Editorial

Educate and Train Healthcare Professionals and Healthcare Profession Students and make Aware Public about Reporting Adverse Drug Reactions (ADRs)

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Every drug used for diagnostic, prophylactic and therapeutic purposes in a human being has adverse effects (AE) or reactions. ADR is "any noxious, unintended or undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis or therapy". ADRs are one of the critical causes of patient sickness, hospitalization, morbidity, mortality, and increased health care costs worldwide [1-3].

The recent study on "Adverse drug reactions (ADR), multimorbidity and polypharmacy" in the United Kingdom (UK) conducted by Osanlou R 2022[1] has revealed ADRs contributed to more than 16% of all hospitals' admissions with an associated death rate of 0.34%. The exact facts about hospital admissions and related mortality rates due to ADRs in Pakistan are unknown. Still, likely more than reported by the UK as polypharmacy is more common in Pakistan, health care professionals are not much focused on this aspect of patient's sickness and not realizing the importance of reporting ADRs.

Thalidomide use in pregnant women to treat nausea from the 1950s till 1961 caused thousands of congenital disabilities in children globally. After this tragedy, the World Health Organization (WHO) 1961 developed a pharmacovigilance centre in Uppsala, Sweden, the first centre of its kind[2,3]. WHO defines pharmacovigilance (PV) as "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems"[4,5]. In Pakistan, the PV mechanism was established after the 2011 incident, after a drug with the trade name Isotab containing 20 mg Isosorbide mononitrate (batch number J093) resulted in the hospitalization of 1000 patients in Lahore, Punjab, Pakistan, and more than 200 patients died of this locally produced drug[2-4].

Pharmacovigilance (PV) monitors the safety of prophylactic and therapeutic drugs and vaccines in the post-marketing and pre-marketing phases, but there is a vast difference in both phases. In a clinical trial, the number of patients is less, highly selective patients have no comorbidity or concurrent problems, and the trial runs for a limited time, so that the side effects profile may be incomplete. While after marketing large population is exposed to the drugs, and there is a possibility of occurrence of new side effects and unexpected and serious ones. So, monitoring drug safety in the post-marketing phase is critical[5].

The first National Pharmacovigilance Center (NPC) in Pakistan was established in 2015 to monitor therapeutic goods' safety across the country by the Drug Regulatory Authority of Pakistan (DRAP). The centre got full affiliation with WHO Uppsala Monitoring Center in 2018[4]. DRAP published the first edition of the Pakistan National Pharmacovigilance Guidelines (PNP-Guidelines) in October 2019. These guidelines are the fundamentals of the PV program. The purpose of the PNP Guidelines is to prepare better all stakeholders to monitor the safety of drugs, diagnostics and vaccines; to detect, evaluate, comprehend, and prevent ADRs/AEs and examine the report, thereby safeguarding the population health of Pakistan[5]. Also, DRAP published the first edition of "Adverse events reporting guidelines for patients, caretakers and consumers" in March 2022. NPC has developed different reporting forms and mobile applications for reporting adverse events (AE) and adverse events following vaccination (AEFI). These guidelines clearly emphasize "why to report", "what to report", "where to report", and "how to report". [6]

Despite all efforts of DRAP and its NPC, various studies found gaps in the implementation process due to a) inadequate knowledge of healthcare professionals (HCPs) and b) inadequate reporting practices among healthcare professionals[7-9], and c) inadequate functioning of the PV system at all levels[4] But these studies also reported about the attitude and behaviour of HCPs towards ADR reporting relatively positive. Most HCPs acknowledged that ADR reporting should be integrated into the health care reporting process. This is a very positive sign[7-9]. It is recommended to train HCPs all over Pakistan, both in the public and private sector, on ADR reporting in detail and make them recognize the significance of why to report ADR; educate undergraduate and postgraduate students of healthcare professions about ADR reporting and create awareness among people at large to realize the importance of reporting ADR and make them feel their obligation to report

ADR. Further, ensure the proper functioning of the PV system at all levels- National, Provincial, public and private hospitals, and national public health program level. These efforts may help improve the safety of patients and reduce the morbidity and mortality associated with ADR.

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