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Adverse drug reactions reporting in Turkey and barriers: an urgent need for pharmacovigilance education

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The World Health Organization (WHO) has defined adverse drug reaction (ADR) as "a noxious, accidental and undesirable outcome of the drug at a normal therapeutic dose".[1] ADRs are very common throughout the globe and are responsible for increased hospitalization and even mortality.[2] In addition, ADRs also increase the length of stay and cost of treatment.[1,3] An effective evaluation and medication surveillance mechanism is crucial for the prevention of ADRs.[3,4] Pharmacovigilance, which involves the identification of responsible causes, recognition, recording, monitoring and taking measures against a problem encountered in drug administration, is a known evaluation mechanism.[5] The main reasons behind ADRs happening are polypharmacy, off-label drug usage, patients with comorbidities, and individual variations in genetic makeup.[1,3]

The WHO established a program for International Drug Monitoring in response to the thalidomide disaster in 1968. The Uppsala Monitoring Center (UMC), a WHO collaborating center was founded in 1978 to support this program. The UMC incessantly monitors ADRs reported from collaborative countries and plays a vital role in decision-making processes for nationwide pharmacovigilance authorities. The profile of ADRs varies from nation to nation because of difference in hereditary qualities (e.g. genetics), medical practices, diet, and traditions of the populations. Moreover, pharmacovigilance systems also vary due to legislation and the structure related differences among WHO participating countries.[3] Therefore, such investigation can guide actions to increase ADR reporting and that are also beneficial for the assessment of pharmacovigilance activities and legislation at a national level.

In 2005, Turkey began a pharmacovigilance program under the name of "Turkish Pharmacovigilance Center" (TUFAM).[2,3] The TUFAM directs the evaluation and monitoring of ADR reports at a national level. An online "Adverse drug reaction notification form" has also been launched by the TUFAM to report any ADRs and adverse events. This form is available for patients, healthcare professionals (HCPs) and pharmaceutical organizations.[6] According to the policy of TUFAM, all hospitals with 50 or more beds have been required to allocate "a pharmacovigilance contact person (PCP)," who should be a medical doctor, pharmacist, or dental practitioner.[3] The responsibilities of the PCP are to promote activities related to pharmacovigilance and ADRs reporting, and also provide education and training to HCPs. It is the responsibility of HCPs to report all ADRs (serious and suspected reactions) related to drugs to TUFAM. The spontaneous ADR reports can be forward by HCPs to the TUFAM, either directly or through the PCP.[7] This type of data regularly informs drug regulatory authorities and provides suggestions to HCPs in improving safe drug usage.[8,9]

Even with establishing a WHO-standard pharmacovigilance system in Turkey, underreporting of ADRs is still a common problem.[2,3] The population of Turkey was 83,429,615 in 2019,[10] and, according to TUFAM, the number of current ADR reports from Turkey in the Vigiflow database is 8251, which is only 98 per million.[11] Therefore, more action is required to further improve ADRs reporting. Recently published studies in Turkey indicated that underreporting of ADRs is associated with the knowledge of the HCPs.[2,10] According to TUFAM regulations, it is compulsory to include pharmacovigilance literature in education program curricula, since no

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relevant global standard exists on teaching and training related to pharmacovigilance at university level for medical, pharmacy, nursing and other paramedical undergraduate students in Turkey.[2,3,12]

Each year, TUFAM organizes one or two training sessions for PCPs, and also follows up their tasks in each health care institution.[7] However, the TUFAM has not systematically followed up the activities of PCPs.[2] The lack of awareness among HCPs about pharmacovigilance, ADR reporting, the monitoring system of their institution, the existence of TUFAM, recording of drug side effects, reporting system requirements, and their role in this system are the commonly reported barriers.[3] Furthermore, the limited number of PCPs and a lack of supportive staff and specific collaborative HCP teams in regional/institutional pharmacovigilance centers are also the main problems in Turkey.[13]

Pharmacovigilance is a crucial component of the health care system and ultimately impacts the provision of quality patient care.[4,5] The establishment of regional pharmacovigilance centers and medication information points for patients and HCPs in all hospitals, and continuous training and education for the HCPs in the future are required for the better safe care of patients. Recommendations suggested by a recently published study emphasize that a program focused on targeted talks about pharmaceutical care activities, including pre- and post-treatment counseling to patients, periodic medication audits, medication error prevention, reviews of discharge medication, and ADR reporting should be implemented in Turkey.[14] In addition, the implementation of a program aimed at building collaborative links between clinical pharmacists or pharmacologists and other HCPs, an updated drug information center, strengthened regional pharmacovigilance centers, enrollment of more PCPs, expanding hospital and clinical pharmacy facilities, and systematic follow up by health care authorities is needed for better services and enhanced pharmacovigilance activities.

Several activities undertaken by the administrative authorities may show benefits, for example, making rational medication use training compulsory in congresses, making ADR reporting information accessible to the public, and increasing awareness of the public by displaying banners/posters about ADRs on the walls of health organizations or by adding ADR reporting information on patient information sheets of pharmaceutical products.[2] We propose that mandatory persistent training modules on the subject of pharmacovigilance, and activities such as illuminating all HCPs on the purpose, importance, attention to accuracy of products identified, and ADR reports are needed for the improved health care of patients. Additionally, close follow up of PCP activities, rational prescribing practices, incorporating an ADR reporting system into the electronic prescribing system inside all private and public health care institutions, and providing timely feedback by TUFAM to ADR reporters and PCPs are the effective interventions needed for improved reporting rates and a better pharmacovigilance system.

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