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PATTERN OF ADVERSE DRUG REACTIONS REPORTED AT THE ADVERSE DRUG REACTION MONITORING CENTRE (AMC-RIPER) AT A TERTIARY CARE TEACHING HOSPITAL IN INDIA: A RETROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Adverse drug reactions (ADRs) are an important cause of morbidity and may adversely affect patient safet. To analyze the demographic and clinical characteristics of reported ADRs and assess their distribution according to reporting source, seriousness, and annual reporting pattern over the study period. A retrospective observational study was conducted at AMC-RIPER, ADR reports documented over a five-year period from January 2021 to December 2025 were reviewed. Descriptive statistics were used for analysis. The VigiFlow export analyzed in the results contained 1,059 ADR report records. Among the 1,059 ADR reports analyzed, females accounted for 583 (55.05%) reports and males for 463 (43.72%), while sex was not reported in 13 (1.23%) reports. The mean age of patients with available age data was 37.25 ± 21.25 years, with a median age of 38 years and a range of 1–93 years. Regarding seriousness, 931 (87.91%) ADRs were classified as non-serious and 128 (12.09%) as serious. ADR reporting increased substantially during the later years of the available dataset, with the highest number of reports recorded in 2025.The study demonstrated a broad spectrum of suspected ADRs reported at AMC-RIPER, with a slight female predominance and adults representing the largest age group among reports with known age classification. Pharmacists made a major contribution to ADR reporting. Although most reported ADRs were non-serious, the presence of serious reactions emphasizes the need for continuous monitoring and timely intervention. The increase in reporting during the later years may reflect improved pharmacovigilance awareness, reporting practices, and documentation. Strengthening multidisciplinary participation, continuous ADR monitoring, timely reporting, and proper documentation may further improve medicine safety and promote rational use of medicines in the hospital setting.

Key Words: Adverse drug reactions; Pharmacovigilance; ADR Monitoring Centre; VigiFlow

1. Introduction

Medicines are an essential component of modern healthcare and have contributed substantially to the prevention, diagnosis, treatment, and management of a wide range of diseases. Despite their therapeutic benefits, all medicines have the potential to produce unwanted and unintended effects when used at therapeutic doses.1 These unwanted effects may range from mild and self-limiting symptoms to serious, life-threatening reactions requiring hospitalization, intensive care, or prolonged treatment. Therefore, monitoring the safety of medicines throughout their clinical use is an important component of patient care and public health2.

ADRs may occur due to several factors, including the pharmacological properties of medicines, dose and duration of therapy, drug interactions, patient-related factors, genetic susceptibility, age, renal and hepatic function, comorbidities, polypharmacy, medication errors, and inappropriate drug use3. Certain patient populations, such as pediatric patients, older adults, pregnant women, and patients with multiple comorbidities, may be particularly vulnerable to drug-related harm4-5

Pharmacovigilance is defined by WHO as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem6. Pharmacovigilance plays a central role in identifying previously unrecognized safety signals, characterizing known ADRs, evaluating risk factors, and supporting regulatory and clinical decision-making7.

Despite the importance of spontaneous reporting systems, under-reporting remains a major limitation of pharmacovigilance8. Suspected ADRs may not be reported because healthcare professionals may fail to recognize the association between a medicine and an adverse event, may be uncertain about causality, may consider the reaction clinically insignificant, or may be unfamiliar with the reporting process9. Under-reporting may therefore result in an incomplete representation of the actual burden and pattern of ADRs within a healthcare institution. Continuous monitoring, pharmacovigilance education, and periodic evaluation of reporting patterns are consequently important for improving ADR detection and reporting practices10-12.

2.Methodology

This Observational retrospective study was performed over 5 years period January 2021 to December 2025 at Adverse Drug Reaction Monitoring Centre (AMC-RIPER) associated with RDT hospital, The centre receives suspected ADR reports from healthcare professionals and other eligible reporters associated with the hospital and participating healthcare departments.

The suspected adverse drug reactions were reported and documented at AMC-RIPER during the study period. A total of 1,057 ADR reports/cases recorded during the five-year study period were included in the analysis, subject to the predefined eligibility criteria. Since this was a retrospective study based on previously documented ADR reports, total enumeration of eligible ADR reports during the study period was performed.

The collected data were entered into a suitable database and analyzed using appropriate statistical software such as Microsoft Excel, IBM SPSS Statistics, R, or equivalent software. Descriptive statistics were primarily used because the main objective of the study was to describe the pattern of reported ADRs

3.Results

The VigiFlow export contained 1,059 report records. The following results were calculated directly from the “Reports” worksheet of the supplied VigiFlow export. Percentages are calculated using the 1,059 exported records. In the VigiFlow export, Female patients accounted for 583 (55.05%) reports and male patients for 463 (43.72%),

Table. Distribution of ADR reports

Category	n	Percentage (%)
Female	583	55.05
Male	463	43.72
Not reported	13	1.23

Reporter qualification

Reporter qualification was predominantly pharmacist-based. After normalization of duplicate repeated entries in the qualification field, pharmacists accounted for 898 (84.80%) reports, followed by other health professionals with 138 (13.03%). Physicians accounted for 5 (0.47%) reports, while reporter qualification was not reported in 18 (1.70%) reports.

Table. Distribution of ADR reports according to reporter qualification

Category	n	Percentage (%)
Pharmacist	898	84.80
Other health professional	138	13.03
Not reported	18	1.70
Physician	5	0.47

Reporter Organisation

After conservative normalization of variations in the reporter-organisation field, RDT Hospital 870 (81.15%) and Saveera Hospital 78 (7.37%) and the reporter organisation was others reported in 111 (10.48%) reports.

Table. Distribution of ADR reports according to reporter organisation

Category	n	Percentage (%)
RDT Hospital	870	81.15
Saveera Hospital	78	7.37
Other	111	10.48

ADR reporting based on seriousness

Of the 1,059 ADR reports, 128 (12.09%) were classified as serious, while the remaining 931 (87.91%) were non-serious. Thus, the majority of reported ADRs were non-serious, accounting for approximately 88% of all reports.

Table. ADR reporting based on seriousness

ADR Report Classification	Number of Reports	Percentage
Serious	128	12.09%
Non-serious	931	87.91%

Annual pattern of ADR reporting

Based on the VigiFlow “Date of report” field, report dates were available for 1,035 records. The export contained 47 reports in 2022, 33 in 2023, 195 in 2024, 624 in 2025, and 136 in 2026. Twenty-four reports had no Date of report recorded. No report dated 2021 was identified in this field.

Table. Annual distribution of ADR reports according to Date of report

Category	n	Percentage (%)
2022	47	4.44
2023	83	3.12
2024	235	18.41

2025	670	58.92

4.Discussion

The Adverse drug reactions (ADRs) are an important concern in clinical practice because they can affect patient safety, treatment outcomes, quality of life, and healthcare resources. The present retrospective observational study evaluated the pattern of ADRs reported to the ADR Monitoring Centre (AMC-RIPER) over five years (2021–2025). A total of 1,059 ADR reports were analyzed.A female predominance was observed, with females accounting for 583 reports (55.05%) and males for 463 (43.72%). Among reports with recorded age groups, adults constituted the largest proportion (404; 57.55%), followed by elderly patients (136; 19.37%), indicating that ADR reporting occurred across different age groups.

Pharmacists were the major contributors to ADR reporting, accounting for 898 reports (84.80%), followed by other healthcare professionals (13.03%) and physicians (0.47%). This finding highlights the important role of pharmacists in pharmacovigilance and also indicates the need to encourage greater participation from physicians and other healthcare professionals through continuous awareness and training programmes. Of the total reports, 128 (12.09%) were serious and 931 (87.91%) were non-serious. The predominance of non-serious ADRs demonstrates that the monitoring system captured a broad spectrum of suspected drug-related events rather than focusing only on severe reactions. Nevertheless, the occurrence of serious ADRs emphasizes the importance of early detection, assessment, documentation, and appropriate clinical intervention.

An increasing trend in ADR reporting was observed during the later years, particularly in 2024 and 2025. This may reflect improved awareness, increased healthcare-professional participation, strengthening of pharmacovigilance activities, and better documentation. However, increased reporting should not be interpreted as an increase in the true incidence of ADRs because spontaneous reporting is influenced by reporting practices, under-reporting, and reporting bias.

The study also included assessment of suspected medicines and therapeutic classes; however, numerical results for these variables were not available in the supplied Results section and therefore cannot be interpreted reliably. Causality assessment was performed using standardized criteria considering the temporal relationship, pharmacological properties, alternative causes, dechallenge/rechallenge, and available clinical or laboratory information.

Overall, the findings demonstrate the important role of AMC-RIPER in systematic ADR detection and reporting. Strengthening multidisciplinary participation, continuous pharmacovigilance education, and accurate documentation may further improve ADR reporting. Since spontaneous reporting systems are subject to under-reporting and reporting bias, these findings should be considered a description of reported ADRs rather than the true incidence of ADRs in the hospital population.

5.Conclusion

The present study demonstrated that ADRs at AMC-RIPER occurred across different age groups, with a slight female predominance and higher reporting among adults. Pharmacists were the major contributors to ADR reporting (84.80%), while most ADRs were non-serious (87.91%). The increasing reporting trend indicates improved pharmacovigilance awareness and reporting practices. Strengthening continuous ADR monitoring, timely reporting, proper documentation, and multidisciplinary participation can enhance patient safety and promote the rational use of medicines.

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