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PROCEEDINGS ABSTRACT

From inception to impact: Iraq's pharmacovigilance journey

Manal M. Younus

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Pharmacovigilance systems in low- and middle-income countries face significant structural, technical, and resource-related challenges that can limit their capacity to protect patients from medicine-related harm. Iraq, a country of approximately 46 million people located in Western Asia with a complex recent history, has established its national pharmacovigilance system relatively late compared to many regional counterparts: the Iraqi Pharmacovigilance Center (IPhvC) was founded on 31 December 2009 under the Ministry of Health's Directorate of Technical Affairs, with a vision of creating a safe medicinal environment and a mission centred on strengthening the detection, the assessment, the understanding, and the prevention of adverse drug reactions and medication errors. Iraq became a full member of the World Health Organization Program for International Drug Monitoring in November 2010. Over the subsequent 15 years, the IPhvC has pursued a sustained, multi-dimensional program of system development spanning ten interconnected areas. The database expansion progressed from a centralised national structure to a three-tiered network encompassing over 510 active VigiFlow (national database) accounts across regional centers, hospitals, specialized centers, and public health districts, including Kurdistan. The quantity of the reports grew substantially while the report quality (measured by VigiGrade completeness scores) consistently exceeded the global average of participating countries, reflecting the impact of structured training, mentoring, as well as the introduction of a dedicated pharmacovigilance unit manual. Furthermore, signal detection evolved from reactive case reviews to a more proactive approach using VigiLyze and disproportionality analysis, with the outputs feeding into regulatory action and safety communications. More importantly, data collection methodologies diversified beyond spontaneous reporting so as to include stimulated reporting introduced in 2019 and sentinel site active surveillance established in 2021, with the latter being applied in the case of the coronavirus disease 2019 (COVID-19) vaccine safety monitoring. The COVID-19 pandemic represented a critical stress test and accelerator for the system, prompting expanded reporting channels, decentralized surveillance structures, active membership in the expanded programme on immunization causality assessment committee, and the production of sixteen periodic safety reports shared with national regulatory and immunization bodies. In the meantime, marketing authorization holder pharmacovigilance has been progressively formalized (since 2012) through successive regulatory circulars, the introduction of national good pharmacovigilance practice guideline, requirements for pharmacovigilance system master files and periodic safety update reports, and the recent introduction of the industry e-reporting system that is aligned with the International Council for Harmonization E2B standard. Additional risk minimization measures grew from domestically identified safety signals, while a dedicated preventable medication errors project is nearing publication. Finally, substandard

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and falsified medicine surveillance, academic collaboration, MedSafetyWeek participation since 2018, the publication of a biannual pharmacovigilance bulletin, and the recent transfer of the national haemovigilance functions to the IPhvC further illustrate the breadth of the system's maturity development [1,2]. Despite this progress, challenges persist, including an uneven system maturity across stakeholders, a variable private-sector engagement, a limited patient involvement, and the need to link pharmacovigilance data with disease registries and health insurance systems. Overall, Iraq's experience demonstrates that a functional and improving national pharmacovigilance system can indeed be built within a complex environment through sustained political commitment, international partnerships, and institution-led capacity building.

Keywords

adverse drug reaction reporting; Iraq; medicine safety; national pharmacovigilance system; pharmacovigilance

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Conflicts of interest statement

None to declare.

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Affiliation(s)

Iraqi Pharmacovigilance Center, Directorate of Technical Affairs, Ministry of Health, Baghdad, Iraq *(MMY)*

Correspondence

Manal M. Younus
Iraqi Pharmacovigilance Center
Directorate of Technical Affairs
Ministry of Health
Baghdad, Iraq
manalyounus@gmail.com