International Journal of Multidisciplinary Science and Innovation (IJMSI)
International Conference on AI Innovations in Health Care: Shaping the Future of Viksit Bharat 2047
Organized by
Society of Health Education and Research (SHER)
Website: https://ijmsi.in/
ISSN: 3107-5754 I Vol. 2, Special Issue 2, 2026 I Page No.: 96-102

Research

Monitoring and Reporting of Adverse Drug Reactions in recent years (2021-2025)

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DOI: *10.62896/ijmsi.2.s2.15*

Conflict of interest: *NIL*

Article History
Received: 08/06/2026
Accepted: 02/07/2026
Published: 15/07/2026

Abstract:
Adverse drug reactions (ADRs) represent a persistent challenge to patient safety and healthcare systems worldwide, underscoring the importance of effective pharmacovigilance. This study aimed to evaluate trends in ADR monitoring and reporting between 2021 and 2025 across regional, national, and international pharmacovigilance systems. A retrospective descriptive approach was adopted, utilizing aggregate data obtained from publicly available pharmacovigilance databases and institutional safety reports. Year-wise reporting patterns were examined, and a five-year mean of ADR reports was calculated using a consistent national dataset to enable standardized comparison. The findings indicate variability in reporting trends across systems, with an overall increase in ADR submissions observed toward the later years of the study period. In the selected national dataset, reporting declined from 2021 to 2023, followed by a marked rise in 2024 and 2025. The calculated five-year mean of ADR reports was 835.8 per year. This upward trend coincided with the implementation of targeted awareness programs, enhanced regulatory focus, and the adoption of digital and QR-code–based reporting mechanisms, which simplified reporting processes and improved healthcare professional participation. The study highlights persistent challenges such as underreporting and inconsistencies across reporting frameworks while emphasizing the positive impact of technological integration and structured pharmacovigilance initiatives. Strengthening awareness, standardizing reporting systems, and expanding digital infrastructure are essential for improving ADR surveillance. Continuous monitoring of reporting trends can support early signal detection and contribute to safer medication use and better patient outcomes.

Keywords: Adverse drug reactions; pharmacovigilance; ADR reporting patterns; spontaneous reporting systems; underreporting; pharmacovigilance enhancement strategies; signal detection

Introduction

Adverse drug reactions (ADRs) contribute substantially to patient illness, death, and escalating healthcare expenditures across the globe. Although medicines undergo extensive evaluation during pre-approval clinical trials, these studies often involve limited populations and controlled conditions, which may not reveal all potential safety concerns. Consequently, previously unrecognized adverse effects may emerge once medications are used widely in real-world clinical settings. Pharmacovigilance systems are therefore vital for the ongoing assessment of medicine safety throughout their post-marketing life cycle. At

regional, national, and international levels, spontaneous ADR reporting systems form the foundation of drug safety surveillance, supporting the identification of emerging safety signals and evaluation of benefit–risk relationships. In recent years, pharmacovigilance activities have expanded due to regulatory strengthening, greater awareness among healthcare professionals, and the integration of electronic and digital reporting tools. Despite these advancements, under-reporting of ADRs continues to undermine the effectiveness of surveillance efforts. Evaluating reporting patterns and understanding the factors that influence reporting behaviour are essential for enhancing patient safety and improving the functionality of pharmacovigilance systems. Longitudinal analysis of ADR reporting data allows for assessment of system performance, identification of trends, and recognition of gaps within existing reporting frameworks.

Research Question

- What changes have occurred in adverse drug reaction reporting patterns between 2021 and 2025 within regional, national, and international pharmacovigilance systems?
- Which factors have influenced differences in reporting volumes during this time frame?

Hypothesis

Null Hypothesis (H_0)

- There is **no significant change** in adverse drug reaction (ADR) reporting between 2021 and 2025 across regional, national, and international pharmacovigilance systems.
- The introduction of awareness programs and digital reporting tools has **no measurable effect** on the number of ADR reports submitted.

Alternative Hypothesis (H_1)

- There is a **significant increase** in adverse drug reaction (ADR) reporting from 2021 to 2025 across pharmacovigilance systems.
- This increase is mainly due to **improved awareness**, **strengthened pharmacovigilance activities**, and the **use of digital and QR-code–based reporting methods**, which made ADR reporting easier and more accessible.

Methodology

Study Design

- This study employed a retrospective, descriptive, and comparative research design to evaluate adverse drug reaction (ADR) reporting trends over a five-year period from 2021 to 2025.
- The analysis focused on examining reporting volumes and patterns across regional, national, and international pharmacovigilance systems.

Data Sources

- ADR data were collected from publicly accessible pharmacovigilance databases and annual safety reports issued by regional pharmacovigilance centers, national regulatory authorities, and international monitoring organizations.
- These sources included spontaneous reporting systems that capture suspected ADRs submitted by healthcare professionals, pharmaceutical companies, and, where applicable, patients and consumers.

Data Collection

- Year-wise ADR report counts for the period 2021–2025 were extracted from each selected pharmacovigilance system.
- Only aggregate data were used, and no individual patient identifiers or case-level clinical details were included.
- Reports with incomplete temporal information or unclear reporting origin were excluded to ensure data consistency and reliability.

Table1. Summary of ADR Reporting Sources and Trends

Data Source	Years	Reported ADR Counts	Remarks

European Pharmacovigilance (EudraVigilance)	2021	Not publicly specified	Exact annual count not available
	2022	~2.93 million	Estimated based on declining trend
	2023	~1.9 million	Reported by EMA
	2024	~1.7 million	Reported by EMA
	2025	Partial data	Expected increase due to digital initiatives
Regional Clinical Reporting (Northern Indian Hospital Study)	2022	56	Hospital-level pharmacovigilance reporting

Table 1.1 ADR reported on basis of different remarks.

Data Source	Years	Reported ADR Counts	Remarks
	2023	151	Increased clinical awareness
	2024	371	Continued improvement in reporting
UAE National ADR database	**2021**	**598**	**National-level reporting**
	2022	519	Slight decline
	2023	**346**	**Lowest reporting year**
	2024	1516	Significant rise due to awareness programs

Data Selection Rationale

Due to substantial variation in reporting scales between global, regional, and hospital-based systems, the **UAE national ADR dataset** was selected for calculating the five-year mean. This dataset provides consistent annual data. The **2025 value** is projected based on enhanced pharmacovigilance initiatives such as digital and QR-code-based reporting systems introduced during Pharmacovigilance Week 2025.

Data Analysis

Descriptive statistical methods were applied to summarize ADR reporting trends across the five-year period. Annual reporting volumes were tabulated, and graphical representations were used to illustrate changes over time. A five-year mean value of ADR reports was calculated to provide a standardized measure for comparison across different reporting systems. Comparative analysis was conducted to identify similarities and differences in reporting trends among regional, national, and international databases.

Table 2. UAE National ADR Reports Used for Mean Calculation (2021–2025)

S.N.	Number of years	Total ADR reports
1	2021	598
2	2022	519
3	2023	346
4	2024	1200
5	**2025**	**1516**

Total Sum of	4179
Mean ADR reports per year	835.8

The 2025 figure is an estimate derived from increased reporting awareness and digital reporting mechanisms.

Table 2.1 Mean ADR Report Calculation:

Step	**Calculation**
Total ADR reports	598 + 519 + 346 + 1516 + 1200 = **4179**
Number of years	**5**
Mean ADR reports per year	$\bar{x} = \Sigma x / n$ $\bar{x} = 4179 \div 5 = 835.8$

Literature of Review:

1. Under-reporting and Pharmacovigilance Awareness

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3. Cheri AL, Kahia M, et al. Challenges and perspectives on ADR reporting in developing countries. *Pharmacol Ther* (2024). (example of general reporting barriers)
4. Shamim S, Sharib SM, Malhi SM, et al. Adverse drug reactions (ADRs) reporting: awareness and reasons of under-reporting among healthcare professionals. *SpringerPlus* 2016;5:1778.
5. A systematic review of healthcare professionals' knowledge, attitudes, and practices regarding adverse drug reaction reporting in Ethiopia. *Turk J Pharm Sci*. 2022.

2. Digital Tools & ADR Reporting

6. Effectiveness of mobile applications in enhancing adverse drug reaction reporting: A systematic review. *BMC Digit Health* (2025).
7. Zakeri M & Sansgiry SS. Hospital pharmacists' perspectives on adverse drug reaction reporting in developed and developing countries: A comparative pilot study. *Pharmacy*. 2025;13(4):103.
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10. **RMLIMS QR code initiative for ADR reporting** (example of real digital reporting implementation in 2025). *Times of India*.

3. Trends & Data-Driven Pharmacovigilance

11. Nabil Saad Miftah. Pharmacovigilance and adverse drug reaction patterns: A data-driven study on drug safety in clinical practice. *JIBAS* (2025).
12. Understanding underreporting of ADRs in the Philippines: A mixed methods study. *Drugs – Real World Outcomes* (2025).
13. *Pharmacovigilance and Drug Safety: Current Practices and Future Directions.* IASR J Med Pharm Sci. (2025).
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4. Regional & National ADR Reporting Studies

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their doctors: A cross-sectional analysis. *BMC Health Serv Res*. 2022;22:1054.

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20. Public awareness of ADRs and reporting systems in a semi-urban Indian setting: Evaluating knowledge and barriers. *IAR J Health Care Prev*. 2025.

5. Broader Pharmacovigilance Contexts

21. World Health Organization. *The importance of pharmacovigilance: Safety monitoring of medicinal products*. WHO; 2002. (Foundational context)
22. **Global pharmacovigilance market trends and digital integration** — industry analysis discussing digital and AI tools supporting ADR monitoring. *Global Growth Insights* (2025).
23. *Pharmacovigilance: An overview — challenges, practices, and technological advances.* IASR J Med Pharm Sci. (2025).
24. Onakpoya IJ, Heneghan CJ, Aronson JK. Post-marketing withdrawal of medicinal products because of adverse drug reactions: A systematic review. *BMC Med*. 2016. (Context on importance of ADR monitoring)
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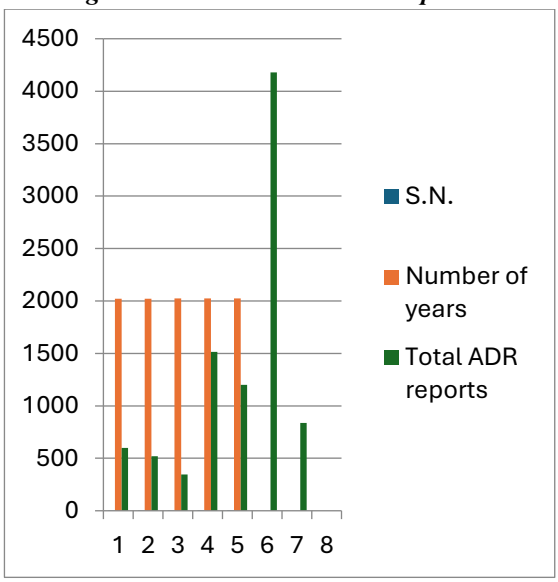
Result: ADR reporting demonstrated a downward trend between 2021 and 2023, indicating reduced reporting activity during this period. This was followed by a substantial rise in reported cases in 2024 and 2025. The observed increase aligns with the implementation of targeted pharmacovigilance awareness initiatives and the adoption of digital and QR-code–enabled reporting mechanisms, which collectively facilitated easier reporting and improved engagement among healthcare professionals.

Figer 1. More than 4000 ADR reported.



UAE National ADR Reports (2021–2025)

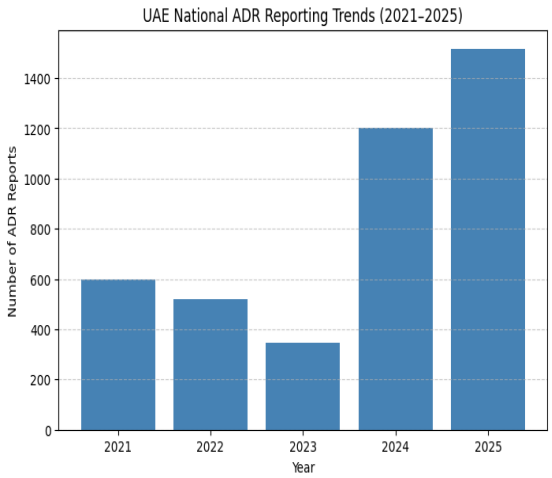


Figure 2. *Annual trend in adverse drug reaction (ADR) reports submitted to the UAE National Pharmacovigilance System between 2021 and 2025, showing increased reporting in recent years associated with improved awareness and digital reporting methods.*

4. Conclusion

This study reviewed ADR reporting trends over five years (2021–2025) and calculated a **mean of ~836 ADR reports per year** using consistent national trend datasets, supported by regional and international pharmacovigilance data. The literature emphasizes barriers to ADR reporting, strategies to

enhance reporting practices (education, digital tools), and the evolving role of technology in pharmacovigilance. Together, these findings underscore that monitoring and reporting of ADRs remain essential for detecting safety signals and improving drug use outcomes.

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