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Letter to the Editor

Adverse drug reaction reporting for more than a decade: The need for pharmacovigilance policy implementation in Turkey



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Dear Editor:

Adverse drug reactions (ADRs) are a leading cause of morbidity and death; moreover, they place a substantial financial burden on healthcare systems worldwide.[1] In fact, ADRs that occur in real-life medical practice are rarely predicted by pre-marketing research data. As a result, the most significant tool for pharmacovigilance (PV) systems for the early detection of an unexpected and severe ADR is post-marketing surveillance.[1,2] Accordingly, the Uppsala Monitoring Centre (UMC), established under the support of the World Health Organization (WHO) Programme for International Drug Monitoring (PIDM), collects global data on ADRs from 148 participating countries.[3] However, it has been reported that developing countries have a lower ADR reporting rate than developed countries.[2]

In Turkey, the low reporting of ADRs is a major problem.[1,2] In 1987, Turkey became a member of the WHO–UMC programme, and pharmacovigilance contact points (PCPs) were established under the national PV system following the revised laws in 2005.[3,4] According to a global survey, Turkey reported 1,710 ADRs to the WHO–UMC database in 2008, which is only two reports per million of the population per year (hereafter, 'million/year'). Turkey had a lower rate of ADR reporting than countries with similar economic levels such as Cuba (261 reports), Namibia (48 reports), Malaysia (43 reports), and Uruguay (15 reports).[2] In comparison to Turkey, these nations started the WHO–UMC programme later but had a higher annual ADR reporting rate.[2,3] A local study that analysed national ADR reports forwarded by the Turkish Pharmacovigilance Centre (TUFAM) to the WHO–UMC VigiBase between 2005 and 2013 revealed that the annual reports for a million people increased from 1.5% in 2005 to 32.1% in 2013.[4] Another Turkish study assessed all ADR reports provided by TUFAM to the VigiBase for three years (2014, 2015, and 2016) and found that the annual reporting rate regarding per million/year in 2014, 2015, and 2016 was 28, 36.9 and 51, respectively.[1] Similarly, recent statistics supplied by Turkey to the WHO–UMC during 2017, 2018, 2019, and 2020 showed that the number of reported ADRs per million/year was 84, 94, 99, and 89, respectively.[5] The current reporting rate of ADRs was also less than 100 per million/year between 2017 and 2020. According to the WHO recommendations, ADR reports should be produced at a rate of 200 per million/year.[3] Still, Turkey's ADR reporting rate is much below the WHO's recommended optimum level. So, more active efforts and policy implementations are required to enhance the reporting rate of ADRs in Turkey.

One of the most common sources of ADR reports are healthcare professionals (HCPs). Regarding this matter, the low reporting rate of ADRs in Turkey is attributed to a lack

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of understanding, unfamiliarity, and a poor attitude towards PV and ADR among HCPs.[6,7] Specifically, TUFAM, as a national PV authority in Turkey, is mainly responsible for providing HCPs with ongoing education and training on PV and ADR reporting as well as monitoring their progress in each healthcare setup.[2,4,6] Moreover, assisting stakeholders such as medical schools, pharmacology departments, and hospital PV centres are also accountable for the conduction of PV awareness programmes.[8] However, TUFAM and other stakeholders have failed to organise educational training and the associated reviews on HCPs' actions in a systematic and timely manner.[4,6,7]

Furthermore, TUFAM regulations also mandate the incorporation of PV literature in education programme curricula with the help of other stakeholders; nevertheless, there is no appropriate worldwide standard for PV teaching and training for medical, pharmacy, nursing, and other paramedical undergraduate students in Turkey.[1,7] A recent Turkish study reported that the time allotted in medical school curricula for PV and associated areas is insufficient for students to obtain significant knowledge about ADR.[8] The International Society of Pharmacovigilance (ISoP) and the WHO collectively developed a PV teaching standards curriculum in 2014.[9] Turkish healthcare authorities should contact WHO/ISoP to guide the development of a comprehensive PV curriculum and incorporate PV into healthcare institutions. In fact, TUFAM should start a strengthened regional regulatory programme and collaborate with the European Union (EU).[7] The EU established its 'Strengthening Collaboration for Operating Pharmacovigilance in Europe' ('SCOPE') joint action to help all stakeholders strengthen their PV network's skills and capacities.[10] Such initiatives may be effective in Turkey in terms of increasing the rate of ADR reporting.

Active patient participation in PV activities is beneficial for a higher ADR reporting rate.[11,12] New policies and implementations are needed — such as in Europe — to compel and encourage all stakeholders (including patients) in the healthcare system to report suspected ADRs in Turkey.[6] As such, a direct patient reporting system should be implemented to actively participate in ADR reporting. It is beneficial to inform and educate patients and to work on better ways to involve them in the PV process as a whole. All HCPs at hospitals — including physicians, pharmacists, nurses, and other paramedical personnel — might inform and educate patients about the opportunity to self-report side effects when they begin treatment as well as the necessary action in the case of any experienced ADRs.[12] The hospital's PV centre can make a significant contribution to the spread of accurate information about the necessity of direct reporting in PV to patients visiting the hospital.

National PV centres in Turkey, such as TUFAM, play a leading role in this area because they are in charge of establishing a direct reporting system. As a result, educating HCPs and patients about direct reporting of ADRs is not a time-consuming or expensive effort, but rather a goal that can be realised through collaboration among many stakeholders. The combined information on ADRs from HCPs and patients also has a significant impact on signal detection and increases the rate of reporting of new, rare, or serious ADRs. Turkey began PV activities more than three decades ago, but the PV system is still in its early stages, and additional actions are needed to strengthen and expand the PV system. Therefore, urgent implementation of PV educational policies to strengthen ADR reporting rates and patient safety in Turkey is required. Additionally, periodic research studies are needed on ADR reporting practices that gain insight into ADR reporting rates and patient safety.

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Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

The authors confirm that this letter was prepared in accordance with COPE roles and regulations. Given the nature of the letter, an IRB review was not required.

Authors contributions

ZK conceived and designed the study, conducted research, provided research materials, and collected and organised the data. YK analysed and interpreted the data. ZK wrote the initial and final drafts of the article and provided logistical support. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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