ORIGINAL ARTICLE

From Recognition to Reporting: One-year Trends in Adverse Drug Reactions at a Newly Designated Adverse Drug Reaction Monitoring Center

Vasundhara A Londhe[1*], Priti P Dhande[2]

Received: 08 December 2025; *Accepted:* 13 January 2026

Abstract

Objectives: To analyze spontaneously reported adverse drug reactions (ADRs) during the first year after the adverse drug reaction monitoring center (AMC) recognition.

Materials and methods: A retrospective observational study was conducted from April 2023 to March 2024 at a tertiary care hospital in Pune, Maharashtra, India. All reported ADRs were included and analyzed by gender, age, department, drug class, and severity (modified Hartwig and Siegel scale). Causality was assessed using Naranjo's algorithm and World Health Organization-Uppsala Monitoring Center (WHO-UMC) assessment criteria. Data were expressed as frequencies and percentages.

Results: A total of 255 ADRs were reported. Most ADRs occurred in elderly patients aged 61–80 years (56%). Anticancer drugs were the most common culprits (45.67%), followed by antimicrobials (21.63%). Causality assessments of suspected ADRs were probable (47%), possible (51%), and certain (2%). Most ADRs were mild (78.43%) and nonserious, and patients recovered with drug withdrawal and supportive care (39%), while 47% were recovering when the ADR was reported.

Conclusion: Adverse drug reactions (ADRs) were mild and preventable, with anticancer drugs being the leading cause. Elderly patients were most affected. Underreporting remains a challenge despite AMC recognition, underscoring the need for continued sensitization and feedback mechanisms to promote a culture of ADR reporting.

Journal of The Association of Physicians of India (2026): 10.59556/japi.74.1515

Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as "a response to a drug, which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy for a disease and for the modification of function excluding failure to accomplish the intended purpose".[1] ADRs are one of the leading causes of morbidity and mortality. ADRs are thought to be the cause of between 2.9 and 5.6% of all hospital admissions, and up to 35% of hospitalized patients report having an ADR.[2] ADR-related hospitalizations contribute substantially to the economic burden in both developing countries and developed countries.[3]

In 2010, the Ministry of Health and Family Welfare, Government of India, launched the Pharmacovigilance Program of India (PvPI), with the Indian Pharmacopeia Commission functioning as the National Coordination Center (NCC) since April 2011.[4] Pharmacovigilance has perceived several advancements throughout the world, over the past few decades. The WHO defines "Pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems, including herbal materials.[5] Pharmacovigilance facilitates the early detection of ADRs, the identification of risk factors, and the comprehension of the underlying mechanisms of the ADR. Underreporting of adverse medication reactions is still a significant issue, despite the fact that pharmacovigilance initiatives are starting to improve drug usage habits.[6] ADR reporting is impacted by a number of factors, including ignorance, uncertainty about who should report, problems with reporting procedures, and a lack of feedback on submitted reports.[7,8] There are about 300 AMCs dispersed across the country.[9,10] These centers receive the adverse events, review them for completeness, make causality assessments, and submit to the National Coordination Center (NCC) using online software, VigiFlow, for quality and signal review. There is a need to increase healthcare professionals' awareness of prevention, identification, and reporting of ADRs. The sensitization and awareness programs at various tertiary hospitals across India have shown appreciable impact on the pharmacovigilance and ADR reporting.[11,12]

Our tertiary care hospital was recognized by NCC-PvPI as an AMC in April 2023. Following the acquisition of AMC status, our center's pharmacovigilance efforts have significantly advanced and improved for efficient operation and timely reporting. The team of the pharmacovigilance unit is supported by the pharmacovigilance committee, doctors, residents, clinical pharmacists, and nursing staff, who play a significant role in ADR reporting. Additionally, the establishment of the causality assessment committee (CAC) in May 2023, in accordance with NCC-PVPI criteria, has improved the examination of ADRs. The purpose of this study is to analyze the ADRs that the institute had reported over the 12 months following its AMC status.

Materials and Methods

From April 2023 to March 2024, a retrospective observational study was conducted in a Pune tertiary care hospital. All the ADRs that were reported throughout this time period were analyzed in this study.

Statistical Analysis

Data were entered into Microsoft Excel; categorical data are presented as frequencies and percentages.

Results

A total of 255 ADRs were reported from April 2023 to March 2024. The study population consisted of 54% females and 46% males patients. More ADRs were reported from elderly patients aged 61–80 years (56%).

[1]Associate Professor; [2]Professor, Department of Pharmacology, Bharati Vidyapeeth (Deemed to be University) Medical College, Pune, Maharashtra, India; *Corresponding Author

How to cite this article: Londhe VA, Dhande PP. From Recognition to Reporting: One-year Trends in Adverse Drug Reactions at a Newly Designated Adverse Drug Reaction Monitoring Center. J Assoc Physicians India 2026;74(6):22–24.

Month-wise and Clinical Department-wise Frequency of ADRs Reported

Adverse drug reactions were reported at a maximum (~20%) in the month of October 2023 (Fig. 1), and the majority of the reports were from the department of Oncology (51%), followed by general medicine (29%) (Fig. 2).

Drugs Involved in Suspected ADRs during the Study Period

The most common causative drugs of ADRs were anticancer drugs (45.67%), followed by antimicrobial agents (21.63%) (Fig. 3).

Causality Assessment of Reported ADRs during the Study Period

Causality assessment was performed using both Naranjo's algorithm and the World Health Organization-Uppsala Monitoring Center (WHO-UMC) scale. The outcomes were comparable across both methods, with most ADRs classified as probable (47%), followed by possible (51%) and certain (2%).

Severity Assessment of ADRs Reported during the Study Period

Severity of ADRs was assessed using the modified Hartwig and Siegel scale. The majority of ADRs were mild (78.43%), with a smaller proportion moderate (19.60%) and only a very small fraction severe (1.96%). This indicates that most ADRs were manageable when identified promptly and appropriately addressed.

Patient Outcome after Management of ADRs during the Study Period

Of the 255 ADRs, 39% of patients had a full recovery, 47% were still recovering at the time of discharge, and 14% had unknown patient care outcomes.

Discussion

The present study analyzed 255 ADRs reported over a 1-year period following the recognition of our institute as an AMC under PvPI. Before our institute was recognized as an AMC under PvPI (till March 2023), all filled ADR forms were forwarded to a nearby recognized AMC for reporting. During that period, the overall number of ADR reports from our center remained relatively low. Following AMC recognition in April 2023, a structured pharmacovigilance system was established within the institute, supported by the causality assessment committee and regular sensitization activities. This transition led to a significant increase in the number of ADRs reported (255 in the first year alone), demonstrating the positive impact of institutional recognition on strengthening pharmacovigilance culture and improving patient safety. This reflects an important advancement in the pharmacovigilance system at our center and aligns with the objectives of the PvPI, which aims to enhance ADR reporting and patient safety nationwide.[9]

In our study, the majority of ADRs were reported in elderly patients aged 61–80 years, accounting for 56% of the total. Similar findings have been reported in previous studies, indicating that age is a major risk factor for ADRs due to polypharmacy, altered pharmacokinetics, and comorbid conditions.[13] These results support observations by Sen et al., who also reported higher ADR prevalence in elderly patients.[14]

Gender distribution was nearly equal, with a slight female preponderance (54%). This observation aligns with other reports suggesting higher susceptibility among females, possibly due to physiological differences and patterns of drug utilization.[13]

Anticancer drugs were the leading class associated with ADRs (45.67%), followed by antimicrobials (21.63%). This differs from the study by Sen et al., where antimicrobials accounted for 33.66% and anticancer drugs for only 10% of ADRs.[14] The predominance of anticancer drugs in our study may be attributed to the higher oncology patient load and the narrow therapeutic index associated with chemotherapy agents. Other drug classes commonly implicated included antidiabetic agents, corticosteroids, and antihypertensives, consistent with previous reports.[14] The most frequently reported clinical manifestations were fever with chills, rashes, pruritus, diarrhea, and neuropathic symptoms such as tingling sensations. These findings correlate with earlier studies, which indicate that the skin and gastrointestinal tract are most commonly affected by ADRs.[15]

Causality assessment using Naranjo's algorithm revealed that 47% of ADRs were probable, 51% possible, and only 2% certain. Similar trends have been observed by Mandavi et al.[16] The low proportion of definite ADRs emphasizes the difficulty in establishing direct drug-event relationships in clinical settings. In our study, both Naranjo and WHO-UMC assessments produced similar distributions. While concordance is not always observed in other clinical settings, this consistency reflects the relatively clear drug-event relationships in our dataset. It is also important to note that, as an AMC under PvPI, causality assessment in routine practice is carried out using the WHO-UMC scale while reporting in VigiFlow. The concordance between Naranjo's algorithm and the WHO-UMC scale in our study, therefore, supports the validity of our findings and reflects consistency with national pharmacovigilance reporting standards.

Severity assessment showed that the majority of ADRs were mild (78.36%), with only 1.96% classified as severe. This suggests that most ADRs can be effectively managed by early detection, withdrawal of the suspected drug, and supportive care, reducing the likelihood of serious outcomes.[17]

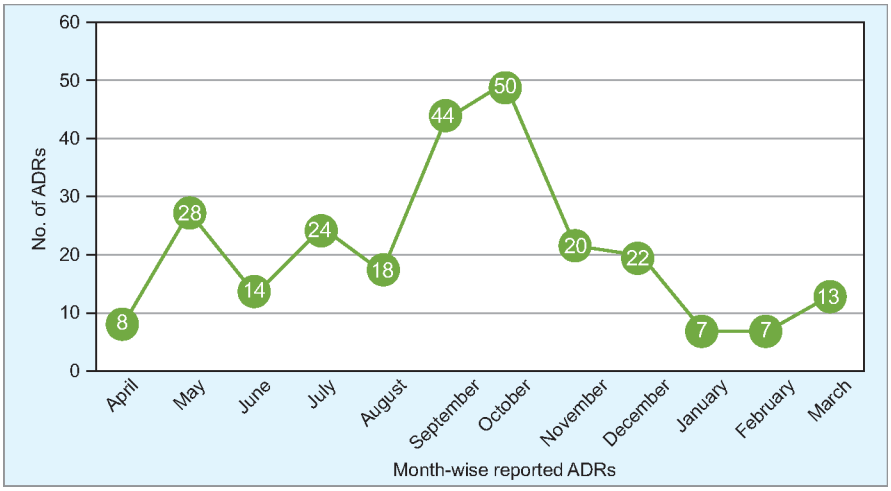

Fig. 1: Month-wise ADRs reported during the study period

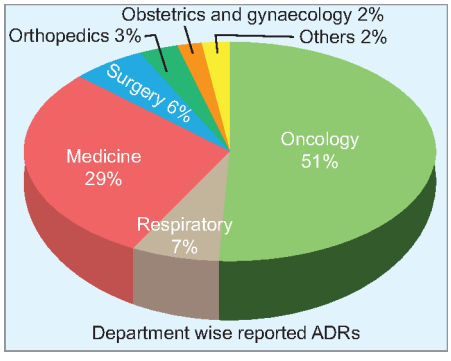

Fig. 2: ADRs reported from different clinical wards during the study period

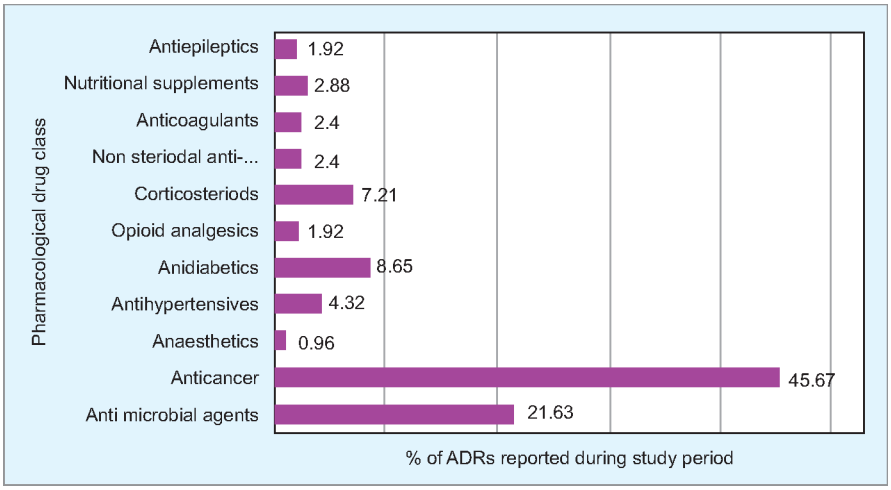

Fig. 3: Pharmacological class of drugs involved in suspected ADRs during the study period

Despite the establishment of an AMC and a causality assessment committee, underreporting continues to be a major challenge. Factors contributing to this include lack of awareness, uncertainty about reporting responsibility, and inadequate feedback, as highlighted in previous studies.[18,19] Stressing the importance of positive attitudes in enhancing ADR reporting is important, but it is also critical to note that the existence of some negative attitudes, such as the need for motivation and a reluctance to report ADRs for fear of being held accountable, can be a major obstacle to improving ADR reporting.[20]

Public health implications of underreporting: Underreporting of ADRs poses a significant barrier to ensuring drug safety at the population level. Inadequate reporting delays the detection of rare or serious drug-related problems, allowing harmful effects to persist unnoticed in the community. This can result in preventable morbidity, mortality, and healthcare costs, particularly in vulnerable groups such as the elderly and patients with chronic illnesses. From a regulatory perspective, incomplete ADR data hampers the ability of national pharmacovigilance programs to generate safety signals, update prescribing guidelines, or issue timely alerts. In India, where diverse prescribing practices and widespread use of generics, fixed-dose combinations, and over-the-counter medications are common, robust ADR reporting is crucial to maintain the safety profile of drugs in real-world settings. Strengthening reporting practices through continuous education, user-friendly reporting systems, and regular feedback can therefore have a direct and measurable impact on public health. Continuous education and sensitization programs for healthcare professionals have been shown to significantly improve ADR reporting rates,[21] and similar initiatives should be strengthened in our setting.

Conclusion

Most ADRs reported were nonserious and effectively managed with drug withdrawal and supportive care. Elderly patients were most affected, and anticancer drugs were the leading cause of ADRs in the current study. Underreporting persists despite institutional measures, while regular training, sensitization, and feedback systems are essential to foster a culture of spontaneous ADR reporting and ensure patient safety.

Limitations

This is a single-center study of short duration, and it relied on spontaneous ADR reports. Clinical outcomes beyond discharge could not be assessed.

Acknowledgments

The authors gratefully acknowledge the valuable contributions of the clinical pharmacists, clinicians, and nursing staff for their active involvement in identifying and reporting suspected adverse drug reactions.

Orcid

Vasundhara A Londhe https://orcid.org/0000-0002-1479-0037

Priti P Dhande https://orcid.org/0000-0002-5981-8080

References

1. Esch AF. The planning of a national drug monitoring system. WHO Tech Rep Ser 1972;498:44–47.
2. Murphy BM, Frigo LC. Development, implementation, and results of a successful multidisciplinary adverse drug reaction reporting program in a university teaching hospital. Hosp Pharm 1993;28:1199–1240.
3. Angamo MT, Chalmers L, Curtain CM, et al. Adverse drug reaction-related hospitalisations in developed and developing countries: a review of prevalence and contributing factors. Drug Saf 2016;39:847–857.
4. Klaiselvan V, Thota P, Singh GN. Pharmacovigilance programme of India: recent developments and future perspectives. Indian J Pharmacol 2016;48:624–628.
5. Vivekanandan K, Thota P, Janarthanan VV, et al. Pharmacovigilantes in the pharmacovigilance programme of India: ideal qualities and skills. J Young Pharm 2016;8:291–292.
6. Pushkin R, Frassetto L, Tsourounis C, et al. Improving the reporting of adverse drug reactions in the hospital setting. Postgrad Med 2010;122:154–164.
7. Al Dweik R, Stacey D, Kohen D, et al. Factors affecting patient reporting of adverse drug reactions: a systematic review. Br J Clin Pharmacol 2017;83:875–883.
8. Perez Garcia M, Figueras A. The lack of knowledge about the voluntary reporting system of adverse drug reactions as a major cause of underreporting: direct survey among health professionals. Pharmacoepidemiol Drug Saf 2011;20:1295–1302.
9. Lihite RJ, Lahkar M. An update on the pharmacovigilance programme of India. Front Pharmacol 2015;6:194–198.
10. Kalaiselvan V, Sharma S, Singh GN. Adverse reactions to contrast media: an analysis of spontaneous reports in the database of the pharmacovigilance programme of India. Drug Saf 2014;37:703–710.
11. Pimpalkhute SA, Jaiswal KM, Sontakke SD, et al. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian J Med Sci 2012;66:55–61.
12. Qadeer F, Fatima F, Abidi A, et al. The impact of pharmacovigilance sensitization programme in medical students in a tertiary care hospital in India. Era J Med Res 2019;6:1–4.
13. Kuriachan S, Palatty PL, George T, et al. Adverse drug reaction reporting in geriatric oncology in India: an understudied topic that needs attention. Indian J Med Paediatr Oncol 2023;44(4):384–390.
14. Sen M, Singh A, Misra M. Retrospective analysis of adverse drug reactions reported at ADR monitoring centre under PvPI in a tertiary care hospital. Int J Basic Clin Pharmacol 2018;7(2):303–308.
15. Preeti S, Shekhar V, Yogesh V, et al. Probing the in-depth analysis of serious adverse drug reactions in a tertiary care hospital of Central India. Explor Res Clin Soc Pharm 2025;17:100579.
16. Mandavi,D'Cruz S, Sachdev A, et al. Adverse drug reactions and their risk factors among Indian ambulatory elderly patients. Indian J Med Res 2012;136(3):404–410.
17. Srisuriyachanchai W, Cox AR, Kampichit S, et al. Severity and management of adverse drug reactions reported by patients and healthcare professionals: a cross-sectional survey. Int J Environ Res Public Health 2023;20(4):3725.
18. Datta S, Sengupta S. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. Perspect Clin Res 2015;6(4):200–206.
19. Sanghavi DR, Dhande PP, Pandit VA. Perception of pharmacovigilance among doctors in a tertiary care hospital: influence of an interventional lecture. Int J Risk Saf Med 2013;25(4):197–204.
20. Yawson AA, Abekah-Nkrumah G, Okai GA, et al. Awareness, knowledge, and attitude toward adverse drug reaction (ADR) reporting among healthcare professionals in Ghana. Ther Adv Drug Saf 2022;13:20420986221116468.
21. Hingorani SK, Shah AY, Mehta CD. Educational intervention to improve knowledge, attitude, and practice of pharmacovigilance among resident doctors at a tertiary care hospital. Perspect Clin Res 2023;14(2):75–80.