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Letter to the Editor

The crucial role of pharmacovigilance in managing infectious diseases in lower and middle-income countries

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Pharmacovigilance is the science and practices involved in detecting, assessing, understanding, and preventing adverse effects or other drug-related issues linked with pharmaceutical products.[1] Generally, adverse drug reactions (ADRs) constitute the leading cause of morbidity, mortality, and socioeconomic burden.[2] Pharmacovigilance is typically associated with monitoring the safety of medications; it plays a crucial role in infectious diseases in several ways, including monitoring vaccine safety, adverse events detection, identification of drug resistance, assessment of drug interactions, post-marketing surveillance, epidemiological studies, public health response, and global health surveillance.[3–5]

Infectious disease is a global problem that has a devastating impact.[6] Infectious diseases continue to be a significant source of illness and death on a global scale, causing over 52 million fatalities annually, which accounts for approximately 33% of all deaths worldwide.[7] Furthermore, half of the world's population remains susceptible to both emerging and re-emerging infectious diseases.[7] Recent statistics reveal that approximately 14 million children under the age of 5 lose their lives each year, with 70% of these deaths attributed to diseases that could have been prevented through vaccination.[8] Astonishingly, 99% of these child deaths occur in developing nations.[7] Despite substantial progress and extensive awareness campaigns on a global level, the prevention and control of infectious diseases encounter substantial hurdles.[8]

Antimicrobial-resistant infections threaten to be catastrophic at the individual, household, and community levels in low- and middle-income countries (LMICs), where people already face a disproportionately high burden of infectious diseases such as tuberculosis, human immunodeficiency virus (HIV), and malaria.[9] The spread of antimicrobial-resistant infections has accelerated by the combination of poor water and sanitation systems, insufficient coverage, and weak healthcare systems in LMICs with the impact of political instability, civil unrest, armed conflict, and population displacement.[9,10] To address the substantial burden of infectious diseases in LMICs, there is a reliance on the mass distribution of new or repurposed medicines, including antiretrovirals, antibiotics, antituberculosis drugs, antifungals, antiparasitic medications, antimalarials, vaccines, and drugs for neglected tropical diseases.[11] One key challenge in LMICs is the limited knowledge of the safety profiles of these medicines. This lack of safety data is primarily because most safety information is generated in high-income countries with different socioeconomic, epidemiological, and genetic characteristics compared to LMICs.[12]

Pharmacovigilance plays a crucial role in managing infectious diseases, and its importance extends to LMICs where these diseases often significantly impact public health.[13] Effective strategies must be implemented in LMICs including systematic collection, analysis, and reporting of ADRs among patients with multiple medications, including antibiotics and antivirals, which is vital for monitoring drug safety.[14] Infectious disease outbreaks can require the rapid deployment of new or repurposed drugs or vaccines; therefore,

strong pharmacovigilance programs can help detect early adverse events associated with these treatments, allowing for quick response and adjustment of treatment strategies to minimize harm.[3] In the context of infectious diseases and vaccine safety, it is essential to focus on the role of vaccines, the monitoring of vaccine effectiveness, and the assessment of safety outcomes.[15] In real-world studies, various factors, including widely heterogeneous populations, vaccine supply, willingness, and medical accessibility, differ significantly from randomized clinical trial conditions. The actual safety and effectiveness of vaccines turn out to be a significant concern of the international community, crucially LMICs.[16] Therefore, loss of effectiveness is a potential safety outcome in vaccine safety. The efficacy of vaccines is crucial in preventing the spread of infectious diseases and protecting individuals and communities.[17]

Monitoring and addressing vaccine safety concerns are paramount to maintaining public trust in vaccination programs. Adverse events following immunization are carefully investigated, and regulatory agencies work to ensure that vaccines on the market meet stringent safety standards. Continuous surveillance, data collection, and transparent communication contribute to the ongoing evaluation of vaccine safety.[18] Therefore, pharmacovigilance is a continuous surveillance system that helps to identify and investigate potential safety concerns, including any loss of vaccine effectiveness or the emergence of new safety issues to safeguard public health. Monitoring adverse reactions to vaccines is a critical component of vaccine safety management. It ensures the ongoing assessment of vaccine safety, facilitates timely responses to emerging safety concerns, and supports the continuous improvement of vaccination programs worldwide.[19] Regulatory authorities rely on pharmacovigilance data to make informed decisions about drug and vaccine approval, labeling, and use. In LMICs, where resources may be limited, such data can be precious for guiding regulatory decisions. Regulatory authorities in LMICs must participate in clinical trial protocol reviews, joint monitoring of trials, deployment of vaccines, and collaboration with regulators from other parts of the world.[3]

A well-functioning pharmacovigilance system promotes public trust and confidence in healthcare systems. In LMICs, where access to healthcare may be a challenge, maintaining trust is essential for successful infectious disease management, and limited resources in LMICs necessitate efficient resource allocation. Therefore, pharmacovigilance data can help prioritize investments in the most effective treatments while avoiding costly mistakes. Moreover, the pharmacovigilance system can be strengthened in LMICs by capacity building (training healthcare professionals, regulators, and researchers in pharmacovigilance principles and practices, establishing pharmacovigilance centers or units within healthcare systems, developing systems mobile health technologies) for collecting and reporting adverse events in resource-constrained settings, foster collaboration between LMICs and international organizations, pharmaceutical companies, and academic institutions to share data, expertise, and resources. In addition, to educate healthcare providers and the public about the importance of reporting adverse events and promoting a culture of safety, to strengthen regulatory agencies to ensure effective oversight of drug and vaccine safety, to integrate pharmacovigilance activities into existing healthcare systems to ensure sustainability and efficiency, to invest in research to better understand the safety profiles of drugs/vaccines and establish surveillance systems for monitoring infectious diseases and drug use can be effective for the proper implementation of pharmacovigilance activities related to infectious diseases in LMICs.

LMICs can involve clinical pharmacists in hospitals and community pharmacists to strengthen pharmacovigilance. Clinical pharmacists can enhance awareness and understanding of pharmacovigilance principles by simplifying ADR reporting processes and incorporating pharmacovigilance into daily pharmacy workflows. Collaboration with other healthcare stakeholders, advocacy for supportive policies, and active involvement in interdisciplinary networks contribute to a comprehensive pharmacovigilance framework. In addition, clinical pharmacists play a crucial role in quality assurance through monitoring medication use, ensuring proper storage conditions, and advocating for resources to support these efforts. Engaging in research, data analysis, and continuous professional development further empowers clinical pharmacists to contribute effectively to the safety of medication use in these resource-constrained settings.

Likewise, community pharmacists can play a vital role in pharmacovigilance by leveraging their direct patient interactions. As a crucial link between healthcare providers and the community, they are well-positioned to detect, assess, and report ADRs. Community pharmacists offer personalized patient counseling, educating individuals about their medications, potential side effects, and the importance of reporting any adverse events. Their accessibility and frequent contact with patients allow for ongoing medication monitoring, facilitating the early identification of ADRs. By actively engaging in these activities, community pharmacists contribute significantly to the safety of medication use and strengthen the pharmacovigilance system within the local healthcare ecosystem.

In conclusion, pharmacovigilance is essential for managing infectious diseases, and its importance is particularly pronounced in LMICs. Effective pharmacovigilance strategies can help ensure the safety and efficacy of treatments, build public trust, and contribute to global health security. Pharmacovigilance contributes to the ongoing management and control of infectious diseases at both the individual and population levels by monitoring and analyzing data related to adverse events, drug interactions, and resistance patterns.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Author contributions
Zakir Khan: Conceptualization; Data curation; Investigation; Methodology; Project administration; Supervision; Validation; Visualization; Writing – original draft; Writing – review & editing.

Ali Ahmed: Conceptualization; Formal analysis; Investigation; Validation; Visualization; Writing – original draft; Writing – review & editing.

Umair Ilyas: Conceptualization; Formal analysis; Writing – original draft; Writing – review & editing.

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References

1. Khan Z, Karatas Y and Hamid SM. Evaluation of health care professionals' knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: a cross-sectional multicentral study. *PLoS One* 2023; 18: e0285811.
2. Seo B, Yang MS, Park SY, *et al.* Incidence and economic burden of adverse drug reactions in hospitalization: a prospective study in Korea. *J Korean Med Sci* 2023; 38: e56.
3. Excler JL, Saville M, Berkley S, *et al.* Vaccine development for emerging infectious diseases. *Nat Med* 2021; 27: 591–600.
4. Habarugira JMV, Härmark L and Figueras A. Pharmacovigilance data as a trigger to identify antimicrobial resistance and inappropriate use of antibiotics: a study using reports from the Netherlands Pharmacovigilance Centre. *Antibiotics (Basel)* 2021; 10: 1512.
5. Lee JM, Jansen R, Sanderson KE, *et al.* Public health emergency preparedness for infectious disease emergencies: a scoping review of recent evidence. *BMC Public Health* 2023; 23: 420.
6. Baker RE, Mahmud AS, Miller IF, *et al.* Infectious disease in an era of global change. *Nat Rev Microbiol* 2022; 20: 193–205.
7. Rana MS, Usman M, Alam MM, *et al.* Changes in the prevalence of infectious diseases before and after the COVID-19 pandemic in Pakistan. *J Infect* 2023; 86: 415–416.

8. Frenkel LD. The global burden of vaccine-preventable infectious diseases in children less than 5 years of age: implications for COVID-19 vaccination. How can we do better? *Allergy Asthma Proc* 2021; 42: 378–385.

9. Goldberg J, Clezy K, Jasovský D, *et al*. Leaving no one behind: the need for a truly global response to antimicrobial resistance. *Lancet Microbe* 2022; 3: e2–e3.

10. Bloom G, Merrett GB, Wilkinson A, *et al*. Antimicrobial resistance and universal health coverage. *BMJ Glob Health* 2017; 2: e000518.

11. Winkler AS, Klohe K, Schmidt V, *et al*. Neglected tropical diseases – the present and the future. *Tidsskr Nor Laegeforen* 2018; 138: 10.4045/tidsskr.17.0678.

12. Kiguba R, Olsson S and Waitt C. Pharmacovigilance in low-and middle-income countries: a review with particular focus on Africa. *Br J Clin Pharmacol* 2023; 89: 491–509.

13. Chandler R, McCarthy D, Delumeau JC, *et al*. The role of pharmacovigilance and ISoP during the global COVID-19 pandemic. *Drug Saf* 2020; 43: 511–512.

14. Khan Z, Karataş Y, Rahman H, *et al*. COVID-19 treatments and associated adverse reactions: the need for effective strategies to strengthen pharmacovigilance system in Lower- and middle-income countries. *Le Pharmacien Clinicien* 2022; 57: 77–80.

15. Meissner HC. Understanding vaccine safety and the roles of the FDA and the CDC. *N Engl J Med* 2022; 386: 1638–1645.

16. Liu Q, Qin C, Liu M, *et al*. Effectiveness and safety of SARS-CoV-2 vaccine in real-world studies: a systematic review and meta-analysis. *Infect Dis Poverty* 2021; 10: 132.

17. WHO. Vaccines and immunization, https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1 (2023, accessed 10 August 2023).

18. Laryea EB, Frimpong JA, Noora CL, *et al*. Evaluation of the adverse events following immunization surveillance system, Ghana, 2019. *PLoS One* 2022; 17: e0264697.

19. Shimabukuro TT, Nguyen M, Martin D, *et al*. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine* 2015; 33: 4398–4405.