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Overview of Pharmacovigilance Practices at the Largest Academic Healthcare System in the State of Qatar

Introduction

Pharmacovigilance (PV) plays a vital role to ensure patient safety. The World Health Organization (WHO) defines 'pharmacovigilance' as a process of detection, monitoring and preventing drug-related harm [1]. Adverse Drug Reaction (ADR) reporting is the cornerstone of PV. The WHO defines ADR as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [2].

ADRs are major global issue, adversely impacting patient safety and health outcomes; they are ranked as fourth and seventh leading cause of death in United States and Sweden, respectively [3,4]. Due to significant under-reporting and vast heterogeneity in the use of definitions, data collection methods, the incidence and prevalence of ADRs vary considerably across countries, ranging from 16% among studies performed in United Kingdom (UK) [5] to 38% in Germany [6], 6% in South Africa [7], to 4.5% and 10.2% among studies performed in Saudi Arabia [8] and United Arab Emirates (UAE) [9]. A meta-analysis (1998) to determine the incidence of ADRs among hospitalized patients suggested that ADRs affected over 2 million patients at an estimated cost of $130 billion annually in the United States (US) alone [10].

PV practices in Qatar are evolving rapidly and ADR reporting systems have undergone significant changes over the last few years. Despite all the recent developments, there is scarcity of published evidence relating to ADR reporting in Qatar. This article explores organizational structure, PV practices and provides information about how ADRs are identified, reported, analyzed and interpreted at a healthcare level. It also provides blueprint of a Medication Safety Center at the largest academic healthcare system in Qatar.

Healthcare system in Qatar

Qatar is a small peninsula occupying 11,437 km^2 of land area and has a total population of 2.6 million, of which only 15% are native Qataris [11]. The quality of healthcare delivery in Qatar is of very high standards with annual healthcare budget exceeding $3,071 per capita (2.2% of GDP) in 2014, one of the highest in the region. The Ministry of Public Health (MoPH) is Qatar's highest health authority, responsible to plan and advise on the national healthcare priorities, to regulate and monitor healthcare systems and provide

services to meet the national healthcare needs. Unlike other high-income countries where people are the main source of healthcare funding, healthcare costs in Qatar are predominantly financed by government revenues, by providing free treatment to the nationals and heavily subsidized treatment options to the residents [12].

Under the regulation of MoPH, the healthcare system in Qatar is primarily divided into private and public healthcare sectors. The current structure of healthcare services can be found in Figure 1.

Figure 1: Qatar Healthcare System (information retrieved from MoPH website)

National Health Strategy 2011-2016

Improving patient safety through 'safe use of medication' is a core component of Qatar's National Health Strategy (NHS) 2011-2016 [14]. NHS advocates developing a world-class healthcare system by ensuring safe and effective use of medications and healthcare products. Establishing a specialized Medication Safety & Quality Center (MSQC) at Hamad Medical Corporation (HMC), the tertiary and academic healthcare provider within MoPH, to monitor the safe and effective use of medications, is one of the key strategies to achieve the goals set by the NHS.

Establishing HMC's Medication Safety & Quality Centre (MSQC)

Since 2016, MSQC is recognized as a center to monitor medication safety practices within HMC, which in turn created a community of medication safety experts within the healthcare system.

How it started?

To better understand the nature and scope of medication-related harm, improve the current medication safety practices, and further strengthen the PV activities, the pharmacy leadership at HMC established a corporate clinical unit called MSQC. Qatar is an associate member of WHO Program for International Drug Monitoring, and a national center exists at MoPH, where majority of ADR data originates from HMC.

Mission

MSQC is committed to develop interventions to reduce medication errors, prevent and manage Adverse Drug Events (ADEs) and encourage safe medication use practices across HMC. MSQC has established a methodical ADR reporting, monitoring, and analyzing system at HMC.

Blueprint

Establishing MSQC require great effort, dedication, proficiency and regular follow-up. Setting up the center demands an organizational framework, recruiting and training Medication Safety Officers (MSOs), and designing the reporting system. MSQC was structured to detect and monitor all PV activities within HMC. MSQC comprises of 11 MSOs (one from each HMC facility), a coordinator, and three administrative staff (Co-Head, Head and Chair) sharing other responsibilities within HMC.

ADR Reporting Policy

HMC has adopted WHO definition of ADRs. ADR reporting at HMC is policy-driven and has migrated from a paper-based system to an electronic system (Cerner®). HMC's policy on suspected ADR reporting and monitoring requires all ADRs to be documented in patients' medical records and to be reported immediately. However, data about the quality, nature and extent of these reports are lacking. Anecdotal evidence indicates that healthcare professionals have different attitudes and affinities to document and report ADRs and there are possibilities of gross under-reporting.

ADR Reporting & Data Acquisition at HMC

The ADR reporting process at HMC is centralized, whereby all suspected ADRs are reported by HCPs (mostly pharmacists, nurses and doctors) electronically. Any drug related problem that implies a causal relation between the drug and the adverse reaction must be reported, with details about the drug, reaction, timings and interventions. The ADR reporting process at HMC is illustrated in Figure 2.

Figure 2: ADR reporting process at HMC

Reports are then reviewed by the hospital specific MSOs and are further classified based on causality, severity, and preventability using different tools (Causality - Naranjo Causality Scale, Severity - Hartwig's Severity Scale, Preventability - Schumock and Thornton Preventability). Once completed, these reports are forwarded to the corporate office (MSQC), where the reports are reviewed and pooled for any potential causal relationship. MSQC generates a monthly report to the pharmacy executive director who then disseminates the findings to MoPH, Quality and Patient Safety Committee (QPS), Risk Management Committee and other key stakeholders (Qatar University, patient safety departments etc.,)for further actions. Furthermore, all clinically relevant ADRs are disseminated to healthcare professionals (HCPs) through presentations, discussions and monthly newsletters. The

dissemination of such information leads to institutional and individual learning and a continuous improvement of patient safety and change in practice.

Memberships and Affiliations

HMC is the only academic health system outside the US to have all its hospitals accredited by the Joint Commission International (JCI), demonstrating its commitment to continuous delivery of safe, high-quality care [15]. Moreover, in collaboration with the Institute for Healthcare Improvement (IHI), HMC is committed to provide the safest, most effective and most compassionate care to each and every patient [16]. MSQC within HMC is a full member of the International Medication Safety Network (IMSN), an international organization committed to prevent medication-related harm and contribute to safer healthcare [17]. Qatar is also an associate member [reports are not shared with the global PV community (WHO database) and will no add to any international signal analysis or learning outside of Qatar] of the WHO Program for International Drug Monitoring [18].

Number and Nature of ADR Reports

MSQC analyzed 1599 ADRs that were reported across HMC between January 2016 and December 2017. A wide variation in reporting rates was observed among different hospitals; National Cancer Center=372 ADRs, Heart Hospital=167, Hamad General Hospital=345, Women's Hospital=231, Al-Khor Hospital=77, Rumailah Hospital=97, Cuban Hospital=63, Communicable Disease Center=19, Al-Wakra Hospital=142, Mental Health Hospital=42, and Home Healthcare Service=44). As illustrated in Table 1, approximately 92% of reported ADRs were 'mild–moderate' in severity scale, whilst less than 9% were 'severe'. Nearly 88% were 'non-preventable'. Majority of ADRs were reported by pharmacists (57.3%).

Table 1: Assessment of ADR reports at HMC

Detection and Management

Individual case reports of suspected ADRs are the primary source of data to detect the unexpected harm caused by medications. This information is vital to effectively manage and reduce the severity of harm due to medications.

Spontaneous reporting system at HMC facilitates timely detection of unknown ADRs. The process of ADR detection or causal relationship between the

suspected drug and the ADR is usually carried out by means of a methodical manual review of all ADR reports submitted using qualitative methods (case analysis). However, spontaneous nature of reporting also possess few limitations, e.g. some complex associations between patient demographics and reported reactions are not always true while fear of consequences also lead to underreporting of serious ADRs.

Examples of qualitative – case analysis at HMC,

- *A case of probable piperacillin/tazobactam-induced bone marrow suppression in a pregnant woman (ElSalem S, et.al, 2017)*
- *A case of probable esomeprazole-induced transient liver injury in a pregnant woman with hyperemesis (Thomas B, et.al, 2016)*
- *A case of probable labetalol induced hyperkalemia in pre-eclampsia. (Thomas B, et.al, 2014)*

Good PV Practices and Risk Reduction Strategies

A set of measures have been developed by MSQC to facilitate and enhance the PV practices at HMC: All healthcare professionals joining HMC are scheduled for a mandatory medication safety educational session. Other activities include

- Encourage, educate and support healthcare professionals and patients to report all suspected ADRs;
- Review the reports for accuracy and completeness;
- Raise awareness about the importance of proper documentation;
- Provide feedback to the reporters;
- Maintain the confidentiality of data about the reporter and patient;
- Assess benefit-to-risk ratio;
- Provide medication safety updates and recommendations through a monthly newsletter;
- Follow the standards and policies set by the MoPH, Qatar.

These initiatives have improved the medication safety practices at HMC resulting in changes in policies of look-alike sound-alike drugs, use of high-alert medications, label change for neuromuscular blockers etc.

Challenges

Despite the substantial progress made over the last few years, PV systems across the world still face a number of challenges with underreporting being

one of them. It often delays the response process such as changing labels, issuing warnings and withdrawing drugs, and thereby compromising patient safety. Factors contributing to underreporting include most notably ignorance, lack of interest or time to report, fear of consequences, judgment bias, and belief that all drugs in the market are safe. [19]

A questionnaire-based study [20] to assess the knowledge, attitude, and barriers to ADR reporting among pharmacists in HMC revealed that although majority of pharmacists showed positive attitude towards ADR reporting, a considerable number exhibited lack of knowledge about ADRs, how to report, and what to report. Approximately 60% of the pharmacists responded did not report any ADR over the previous 12 months, mostly due to lack of time, busy schedule, cultural issues, and lack of awareness about what to report. Pharmacists also revealed that they did not receive any feedback to their previous reports, discouraging to report future incidents. Poor knowledge and lack of engagement of general public and patients towards PV practices were also among the challenges noted during the study. The findings were similar to what has been reported in other studies from the region and further afield [19, 21-23]. Hence, strategies need to be focused towards creating awareness among pharmacists about ADRs and importance of reporting.

Conclusion

Clear understanding of the characteristics and knowledge of patient safety practices are cornerstone to PV activities. As in other developing countries, PV in Qatar is evolving rapidly. Spontaneous reporting, transparency and active surveillance are new advancements in the reporting system at HMC. Further developments aim at automatic signal generation, patient reporting, and educational interventions to healthcare professionals and patients, to enhance the quality of ADR reports.

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Conflict of Interest

All the authors declare that they have no conflict of interest.

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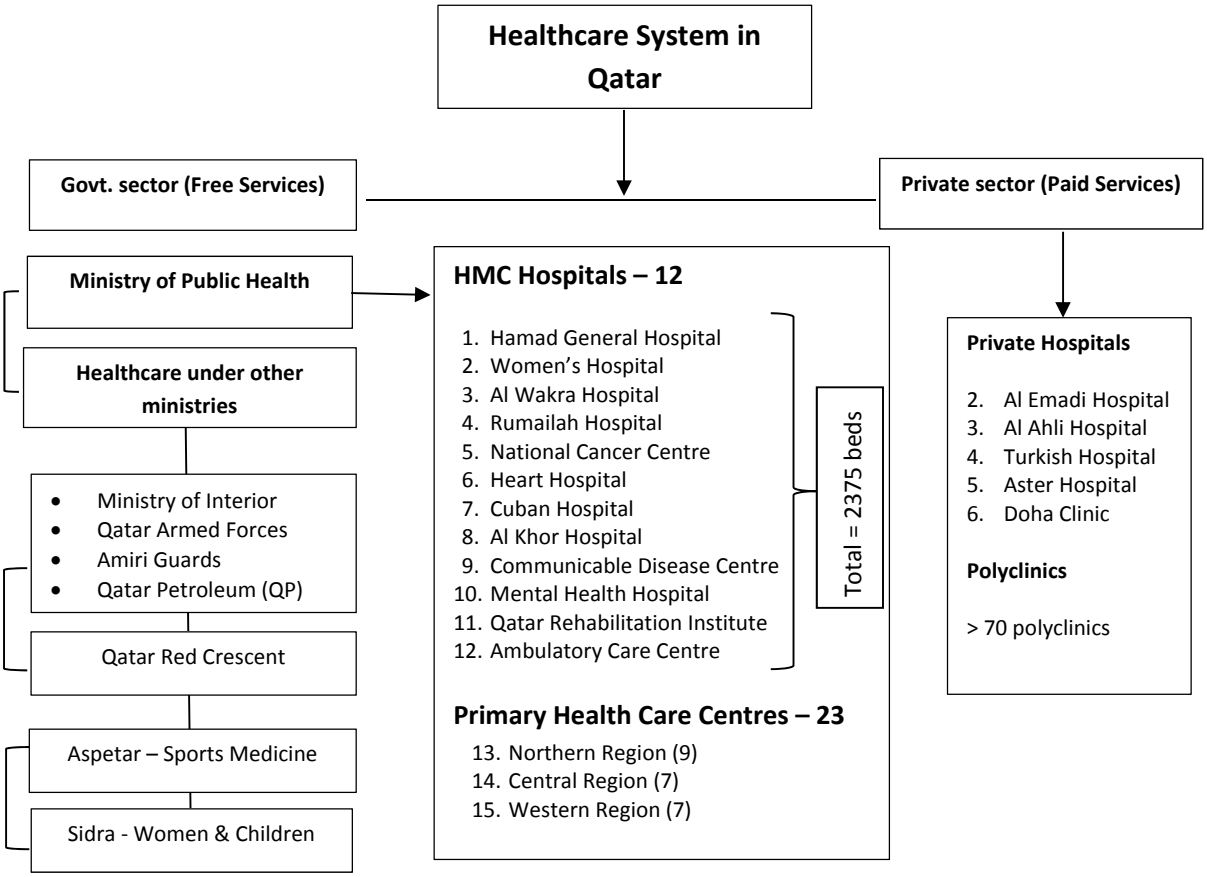
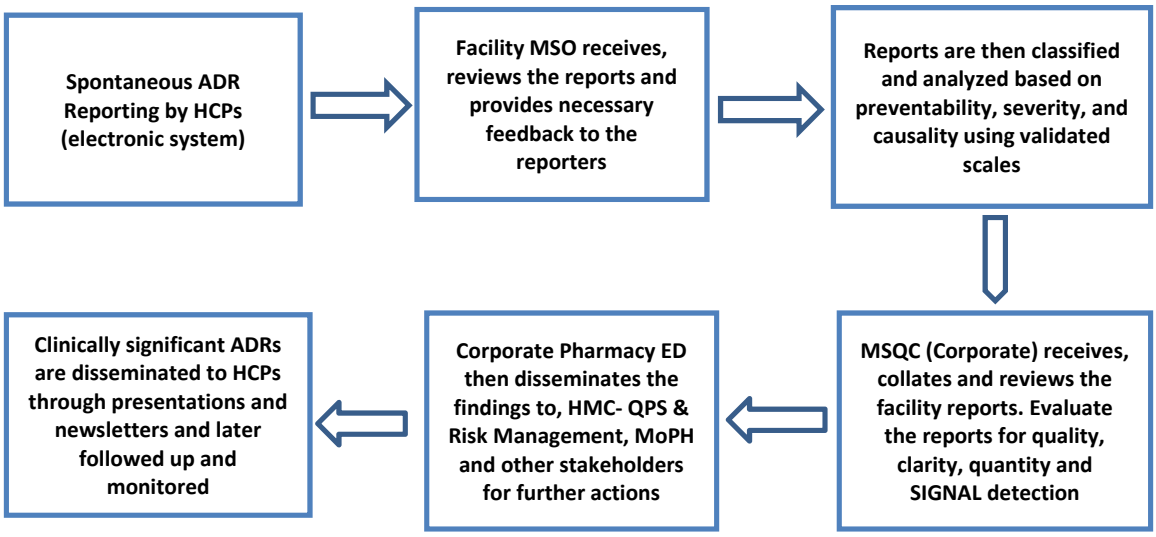


Figure 1: Qatar Healthcare System (information retrieved from MoPH website)



ADR – Adverse Drug Reactions, MSO – Medication Safety Officers, MSQC – Medication Safety & Quality Center, ED – Executive Director, QPS – Quality and Patient Safety, MoPH – Ministry of Public Health, HCP – Healthcare Practitioners

Figure 2: ADR reporting process at HMC

Table 1: Assessment of ADR reports at HMC

Assessment	Category	No. of ADRs (%) n=1599
Causality (Naranjo's Scale)	Definite	94 (5.8)
	Probable	799 (49.9)
	Possible	690 (43.1)
	Doubtful	16 (1.0)
Preventability (Hartwig's Scale)	Not Preventable	1406 (87.9)
	Probably Preventable	175 (10.9)
	Definitely Preventable	18 (1.1)
Severity (Schumock & Thornton's Scale)	Mild	764 (47.7)
	Severe	113 (7.0)
	Moderate	722 (45.1)
Reported by	Pharmacist	913 (57)
	Nurse	556 (34.7)
	Doctor	130 (8.1)