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Commentary Article

Pharmacovigilance in Low and Middle-Income Countries: The Case of Pakistan

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ABSTRACT
Countries around the world are increasingly focusing on pharmacovigilance and medicine safety issues. To do so, high income countries have developed fully functional pharmacovigilance centres, and collaborating with the World Health Organization's Collaborating Centre for International Drug monitoring in Uppsala, Sweden. However, low and middle-income countries are still in the various phases of improving and strengthening their pharmacovigilance systems. Pakistan, being the sixth most populous country in the world lacks a stable and rigorous functioning system to monitor medicine safety. In this article, we discuss overall situation and steps needed to improve the situation in Pakistan.

Keywords: pharmacovigilance, Pakistan, LMIC, adverse drug reaction, safety.

INTRODUCTION

For the past half century, the health and safety of people has been a major concern in many parts of the world[1] and the functioning of healthcare systems can be measured by issues related to pharmacovigilance and patient safety[2.] Adverse drug reactions lead to direct harm and waste and largely contribute towards morbidity and mortality[3]. To ensure safe medicine use, World Health Organization formed Centre for International Drug monitoring[4], which has launched the WHO Programme for International Drug Monitoring, where adverse drug reaction monitoring data is compiled and safety alerts are issued worldwide[5]. WHO Programme for International Drug Monitoring, not only helps to improve patient safety but also disseminates the information about prevention and treatment of adverse drug reactions[4].

Many developed countries like United Kingdom, Canada, United States have developed efficient ADR reporting systems. These reporting systems are managed by national ADR and pharmacovigilance reporting centers[6]. Majority of these reporting systems are voluntary, primarily relying on the vigilance of healthcare professionals[7]. A study by Harvard Public School of health on unsafe medical care has revealed that in high income countries, 5% of adverse events (unsafe medical experiences during the course of treatment) in hospitals were related to adverse drug reactions, while 2.9% of adverse events were drug use related in low and middle income countries[2]. The difference in number may be attributed by under- reporting of these adverse drug reactions to the national pharmacovigilance centers in low and middle-income countries (LMICs). Though, many patients are at risk of medicines related adverse effects when they are in hospitals but unfortunately there are no proper standard procedures to monitor these medicines[8]. Furthermore the studies on ADRs are very few[9]. In this context, the establishment and maintenance of a robust pharmacovigilance system in LMICs is a massive challenge.

Pharmacovigilance system in Pakistan

Pakistan is the 6th most populous country in the world. It's a low-income country with a population of 207.8 million[10]. In Pakistan, though efforts are being made to improve healthcare of people, still the optimum healthcare goals for population are not achieved[11]. The issues in the country include over population, limited resources and low investment in the health sector by the government[11]. The quality of the medicines has always remained an issue and looking at the statistics of ADR related deaths in the country, no actual figures or data is available in Pakistan[11]. In 2012, in Punjab, which is the biggest province with over 82 million inhabitants covering 56% of total population of Pakistan[12] more than 200 cardiac patients died after taking a substandard cardiovascular drug (Isotab-20mg, Isosorbide mononitrate, batch number J093). This drug was contaminated with large quantities of antiparasitic drug pyrimethamine, as a result of which, 1000 patients were reported to be hospitalized[13]. This happened in a cardiac specialty public hospital in Lahore (Punjab). The incident raised serious concerns regarding the quality and safety of medicinal products produced[14]. It also highlighted the gap in the reporting and monitoring of adverse reaction system in the country[11]. As a result, the Drug Regulatory Authority of Pakistan (DRAP) was formed under DRAP act 2012[15], and now DRAP is a WHO collaborating member for medication safety, however still the system is underdeveloped at hospital level[11]. There are few hospitals in the country, like Dow University Hospital

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Karachi, Sindh which are participating in the pharmacovigilance programme[16]. However, the data from these settings on adverse drug reaction is not large enough to extrapolate the figures at large scale or at national level. Similarly, one of the biggest public hospital (Mayo Hospital) in Lahore (Punjab) has introduced the ADR reporting system at hospital wards level. The staff including doctors and nurses have been trained to report any ADRs on the specifically designed ADRs forms to the pharmacists in the hospital [17]. Government has also planned and initiated many reforms including the formulation of pharmacovigilance rules 2018, launch of an online ADR reporting portal and increasing collaboration with the WHO[14,18].

What is next in Pakistan?

ADR reporting needs a multi stakeholders approach by involving policy makers and healthcare professionals together. It needs a strong political commitment and development of reporting ADR reporting culture in the country. One possible option to improve and strengthen this pharmacovigilance system is to link hospitals all around the country to an online ADR portal. A standardized method to assess severity, causality and preventability of possible adverse drug reactions in public hospitals should be developed. This would help towards the better understanding of the nature and extent of the adverse drug reactions. Pharmacists are in a vital position to detect and report ADRs and hence they can serve as a link between the prescribing and dispensing of medicines. These initiatives would be helpful to promote safe use of medicines and to strengthen the health system of the country.

ABBREVIATIONS

WHO: World Health Organization, UMC: Uppsala Monitoring Centre, ADR: Adverse drug reaction, LMIC: Low and middle-income country, DRAP: drug regulatory authority of Pakistan

AUTHORS' CONTRIBUTIONS

RH wrote the manuscript, FH and AH reviewed and approved the manuscript for publication.

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