an activity.

II. Regarding signal evaluation, the MOPH commented that there is a lack of awareness about how to perform signal evaluation, including the use of relevant tools and methods.

III. Because the PV system is not in place, the MOPH informants reported that MOPH responsiveness to addressing drug safety issues is not appropriate, as the actions taken are not documented and not well monitored or evaluated for their short-term and long-term impact.

IV. The MOPH reported that the route from receiving a report to the initiation of feedback or taking an action follows an inappropriate review process compared to that in other, appropriate PV systems.

V. Regarding national data, the HQPS reported that service delivery organizations do not report hospital admission data.

VI. Regarding the outcome indicators that deal with financial outcomes and clinical outcomes, it was reported that it is difficult to quantify such data, as most sectors do not have the human and technical resources required for the collection and analysis of data. In addition, the financial resources required for auditing of PV outcomes is limited in the private sector.

VII. The ability of the private and public sectors to identify and evaluate signals is limited due to a deficiency in expert human resources and the underreporting problem.

VIII. The private sector informants reported that there could be some delays in receiving regulatory actions from the ministry, e.g., delay in receiving MOPH circulars.

IX. MOPH does not conduct financial analysis relevant to PV and medication safety activities.

X. There are no national data on medicine-related admissions and medicine-related deaths.

CHAPTER V: DISCUSSION AND CONCLUSION

Pharmacovigilance (PV) systems are an important part of healthcare systems. Their existence and sustainability are required to safeguard public health and ensure medication safety. The challenges and performance inadequacy of these systems are well documented in the literature, especially in developing countries. The operational capacity and requirements for development of PV systems exert continuous pressure on developing countries' healthcare systems. Therefore, it is of paramount importance to ensure that such systems are properly evaluated and monitored to ensure that they are meeting their objectives. Previously published work has reported many challenges regarding PV and medication safety in Qatar. The main challenge is the nonexistence of a national PV center to coordinate PV activities across all levels of the national healthcare system. To address the reported challenges and to improve PV in Qatar, it is essential to understand the baseline situation of the country and identify critical gaps. In addition, it is important to consider the views and perceptions of national PV stakeholders since the challenges burdening PV systems can be country-specific, and solutions may need to be tailored to the country's social, economic, cultural, and political contexts. Accordingly, this research aimed to conduct a comprehensive analysis of the existing PV and medicine safety systems in Qatar at different levels of the healthcare system with reference to the WHO PV framework. Additionally, the input of national PV stakeholders was sought to gain a better understanding of the PV system status in terms of performance, challenges, opportunities, and potential recommendations. To our knowledge, this project was the first MMR designed to evaluate the PV system in Qatar.

1. The Baseline Pharmacovigilance Situation Based on the WHO Framework and Key Informants' Contributions

1.1. Overall Qatar Pharmacovigilance System Performance

1.1.1. WHO Pharmacovigilance indicators

This study provided a baseline description for the current status of PV following a system-based approach of structures, processes, and outcomes. Based on the literature covering PV system capacity and evaluation, for any PV system to be functional, it must fulfill the system requirements of the structure, process, and outcome elements (10, 11, 32). The assessment indicated that there are current disparities in the national PV subsystems with respect to the performance of these three major elements (Figure 16). This is expected to affect the national capacity to monitor and ensure the safe and effective use of medication in Qatar. When the data were analyzed in more detail by combining the means of PV subsystem performance to achieve a result that represents overall performance of the country's PV system (Figure 18), it was found that there is good performance (71.6%) in the structural indicators domain, but the system showed less-than-desired performance in both the process (51.2%) and outcome (32.3%) domains. This total performance within the average range (54.7%) conveys that there are limitations that affect the system's ability to achieve the desired performance in the basic PV requirements determined by the WHO framework. In addition, there is a need to target gaps following a phased approach starting from the structural indicator requirements, moving to PV processes, and finally reflecting on the potential benefits of targeting outcome indicators in the future. The overall performance of the country, if PV is addressed properly following a system-based approach, is expected to lead to successful implementation of PV within the healthcare system. For instance, Abiri and Johnson indicate that due to the satisfactory performance of the national PV center in

Sierra Leone, which they evaluated using the IPAT tool, the center has the potential to offer leadership for PV implementation (52).

1.1.2. WHO Minimal Requirements for a Functional System

According to the WHO, a functional national PV system has the following minimal requirements (40): 1) A national PV center with basic financial assistance and one dedicated full-time staff, 2) A national spontaneous reporting system and a dedicated form for ICSR reporting, 3) A national database, 4) A national PV advisory committee, and 5) A communication strategy that includes crisis communication. According to these WHO recommendations, Qatar does not have any of the required elements for an operational PV system. The assessment indicates that efforts by national PV stakeholders need to be consolidated to improve the current PV scenario to comply with the defined five areas. Addressing these five areas will ensure the attainment of satisfactory PV system capacity to serve the country. For instance, in their study, Suwankesawong et al. evaluated the PV systems in ASEAN countries for their ability to meet the five requirements. The authors reported that the five areas enabled the identification of PV system deficiencies that should be addressed to help the countries resolve system capacity and functionality issues. For example, countries with less developed PV systems (e.g., Cambodia) reported a challenge in developing a clear communication strategy; therefore, the authors recommended improving PV communication and ensuring rapid information dissemination (85).

1.2. Performance of the MOPH Pharmacovigilance System

This research provided insight into the pattern of PV practices at the MOPH, the healthcare regulatory body of Qatar. All interviewed key informants from MOPH recognized the need for PV. Additionally, they reported that the country hopes to

become a full member of the WHO PIDM in the future. This implies the MOPH members' awareness of the importance of PV and postmarketing surveillance to ensure effective medication safety monitoring in Qatar. However, the MOPH system has achieved average performance status in PV structure indicators (40.3%) and poor performance status in the PV process (17.2%) and outcome indicators (9.1%). In addition, the total MOPH system performance achieved poor performance status (23.8%) (Figure 16). This implies that the MOPH PV system is weak and that the system functionality status may impede the MOPH's leadership role in PV implementation in Qatar.

The details of the system analysis indicate that there is a major weakness in the performance in structural indicators, as the MOPH does not have the core PV structures, including national policies and guidelines relevant to PV, an organized PV center to oversee PV activities, national reporting forms, and national computerized systems for reporting, in place. This implies the need to prioritize PV within the MOPH agenda and the need to commit to implementing the PV structures required for the operation of the system as well as to satisfy the outcome indicators criteria determined by the WHO.

Examining the details of the two departments overseeing the activities related to PV, medication safety, and patient safety, the study found variation in the implementation of PV procedures. For instance, the Department of Pharmacy and Drug Control collects and analyzes data from the international pharmaceutical industry, while the HQPS receives national data on medication errors only, and no further data analysis is performed, as the department is still in the planning stage of the medication safety plan. This implies that the current PV system performance requires major improvements from the national stakeholders' side and that the modern scope of a PV system is not comprehensively covered under the current MOPH operations. In

addition, it sheds light on the fact that PV activities are not coordinated between the MOPH departments. This situation may lead to shortfalls in the effective management of PV, medication safety, and patient safety due to errors of omission, commission, and/or duplication.

The section below will address the current PV landscape in detail, as the MOPH system is considered the current national PV system by national stakeholders, and many shortcomings were identified in the system analysis.

1.2.1. Regulatory Framework

The assessment found that the MOPH (i.e., CST3) has a regulatory framework that includes a defined pharmaceutical law as well as established registries for drug and health-related facilities. It also found that stringent regulations to manage the pharmaceutical market exist and that issues such as counterfeit medications are not a threat to the country, in contrast to the situation in other developing countries (10, 20, 21, 73). This is a positive attainment for the national healthcare system, as the literature pertinent to national regulatory frameworks indicates that regulatory authorities at the national level are expected to establish effective governance structures and systems (10, 137). The effectiveness of this regulatory framework cannot be addressed by this research. However, the details provided indicate that Qatar has a legal basis and mandates for MAHs to report ADRs to the MOPH. This means that the MOPH has dedicated resources to ensuring that safety data on registered products are collected. Based on the literature, this is a standard practice in countries with stringent PV systems (138). Further, the law provides no requirement for healthcare professionals to report ADR cases. The subject of mandatory reporting has been debated in the literature, and there is no substantial evidence for its effect on reporting rates (67). If the MOPH considered defining mandates on ADR reporting, it would require the proper

consideration of national PV stakeholders' views and recommendations, especially because Qatar does not have a medical court. Without appropriate consideration and effective execution, the introduction of this measure could burden the national PV system. However, it is worth mentioning that a legal basis for reporting has been incorporated into PV systems in some high-income countries (56), such as France, where ADR reporting has been mandated since 1984. The reporting of ADRs in France was evaluated over a 16-year period, and the reporting rates showed an annual linear increase, but the country still considers underreporting of ADRs a challenge (139). In addition, Qatar does not have a national medicine policy. This finding indicates the need to develop a national medicine policy that is based on the internationally recognized standards of the WHO. According to the WHO, a national medicine policy is an essential document that should include medication safety, product quality, and PV as essential elements. The WHO has also indicated that requirements for the institutionalization of a national PV system can be unequivocally included in the national medicine policy (140).

1.2.2. Pharmacovigilance Policy and Guidelines

In Qatar, a PV policy or guideline (i.e., CST2) does not exist, and the current pharmaceutical law does not employ the specific term PV. Key informants from MOPH reported that the current law does not comprehensively cover medication safety and PV elements. Therefore, Qatar is in need of well-designed and comprehensible PV legal provisions to enable the implementation and enforcement of passive and active PV in the country. Without defined and enforced PV legal provisions, the standardization of PV across the subsystems, the proper coordination of PV subsystems, and the effective functionality of the national PV system will remain unattainable. This claim is based on major works of the SPS and the SIAPS program. It has been documented that the

existence of defined policies on PV reflects a country's commitment to and prioritization of medication safety, and such policies are a tool that guides national stakeholders to comply with standard PV practices to ensure medication safety and to prevent drug-related issues (10, 29, 51). For instance, an evaluation of the Ghana PV system indicated that the lack of essential laws and regulations relevant to PV reflected many limitations of the system to enforce drug safety monitoring (51).

The MOPH key informants reported that due to restrictions and overregulation by the higher authorities, projects on the healthcare system agenda aimed at strengthening medication safety and PV have been disorganized (i.e., Qatar national formulary ADR reporting) or delayed (i.e., eHealth strategy) (141). This overregulation that prevents the implementation of PV has been reported as a challenge in the literature (18).

1.2.3. MOPH Role in Pharmacovigilance and Pharmacovigilance Center Establishment

The role of regulatory bodies in establishing and ensuring the sustainability of PV systems has been clearly delimited by the WHO (67). In developing countries, PV systems often do not receive the support required for successful operation or institutionalization (20, 21, 72). However, the findings of this study showed that the MOPH is in the planning stage to implement initiatives aimed at improving medication safety and patient safety. This indicates increased awareness and commitment from the MOPH toward PV implementation, as the initiatives extend to PV-related elements. Nevertheless, discussion with the MOPH key informants about details on the PV system in terms of the structure and infrastructure did not indicate an inclination to establish a national PV center (i.e., CST1). Without a visible PV center, opportunities to take advantage of the available resources and human resources will remain unfeasible. The

literature indicates that a national PV center is the central point for conducting and coordinating PV activities following an organized and systematic operational approach. If PV systems do not exist or are fragmented, the country can be prevented from making the informed decisions required to ensure medication safety and protect public health. In addition, in developing countries, the lack of dedicated PV centers has been identified as an area requiring targeted national and international efforts (21, 73, 82). Finally, the WHO recommends that once a national PV system is sufficiently developed, a country can apply to join the WHO PIDM by following the process of enrollment (40, 67).

1.2.4. Pharmacovigilance Advisory Committee

The Pharmacy and Drug Control Department is currently responsible for providing advice on PV and medication safety as part of its roles and responsibilities. However, the lack of an organized and dedicated PV or medication safety advisory committee (i.e., CST10) can hinder PV development in the country. The assistance such a committee can offer, if established, includes but is not limited to safety data collation and evaluation, risk evaluation and minimization, PV communication, and provision of information (1, 67). This finding is supported by the national PV stakeholders' remarks. Regardless of the sector in which they worked, the national PV stakeholders addressed the need for such a committee and the benefits it could provide for the subnational systems and the country. Moreover, the WHO has identified the existence of a PV advisory committee as one of the five areas required for a functional PV system (40).

1.2.5. Drug Information Center

The study found that the provision of PV information is an important area that requires attention. Additionally, stakeholders in national PV subsystems identified the

need for a dedicated system for the provision of information, such as a drug information center. The country would benefit from the establishment of a drug information center or a committee within the MOPH to provide this function. The drug information center, if established, would assist both the private and public sectors by providing expertise in the area of drug information. The drug information center could also be linked to the PV center to support the scope of PV services provided in the country (142).

1.2.6. Pharmacovigilance Stakeholder Coordination

The study found a wide gap in national PV stakeholders' coordination, which is an important element for PV success. In Qatar, there is no formal or structured approach for multisectoral involvement in PV or for subnational PV systems to interface. Coordination and communication mechanisms need to be developed by the MOPH. Based on evidence from the literature, the engagement of national stakeholders through collaboration, cooperation, and advocacy patterns can enable PV. Major global PV stakeholders such as the WHO and MSH have recognized stakeholder involvement and commitment as a major source of PV development, especially in developing countries (29). For instance, MSH has emphasized that broken relations between stakeholders can often lead to failure in PV implementation and development (69). In addition, stakeholder coordination is an important aspect, as even when legislation exists, stakeholder participation is affected by other factors (107).

On the other hand, patterns of interaction between the MOPH, WHO and UMC are promising and have had a positive influence on medication safety. To illustrate, the MOPH key informants reported that some WHO standards are being considered for future projects. In addition, they reported that the WHO is encouraging the country to establish a PV system and become a full member of the PIDM. This finding is consistent with the literature on the positive influence that external parties can offer to

PV (e.g., advocacy support, financial support, technical capacity building, capacity building) (102, 143). Additionally, this study found that the reported functionality of the national PV system in relation to the pharmaceutical industry and service delivery healthcare institutions diverged and did not align with the performance required at the national level. According to the MOPH informants, the PV system is considered functional by the pharmaceutical industry and international stakeholders. However, from the national stakeholder perspective, the current PV system can be considered nonfunctional.

1.2.7. National Reporting Form

The country has no ICSR or ADR reporting form (i.e., CST6). The study indicates that without data collection tools for PV, the ability of Qatar to use information to improve medication safety and patient safety as final outcomes is undermined, and the quality of patient care is greatly affected (51). This is consistent with the findings of Wilbur, who identified the nonexistence of a standardized reporting form in Qatar as a potential factor for healthcare professional underreporting (36, 37). In addition, the literature on the challenges in PV systems indicates that without data collection tools for PV, the potential use of the information remains unfeasible (1, 10, 20, 71, 72). It is recommended that the national ICSR form be designed to conform with global standards to ensure that any data collected comply with the international WHO PIDM database (i.e.,VigiBase) and that the country's potential contribution to global data will therefore be of value (18, 79).

1.2.8. The Underreporting Problem

An evaluation of the MOPH system identified the problem of underreporting by national stakeholders. The MOPH reported that during a one-year period, only 10 safety

case reports (i.e., CP1) were received from one healthcare institution. The underreporting problem is apparent even with the availability of the previous national ADR form. The report also indicated that there is resistance to sharing PV data even from governmental institutions. This challenge has important implications since the national system represented by the MOPH suffers from gaps in other key PV requirements for a functional system. Underreporting implies that the country is not able to collate data on the safety, quality, and effectiveness of products that are available in the market but have not been tested in the population. Consequently, the subsequent processes, including data analysis, signal identification, regulatory actions, and communication and feedback mechanisms, will remain stagnant. This in turn will affect the national system capacity and implementation of PV at the national level. Based on the literature, the threshold for the satisfactory performance of the PV system measured by reporting rate would require the system to receive 300 reports per million of population per year (144). Likewise, under the SPS program, the PV system cannot be considered functional with the receipt of a few reports. The SPS program depends on the IPAT tool threshold that requires 100 reports per million of population per year an acceptable threshold for PV system operational capacity (32, 51). Hence, Qatar does not achieve the threshold of an operational PV system. The establishment of a PV center will be essential to address the underreporting problem. Zhang et al. reported that without a PV center, it is difficult for healthcare professionals and the general public to report ADR cases (81).

1.2.9. The Quality of National Reports

The quality of the national reports received by the MOPH (i.e., CP5) was deemed minimal by both departments concerned with medication safety, as the information provided does not permit a proper data analysis (e.g., causality assessment)

(i.e., CP4) to be conducted. The quality of the data submitted and the completion of the elements required for further data analysis can either undermine or improve PV in the country. Therefore, identifying the root cause of the problem at each stakeholder level is recommended as the first step. For instance, at the national level, there is no uniform ADR form, so the ability to standardize data collection to fulfill all the requirements across various stakeholder systems is not feasible. Additionally, at the service delivery level, the design of the reporting form and its ability to meet standards of quality as well as the awareness of the healthcare workers of the elements that need to be satisfactorily completed should be investigated. Identifying the root of the problem at the national level as well as at the subsystem level will enable the design and implementation of targeted solutions that would address the gaps in PV systems (11, 79).

1.2.10. The Pharmacovigilance Culture

Based on interviews with the MOPH key informants, some reports (e.g., reports that include no serious cases or documented cases) may not receive feedback (i.e., CP3). This could be disadvantageous for the reporting culture, particularly when the national system is experiencing many gaps in PV elements. This finding is supported by the study conducted by Wilbur, who found that pharmacists in Qatar reported an issue in receiving feedback because the fate of a submitted report can be ambiguous (37). Similarly, in interviews with national PV stakeholders, the study found that representatives of the public sector felt that efforts to report can be underappreciated. Regarding the PV culture, the WHO has indicated that systems with limited capacities or systems at an early stage of development should be encouraged to welcome all types of reporting (i.e., serious and not serious as well as documented and not documented) and provide feedback. This will enable the country to create the “notification culture”

required for the initial implementation of PV. The study recommends that for effective PV, the culture needs to be improved. This improvement will require time and the sharing of responsibility by the reporters and the MOPH system. The culture needs to ensure the proper alignment of priorities and stakeholder accountability to avoid the conflicts of interest and communication gaps that can impede PV. Building a positive culture for PV entails specific national communication strategy, educational interventions, efforts to streamline reporting (e.g., the distribution of ADR reports), training provisions, a feedback mechanism, the dissemination of information, and MOPH assistance in building the resources and capacities of national PV subsystem (20, 46, 67, 86). The literature indicates that the culture of PV is founded on a culture of safety that requires the input of various PV experts (88). The improvement of the PV culture will have positive implications for the gaps found in PV systems, including the underreporting of ADRs. Edwards et al. suggest that contemporary PV systems need to improve the PV culture (145).

1.2.11. Data Management

The study investigated the management of drug safety data within the MOPH system. It found defects in the data management process. At the current stage, the MOPH does not have a formalized data management system. Additionally, according to the HQPS key informants, without PV structures in place, the MOPH PV system will remain nonfunctional. Therefore, the implementation of an integrated data management system is proposed to maximize data use and evaluation, including causality assessment, signal identification, and signal evaluation. In turn, those processes will ultimately inform effective information dissemination, decision-making processes, and feedback mechanisms to national stakeholders and possibly external parties (e.g., the WHO and international pharmaceutical industry) (10, 51, 146). Moreover, in the

absence of a structured and standardized data management process, the country may suffer from stagnant decision-making processes. This is apparent to some degree, as the MOPH stakeholders reported a general reliance on external data to inform national regulatory actions and decision-making processes. For the MOPH to improve the national PV scenario and realize the process of continuous drug monitoring, the system will require the careful implementation of basic PV processes outlined in the WHO PV indicator manual.

The HQPS department reported that per the health service performance agreements, service delivery organizations are required to submit medication error data only. This can limit the scope of the collected national PV data. The study found that national service delivery organizations do not report ADRs, hospital admission data, deaths due to medication errors, and therapeutic ineffectiveness. However, it is promising that the HQPS informants remarked that capturing these data might be part of the future reporting system. The collation and use of such data is recommended even before the future program is implemented. Health facilities can be requested to provide the data along with medication error data to avoid lost opportunities to address national medication safety issues (29, 51). In the future, the national unified reporting form could include such data to facilitate their collection.

1.2.12. Technical Capacity

Technical capacity was identified as a barrier within the MOPH system, which may undermine the ability to efficiently and effectively implement PV processes. This challenge is often reported as a burden in less developed PV systems, especially in developing countries or high-income countries with less developed systems. The issue of staffing deficiencies (i.e., CST5) in terms of quality and quantity has been reported as a major challenge affecting systems functionalities and legislative frameworks in

developing countries (20, 21, 29, 31, 73), for instance, among Arab countries, including Qatar (25). Hence, to improve PV, there is a need to build national resource capacities, notably with respect to human resources, including the expertise and skills of individuals or teams operating within the MOPH system. Moreover, the threshold recommended by the IPAT for individuals receiving training in PV is 5% per institution, and the inability to meet the threshold is considered a failure to provide the training required to ensure system functionality (51). The WHO PV indicator manual does not provide a threshold for PV training. However, the literature recommends that the threshold of the required capacity to handle individual safety case reports would involve the number of reports received per year per designated staff (29). Additionally, the WHO requires a minimum of one dedicated full-time member in the PV center for the national system to be considered functional (40).

The MOPH in Qatar is not very active in providing PV training at the national level, apart from vaccine training, which is well implemented. Interviews with key informants from the MOPH indicated that currently, the MOPH has enough capacity to provide training on basic PV activities to address the observed limited awareness. Therefore, the study recommends the effective provision of training and education to various national stakeholders to improve the operational capacity of the PV system. Furthermore, in the future, the successful implementation and operation of a unified PV center will require the input of well-informed and knowledgeable stakeholders. In fact, the literature indicates that the provision of training and education for healthcare professionals and the public is one of the key resources for functional PV systems (46, 82).

1.2.13. Information and Communication Technologies

The research findings indicate shortcomings in the acquisition of sophisticated information (i.e., CST7) and in communication technologies (i.e., CST9). The gaps in technological advances are linked to overregulation and ethical concerns regarding the confidentiality issues associated with data collation. The study proposes the utilization of advanced technologies to allow the country to improve, standardize, and sustain the provision of PV services. Ethical and legal issues related to PV data can be resolved if they are clearly defined in policy-related documents. Well-designed policies can determine the roles and responsibilities of stakeholders and define the parties who have access to and manage national PV data (18, 67, 143). MOPH future projects, if implemented and sustained appropriately, can improve the national PV system capacity and address national stakeholder requests for streamlining PV processes and networking. It is also recommended that the use of technology in PV be optimized to ensure that the PV systems can cope with the expansion of PV and the challenges associated with this expansion (1, 20, 46). In fact, PV system evaluations in many African and Asian countries have suggested that regulatory authorities need to invest in communication technologies to improve national PV system operational capacity as well as to improve the dissemination of essential PV information to national stakeholders (29, 31, 51).

1.2.14. Decision Making and Regulatory Actions

The MOPH informants reported that their responsiveness to drug safety issues (i.e., CO2) is good. The study found that the MOPH relies on benchmark countries with stringent regulations; therefore, cases of delay in acting were linked to the unavailability of full information for the MOPH to obtain a clear picture. However, the key informants reported that the system is challenged by the process of communication within MOPH

departments, which is tedious and can be slow. Therefore, it is recommended that details on decision making and regulatory actions, including risk management and risk communication, with defined timelines be included in the MOPH policies. This will permit the MOPH to map the involved teams or individuals and thus reduce the burden on other, less relevant MOPH departments. The research findings also indicate that following a systematic approach or a standardized process to manage safety alerts from external sources would improve PV risk management and communication (10, 51).

Without informed decisions and regulatory actions based on national data, the MOPH system will not be able to monitor medication experiences in the Qatari population, which is socially, genetically, and culturally diverse. Data generated from diverse populations can provide benefits to global PV as well as national PV (1). In fact, under the SIAPS program, countries are expected to identify medication risks subsequent to signal generation at the national level. The program also recommends periodic reviews of national submitted reports and information collected subsequent to national active PV because they are fundamental to the functionality of a comprehensive national PV system (29).

1.2.15. Communication Mechanisms for Pharmacovigilance

The MOPH informants acknowledged the availability of communication mechanisms (i.e., CST9) for PV and medication safety, mainly including the website, circulars, and emails, to communicate with national stakeholders and those within the MOPH. Further, the MOPH requests that pharmaceutical companies inform national stakeholders directly, as national stakeholders do not utilize the MOPH website at the anticipated level. The interviews with national stakeholders indicated that circulars sometimes reach the facilities at a late stage, and feedback can be received after months. This indicates that the communication profile is low and not uniform at the national

level. Therefore, it is recommended that a standardized process for PV communication be established and that the outcomes of this process be documented, monitored, and evaluated. Additionally, a national communication strategy can help the MOPH to improve PV in Qatar. In addition, the findings suggest that a newsletter can serve as a mechanism of communication with national stakeholders. The newsletter, if well designed and sustained, could ultimately lead to developing desirable behaviors and serve as a valuable tool of communication with the reporters.

1.2.16. Risk Minimization and Management

The study indicates the need for effective PV data utilization to improve safe medication use by risk minimization and management activities, as recommended by the SPS and SIAPS programs (10, 29, 51). The national system would benefit from defining feasible risk mitigation activities at the national level. This definition process could have vital implications for the MOPH capacity to improve PV and minimize the harm associated with medications because it would influence the conduct of postmarket surveillance, risk mitigation, and risk communication activities. Such activities would require sustainable funding from the MOPH for successful implementation. The benefit of risk mitigation systems has been reported by a study using the IPAT indicator tool to evaluate the PV system in Benin. Allabi and Nwokike recommended the implementation of risk mitigation systems and protocols to ensure that medication safety is emphasized at each stage of the country system (50).

1.2.17. Evaluation of Benefit-Risk Ratio

The MOPH informants reported that at the current level, their system does not have the capacity to conduct such activities because the process is not simple, requires expertise, and possibly requires the input of a specific committee. To strengthen PV,

MOPH could advocate for expanding PV provisions and coordinate this initiative with other national stakeholders that may have the technical capacity for such an advanced process e.g., higher academic institutions.

1.2.18. Active Pharmacovigilance

MOPH reported that currently, the system does not have enough capacity to conduct active PV activities (i.e., CP9). Also, the MOPH is informed about national PV initiatives, including active PV, at a late stage. The study recommends MOPH collaboration with other sectors to implement active PV in the country. The reason is that active PV provides an innovative approach to collecting and analyzing drug safety data and can generate quantitative information in addition to the qualitative information obtained by passive surveillanc (29). Moreover, the MOPH informants reported that they favor relying on third parties and pharmaceutical companies because active surveillance activities are very expensive and require advanced technical knowledge, and most of the pharmaceutical companies can perform them successfully. It is recommended that subsequent to the establishment of a PV center and the initial streamlining of passive surveillance activities, the national PV system can investigate the available opportunities to implement active PV and promote the understanding of active PV across the subsystems in the country. Under such conditions, efforts should be made to identify the measures required to define the elements of active PV in national policies, regulations and conceivably laws. The MOPH can also investigate how national stakeholders could contribute to active PV through multistakeholder collaborative efforts. For instance, medical research centers and universities could shape the implementation of active PV in the national PV system (31, 51). Possible active PV activities that could benefit the country are the use of registries and intensive medicine monitoring (68, 147).

1.2.19. Clinical Trials and Pharmacovigilance-Related Research Activities

Challenges in sharing safety information, the outcomes of clinical trials, and other medication safety initiatives (i.e., CP9) were reported by the MOPH informants. The study recommends that PV data (e.g., drug safety and effectiveness outcomes) from national stakeholder clinical trials and other research activities be shared with the MOPH to serve as a potential source to inform decision making and regulatory actions at the national level. If such information is not used, the opportunity for Qatar to become involved in advanced PV activities will remain unfeasible. In the future, the possibility of linking PV data between stakeholders could be investigated (29). Furthermore, the study identified a challenge in the current policies and regulations regarding clinical trials. The MOPH informants acknowledged that a specific policy or law that covers PV training and the conduct of clinical trials is not available, which could be a risk. The research division of the MOPH that is responsible for establishing research policies covers only certain processes and requirements for research on human subjects (148).

1.2.20. The General Public

The study found that the general public makes a minimal to no contribution to the national PV system. The reasons for this minimal contribution were the lack of awareness of PV, time constraints and cultural and linguistic diversity. Additionally, the MOPH key informants reported that the public is not involved in the PV policy setting or decision-making process. Further, there is no official reporting form for public reporting of medication safety issues (i.e., CST6). However, on the MOPH website, the GHCC allows the public to register any complaints, inquiries, and requests. In addition, safety warnings are communicated through newspapers and/or media. This indicates a good standing in the current stage, but a clear framework that involves the public in PV is recommended. This framework must accommodate the population

literacy level and cultural diversity.

Public inclusion should follow a phased approach and will require time and dedicated resources. In the initial steps, the general public will be sensitized to PV and medication safety (e.g., awareness campaigns); then, efforts should be made to involve them in the reporting process (e.g., wide distribution of electronic and/or paper-based reporting tools). In addition, it is important to note that the use of media is a potential recommendation, but it requires careful consideration and planning. Media can serve as an effective tool for communicating with the public or can present risks to the PV system, such as the damaged reputation of an institution or a lack of public trust and confidence in the healthcare system. Therefore, the use of media should be discussed with various stakeholders at the national level, including the media, to ensure that the information communicated is balanced and that the media are effective partners in improving PV at the national level. Furthermore, long-term efforts to increase public participation can include collaboration with schools to educate the students who constitute the future generation. This could apply to universities as well. (1, 149).

Additionally, in the future, representatives of the general public could participate in the PV policy setting, PV agenda reforms, and PV decision-making process (150). Public involvement in PV has been highlighted in the literature, and many countries recognize the public as main stakeholders in PV (151). In addition, there is explicit documentation of the benefits of public inclusion in PV. Currently, more than 60 countries have developed reporting systems to benefit from public input and to ensure the provision of optimal care (152).

1.2.21. Pharmacovigilance System Outcome Evaluation

The study found that information on the financial outcome aspects (i.e., CO6, CO8) of the MOPH PV system is currently not available. The collection of some PV

KPIs was considered feasible by the MOPH informants, but planning would be required to develop a methodology of collation and analysis. PV outcome evaluation will be feasible and accurate if the MOPH system is reformed and improved, starting with structural elements and then moving on to process elements. Based on the WHO indicator manual, financial aspects should be emphasized by MOPH in healthcare planning and for the evaluation of PV intervention effectiveness. Additionally, if data are collected, the national and subnational PV systems with various levels of development can identify their ability to fulfill the final desired outcomes relevant for the PV system and to monitor progress over time (11, 30, 47). The study indicates that this process would also apply to clinical outcomes (i.e., CO3, CO4, CO5, CO7).

1.2.22. Counterfeit and Substandard Medications

The study found that counterfeit or substandard medications (i.e., O4) can enter Qatar only through drug product promotion and sales through social media (mainly Instagram) as well as through the airport. The country has no regulations to control the purchase and trade of medications through social media. Therefore, it is recommended that this issue be addressed by higher levels within different governmental ministries, possibly including the MOPH, the Ministry of Transport and Communication (because it is responsible for trade through social media), the Ministry of Commerce and Industry, and the Ministry of Municipality and Environment.

1.2.23. Drug Quality Control laboratory

The MOPH informant remarks regarding the drug quality control laboratory (i.e., ST6) under the Pharmacy and Drug Control Department were positive. This indicates that the MOPH is committed to ensuring that the country is able to conduct quality testing for medications as well as to detect defects in products registered in

Qatar. In the future, it is recommended that the laboratory establish effective collaboration with the established PV center and ensure compliance with the WHO qualification requirements (10, 11).

1.3. Performance of the Public Sector Pharmacovigilance System

The public sector involves the HMC PV system and the PHCC PV system. The study focused on the structure, process, and outcome components of these systems. Both systems achieved an overall good PV system performance (between 50% and 77.9%). This indicates that both PV systems have been satisfactorily developed and that their functionality status signifies their public sector role as important stakeholders in PV implementation at the national level.

The system analysis found that there is consistency in the performance on structural indicators, as both systems had the core PV structures in place, including policies and guidelines relevant to PV and related elements (i.e.CST2), a department overseeing PV activities (i.e., CST1), reporting forms (i.e., CST6), and computerized systems for reporting (i.e., CST7 and ST5). This implies a commitment to implementing the PV structures required for the operation of the system. The study examined the details of the two systems and found variation in the implementation of PV structures. For instance, HMC has reporting forms for patients and for healthcare professionals, while PHCC does not have a form for patients to report. Similarly, PHCC had two electronic software systems in place, the Datix system and the Cerner system, while HMC has only the Cerner system. PHCC can use the Datix system, which allows a feedback process, and this feedback is shared across the 25 centers.

In terms of process indicators, the study found discrepancies in the operations of the PV systems. These were is expected because HMC is concerned with the

provision of secondary and tertiary healthcare services, while PHCC provides only primary care for the Qatari population. In addition, the performance of the HMC system might have been higher, but due to missing information for some PV KPIs (i.e., data was not provided), the HMC system score was lower than that of the PHCC system.

For PV outcomes, both systems collected data based on the relevant scope of services provided; therefore, we noted that PHCC has only one relevant core outcome indicator relevant to signal identification and generation (i.e., CO1). PHCC achieved a score of zero, as it does not perform this activity on the submitted reports. The study proposes that signal identification be implemented given that a large number of the population is covered by the PHCC system.

The study found that HMC is considering developing its service to include active PV activities (i.e., CP9). Further, HMC has conducted projects relevant to the outcome indicators, including following up potential signals. In addition, HMC has successfully published identified cases and communicated them to the WHO. This implies that HMC is striving to achieve the best possible system functionality status as well as being committed to contributing to PV implementation as a visible PV stakeholder.

Both public sector systems reported an increased reporting rate (i.e., CP1). Furthermore, regarding the quantitative and qualitative information of the generated ADR reports, the study found that the HMC system alone reached the desired IPAT threshold (100 reports/million of population/year) (32). HMC reported receiving 1599 ADR reports in 2017, while PHCC reported receiving 50 ADR reports for 2017 that are documented in the Datix system. The appropriate threshold for health facilities is based on the number of people served per facility (e.g., an institution serving 10,000 patients would require a minimum of one report per year for a satisfactory performance). This

can have a positive implication for the collation of national drug safety data, especially because HMC is responsible for providing care to the majority of the Qatari population.

The stakeholders in the HMC PV system, represented by the MSQC, reported that there is a need to address the quality of the documented reports (i.e., CP5), as some had inadequate information (30% of reports have missing information). Similarly, PHCC reported that to date, some of the received reports have had a degree of irrelevancy or deficiency. Some healthcare professionals have a lack of knowledge of ADRs, and some fail to differentiate between ADRs and side effects. In addition, some healthcare professionals report ADRs but do not provide the full information required for further analysis. Therefore, the study recommends improving awareness of ADR reporting; providing training in methods of collecting the PV data required for subsequent analysis, including transcribing data from patients' health records; and improving the accountability of staff to ensure the completeness of the reports (29, 46). However, it is important to mention that to address the challenge of the quality of the reports, both systems had conducted training and educational initiatives on PV. HMC also reported an initiative to improve staff technical capacity by sending some MSQC staff to receive training in Uppsala, Sweden. This indicates a commitment to improving PV practices, technical capacity, and PV culture in the public sector. Moreover, PHCC has included ADR reporting as a staff key performance indicator to improve reporting. In line with this, the study recommends the use of key performance indicators, as it can be helpful to ensure that staff are aware of the system objectives and to monitor the achievement of the system objectives.

A comparison between the two systems regarding the type or source of the submitted reports (i.e., P2) was not feasible, as PHCC was not able to provide details on the healthcare professional groups that reported because the Datix system records

data anonymously. For HMC, most reports were sent by pharmacy professionals (70-80%), followed by nurses (10-15%), medical doctors (5%), and dentists (0%). HMC reported that despite efforts to increase reporting rates and improve the reporting culture among nursing professionals, the underreporting problem persists. The study suggests that the challenge could be related to culture. To illustrate, the hierarchical nature of the healthcare professions could be a potential cause of the discrepancies observed. This claim is supported, as even across the EU PV system, the issue of underreporting has been linked to the hierarchical nature of the healthcare system (91). Similarly, in developing countries, this hierarchical nature has been linked to the subject of underreporting by some professions (71). Consequently, it is recommended that reporting be encouraged and that all healthcare professionals feel included by providing the necessary assurance that their efforts are appreciated and that they will not be threatened, since the safety culture is a shared aspect among healthcare professionals. Clarifying the responsibility of each healthcare profession across the PV system would also increase the involvement of various healthcare professionals and avoid possible duplication of efforts. In addition, major awareness campaigns on the subject of reporting to sensitize healthcare professionals and ensure their compliance with best practices are recommended. Another potential opportunity is to use the Medical Education Department at HMC to build internal capacity by educating medical students or other students from various healthcare professional backgrounds on PV activities that extend beyond ADR reporting (91).

For public and/or patients' contributions, HMC reported that despite the availability of forms, the MSQC has not received any reports from patients (i.e., P2). This is consistent with the findings at the MOPH level and the PHCC system, as patients make a minimal contribution to PV. Public underreporting is a challenge that requires

attention. Lack of reporting has been attributed to a lack of awareness and time constraints among patients and/or the general public. This finding is consistent with the patient underreporting problem even in countries with well-developed PV systems (151, 153). However, patient reporting at HMC needs to be targeted and improved to ensure that the country benefits from this valuable source of data (154). In general, the study recommends that initiatives to increase public awareness focus on both short-term and long-term (i.e., impact) initiatives. Short-term initiatives can include PV communication through social media (given the high availability of mobile technology in Qatar), TV, and newspapers (91). Additionally, at the HMC level, a short-term initiative is the possibility for patients to report directly without the assistance of a pharmacist to avoid any barrier (155); if required, the pharmacist could be involved based on whether the patient decides to simplify the process. Long-term efforts include collaboration with schools and universities to educate the students who constitute the future generation (1, 149).

Regarding PV data analysis (i.e., core process indicators) and signal identification (i.e., CO1), variations were also reported. For instance, HMC follows a systematic and evidence-based approach for causality assessment, while PHCC does not conduct causality assessment of the received ADR reports. Therefore, it is recommended that causality assessment be implemented in the operation of the PHCC system, as the opportunity to utilize the data collected on ADRs will be lost without proper analysis. In addition, the study found that data on therapeutic effectiveness are collated but not analyzed by PHCC. Therefore, it is recommended that all forms of PV data be used in the initiatives required to improve patient safety (156).

In relation to human resources (i.e., CST5), HMC reported that all staff working at the MSQC are part-time. This implies that there is a shortage in human resources, as

the threshold of the required capacity to handle individual safety case reports would involve the number of reports received per year per designated staff (29). For PHCC, the study could not identify the exact number of individuals involved in the process. The shortcomings in data analysis and subsequent PV activities were attributed to technical capacity, the limited number of reports received, the limited number of expert human resources, and the fact that PV is still considered to be an emerging concept. Therefore, allocating resources to hire experts and building the current staff technical capacity by providing training in PV activities, namely, data analysis, data management, communication and feedback, and decision-making processes, are recommended. Addressing technical capacity can be challenging, as this issue has cost implications and requires access to experts who can share their experience and skills. Therefore, the study suggests that technical capacity building be discussed with universities, which could provide peer experts or theoretical education for healthcare professionals. The recommended IPAT threshold for individuals receiving training in PV is 5% per institution; inability to meet the threshold is considered a failure in the provision of the training required to ensure system functionality (32, 51).

In terms of financial resources (i.e., CST4), the study found that the resources were sufficient. However, as there is no budget allocated for PV, the study suggests the allocation of an annual budget for PV and medication safety activities to avoid possible fluctuations in PV service provision and PV implementation (11). This is strongly recommended for the MSQC, given the limited amount of human capacity to handle PV activities, the high number of patients served, and the number of reports generated per year.

The study found good system networking and collaboration between the HMC and PHCC systems. The systems are linked through the Cerner system, and both had

good communication. The study suggests that leveraging more collaborative efforts on PV could further improve the system through the sharing of experiences and system structures. On the other hand, coordination and communication with the MOPH were reported as an area that requires improvement. Therefore, the study suggests improving transparency between the public sector and the MOPH system. The improvement in communication between systems is essential for the effective and efficient operation of PV at the national and subnational levels. Without effective communication, collaboration opportunities can be lost, which can impede PV (1, 157). Finally, the development of a clear national communication strategy is recommended to improve transparency and avoid conflict of interest between national PV systems (40).

Only the HMC system reported the consideration of active PV studies (i.e., CP9). The HMC plans to expand to include more robust active PV activities are promising. Ideally the optimal PV system performance would be achieved. However, striving for the optimal state requires time and resources. Therefore, the study recommends that before the introduction of advanced services, specific organizational challenges be identified and efforts and investment be prioritized to further improve the public sector systems. Finally, it is proposed that the public sector invest in the harmonization or standardization of active PV practices and base the standards on existing international standards or models.

In conclusion, the study indicates that based on the total system performance, both systems can contribute to the country's PV and medication safety. Both systems could provide leadership, management, and operational support for the improvement of PV in Qatar. For instance, the MSQC could provide support for the future implementation of a national PV system.

1.4. Performance of the Private Sector Pharmacovigilance System

The private sector involves private healthcare institutions and private community pharmacies. The study focused on the structure, process, and outcome components of the PV system.

1.4.1. Healthcare Institutions

For healthcare institutions, the system analysis found a degree of consistency in the total PV performance in the three indicator categories. Four out of five healthcare facilities showed a good PV system performance, indicating that PV implementation can be considered appropriately functional. This can be attributed to the fact that the sample involved had accreditation requirements to adhere to. Only one healthcare facility, Hospital D, achieved an average performance (49.3%), which was near the upper limit of average performance (i.e., 25%-49.9%).

The satisfactory performance in structural indicators can be explained by the healthcare institutions' ability to meet the PV indicator requirements, including the availability of a department or network of departments (although not dedicated to PV) to oversee PV implementation (i.e., CST1) at the organizational level; the existence of main PV structures, including policies and guidelines relevant to PV and related elements (i.e., CST2); reporting forms (i.e., CST6); advisory committees to support PV implementation (i.e., CST10); databases for documentation of drug-related incidents; feedback mechanisms; and communication tools. Nevertheless, when we examined the details of the systems, we found discrepancies in the implementation of PV structures. For instance, the available policies on medication safety and PV-related elements varied in the content covered and the number of policies covering aspects of medication safety. Only one institution, Hospital D, reported that it had no specific policies on PV or ADR reporting. However, due to changes in management, the hospital was in the process of

developing new medication management policies that would cover many aspects of medication safety, medication errors, ADRs, and medication quality. This indicates that leadership at the organizational level can have a positive influence on PV development and implementation.

Differences in the type of available reporting forms (i.e., CST6) were observed. Hospital C had medication error reports, ADR reports, and recall reporting forms, while Hospital A had clinical and nonclinical incident reporting forms. Hospital B also had an electronic form for healthcare professionals reporting and paper-based forms for patient reporting. The design of the reporting form can display the level of commitment and the target data that the institution aims to collect. Also, it can show the effect of the different accreditation programs (e.g., Canadian vs American accreditation) on the implemented PV structures.

Only Hospital B had a reporting form for patients; other institutions relied on their complaint systems to receive any concerns or comments from patients and caregivers. This indicates that Hospital B recognizes the public as important PV stakeholders and that the higher-level authorities prioritize patient safety. The study found that differences in financial resources influenced the implementation of sophisticated PV tools and methods among healthcare institutions. For instance, Hospital B used the Cerner system in its report management process, while other hospitals relied on paper-based reporting that would later be entered into the in-house database.

The content of the reporting form (i.e., CST6) varied, but a common feature was that information relevant to counterfeit medications, therapeutic failure, and abuse and misuse of medications could be recorded in a free text area by the healthcare professionals. It is recommended that a form for medication-related incidents be

developed based on standards from the literature to ensure the complete and relevant collation of information. This is strongly recommended for institutions that have a general incident report form that is not specific to medications. The design of the reporting form is essential for effective PV operations. The quality of ADR reporting forms and the resulting effect on the quality of the information required for further analysis have been described in various countries by Bandekar et al. (79).

Two institutions reported plans to implement an electronic report management system, such as the Datix system, to improve the existing reporting process (i.e., ST5 and CST7). This study also showed that information on ADRs and other PV-related data can be found in electronic health records or paper-based patient files. Such data have been used by some institutions to ensure the completion of reporting forms before the report assessment process. In line with this, it is recommended that PV data be transcribed from patients' records and communicated to the relevant authorities at the organizational and national levels (11, 29).

None of the institutions involved in the present study had a budget dedicated to medication safety or PV activities (i.e., CST4). The budgets were deemed sufficient for current operations but insufficient for the expansion of services by some key informants. Thus, the allocation of a dedicated annual budget for PV and medication safety is recommended to ensure that PV-related activities, including education, training, reporting tools, systems, and communication facilities, will be sustainable (11).

In addition, the study found that policies relevant to medication safety and PV (i.e., CST2) are considered not comprehensive in coverage for the full scope of PV. For example, none of the healthcare institutions reported the inclusion of active PV initiatives; this omission was associated with the scope of services provided and the

belief in the relative safety of products utilized in the private sector. Consequently, it is recommended that awareness of the full scope of passive PV and active PV be increased to ensure that healthcare institutions are aware of how various sources of PV data could be used to improve the safe use of medicines and patient care.

Some of the key informants reported that the scope of services and the profile of products can be considered relatively safe in the private sector compared to the public sector. Therefore, the study recommends increasing the awareness of the need for passive surveillance or monitoring activities for all drug products, including both high-risk and low-risk medication. Without continuous monitoring, the occurrence of harm cannot be mitigated. The reason is that the occurrence of drug-related problems depends on many factors associated with the medical product itself and/or other factors, e.g., therapeutic factors and patient-specific factors (1, 11, 68, 158).

The study found that the term PV may not be specifically employed (e.g., policies and training provisions may not employ the term), but the current operation of healthcare institutional systems covers some of the elements relevant to PV. Consequently, it is recommended that efforts be made to increase the visibility of PV and ensure that organizations will link PV directly to medication safety and optimal patient care. This could increase awareness at the organizational level of the PV culture and its importance. In addition, it will enable healthcare professionals to appreciate the potential value of PV in ensuring the safety and effectiveness of medications. In addition, it will eventually stimulate the reporting culture and interest in continuous vigilance (1, 29).

The study found that pharmacy and therapeutics committees had an essential role in the institutions' PV systems. The committees were responsible for supporting the development of internal PV activities, guiding the implementation of those

activities, and developing PV-related strategies at the hospital level. In the literature, Nwokike and Joshi identified the need to strengthen pharmacy and therapeutics committees in Rwanda to help improve PV in the country (99). Similarly, this study recommends building the technical capacity of such committee in aspects relevant to data management, operational procedures, and system development. It also recommends including PV and safety aspects in the committee terms of reference, key performance indicators, and contract agreement. This may help the committee ensure that it is meeting the objectives relevant to PV at the organizational level. Those recommendations apply to the departments directly involved in PV functions, such as pharmacy and therapeutics committees and quality improvement departments.

For process indicators, the study found discrepancies in the details of PV operations across the systems. This can be attributed to discrepancies in the organizational structure, the available reporting systems, communication systems, organizational culture, resource management process and information and knowledge management. The aforementioned factors can influence PV implementation (159). However, the level of interest in medication safety, patient safety, and PV was determinable. The findings represent the private sector's various efforts to improve medication safety and the safety culture at the organizational level.

The PV system process component performance of Hospital B might have been higher, but because information was not provided for some process indicators, the system scored lower than it might have. Furthermore, although there was a reported increase in the number of reports generated over time across the institutions (i.e., CP1 and CP2), the study found that underreporting was a common challenge for the private sector. For instance, only Hospital D reported receiving an actual ADR report in 2018 (i.e., CP1), while the others reported receiving reports of other types of cases. The

appropriate threshold for health facilities is based on the number of people served per facility (e.g., an institution serving 10,000 patients would require a minimum of 1 report per year for a satisfactory performance) (32, 51). Further, the study found that each organization used different measures to address the quality of the documented reports (i.e., CP5). Measures included the role of the clinical pharmacist in following up and completing reports that had inadequate information, direct follow-up with the reporter to complete a report, the utilization of patient profiles to fill in missing information, and direct follow-up with patients when possible. Similarly, all institutions reported the continuous provision of training for healthcare professionals regarding medication safety and ADRs reporting. The quality and effectiveness of the provided training are not within the scope of this study. However, based on details from the interviews, the measures have been successful in improving reporting rates, staff awareness, and the positive disclosure culture.

Many efforts from the private sector aimed at increasing reporting and improving the reporting culture among healthcare professionals were described. A comparison of the sources of the submitted reports indicates differences in the backgrounds of the healthcare professionals generating reports at each institution:

I. Hospital A: most reports were sent by nursing professionals (80%), followed by pharmacists (15%), and medical doctors (5%).
II. Hospital B did not provide the data required for the indicator code (P2).
III. Hospital C reported that different types of reports were submitted by different healthcare professions. ADR reports were sent only by medical doctors (100%), while medication errors were generated by pharmacists (70%) and nurses (20%). The hospital reported that doctors are the custodians of patients and are

responsible for identifying ADRs cases; ADR reports are submitted and the reported details enclosed by the pharmacist in charge.

IV. Hospital D reported that for different types of reports, the majority are generated by medical doctors (70%), followed by nurses (15-20%), dentists (5%) and pharmacists (5%).

The study indicated that the discrepancies observed in reporting could be related to the organizational culture. Nevertheless, the safety culture is a shared aspect among healthcare professionals; therefore, it is recommended that all types of reporting be encouraged and that all healthcare professionals feel included. The perception that PV is a shared responsibility between healthcare professionals across the PV system needs to be improved. Additionally, the KAP (knowledge, attitude and practice) model or Inman's model of the seven deadly sins of underreporting is proposed to target the underreporting professional categories and determine the causes of underreporting (160, 161).

The procedures and methods of PV data analysis (i.e., core process indicators) varied between the institutions' PV systems (e.g., causality assessment, i.e., CP4). The study found that some hospitals adhere to a formal process of data analysis and use evidence-based tools, while others rely on individual or team efforts and experiences for an informal method of analysis. Technical capacity issues and the need for experts to cover the scope of data analysis were also reported by some key informants. To address the challenges in data analysis, systems are advised to conduct continuous training and educational initiatives on PV data analysis and management, ensure the availability of evidence-based and validated tools, invest in proper documentation systems, and ensure access to proper information sources and systems. For instance,

Hospital D reported that staff could benefit from access to better information sources (i.e., ST4). Accordingly, the study proposed collaboration with and support of the private sector from the MOPH, universities, and the Qatar National Library. These parties could establish an agreement to use information sources that can be helpful to ensure that staff are aware of and can access PV and other medication safety information. Additionally, the aforementioned parties can improve staff technical capacity by providing some healthcare professionals with training on the subject of information management.

The study found that for PV outcomes, all systems showed low performance. The healthcare institutions reported that the collected data were based on the relevant scope of services provided. In addition, the study found that the private sector is not well equipped for signal identification and generation activities. The majority of institutions reported that data on signals were acquired from external sources or the MOPH system. The study found that Hospital A was considering developing its system to include research activities. It was reported that the hospital was at the foundational stage of establishing a research profile and had plans to collaborate with universities in Qatar to support research activities. In the future, the private sector can be expected to play a role in active PV, clinical research, and clinical trials under the following conditions: MOPH support, collaborative opportunities with universities and the public sector, and policies and guidelines mandating the collation of real-world data.

The study found that institutions lack strategies to collate and evaluate the outcomes related to PV activities. For instance, it was reported that it is difficult to conduct economic studies owing to a lack of human resources, technical capacity, and financial resources as well as low interest and/or prioritization. Some institutions reported that in the future, a third party (e.g., the MOPH) will need to support and provide advice for

such activities if implemented. In addition, almost all institutions reported that such PV KPIs are well suited to the scope of the MOPH system. Even though the same challenges were reported, Hospital B stated that cost data are available in the system, but the number is not recorded as a value. The hospital staff document the cost of cases in the system as a bundle. Therefore, cost data can be extracted if desired for specific drugs or interventions but not for diseases or conditions. Additionally, the hospital conducted a cost-saving study on medications in general but has not specifically studied PV or safety alone. The study recommends that cost and clinical outcome data be collated and communicated to the MOPH to support further analysis and data utilization at the national level; this should be feasible, as not many cases of medicine-related illnesses were reported. In addition, the implementation of outcome evaluation at the organizational level will require prioritizing the PV KPIs that need to be implemented and assessed. The PV outcome evaluation will require real-world data. The collation of these data is a time-consuming process that will require different types of resources (e.g., money, expertise) (11).

The study found that for PV KPIs, promising initiatives were mentioned that can assist the sectors to collate data that are relevant to the outcome and process indicators. It was reported that two drivers will encourage clinical coding across the country in the near future. First, a new national health insurance scheme is being introduced that will require hospitals to conduct clinical coding for every patient. Second, the Minister of Health has committed to an international forum that will promote clinical coding across the country.

Finally, Olsson et al. recommend including the private sector in national PV implementation and ensuring the inclusion of quality assurance systems in accreditation requirements for the private sector. This will aid in developing PV systems and ensuring

the safe use of medication in the private sector (20).

1.4.2. Community Pharmacies

For community pharmacies, the analysis indicated that chain pharmacies and independent pharmacies showed discrepancies in PV system performance, showing that PV implementation at the community pharmacy level was not uniform. The community pharmacy PV system is facing many challenges that can lead to weak system performance. The PV system weaknesses were attributed to the lack of reporting forms at the national level and facility level, lack of a dedicated budget for medication safety and PV, lack of national training and educational interventions, and limited awareness of PV. However, since the WHO PV indicator checklist was designed for use at the national level, the performance of the chain pharmacy group can be considered appropriately functional (total performance 57.1%), which can be attributed to the fact that the pharmacy group has developed a database for medication safety data, encouraged the reporting of recurrent drug-related problem cases, provided training and educational interventions on medication safety, communicated with patients about medication-related problems, developed a newsletter (not specific to PV) for the internal communication and dissemination of information, had a dedicated staff for the data management process and educational interventions, collaborated in research efforts with QU, had access to the QU e-library, and acknowledged that PV is an essential aspect that it plans to implement and improve in the future. On the other hand, the independent pharmacy group (total performance 20.2%) reported the need for ADR reporting forms, educational interventions, external support for PV activities, and information sources as well as improved PV communication and feedback from the MOPH.

The study indicated that PV is weak and not well developed at the community

pharmacy level. This level needs to receive more support to address the aforementioned challenges. PV implementation in community pharmacies is crucial since the community pharmacy can be the first point of contact for patients. Further, the key informants reported that the scope of the practice is relatively safe, as the medications prescribed are generally safe. However, awareness needs to be improved to sensitize pharmacists and pharmacy technicians to the need for continuous monitoring of over-the-counter medications, prescription medications, and herbal medications. The community pharmacies can generate unique national data (e.g., herbal medication ADR cases), and communicating these data to the national level can improve medication safety and treatment outcomes. Finally, community pharmacies would benefit from national policies and guidelines on PV as well as a focal contact point at the national level (e.g., the MOPH system or a potential PV center) to facilitate medication safety management, improve community pharmacy contributions to PV, improve communication with patients on drug safety, and increase involvement in national risk mitigation activities (1, 11, 29).

1.5. Performance of the Pharmaceutical Industry Pharmacovigilance System

One of the healthcare-related companies (i.e., a pharmaceutical company) available in Qatar agreed to participate in this study. The assessment found that the overall performance of the industry PV system was 68%, indicating a good system performance. This finding implies that the pharmaceutical company had a functional PV system. In examining the details of the structure, process, and outcome indicators, the study found that the company met the requirements of structural indicators (91.3%, within the excellent range) but was unable to provide effective PV operation (45.2%, within the good range). PV activities, including data analysis (e.g., causality

assessments and signal generation), were deemed not feasible, as the company reported that no critical cases in relation to its products had been received. Consequently, the performance in the outcome domain was within the average range (58.3%); The company reported that internal PV actions exist, and that the company adheres to the regulatory requirements of external sources, e.g., the MOPH and international regulatory bodies. Moreover, the study found that the PV policies and risk management activities of the company were under the GCC guidelines. This had implications for the high performance in the structural indicators, as the GCC guidelines design was influenced by stringent regulatory authorities, e.g., the EMA (163). In addition, the pharmaceutical industry was the only national stakeholder to report the allocation of an annual budget dedicated to PV (i.e., CST4) as well as a specific PV department (i.e., CST1). Such adherence to stringent standards and the PV KPIs can increase the competency of the national pharmaceutical industry. Furthermore, the assessment found that the company adhered to the MOPH requirements and that the MOPH conducts inspections of the company system. For instance, the company changed its ADR reporting form based on the requirements of the MOPH; The quality of the reporting form was not assessed, as the ADR reporting form was not shared, and the quality of the report design is outside the scope of this study.

The study indicates that in the absence of national PV guidelines and policies, the pharmaceutical industry involvement in national PV and medication safety activities, as well as the implementation of risk management activities and plans, will remain limited. Without national PV regulations, the potential role of the pharmaceutical industry in improving medication safety, quality, and effectiveness, as well as patient safety, may be inadequate. The scope of the pharmaceutical industry is more profit-driven; therefore, without formal structures and a national PV center in

place to ensure its optimal engagement in PV, future issues with national drug products and conflict of interest may arise (29).

1.6. Pharmacovigilance Implementation in Mental Health Strategy

One of the healthcare-related programs and organizations (i.e., MHS) available in Qatar agreed to participate. The system assessment found that the MHS produces the "National Mental Health Strategy Impact Evaluation 2015" (162), a document with specific sections on medication safety. This indicates that the MHS recognizes the importance of medication safety in the operation of the organization. However, the MHS reported a lack of the PV tools required for data collection (i.e., ADR reports) and data management (i.e., database). Even with the lack of these required tools, the MHS reported efforts to analyze data and share them with national stakeholders. Also, the MHS processes information from external sources and has audits for monitoring purposes. This shows the level of commitment of the MHS to ensuring medication safety. Moreover, it has a positive implications for improving the communication profile on the subjects of medication safety and PV across the stakeholder system. In the future, collaborative and coordinated PV activities to target specific drugs or groups could be exploited.

The MHS reported that at the national level, there is a need for a standardized reporting form. This indicates that a common key PV challenge is that the process of reporting is not centralized in the MOPH or at the national level. The study proposes that a centralized PV system can offer a visible focal point for national stakeholders to coordinate PV activities. In addition, the study suggests that the lack of national policies and guidelines on PV may limit the MHS capacity and commitment to implement PV activities at the organizational level as well as with other stakeholder systems. For

instance, the capacity to collect data and use it in risk mitigation activities or signal generation was limited. Hence, legal documents defining the roles and responsibilities of various stakeholders in PV can be of value to improve patient safety and medication safety across the healthcare system.

1.7. Pharmacovigilance Implementation at the Higher Academic Institutions

The main purpose was to research the level of PV inclusion in educational programs in Qatar within the university curricula of medical doctors, pharmacists, nurses, pharmacy technicians, and health scientists (i.e., CST8). The study found that basic elements relevant to medication safety and PV, such as spontaneous reporting, have been implemented in all programs except that of QU College of Health Sciences, as PV is not included in the curriculum. Hence, the study recommends including the concepts of PV and ecopharmacovigilance in College of Health Sciences courses. In addition, the number of credit hours devoted to PV teaching across different programs was 2 credit hours or less over the years of the programs. Not all the key informants reported the number of credit hours, as the curriculum may not employ the specific term PV, but elements related to PV were included in the courses. The key informants also reported that the capacity of students to conduct data evaluation (e.g., causality assessment) can be very limited. This indicates that the level of commitment and the time committed to PV teaching for undergraduate and postgraduate degree courses might be inadequate. Contemplating the importance of PV in the safe use of medications and optimal patient care, the study recommends that more time could be dedicated to PV in healthcare and health-related science courses. In doing so, undergraduates and graduates can become better informed on the potential role of PV, including its role in ensuring medication safety and protecting public health, which will

help improve PV implementation in the country, e.g., by increasing ADR reporting. Recently, the WHO developed a PV core curriculum for universities to follow that includes a set of essential PV components and competencies for students. The WHO PV curriculum can be integrated or offered as a separate course (163).

Academic universities can play a substantial role in PV (29). The study indicates that many untapped resources exist, including training capacity, research capacity, student participation, PV expertise, technical resources, and financial resources. Some key informants also reported that the universities could contribute directly through hosting a national PV center or closely collaborating with the national PV center when established. Potential collaboration at the national level through the provision of training or research opportunities was reported. This implies that without a PV system and structures in place, the contribution of universities to PV may be limited. In addition, effective engagement could aid the country in building internal capacity for PV to help secure PV sustainability. Finally, the study suggests that establishing a PV center (with membership status in the WHO PIDM) at a university would help the country to improve the current PV situation and enhance the reputation of its national educational programs at the global level (e.g. accreditation of national educational programs).

The study found that the communication gap in PV can contribute to the limited awareness of ongoing PV and medication safety research activities on the premises of universities, as there is no structured process in place to communicate this information to regulatory bodies or other national stakeholders. Therefore, communication can be improved to help PV stakeholders explore the opportunities available for effective coordination, resource sharing, information sharing, and the effective division of PV responsibility at the national level. In doing so, PV can have a greater impact on public

health and reducing drug-related harm as final outcomes (1).

2. Future Direction Based on the Research Findings

2.1. Future Work

The recommendations and future work based on the WHO framework were discussed in detail in the results chapter (key informants' perspective) and discussion chapter (researcher's and key informants' perspectives). This study highlights the challenges, strengths, and opportunities available for PV advancement. It recommends addressing the challenges and implementing the recommendations to improve PV in Qatar. The study proposes that the WHO PV indicators can be used to generate many potential strategies, studies, and activities that can be applied at the national level and the stakeholders' system levels. However, policymakers and administrative authorities are advised to prioritize based on the influence of a specific challenge or aspect on the PV system to implement corrective actions and/or improvement measures. This would involve identifying robust methodologies and consulting experts in the field. Furthermore, identifying the challenges to be addressed should follow a system-based approach. For instance, technical capacity has been mentioned as a challenge affecting various stakeholders' PV systems in terms of the structure, process, and outcome domains; therefore, it should be a high priority. The prioritization and the evaluation of challenges and their impact on the PV system as well as the healthcare system require real-world data that are specific to the organizational level or the country. This process must be executed carefully, as the collation of these data is a time-consuming process that will require different types of resources (e.g., money, expertise) (11). If not well planned and executed, it may lead to failure and the waste of valuable resources.

Moreover, it is recommended that a study utilizing the WHO methodology be

conducted on a larger scale to include the stakeholders that were not covered in the present research, for instance, medical centers, MAHs and drug representatives, medical device companies, patient organizations, and external actors such as the WHO and UMC. This study can be conducted by the MOPH to increase the number of the sample representing the country. Email surveys can be sent to national stakeholders, one covering the WHO PV indicators and another to identify the barriers and opportunities of effective PV in Qatar. This assessment can collect data for the WHO PV background information indicators to allow calculation and comparison. In addition, a PV system evaluation could be performed every 3 or 5 years to monitor the country's PV development (11).

In addition, the use of the PG framework is proposed for a better understanding of the factors enabling PV in the country. This framework allows a qualitative assessment of the PV system and PG, including the influence of stakeholders operating in the system. The framework suggests that a good PG can enable PV in the country (102). The use of the framework is feasible, as the current study obtained ethical approval to use the PG framework, but due to the limited number of participants agreeing to use it, the PG framework findings were not included. Only the private sector stakeholders agreed to utilize the PG framework to give recommendations at the country level.

Below are some examples of areas to be explored in Qatar and possibly in other countries, guided by the WHO PV indicator manual and the study findings:

I. Use the WHO PV indicators to assess the PV system in relation to vaccines, herbal products, and medical devices in Qatar.
II. Conduct a study evaluating the design, understandability, and implementation of policies relevant to PV, for instance, the healthcare professionals' level of

comprehension of the available organizational PV policies and the effect on their PV practices e.g., ADRs reporting.

III. Conduct a study evaluating the design of the ADR form and its impact on the data quality and reporting rate.

IV. Assess the public perception of PV and ADR reporting.

V. Understand the causes of underreporting among healthcare professionals. Use the KAP model or Inman's model of the seven deadly sins of underreporting to determine the incidence of ADRs and other drug-related problems in various service delivery settings, e.g., emergency settings.

VI. Conduct economic studies to evaluate the impact of ADRs on the system, e.g., the HMC system.

VII. Study the impact of the planned projects (e.g., the national e-reporting system, e-health strategy) (141) in the MOPH environment in relation to professional staff views, training preparation, and professional qualification attainment.

VIII. Research the elements that determine highly qualified PV professionals in employment assessments set by organizations (e.g., the elements that determine a highly qualified PV professional in employment tests set by the human resources departments).

IX. Address the absence of a professional health court, including the causes and the need for such an entity. This can apply to a drug information center as well.

X. Investigate healthcare students' perceptions, views, willingness, and readiness to be involved in PV activities at the national level.

XI. Understand the role of health insurance companies in the safe use of medicines, PV, prescribing patterns, and polypharmacy. This can help clarify the impact of

insurance companies on private sector practices in relation to PV and medication safety.

Further, the value chain analysis, the 5 whys method, and the Fishbone diagrams are recommended for a better understanding of the root causes of the reported challenges faced at each stakeholder level as well as the national level. This may help improve our understanding of the PV system challenges at the strategic level and help identify solutions at the operational level. Moreover, it is recommended that national PV stakeholders discuss conducting a feasibility study on establishing a national PV center, including barriers to its implementation. Initial steps can be taken through the use of focus groups method and the 5W2H method (159).

2.2. Proposal for Pharmacovigilance Center Organizational Structure

This solution (i.e., a national PV center) is proposed because the Qatari health care system is expected to experience rapid growth (54); therefore, the healthcare system and pharmaceutical system will require stronger control over the market. The proposed PV center (Figure 19) will serve to enable this control by relying on the proposed sections that should have a clear and documented division of duties and depend on a high level of scalability. Refer to Appendix C for details of the organizational structure departments and sections.

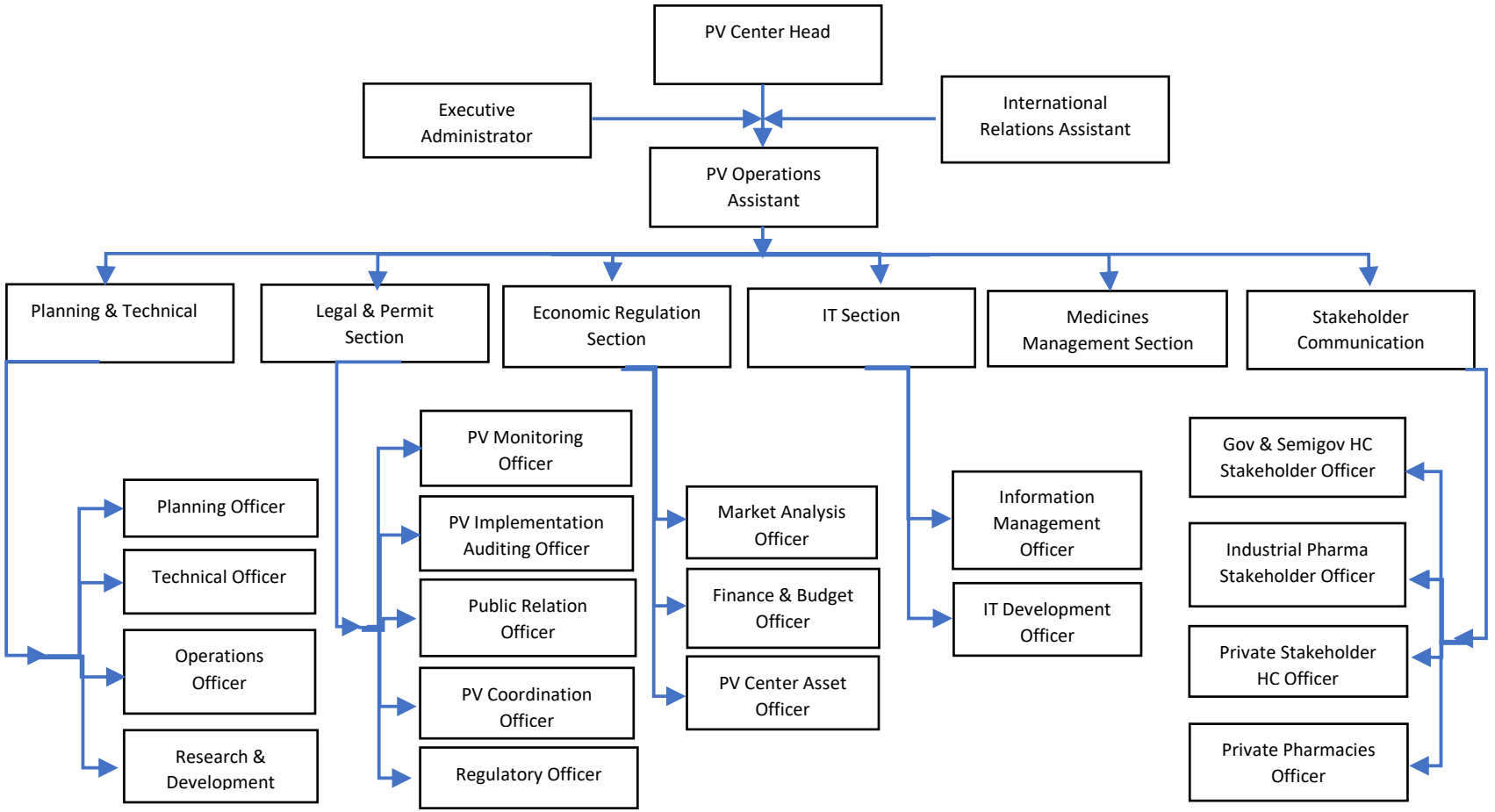

Figure 19. Organized pharmacovigilance center organizational structure

3. Strengths and Limitations of the Study

3.1. Strengths

I. This is the first study to assess the PV and medication safety system in Qatar following a comprehensive system-based approach. The study undertook the system evaluation using MMR.

II. The quantitative part and qualitative part were used for convergence, conformation, and triangulation purposes. The two parts provided a complementary picture of the PV situation in Qatar.

III. The quantitative data permitted the characterization and visualization of the performance of the national and subnational systems to understand the PV system capacities at each level as well as the comparison of national PV subsystem capacities.

IV. The qualitative data provided an in-depth understanding of the views and perceptions of national PV stakeholders who operate in the Qatari healthcare system.

V. The study was able to fulfill its intended main aim and objectives. The findings highlighted the baseline PV situation and the complexity of the PV landscape across the national subsystem as well as the national system level.

VI. The MMR allowed us to obtain an in-depth understanding of the current PV scenario using various internationally recognized tools and research procedures, including the WHO PV indicators, the minimum requirements of the WHO for a functional PV system, and the input of national PV stakeholders.

VII. A scoring system was developed to allow the quantitative information to be clearly presented. This allowed us to compare the PV system performance status to the

WHO PV indicator requirements as well as between national stakeholders' PV systems.

VIII. The qualitative approach allowed us to address the limitations inherent to the WHO PV indicators.

IX. To our knowledge, this is the first MMR in the MENA region to cover the full WHO PV indicator manual, including the three indicator domains, structure, processes, and outcomes, as well as the main core and complementary indicator categories.

X. The study involved various levels of the healthcare system, e.g., regulatory bodies, the private sector, the public sector, universities, the pharmaceutical industry, and healthcare-related organizations. This multistakeholder involvement allowed us to understand the PV challenges from different points of view and system perspectives.

XI. A major strength is the analysis of strengths, weaknesses, and opportunities as well as the formulation of recommendations based on the key informants' perspectives as well as the researcher's perspective. This approach aided in the generation of feasible recommendations and potential solutions to be implemented in Qatar.

XII. The study is in alignment with current national efforts to improve medication safety and patient safety, as outlined in the National Health Strategy (54), the PHCC Strategy (164), the establishment of the new MSQC in HMC, and the MOPH initiatives to improve the awareness of the safe use of medications and patient care in Qatar Patient Safety Week (165).

XIII. A PV system assessment conceptual framework was developed to guide the study and to provide a model for the future implementation of a PV center. It outlines the components of the system, factors influencing the system, and the final objectives of the PV system.

XIV. A PV center organizational structure and project idea report (terms of reference) for the center were developed. This could aid policymakers as a model for the development of a centralized national PV system in Qatar.

XV. The study includes the pharmaceutical industry as a main PV stakeholder in the assessment and inquired about traditional medicine during the interviews per the qualitative part of this MMR. The reason is that the literature on the WHO PV indicators has reported that collecting details on the industry and traditional medical practices is required for a complete system assessment (18).

XVI. The study followed a systematic approach and a specific sequence that was used for all the subnational systems from the planning stage to the end of the data collection process. The reason is that the literature on the WHO PV indicators has noted that it may be necessary to position the PV KPIs across the subnational PV systems following a harmonized and appropriate process to ensure the ability to conduct a comparative analysis and to successfully generate and exchange data (18).

XVII. In addition, approvals were obtained from all the applicable ethics committees; the higher authority at each site was approached, and the QU College of Pharmacy was approached to provide a support letter. In doing so, the study gained more official ground to conduct interviews with national stakeholders. This is according to the WHO remark that the successful implementation of the WHO PV indicators and the collection of all required data will depend largely on the respondents providing full support during the process of data collection.

XVIII. The scoring system used allowed us to make an assessment based on the observed and reported levels of compliance of the stakeholder PV system with the WHO PV framework. This was useful in cases where no proof of evidence on the availability of the confirmed subject activity was provided or when certain stakeholders

reported that following the WHO PV indicator checklist might reflect an unfair assessment score that could affect or provide an incomplete picture of the stakeholder system performance regarding compliance with the WHO requirements (166).

XIX. The outcomes of this research include 1) a comprehensive analysis of the Qatar PV system; 2) a published systematic scoping review paper titled "A Systematic Scoping Review of the State of Pharmacovigilance and Governance in the MENA Region: Challenges and Opportunities"; and 3) a potential in-hand paper for publication titled "Evaluation of the Pharmacovigilance System in Qatar: A Mixed Method Study on Structure, Process and Outcome."

3.2. Limitations and Measures to Limit Influences

3.2.1. Limitations Inherent to the WHO PV Indicators

For each indicator, a specified limitation is mentioned in the WHO PV manual (11). For instance, the structural indicators are limited in their ability to capture full details of the actual spectrum of structures within a system since the response is dichotomous, qualitatively indicating the existence or absence of a specific measure. This limitation was addressed with follow-up questions to understand the situation in a more comprehensive manner.

In this research, a simple scoring scheme was developed to address the PV indicator limitations (i.e., no scoring scheme). However, the study did not include official testing of the scoring system reliability (i.e., it relied on discussion with an expert only). Notably, the WHO foresees the opportunity to develop a scoring scheme for the PV KPIs.

Outcome indicators usually require official studies with standard protocols or depend heavily on data with a level of granularity. This limitation was difficult to address;

therefore, we depended on the stakeholders' ability to provide such data.

3.2.2. Limitations Inherent to the Study

3.2.2.1. Response Bias

In this study, bias could occur when the selected sample reported data to please the interviewer. For instance, the sample might have reported compliance with the WHO indicators because it was convenient and pleased the interviewer. This is especially an issue when the stakeholders perceive that a negative response might have consequences or affect the reputation of their system (167). In addition, bias can occur in circumstances where the interviews include up to 7 key informants from the same data collection site; some individuals might provide answers that are favored by the other key informants even if they had a different opinion. Therefore, the participants were assured that their responses would be anonymous to reduce the occurrence of this issue, and when the participants requested that recording be stopped, this request was fulfilled.

In this research, response bias was difficult to control. However, some measures were applied to minimize this issue. First, for data triangulation, the national stakeholders showed the title pages of current policies or documents and the numbers or values available in databases or reports noting that PV-related elements are available in addition to participating in the semistructured interviews. Second, the nature of this research in involving more than one key informant at each data collection level ensured that the responses were agreed upon by more than one key informant. Third, the literature was searched for proof of evidence, and further investigations were made through second visits or sending emails with the transcripts of the interviews and/or the PV indicator checklist itself to request further clarifications. Fourth, when there was no proof of evidence, the scoring system allowed including the response "yes, partially satisfactory performance". Fifth, the initial key informant or the higher authority at the study site was responsible for

the allocation of potential candidates; therefore, the credibility of the sources in representing the data site was high. Sixth and finally, the qualitative component helped to elaborate the minor details for each study site to show the actual performance of the subnational systems for each indicator.

3.2.2.2. Generalizability

According to Yin, the case study as a design can have some form of generalizability when researchers use case study results to form a broader theory. However, generalizability is not the aim of this study. The coverage of this study of many sites aimed to give a indications about the current PV situation within Qatar, but the findings cannot be generalized.

For this study, selection bias might have occurred, as the sample might have included stakeholders with more robust PV implementation. However, the study used multiple case studies following the same methodological steps. In addition, the samples were selected based on a prioritized list of the main PV stakeholders. For example, the MOPH is the regulatory body; HMC is the main public health services provider; PHCC is the main primary care provider; the private hospitals that were included were reputable and accredited; the academic institutions involved were all institutions with relevance to healthcare and PV; and the pharmaceutical industry was involved.

For the private sector, the sample can affect the generalizability of findings to the Qatar context, as institutions with lower capacities (e.g., medical centers) can have different PV system implementation. However, it is important to note that some stakeholders with lower PV system implementation were approached, but they declined to participate due to their inability to meet the standards required by the WHO framework. This was declared by an email from one hospital (indicating that the PV and medication safety department or unit was in the process of establishment and the hospital could not participate in the current

state), verbal feedback during a face-to-face meeting (indicating that the institution had not received ADR reports), and phone conversation with a hospital and private sector pharmacies. Other potential stakeholders did not respond to emails even after the initial visit of recruitment.

3.2.2.3. The Validity of the Interview Scripts

Not all interview scripts were checked to ensure their validity. The study key informants were informed that they would be able to validate the findings at their level, so the key informants were involved in the process based on their preference. Some, e.g., HMC, requested the full interview script; others, e.g., a private health organization, requested tabulated results; and others requested a final report and discussion to validate the findings. For example, the MOPH requested a one-hour meeting and an 8-page report discussing the findings; this meeting involved the primary supervisor and covered the MOPH case as well as the country PV scenario. Other stakeholders did not request any results, so no measures were taken.

3.2.2.4. Other Practical Limitations

I. Discrepancies in awareness of PV science among some stakeholders. This may have led to an arbitrary interpretation of the indicator requirements.
II. Difficulties encountered with high-level participant recruitment.
III. Difficulties in the process of interview organization (e.g., time consuming, organizational reasons or issues).
IV. Limitations in the interview process (e.g., inadequate interview time allocated, level of information provided).
V. Limitations related to participants (e.g., data provision, recall reliability, representation, and follow-up).

VI. Lack of reliable data sources and information for some PV KPIs (i.e., estimations were provided).

VII. Missing values and issues in follow-up (several stakeholders did not respond to emails requesting missing values for some PV KPIs).

VIII. Ethical approval delay (it took more than 7 months from the application date to obtain the HMC-MRC approval).

IX. Organizational issues related to participation and resistance to data sharing.

4. Recommendations

"What are the most important measures to improve the pharmacovigilance system in Qatar based on the WHO PV framework?" This question will be answered in the form of recommendations based on the structure, process, and outcome indicators:

4.1. Structure

I. The visibility of PV could be increased by establishing an independent national PV center to monitor the safety, effectiveness, and quality of medication in the country.

II. The PV center could be chaired by a PV expert capable of aiding the MOPH to produce high-quality, sufficient, and relevant data on medication safety and PV. Members of the PV center will need to have multidisciplinary backgrounds in order to achieve the desired PV goals.

III. There is a need to strengthen the PV regulatory framework and mechanisms in the country. It is advisable to identify and fill any gaps in the current laws and policies and ensure that they comply with the minimum functionality standards of PV systems. This should include the development, implementation, and enforcement of PV-specific legislation and a national medicine policy.

IV. Benchmark countries (e.g., the UK) and international PV regulations can be used as models for the development of the regulatory framework and the PV center. For instance, if feasible at the MENA region level, the Morocco PV system could be used as a benchmark.

V. Strategies aimed at streaming spontaneous reporting could be developed and implemented. They could include but are not limited to establishing a national database, developing national reporting forms, ensuring access to forms, providing various forms of incentives, protecting the rights of healthcare professionals and reporters in general, and safeguarding the ethical aspects.

VI. A specific committee or a focal contact point at each health institution could be implemented. This team or individual should be accountable for PV and drug safety at the institutional level e.g., a drug and therapeutics committee.

VII. Special technical tools, e.g., tools for data mining and signal generation, could be introduced for data analysis in future electronic databases.

VIII. The MOPH could establish a national PV committee as a solution to monitor drug safety and coordinate with representatives from various stakeholder systems until a specific center is established. This committee should have clear mandates that cover all aspects of PV. This committee along with the PV center establishment could optimize the interaction between stakeholders.

IX. A specific communication and transparency strategy could be developed to ensure that all parties (e.g., the public, academic institutions) are involved in the field of PV. This strategy needs to cover routine and crisis communication.

X. Resource acquisition (monetary and nonmonetary) for PV needs to be improved to ensure sustainable funding for PV. In addition, PV resource allocation needs to be strategically executed to ensure equity. Finally, PV resource accumulation must be

a priority at the managerial and administrative level across the country to ensure effective capacity building.

XI. Adequate inclusion of PV in educational programs must be a national priority to ensure the development of internal capacities.

XII. PV implementation in specific healthcare programs and organizations is strongly recommended. This can ensure the collation of PV data for specific populations, e.g., mental health and diabetes patients.

XIII. The pharmaceutical industry should be vigorously involved in PV to ensure effective national drug product monitoring. Also, medical device vigilance is required to ensure optimal monitoring of healthcare-related products.

XIV. Risk mitigation systems need to be developed and/or improved.

XV. Future strategies should be developed to plan and implement studies and activities that cover active PV aspects.

XVI. The visibility of the general public as key stakeholders in PV should be improved; this can include increasing the awareness of the public about PV as well as implementing public reporting.

XVII. Public reporting could be incorporated into the MyHealth patient portal (168).

XVIII. A drug information center or a drug information service could be established at the national level. This could be part of the PV center to reduce the cost and other resource implications. It is also recommended for the PV and drug information center to collaborate with the Qatar Poison Centre.

XIX. Strengthen the PV at the healthcare delivery level e.g., strengthen the drug and therapeutics committees.

4.2. Process

I. It is crucial to ensure strong links between the MOPH and other stakeholders through a mutually beneficial and participatory relationship.

II. Undergraduate and graduate students at different higher education institutions could be utilized to carry out some of the activities or studies for the MOPH system in relation to PV and drug safety issues. This would benefit them with hands-on experience and learning opportunities.

III. Continuous education and in-service training should be provided for healthcare professionals of different backgrounds.

IV. It is recommended that the MOPH review the relative contribution of different data sources (e.g., spontaneous reporting, medication-related studies, PSUR) to national drug safety information.

V. New methods, e.g., the use of information technology, are needed to address the issues of PV in a proactive manner.

VI. The current decision-making process at each level needs to be reviewed and shared in a more transparent manner to improve the process with respect to quality, effectiveness, time frame, and economics.

VII. Consider the feasibility of including higher educational institutions (one institution or more) in advanced studies for drug monitoring e.g., intensive drug monitoring.

VIII. Stakeholders are encouraged to review and improve the current methodologies used for risk mitigation activities, PV data analysis and management activities, and benefit/risk analysis.

IX. More awareness of the basic principles of PV systems, quality management systems, and risk management systems is necessary. The principles need to be understood at the administrative and practical levels.

X. Stakeholders need to set “SMART goals” for some PV KPIs in the future; those targets can be monitored regularly to continuously improve the capacity of the systems.

XI. The social media promotion and sale of medications need to be monitored by the relevant regulatory bodies.

4.3. Outcome

I. There is a need to utilize statistical methods and data analysis procedures to analyze the current healthcare system with respect to PV and drug safety outcome monitoring and/or evaluation. This includes reporting trends and the impact of PV activities on the financial outcomes as well as clinical outcomes.

II. The evaluation of the outcomes of PV warrants further investment (e.g., technical capacity, resources allocation, regulatory policies) at the national level since emerging safety information is needed.

III. Utilize PV data on health planning to optimize the utilization of national resources.

IV. Utilize PV data on auditing of PV targets and measuring the effectiveness of interventions to optimize patient care as well as the quality of services, regulatory framework, structures, and systems in general.

V. Systematically review and improve decision making process, regulatory actions and PV communication.

5. Conclusions

This mixed-methods research provides an in-depth understanding of the baseline pharmacovigilance (PV) situation in the state of Qatar through a comprehensive PV system assessment using internationally recognized tools developed by the World Health Organization (WHO). According to the WHO minimum requirements for a functional system, Qatar has none of the 5 elements required for an operational PV system. Consequently, the regulatory body for the PV system (the MOPH) achieved a weak total PV system performance status, which can impede the MOPH role in providing leadership for PV implementation. The main challenges faced by the MOPH are the lack of an organized PV center, lack of PV-specific statutory provisions to implement and enforce PV in Qatar, and limitations to communication and coordination with national stakeholders. The public sector (i.e., HMC and PHCC) achieved a good total PV system performance, signifying its important role in PV implementation. Similarly, most private sector healthcare institutions had a good total PV system performance, indicating that PV implementation in that sector can be considered appropriate. Gaps for both sectors were related to shortfalls in the technical capacity required for PV data analysis, including risk management and signal generation, the underreporting problem and lack of awareness of PV among the healthcare professionals, and communication gaps with national stakeholders. Moreover, the pharmaceutical industry PV system had a good total system performance. However, without national PV legislation, the potential role of the pharmaceutical industry in improving PV can be inadequate.

The national PV systems assessed across the different levels of the health care system showed discrepancies in PV system performance. National stakeholders' interest in PV was in the form of fragmented efforts aimed at improving PV in Qatar. The overall performance of the country, if addressed properly following a system-based approach, is

expected to result in the successful implementation of PV within the healthcare system. In addition, it is recommended that policymakers and administrative authorities prioritize challenges or specific aspects based on their influence on their PV system to implement corrective actions and/or improvement measures. To improve the national PV scenario and achieve the best possible PV system performance, the following steps must be taken. First, strengthen the PV regulatory framework, e.g., develop PV specific statutory provision. Second, establish an organized national PV center following benchmark countries, e.g., Morocco, as a model. Third, implement strategies to streamline spontaneous reporting, e.g., develop a national reporting system. Fourth, strategically execute resource acquisition, resource allocation, and resource accumulation for PV to ensure sustainability, equity, and effective capacity building. Fifth, develop a specific communication strategy to ensure strong links between the MOPH and other stakeholders. Sixth, improve the current methodologies used for risk mitigation activities, PV data analysis, and data management activities. Seventh, ensure the development of internal capacities through the adequate inclusion of PV in educational systems. Finally, implement active PV activities through multisectoral collaboration, e.g., among academia, research centers, and the MOPH. The outcomes of this research can potentially serve to target the challenges and utilize the available opportunities to help improve the current PV situation and ensure effective system performance and adequacy. Future investigations can focus on aspects relating to the governance of the PV system and the feasibility of establishing the proposed PV center organizational structure.

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APPENDIX A: METHODOLOGY CHAPTER RELATED CONTENT

M1. Qatar University ethical related documents:

1. QU-IRB research ethics approval (No. QU-IRB 826-E/17).

جامعة قطر
QATAR UNIVERSITY

Qatar University Institutional Review Board
QU-IRB

October 17, 2017

Ms. Abeer Abdullah Hamid
Graduate Student
Qatar University
Tel.: 33980023
Email: ah1513102@qu.edu.qa

Dear Ms. Abeer Hamid,

Sub.: **Research Ethics Review Exemption / Graduate Student Project**
Ref.: **Project titled, "A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar"**

We would like to inform you that your application along with the supporting documents provided for the above proposal, is reviewed and having met all the requirements, has been exempted from the full ethics review.

Please note that any changes/modification or additions to the original submitted protocol should be reported to the committee to seek approval prior to continuation.

Your Research Ethics Approval No. is: **QU-IRB 826-E/17**

Kindly refer to this number in all your future correspondence pertaining to this project.

Best wishes,

K. Hale

Dr. Khalid Al-Ali
Chairperson, QU-IRB

جامعة قطر
QATAR UNIVERSITY
Institutional Review Board
(IRB)
Office Of Academic Research

2. QU- College of Pharmacy Support Letter.

كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY جامعة قطر

Date: 27 September, 2017

To Whom It May Concern

Dear Sir/Madam,

Ref: Ms Abeer Abdullah Hamid, MSc Student at College of Pharmacy, Qatar University

Ms Abeer is a MSc student who is doing her MSc in Pharmacy Program at Qatar University.

She is conducting a research under my supervision. Her research topic is related to Pharmaceutical Policy and she is doing an Assessment of the PharmacoVigilance System in Qatar.

Your cooperation and support are very much appreciated and will definitely help in her MSc program.

Thank you.

Sincerely yours,

كلية الصيدلة
College of Pharmacy
جامعة قطر
QATAR UNIVERSITY

Mohamed Izham b. Mohamed Ibrahim, BPharm, PhD (PCPS, USA)
Professor of Social & Administrative Pharmacy
College of Pharmacy
Qatar University
P.O Box 2713
Doha, Qatar.
Tel: +974-44035580

3. QU- IRB approved consent form.

Refer to the PHCC consent form**.**

M2. Primary Healthcare Corporation (PHCC) ethical related documents:

1. PHCC Ethics Committee research ethics approval (first page only).

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

Primary Health Care Corporation
Clinical Affairs
Research Section
researchsection@phcc.gov.qa
Form RS/AF1

Research/Project/Study Approval Notice Form

Title of the Project:	A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar
Reference No:	**PHCC/IEC/17/10/036** **Date:23/11/2017**
Principal Investigator:	
Name	Ms. Abeer Abdullah Hamid
Title	Graduate student MSc
Department/Organization	Qatar University
Contact details	Email: ah1513102@qu.edu.qa ; Tell: 33980023

Required Information Checklist	**Ref. No**	**Yes**	**No**	**N/A**	**Date**
Research Proposal Submission Form signed and Completed		✓			
Research Proposal Supplementary Form Completed				✓	
HMC /WCMCQ IRB Approval Obtained, (or Previously HMC Research Committee Approval)				✓	
PHCC Research Committee Approval Obtained		✓			
Investigator agreement Form Signed		✓			
Other Ethics Committee Approval (Please specify) e.g. Qatar University		✓			
Informed Consent Form Copy Provided		✓			
Sponsors	Qatar University				

Dear Ms. Abeer,

Having considered the ethical and logistical (site specific) issues relating to the above project, the PHCC Independent Ethics Committee confirms that there are no objections to carrying out this project. Therefore the departments of Clinical Affairs and Operations give **approval** for it to commence. Please see the accompanying letter which sets out the **specific terms and conditions** of this approval that must be adhered to in carrying out your data collection.

We wish you every success in this endeavor.

Kind Regards,

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION
03 DEC 2017
Department Of Clinical Affairs

Dr. Hanan Al Mujalli
Executive Director of Clinical Affairs

30/11/17

Dr. Samya Ahmad Al Abdulla
Executive Director of Operations

For more information: Researchsection@phcc.gov.qa

2. PHCC consent form (first two pages only).

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

Primary Health Care Corporation
Clinical Affairs
Research Section
researchsection@phcc.gov.qa

Generic Signed Consent Form	موافقة مستبينة للمشاركة بدراسة بحث طبى
Participant Id:	رقم السجل:
DOB:	تاريخ الميلاد:
Gender:	الجنس (ذكر | أنثى) :
Nationality:	الجنسية:
A. General Information about Consent You are free to ask as many questions as you like before, during or after you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part and your refusal to participate will involve no penalty or loss of rights to which you are entitled. The investigator(s) may stop your participation in the study without your consent for reasons such as: it will be in your best interest; you do not follow the agreed study plan; or you experience a study-related adverse effect, discomfort, injury or other unexpected incident.	**أ. معلومات عامة حول الموافقة** كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل , أثناء إجراء, أو بعد إكمال إجراء البحث إذا قررت إعطاء الموافقة على المشاركة في هذا البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة والمشروعة. لأعضاء فريق البحث العلمى الخاص بهذه الدراسة الحق في إيقاف أو إلغاء مشاركتكم في هذه الدراسة إذا رأو مصلحة لكم فى هذا الإيقاف أو الإلغاء أو فى حالة عدم التزامكم بخطة البحث الموضوعة أو إذا تبين لهم ضرر أو إصابة نتيجة إجراء الدراسة وذلك دون أخذ موفقتكم
Project Title: **A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar**	**عنوان المشروع:** **نظام شامل للتيقظ الدوائي في دولة شرق أوسطية: تحليل نظام قطر**
Name of Principal Investigator Mohamed Izham B. Mohamed Ibrahim, PhD	**اسم الباحث الرئيسي** د. محمد إزهام محمد محمد إبراهيم
Each item given below has to be filled. Where not applicable, please state so.	يجب ملئ كل البنود أدناه وفي حال عدم توافر الإجابه الرجاء كتابة غير متوفر.

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends. No need for Stamp]* The present study involves multiple departments under each health institution. Also, the interviews will be conducted during the working hours of each Health institution. Interview location will depend on the participant department or unit (e.g. Quality Control Unit). The face-to-face interviews will be held privately with the participant as arranged with the researcher through phone or email. **Researcher name:** Abeer Abdullah Hamid **Role:** Graduate student (MSc Pharmacy) **Mobile**: +97433980023 **Email Address:** ah1513102@qu.edu.qa	**موقع إجراء البحث وأرقام الهواتف** *(أثناء أوقات الدوام, بعد الدوام و في العطلات)*: تتضمن هذه الدراسة إدارات متعددة تحت كل مؤسسة صحية. أيضا، سيتم إجراء المقابلات خلال ساعات عمل كل مؤسسة. ويتوقف موقع المقابلة على قسم أو وحدة المشاركين (مثل ووحدة مراقبة الجودة). وستجرى المقابلات وجها لوجه على انفراد مع المشاركين كما هو مرتب مع الباحث من خلال الهاتف أو البريد الإلكتروني. **اسم الباحث:** عبير عبد الله حامد **وظيفة:** طالبة دراسات عليا ماجستير **رقم الجوال:**+97433980023 **عنوان البريد الإلكتروني:**ah1513102@qu.edu.qa
1. **What is this research about?** *[A brief introduction is given about the research, what it hopes to achieve, who is conducting it etc.]* A pharmacovigilance (PV) system is an essential part of any medication safety system that is required to ensure the safe and effective use of medicines. The purpose of this study is to conduct an in-depth analysis of the existing PV and medicine safety system as a specific PV center is non-existing in Qatar. The study will be carried by a Graduate student (MSc) at Qatar University (Abeer Abdullah Hamid), under the mentorship of Dr. Mohamed Izham a Professor of Social & Administrative Pharmacy. A face-to-face interview will be conducted with potential stakeholders involved in ensuring medication safety and PV activities. We believe that you are a potential stakeholder and we hope that you will provide us with useful information about the current status of a pharmacovigilance (PV) in Qatar. The duration of each interview will vary between participants (from 30 minutes to 2 hours) depending on the availability and working hours. Also, when necessary multiple interviews can be held with the same participant such arrangement will be organized with the graduate student.	**1. مقدمة عن البحث الطبي** *(وصف موجز للدراسة وما يمكن تحقيقه من إجراء البحث ومن يقوم بإجراء البحث).* نظام التيقظ الدوائي هو جزء أساسي من أي نظام لسلامة الدواء وهو مطلوب لضمان الاستخدام الآمن والفعال للأدوية. الغرض من هذه الدراسة هو إجراء تحليل متعمق لنظام السلامة الدوائية الحالي في قطر نظرا لعدم وجود مركز محدد للتيقظ الدوائي في الدولة. سيتم إجراء هذه الدراسة من قبل طالبة ماجستير في علوم الصيدلة في جامعة قطر (عبير عبد الله حامد)، تحت إشراف الدكتور محمد ازهام أستاذ في الصيدلة الاجتماعية والإدارية. سيتم مقابلة أصحاب المصلحة المشاركين في ضمان سلامة الأدوية وأنشطة التيقظ الدوائي. نحن نؤمن بأنك أحد أصحاب المصلحة، ونأمل أن تزودنا بمعلومات مفيدة عن اليقظة الدوائية في قطر والوضع الحالي لها. ومدة كل مقابلة تختلف بين المشاركين في الدراسة (من 30 دقيقة الى 2 ساعة) اعتمادا على توافر الشخص وساعات العمل. أيضا، عند الضرورة يمكن إجراء مقابلات متعددة مع نفس المشارك سيتم تنظيم هذا الأمر مع طالبة الدراسات العليا.
2. **What is the Purpose of the research?:** *[Brief, clear description of the purpose, goals and objectives of the research are provided here]* ***50words***	**2. الغرض من إجراء دراسة البحث** *(وصف مختصر و واضح للغرض و الاهداف من وراء البحث).*

3. PHCC participant information sheet (first page only).

مؤسسة الرعاية الصحية الأولية
PRIMARY HEALTH CARE CORPORATION

Primary Health Care Corporation
Clinical Affairs
Research Section
researchsection@phcc.gov.qa

PARTICIPANT INFORMATION SHEET

Title of Project: A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar

Dear Participant,

We invite you to take part in this research project which we believe will help us to gather useful information about the current status of a pharmacovigilance (PV) and medicine safety system in Qatar. You are being invited because you are a potential stakeholder involved in ensuring medication safety and improving public health through your participation in different activities, process, and/or programs at your institution. We hope by taking part you will help us to gather the information we need. In this letter, we have provided answers to questions that you might wish to ask about the research.

What is this research and what is the Purpose of this research?:
A pharmacovigilance (PV) system is an essential part of any medication safety system that is required to ensure the safe and effective use of medicines.

The purpose of this study is to conduct an in-depth analysis of the existing PV and medicine safety system as a specific PV center is non-existing in Qatar. We aim to evaluate the baseline pharmacovigilance and medicine safety system structures, process, and achieved outcomes in Qatar. Also, we hope that we will be able to identify potential limitations and opportunities in the existing system that can help us to propose practical recommendations for the establishment of a national pharmacovigilance center.

The study will be carried by a Graduate student (MSc) at Qatar University (Abeer Abdullah Hamid), under the mentorship of Prof. Mohamed Izham a Professor of Social & Administrative Pharmacy.

Why have you been invited to participate as a research subject?: We are inviting you to join because you are a potential stakeholder involved in ensuring medication safety and improving public health through your participation in different activities, process, and/or programs at your institution. The information you provide us with and your work experience both are important to us.

How does this research differ from your routine care? [Optional]: Not Applicable.

What procedures will be carried out and why? : You will be introduced to the World Health Organization Pharmacovigilance Indicator Manual and an interview guide through email (1-4 weeks before the meeting). Based on the WHO PV indicators manual, the system analysis requires information from official documents and representative members at each institution. We will collect information by asking questions during a recorded interview and we will require reviewing documents from your institution. Also, the documents will be used with respect to the legal requirement at each study site.

Are there any risks and discomforts involved? What safety precautions are we taking in this research?: The interview will take some of your time to complete it and some of your confidential information like your contact number will be collected for the purpose of research still measures have been taken into consideration to keep your information confidential and minimize any associated risks. In addition, there might be risks that we can't predict at this time.

What are the benefits of the study?: This study does not offer direct benefit to the participant. However, possible benefits to others can be achieved as the results and proposed recommendations can help to plan for policies, activities, and programs to improve public health and ensure medication safety in Qatar.

In case of Injury or if you wish to make an enquiry during the research, who do you contact?
You can contact the principal investigator for any concerns and/or complaints about the study or to report any injury or discomfort.
Name: Mohamed Izham B. Mohamed Ibrahim, PhD

Dec, 2014

M3. Hamad Medical Corporation (HMC) ethical related documents:

1. The Medical Research Center at HMC approval.

5/14/2018

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

CLOSURE NOTICE
MEDICAL RESEARCH CENTER
HMC, DOHA-QATAR

Dr. Moza Sulaiman H Al Hail **Executive Director Pharmacy** **Clinical Services Unit** **Hamad Medical Corporation**	**Date: 08th May 2018**
Protocol No.	MRC-01-17-069
Study Title:	A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar
Team Member List:	Dr. Moza Sulaiman H Al Hail , Mrs. Abeer Abdullah Hamid , Prof. Mohamed Izham Mohamed Ibrahim
Subject:	Closure Notice- Quality Improvement Project

We would like to inform you that Medical Research Center has determined this project as 'Quality Improvement/Audit' and hence will not come under the purview of the Medical Research Center.

It is the responsibility of the Principal Investigator to ensure that appropriate approvals from Hospital/Department are in place.

Yours sincerely,

Prof. William John Mckenna
Institutional Officer for Research
HMC

Prof. William John McKenna
Chief Executive Office & Medical Director
Heart Hospital - HMC
038438

Medical Research Centre
Hamad Medical Corporation - Doha - Qatar

Date: 08th May 2018

1/1

2. HMC Consent form (first two pages only).

1. Title of research

A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar

2. Principal Investigator

Professor Moza Al Hail, Executive Director of Pharmacy, Hamad Medical Corporation

3. Why are we inviting you to join this research?

The investigator and colleagues at Qatar university College of Pharmacy and Hamad Medical Corporation (HMC) are conducting this research.

We are inviting you to join because you are a potential stakeholder involved in ensuring medication safety and improving public health through your participation in different activities, process, and/or programs at your institution. The information you provide us with and your work experience both are important to us.

4. What should you know about this research?

- We will explain the research to you
- Whether or not you join is your decision (you can accept or refuse no matter who is inviting you to participate)
- Please feel free to ask questions or mention concerns before deciding, or during or after the research
- You can say yes but change your mind later
- We will not hold your decision against you

5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:

- Name: Mohamed Izham B. Mohamed Ibrahim, PhD
- Email address: mohamedizham@qu.edu.qa
- Contact number (Telephone): 4403-5580

- Researcher name: Abeer Abdullah Hamid
- Role: Graduate student (MSc Pharmacy)
- Mobile: +97433980023
- Email Address: ah1513102@qu.edu.qa

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC Institutional Review Board (HMC-IRB) Chair at 5554 6316
- HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.qa

6. Why are we doing the research?

The purpose of this study is to evaluate the baseline pharmacovigilance and medicine safety system structures, process, and achieved outcomes in Qatar.

We hope that we will be able to identify potential opportunities and limitations and in the existing system that can help us to propose practical recommendations for further improvement in the current system as well as for the establishment of a national PV center

7. How long will the research take?

We think that you will be in the research for at least one interview that lasts for 30 minutes. As the duration of the interview for each participant will be different. After you provide your consent to participate you will be interviewed from 30 minutes to 2 hours. Also, when necessary multiple interviews can be held with you, such arrangement will be organized with the graduate student.
We expect the research to last for 5 months.

8. How many people will take part?

We plan to study 10 people. The research will include at least 25 people across all locations.
No specific sample size will be required. As we are following a research method that requires the collection of all related information. Thus, no specific number of participants can be determined at the current time.

9. What happens if you take part?

If you agree to join, we will ask you to do the following:

- You will be introduced to the World Health Organization Pharmacovigilance Indicator Manual and an interview guide through email (1-4 weeks before meeting).
- We will collect information by asking questions during a recorded interview that lasts from 30 minutes to 2 hours.
- We will require to review documents from your institution (e.g. policy documents, hospital databases, records, relevant official documents, surveys that are specific to each study site) . Also, the documents will be used with respect to the legal requirement at each study site.
- You will be contacted by the graduate student if further information is required.

10. Could the research be bad for you?

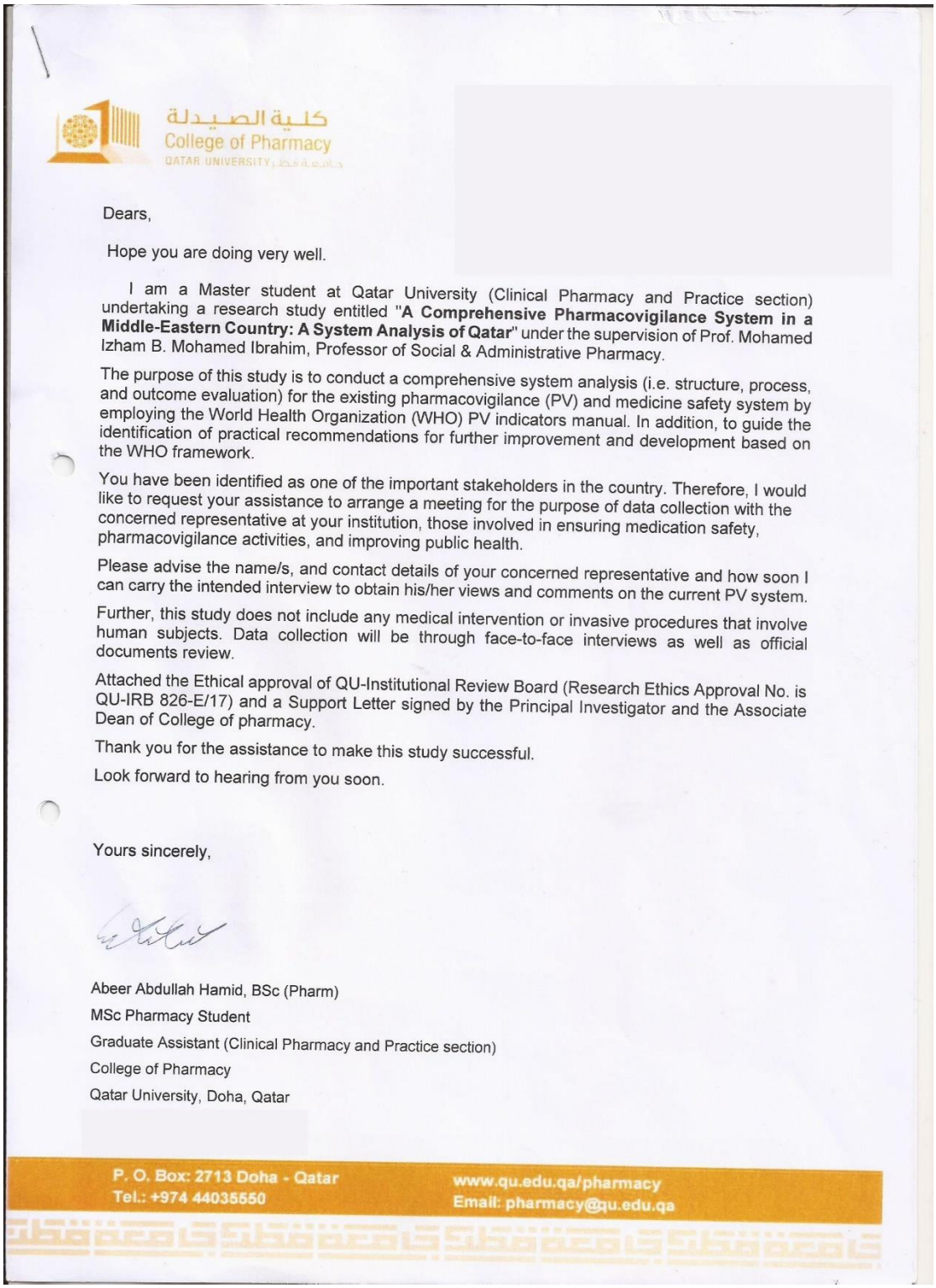
The interview will take some of your time to complete it and some of your confidential information like your contact number will be collected for the purpose of research still measures has been taken in consideration to keep your information confidential and minimize any associated risks.

11. Could the research be good for you?

There are no benefits to you from joining this research. However, possible benefits to others include using the results and proposed recommendations of the study to plan for policies, activities, and programs to improve public health and ensure medication safety in Qatar.

12. What happens to information about you?

M4: Email and hard copy invitation letter.



كلية الصيدلة
College of Pharmacy
QATAR UNIVERSITY

Dears,

Hope you are doing very well.

I am a Master student at Qatar University (Clinical Pharmacy and Practice section) undertaking a research study entitled "**A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar**" under the supervision of Prof. Mohamed Izham B. Mohamed Ibrahim, Professor of Social & Administrative Pharmacy.

The purpose of this study is to conduct a comprehensive system analysis (i.e. structure, process, and outcome evaluation) for the existing pharmacovigilance (PV) and medicine safety system by employing the World Health Organization (WHO) PV indicators manual. In addition, to guide the identification of practical recommendations for further improvement and development based on the WHO framework.

You have been identified as one of the important stakeholders in the country. Therefore, I would like to request your assistance to arrange a meeting for the purpose of data collection with the concerned representative at your institution, those involved in ensuring medication safety, pharmacovigilance activities, and improving public health.

Please advise the name/s, and contact details of your concerned representative and how soon I can carry the intended interview to obtain his/her views and comments on the current PV system.

Further, this study does not include any medical intervention or invasive procedures that involve human subjects. Data collection will be through face-to-face interviews as well as official documents review.

Attached the Ethical approval of QU-Institutional Review Board (Research Ethics Approval No. is QU-IRB 826-E/17) and a Support Letter signed by the Principal Investigator and the Associate Dean of College of pharmacy.

Thank you for the assistance to make this study successful.

Look forward to hearing from you soon.

Yours sincerely,

Abeer Abdullah Hamid, BSc (Pharm)
MSc Pharmacy Student
Graduate Assistant (Clinical Pharmacy and Practice section)
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M5. Data Collection instrument 1: The World Health Organization pharmacovigilance indicators ready-to-use checklist.

WHO Pharmacovigilance Indicators

A Practical Manual for the Assessment of Pharmacovigilance Systems

[Assessment Checklist]

World Health Organization

PART 1: CORE INDICATORS

CORE STRUCTURAL INDICATORS

	Assessment questions	Data sources used	Answer (yes=2/no=0) or value)	Optional: proposed next steps?
CST1	Is there a pharmacovigilance centre, department or unit with a standard accommodation?			
CST2	Is there a statutory provision (national policy, legislation) for pharmacovigilance?			
CST3	Is there a drug regulatory authority or agency?			
CST4	Is there any regular financial provision (e.g. statutory budget) for the pharmacovigilance centre?			
CST5	Does the pharmacovigilance centre have human resources to carry out its functions properly?			
CST6	Is there a standard ADR reporting form in the setting?			
	CST6a: Are there relevant fields in the standard ADR form to report suspected medication errors?			
	CST6b: Are there relevant fields in the standard ADR form to report suspected counterfeit/ substandard medicines?			
	CST6c: Are there relevant fields in the standard ADR form to report therapeutic ineffectiveness?			
	CST6d: Are there relevant fields in the standard ADR form to report suspected misuse, abuse and/or dependence on medicines?			
	CST6e: Is there a standard ADR reporting form for the general public?			
CST7	Is there a process in place for collection, recording and analysis of ADR reports?			
CST8	Is pharmacovigilance incorporated into the national curriculum of the various health care professions?			

Core structural indicators *(continued)*				
	Assessment questions	**Data sources used**	**Answer (yes=2/no=0) or value)**	**Optional: proposed next steps?**
CST8	CST8a: Is pharmacovigilance incorporated into the national curriculum of medical doctors?			
	CST8b: Is pharmacovigilance incorporated into the national curriculum of dentists?			
	CST8c: Is pharmacovigilance incorporated into the national curriculum of pharmacists?			
	CST8d: Is pharmacovigilance incorporated into the national curriculum of nurses or midwives?			
	CST8e: Is pharmacovigilance incorporated into the national curriculum of others – to be specified?		(yes/no, **and** specify "others")	
CST9	Is there a newsletter, information bulletin or website (a tool for pharmacovigilance information dissemination?)			
CST10	Is there a national ADR or pharmacovigilance advisory committee or an expert committee in the setting capable of providing advice on medicine safety?			
CORE PROCESS INDICATORS				
CP1	What is the total number of ADR reports received in the previous year?			
	CP1a: What is the total number of ADR reports received in the previous year per 100 000 people in the population?			
CP2	How many reports are (current total number) in the national/regional/local database?			
CP3	What is the percentage of total annual reports acknowledged/issued feedback?			
CP4	What is the percentage of total reports subjected to causality assessment in the past year?			

	Assessment questions	Data sources used	Answer (yes=2/no=0) or value)	Optional: proposed next steps?
CP5	What is the percentage of total annual reports satisfactorily completed and submitted to the national pharmacovigilance centre in the previous year?			
	CP5a: Of the reports satisfactorily completed and submitted to the national pharmacovigilance centre, what percentage were committed to the WHO database?			
CP6	What is the percentage of reports of therapeutic ineffectiveness received in the previous year?			
CP7	What is the percentage of reports on medication errors reported in the previous year?			
CP8	What percentage of registered pharmaceutical companies have a functional pharmacovigilance system?			
CP9	How many active surveillance activities are or were initiated, ongoing or completed in the past 5 years?			
CORE OUTCOME/IMPACT INDICATORS				
CO1	How many signals were generated in the past 5 years by the pharmacovigilance centre?			
CO2	How many regulatory actions were taken in the preceding year consequent on national pharmacovigilance activities?			
	CO2a: how many product label changes (variation)?			
	CO2b: how many safety warnings on medicines to: CO2bi, health professionals CO2bii, the general public?			
	CO2c: how many withdrawals of medicines?			
	CO2d: how many other restrictions on use of medicines?			

Core outcome/impact indicators *(continued)*				
	Assessment questions	**Data sources used**	**Answer (yes=2/no=0) or value)**	**Optional: proposed next steps?**
CO3	What is the number of medicine-related hospital admissions per 1000 admissions?			
CO4	What is the number of medicine-related deaths per 1000 persons served by the hospital per year?			
CO5	What is the number of medicine-related deaths per 100 000 persons in the population?			
CO6	What is the average cost (US$) of treatment of medicine-related illness?			
CO7	What is the average duration (days) of medicine-related extension of hospital stay?			
CO8	What is the average cost (US$) of medicine-related hospitalization?			
PART 2: COMPLEMENTARY INDICATORS				
COMPLEMENTARY STRUCTURAL INDICATORS				
		Data sources	**Answer (yes=1/no=0)**	**Optional:**
ST1	Is there a dedicated computer for pharmacovigilance activities?			
ST2	Is there a source for data on consumption and prescription of medicines?			
ST3	Are there functioning and accessible communication facilities in the pharmacovigilance centre?			
ST4	Is there a library or any other reference source for drug safety information?			
ST5	Is there a computerized case report management system?			
ST6	Is there a programme (including a laboratory) for monitoring the quality of pharmaceutical products?			
	ST6a: Is the programme (including a laboratory) for monitoring the quality of pharmaceutical products, collaborating with the pharmacovigilance programme?		Not applicable or yes or no	

	Assessment questions	Data sources used	Answer (yes=1/no=0) or value)	Optional: proposed next steps?
ST7	Is there an essential medicines list in use?			
ST8	Are pharmacovigilance data considered when developing the main standard treatment guidelines?			
ST9	Does the pharmacovigilance centre organize training courses? ST9a: for health professionals? ST9b: for the general public?			
ST10	Are web-based pharmacovigilance training tools available? ST10a: for health professionals? ST10b: for the general public?			
ST11	Are there requirements mandating market authorization holders to submit periodic safety update reports?			
COMPLEMENTARY PROCESS INDICATORS				
P1	Last year, what was the percentage of health-care facilities that had a functional pharmacovigilance unit (i.e. submits ≥ 10 reports annually to the pharmacovigilance centre)?			
P2	What was the percentage of total reports sent in the previous year by the different stakeholders:			
	P2a: percentage of the total reports sent by medical doctors			
	P2b: percentage of the total reports sent by dentists			
	P2c: percentage of the total reports sent by pharmacists			
	P2d: percentage of the total reports sent by nurses or midwives			
	P2e: percentage of the total reports sent by members of the general public			
	P2f: percentage of the total reports sent by manufacturers			

Complementary process indicators *(continued)*				
	Assessment questions	**Data sources used**	**Answer (yes=1/no=0) or value)**	**Optional: proposed next steps?**
P3	What is the total number of reports received per million population per year?			
P4	What is the averagenumber of reports per total number of health-care providers per year?			
	P4a: number of reports per total number of medical doctors			
	P4b: Average number of the total of reports sent by dentists			
	P4c: Average number of the total of reports sent by pharmacists			
	P4d: Average number of the total of reports sent by nurses or midwives			
P5	What is the percentage of health-care providers aware of and knowledgeable about ADRs per health facility?			
P6	What is the percentage of patients leaving a health facility aware of ADRs in general?			
P7	How many face to face training sessions were conducted on pharmacovigilance in the previous year? P7a: number of face to face pharmacovigilance training sessions for health professionals P7b: number of face to face pharmacovigilance training sessions for general public			
P8	How many individuals received face to face training in pharmacovigilance in the previous year? P8a: number of health professionals P8b: number of individuals from general public			
P9	How many national reports for a specific product per volume of sales of that product in the country (product specific) from the industry?			

	Assessment questions	Data sources used	Answer (yes=1/no=0) or value)	Optional: proposed next steps?
P10	How many registered products with a pharmacovigilance plan and/or a risk management strategy from market authorization holders exist in the country?			
	P10a: what is the percentage of registered products with a pharmacovigilance plan and/or a risk management strategy from market authorization holders in the country?			
P11	What is the percentage of market authorization holders submitting periodic safety update reports (PSURs) to the regulatory authority as stipulated in the country?			
P12	Last year, how many products were voluntarily withdrawn by market authorization holders because of safety concerns?			
	P12a: Last year, how many summaries of product characteristics (SPCs) were updated by market authorization holders because of safety concerns?			
P13	How many reports per each registered pharmaceutical industry were received by the pharmacovigilance centre in the previous year?		One number per registered pharmaceuti-cal company	
COMPLEMENTARY OUTCOME/IMPACT INDICATORS				
O1	What is the percentage of preventable ADRs out of the total number of ADRs reported in the preceding year?			
O2	How many medicine-related congenital malformations per 100 000 births?			
O3	Number of medicines found to be possibly associated with congenital malformations in the past 5 years			
O4	Percentage of medicines that are counterfeit/substandard in the pharmaceutical market			
O5	Number of patients affected by a medication error in hospital per 1000 admissions in the previous year			

Complementary outcome/impact indicators *(continued)*				
	Assessment questions	**Data sources used**	**Answer (yes=1/no=0) or value)**	**Optional: proposed next steps?**
O6	Average work or schooldays lost due to drug-related problems			
O7	Cost savings (US$) attributed to pharmacovigilance activities			
O8	Health budget impact (annual and over time serial) attributed to pharmacovigilance activity			
O9	Average number of medicines per prescription			
O10	Percentage of prescriptions with medicines exceeding recommended dose			
O11	Percentage of prescriptions containing medicines with potential for interaction			
O12	Percentage of patients receiving information on the use of their medicines and on potential ADRs associated with those medicines			
PART 3: INDICATORS FOR PUBLIC HEALTH PROGRAMMES (PHP)				
PH1	Are pharmacovigilance activities in place within the public health programme (PHP)?			
PH2	Do all main treatment guidelines or protocols in use within the PHP systematically consider pharmacovigilance			
PH3	Is there a standard ADR reporting form in the setting?			
	PH3a: are there relevant fields in the standard ADR form to report suspected medication errors?			
	PH3b: are there relevant fields in the standard ADR form to report suspected counterfeit/substandard medicines?			
	PH3c: are there relevant fields in the standard ADR form to report therapeutic ineffectiveness?			

	Assessment questions	Data sources used	Answer (yes=1/no=0) or value)	Optional: proposed next steps?
PH3	PH3d: are there fields in the standard ADR form to report suspected misuse, abuse and/or dependence on medicines?			
PH4	What is the total number of ADR reports collected within the PHP in the previous year?			
PH5	How many ADR reports (per 1000 individuals exposed to medicines in the PHP) were reported in the previous year?			
PH6	How many reports on therapeutic ineffectiveness were made in the previous year?			
PH7	What percentage of completed reports were submitted to the national pharmacovigilance centre in the previous year?			
	PH7a: Of the reports satisfactorily completed and submitted to the national pharmacovigilance centre, what is the percentage of reports committed to the WHO database?			
PH8	What is the number of medicine-related hospital admissions per 1000 individuals exposed to medicines in the PHP in the previous year?			
PH9	What is the number of medicine-related deaths per 1000 individuals exposed to medicines in the PHP in the previous year?			

M6: PV indicators used at each data collection level.

Table M6: PV indicators used at each data collection level.

Table: PV indicators used at each data collection level.		
Stakeholder level	Relevant indicators	Not relevant indicators
Regulatory body system level (MOPH)	Core: (structure): 1-10 relevant (process) 1-9 relevant (outcome)1-8 relevant	
	Complementary: (structure) 1-11 relevant (process) 1-4,7-13 relevant (outcome) 1-4,7-8 relevant	Complementary: (process) 5-6 not relevant (outcome) 5-6,9-12 not relevant

Public sector level (HMC)	Core: (structure): 1-2, 4-7,9-10 relevant (process): 1-7,9 relevant (outcome): 2,3-4,6-8 relevant	Core: (structures): 3,8 not relevant (process): 8 not relevant (outcome): 2,5 not relevant
	Complementary: (structure): 1-5,7-10 relevant (process): 2,4-8 relevant (outcome): 1,9-12 relevant	Complementary: (structures): 6,11 not relevant (process): 1,3,9-13 not relevant (outcome): 2-8 not relevant
Public sector level (PHCC)	Core: (structure): 1-2,4-7,9-10 relevant (process): 1-7,9 relevant (outcome):1 relevant	Core: (Structure): 3,8 not relevant (process): 8 not relevant (outcome):2-8 not relevant
	Complementary: (structure):1-5,7-10 relevant (process):2,4-8 relevant (outcome): 1,9-12 relevant	Complementary: (structure):6,11 not relevant (process):1,3,9-13 not relevant (outcome): 2-8 not relevant
Private sector level (Health institutions)	Core (structure):1-2,4-7,9-10 relevant (process):1-7,9 relevant (outcome):1,3-4,6-8 relevant	Core (structure): 3,8 not relevant (process): 8 not relevant (outcome):2,5 not relevant
	Complementary (structure):1-5,7-10 relevant (process): 2,4-8 relevant (outcome):1,5-12 relevant	Complementary (structure): 6,11 not relevant (process): 1,3,9-13 not relevant (outcome): 2-4 not relevant
Private sector level (pharmacies)	Core (structure):1-2,4-7,9-10 relevant (process):1-3,5 relevant (outcome):All not relevant	Core (structure): 3,8 not relevant (process): 4,6-9 not relevant (outcome):All not relevant

	Complementary (structure):1-5,9-10 relevant (process):5-8 relevant (outcome):1,7-12 relevant	Complementary (structure):6-8,11 not relevant (process):1-4,9-13 not relevant (outcome):2-6 not relevant
Pharmaceutical industry		
	Core (structure):1-2,4-7.9-10 relevant (process):1-5,8-9 relevant (outcome):1-2 relevant	Core (structure):3,8 not relevant (Process):6-7 not relevant (outcome):3-8 not relevant
	Complementary (structure):1,3-6,9-10 relevant (process):2,4,7-8,10-12 relevant (outcome):7-8 relevant	Complementary (Structure):2,7-8,11 not relevant (process):1,3,5-6,9,13 not relevant (outcome):1-6,9-12 not relevant
Academic institutions	CST8	

M7: A List of Stakeholders who were approached but did not agree to participate.

I. Private hospital: refused to participate by email as they do not have a pharmacovigilance or medication safety unit at that time.

II. Private hospital: refused to participate as they said that they are busy with renewing the license.

III. Private hospital: did not want to participate in a face to face interview they wanted by email thus I did not include them.

IV. Chain pharmacy group: did not agree or disagree to participate. I have sent emails and contacted them through phone communication, but they did not arrange a final meeting.

V. Chain pharmacy group: did not agree or disagree to participate I have sent emails for 4 people and contacted them through phone, but they did not reply to arrange a final meeting.

VI. Qatar Diabetes Association: refused to participate through verbal communication as they do not have pharmacovigilance related activities e.g. ADRs report collection.

VII. National Cancer Strategy: did not respond to emails.

VIII. National Diabetes Strategy: did not agree or disagree to participate. I have sent emails, but they did not arrange a final meeting.

IX. Pharmaceutical industry: did not respond to emails or phone calls.

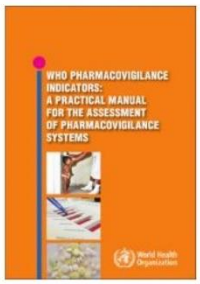
M8. Stakeholder level enrolment and meeting details.

Table M8. Stakeholder level enrolment and meeting details

Stakeholder level	**Ethical approval**	**First approached (emails and site visit)**	**Meeting details**
Ministry of Public Health (MOPH): • The Department of Pharmacy and Drug Control • The Department of Quality and Patient Safety (HQPS)	QU-IRB	November 2017	Five meetings 2/2018 to 6/2018
Primary Healthcare Corporation (PHCC): • Medication Management Section • Risk management section • Clinical Information Systems team • Health Information Management team	PHCC Ethics committee	December 2017	Two meetings • 2/2018 • 5/2018
Hamad Medical Corporation (HMC): • Medication Safety and Quality Center (MSQC) • HMC Pharmacy Department	HMC-MRC	May 2018	Five meetings, from 6/2018 to 6/2019
Academia universities: 6 universities and/or colleges	QU-IRB	November 2017	One meeting for each university,

Stakeholder level	Ethical approval	First approached (emails and site visit)	Meeting details
			from 1/2018 to 5/2018
Mental Health Strategy	QU-IRB	November 2017	One meeting, 5/2018
Pharmaceutical industry	QU-IRB	November 2017	Two meetings, 5/2018
The private sector, a total of five health facilities: • Three private hospitals • One semi-governmental hospital • One private healthcare group	QU-IRB and Hospital Ethics approval when applicable	November 2017-December 2017	• Hospital: one meeting, 3/2018 • Hospital: five meetings, 1/2018 • Hospital: three meetings, 4/2018 • Hospital: four meetings, 4/2019 • Hospital: four meetings, 5/2019
Community pharmacy, a total of two: • One independent pharmacy (24 hours service delivery) • One chain of pharmacies	QU-IRB	November 2017	• Chain pharmacy one meeting, 5/2018 • Independent pharmacy one meeting, 4/2018

M9. Data collection instrument 2: Semi-structured interview protocol (General).



WHO PHARMACOVIGILANCE INDICATORS

A practical manual for the assessment of pharmacovigilance systems

ABSTRACT

This document summarizes the assessment questions and the purpose of each assessment question.

Abeer Abdullah Hamid

PART 1: CORE INDICATORS			
CORE STRUCTURAL INDICATORS			
	Assessment questions (Main)	**Assessment questions (supplementary from the indicator manual)**	**Purpose of the indicator (quotations from WHO)**
CST1	Is there a pharmacovigilance centre, department or unit with a standard accommodation?	• Does the accommodation have basic equipment's and facilities required to receive, analyze, and transmit ICSR? • Does the pharmacovigilance center, department or unit provide the necessary feedback and enable PV communication? • Comment on the functionality and the stage of development of this pharmacovigilance center, department or unit?	The existence of a space for pharmacovigilance activity provides the necessary visibility for pharmacovigilance and a meeting point for interaction. It also indicates political and administrative commitment towards achieving pharmacovigilance objectives.
CST2	Is there a statutory provision (national policy, legislation) for pharmacovigilance?	• Who is the body responsible for the development and implementation of legislation and policy? • The existing legislation and policy are: 1. Specific to PV and medication safety 2. Comprehensive in covering PV aspects 3. Up to date 4. Well enforced and implemented	The existence of this instrument underscores the commitment of the government of the setting to ensuring the safe use of medicines. The instrument should spell out specifics empowering the appropriate authorities to carry out pharmacovigilance activities with well-defined roles and responsibilities.
CST3	Is there a drug regulatory authority or agency?	• None.	The presence of a regulatory agency suggests the availability of a regulatory framework for pharmaceutical products in the setting being an important stakeholder and focal point for promoting pharmacovigilance.
CST4	Is there any regular financial provision (e.g. statutory budget)	• What is the actual budgetary allocation (the total amount)?	The availability of funding represents the possibility for the centre to carry out

	for the pharmacovigilance centre?	• Is the current budget considered sufficient to ensure the effective operation of PV?	pharmacovigilance activities in the setting. It also signifies a gesture, the commitment and political will of the sponsors and the general importance given to pharmacovigilance.
CST5	Does the pharmacovigilance centre have human resources to carry out its functions properly?	• Describe the number of full and part-time staff. • Describe the level of staff expertise and how they are being assessed. • Are the staff trained in PV aspects? • Are they considered sufficient to ensure the effective operation of PV?	This indicator suggests the presence of human resources in the pharmacovigilance centre, department, unit to take on the various duties and responsibilities expected.
CST6	Is there a standard ADR reporting form in the setting? Subset indicators: The standard reporting form provides for reporting: CST6a: suspected medication errors; CST6b: suspected counterfeit/substandard medicines; CST6c: therapeutic ineffectiveness; CST6d: suspected misuse, abuse of and/or dependence on medicines; CST6e: ADRs by members of the general public	• Does the reporting form contain all the required elements for causality assessment (as per ICH-E2A: 1. Reporter; 2. identifiable patient; 3. suspected medicines; 4. adverse reaction.)? • The reports, are they fully integrated into the system and been utilized effectively? • What is the process to avoid duplication of reports? • Do you consider the general public as an important stakeholder in PV? • Describe your institution preparedness to support reporting by the general public including ADR reporting?	The indicator measures the presence in the setting of a data collection tool for pharmacovigilance operations. It suggests that the requisite tool for collecting critical information on a suspected case of medicine-related harm has been fully integrated into the pharmacovigilance system. The reporting form should contain all elements normally required to enable causality assessment of a case based on clinical evidence.
CST7	Is there a process in place for collection, recording and analysis of ADR reports?	• Describe the presence of a report management process including the electronic database, the evidence-based causality assessment, and the provision of feedback.	This indicator is a measure of the functionality and presence of an operational process in the pharmacovigilance centre.

CST8	Is pharmacovigilance incorporated into the national curriculum of the various health care professions? includes subset indicators: CST8a: for medical doctors; CST8b: for dentists; CST8c: for pharmacists; CST8d: for nurses or midwives; CST8e: for others – to be specified)	• Refer to the CST8 Indicator Meeting Agenda.	The incorporation of pharmacovigilance into the national curriculum for training health professionals suggests an early exposure to pharmacovigilance for the various categories of personnel engaged in the care of patients.
CST9	Is there a newsletter, information bulletin or website (a tool for pharmacovigilance information dissemination?)	• Describe the system used for regular dissemination of PV information to the health care professionals and the general public. • Comment on the quality, frequency, and relevance, and effectiveness of information communicated on the subject pharmacovigilance. • How do you measure the impact of information on healthcare professional behavior? • Describe your strategy of communication during crises. • Comment on the institution actual preparedness to communicate in the event of crises.	A clear strategy for routine communication and communication during crises is one of the minimum requirements for a functional national pharmacovigilance system.
CST10	Is there a national ADR or pharmacovigilance advisory committee or an expert committee in the setting capable of providing advice on medicine safety?	• Describe the qualification, sufficiency, competency, and accessibility to support and give advice on basic PV activities like causality assessment, risk assessment, risk management.	This refers to the existence of a qualified committee that can provide advice and technical assistance on causality assessment, risk assessment, risk management, case investigation and,

		• Describe the number of people, the professional background of the committee members. • How regularly do the members meet on routine and emergency bases? • How relevant their advice to PV?	where necessary, crisis management including crisis communication.
CORE PROCESS INDICATORS			
CP1	What is the total number of ADR reports received in the previous year? Also expressed as CP1a: What is the total number of ADR reports received in the previous year per 100 000 people in the population?	• Comment on the healthcare professional's awareness of ADRs and willingness to report. • What are the measures taken to improve reporting? • Comment on the quality of documentation and its relevance for signal identification.	The indicator serves to measure the pharmacovigilance activity in the setting, the awareness of ADRs and the willingness of health professionals to report.
CP2	How many reports are (current total number) in the national/regional/local database?	• Comment on the strength of your created database with respect to its size and pace of growth over time. • Comment on reporting trends and rationale behind the observed trends.	It is a measure of pharmacovigilance activities in the setting and the strength of the database.
CP3	What is the percentage of total annual reports acknowledged/issued feedback? The indicator can then be calculated as follows: (Number of reports provided with feedback during the one-year period /Total number of reports received during the one-year period) × 100	• Describe the acknowledgment and feedback process. • Comment on the quality of the feedback provided. • what is the estimated time lag between receiving a report and issuing feedback? • How do you address cases where delay in feedback occurred? • Do you document the feedback provided?	It is expected that in response to receiving a report, the personnel in the pharmacovigilance centre will provide an informed acknowledgement to the reporting health-care personnel. The number of reports provided with this feedback is documented. It is a measure of the responsiveness of the centre to submitted reports.
CP4	What is the percentage of total reports subjected to causality assessment in the past year?	• Describe the process of causality assessment including tools or statistical analysis.	The proportion of reports assessed in the centre is an indication of the level of commitment to processing the safety data
	The indicator value can be calculated as follows: (Number of reports subjected to causality assessment in the year/Total number of reports received in the same period) × 100	• Comment on the level of commitment in processing safety data and how do you ensure the quality of this process. • Comment on the level of expertise and the number of people carrying out the causality assessment process.	and ensuring its quality, especially when committing reports to the WHO database. Low values might suggest a lack of the necessary expertise to carry out causality assessment and a weak pharmacovigilance system.
CP5	What is the percentage of total annual reports satisfactorily completed and submitted to the national pharmacovigilance centre in the previous year? The indicator value can be calculated as follows: (Number of reports filled satisfactorily during the year/Total number of reports received during the same period) × 100 CP5a: Of the reports satisfactorily completed and submitted to the national pharmacovigilance centre, what percentage were committed to the WHO database? The value of the subset indicator CP5a is obtained as follows: (Number of reports filled in satisfactorily and committed to the WHO database during the year/Total number of reports	• Comment on the level of healthcare professionals understanding of the required elements to be filled in the form. • Comment on the level of commitment to send reports to the Ministry of Public Health as well as the pharmaceutical industry. • Is there a systematic evaluation process? • Is there a future plan to incorporate a routine systematic evaluation in the institution system? • What are the perceived limitations to establish a systematic evaluation process (e.g. expertise, time, resources, efforts, etc.)?	The indicator value reflects the quality of reports received by the centre. It is an indication of the understanding by the health professionals of the elements in the ADR forms and the willingness and care taken to fill in the forms before submitting them to the centre. The value of the subset indicator reflects the commitment of the centre to sending reports to the WHO database, which is a requirement for national pharmacovigilance centres that are full members of the WHO Programme for International Drug Monitoring.

	received during the same period) × 100		
CP6	What is the percentage of reports of therapeutic ineffectiveness received in the previous year? The indicator value can be calculated as follows: (Number of reports of therapeutic ineffectiveness received in the year/Total number of reports received in the same year) × 100	• Do you document the factors that contribute to the therapeutic failure (e.g. quality of medication, drug resistance, patient adherence, etc.)? • Do you keep documentation of therapeutic failure trends? • Describe the process established to determine the existence of a therapeutic issue or pharmaceutical issue.	This indicator identifies failed treatments owing to lack of effectiveness of medicines used in the health-care system. The occurrences of failed treatment in the health setting attributable to medicines suggest the existence of pharmaceutical or therapeutic issues that should be addressed.
CP7	What is the percentage of reports on medication errors reported in the previous year?	• Describe the process that you follow to ensure a positive disclosure from the stage of detection to the stage of communication. • Do you conduct an in-depth review of reports to detect any medication errors reported solely as an adverse drug reaction? • Comment on the magnitude of medication error in your institution is it high, moderate, or low? • What are the factors that affect the process of medication error reporting?	This indicator identifies failure in treatment processes that resulted in harm to patients. The occurrence of these errors suggests the existence of fundamental systemic issues which should be addressed to ensure patient safety. Absolute numbers should be documented and the trend noted over time. This value may need to be expressed as a proportion of total reports (ADRs + all other reports), especially where there is a unified reporting system.
CP8	What percentage of registered pharmaceutical companies have a functional pharmacovigilance system? The indicator value can be calculated as follows:(Number of pharmaceutical companies with a functional pharmacovigilance	• Do you have a clear and systematic scheme of evaluation of registered pharmaceutical companies? • How frequent this evaluation is undertaken? • Do the registered pharmaceutical companies acquire the following functions of a pharmacovigilance system: 1. Provision of standard	This indicator states the proportion of registered pharmaceutical companies that have a functional pharmacovigilance system. It identifies the pharmaceutical outfit as a key stakeholder of pharmacovigilance. The indicator provides information on the proportion of industries in the setting that contribute towards ensuring the safety of medicines.

	system/Total number of registered pharmaceutical companies in the setting) × 100	accommodation; 2. Engagement of a qualified person for pharmacovigilance; 3. Effective reporting system; 4. Development and submission of periodic safety update report; and 5 other pharmacovigilance related activities.	
CP9	How many active surveillance activities are or were initiated, ongoing or completed in the past 5 years?	• Comment on the awareness of healthcare professionals in the setting of such activities. • If conducted comment on the quality of such initiatives. • In the future are there plans to conduct such activities and how it would benefit the setting?	The value of this indicator reflects the dynamism of pharmacovigilance and regulatory activities in a setting as well as the awareness of the pharmacovigilance centre of such efforts.
CORE OUTCOME/IMPACT INDICATORS			
CO1	How many signals were generated in the past 5 years by the pharmacovigilance centre?	• Describe the process of signal detection in your current system. • Comment on the level of expertise of your staff to detect signals. • Comment on the quality of documentation in your database. • Is causality implied from all the collected reports? • Comment on the estimated time lag between detection and issuing a signal. • Comment on the quality of subsequent communication to the target audience (i.e. healthcare professionals and the general public). • How dose healthcare professionals utilize this information on signals? • In the future, how are planning to address delay in the process of signal	This indicator contributes to measuring the ability of the pharmacovigilance system to ensure the safety of medicines. This ability of the pharmacovigilance system to detect signals underscores its relevance in ensuring the safe use of medicines.

		detection (i.e. measures, technology, experts, etc.)?	
CO2	How many regulatory actions were taken in the preceding year consequent on national pharmacovigilance activities? national pharmacovigilance activities includes CO2a: number of product label changes (variation); CO2b: number of safety warnings on medicines to: (i) health professionals, (ii) general public; CO2c: number of withdrawals of medicines; CO2d: number of other restrictions on use of medicines	• How did the actions undertook (e.g. decision making and issuing advice) impacted the safe use of medicine in your institution? • Do you take actions based on internal or external data? • How do you conclude the appropriateness of actions on the short-term and the long-term? • Where there any factors that affected the initiation of actions (e.g. political, media, industry, etc.). • Comment the interface of your system with other stakeholder systems (e.g. expectations and future directions).	The issuance of advice and taking of appropriate actions by the regulatory authorities is a major output of the pharmacovigilance system that has enormous impact on safe use of medicines. Absence of these measures suggests non-functional or dysfunctional pharmacovigilance or regulatory systems and a failure to monitor medicines for safety.
CO3	What is the number of medicine related hospital admissions per 1000 admissions? The indicator value can be calculated as follows:(Number of people admitted owing to a medicine-related illness/Total number of people admitted to the same hospital or setting) × 1000	• What are the current mechanisms that were effective to ensure medicine and patient safety? • How do you monitor the impact of such mechanisms or interventions? • How do you measure the burden of medicine-related admissions? • How does documentation aids in the process of identifying problems and addressing them? • Do you conduct trends analysis of medicine-related hospital admissions? • Is there an underestimation of the medicine-related hospital admissions? • Comment on the institution ability to diagnose medicine-related hospital admissions?	This indicator is a measure of injury to health resulting from medicines – ADRs, medication errors, misuse or abuse of medicines, counterfeit/ substandard medicines, and poisonings. To a large extent, it measures the effectiveness of provisions put in place to safeguard health through safe medicines and their safe use.
CO4	What is the number of medicine related deaths per 1000 persons served by the hospital per year? The indicator value can be calculated as follows:(The indicator value is calculated as follows: Number of medicine-related hospital deaths (outpatients and inpatients) /Total number of inpatients and outpatients of the hospital during the period) ×1000	• Do you conduct trend analysis of medicine-related hospital deaths? • Is there an underestimation of the medicine-related hospital deaths? • Comment on the institution ability to diagnose medicine-related hospital deaths. • Do you use official studies to assess this issue?	The indicator will be a measure of the harmful effects of medicines in the community, on patients in hospital or patients who are not in hospital. It highlights the safety of medicines circulating in the health-care system, the appropriateness of their use by health-care personnel and the impact of the pharmacovigilance system and regulatory mechanisms in ensuring safe use of medicines. Such a mortality figure suggests systemic issues that need to be addressed to reduce the burden on the society and on the health-care system.
CO5	What is the number of medicine related deaths per 100 000 persons in the population?	• None.	The indicator measures the harmful effects of medicines using mortality as the endpoint. It measures deaths that are related to poor practices along the entire chain, from the manufacture of the medicine, right up to its use.
CO6	What is the average cost (US$) of treatment of medicine-related illness?	• Comment on the impact of medicine-related illness on your system. • Do you consider data on the average cost of treatment of medicine-related illnesses to support 1. Evaluation of interventions; 2. Trend analysis; and 3. Planning for healthcare. • Do you conduct cost of illness studies? • In the future are you planning to utilize health economist to conduct such studies?	This indicator is an estimate of the financial burden imposed by medicine related illness. It provides information on the impact on the health-care system of medicine-related illnesses. It also supports the evaluation of the costs of interventions and trends analyses. It provides useful information in planning for health care.
CO7	What is the average duration (days) of medicine-related extension of hospital stay?	• Are there any ongoing or past studies on this aspect?	The indicator measures the period of hospitalization as a result of noxious or inadvertent effects of medicines. The

		• Do you consider data on the average duration of extension of hospital stay to support 1. Evaluation of interventions; 2. Trend analysis; and 3. Planning for healthcare.	occupancy of hospital beds by patients with medicine related illnesses deprives patients with other diseases of bed space for inpatient care. The indicator is a useful tool for health planning purposes.
CO8	What is the average cost (US$) of medicine-related hospitalization?	• Are there any ongoing or past studies on this aspect? • Do you consider data on average cost of medicine-related hospitalization to support 1. Evaluation of interventions; 2. Trend analysis; and 3. Planning for healthcare.	This indicator is a measure of the financial burden on a hospital attributable to medicine-induced illness. The values of this indicator will be useful in monitoring the trends in hospitalization over time and the effects of intervention measures.
PART 2: COMPLEMENTARY INDICATORS			
COMPLEMENTARY STRUCTURAL INDICATORS			
ST1	Is there a dedicated computer for pharmacovigilance activities?		
ST2	Is there a source for data on consumption and prescription of medicines?		
ST3	Are there functioning and accessible communication facilities in the pharmacovigilance centre?		
ST4	Is there a library or any other reference source for drug safety information?		
ST5	Is there a computerized case report management system?		
ST6	Is there a programme (including a laboratory) for monitoring the quality of pharmaceutical products? • ST6a: Is the programme (including a laboratory) for monitoring the quality of pharmaceutical products, collaborating with the pharmacovigilance programme?		
ST7	Is there an essential medicines list in use?		
ST8	Are pharmacovigilance data considered when developing the main standard treatment guidelines?		
ST9	Does the pharmacovigilance centre organize training courses? • ST9a: for health professionals? • ST9b: for the general public?		
ST10	Are web-based pharmacovigilance training tools available? • ST10a: for health professionals? • ST10b: for the general public?		
ST11	Are there requirements mandating market authorization holders to submit periodic safety update reports?		
COMPLEMENTARY PROCESS INDICATORS			

P1	Last year, what was the percentage of health-care facilities that had a functional pharmacovigilance unit (i.e. submits ≥ 10 reports annually to the pharmacovigilance centre)?
P2	What was the percentage of total reports sent in the previous year by the different stakeholders: • P2a: percentage of the total reports sent by medical doctors • P2b: percentage of the total reports sent by dentists • P2c: percentage of the total reports sent by pharmacists • P2d: percentage of the total reports sent by nurses or midwives • P2e: percentage of the total reports sent by members of the general public • P2f: percentage of the total reports sent by manufacturers
P3	What is the total number of reports received per million population per year?
P4	What is the average number of reports per total number of health-care providers per year? • P4a: number of reports per total number of medical doctors • P4b: Average number of the total of reports sent by dentists • P4c: Average number of the total of reports sent by pharmacists • P4d: Average number of the total of reports sent by nurses or midwives
P5	What is the percentage of health-care providers aware of and knowledgeable about ADRs per health facility?
P6	What is the percentage of patients leaving a health facility aware of ADRs in general?
P7	How many face to face training sessions were conducted on pharmacovigilance in the previous year? • P7a: number of face to face pharmacovigilance training sessions for health professionals • P7b: number of face to face pharmacovigilance training sessions for general public
P8	How many individuals received face to face training in pharmacovigilance in the previous year? • P8a: number of health professionals • P8b: number of individuals from general public
P9	How many national reports for a specific product per volume of sales of that product in the country (product specific) from the industry?
P10	How many registered products with a pharmacovigilance plan and/or a risk management strategy from market authorization holders exist in the country? • P10a: what is the percentage of registered products with a pharmacovigilance plan and/or a risk management strategy from market authorization holders in the country?
P11	What is the percentage of market authorization holders submitting periodic safety update reports (PSURs) to the regulatory authority as stipulated in the country?
P12	Last year, how many products were voluntarily withdrawn by market authorization holders because of safety concerns?

	• P12a: Last year, how many summaries of product characteristics (SPCs) were updated by market authorization holders because of safety concerns?		
P13	How many reports per each registered pharmaceutical industry were received by the pharmacovigilance centre in the previous year?		
COMPLEMENTARY OUTCOME/IMPACT INDICATORS			
O1	What is the percentage of preventable ADRs out of the total number of ADRs reported in the preceding year?		
O2	How many medicine-related congenital malformations per 100 000 births?		
O3	Number of medicines found to be possibly associated with congenital malformations in the past 5 years		
O4	Percentage of medicines that are counterfeit/substandard in the pharmaceutical market		
O5	Number of patients affected by a medication error in hospital per 1000 admissions in the previous year		
O6	Average work or schooldays lost due to drug-related problems		
O7	Cost savings (US$) attributed to pharmacovigilance activities		
O8	Health budget impact (annual and over time serial) attributed to pharmacovigilance activity		
O9	Average number of medicines per prescription		
O10	Percentage of prescriptions with medicines exceeding recommended dose		
O11	Percentage of prescriptions containing medicines with potential for interaction		
O12	Percentage of patients receiving information on the use of their medicines and on potential ADRs associated with those medicines		
PART 3: INDICATORS FOR PUBLIC HEALTH PROGRAMMES (PHP)			
PH1	Are pharmacovigilance activities in place within the public health programme (PHP)?	• Do you consider including pharmacovigilance related activities in the PHP work plans and within your other medicine-related activities? • Describe the pharmacovigilance related activities implementation in your system. PHP is expected to provide (minimum): 1. To report ADR cases to the MOPH using a standard ADR form recommended by the MOPH; 2. To have an open communication link with the MOPH to analyze and react on ADR and other drug-related problems. • Comment on the quality and sustainability of your pharmacovigilance related activities.	The indicator measures the presence or absence of key pharmacovigilance activities in the PHP. Key activities include the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem.
PH2	Do all main treatment guidelines or protocols in use within the PHP systematically consider pharmacovigilance	• How do you standardize and enhance the quality of drug-related prevention services? • How do you ensure that pharmacovigilance is consistently considered and implemented by healthcare workers and other staff involved in the PHP? • Do the existing guidelines provide a sample of the form for reporting of suspected ADR?	The consideration of pharmacovigilance within these documents is a major step towards ensuring that pharmacovigilance is considered by health workers and other staff involved in the PHP.
PH3	Is there a standard ADR reporting form in the setting? The standard reporting form provides for reporting: PH3a: suspected medication errors; PH3b: suspected counterfeit/substandard medicines; PH3c: therapeutic ineffectiveness; PH3d: suspected misuse, abuse of and/or dependence on medicines.	• How the form is being integrated into the PHP system? • Does the form contain all elements required for evidence-based causality assessment? • Do you utilize tools other than the reporting forms (e.g. electronic medical records) to capture some elements relevant to the ADR and other drug-related problems?	This indicator reports the presence of a data collection tool for pharmacovigilance operations. It suggests that the requisite tool for collecting critical information on a suspected case of medicine-related harm has been embedded in the PHP.
PH4	What is the total number of ADR reports collected within the PHP in the previous year?	• Comment on the quality of reporting with respect to the reports content and the time lag for reporting and information sharing.	This indicator measures the extent of involvement of the staff working in the PHP in reporting ADRs to the pharmacovigilance centre. It also reflects how well guidance on pharmacovigilance is implemented within the PHP.
PH5	How many ADR reports (per 1000 individuals exposed to medicines in the PHP) were reported in the previous year?	• Do you consider this data in comparing reporting trends over time? • Do you use this data to monitor your PHP involvement in pharmacovigilance and compare it to other programs?	This indicator refers to the number of reports on ADRs that were made within the population taking the medicines as part of the implementation of the PHP.

		• Do you sue this data to monitor the impact of specific activities to promote pharmacovigilance, rational use of medicine, and patient safety? • Comment on the quality of documentation and its relevance to signal detection.	
PH6	How many reports on therapeutic ineffectiveness were made in the previous year? The indicator value can be calculated as follows: (Number of reports of therapeutic ineffectiveness received in the year from a PHP/ Total number of reports received in the same year from the same PHP) × 100	• What process do you follow to distinguish whether the cause is a pharmaceutical or therapeutic issue? • Comment on the magnitude of therapeutic ineffectiveness within your PHP. • Do you document the factors that contribute to the therapeutic failure (e.g. quality of medication, drug resistance, patient adherence, etc.)?	This indicator identifies failed treatment owing to lack of effectiveness of medicines used in the PHP. The occurrences of treatment failure attributable to medicines in use in the PHP suggest the existence of pharmaceutical or therapeutic issues that should be addressed.
PH7	What percentage of completed reports were submitted to the national pharmacovigilance centre in the previous year? The indicator value can be calculated as follows: (Number of reports from the PHP filled in satisfactorily during the year/Total number of reports received from the PHP during the same period) × 100 PH7a: Of the reports satisfactorily completed and submitted to the national	• Comment on the quality of submitted reports to the MOPH. • Comment on the possibility and the resources required to initiate the process of report evaluation in the future.	The indicator value reflects the quality of reports received by the centre. It is an indication of the understanding by health professionals of the elements in the ADR forms, and of the willingness and care taken to fill in the forms properly before submitting them to the pharmacovigilance centre. The value of the subset indicator reflects the commitment of the centre to sending reports to the WHO database, which is a requirement for national pharmacovigilance centres that are full members of the WHO Pharmacovigilance Programme.
	pharmacovigilance centre, what is the percentage of reports committed to the WHO database? The indicator value can be calculated as follows: (Number of reports from the PHP filled in satisfactorily and committed to WHO database during the year/Total number of reports from the PHP received during the same period) × 100		
PH8	What is the number of medicine related hospital admissions per 1000 individuals exposed to medicines in the PHP in the previous year? The indicator value can be calculated as follows: (number of patients admitted to hospital with a medicine-related illness attributable to a preventive or healing regimen of the PHP, taken during the previous year/ total number of individuals exposed to medicines in the PHP) × 1000	• Comment on the institution ability to diagnose medicine-related hospital admissions. • Is there an underestimation of the medicine-related hospital admissions (e.g. lack of awareness of the problem or low suspicion index)? • Do you conduct trend analysis of medicine-related hospital admissions? • How does documentation aids in the process of identifying problems and addressing them? • What are the current mechanisms that were effective to ensure medicine and patient safety? • How do you monitor the impact of such mechanisms or interventions? • In the future are there any plans to conduct specific standardized studies like cohort event monitoring or targeted spontaneous reporting?	This indicator refers to the number of patients admitted to hospital as a result of events associated with the use of PHP medicines within the population exposed to the medicines in the PHP. This indicator is a measure of injury to health resulting from the medicine and its unsafe use – ADRs, medication errors, misuse or abuse of medicines, dependence, interactions, counterfeit/substandard medicines, and poisonings.
PH9	What is the number of medicine related deaths per 1000 individuals exposed to medicines in the PHP in the previous year? The indicator value can be calculated as follows: (Number of PHP medicine-related deaths during the year/Total number of individuals exposed to medicines in the PHP during the year) × 1000	• Is there an underestimation of the medicine-related hospital deaths? • Comment on the institution ability to diagnose medicine-related hospital deaths. • Do you conduct trend analysis of medicine-related hospital deaths? • Do you consider data to support 1. Evaluation of interventions; and 2. Planning for strategies.	This indicator is a measure of total number of deaths resulting from PHP medicine-related illness, attributable to any of the medicines provided by the PHP. It highlights the safety of medicines circulating in the PHP, the appropriateness of their use by health-care personnel and the impact of the pharmacovigilance system and regulatory mechanisms in ensuring safe use of medicines in the PHP.

M10. Data collection instrument 3: Semi-structured interview protocol (system-based approach):

1. Pharmaceutical Industry interview protocol.

MSc Research on Pharmacovigilance

Dears,

Hope you are doing very well.

I developed few tables to guide the development of recommendations for further improvement in the system.

Below are tables for specific aspects that are important for PV systems to be functional. Some aspects are available in Qatar while others are not. Further, if an aspect is not existent please direct the comments to the opportunity to have it in the future; if you wish to include other aspects that I did not cover in the tables please feel free to provide your comments.

Pharmacovigilance:

Healthcare systems rely on the availability of safe, effective, and good quality medicine. However, in many countries, neither PV systems nor regulatory systems are fully functional. This calls for efforts to improve systems and their capacities in order to ensure medicines safety, patients safety, and public health.

Kindly, provide your comments on the below-built points in the tables from the perspective of your organization:

- Presence or absence;
- Weakness or strengths;
- Suggestion for improvement; And future opportunities e.g. Feasibility and utility (usefulness)

SYSTEM BASED APPROACH	
Aspect	**Comment**
Domain: governance, policy, law, and regulation	
National level: • Awareness of the existence of a national site/department/ committee within the MOPH covering PV related aspects • Awareness of the national policy for monitoring and reporting of medication safety issue e.g. adverse events/ADRs • Receiving medicine safety information or bulletins from the MOPH	

Internal level (industry) : • The existence of own policies and procedures that define how the industry ensure its compliance with the national laws and policies • Industry have SOPs to address medication safety and PV in the quality system of the company • SOPs that address procedures that mention legal provisions for PV and medication safety • SOPs that address the submission of PSURs • Mandatory reporting requirements for ADRs within the company • Mandatory requirements to conduct post marketing surveillance • Procedures for addressing product quality assurance • Procedures for addressing PV or medication safety information in advertising and promotional materials	
Domain: system, structures, and stakeholders coordination	
National level: • Having a national PV center • Awareness of a service at the national level as well as the organizational level to ask questions related to ADRs and medicine safety • Awareness of a platform for coordination of national PV activities (or related to ADRs and medicine safety) • Do you view pharmaceutical industry as an important stakeholder ensuring medication safety at the national level • The exact pattern of interaction with other stakeholders/systems (e.g. MOPH, Public or private institutions)	
Industry level: • The existence of a stand-alone unit or a subset with an assigned	

responsibility for monitoring medication safety • As an internal evaluation do you consider Qatar Pharma to be: 1. Fully operational; 2. Have a clear mandate, structures, and delineation of roles responsibilities; 3. Implemented PV related activities; 4. Have PV inspection conducted regularly; 5. Have PV audits and inspections in the company quality system 6. Have an existent and functional quality control units 7. Have a system to prepare for PV inspections 8. Has an audit of the PV quality management system	
Domain: signal generation and data management	
National level: • Standardized national adverse event form • The type of data collected (e.g. Suspected ADRs, product quality issues, medication errors, treatment failure) • Availability of the reporting forms for various stakeholders (e.g. consumers as well as pharmacies staff) • Underreporting problem	
Industry level: • Are you fully engaged in the generation of medication safety signals • The existence of a system to allow medication safety-related documents storage and archiving • The system for data storage is it ICH E2B complaint and allow the company to track activities and workload	

• The system has a sufficient capacity for electronic submission of ADRs to MOPH • Standard terminologies (e.g. MedDRA) are used in the current database • Reporting forms are available and cover aspects of Adverse events, product quality, lack of efficacy, treatment failure	
Domain: risk assessment and evaluation	
Industry level: • The conduct of causality assessment for the collected ADRs reports • The conduct of an in-depth evaluation of the safety signals that have been detected • The conduct of: 1. Product quality surveys (product quality assurance) 2. Medication error studies 3. Medicine utilization review 4. Postmarketing surveillance activities	
Domain: risk management and communication	
National level: • Medicine information process (i.e. Information quest and response) • Awareness of medicine safety actions taken in the country (e.g. product withdrawal) • Awareness of strategies or plans (e.g. medication guides) to mitigate or restrict the use of high-risk medication	
Industry level: • Medicine information process (i.e. Information quest and response) serving as a source of information on medication safety for the health sector and the public • Publication of medicine safety alerts or bulletins	

• Internal plans to mitigate or restrict the risk medications (plans require European Union or United States mitigation strategies) • Communication and taking action on medicine safety issues that are external to the country actions to members affiliated with the organization or other stakeholders in the country • Awareness of medicine safety actions taken in the country by MOPH and informing other national stakeholders for purposes of clinical management, guideline revision, education, etc...	

RECOMMENDATIONS FOR IMPROVEMENT	
Domain: Industry level recommendations	
• Do we need to strengthen industry commitment to PV? • Comment on the existence of some legal provisions to ensure that product sponsors are conducting post-marketing surveillance activities. • Comment on the existence of adequate legislation for product stewardship. • The existence of risk management plans (if not available should the industry offer and implement such plans?) • Comment on the harmonization (e.g. with the EMA standards) of standards in relation to risk minimization plans? • How can we implement PV audits and inspections (including, a potential collaboration with MOPH)? • How to improve adverse events reporting within the industry (including, the use of the E2B or CIOMS I forms)?	
Domain: national level recommendations	

Regulatory policies and framework: • Do we need new regulatory policies and frameworks; or do we need to revise existing legislation? • Are the current regulations effective and in the public interest? • Are the current legislations congruent with other relevant local laws?	
Organizational structures: • Do we need to reform our organizational structures? • If yes, how to accomplish this in order to achieve an integrated medication safety system?	
Visibility of PV as a public health priority: • How to improve the visibility of PV (i.e. awareness on PV as well as the understanding of its importance)? • Do we need media campaigns and public services to announce or communicate key messages on Medication safety?	
PV funding: • Should we consider reviewing resource allocation for PV activities? • Are new resources for funding required e.g. donor funding?	
Spontaneous reporting: • Do we need to adopt reporting standards? • Do we need to develop consumer reporting forms and mechanisms? • Do we need to explore opportunities to use new information technology? • Is there a need to consolidate and streamline national reporting forms? • What products and information should be /captured covered under a national reporting form? • What are the best approaches to streamline as well as improve spontaneous reporting system at the service delivery level?	

Falsified and substandard medicine: • What are the available current instruments for addressing this issue?	
MOPH role in developing PV at the health facilities or service delivery level: • Does MOPH need to expand their efforts to provide training and education on PV for healthcare providers?	
Academic institutions role in developing PV at the health facilities or service delivery level: • Do academia need to expand efforts by providing training and education on PV for healthcare providers (e.g. what do you expect from Qatar University-College of Pharmacy to offer in relation to PV activities)? • What are the opportunities available for effective collaboration and communication (e.g. research activities)? • Is there a need for academia to share their information as well as resources in relation to medication safety?	

CAPACITY AND PERFORMANCE OF PV SYSTEMS	
Which state represent Qatar (select from 1 to 4)?	Comment
1.minimal organization structures and capacity for PV	
2.policy and legal frameworks, basic organizational structures (e.g. Guidelines safety advisory committee, and SOPs)	
3.capacity to collect and evaluate safety data on the base of the legal organizational structure	
4.performing PV system to detect, evaluate, and prevent medicine safety issues	

2. Academic institutions interview protocol.

MSc Research on Pharmacovigilance

Meeting topics

A) Indicator CST8
Describe the indicator CST8

- If available/If absent
- Quality and extent of implementation
    - Is it a compulsory subject?
    - At, which level?
    - Full course or part of a course?
    - Number of credit hours.
    - Philosophy in education: traditional, case-based, group discussion, the mixture.
    - Do you have post-graduate specialized courses?

Phase 1. Curriculum

- The scope of PV: Regulatory vs practice PV-----Specific sub-subjects
- PV systems
    - Regulatory vs practice PV
    - Role of the regulatory authority
    - Medication safety system in Qatar HMC, PHCC, Private sector
- Phases of PV process (data collection, data management, signal detection, safety assessment, decision-making, and communication and action)
- WHO patient safety curriculum
- Medication errors and other important definitions
- Reporting process including ADRs
- Decision-making and practice
- Principals of accountability and transparency (PG); code of ethics; stakeholder coordination
- The number of qualified staff/human resources for training/education
    - Who gives the courses academic staff vs external to the college?
    - In the future, whom would you suggest to give the sessions?
- CPD and IPE
- Financial provision
- Further recommendations to improve the system

Phase 2. Establishing a center (external to QU)

- Mission statement specifically in relation to PV

- Your role and capacity as part of the system (research, provide training and educational programs)
- Success factors (available /needed)
- Recommendation

Phase 3. Establishing a center (QU)

- Utility (useful)
- Feasibility (practical and cost-effective)
- Propriety (standards codes and ethical)
- Technical adequacy (financial and human resources)
- Success factors
- Recommendation

Phase 4. Any further recommendations

Examples:

- Improvement in the curriculum
- Improvement at the national level and/or college level
- What can be the role of QU-CPH in relation to PV (i.e. offer PV activities)?
- What is expected from Qatar medicine regulatory authority (MOPH); MOPH role in developing PV at the level of academic institutions?
- Collaboration between stakeholders

3. Service delivery organizations (private healthcare institutions and community pharmacy).

MSc Research on Pharmacovigilance

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Below are tables for specific aspects that are important for PV systems to be functional. Some aspects are available in Qatar while others are not. Further, if an aspect is not existent please direct the comments to the opportunity to have it in the future; if you wish to include other aspects that I did not cover in the tables please feel free to provide your comments.

Pharmacovigilance:

Healthcare systems rely on the availability of safe, effective, and good quality medicine. However, in many countries, neither PV systems nor regulatory systems are fully functional. This calls for efforts to improve systems and their capacities in order to ensure medicines safety, patients safety, and public health.

Kindly, provide your comments on the below-built points in the tables from the perspective of your organization:

- Presence or absence;
- Weakness or strengths;
- Suggestion for improvement; And future opportunities e.g. Feasibility and utility (usefulness)

SYSTEM BASED APPROACH	
Aspect	**Comment**
Domain: governance, policy, law, and regulation	
Awareness of the existence of a national site/department/ committee within the MOPH covering PV related aspects	
Awareness of the national policy for monitoring and reporting of adverse events/ADRs	
Awareness of the laws and regulations for monitoring and reporting of adverse events/ADRs	
Receiving medicine safety bulletins from the MOPH	

Awareness of strategies or plans (e.g. medication guides) to mitigate or restrict the use of high-risk medication	
Medicine safety bulletins provided by MOPH or internal to the organization	

RECOMMENDATIONS FOR IMPROVEMENT	
Domain: national level recommendations	
Regulatory policies and framework: • Do we need new regulatory policies and frameworks; or do we need to revise existing legislation? • Are the current regulations effective and in the public interest? • Are the current legislations congruent with other relevant local laws?	
Organizational structures: • Do we need to reform our organizational structures? • If yes, how to accomplish this in order to achieve an integrated medication safety system?	
Visibility of PV as a public health priority: • How to improve the visibility of PV (i.e. awareness on PV as well as the understanding of its importance)? • Do we need media campaigns and public services to announce or communicate key messages on Medication safety?	
PV funding: • Should we consider reviewing resource allocation for PV activities? • Are new resources for funding required e.g. donor funding?	
Spontaneous reporting: • Do we need to adopt reporting standards? • Do we need to develop consumer reporting forms and mechanisms? • Do we need to explore opportunities to use new information technology?	

Domain: system, structures, and stakeholders coordination	
Having a national PV center	
Awareness of a service at the national level as well as the organizational level to ask questions related to ADRs and medicine safety	
Awareness of a platform for coordination of national PV activities (or related to ADRs and medicine safety)	
Do you view community pharmacy as an important stakeholder ensuring medication safety at the national level	
Health professionals affiliated do they receive training in PV topics	
Having a national PV center	
Dedicated annual budget PV related activities	
The exact pattern of interaction with other stakeholders/systems (e.g. MOPH, Public or private institutions)	
Domain: signal generation and data management	
Standardized national adverse event form	
The type of data collected (e.g. Suspected ADRs, product quality issues, medication errors, treatment failure)	
Reporting by consumers or the public	
Availability of the reporting forms for various stakeholders (e.g. consumers as well as pharmacies staff)	
Underreporting problem	
Domain: risk assessment and evaluation	
The conduct of: • Product quality surveys • Medication error studies • Medicine utilization studies • Active surveillance activities	
Domain: risk management and communication	
Medicine information process (i.e. Information quest and response)	
Awareness of medicine safety actions taken in the country (e.g. product withdrawal)	
Communication of medicine safety actions to members affiliated with the organization	

• Is there a need to consolidate and streamline national reporting forms? • What products and information should be /captured covered under a national reporting form? • What are the best approaches to streamline as well as improve spontaneous reporting system at the service delivery level? • The use of call centers and/or websites by consumers to submit information on medication safety is it needed and why?	
Falsified and substandard medicine: • What are the available current instruments for addressing this issue?	
MOPH role in developing PV at the health facilities or service delivery level: • Does MOPH need to expand their efforts to provide training and education on PV for healthcare providers? • The civil society role in good governance in the pharmaceutical sector?	
Academic institutions role in developing PV at the health facilities or service delivery level: • Do academia need to expand efforts by providing training and education on PV for healthcare providers (e.g. what do you expect from Qatar University-College of Pharmacy to offer in relation to PV activities)? • What are the opportunities available for effective collaboration and communication (e.g. research activities)? • Is there a need for academia to share their information as well as resources in relation to medication safety?	

CAPACITY AND PERFORMANCE OF PV SYSTEMS	
Which state represent Qatar (select from 1 to 4)?	Comment
1.minimal organization structures and capacity for PV	
2.policy and legal frameworks, basic organizational structures (e.g. Guidelines safety advisory committee, and SOPs)	
3.capacity to collect and evaluate safety data on the base of the legal organizational structure	
4.performing PV system to detect, evaluate, and prevent medicine safety issues	

M11. Data collection instrument 4: Researcher created instrument (includes observational protocol).

Survey

Title of Project: A Comprehensive Pharmacovigilance System in a Middle-Eastern Country: A System Analysis of Qatar

Dear participant,

You are invited to join this study. We hope that it will help us to collect useful information about the current status of a pharmacovigilance (PV) and medicine safety system in Qatar. You are being invited because you are a potential stakeholder involved in ensuring medication safety and improving public health through your participation in different activities, process, and/or programs at your institution.

Study site	
Data collection level	
Institution name	
Public or Private	
Location	

Study participants		
	Primary/ initial informant	**Secondary key informant**
Name		
Designation		
Phone number		
Email Address		
No of years in the present position		

Documents review

This survey is completed as a researcher administered survey.

	Document name	**Year**	**Source/ reference**
1.			
2.			
3.			
4.			

Interview Objectives	
1.	
2.	
3.	
4.	
5.	

Interview Log			
Date & duration	**Method of data collection**	**Notes (topics discussed, targeted indicators, recommendations, opinions, etc..)**	**Next interview plan**

This survey is completed as a researcher administered survey.

This survey is completed as a researcher administered survey.

Additional Notes

This survey is completed as a researcher administered survey.

M12: Examples of the deductive content analysis process.

Table M12: Examples of the deductive content analysis process.

Table M12: Examples of the deductive content analysis process.

Category	Code	Condensed text	Text verbatim
Structure	PV centre/department	A department is concerned about PV and medication safety.	Yes, there is but it is not a center we have both indicators for medications and adverse drug reactions under the medication safety center... Just a center to collect all safety data you can call it semi pharmacovigilance.
Structure	Policy or legislation or guidelines	Legal mandates for marking authorization holders to report ADRs.	Because it is required by law that marketing authorization holders the local agent should declare to the MOPH represented by the Pharmacy And Drug Control if there is any quality or safety issue they have to report it I think it's even mentioned in the law within 10 days or within 1 month.
Process	Causality assessment	Causality assessment following evidence-based methodology.	See this is how adverse drug reactions have been reported across from all Medical Centre as well as Hospital. And they reach the clinical pharmacist for further analysis. They do the probability scaling, Naranjo scaling and based on that they prepare a monthly summary.
Structure	Healthcare system regulatory authority	No structured or established national reporting system.	Within the organization, yes, it is not going outside because there is no structured way to report to any regulatory authority.
Structure	Pharmacovigilance education	The college program covers PV through all the years for two credit hours.	So, it's a, it's a tough question because there's no actual course…our students typically take… anywhere between I would say 30 and 36 credit units total per academic year and maybe perhaps one to two of those credit units were associated with instruction for PV… but for example, professional skills as a two-credit course, but the whole course is not designated for PV. But part of that two credits would be, would be dedicated.
Additional system-based approach	Leadership and management	Leadership involvement to improve the PV and	We are trying to get our leadership involved from the beginning stage we are trying to do a lot of lectures for them, we're trying to explain to them that some

	Culture	reporting culture in the hospital.	mistakes happen because the system has failed, the system allows that to happen. And then sometimes individual responsibilities as well. So, we try to invite that we are taking some measures, we do leadership rounds, but I think it will take some time before we can get to the just culture. I don't think any organization can claim that they have just culture, it's very difficult to determine, you know, which one is an individual responsibility and which one system-related failure. So, I think we're getting there. But the measures that we're taking right now is to get the leadership involved. I think once the leadership gives you the assurance that we won't penalize you, It makes it easier for people to understand, I mean you could write as many, as much you like in policies, but there should be, you know, a follow up through leadership. So that's what we're trying to do right now.

APPENDIX B: RESULTS CHAPTER RELATED CONTENT

1) National and Subnational PV System Performance Values and Calculations.

Table R1a: National and Subnational PV System Performance Values and Calculations.

National PV system	Actual performance					Desired performance			
	S: structure	P: process	O: outcome	Overall sum	Overall percentage	S: structure	P: process	O: outcome	Overall sum
MOPH	12.5	5	2	19.5	23.78%	31	29	22	82
HMC	20.5	16	9	45.5	65%	25	22	23	70
PHCC	20.5	14	4	38.5	71.30%	25	22	7	54
PRIVATE SECTOR (calculated from the means S, P, &O of the five hospitals)	17.8	14.9	7	39.7	58.4%	25	22	21	68
INDUSTRY	21	9.5	3.5	34	68%	23	21	6	50
MEANS (of stakeholder)	18.46	11.8	5.1	-	-	25.8	23.2	15.8	-
PERCENTAGE (calculated based on the means of stakeholder)	71.6%	51.2%	32.3%	-		100%	100%	100%	-
TOTAL PERFORMANCE OF QATAR PV SYSTEM	35.44 (54.7%)					64.8 (100%)			

R1b) Excel spreadsheet database.

WHO PV indicators			Stakeholders Reference recorded values										
Indicator Code	Indicator Category	Code Ref	MOPH	HMC	PHCC	H-A	H-B	H-C	H-D	H-E	Industry	P-A	P- B
Core Indicators	Structure	CST1	0	2	1	1	1	1	1	1	2	1	0
		CST2	0	2	2	2	1	1	0	1	2	0	0
		CST3	2	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
		CST4	0	0	0	0	0	0	1	0	2	0	0
		CST5	0	1	2	2	1	1	1	2	2	2	1
		CST6	0	2	2	2	2	2	2	1	2	0	0
		CST7	0	2	2	2	2	2	1	1	2	2	0
		CST8	2	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
		CST9	2	2	2	2	2	2	2	2	2	2	0
		CST10	1	2	2	2	2	1	2	2	2	2	0
	Total		7	13	13	13	11	10	10	10	16	9	1
	Process	CP1	0	2	2	1	1	2	2	1	1	0	0
		CP 2	0	2	1	2	1	1	1	2	1	1	0
		CP 3	0	2	2	2	2	2	2	2	1	2	0
		CP 4	0	2	1	2	2	2	0	0	1	(-)	(-)
		CP 5	0	1	1	2	2	1	2	1	0	0	0
		CP 6	0	1	1	2	2	2	1	2	(-)	(-)	(-)
		CP 7	0	1	2	2	1	2	1	2	(-)	(-)	(-)

		CP 8	2	(-)	(-)	(-)	(-)	(-)	(-)	(-)	2	(-)	(-)
		CP 9	0	1	0	0	0	0	0	0	0	(-)	(-)
	Total		2	12	10	13	11	12	9	10	6	3	0
	Outcome	CO 1	0	2	0	0	1	1	0	0	1	(-)	(-)
		CO 2	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	2	(-)	(-)
		CO 3	0	1	(-)	0	1	2	1	0	(-)	(-)	(-)
		CO 4	0	1	(-)	0	2	1	1	1	(-)	(-)	(-)
		CO 5	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
		CO 6	0	0	(-)	0	0	0	0	0	(-)	(-)	(-)
		CO 7	0	0	(-)	0	1	0	0	0	(-)	(-)	(-)
		CO 8	0	1	(-)	0	0	0	0	0	(-)	(-)	(-)
	Total		1	5		0	5	4	2	1	3	(-)	(-)
Complementary Indicators	Structure	ST1	0	1	1	1	1	1	0	1	1	1	0.5
		ST 2	0	1	1	1	1	1	1	1	(-)	1	1
		ST 3	0	1	1	1	1	1	1	1	1	1	1
		ST 4	1	1	1	1	1	1	0	1	1	1	1
		ST 5	0	1	1	1	1	0.5	0	1	1	0.5	0
		ST 6	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	0.5	(-)	(-)
		ST 7	1	1	1	1	1	1	1	1	(-)	(-)	(-)
		ST 8	1	1	1	1	1	1	1	1	(-)	(-)	(-)
		ST 9	0.5	0.5	0.5	0.5	1	0.5	0	0.5	0.5	0.5	0
		ST 10	0	0	0	0	0.5	0	0	0.5	0	0	0

	ST 11	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Total		5.5	7.5	7.5	7.5	8.5	7	4	8	5	5	3.5
Process	P 1	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	P 2	0	1	0.5	1	0	1	1	1	0.5	(-)	(-)
	P 3	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	P 4	0	0	0.5	0	0	1	0	1	0.5	(-)	(-)
	P 5	(-)	1	1	1	0.5	1	1	1	(-)	1	1
	P 6	(-)	1	1	1	1	1	1	0.5	(-)	1	0
	P 7	0.5	0.5	0.5	0.5	0.5	0.5	0	0.5	0.5	0.5	0
	P 8	0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
	P 9	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	P 10	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	0.5	(-)	(-)
	P 11	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	0	(-)	(-)
	p12	0.5	(-)	(-)	(-)	(-)	(-)	(-)	(-)	1	(-)	(-)
	p13	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
Total		3	4	4	4	2.5	5	3.5	4.5	3.5	3	1
Outcome	O1	0	1	0	1	0	1	1	1	(-)	0	0
	O2	0	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	O 3	0	0	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	O 4	1	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)
	O 5	(-)	1	(-)	1	0	1	0	1	(-)	(-)	(-)
	O 6	(-)	0	(-)	0	0	0	0	0	(-)	(-)	(-)

		O 7	0	0	(-)	0	0.5	0	0	0	0	0	0
		O 8	0	0	(-)	0	0	0	0	0	0.5	0	0
		O 9	(-)	1	1	0.5	0	1	1	1	(-)	1	1
		O 10	(-)	0	1	0.5	0	1	1	1	(-)	1	1
		O 11	(-)	0	1	0.5	0	1	1	1	(-)	1	0
		O12	(-)	1	1	1	1	1	1	1	(-)	1	1
	Total		1	4	4	4.5	1.5	6	5	6	0.5	4	3

2) National PV System Performance at the MOPH Level.

Table R2: MOPH PV system performance and capacity results measured by WHO core PV indicators.

CORE STRUCTURAL INDICATORS

Code	Response	Score *	Assessment (Qualitative)
CST1	No specific PV department or center.	(0)	• No specific PV department. However, PV activities are incorporated within the daily activities. They hope to become a full member after they set up a national PV center. • The Department of Pharmacy and Drug Control collects data from the MAH and the international pharmaceutical industry. However, the department stopped receiving ADRs data from healthcare institutions. The department considers the current PV system to be functional with the external stakeholders' side and non-functional from the national stakeholders' side. • The Department of Healthcare Quality and Patient Safety have future projects that involve medication safety (i.e. medication safety plan and national reporting system). Additionally, the department receives reports on medication errors as per the health performance agreement, but the data captured does not have enough details to conduct in-depth analysis. • It was recommended that a specific PV center would be best established as a centralized system in the MOPH and collaborative efforts with universities could be pursued for the management and operation of the center.

CST2	No specific national PV policy or guidelines.	(0)	• Qatar is a member of the GCC countries. Therefore, they have well-established guidelines for drug registration including PV. Additionally, the pharmaceutical law of Qatar covers aspects of medication safety, but the specific term of PV is not used. • The regulatory framework is defined by the pharmaceutical law. Sections in the law related to PV medication safety are covering MAHs. No mandatory reporting for healthcare professionals.
CST3	Yes.	(2)	• Yes, the MOPH. The Pharmacy and Drug Control is responsible for pharmaceutical sector management and regulations.
CST4	No specific budget allocated for PV.	(0)	• There is no allocated budget for PV within the MOPH because there is no independent body or segregated body responsible for PV. • The current budget that is used for covering medication safety activities does not reflect the PV functions directly. • It was stated that the budget is sufficient for the current operation of the system. However, if such a center will be established an additional budget needs to be allocated properly.
CST5	No. Not-applicable.	(0)	• It was reported that a dedicated human resource will be required once a dedicated PV center is established as the current manpower will not be enough. • The Department of Healthcare Quality and Patient Safety reported that they need human resources dedicated to the planned medication safety program. • The Department of Pharmacy and Drug Control indicated that there is no dedicated staff for PV. But the number of people covering PV and medication safety in the current state is sufficient. The MOPH provided training related to vaccine PV only. Otherwise, a limited number of MOPH employees make individual efforts to receive training on PV.
CST6	No national standardized ADR reporting form.	(0)	• Currently, there is no national standardized ADRs reporting from or any form to collect national data on medicine-related safety issues. • The MOPH plans to create and implement a national patient safety reporting system in the near future. • There is no reporting form for the general public. However, the public can report their complaints through the MOPH website, but it is not specific to medications.
CST7	No.	(0)	• No PV structures to undertake the basic PV activities. • Absence of a national database system for the collection of PV data from all sources. • Methods of data collection and transmission were indicated to be nonfunctional for national postmarketing surveillance activities but functional for the PV in the registration

			process and with the pharmaceutical companies. • No formal documentation system to collect data from pharmaceutical companies (e.g. no records kept for the number of reports). • The future project medication safety plan includes requirements for the electronic database and at the time of implementation, the MOPH will have to discuss with the company and establish all the required details with other stakeholders.
CST8	Yes.	(2)	• Yes, refer to the results chapter section 1.6. higher academic institutions level.
CST9	Yes.	(2)	• The Department of Pharmacy and Drug Control distributes circulars at the national level e.g. safety warnings in the form of memos. Additionally, the MOPH website exists but it is not usually used as desired. Thus, the MOPH prefers sending feedback directly to national PV stakeholders. • The Department of Healthcare Quality and Patient Safety does not have a process in place to ensure that the department is following up on medication safety.
CST10	No.	(1)	• There is no specific PV or medicine safety advisory committee. Therefore, it was stated that in the future, having a functional committee will serve the needs of the country. • The Pharmacy and Drug Control Department is currently the body responsible for information dissemination and provision of advice on medication safety and PV.
Total Score		(7)	Out of 10 [10*2= (20)] is [(100%)] relevant indicators the obtained score was [(7) =35%]

CORE PROCESS INDICATORS

Code	Response	Score *	Assessment (Qualitative)
CP1	The number of records is not documented.	(0)	• The Department of Pharmacy and Drug Control reported that currently there is no national database for PV data management. Additionally, the number of reports that have been received is very limited (i.e., less than 10 ADRs reports were received in 2017 from Qatar petroleum). The underreporting issue is expected to continue without the existence of an appropriate documentation system and national ADR reporting forms. • The Department of Healthcare Quality and Patient Safety stated that since there is no structure in place the process indicators are also not in place for the reporting of medication safety issues.
CP2	The number of records is not	(0)	• No national database or a formal documentation system.

	documented.		
CP3	The number of records is not documented.	(0)	• The Department of Pharmacy and Drug Control reported that any issue that is received from the external pharmaceutical industry will be communicated to the Qatar Council for Health Care Professionals to make it as circulars with instructions and guidelines for physicians on how to submit or how to act in cases with that specific medication. • The Department of Healthcare Quality and Patient Safety stated that there is no formal process in place to ensure that the department is following up on medication safety. This process will be included in the future plan to have a medication safety program.
CP4	The number of records is not documented.	(0)	• The Department of Pharmacy and Drug Control reported that for passive surveillance activities the capacity for evidence-based causality assessment, signal investigation and other forms of PV data analysis is inadequate. Thus, it is recommended that awareness and training are mandatory as such process requires experience and expertise in all elements of health care. • The Department of Healthcare Quality and Patient Safety stated that the data captured does not have sufficient details to conduct in-depth analysis.
CP5	The number of records is not documented.	(0)	• The number of records is not documented reports sent from hospitals do not have sufficient details and the quality of reports is not satisfactory.
	CP5a: None.	(0)	• MOPH has a good relationship with the UMC and they have already been successful to be an associate member with UMC. • MOPH has been given the privilege to access the international system that is designed to submit reports. • To improve PV, it was recommended that the country needs to take action to develop the national PV system, establish the PV center, hire suitable manpower, and start submitting reports.
CP6	The number of records is not documented.	(0)	• The number of records is not documented.
CP7	The number of records is not documented.	(0)	• The number of records is not documented.
CP8	100%.	(2)	• It is a requirement for registered pharmaceutical companies to have a functional PV

			system.
CP9	None.	(0)	• For active surveillance activities, MOPH did not report any examples of studies at the national level. • It was reported that the MOPH does not have enough capacity to conduct such studies. • Collaboration with other sectors to conduct such studies was deemed as a potential suggestion. The MOPH is aware of the limitations and the risk for such activities. • Active surveillance activities are very expensive, require a lot of technical knowledge, and most of the pharmaceutical companies do it successfully. Therefore, it was reported that it is best to rely on third parties and pharmaceutical companies as they can do it successfully.
Total score		(2)	Out of 9 [9*2= (18)] is [(100%)] relevant indicators the obtained score was [(2)=11.1%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CO1	None.	(0)	• External data is used only and there are no signals generated at the national level. • The Department of Pharmacy and Drug Control commented on signal evaluation that there is a lack of awareness about how to do signal evaluation including the use of relevant tools and methods. Additionally, it was stated that signal evaluation requires a good effort from national stakeholders through improving their reporting rate and quality of submitted reports. • The Department of Healthcare Quality and Patient Safety reported that signal identification and evaluation is not part of their activities.
CO2	The number of records is not documented.	(1)	• Both internal and external data will be considered. However, no documentation system is available to record the number. • The MOPH has more than 4500 registered pharmaceutical products. Hence, the MOPH receives many reports from external sources and issue actions based on them. • The registration committee will be responsible for taking regulatory actions. • For decision making and regulatory actions, the MOPH mostly relies on benchmarks from other countries with stringent regulatory agencies. Because sometimes the national reports that they receive does not concise with the global data. Consequently, the MOPH cannot immediately take regulatory actions.
CO3	No data provided.	(0)	• The Department of Healthcare Quality and Patient Safety reported that service delivery organizations do not report hospital admission data.
CO4	No data	(0)	

	provided.		• The Department of Healthcare Quality and Patient Safety reported that service delivery organizations do not report death due to medication error data. • This data could be part of the morbidity and mortality data. However, it is planned for these data to be part of the future reporting system.
CO5	No data provided.	(0)	
CO6	No data provided.	(0)	• According to the health economist in MOPH, the Financial aspects of the PV system (i.e., core outcome indicators number 6,7, and 8 as well as Complementary outcome indicators number 7 and 8) this information currently is not available in MOPH. However, it is very important and worthy to be collected especially indicator number 7 which is considered feasible. Nevertheless, this needs good planning for the methodology.
CO7	No data provided.	(0)	
CO8	No data provided.	(0)	
Total Score		(1)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(1) =6.3%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R3: MOPH PV system performance and capacity results measured by WHO complementary PV indicators.

COMPLEMENTARY STRUCTURAL INDICATORS

Code	Score*	Answer qualitative
ST1	(0)	No, as a specific center does not exist.
ST2	(0)	No, not relevant. As the MOPH only regulates medications and not related to the consumption of medicine, this indicator is relevant to service delivery organizations.
ST3	(0)	No: there is no PV center.
ST4	(1)	Yes, however, there is no library. The MOPH uses regulatory authorities' website information e.g. FDA, EMA, WHO references.
ST5	(0)	No, this indicator is relevant to service delivery organizations.
ST6	(1)	Yes. Quality Control Lab is a big section (not specific for PV). The lab collaborates with the MOPH Pharmacy and Drug Control department because it is a section under it. This lab is linked with the full registration process, and PV is part of it.
ST7	(1)	No, all medications are essential for MOPH.
ST8	(1)	Yes.
ST9	(0.5)	• ST9a: Yes, they have PV related issues covered under vaccine training (not specific to PV). Additionally, they organize

		pharmacy conferences that have a separate theme for PV and medication safety. • ST9b: no, none for the general public.
ST10	(0)	No.
ST11	(1)	Yes. The Pharmacy and Drug Control department used to include it on the MOPH website. However, the department realized that not all healthcare practitioners are reading the information provided. Therefore, now the Pharmacy and Drug Control assigns the companies to distribute it directly to the healthcare organization.
Total score	(5.5)	Out of 11 [11*1= (11)] is [(100%)] relevant indicators the obtained score was [(5.5) =50%].
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(0)	No adequate data. The percentage cannot be calculated as there is no database. Less than 10 reports were sent to the Pharmacy and Drug Control department from Qatar petroleum.
P2	(0)	No adequate data. The percentage cannot be calculated because there is no database.
P3	(0)	No adequate data. The percentage cannot be calculated because there is no database.
P4	(0)	No adequate data. The percentage cannot be calculated because there is no database.
P5	(-)	Not relevant.
P6	(-)	Not relevant.
P7	(0.5)	• P7a: yes, one on vaccines (not specific for PV). It was a component that included ADRs of vaccines for health professionals. • P7b: no, none for the general public.
P8	(0)	No adequate data.
P9	(0)	Only external data.
P10	(1)	4500 products. P10a: more than 90% of products, as per the agreement. MOPH follow the EMA, USA, Arab guidelines.
P11	(1)	85% submit PSURs only Arab countries do not submit and this is a challenge for PV.
P12	(0.5)	• P12: no, no adequate data. • P12a: yes, 20-25 SPCs due to minor variations.
P13	(0)	None from the national pharmaceutical industry. Although they have a PV system in the industry, they are trying to improve it.
Total score	(3)	Out of 11 [11*1= (11)] is [(100%)] relevant indicators the obtained score was [(3) =27.3%]

COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(0)	No report.
O2	(0)	No report.
O3	(0)	No report.
O4	(1)	Less than 1% as there are stringent regulations and medications from reputable sources and mainly brand medications are available in Qatar.
O5	(-)	Not relevant.
O6	(-)	Not relevant.
O7	(0)	Beyond the scope of the Pharmacy and Drug Control Department.
O8	(0)	Beyond the scope of the Pharmacy and Drug Control Department.
O9	(-)	Not relevant.
O10	(-)	Not relevant.
O11	(-)	Not relevant.
O12	(-)	Not relevant.
Total score	(1)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(1)=16.7%]

(*) Score: Yes (1), No (0)
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B)
(*) Score (-): Not relevant for the evaluation of system performance with WHO Indicators.

3) Public Sector: HMC PV System Performance.

Table R4: HMC PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes, within the MSQC.
ST2	(1)	Yes.
ST3	(1)	Yes, phone, email, and fax.
ST4	(1)	Yes, the e-library has different resources including books and journals. Additionally, MSQC-Drug information.
ST5	(1)	Yes, MSQC has ADR reporting through the Cerner system.
ST6	(-)	Not relevant to HMC.
ST7	(1)	Yes, there is no official essential medication list. However, HMC has an essential list in the drug supply department, and it follows the WHO essential medicines list model.
ST8	(1)	Yes. PV data is considered by the CP&TC to develop HMC guidelines.
ST9	(0.5)	• ST9a: Yes, HMC has yearly conferences on medication safety that includes PV. In conferences, HMC provides training in workshops and there are lectures open for all the healthcare providers. To date, HMC conducted these two times. Additionally, HMC pharmacy conferences have a separate theme for PV. • ST9b: No.
ST10	(0)	No, however, it is under future plans.
ST11	(-)	Not relevant to HMC.
Total score	(7.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(7.5) =83.3%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant to HMC.
P2	(1)	Yes. • P2a: Medical doctors, 5%. • P2b: Dentists, 0%. • P2c: Pharmacists, 70-80%. • P2d: Nurses, 10-15%. • P2e: The general public, i.e., HMC patients 0%,

		• P2f: Manufacturers, no, that process is not relevant to HMC.
P3	(-)	Not relevant to HMC.
P4	(0)	No. HMC does not have this data.
P5	(1)	Yes. An estimate of 70 to 80% are aware of processes of ADR reporting, 100% are aware of the term ADR, and only 40 % of them report.
P6	(1)	Yes, patients receive complete education and ADR is a part of the education. Therefore, 90% of them get an education but understanding of areas where to report could be an issue that contributes to not receive any reports from the patients.
P7	(0.5)	• P7a: For the year 2018, one conference and one symposium on medication safety. The symposium had different themes including PV. Additionally, HMC provided training to community pharmacists on medication safety, which included PV and ADR. • P7b: None, for the public.
P8	(0.5)	• P8a: Number of healthcare professionals attended the conference on medication safety was 700, the medication symposium was 250, and community pharmacy around 70 people. • P8b: None, for the public.
P9	(-)	Not relevant to HMC.
P10	(-)	Not relevant to HMC.
P11	(-)	Not relevant to HMC.
P12	(-)	Not relevant to HMC.
P13	(-)	Not relevant to HMC.
Total score	(4)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(4) =66.7%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(1)	Yes, the percentage of preventable ADRs is 5% for all HMC hospitals for the year 2018.
O2	(0)	No, MSQC does not have these data, HMC indicated that this data could be with the Fetomaternal Medicine Unit or the MOPH.
O3	(0)	No, MSQC does not have these data.
O4	(-)	Not relevant to HMC. No cases in HMC.
O5	(1)	Yes, for the past three years 0.16 per one thousand admissions.
O6	(0)	No, HMC does not have these data. HMC indicated that it is non-applicable because it was reported that it is not an indicator for HMC, therefore, they do not capture these data.
O7	(0)	There are plans for “Economic Studies”, however, HMC did not conduct such studies. MSQC indicated that there is one ongoing

		study about clinical interventions of pharmacists and its impact on the cost and length of stay. However, the study is still under process results is not calculated yet.
O8	(0)	No, HMC does not have these data.
O9	(1)	Yes, four medicines per prescription for the whole HMC system.
O10	(0)	No. HMC captures these data, however, HMC does not analyze overdosing, HMC analyzes only dosing errors. However, if they plan to investigate the medication error data to capture overdosing data HMC may get this information. HMC reported that the percentage of dosing errors is 40% as an estimation.
O11	(0)	No, HMC does not have these data. Data is captured. However, there is no formal process to conducted analysis and get the percentage.
O12	(1)	Yes, from 90 to 100% of patients receive this information because 90% receive complete education including ADRs.
Total score	(4)	Out of 11 [11*1= (11)] is [(100%)] relevant indicators the obtained score was [(4) =36.4%].

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

4) Public Sector Level: PHCC PV System Performance.

Table R5: PHCC PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes. There are systems that can be accessed from different computers (i.e., Multum, Cerner, and Datix systems).
ST2	(1)	Yes.
ST3	(1)	Yes.
ST4	(1)	Yes, e-library that includes journals, UpToDate, and many other sources.
ST5	(1)	Yes, the Datix system.
ST6	(-)	Not relevant.
ST7	(1)	Yes, an essential medicine list. This is a mandatory aspect and it is included in the polices.
ST8	(1)	Yes, PHCC has a guidelines committee (includes more than 14 consultants) that uses internal (national level guidelines) and international sources of information (guideline references) to develop the clinical guidelines used in primary care.
ST9	(0.5)	• ST9a: Yes, for example, ADRs reporting. • ST9b: For the general public only raising awareness (not specific to PV), e.g., antibiotic awareness week, medication reconciliation, and declaring allergy status.
ST10	(0)	No tools are available. It was reported that PHCC needs to specialize in PV in the next steps.
ST11	(-)	Not relevant.
Total score	(7.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(7.5) =83.3%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(0.5)	No answer was provided. It was reported that PHCC cannot provide by stakeholders because the reporting in the system is anonymous.
P3	(-)	Not relevant.
P4	(0.5)	No answer was provided. PHCC cannot provide by stakeholders because the reporting is anonymous.
P5	(1)	80% are aware because PHCC conducts Contentious Professional Development programs. This includes ADRs that are considered one of the Required Organizational Practice (ROPs) recommended by the accreditation body Joint Commission International.
P6	(1)	10-20% are aware of ADRs and 100% are aware and get counseling on medication use and side effect.

P7	(0.5)	• P7a: yes, once per year. • P7b: no, patient counseling and the patient antibiotic week includes medication safety but not specifically for PV.
P8	(0.5)	• P8a: 80 pharmacists and nurses. • P8b: more than one thousand.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(4)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(4) =66.7%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(0)	PHCC does not have this assessment.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(-)	Not relevant.
O6	(-)	Not relevant.
O7	(-)	Not relevant.
O8	(-)	Not relevant.
O9	(1)	4 to 5.
O10	(1)	5% estimate.
O11	(1)	30%. The Datix system sends alerts and PHCC staff make the decision to reject or accept based on the category of interaction from A to X, e.g., B or C accept and X reject.
O12	(1)	10-20% are aware of ADRs and 100% are aware and get counseling on medication use and side effects.
Total score	(4)	Out of 5 [5*1= (5)] is [(100%)] relevant indicators the obtained score was [(4) =80%].

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

5) Private sector: Healthcare Institutions PV system performance.

1. Hospital A

Table R6: Hospital "A" PV system performance and capacity results measured by WHO core PV indicators.

CORE STRUCTURAL INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CST1	Yes.	(1)	• Applicable however no specific PV department, The Safety and Quality Department in collaboration with the Pharmacy Department are responsible for medication safety and PV aspects. • An incident reporting system that's divided into two functions clinical incident function and the non-clinical incident function. • The hospital is functional in terms of reporting of individual cases and there is an increase in reporting over time. The hospital tried to develop and nurture a positive culture so that people will feel more inclined to report incidents without any threat of being blamed or punished or disciplined. The hospital has policies that support this philosophy. Nevertheless, it was noted that reporting could be improved further.
CST2	Yes.	(2)	• From a hospital perspective, a range of policies and procedures, which are mainly focused on medication safety and outlines the requirements for PV. However, those are not specific to PV. Those are hospital-based policies that are aligned with national requirements and accreditation requirements. • In terms of policies on medication safety, it is comprehensive and regularly updated. • There is a regular process of identifying any new policies or procedures as a part of the informing processes through incident reporting. For example, if there are incidents related to a particular issue the hospital would update the policies and procedures and offers education related to those medications.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No dedicated budget for PV.	(0)	• No specific budget allocated for PV. The hospital doesn't have a specific budget for medication safety. • A number of medication safety initiatives and practices have been implemented and were supported, some of which have had a cost implication, and the budget has been provided. • If the requested initiative can justify a safety improvement, or an efficiency improvement resources will be provided. • It was reported that there are no barriers with respect to the resources required to address

			medication safety.
CST5	Yes.	(2)	• Yes. Human resources are sufficient, but it's not dedicated. • The people who are involved in the review and analysis of incidents related to medication safety are full-time staff.
CST6	Yes.	(2)	• An incident reporting system that's divided into two functions clinical incident function and the non-clinical incident. Therefore, from a clinical perspective, if there were any incidents related to medication safety, it would be recorded. For the non-clinical reporting perspective, if there was an issue around the storage of medication or supplies or breakage or incidents that don't involve a patient. • It is a paper-based system. The incidents will be collated on a monthly basis. The Safety and Quality Department will look at incidents in the near-miss of all types, but one of the subcategories is specifically related to medication safety. It was noted that this will offer an opportunity to capture the information and to review incidents to implement improvement. Hence, the hospital legitimizes that by giving its own subcategory. • Reporting by the public can be through the feedback forms, however, it is a generic form and it does not categorize the feedback. The documentation is a free text format and allows the patient to raise an issue or provide either negative or positive feedback.
CST7	Yes. A process and database exist.	(2)	• Incidents will be documented in a database that collects information based on the type of incident. For medication-related, it also categorizes the risk level of the incident and the Safety and Quality Department uses the severity assessment code, which applies levels of risk to stratify the seriousness of the incident. • For lower risk levels the analysis and feedback will be at the department level however for the more serious levels, the Safety and Quality Department will take this responsibility. • The Safety and Quality Department has a documented process in terms of time frames for analysis and providing feedback and/or recommendations. The hospital has a complete feedback loop in terms of communicating the process of investigation, the outcomes, recommendations for improvements. • The hospital has a very structured electronic medical record and it is easy to interrogate the system and gather any missing information. Hence, the information will be captured in two places. • The databases are an Excel spreadsheet. It was noted that it is a labor-intensive system database, and the hospital is planning to implement an automated system.
CST8	Not relevant.	(-)	• Not relevant.

CST9	Yes.	(2)	• The hospital has a website with a range of resources that support safety and quality for patients. This includes policies and procedures related to medication safety. Additionally, the hospital has information bulletins that highlight any changes in practice, or any new standard related to medication safety. The hospital has a robust IT system which is the basis of communication. • An example of hospital communication with the public includes the collaboration with media for health promotion as well as social media distribution to provide key information to the community. In addition, on the webpage, there is information for patients in terms of how they can contribute to the safety of their own care.
CST10	Yes.	(2)	• The Pharmacy and Therapeutics Committee is responsible and accountable for all aspects of medication safety and management. It is chaired by a medical consultant and has representation from across the hospital including the pharmacy department.
Total Score		(13)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(13) =81.3%]
CORE PROCESS INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CP1	Yes.	(1)	• All the reports were preventable. • For medication incidents, the total number for 2017 was 72 reports. Medication incidents per 100,000 occupied beds days (OBDs) was 0.30 for the year 2017. • The hospital reinforces the need to report and they are promoting positive culture towards safety as it gives an opportunity to focus on the system's aspect rather than the individual aspect. Currently, the staff is much more willing to report. Additionally, on a regular basis, the hospital assesses the safety culture, and the results demonstrate that people are becoming more confident to report.
	CP1a: Not relevant.	(-)	
CP2	Yes.	(2)	• For medication incidents, the total number from 2014 to 2017 was 329 reports. The majority are in the low-risk category. Most of these would be near misses rather than actual incidents. • From a governance perspective, the database gives a clear picture of areas where there is a need for focus in terms of policies, procedures, education, or improved supervision. For example, the hospital had several prescription errors and the database showed a very clear pattern related to prescription. As a result of that, the hospital implemented an electronic prescription system. Hence, the current system formalizes the reporting process, improves communications, and reinforces the need to report to the hospital staff.
CP3	100%.	(2)	• The hospital doesn't keep a record, but an estimate will be close to 100%. After the investigation feedback is provided to 100% of the incidents. • The feedback loop is considered complete and quite rapid. The hospital policies define the time

			frames, but some incidents require more investigation. The Safety and Quality Department often will do root cause analysis on such cases and this might be delayed if a key person is on leave.
CP4	100%.	(2)	• The Safety and Quality Department conducts analysis on all the reports; however, it may be in a relatively informal sense. A formal process like a root cause analysis will be done for the high-risk category, which is a limited number of cases. But the majority includes near misses those will be reviewed in a less structured and less formal way. • The hospital has sufficient expertise in terms of root cause analysis. Members individually or collectively involved are the Safety and Quality Department director, the Deputy Chief of medical staff, and the quality assurance committee. However, it was stated that for data analysis it would be good to have a statistician with more developed statistical and analytical skills and to have specific software for analysis as well. • For the lower-level risk cases, the department head would conduct the review, and they have the required skills.
CP5	100%	(2)	• All are satisfactory or completed. If they're incomplete, the Safety and Quality Department will return the report until it will be satisfactorily completed with all the key information required. • The capacity of people across the organization to complete the documentation correctly is quite high. In addition, it is included in the orientation for new staff. • The hospital does report to the MOPH, only a few key performance indicators will be reported to MOPH. One of the indicators relates to medication incidents. The hospital report on a quarterly basis, but data will be provided by month. Then the MOPH provides the hospital with the benchmark results to do a comparative analysis between hospitals across the country.
	CP5a: Not relevant.	(-)	
CP6	No cases.	(2)	• The hospital doesn’t have any cases reported.
CP7	No cases.	(2)	• In 2017, no cases were reported. In 2016, two cases were reported, one of these cases were related to vaccination. The majority of incidents are reported near misses.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• The hospital doesn’t get involved in medication research or clinical trials. But it was noted that the hospital is at the foundation stage of establishing a research profile and collaborating with some of the universities in Qatar to support research activities. The hospital foresees a role for the private sector to be involved in research and conducting clinical trials in the future. • The hospital has some surveillance activities however not from a research perspective, e.g., infection control, hand hygiene, staff surveillance. Additionally, the hospital looks longitudinally at the data and the trends. For example, the hospital identified through incidents reported that high

			concentration electrolytes were being managed at a unit level, and medications were being reconstituted by nurse staff rather than the pharmacy staff. Therefore, through risk management processes, and by proactively looking from a risk point of view this was made as a centralized function under pharmacy by professional pharmacy staff.
Total Score		(13)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(13)=81.3%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CO1	None.	(0)	• None.
CO2	Not relevant.	(-)	• Not relevant.
CO3	No.	(0)	• The hospital doesn't have this information documented. Over the last year, there was one reported case of a deliberate overdose with the misuse and abuse of medications. • The hospital reported that from a clinical coding point they do not have comprehensively coded data on that information either. The hospital staff does not code every admission, only admissions where the insurance company requires clinical coding. Additionally, the hospital classifies admissions into specialties rather than into conditions, e.g., medicine or surgery, obstetrics, etc. • It was stated that there could be an underestimation of the connections between medication and presenting conditions. • It was reported that there are two drivers to encourage clinical coding across the country in the near future. First, a new national health insurance scheme being introduced later this year, and part of it will require hospitals to conduct clinical coding on every patient. Second, the Minister of Health has given the commitment to an international forum, and this can promote clinical coding across the country.
CO4	No Cases.	(0)	• No documentation for this indicator. • In the last two years, no cases of death were reported.
CO5	Not relevant.	(-)	• Not relevant.
CO6	No.	(0)	• The hospital does not have any specific information on that because the occurrence of medicine-related illness is very low. Additionally, the hospital does specific clinical costing for outliers only. • It was reported that the hospital will definitely consider the cost implications if it was relevant to their practice.
CO7	No.	(0)	• The hospital does not have this information documented. Additionally, no cases were relevant to this indicator in practice.

CO8	No.	(0)	• The hospital does not have this information documented. Additionally, no cases were relevant to this indicator in practice.
Total Score		(0)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators the obtained score was [(0) =0%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R7: Hospital "A" PV system performance and capacity results measured by WHO complementary PV indicators.

COMPLEMENTARY STRUCTURAL INDICATORS

Code	Score*	Answer qualitative
ST1	(1)	Yes, in the pharmacy a few computers are dedicated to the management of all aspects of medication and pharmacy practice. And for prescribing or access to pharmacological information, any computer in the organization can be used.
ST2	(1)	Yes, the pharmacy department manages and compute the storage and distribution of medications. Part of pharmacy key stakeholders has access to stores databases, and pharmacy reports utilization of medication on a regular basis.
ST3	(1)	Yes, a good system of communication and it's available to all staff, e.g., emails and a website.
ST4	(1)	Yes, access to regulations, policies, and procedures. Additionally, specific medications resources including drug Information sheets, the BNF and other formularies.
ST5	(1)	Yes, a database that has been developed in house, it's an internal system.
ST6	(-)	Not relevant.
ST7	(1)	Yes, maintained by the Pharmacy Department. It comprises a couple of critical medications and emergency medications.
ST8	(1)	Yes. About 20 staff are involved in developing guidelines for specific conditions. Those guidelines are based on international standards of care and international treatment guidelines. In addition, they've been customized to the local environment to be more specific, and those include certain safety precautions.
ST9	(0.5)	Yes. • ST9a: for health professionals, the hospital provides training on medication safety or any specific medication safety initiatives. Additionally, the hospital supports national medication initiatives. For example, workshops and activities at the MOPH related to antibiotic usage and prescription administration. • ST9b: little effort made with the general public, only through media.
ST10	(0)	No.
ST11	(-)	Not relevant.

Total score	(7.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(7.5) =83.3%]

COMPLEMENTARY PROCESS INDICATORS

Code	Score*	Answer qualitative
P1	(-)	Not relevant.
P2	(1)	No, no specific record in the database on such categorization. The hospital collects information on reporting including the healthcare profession, however, the information is not analyzed. Estimates on the overall clinical incident reporting (i.e., not exclusive to medication) are 80% nursing, 15% pharmacist, and 5% medical doctors.
P3	(-)	Not relevant.
P4	(0)	No, no specific record in the database on such categorization. The hospital collects information on reporting including profession, but the information is not analyzed. Estimates on the overall clinical incident reporting (i.e. not exclusive to medication) are 80% nursing, 15% pharmacist, and 5% medical doctors.
P5	(1)	On ADRs, it is very high 100%. It's part of the orientation for all new staff. Additionally, the old staff are subjected to regular education.
P6	(1)	An estimate of 5%. The hospital encourages disclosure, and the policy supports this disclosure, but the hospital doesn't capture or formally collate the present picture. It was reported that people are fearful of the law and fearful of the implications for them from a licensing perspective because although the hospital promotes reporting culture internally and focus more on systems, the government departments have less of a focus on safety culture and more on the disciplinary approach.
P7	(0.5)	Yes. • P7a: For the healthcare professionals as an estimate about six sessions. The hospital focusses mainly on medication safety and doesn't tend to use the term PV. • P7b: For the public, the hospital doesn't conduct any specific sessions or any activities specific to medication safety. All the patients are given medication counseling.
P8	(0.5)	Yes. • P7a: For the healthcare professionals' participation would be about 400 approximately it covers a combination of pharmacy, medicine and nursing staff. • P7b: For the public, none.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.

P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(4)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(4) =66.7%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(1)	100% as most of the cases relate to human error which would be preventable.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(1)	In 2017 one case that was a specific medication error. A vaccination that was given twice to the same child. But based on the literature for that medication, there was no harm associated with it. Therefore, it was reported that the number of patients affected for the physical effect would be zero, and the number of patients involved is one.
O6	(0)	The hospital doesn't have that information, not recorded.
O7	(0)	The hospital doesn't have that information, not recorded or calculated.
O8	(0)	The hospital doesn't have a specific budget related to medication safety or PV activities.
O9	(0.5)	The pharmacy department captures these data.
O10	(0.5)	The pharmacy department captures these data.
O11	(0.5)	The pharmacy department captures these data.
O12	(1)	The hospital provides medication counseling for all patients, 100% medicine use and 5% ADR.
Total score	(4.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(4.5) =50%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

2. Hospital B

Table R8: Hospital "B" PV system performance and capacity results measured by WHO core PV indicators.

CORE STRUCTURAL INDICATORS

Code	Response	Score *	Assessment (Qualitative)
CST1	No specific PV department.	(1)	• The Quality Department is responsible for covering medication safety and PV. • In addition, the Pharmacy and Therapeutics Committee and the Pharmacy Director all are coordinated at the hospital level to cover PV and medication safety. • All concerned parties have available communication tools to ensure medication safety at the hospital level. Every month all concerned parties have a joint meeting.
CST2	Yes.	(1)	• Range of policies that focus on medication safety, however, policies are not specific to PV. • The hospital considers the laws and policies of the country to ensure that there are complying with the country laws.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget for PV.	(0)	• There is no specific budget dedicated to PV. However, generally, the hospital considers the budget sufficient to cover medication safety activities.
CST5	Yes.	(1)	• It was reported that the quality department does not need a dedicated full-time staff for PV as the practice of PV is coordinated at the hospital level and their expertise is good and sufficient. • The Pharmacy and Therapeutics Committee has multidisciplinary staff. • The clinical pharmacist is responsible for conducting data analysis including severity assessment and causality assessment.
CST6	Yes.	(2)	• The hospital has two report forms an electronic form for healthcare professionals and paper-based patients forms or cards. • The patient cards were developed in a very simple way so that the patient will be encouraged to report. Patients can submit the card directly or send a photo to the hospital WhatsApp number. The hospital staff noticed that the patients are responding and up taking this. For example, some people sent photos to the hospital using WhatsApp. • There are no specific field for medication counterfeit or substandard or therapeutic ineffectiveness, suspected misuse, abuse of medication. The hospital wants to streamline reporting thus the form will be initially filled by the reporter and the missing information will be generated by the clinical pharmacist.

CST7	Yes. A process and database exist.	(2)	• It was reported that the electronic database is the Cerner system. • The clinical pharmacist will follow-up with the reporters to complete all key information required for analysis. Then he/she will examine the patient case using scientific tools and methods. This includes determining the preventability of ADR, the causality assessment using Naranjo nomogram for adverse drug reaction assessment, and severity assessment using the Hartwig severity assessment scale. • After the clinical pharmacist completes the received reports checking process, it will be sent to the quality department. The quality department will then do more processing and will issue feedback. • Feedback to healthcare professionals is through the "Thank you Doctor letter". Feedback will be provided for everyone who has reported in order to encourage staff and increase the reporting rate. Additionally, the hospital endorses the concept of no-blame culture to the staff.
CST8	Not relevant	(-)	• Not relevant.
CST9	Yes.	(2)	• The hospital had a previous project to develop a bulletin and it had all PV related information. However, unfortunately, there were many challenges with the marketing administration, therefore the project was canceled. It was reported that the hospital is very strict with branding and visualization. Hence, currently, the staff communicate by email. • Additionally, the webpage will be used for communication with staff members, clinicians mainly. For example, any subject discussed in the Pharmacy and Therapeutics Committee, e.g., decisions or the actions that are undertaken will be included in a specific part of the webpage.
CST10	Yes.	(2)	• The Pharmacy and Therapeutics Committee is governing medication management and use. Hence, it is the main committee to discuss and advise on safety issues and medication-related information. • It is a multi-disciplinary committee and ad-hoc members can be added when necessary. As per the policy, the committee members are ought to have a meeting every quarter.
Total Score	(11)		Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(11) =68.8%]
CORE PROCESS INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CP1	The value was not provided.	(1)	• Data is available but the value was not provided. The Canadian accreditation body requires hospital data to be presented along with a full analysis. This includes but not limited to the rate of medication errors, ADRs reporting through the last 3 years, the number of reports from different healthcare professional backgrounds, and clinical pharmacist intervention.
	CP1a: Not relevant.	(-)	
CP2	The value was not provided.	(1)	• Data is available; however, the value was not provided. • The reporting rate in the hospital increased after some initiatives. The clinical pharmacist was

			assigned to be involved in the educational campaign for the staff. The reporting forms were distributed in the hospital to be accessible to everyone. The pharmacists are in close communication with healthcare practitioners and can assist them in reporting. Additionally, the staff were encouraged to report.
CP3	100%	(2)	• Feedback is documented. Every reporter will receive a Thank you letter. • The hospital will give reporters a thank you letter in front of everybody to encourage them and to change the perception of people who think that when they report an ADR it means that they have made an error. The hospital wants to exclude this fear and make reporting an open manner.
CP4	100%	(2)	• Every report will be assessed following a structured process.
CP5	100%	(2)	• Cerner system will be used to extract missing information from the patient records. • The clinical pharmacist will ensure to complete the report information before conducting the analysis. • In addition, a report will be prepared to be discussed in the Pharmacy and Therapeutics Committee meeting.
	CP5a: Not relevant.	(-)	• The hospital sends the compiled and approved report to the Healthcare Quality and Patient Safety Department in the MOPH because it is requested to send them the medication errors report on monthly bases.
CP6	No cases.	(2)	• No cases were encountered. The clinical pharmacist will work with the physicians if there are any suspected cases or contributing factors including patient adherence.
CP7	The value was not provided.	(1)	• Data is available for medication errors from 2016 to 2018; however, the value was not provided. • The hospital will put the category of harm based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). • Additionally, root cause analysis for medication errors was conducted more than once even though it did not cause harm for the patient.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• None.
Total Score	(11)		Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(11) =68.8%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**

CO1	Yes.	(1)	• It was reported that glucosamine in more than one patient caused swelling in the joint area, and there were cases with vancomycin that had the same report.
CO2	Not relevant.	(-)	• Internal actions will be documented in the Pharmacy and Therapeutics Committee, and by the end of the year, it will be included in the annual report. Appropriateness of internal actions will be assessed based on the case this can include tracking changes in reporting rates and communicate directly with staff. • It was reported that there is no feedback from the MOPH this was recognized as the MOPH are at the phase of data collection. It was recommended that MOPH can utilize this data and share it at the national level for health institutions to reflect on their current performance compared to others, e.g., the issues that are happening in other systems. This can result in the development of awareness programs for healthcare professionals, patients, and the public.
CO3	No cases.	(1)	• No cases. • The hospital does not have this record because their patients are mainly admitted to surgeries. Thus, this was noted as not applicable to the hospital context. Based on the data for the year 2017 there was zero rate infection. Hence, there were no cases of readmission.
CO4	No cases.	(2)	• No cases of death. • The hospital does not have documentation, because no cases of death occurred. However, it was stated that if death will occur this will be addressed including investigation and conducting root cause analysis to prevent the occurrence of future cases.
CO5	Not relevant.	(-)	• Not relevant.
CO6	Not documented.	(0)	• Data is available in the system, but the number is not recorded as a value. The hospital staff document the cost of cases in the system as a bundle. Cost data can be extracted if they want to for specific drugs or interventions, not disease or conditions. Also, no cases of medicine-related illnesses were reported.
CO7	No cases.	(1)	• No cases required an extension of hospital stay.
CO8	Not documented.	(0)	• It was reported that conducting economic studies will be difficult as the staff number is small and resources are not enough. If needed in the future the hospital may need a third party to consult in such studies.
Total Score		(5)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators the obtained score was [(5) =41.7%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R9: Hospital "B" PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes, the Cerner system can be used from any computer.
ST2	(1)	Yes, in the Cerner system.
ST3	(1)	Yes, emails and the website.
ST4	(1)	Yes, UpToDate, Lexicomp, and other online sources. Additionally, hard copies are available in the pharmacies, however, online sources are mainly used.
ST5	(1)	Yes, the Cerner system.
ST6	(-)	Not relevant.
ST7	(1)	Yes, the Pharmacy and Therapeutics Committee will meet to update the Cerner formulary regularly.
ST8	(1)	Yes.
ST9	(1)	Yes. • ST9a: lecture series and journal clubs will be held regularly. Additionally, workshops and conferences are ongoing. • ST9b: the patient reporting cards, medication reconciliation, and the hospital follow the teach three techniques (i.e. informing patients on drug indication, drug use, and drug side effects) with patients.
ST10	(0.5)	Yes. • ST10a: for health professionals, competency questions will be available. • ST10b: none. It was noted that public involvement will need human and financial resources. The idea is possible and there is a consideration from the hospital side, however, it is not easy to ensure its sustainability and it will need a special project.
ST11	(-)	Not relevant.
Total score	(8.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(8.5) =94.4%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(0)	The data is available; however, values were not provided. • P2a: • P2b: • P2c: • P2d:

		• P2e: • P2f:
P3	(-)	Not relevant.
P4	(0)	The data is available; however, values were not provided. • P4a: • P4a: • P4a: • P4a:
P5	(0.5)	No percentage provided however the hospital conducts regular training and academic detailing.
P6	(1)	100%. Patients awareness is high as a result of the following initiatives the patient reporting cards, medication reconciliation, and the teach three techniques (i.e., informing patients on drug indication, drug use, and drug side effects).
P7	(0.5)	Ongoing training is available based on needs. The hospital does not keep records (i.e., no documentation). • P7a: • P7b:
P8	(0.5)	• P8a: The numbers were not provided because there is no documentation system for such initiatives. However, the hospital conducts face to face training for new joining members or on the occurrence of trends or cases that require training. • P8b: The numbers were not provided because there is no documentation system for such initiatives.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(2.5)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(2.5) =41.7%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(0)	The data is available; however, no value was provided.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(0)	Not documented in this format, therefore, data was not provided.

O6	(0)	Not documented.
O7	(0.5)	The hospital did a cost-saving study on medications in general including safety and improving the processes, the hospital saved a half-million Qatari Riyal for different things related to medications. However, there is no specific study on PV or safety alone.
O8	(0)	No, specific data on PV.
O9	(0)	Data is available; however, no value was provided.
O10	(0)	Data is available; however, no value was provided.
O11	(0)	Data is available; however, no value was provided.
O12	(1)	100%.
Total score	(1.5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(1.5) =16.7%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

3. Hospital C

Table R10: Hospital "C" PV system performance and capacity results measured by WHO core PV indicators.			
CORE STRUCTURAL INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CST1	No specific PV department.	(1)	• Applicable but no specific PV department, there is a Pharmacy and Therapeutics Committee. • The Role of this committee is to govern many aspects including ADR. Additionally, the group has indicators to follow including ADRs. For example, ADRs reports will be collated from across all medical centers and the Hospital. • The committee encompasses multidisciplinary members. The committee reaches the clinical pharmacist for further analysis and based on that a monthly summary will be prepared and disseminated among all healthcare providers on a timely basis.
CST2	Yes.	(1)	• Yes, a range of policies that cover aspects relevant to PV. • It was reported that at the national level there is no policy document for PV.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget for PV.	(0)	• It was reported that there is no dedicated budget for PV. The allocation of resources will be based on request when the committee requires anything it will be supported, e.g., educational activities, purchasing a software, etc.
CST5	Yes.	(1)	• The current human resources are enough to cover PV and medication safety. All members are full time, and all are briefed about terms of reference including their roles and responsibilities.
CST6	Yes.	(2)	• The group has three paper-based reporting forms this includes ADRs reporting form, medication errors reporting form, and a medication recall form. • Misuse and abuse are not common. The group does not have any report on patient use for medication this is only included during patient examination for clinical information. • It was reported that staff are trained on reporting and that the reporting rate has increased by 45-55%. Healthcare professions showed an increased awareness on the subject of reporting. • It was reported that there is no form for the public because this must be under the MOPH. However, there is a complaint system and the staff do work to resolve any issue within a maximum of 30 working days.
CST7	Yes. A process and a database exist.	(2)	• It was reported that the doctors are the custodian of patients and are responsible for identifying ADR. ADRs reports will be submitted and details reported will be enclosed by the pharmacist in charge. Then the severity will be rated, and the Naranjo scale will be used to show the probability. Within 48 hours it will go to the quality department. Then the committee will hold a monthly

			discussion on the subject. • The database is in the form of an Excel spreadsheet. In the future, there is a plan to purchase software that was implemented in one of the hospitals as a testing phase. • The feedback will be provided to healthcare professionals on the group internet website and Yammer group website.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• The feedback will be provided to healthcare professionals on the group website and Yammer group website. • The quality department will update the news for the internet website in the form of files that are accessible to all medical centers and hospitals. For example, a summary of medication errors will be posted in one sheet accessible for all relevant staff.
CST10	Yes.	(1)	• Pharmacy and Therapeutics Committee is responsible for governing aspects related to medication safety and taking a joint decision on relevant aspects. The committee provides advice to ensure patient safety across the group. • The group has quarterly meetings to address the challenges or concerns raised, and they have immediate meetings on emergency basis.
Total Score		(10)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(10) =62.5%]
CORE PROCESS INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CP1	One case in 2017.	(2)	• To improve reporting across the medical centers and hospitals. The group undertook measures to improve reporting this includes leadership programs, enforcing the concept of no blame culture, and following up on reporting in a timely manner. Additionally, the group provides over time and after job time training.
	CP1a: Not relevant.	(-)	
CP2	Yes.	(1)	• The value can be obtained from the database. The numbers will be compiled, 87 cases were reported in 2017. • It was reported that the rate and quality of reporting have increased and when gaps are identified feedback will be provided. In 2016, they only had 5 to six reports submitted while in 2017 there was an improvement of more than 300-400% fold. This surge was indicated as a result of all the initiatives undertaken to increase the awareness of healthcare professionals. Along with the development of a standardized reporting form with mandatory fields of reporting.
CP3	100%.	(2)	• Feedback is provided to all reports.

			• The feedback will be provided as verbal feedback on some cases that have room for improvement, however, if nothing must be improved the staff will be informed about the incidents and their numbers only. • The group issue feedback in a consolidated monthly report thus at the monthly rounds feedback will be given to all reports. For critical cases, the whole team will be informed directly. • The group has a safety meter in all the medical clinics this includes ADR reporting.
CP4	100%.	(2)	• They conduct the assessment for all the received reporting forms. • The process includes ensuring that minimum documentation required to analyze the data is captured during the reporting itself. Then, the clinical pharmacist will do analysis e.g. the probability scaling, preventability, and severity. In addition, they will determine if the case is an idiosyncratic reaction or an actual ADR. • It was reported that assessment is done based on scientific tools and guidelines to ensure that the process is meeting most of the requirements of evidence-based assessment. • The level of expertise to conduct causality assessment is sufficient as no complicated cases are encountered in the scope of the group practice.
CP5	Yes.	(1)	• It was reported that within the organization all reports will be satisfactorily completed and sent to the quality department for compilation. • For ADR reporting to the MOPH, it was reported that there is no structured way to report to any regulatory authority, e.g., the pharmacy and drug control department would not request any ADR reports. For medication error data, it will be sent to the MOPH as part of the key performance indicators.
	CP5a: Not relevant.	(-)	• Not relevant.
CP6	No cases.	(2)	• No cases were received. The group follows the trends for internal purposes only. • The report forms include predisposing clinical factors for reporters to complete, e.g., renal dysfunction, genetics, age, gender, multiple therapies, and so on. • The patients will be counseled on the importance of following the regimen and the provided additional instructions.
CP7	4.19% for 2017.	(2)	• It was reported that their measures to build a culture that supports reporting have increased the number of reports however underreporting can be attributed to resistance to change for some staff with more than 15 years of practice.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• It was reported that the private sector is not permitted to conduct this type of research in their

			centers and only therapeutic follow up is permitted.
Total Score		(12)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(12) =75%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CO1	One case.	(1)	• It was reported that one case with the injection Voltic, there were many ADRs coming due to the single brand, and it was not a piece of information provided from the MOPH, it was an internal call. The group had cases reported frequently and they did test doses. Therefore, one signal was given internally, and the group withdraws the drug from their system. • The staff are aware of the subject matter as there is a policy on signal cases and on drug recalls. • The group will use interoffice notes to communicate signals to end-users. There is an action plan to communicate signals to external parties if needed. • The group will depend on causality analysis to know if this is happening in all centers then this will be referred to the committee to make the decision, based on the severity and frequency of reports the action will be taken. Actions implemented after a signal notice is the responsibility of the committee. There is no delay in such cases that affect patient safety.
CO2	Not relevant.	(-)	• The group will act as directed by the MOPH. Additionally, the group relies on external reputable sources like the US FDA.
CO3	One case.	(2)	• One reported case from 2016 to date; Allopurinol and Stevens-Johnson syndrome. • The group does not quantify the burden of medication-related hospitalization because it will be referred to the public sector, e.g., financial burden.
CO4	No cases.	(1)	• No cases encountered. • It was reported that the inclusion of this indicator in the group system will require staged execution and building of the capacity including infrastructure, manpower, and others. Therefore, capturing this indicator and ensuring that the process is sustainable will require a period of time.
CO5	Not relevant.	(-)	• Not relevant.
CO6	No.	(0)	• Not estimated. • The group does not have a health economist. • It was reported that for this indicator information is sensitive and hard to extract. This needs to happen within the MOPH and there should be a system in place for such studies.
CO7	No.	(0)	• Not available or documented. • It was recommended that this information will be beneficial for health planning if it was estimated at the national level under the regulatory body.

CO8	No.	(0)	• Not available or documented.
Total Score		(4)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators the obtained score was [(4) =33.3%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R11: Hospital "C" PV system performance and capacity results measured by WHO complementary PV indicators.

COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes.
ST2	(1)	Yes. The British National Formulary and they compare against the prescription bill.
ST3	(1)	Yes.
ST4	(1)	Yes, the British National Formulary.
ST5	(0.5)	Yes. Excel spreadsheet.
ST6	(-)	Not relevant.
ST7	(1)	Yes, critical medicine list. The group does perform VED analysis (vital, essential, and desirable matrix).
ST8	(1)	Yes, there are certain conditions to be monitored like antibiotic prophylaxis.
ST9	(0.5)	• ST9a: Yes, mandatory once every quarter for all staff related to medication safety, e.g., physicians, pharmacists, dietitians, and others. • ST9b: For the public, radio talks on medication safety and other aspects. Additionally, antibiotic awareness week the group communicated with the public through social media and website platforms.
ST10	(0)	No, no tools used, however, they train them based on their internal data.
ST11	(-)	Not relevant.
Total score	(7)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score is [(7) =77.8%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(1)	Yes. • P2a: 100% ADR and 10% medication errors. • P2b:

		• P2c: 70% medication errors, prescription errors mainly. • P2d: 20% medication errors. • P2e: • P2f:
P3	(-)	Not relevant.
P4	(1)	Less Than 1%.
P5	(1)	All relevant groups are knowledgeable. 100%, because it is a part of the group induction models, on quarterly bases the staff is training on that.
P6	(1)	Yes, 100% receive counseling by pharmacists. Drugs that have the potential to cause an ADR are explained very well by the pharmacist when they dispense.
P7	(0.5)	Yes. • P7a: Compulsory mandatory module is conducted (more than 25 sessions in 2017), and every quarter the group do refresher training for pharmacy staff. • P7b: Radio talk to the public on medication safety and there is a platform to address their concerns.
P8	(0.5)	• P8a: Yes 70-80% of healthcare professions, 280 individuals. • P8b: radio talk for the general public.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(5)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(5) =83.3%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(1)	One case.
O2	(-)	Not relevant. No cases were encountered.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(1)	One case.
O6	(0)	Not able to quantify.
O7	(0)	The group does not have these data.

O8	(0)	Not able to quantify.
O9	(1)	Yes, Five.
O10	(1)	Yes 10 to 12%
O11	(1)	No, no cases
O12	(1)	Yes, 100%.
Total score	(6)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(6) =66.7%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

4. Hospital D

Table R12: Hospital "D" PV system performance and capacity results measured by WHO core PV indicators.			
CORE STRUCTURAL INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CST1	No specific PV department or unit.	(1)	• The Quality and Patient Safety Department are responsible for the collation and analysis of medicine-related safety issue reports. The department does not have a well-established system or protocols for PV and ADRs. • At the current state, they are focused on patient safety and enhancing quality. The department members are planning to initiate the processes which enhance patient safety. Plans include educational programs and the priority is to educate the staff on the importance and process of reporting.
CST2	No specific PV policy or guidelines.	(0)	• No, the hospital does not have specific policies on PV or ADR reporting. • The hospital is in the process of developing all medication management policies. The new policies will cover many aspects of medication safety, medication errors, ADRs, quality of the medication. The new policies will have a certain timeline to be revised and updated regularly by the management
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget allocated for PV.	(1)	• There is no dedicated financial provision for PV activities. • The department has support from the management for their need's fulfillment by request (case by case), e.g., educational aspects. Currently, the budget is sufficient because the system is not very well established.
CST5	Yes. Not sufficient.	(1)	• The department has 3 full-time members, one from a pharmacy background and two from a nursing background. The department reported that to have a well-established PV system in the future the current human resources is not enough. It was reported that there is a need for pharmacy background professionals to support educational activities on medication management and safety. Additionally, there is a need for staff with experience in vigilance and medication safety, data analysis, and risk management. • The current members are enthusiastic and are self-directed toward improvement even if there is no formal education provided for them at the current position. • The department developed a competency chart that mentions all the activities for clinical pharmacists, and it includes the process of ADR detection and reporting.

CST6	Yes.	(2)	• The hospital has two paper-based reporting forms, and they are fully integrated into the system. First, the occurrence variance report, it is used for reporting medication errors and other safety issues. This report has space (i.e., free text area) to write manually the sub-indicators CST6b to CST6c, and CST6d. Second, ADR s reporting form that is available in the previous policy manual. The current ADR form does not have all elements required for causality assessment the new one that they will implement will be more appropriate. • There are no report forms for patients CST6e. However, they are planning to educate the patients on how to observe any untoward reaction, how to report it, and how to get back to the hospital. The department noted that there is a lack of communication from the patient side as they do not report or get back to the facility to address their concerns or complaint.
CST7	Yes, they have a process and an excel database.	(1)	• A process for data collection, analysis, and feedback exits but it is not well developed. The department collects information from the paper-based reports in an Excel sheet database. • The department performs data analysis on the received reports mainly medication error reports and follows that with categorization and trend analysis. Additionally, the outcome of the analysis is used to provide recommendations to inform the prescribers. They have already recruited clinical pharmacists to have an oversight on all the medication-related activities including reporting. As a result of their efforts in the past two years, they noticed that medication errors are not being repeated compared to previous years. • The pharmacist will categorize the medication errors and make the final report every month. This report will be sent to the medical director to forward it to the hospital staff to avoid repeating these medication errors in the future. • Feedback can include calling the prescribers or they send a report with the reference to ask for their explanation in case of medication errors. • The hospital has medication error boards, which are submitted to the quality improvement team or pharmacist to enter data in the system as key performance indicators. Then they submit this data to MOPH. • The department reported some barriers to implement Electronic Medical Records (EMR) for the inpatient consequently they have manual or paper-based medical records.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes, monthly newsletter.	(2)	• Yes, the hospital publishes a monthly newsletter that includes PV and medication safety issues e.g. safety warnings from FDA website. The impact of information shared on professional behavior is

			considered profound because the staff became more vigilant and if they have any concerns, they will call the pharmacist or other responsible staff. This feedback is offering an educational benefit and is reducing medication error cases. The future plan includes developing a specifically approved format for the newsletter. • They do not have a system for the public. However, the hospital plans to develop patient's instruction cards at the time of discharge to include information on medication uses, side effects, how to take the medication, etc. • The current policy manual doesn't specify the communication flow, timelines, and communication and emergencies. They do it at the individual level and there is no proper standardized process to follow.
CST10	Yes, The Pharmacy and Therapeutics Committee.	(2)	• The Pharmacy and Therapeutics Committee can provide relevant advice on medication safety and PV and are responsible for the decision-making process. The timelines for meetings are specified in the policy (every three months) but the members meet frequently (once per month) and in emergencies, they have immediate meetings. • They are working on plans to developing drug formulary, changing the policy manual, developing guidelines, developing drug protocols for staff, and preparing instruction cards. • The committee consists of nine members of different professional backgrounds including medical director, chief clinical officer, quality manager, chief nursing officer, infection control nurse, clinical pharmacist, supply chain manager, and a manager from the internal medicine. • The committee requires a clinical pharmacist and an expert in data management and data analysis to fulfill their future plans successfully.
Total Score		(10)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(10) =62.5%]
CORE PROCESS INDICATORS			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CP1	One reported ADR case in 2018.	(2)	• It was reported that a minimum number of people are interested in reporting this causing an under-reporting problem. The barriers to reporting were lack of knowledge, fear, and reluctance to report. The latter is an issue especially among nurse practitioners, this due to the previous management that was in favor of doctors, they were considered the ultimate authority in the care of patients. • They continuously address the under-reporting issue by educating the staff, increasing awareness on the importance of reporting, encouraging staff to report, publishing the newsletter, and the full support provided by the new management to endorse teamwork. After introducing the new policies, the department has plans to implement regular educational programs for the staff for
	CP1a: Not relevant.	(-)	

			training and education on various issues.
CP2	16 total reports in 2018.	(1)	• The most frequently reported cases in 2018 were medication errors (n=15) and non-preventable ADR case (n=1) reported by a nurse. • After the department started analyzing the reports and making final monthly reports to be sent to the medical director who will communicate with the prescribers, they observed over time that the frequency of reports on medication errors was reduced.
CP3	100%	(2)	• Every report will be analyzed, and the department will provide feedback within 3 weeks or less to prepare the monthly report.
CP4	No evidence-based causality assessment.	(0)	• Estimation of 60 to 70% will be assessed but no evidence-based tool will be used reports assessment rely on the discussion between department members and based on the evidence provided in the literature. The reports will be assessed but it's not a hundred percent, because some of the doctors, they're visiting doctors. Thus, it may difficult to communicate with them for the cases. • The results will be submitted in a report to the pharmacy and therapeutics committee to develop strategies. • The department noted that there is a need for experts in the future who are able to conduct the data analysis utilizing validated tools and statistical methods.
CP5	100%.	(2)	• 100% of medication error reports are submitted to the MOPH. • The department is required to create an Excel file key performance indicator where all the medication error data will be submitted to the MOPH. The ADR case was included in the same file. However, the department doesn't receive any feedback from the MOPH and the didn't get any communication on how to improve.
	CP5a: Not relevant.	(-)	• There is a focus from the MOPH on vaccine safety and reporting. The vaccination department is responsible for sending reports and recording their files in a registry. Additionally, they are in continuous communication with the MOPH regarding any memo or procedure they need to follow. Moreover. the MOPH is coming for frequent inspections to see whether if the hospital complies with the rules and regulations for vaccines. In addition, MOPH conducted workshops on vaccines, therefore the hospital is following the proper procedures for vaccines. It was reported that this focus needs to be on medications as well.
CP6	No reported cases.	(1)	• No reported cases from healthcare professionals or patients. They do not have a specific process to distinguish the causes of therapy failure they depend on observation only. • Underreporting of therapeutic ineffectiveness was linked to the underreporting issue, lack of sufficient human resources (i.e., only one pharmacist to cover many areas), lack of knowledge, and patients' complaints are not documented.

CP7	93.75%	(1)	• Out of 16 reports, 15 were medication error cases. • It was reported that medication error reporting varies between various hospital settings. Additionally, in outpatient settings, there is no reporting on medication errors.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• No studies. It was reported that healthcare professionals will only be aware of active surveillance activities once they receive training, education, have a proper protocol in place, and the initiation of such studies.
Total Score		(9)	Out of 9 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(9) =56.3%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CO1	None.	(0)	• No signals identified and no systematic process in place to identify signals. • It was conveyed that the possibility of introducing the process in the dynamics of the system in the future will require a well-established reporting system, advocating healthcare practitioners on reporting, a team of experts in this field, and a protocol to verify whether it was related to the drug.
CO2	Not relevant.	(-)	• The hospital depends on the MOPH circulars and guidelines. Additionally, the hospital contacts the MOPH to ensure they are following the right procedures and following practice standards. • The pharmacy and therapeutics committee is responsible for taking internal actions, guiding the implementation of those actions, and develop strategies at the hospital level. The hospital does not have strategies to evaluate the outcomes of the internal actions on the long term. • At the individual level hospital staff (various departments) will check the FDA website and other official websites to follow on aspects that can be addressed at the hospital level. This will be done in case if there is a warning or an instruction not provided from the MOPH side. For instance, there was no warning for fluoroquinolones from the MOPH, but it was reported on the FDA website. • Information from MOPH and other global sources will be communicated in the monthly newsletter.
CO3	One case in 2018.	(1)	• One admission, the patient was allergic to Cefuroxime this was mentioned in the patient profile, but the doctor prescribed without checking and the patient was admitted to the emergency department. The burden of medication-related admissions is not documented in a database. • The hospital reported a few barriers that can lead to undetected hospital admission due to medicine-related problems. The absence of software to report and record errors. The limited number of expert manpower able to detect this indicator. Also, reporting by a healthcare professional is inadequate.

			• The hospital aims to establish a well-developed system that includes analysis of the burden of medicines-related problems and their impact on hospital admissions to identify the problems and address them accordingly.
CO4	None.	(1)	• No reported or detected cases of death.
CO5	Not relevant.	(-)	• Not relevant.
CO6	No data documented.	(0)	• There is no documentation system for this data. • If such data will be generated the hospital will require expert manpower for this indicator.
CO7	No data documented.	(0)	• There is no documentation system for this data.
CO8	No data documented.	(0)	• There is no documentation system for this data.
Total Score		(2)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators the obtained score was [(2) =16.7%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R13: Hospital "D" PV system performance and capacity results measured by WHO complementary PV indicators.

COMPLEMENTARY STRUCTURAL INDICATORS

Code	Score*	Answer qualitative
ST1	(0)	No.
ST2	(1)	Yes. The internet.
ST3	(1)	Yes, Phone and email.
ST4	(0)	No, there are no sources of information or a dedicated library. The staff has their personal references like the British National Formulary (BNF).
ST5	(0)	No.
ST6	(-)	Not relevant.
ST7	(1)	Yes, there is no official essential medication list, but the hospital has a drug formulary.
ST8	(1)	Yes. PV data is continuously considered to develop hospital guidelines. Additionally, they follow the MOPH guidelines for some diseases.
ST9	(0)	• ST9a: No, they educate the prescribers at the individual level and they disseminate safety alerts and a newsletter. The hospital has plans to conduct educational and training sessions after the implementation of the new policies.

		• ST9b: No, only patient counseling. The hospital has plans to develop medication instruction cards.
ST10	(0)	No, but the hospital wants to have recommendations to develop tools used in hospitals with well-established systems.
ST11	(-)	Not relevant to HMC.
Total score	(4)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(4) =44.4%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(1)	Yes. • P2a: Medical doctors, 0%. • P2b: Dentists, 0%. • P2c: Pharmacists, estimate 95%. • P2d: Nurses, estimate 5%. • P2e: The general public, patients 0%, • P2f: Manufacturers, no, that process is not relevant.
P3	(-)	Not relevant.
P4	(0)	No. The hospital does not have this data.
P5	(1)	Yes. An estimate of 60% aware of ADR.
P6	(1)	Yes, patients receive education and ADR is a part of the education for some selected drugs. Thus, 30% of them get an education on ADR and side effects to avoid the issue of non-adherence from the patients.
P7	(0)	• P7a: For the year 2018, no face to face training. Education is through the publication of a monthly newsletter, monthly internal seminars or sessions, and instructions handouts which include PV and medication safety. Training is not defined in the policy documents, but it is done by the Quality and Patient Safety Department that takes into consideration the needs and the required content for training and education. • P7b: None, for the public.
P8	(0.5)	• P8a: number of health professionals involved in educational efforts from 40-60 prescribers, nurses, pharmacists or other relevant professionals. • P8b: None, for the public.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.

P13	(-)	Not relevant.
Total score	(3.5)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(3.5) =58.3%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(1)	Yes, the percentage of preventable ADRs is 0% for the one case received in 2018.
O2	(-)	Not relevant.
O3	(-)	No, the hospital does not have this data, and no cases were reported or observed.
O4	(-)	Not relevant. One case of acetaminophen discoloration from the national pharmaceutical industry this was reported to the MOPH.
O5	(0)	Data not documented for this indicator.
O6	(0)	No, the hospital does not have this data. The hospital indicated that it is non-applicable as it is not an indicator relevant for the private sector therefore, they do not capture this data.
O7	(0)	No, the hospital does not have this data. The hospital indicated that it is non-applicable as it is not an indicator relevant for the private sector therefore, they do not capture this data.
O8	(0)	No, the hospital does not have this data. The hospital indicated that it is non-applicable as it is not an indicator relevant for the private sector therefore, they do not capture this data.
O9	(1)	Yes, a minimum of five medicines per prescription. Polypharmacy is a reported issue among prescribers.
O10	(1)	10% as an estimation.
O11	(1)	5% as an estimation. The hospital does not have this data for the outpatient pharmacy. Data is captured for the inpatient setting only.
O12	(1)	Yes, 100% of patients receive information on the use of their medications and 30% of the people receive education including ADRs.
Total score	(5)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(5)=55.6%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

5. Hospital E

Table R14: Hospital "E" PV system performance and capacity results measured by WHO core PV indicators.

CORE STRUCTURAL INDICATORS

Code	Response	Score *	Assessment (Qualitative)
CST1	No specific PV department.	(1)	• The Pharmacy department is overseeing aspects related to PV and medication safety. The department has the technical knowledge, skills, and appropriate resources. The department communicates through email with all healthcare providers on medication-related safety issues. • The pharmacy department collaborates with the Quality Improvement Department which offers a more generic role in medication safety. The quality improvement coordinator trends data for adverse drug events and the pharmacists provide consulting or advisory services. • The hospital does not have formalized structures, the PV system is at an early stage of development. • If needed the Pharmacy and Therapeutics Committee will be included.
CST2	No specific policy on PV.	(1)	• No specific policy on PV. The hospital has an internal policy on adverse event reporting, which encompasses medication errors, safety. Additionally, other policies relevant to medication safety like high alert or high-risk medications and dispensing guidelines. • The existing policies are not comprehensive to cover the full scope of PV. Policies are updated every two years. • The Head of the Pharmacy Department is responsible for developing and enforcing those policies.
CST3	Not relevant.	(-)	• Not relevant.
CST4	No specific budget for PV.	(0)	• The hospital is in the process of expansion by adding another facility. Hence, looking at newer innovations and challenges coming, a specific budget that is assigned for medication safety will be required.
CST5	Yes.	(2)	• Yes, human resource for the existing system is enough. The level of expertise of staff conducting the analysis is sufficient for the institution. • For PV activities including ADRs one or two full-time, pharmacists' staff are available. The job description includes medication safety and ADR reporting, however, the staff are not trained specifically on PV. • With the upcoming expansion, there is a need for more expressive including a pharmacist who has experience in PV to contribute to the development of new policies and providing training and education.

CST6	No.	(1)	• No, ADR reporting form. The hospital has an adverse event reporting form, not specific for medications. Both harder and soft copies are available. • The form has specific fields and subcategories e.g. ADR, drug interactions, drug alerts, and safety issues. It is like an occurrence variance report form format. For example, if the pharmacist wants to report substance abuse or something there is an insert format to mention that on the form. • The report form is a standalone or separate system, it's not linked to the EMR. The hospital has an in-house developed system. • No standard reporting form for the general public. It was reported that A national PV policy can include this form. The hospitals cannot initiate such activity alone as the MOPH has defined very specific national patient rights and responsibilities. The hospital is by law required to abide by that and the hospital responsibilities have been revised to reflect that. • The hospital has defined complaint policy. The Public Relations Department is responsible for managing patients' complaints. If a patient has some complaints regarding medication, this will be sent to the quality improvement and risk management committee to review the case file. The hospital must respond within seven working days of receiving it. Most cases reported are dispensing errors and one complaint was an adverse response to a drug.
CST7	Yes. They have a process and an excel database.	(1)	• There is a process but it's not very formalized. The hospital system does have a database, but the information is stored in an Excel spreadsheet. • Means of providing feedback includes mail communication and verbal discussion. • The recording and analysis are done for every report received this will include drug-related problems reports and other incidents. The data from all reports are reviewed by the quality improvement coordinator to collate and analyze the data. • The hospital will investigate to determine the cause of the incidents, whether the drug was responsible. Therefore, the hospital tries to do a root cause analysis for all investigations. Then, then the information will be combined to see the possibility of initiating system changes. The Failure Mode and Effects Analysis (FMEA) will be used to look at the probability, occurrence, and severity. • It was reported that a comprehensive system for risk management and an incident report will be beneficial as the in-house system has its own limitations and is not built by experts. However, the budget will not be sufficient, and the management may not accept such change.
CST8	Not relevant.	(-)	• Not relevant.
CST9	Yes.	(2)	• The hospital has a newsletter published every quarter and they have their own website. • For the newsletter, it can include safety information or warnings. However, it is not very

			comprehensive feedback but the general perception among healthcare professionals that it adds value, but it needs to cover more topics. The quality of reported information will be checked this includes a review of the source of information. It should be from a recognized peer-reviewed journal and from a regulatory authority a credible source like the US FDA, t EMA, or MOPH. • For the website, it is not used for PV or drug safety information communication. It was reported that MOPH overregulates such activities so if they will add information on it has to be approved by the MOPH. Hence, it was reported that the best resource or tool for having a safety alert is the MOPH website. • Emergency and disaster preparedness plan is available and part of it includes the pharmacy department activities and medicines. Further, the hospital participates at the ministerial level in the National Health and Disaster Preparedness Committee meetings.
CST10	Yes.	(2)	• The Pharmacy and Therapeutics Committee serves as an advisory committee on medication safety. It encompasses six people from a different professional background. However, depending on the topic discussed members can be added. The committee meets every three months. • The committee reviews the procurement of new medicine, medication safety issues of current medicines, and new systems to improve medication management in the hospital.
Total Score		(10)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(10) =62.5%]

CORE PROCESS INDICATORS

Code	Response	Score *	Assessment (qualitative)
CP1	No cases reported in 2018.	(1)	• Out of the 65 reports received in 2018, none were cases of ADRs. It was reported that it is difficult to determine if the cases are ADR because it needs a lot of expertise. • The culture of reporting among healthcare practitioners is positive. The number of reports has improved over the years with the new policies and strategies implemented. However, underreporting remains a challenge. Healthcare professionals understand that reporting is important, and it can improve the system, however, some are still afraid to report and this will take time to change. • The quality of documentation is good for data analysis and it is determined internally by internal policies and externally by the MOPH and the accreditation body.
	CP1a: Not relevant.	(-)	
CP2	More than 1000 reports.	(2)	• More than 1000 reports. • In 2011, they had 3 reports however now reporting has improved dramatically. • The strength of the database is good for the moment; however, it lacks the capacity to expand. With the hospital expansion plans, there is a need to procure a more professional and robust report

			management system. • To improve reporting rates and culture the hospital gets the leadership involved and they are conducting a lot of lectures. The hospital does leadership rounds, but it will take some time to achieve a just culture because it's difficult to determine if the error is an individual responsibility or system-related failure. Therefore, leadership involvement will give the assurance that there will be no penalization. The hospital did a patient safety culture survey for the staff and based on the results the line managers were informed to give the staff assurance that they won't be penalized. Additionally, the hospital does reviews of incentive potency.
CP3	100%.	(2)	• 100% of the reports receive feedback. • The process is very formalized. A copy of the report and the feedback in the form of recommendation or course of action will be sent by email. The email will be sent to the head of the department to disseminate that information within that department. A file will be used to document all the feedback reports provided. • The hospital has defined timelines for any investigation or review. Within seven days feedback must be received otherwise the reporters can formally make a complaint that they have not received any feedback. No delays were encountered because a lot of resources are dedicated to this process. However, when the balance of information is not enough this will be acknowledged by email, indicating that this process might take some time because all the relevant information required for feedback is not collected yet.
CP4	No cases of ADRs.	(0)	• An estimate of 90% of the reports will be assessed; Not all the reports require an assessment. • The level of pharmacy staff expertise is enough. When the pharmacy department does not have the capacity to review a case, because the internal expertise is not sufficient the hospital will get a peer review, either internally from the organization or externally through HMC or some other organization whom the hospital has collaborated with.
CP5	Yes.	(1)	• Reports are not sent to the MOPH. However, they submit the information that has an impact on the MOPH (Pharmacy and Drug Control Department). In addition, every quarter, medication error data will be sent to the MOPH as key performance indicators requirements, ADRs data is not requested from the MOPH. It was reported that it's an informal system and it's not a very formalized structure. • The MOPH monitoring on vaccines is very robust, there's a formal system. There are defined forms, hotlines to contact with the MOPH, regular inspections, and provision of training. • The clinical investigations from MOPH exist however there are no timelines defined and proper formal instruction for the investigation is not provided.

	CP5a: Not relevant.	(-)	• Not relevant.
CP6	3%.	(2)	• In 2018, two reported cases with fertility medications. • This data is documented, and the investigation is done following a specific format. For example, if the staff get a case, they try to categorize the possible reason for failure. First, if the medication properly indicated for the patient. Second, whether the patient met the criteria for the medicine (e.g., ethnic variation). Third, the storage conditions for the medicine, Fourth, if the route of administration was done correctly and so on. Hence, the staff will follow the omission methodology or exclusion. • The investigation is very intensive, and it requires a lot of expertise and it may require consulting expertise from the MOPH or other organizations.
CP7	76.92%	(2)	• In 2018, out of all the 65 reports received 50 reports were medication error cases. Most of them were near misses, only one or two were not a near miss. • The number of cases is limited because their scope of service is defined and mostly includes relatively safe drugs (e.g., no chemotherapy drugs). However, it can also be attributed to healthcare professionals underreporting and patients not reporting or getting back to healthcare professionals to address drug-related problems.
CP8	Not relevant.	(-)	• Not relevant.
CP9	None.	(0)	• The awareness is not very uniform or consistent among healthcare professionals on active PV, there's always a lack of understanding of these studies. • The factors that enable private hospitals to participate in such studies would include. First, that such studies are mandated by the MOPH. Because active PV is not in alignment with the scope and nature of work and it is very difficult for private organizations to engage in this activity as it doesn't generate any revenue. Second, if there's a policy at the national level to cover active PV. Third, if there will be some incentives for organizations that are doing active surveillance. Incentives would include MOPH support by providing expertise in PV and statistical analysis.
Total Score		(10)	Out of 8 [8*2= (16)] is [(100%)] relevant indicators the obtained score was [(10) =62.5%]
CORE OUTCOME/IMPACT INDICATOR			
Code	**Response**	**Score ***	**Assessment (Qualitative)**
CO1	No.	(0)	• None.

CO2	Not relevant.	(-)	• For internal actions, it was noted that it regulates the practice and gives the clinicians a broader understanding that review and monitoring are undertaken. Additionally, many healthcare professionals value the feedback provided. • The Pharmacy and Therapeutics Committee is responsible for concluding the appropriateness of internal measures. Additionally, the committee reviews any action or warning provided by the MOPH. For complaint-based concerns the Quality Improvement, Risk Management Committee, and the Medical Administration will be responsible; mainly the Quality Improvement.
CO3	Not documented.	(0)	• Not quantifiable as it does not align with the objectives of private healthcare providers. • It was reported that despite the admission diagnosis, the determination is made by the consultant.
CO4	No cases.	(1)	• No cases and data are not documented for this indicator.
CO5	Not relevant.	(-)	• Not relevant.
CO6	Not documented.	(0)	• No, it was reported that it is difficult to quantify and that the hospital doesn't have the means and the intention to measure this indicator. • In terms of costing, it was reported that this will benefit the organization for investing in important areas, but the private institutions are not in the business of prevention; They're in the business of care. • It was reported that the MOPH does have cost analysis and does perform a cost-benefit analysis. But it can be not as robust as desired and MOPH may lack experts in the field of economy. For instance, MOPH used to release a healthy economy magazine every year, but the hospital did not see this for a very long period.
CO7	Not documented.	(0)	• The hospital doesn’t have enough information to quantify that data.
CO8	Not documented.	(0)	• No information as it is does not align with the organization's scope of practice. It was reported that if this indicator will be of importance or significance to the current practice the hospital will definitely monitor.
Total Score		(1)	Out of 6 [6*2= (12)] is [(100%)] relevant indicators the obtained score was [(1) =8.3%]

(*) Score: (2) Yes fully satisfactory; (1) Yes partially satisfactory (2); and (0) No includes not satisfactory, missing data, no values, not applicable.
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R15: Hospital "E" PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes, the Pharmacy Department, analyzes the data using computers.
ST2	(1)	Yes. The hospital system uses electronic prescription thus it's easy to monitor. The hospital reports called Consumption Reports, to see which doctors are prescribing, the consumption rate for medicine, and others.
ST3	(1)	Yes, Phone, email.
ST4	(1)	Yes, The British Pharmacopoeia and Qatar National Formulary application.
ST5	(1)	Yes, electronic health records.
ST6	(-)	Not relevant.
ST7	(1)	Yes, there is no official essential medication list. However, a hospital formulary of essential drugs that is updated every three years or when drugs are added or deleted.
ST8	(1)	Yes. PV data is considered.
ST9	(0.5)	• ST9a: not specifically for PV. But the hospital does train the staff on new drugs including the indications and guidelines. Additionally, aspects of medication safety the hospital has an adverse event reporting training at the staff orientation and every year. • ST9b: No. patient counseling only. Additionally, the hospital made educational efforts in schools to educate them about antibiotics to explain that antibiotics should not be taken very regularly, and the person should question the need for the antibiotic written by doctors. Furthermore, students were told about antimicrobial resistance and how it is building up in the world.
ST10	(0.5)	• ST10a: Yes, the hospital has developed tools for adverse event reporting online. In addition, policies are available online through the portal. • ST10b: No.
ST11	(-)	Not relevant.
Total score	(8)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(8) =88.9%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(1)	Yes. The hospital sends a combined report to the MOPH regarding medication-related admissions or errors and patient safety issues. It is difficult to quantify in terms of percentage. However, as an estimate: • P2a: Medical doctors, 70%.

		• P2b: Dentists, 5%. • P2c: Pharmacists, 5%. • P2d: Nurses, 15-20%. • P2e: The general public, 2-3% patient-provider occurrences. • P2f: Manufacturers. The companies do send a circular if there is an issue, but the hospital did not receive any so far.
P3	(-)	Not relevant.
P4	(1)	Yes. From 60 to 65 total reports: • P4a: 30 or 48. • P4b: 1 or 2. • P4c: 3 or 4. • P4d: 15.
P5	(1)	Yes. 100%.
P6	(0.5)	Yes. Difficult to quantify as it is not documented. The patients receive counseling at two areas one at the consultation stage where the doctor tells them about the adverse event of the medications, and then with the pharmacists. Consequently, health professionals educate patients about medication safety using the terms adverse event or side effects that are not present in the leaflet, but ADR as a term maybe not used.
P7	(0.5)	• P7a: Three to four last year. For example, initially during orientation and then every six months as a refresher course; This is a requirement. • P7b: None.
P8	(0.5)	• P8a: Yeah, 100% received training. The healthcare staff number was around 280 to 290. • P8b: None.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(4.5)	Out of 6 [6*1= (6)] is [(100%)] relevant indicators the obtained score was [(4.5) =75%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(1)	No cases.
O2	(-)	Not relevant.

O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(1)	No cases.
O6	(0)	Not documented.
O7	(0)	Not documented.
O8	(0)	Not documented.
O9	(1)	Yes, 5 per prescription.
O10	(1)	2-3%.
O11	(1)	4-5%.
O12	(1)	Yes, 100% of patients receive this information.
Total score	(6)	Out of 9 [9*1= (9)] is [(100%)] relevant indicators the obtained score was [(6) =66.7%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

6) Private Sector: Healthcare Institutions PV System Performance Comparison.

Table R16: Private sector level Healthcare Institutions PV system performance comparison.

	Desired performance	Mean	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E
Core structure indicators	16	10.8	13	11	10	10	10
Core process indicators	16	11	13	11	12	9	10
Core outcome indicators	12	2.4	0	5	4	2	1
Complementary structure indicators	9	7	7.5	8.5	7	4	8
Complementary process indicators	6	3.9	4	2.5	5	3.5	4.5
Complementary outcomes indicators	9	4.6	4.5	1.5	6	5	6
Total structural score	25	-	20.5	19.5	17	14	18

Total process score	22	-	17	13.5	17	12.5	14.5
Total outcome score	21	-	4.5	6.5	10	7	7
Sum of total Structure, process, and outcome	68	-	42	39.5	44	33.5	39.5
Percentage	100		61.76471	58.08824	64.70588	49.26471	58.08824

7) Private Sector: Community Pharmacies PV System Performance.

Table R17: Community Pharmacy A" PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes, since the is a confidentiality factor reports are being stored in a single computer.
ST2	(1)	Yes. Access to information from MOPH circulars and access to Qatar University library.
ST3	(1)	Yes, emails and phones.
ST4	(1)	Yes, online resources, Qatar University library, BNF hard copy, BNF online, and access to Lexicomp.
ST5	(0.5)	Yes, however, as an Excel spreadsheet.
ST6	(-)	Not relevant.
ST7	(-)	Not relevant.
ST8	(-)	Not relevant.
ST9	(0.5)	• ST9a: Yes, monthly meetings and once in two months' training. • ST9b: None for the public.
ST10	(0)	None.
ST11	(-)	Not relevant.
Total score	(5)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(5) =71.4%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(-)	Not relevant.
P3	(-)	Not relevant.
P4	(-)	Not relevant.
P5	(1)	100% are aware of ADR reporting but the staff have not been specifically trained for higher levels of practice (i.e., advanced).
P6	(1)	Yes, less than 20%. It was reported that there there's a need for widespread training among healthcare professionals to counsel the patients on ADRs.
P7	(0.5)	• P7a: a total of six in 2017. • P7b: none.

P8	(0.5)	• P8a: 82. • P8b: none.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(3)	Out of 4 [4*1= (4)] is [(100%)] relevant indicators the obtained score was [(3) =75%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(0)	One case could have been prevented. A patient having a penicillin allergy and was prescribed cephalosporin, which was still a safe choice, but the patient had an allergic reaction.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(-)	Not relevant.
O6	(-)	Not relevant.
O7	(0)	No official documentation. It was reported that cost-saving aspects in relation to the community pharmacy if taken into consideration, the investment made on PV will reflect upon the image of a particular chain of pharmacies, which could be a cost contributing by attracting others.
O8	(0)	No official documentation.
O9	(1)	Two.
O10	(1)	One.
O11	(1)	Less than one.
O12	(1)	More than 50%. There is a need for a structured way to counsel the patients. The pharmacy group can recommend this initiative at the ministry level as currently, pharmacists are counseling patients on ADRs out of their own interest or commitment. But if it becomes a part of the legal framework or a part of the compulsory professional practice it will make a significant change.
Total score	(4)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(4) =57.1%]
(*) Score: Yes (1), No (0).		

(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

Table R18: Community Pharmacy B PV system performance and capacity results measured by WHO Complementary PV indicators.

COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(0.5)	Yes, there is a computer but for general use by pharmacists, the pharmacy has a limited number of websites to have a connection and use information.
ST2	(1)	Yes. Medscape, prescriptions, PubMed, and BNF.
ST3	(1)	Yes, emails and phones.
ST4	(1)	Yes, Medscape, PubMed, BNF.
ST5	(0)	None.
ST6	(-)	Not applicable.
ST7	(-)	Not relevant.
ST8	(-)	Not relevant.
ST9	(0)	None. face to face communication between pharmacists. The pharmacy has a limited number of pharmacists and good internal communication. The pharmacist provides information for patients and some attend conferences that can include medication safety.
ST10	(0)	None.
ST11	(-)	Not relevant.
Total score	(3.5)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(3.5) =50%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(-)	Not relevant.
P3	(-)	Not relevant.
P4	(-)	Not relevant.
P5	(1)	3 out of five.
P6	(0)	Based on the individual pharmacist.
P7	(0)	None.

P8	(0)	None.
P9	(-)	Not relevant.
P10	(-)	Not relevant.
P11	(-)	Not relevant.
P12	(-)	Not relevant.
P13	(-)	Not relevant.
Total score	(1)	Out of 4 [4*1= (4)] is [(100%)] relevant indicators the obtained score was [(1) =25%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(0)	Cases of harm reached the patient, cases of side effects occurred 3 to 4 during a one-year period. However, for Atropine spray, there are so many people who are suffering and cases occur almost on a daily basis.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(-)	Not relevant.
O6	(-)	Not relevant.
O7	(0)	None. Because the community pharmacy doesn't have this kind of complicated aspects like hospital pharmacy.
O8	(0)	None.
O9	(1)	4
O10	(1)	40%, it occurs frequently, and it is a big problem specifically with antibiotics use patients are given high doses or treatment for a longer duration.
O11	(0)	Not quantified. There is a limited number of higher risk mediations that the pharmacy can prescribe e.g., a limited number of medications for chronic use. About 2% of prescription comes with an allergy thus the pharmacist discusses with the doctor to change it.
O12	(1)	Yes, 10% on ADR and 100% on the use of their prescription medication. Some pharmacists counsel for all types of medications e.g. adverse effects of herbal medications.
Total score	(3)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(3) =42.9%]

(*) Score: Yes (1), No (0).
(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

8) The Pharmaceutical Industry Pharmacovigilance System Performance.

Table R19: Pharmaceutical Industry PV system performance and capacity results measured by WHO complementary PV indicators.		
COMPLEMENTARY STRUCTURAL INDICATORS		
Code	**Score***	**Answer qualitative**
ST1	(1)	Yes, a dedicated computer and FTP server.
ST2	(-)	Not relevant.
ST3	(1)	Yes, functional communication (24/7), this includes phone, email, webpage, and server.
ST4	(1)	Yes, internet access, websites of regulatory bodies, books, access to reference materials like GCC PV guidelines.
ST5	(1)	Yes. Excel sheets will be used for documentation through the system. Once completed they approve it in each department then it will go to the documentation room. The company has a proper filing system.
ST6	(0.5)	Quality Assurance decisions will be made according to the Quality Control laboratory analysis. The company complies with the MOPH requirement, however, this is not in the form of collaboration.
ST7	(-)	Not relevant.
ST8	(-)	Not relevant.
ST9	(0.5)	• ST9a: The company has training procedures internal and external, also they use presentations for educational purposes. • ST9b: No training courses for the general public but sometimes when they launch their products, they will share information with guest e.g. media.
ST10	(0)	Web-based PV training tools are not available.
ST11	(-)	Not relevant.
Total score	(5)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(5) =71.4%]
COMPLEMENTARY PROCESS INDICATORS		
Code	**Score***	**Answer qualitative**
P1	(-)	Not relevant.
P2	(0.5)	No reports received.
P3	(-)	Not relevant.
P4	(0.5)	No, the company does not have this data.
P5	(-)	Not relevant. Yes, 100% of all staff are well knowledgeable about ADRs.
P6	(-)	Not relevant.

P7	(0.5)	• P7a: Face-to-face training sessions as part of the quality assurance program. Every quarter they conduct the training, thus every year they have a training plan for each department. Additionally, training on the job or of the new employees is provided. • P8b: None.
P8	(0.5)	• P8a: Every department will conduct their training. It is cross-functional hence no specific number, but 100% of staff received it. • P8b: None.
P9	(-)	Not relevant.
P10	(0.5)	No. Risk management plan not applicable to their products, Total products with PV plan, Total 780 products.
P11	(0)	It was reported that PSUR is not applicable to their products. For PSUR, they have GCC guidelines that they follow.
P12	(1)	No cases for products; no safety issues.
P13	(-)	Not relevant.
Total score	(3.5)	Out of 7 [7*1= (7)] is [(100%)] relevant indicators the obtained score was [(3.5) =50%]
COMPLEMENTARY OUTCOME/IMPACT INDICATORS		
Code	**Score**	**Answer qualitative**
O1	(-)	Not relevant.
O2	(-)	Not relevant.
O3	(-)	Not relevant.
O4	(-)	Not relevant.
O5	(-)	Not relevant.
O6	(-)	Not relevant.
O7	(0)	The company noted that data on cost-saving due to PV activities is not documented.
O8	(0.5)	According to the company representative health budget impact is the responsibility of the financial team. The company did not share value.
O9	(-)	Not relevant.
O10	(-)	Not relevant.
O11	(-)	Not relevant.
O12	(-)	Not relevant.
Total score	(0.5)	Out of 2 [2*1= (2)] is [(100%)] relevant indicators the obtained score was [(0.5) =25%]
(*) Score: Yes (1), No (0).		

(*) Score (0.5): For Indicators with two Parts (A & B) If (A the answer is No Score to be (0.5) and vice versa for B).
(*) Score (-): Not relevant for the evaluation of system performance with WHO indicators.

APPENDIX C: PROPOSAL FOR ESTABLISHMENT OF NATIONAL PHARMACOVIGILANCE CENTER

National Pharmacovigilance Center Project Idea

1. Why This Solution Is Proposed in Qatar?

The Qatari health care system is expected to experience rapid growth. Therefore, the healthcare system and the pharmaceutical system will require stronger control over the market. The proposed PV center will serve as the organization that will enable this by relying on the proposed sections that should have a clear and documented segregation of duties and depend on a high level of scalability.

After the implementation of the anticipated new pharmaceutical law, the section concerned with the legal aspects will be crucial to enable facilitating the communication and disputes resolution between stakeholders as well as for providing clarification and updates to stakeholders on regulations.

The different sections are proposed, and each should have a specific responsibility as the nature of activities required from each requires a different set of competencies and skills.

2. Overview of National PV Centers

International standards require that any drug to be released in the market it has to follow a specific system that ensures the efficacy and safety of the drug in preclinical testing and clinical trial testing. Further, after the realization of the need for continuous monitoring of released products the system of post-marketing surveillance was introduced. Postmarketing surveillance monitor the safety profile of marketed drugs this can include but not limited to detecting ADRs.

Postmarketing surveillance requires systems and structures in place to undertake the required functions. Therefore, PV centers were established in many countries to ensure that a

systematic process will be followed to guarantee drug safety in the country. To establish an effective PV center some specific criteria can be followed. This process follows an almost harmonized process as many global parties (e.g., WHO and SPS program) have shaped the criteria required by countries to create the fit for purpose plan to build an effective PV center.

Countries aiming to succeed in building and sustaining an active PV center will require to study the various issues that could be encountered during the process. This can include the level of national healthcare system advancement as well as the degree of involvement and participation expected from the national PV stakeholders. Therefore, fit for the purpose set up at first is the guide to the success of a PV Centre.

The PV center can be established under the health authority, governmental professional body, or other governmental departments. Additionally, some countries establish national PV centers under higher academic institutions or hospital organizations. Irrespective of the body overseeing PV the establishment of a PV center will require national PV stakeholders to maintain effective communication that is required to ensure the enhancement of the PV center performance and effectiveness to meet its objectives. In line with this, the establishment of the PV center will require a focal point and an appointed professional staff from each national PV stakeholder. In addition, to effective communication, effective collaboration and coordination between stakeholders as well as good public relations all are essential elements to ensure the effectiveness of the PV center.

3. The Need for PV Center

The obligation to have a persistent vigilance on medicines throughout the product life cycle and at each stakeholder system, including the use of medicine in the post-marketing period. This center can provide direct input or better advice for PV related processes including reporting, assessment, and management of medications as well as the consumers of

medications.

4. The Objective of The PV Center

A PV center is an organized entity that utilizes various resources to ensure medication safety, protect the public from medication harm, and prevent or minimize the occurrence of possible ADRs and other drug-related problems. The PV center can identify, collate, assess data on drug safety as well as prevent the occurrence of drug safety issues. Additionally, the PV center can communicate the risk associated with drugs to support the implementation of necessary actions and decision-making process to minimize the risk at the national level. Ultimately the PV center will reduce the morbidity and mortality associated with drug-related problems as well as it will protect the public health.

5. The PV Center Functions

An organized PV center capacity to operate will require resources, manpower, structures, and systematic functions. It is expected from the PV center to deliver the following:

I. Promote PV in the country by gathering and managing reports on ADRs and other drug-related problems.
II. Performs PV activities at the national level and international level.
III. Identify, evaluate, and communicate signals of drug safety.
IV. Evaluate the risks associated with drug-related problems and implement actions to manage the risks.
V. Detect quality issues with drugs that could potentially lead to the occurrence of ADRs.
VI. Detect any issues related to the promotional activities of drugs or irrational prescribing of medicine to aid national PV systems to prevent and eradicate such activities.
VII. Guarantee effective communication with the general public and other PV stakeholders to ensure the safe use of medications and protect the health of medication consumers in the

country.

VIII. Integrate the outcomes of research activities in the national policies, standard treatment guidelines, and health programs or activities.

IX. Generate, manage, and maintain medication utilization information.

6. The PV Center Organizational Structure

6.1. Administration

1 Head of the Center.

2 Assistant to International Relations.

3 Executive Assistant (Secretary).

Note: the relationship should be direct and exclusive between the head and the assistant.

6.2. Sections

1. Planning and Technical

- Personnel is responsible for planning (leaders of the creation of regulations, studies, and operation procedures).
- Personnel is responsible for technical services and research and development.

2. Legal and Permits

- Monitoring the implementation and compliance with the regulations.
- Issuing permits to stakeholders (e.g. how to use medications in the organization, what studies could be conducted).
- Responsible for stakeholder coordination (how to arrange with other national stakeholders, how to connect the responsibilities of the PV center with other administrators from different organizations (i.e., interface of systems).
- Responsible for official relations with the public, media, and international parties.

3. Economic Regulations

- Analyze the healthcare system and the pharmaceutical market of Qatar and manage the budget required for the PV center.

4. Internet Technology Section

- Management of Information e-services and communication support to PV stakeholders.
- Development of information technology infrastructure solutions and unified telecommunications facilities including solutions for physical and virtual meetings.

5. Medicine Management Section

- Medicines care records and reporting.
- PV stakeholders report management and recording.

6. Stakeholder Communication Section

- Management of MOPH communication.
- Management of government & semi-government, pharmaceutical industry, private sector stakeholders, and all healthcare stakeholders PV relevant communication.
- Management of pharmacies PV relevant communication.
- Administration and management of PV relevant Records.

Notes:

1. Under each section, there could be a unit responsible for each aspect or else a person who has the capacity to serve different aspects at once.
2. The employees under each section could be part-time only.
3. The expected minimum number of required manpower for the PV center is 4 (I head + 3 members).

7. Meeting requirements

- The routine meeting is advised to be held on a quarterly basis.
- The emergency meeting is advised to be held within 24-48 hours.

8. PV center funding

The annual budget required for the operation of the PV center will depend on the population size, the rate of reporting, and the method and expense for collecting PV related data from various stakeholders. The estimated required budget can be provided by the regulatory authority of Qatar.

9. Capacity Building

The organized PV center will require effective building up of formal capacities that are required for effective, efficient, and sustainable functionality and development. This will mainly depend on the function of the legal framework and PV policies. Those will define the system and roles. Building capacities would also entail the proper management and monitoring of medications and other health-related products. This will be feasible with the proper utilization of workforce and infrastructure. The later will aid the effective utilization of service and equipment. All the aforementioned components if managed well and benefited from proper coordination will ensure effective capacity building. In so doing, a robust PV system will be established without the need to implement inconvenient changes in the resources, social structures, technologies, and personalities.

10. Conclusion

PV center can be the best-fit idea for many countries to activate the post-marketing surveillance of drug products, enable effective PV implementation, and achieve context-specific regulatory decisions. However, to establish an effective, efficient, and sustainable PV system a holistic approach must be followed that includes baseline analysis; effective planning;

efficient implementation approaches; and effective national PV stakeholders participation, communication, and accountability.

11. Resources

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