

## ARE OUR HEALTHCARE PRACTITIONERS PHARMACOVIGILANT: SHOULD THIS BE AN ISSUE OF CONCERN?

**Shahid Mahmood, Maria Arshad,**

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Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicines or vaccines or any related problem.<sup>1</sup> Etymologically, the word pharmacovigilance has been derived from “Pharmakon” and “vigilia” meaning “to keep watch of medicinal substance”.<sup>2</sup>

Historically, the theme of Pharmacovigilance dates back to year 1848 when a young girl named Hannah from England died after receiving chloroform anesthesia for removal of an infected toenail; however investigation implicating chloroform as the cause of her death remained inconclusive.<sup>3</sup> In 1961, Dr. McBride wrote a letter to the editor of the Lancet Journal in which he suggested a connection between congenital malformation of babies and thalidomide (a drug used as hypnosis and relieving nausea symptoms in pregnancy). He observed that the incidence of congenital malformations of babies (1.5%) had increased up to 20% in women who had taken thalidomide during pregnancy.<sup>4</sup> The tragedy of thalidomide brought to light many problems and critical issues in healthcare system. In particular, this tragedy changed the system of Pharmacovigilance; a systematic reporting of adverse drug reaction (ADR) related to prescribed medicine initiated and a regulatory mechanism evolved.<sup>2</sup> In USA, during 1960s, federal food, drug and cosmetic act required practitioners to provide safety data, whereas United Kingdom introduced yellow card system to report adverse effect of prescribed medicine in 1964. World Health Organization (WHO) started a program for international drug monitoring in 1968.<sup>4</sup>

In Pakistan, National Drug Policy of Pakistan in 2003 recommended to establish a drug monitoring and surveillance system. Under Drug Regulatory Authority of Pakistan (DRAP) Act in 2012, a drug regularity authority was established with a National Pharmacovigilance Centre (NPC) in federal capital in 2017 and regional pharmacovigilance centers in provincial capitals during 2018.<sup>5,6</sup> Pakistan became the full member of Uppsala Monitoring Centre (UMC) in 2018.<sup>7</sup> The main aim of pharmacovigilance is to provide data on adverse effects of drugs and vaccines after approval for its use in a country. However, it also intends to promote understanding among health care service providers through clinical training and public about safety of medicines. Adverse drug reactions (ADRs) are among the leading causes of death globally. The ADR reporting is an important part of post marketing surveillance of drugs. According to WHO, Adverse drug reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.<sup>7</sup>

Despite all efforts from national healthcare initiatives, there is still lack of awareness among healthcare practitioners about pharmacovigilance and very few of these practitioners even practice to report adverse side effects to the regularity authority. According to a recent study conducted in a public sector tertiary care hospital, one -third of healthcare professionals were not aware of the mechanisms to report adverse drug reactions to drug regulatory authority.<sup>8</sup> Similarly, in another study, 83% of healthcare professionals did not know where and how to report ADR.<sup>9</sup> However, these professionals do realized the necessity to report ADRs. Despite poor awareness, many health professionals showed positive attitude towards reporting ADRs.<sup>10</sup> The main factors associated with poor reporting of ADRs are lack of time to report especially in busy hospitals in developing countries, unavailability of formal

1,2. Department of Community Medicine Allama Iqbal Medical College Lahore

**Correspondence:**

Dr. Shahid Mahmood, Associate Professor, Department of Community Medicine Allama Iqbal Medical College Lahore.  
shahidsethi@hotmail.com

reporting system and no monitoring by the hospital management. It has been observed that the ADR reporting practice among physicians, nurses and pharmacists in Pakistan is far below than expectations.<sup>11</sup> In developed countries, good practice of ADR reporting may be attributed to periodic training of healthcare professionals on pharmacovigilance and seminars being conducted on regular basis.<sup>9</sup>

To strengthen spontaneous reporting of an ADR, the Drug Regularity Authority of Pakistan (DRAP) launched an online reporting form named as “Med Vigilance” on DRAP's official website in 2018 which is available for patients, pharmaceutical companies and healthcare professionals to report any adverse drug reaction and adverse events. National Pharmacovigilance Centre (NPC) has provided 'Electronic Reporting System', 'Med Vigilance E Reporting System', 'Med Safety Mobile Application', 'Manual Reporting (Yellow Reporting Form)', and 'Reporting by Industry (E2B Reporting)'. By undertaking these measures, NPC is not only fulfilling WHO's aim of improving patient care and safety from medicine's use perspective but also contributing towards the assessment of benefits, risks and cost-effective use of medicines.<sup>8</sup> However, the healthcare professionals are still not aware of these forms and this has not been taught during medical training of doctors, nurses and specialists. This is need of time to propagate the existence of pharmacovigilance mechanisms in Pakistan and hospital management should ensure that healthcare professionals report ADRs using online forms of DRAP.

Physicians play a critical role in identifying, reporting and treating adverse drug reactions (ADR). Pharmacists also play a crucial role in ensuring drug safety by detecting and reporting ADRs. Pharmacists tend to have highest percentage of knowledge of pharmacovigilance than doctors and nurses.<sup>12</sup>

ADRs pose a serious threat to public health and need urgent attention of health authorities. With growing pharmaceutical companies and their dubious marketing strategies in our hospitals, ADRs reporting is now more important than ever as a mechanism to recognize early the health issues related to the use of new medicines being in market. Under reporting or no reporting may lead to poor

drug surveillance and deficient safety measures to protect the health of our patients. There are instances where pharmacovigilance saved considerable numbers of lives. For example, a drug 'practolol' which caused blindness was withdrawn from market in 1998 after five years of approval. Similarly, another drug, 'terfenadine' was withdrawn after thirteen years in market due to adverse reaction of producing fatal cardiac arrhythmia. These examples show that if there is constant watch on ADR by the healthcare professionals, precious lives can be saved.

A holistic approach involving manufacturers, market forces, healthcare professionals and regulatory bodies in healthcare system is required to prevent ADRs. Promotion of spontaneous reporting where healthcare professionals identify and report suspected drug reaction to national drug regulatory bodies and mandatory reporting from manufacturer periodically will ensure reasonable pharmacovigilance in Pakistan. ADR reporting practice can also be achieved by periodic training of health professionals, repeated seminars about DRAP procedures and forms, and availability of online systems in wards will improve ADR reporting. DRAP link can be used to learn more about adverse reaction reporting system available in Pakistan: <https://www.dra.gov.pk/safety-information/safety-communication/how-to-report-adrs/>

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