

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20263789>

Original Research Article

Pattern of adverse drug reactions reported through Vigiflow at a tertiary care teaching hospital in North India: a retrospective analysis

Veena Verma, Anugya Kushwaha*, Preeta Kaur Chugh, Himanshu Singh Saini

Department of Pharmacology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, Delhi, India

Received: 16 September 2026

Accepted: 13 October 2026

*Correspondence:

Dr. Anugya Kushwaha,

Email: shonaraichand@gmail.com

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ABSTRACT

Background: To analyse adverse drug reactions (ADRs) reported to the VMMC & Safdarjung Hospital, New Delhi, entered into Vigiflow analysing causality, severity, preventability and outcome.

Methods: Individual case safety reports (ICSRs) entered into Vigiflow from March 2021 to March 2026 were retrospectively reviewed. Reports lacking a documented suspect drug and reaction term were excluded as incomplete. Complete reports were analysed for demographics, system organ class (SOC), suspect drug classes, causality (WHO-UMC and Naranjo scales), severity (Modified Hartwig and Siegel scale), preventability (Schumock and Thornton criteria) and outcome.

Results: Of 974 ICSR, 925 (95.0%) were evaluable. Mean age was 38.9 ± 17.6 years; 54.2% were male. Gastrointestinal (27.4%), skin/subcutaneous (25.1%) and general/administration-site disorders (20.1%) were most affected. Antimicrobials (24.0%), antineoplastics (13.1%) and cardiovascular drugs (11.4%) were leading suspect classes. WHO-UMC causality was probable/likely (73.4%) or possible (25.7%), with similar Naranjo findings. Reactions were mostly mild (63.4%) or moderate (29.8%); 6.8% were severe and 8 (0.9%) fatal, six linked to antineoplastic chemotherapy. Preventability was noted in 88.6%; recovery was documented in 44.6%.

Conclusions: Antimicrobials, antineoplastics and cardiovascular drugs predominated among ADRs, most being probable, mild-to-moderate and preventable. Strengthening dose monitoring, allergy screening, drug-interaction checks and ICSR completeness may reduce ADR burden, especially in oncology and radiocontrast use.

Keywords: Adverse drug reaction, Naranjo scale, Preventability, Pharmacovigilance, Vigiflow, WHO-UMC causality scale

INTRODUCTION

Medicines help prevent, diagnose and treat disease. But their use carries risk. The WHO defines an ADR as a harmful, unintended reaction to a medicine. This reaction occurs at doses normally used for prevention, diagnosis or treatment.¹ ADRs are a type of adverse drug event. Some ADRs are predictable and dose related, linked to the known action of the drug. Others are unpredictable and idiosyncratic. Clinically, ADRs range from mild to severe. Mild reactions include nausea and rash. Severe, life-threatening reactions include anaphylaxis, Stevens-Johnson syndrome and organ failure.² ADRs cause illness and longer hospital stays. They raise healthcare costs and

sometimes cause death. Recent estimates suggest that ADRs account for 5-10% of hospital admissions worldwide. Fatal ADRs are among the leading causes of preventable death in hospitalised patients.³ Pre-marketing clinical trials have small sample sizes and short duration. They often exclude vulnerable groups. Because of this, many ADRs are only discovered after a drug reaches the market and is used in real-world populations.⁴ This makes pharmacovigilance (PV) important. WHO defines PV as the science and activities related to detecting, assessing, understanding and preventing adverse effects or other medicine-related problems.⁵ Pharmacovigilance helps ensure that medicines are used safely and rationally.

It protects public health. It also helps patients trust their treatments.

India launched the pharmacovigilance programme of India (PvPI) in 2010. The central drugs standard control organization set it up. The Indian Pharmacopoeia Commission, Ghaziabad serves as the national coordination centre.⁶ The share of serious ADRs recorded in the PvPI database has varied by year. It was 23.4% in 2019-20, 28.1% in 2020-21, 19.5% in 2021-22 and 27% in 2022-23. The national database has also grown. It held 380,609 ICSRs by March 2019. By June 2024, this had risen to about 0.85 million ICSRs. This growth reflects increasing participation by ADR monitoring centres (AMCs) and drug companies across the country.⁷

PvPI collects and analyses ICSRs through Vigiflow. Vigiflow is a web-based case management system. The Uppsala monitoring centre (UMC), Sweden developed it. Vigiflow allows standard entry, assessment and transmission of ADR reports. These reports feed into the WHO global safety database, Vigibase.⁸ Vigiflow data show useful patterns. These include which drug classes are commonly involved, demographic trends and preventable risk factors. Other spontaneous reporting systems work in a similar way. These include Vigibase and the US FDA adverse event reporting system (FAERS). Such systems are used worldwide to detect safety signals and study drug safety beyond controlled trials.⁹

Several recent studies, from India and elsewhere have described patterns of reported ADRs. Gupta et al studied ADRs reported at a regional pharmacovigilance centre in North India. They described patient demographics, drug characteristics, causality, severity and seriousness.¹⁰ Yadav et al conducted a prospective study in Goa. They found an overall ADR incidence of 0.65%. Skin reactions to antibiotics were most common. Causality was probable in 75.1% of cases.¹¹ Vemuri et al reviewed six years of ADR reports from a hospital in Navi Mumbai. Antimicrobials and antitubercular drugs were the leading suspect classes. Female patients were affected more often and the fatality rate was 3.16%.¹² Hammour et al described 1340 ADR reports from Jordan. Cardiovascular and Gastrointestinal related drugs were most often involved. Most reactions were non-serious.¹³ A study from Ballari, Karnataka found cephalosporins to be the leading cause of ADRs. Causality was probable in 60% of cases. Severity was moderate in 64% of cases.¹⁴

Despite this literature, few Indian studies have examined Vigiflow-based ADR patterns from a very large, high-volume tertiary referral hospital. Such hospitals cover many specialties, such as oncology, tuberculosis, psychiatry, nephrology and radiology. In this setting, the range of suspect drugs and reactions is likely to differ from single-department studies. A retrospective review of institutional ADR records can help identify these patterns. It can also highlight reporting gaps and strengthen pharmacovigilance practice. This, in turn can guide

prescriber education, safer prescribing policies and patient awareness programmes. Authors therefore designed this study with three aims. First, to analyse ADRs reported at our institution by causality assessment. Second, to identify the commonly implicated drug classes and system organ classes. Third, to categorise the severity and preventability of the reported ADRs.

METHODS

Study design, setting and duration

This was a retrospective, record-based study of ADRs. All reports had been submitted to the institutional ADR Monitoring Centre and entered into the Vigiflow database under the Pharmacovigilance Programme of India. The study was conducted in the Department of Pharmacology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi. We retrieved all Individual Case Safety Reports (ICSRs) documented in Vigiflow over the preceding five years (March 2021- March 2026). This was done after obtaining approval from the Institutional Ethics Committee IEC/VMMV/SJH/CERT/2025-October/96. Data extraction and analysis were completed within six months of approval. This was a retrospective, non-interventional review of existing anonymised records. No drug was administered and no patient was contacted as part of this study. No prospective trial registration was required.

Inclusion and exclusion criteria

Authors included all ADR reports from Vigiflow that recorded at least one identifiable suspect drug. Each of these reports also had at least one specific ADR/SOC term. Authors classified these as complete reports. Some reports lacked key data. Specifically, they had an unknown suspect drug together with no recorded reaction term. Authors classified these as incomplete ICSRs. Authors tabulated incomplete reports separately to measure institutional reporting completeness. Authors then excluded them from all further analyses. This included analyses of SOC, drug class, causality, severity, preventability and outcome. We took this approach because causality and severity cannot be meaningfully assessed without a documented drug-reaction pair.

Data variables

For each complete ICSR, we extracted a set of variables from Vigiflow into a master Microsoft Excel sheet. These included a de-identified worldwide unique report identifier, patient age and sex and suspect and concomitant drugs. Authors also extracted the SOC and verbatim ADR term(s), coded as per the WHO adverse reaction terminology. Finally, we recorded the causality assessment, severity grade, preventability category and reported clinical outcome. Two independent reviewers grouped suspect drugs into pharmaco-therapeutic classes for class-level analysis. Examples of these classes include

antimicrobials, antineoplastic agents, cardiovascular drugs, antitubercular drugs, radiocontrast media and psychotropic agents. The two reviewers resolved any disagreements by discussion.

Causality assessment

Causality is how likely it is that a suspected drug caused the reported reaction. Authors assessed causality using two methods. Both were already recorded in Vigiflow at the time of original reporting. The first method was the WHO-UMC causality system. It classifies reports into six categories: certain, probable/likely, possible, unlikely, conditional/unclassified or unassessable/unclassifiable. This classification is based on the timing of the reaction, dechallenge/rechallenge information and other possible explanations.¹⁵ The second method was the Naranjo adverse drug reaction probability scale. This is a ten-item questionnaire. It scores reactions as definite, probable, possible or doubtful.¹⁶

Severity and preventability assessment

Authors graded severity using the Modified Hartwig and Siegel scale. This scale has seven levels. Authors grouped these into three categories: mild (levels 1-2), moderate (levels 3-4) and severe (levels 5-7). The grouping was based on clinical consequences and the management each reaction needed.^{17,18} Authors assessed preventability using the Schumock and Thornton criteria.¹⁹ These criteria classify ADRs into three categories definitely/probably preventable, probably not preventable or not preventable. The assessment considers factors such as dose appropriateness, known allergy history, drug interaction monitoring and adherence to therapeutic drug monitoring where relevant.^{18,19}

Statistical analysis

Authors entered data into Microsoft Excel and cleaned it before analysis. We calculated descriptive statistics using Python (pandas library, version 2X). Authors present categorical variables as frequencies and percentages. These variables include sex, SOC, drug class, causality, severity, preventability and outcome. Authors present the one continuous variable, age, as mean $\pm$ standard deviation and median. This was a purely descriptive study of a single reporting group, with no comparison arm.

Because of this, Authors did not perform formal hypothesis testing, effect-size estimation or between-group confidence intervals. A single ICSR could report more than one SOC term, more than one suspect drug or more than one outcome. Because of this, percentages for these variables are based on the total number of complete reports (n=925). They are not based on individual drug/reaction mentions. Authors note clearly where totals sum to more than 100%.

Ethical considerations

The study was approved by the Institutional Ethics Committee, Vardhman Mahavir Medical College and Safdarjung Hospital vide IEC/VMMV/SJH/CERT/2025-October/96. It followed the Indian Good Clinical Practice guidelines harmonised with ICH-GCP. This was a retrospective review of anonymised existing pharmacovigilance records. There was no direct patient contact or intervention. Because of this, the risk to patients was minimal.

RESULTS

Authors retrieved 974 ICSRs entered into Vigiflow at the institution over the preceding five years. Of these, 49 (5.0%) lacked a documented suspect drug and an identifiable reaction/SOC term. We classified these as incomplete ICSRs. We excluded them from further analysis. This left 925 (95.0%) complete, evaluable reports (Table 1).

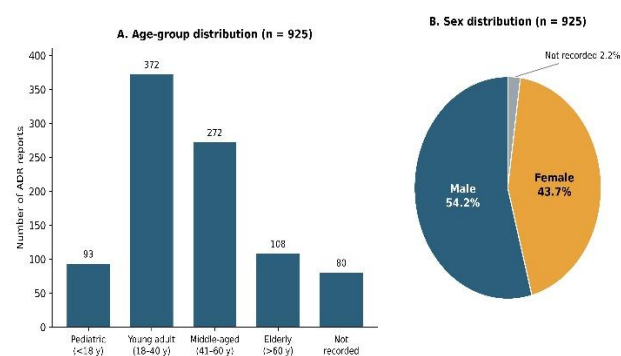


Figure 1 (A, B): Age-group distribution and sex distribution among complete ADR reports (n=925).

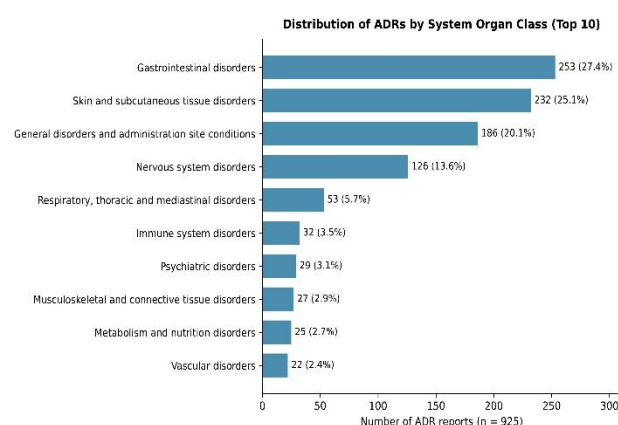


Figure 2: Distribution of ADRs by SOC, top 10 categories (n=925). Bars are labelled with the number and percentage of complete reports involving each SOC.

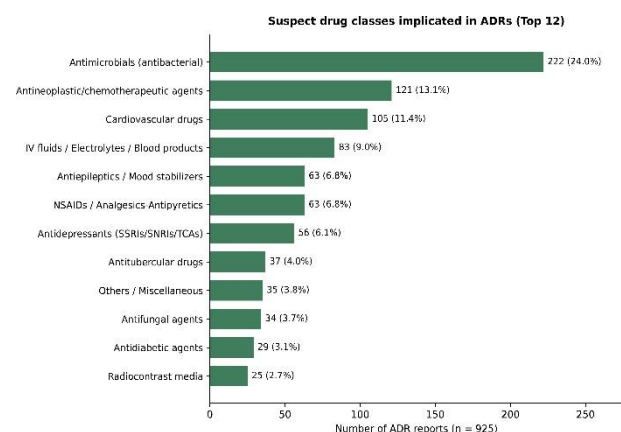


Figure 3: Suspect drug classes implicated in ADRs, top 12 categories (n=925).

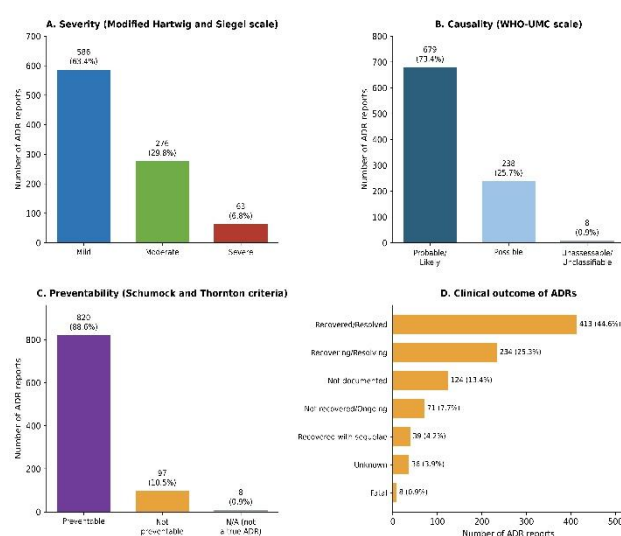


Figure 4 (A-D): Severity (Modified Hartwig and Siegel scale), causality (WHO-UMC scale), preventability (Schumock and Thornton criteria) and clinical outcome of ADRs (n=925).

Figure 1 shows the age-group and sex distribution of the 925 complete reports. Most reports came from young adults (18-40 years, 40.2%) and middle-aged adults (41-60 years, 29.4%), with a modest male preponderance (54.2% vs. 43.7% female).

The SOCs most often affected were gastrointestinal disorders (27.4%), skin and subcutaneous tissue disorders (25.1%) and general disorders/administration-site conditions (20.1%). Less common SOCs included nervous system disorders (13.6%), respiratory disorders (5.7%) and immune system disorders (3.5%) (Figure 2). Several reports listed more than one SOC. Because of this, these percentages sum to more than 100% of complete reports. The most frequently reported individual ADR terms (after merging minor spelling variants, e.g. "diarrhoea"/"acute diarrhoea") were shivering/chills (9.5%), fever (8.1%), diarrhoea (7.8%), rash (5.8%), vomiting (4.3%), nausea

(4.0%) and headache (3.8%) (Table 2). Authors classified suspect drugs into 27 pharmaco-therapeutic classes. Antimicrobials (24.0%) were the single most common class. This was followed by antineoplastic/chemotherapeutic agents (13.1%), cardiovascular drugs (11.4%) and intravenous fluids/electrolytes/blood products (9.0%). Antiepileptics/mood stabilisers and NSAIDs/analgesics-antipyretics were each implicated in 6.8% of reports. Antidepressants were implicated in 6.1% of reports (Table 3, Figure 3).

The mean number of suspect drugs recorded per ICSR was 1.36. In total, 216 reports (23.4%) involved two or more concomitantly suspected drugs. On WHO-UMC assessment, causality was probable/likely in 679 reports (73.4%). It was possible in 238 reports (25.7%). Eight reports (0.9%) were unassessable/unclassifiable. These corresponded to non-ADR events, such as missed doses or product-quality complaints without a true adverse reaction. The Naranjo scale gave closely similar results. It showed a probable-range score in 679 reports (73.4%) and a possible-range score in 238 reports (25.7%).

Authors graded severity using the Modified Hartwig and Siegel scale. It was mild in 586 reports (63.4%; Levels 1-2). It was moderate in 276 reports (29.8%; Levels 3-4). It was severe in 63 reports (6.8%; Levels 5-7). On the Schumock and Thornton criteria, most ADRs (820, 88.6%) were judged preventable. A smaller share, 97 reports (10.5%), were judged not preventable.

Authors recorded clinical outcome in several categories. Complete recovery/resolution was documented in 413 reports (44.6%). Recovering/resolving was documented in 234 reports (25.3%). Not recovered/ongoing was documented in 71 reports (7.7%). Recovered with sequelae was documented in 39 reports (4.2%) and unknown outcome in 36 reports (3.9%). Outcome was not documented at all in 124 reports (13.4%). Eight reports (0.9%) had a fatal outcome (Table 4, Figure 4).

Of the eight fatal reports, six were linked to antineoplastic chemotherapy regimens. Two patients on carboplatin/docetaxel/trastuzumab-based regimens developed interstitial pneumonitis. One patient on a cyclophosphamide/doxorubicin/vincristine regimen developed pancytopenia, acute kidney injury and septic shock.

One fatal report was linked to an iodinated radiocontrast agent, iohexol. This caused a suspected anaphylactoid reaction. The remaining fatal report listed the suspect drug as a CDK4/6 inhibitor, palbociclib. The cause of death was not further specified in the record. All eight fatal reports were rated "possible", not "probable", on WHO-UMC causality. This reflects the difficulty of establishing a clear causal link in critically ill oncology patients who receive several medicines at once.

Table 1: Reporting completeness and baseline demographic characteristics of ADR reports (n=974).

Parameter	Category		%
Total ICSRs retrieved	-	974	100.0
Incomplete ICSRs (excluded)	Unknown suspect drug and unknown reaction	49	5.0
Complete ICSRs (analysed)	-	925	95.0
Sex (n=925)	Male	501	54.2
	Female	404	43.7
	Not recorded	20	2.2
Age (in years) (n=925)	Mean±SD (of 845 with recorded age)	38.9±17.6	-
Age group (n=925)	Pediatric (<18 years)	93	10.1
	Young adult (18-40 years)	372	40.2
	Middle-aged adult (41-60 years)	272	29.4
	Elderly (>60 years)	108	11.7
	Not recorded	80	8.6

Table 2: Most frequently reported individual ADR terms (top 15) (n=925).

ADR term	N	%
Shivering / Chills	88	9.5
Fever	75	8.1
Diarrhea	72	7.8
Rash	54	5.8
Vomiting	40	4.3
Nausea	37	4.0
Headache	35	3.8
Itching	33	3.6
Dizziness	28	3.0
Drowsiness	24	2.6
Petechiae	20	2.2
Constipation	14	1.5
Maculopapular rash	14	1.5
Insomnia	14	1.5
Allergic reaction	13	1.4

Table 3: Suspect drug classes implicated in ADRs (top 12 and aggregated remainder) (n=925).

Drug class	N	%
Antimicrobials (antibacterial)	222	24.0
Antineoplastic /chemotherapeutic agents	121	13.1
Cardiovascular drugs	105	11.4
IV fluids/electrolytes/blood products	83	9.0
Antiepileptics/mood stabilizers	63	6.8
NSAIDs/analgesics-antipyretics	63	6.8
Antidepressants (SSRIs / SNRIs / TCAs)	56	6.1
Antitubercular drugs	37	4.0
Unclassified/miscellaneous agents	35	3.8
Antifungal agents	34	3.7
Antidiabetic agents	29	3.1
Radiocontrast media	25	2.7
All other classes combined (16 categories, each <3%)	151	16.3

Table 4: Causality, severity, preventability and clinical outcome of reported ADRs (n=925).

Assessment	Category	N	%
Causality-WHO-UMC scale	Probable/Likely	679	73.4
	Possible	238	25.7
	Unassessable/unclassifiable (not a true ADR)	8	0.9

Continued.

Assessment	Category	N	%
Causality-Naranjo scale	Probable (score ≥ 3)	679	73.4
	Possible (score 1-2)	238	25.7
	N/A (not a true ADR)	8	0.9
Severity-Hartwig & Siegel	Mild (levels 1-2)	586	63.4
	Moderate (levels 3-4)	276	29.8
	Severe (levels 5-7)	63	6.8
Preventability-Schumock & Thornton	Preventable (definitely/probably preventable)	820	88.6
	Not preventable	97	10.5
	N/A (not a true ADR)	8	0.9
Clinical outcome	Recovered/resolved	413	44.6
	Recovering/resolving	234	25.3
	Not documented	124	13.4
	Not recovered/Ongoing	71	7.7
	Recovered with sequelae	39	4.2
	Unknown	36	3.9
	Fatal	8	0.9

DISCUSSION

This retrospective study reviewed 974 ICSRs entered into VigiFlow at a large North Indian tertiary care hospital. Authors found that 95.0% of reports were complete and evaluable. The remaining 5.0% lacked a documented suspect drug and reaction, so we excluded them from outcome analysis. This completeness rate compares favourably with data-quality concerns raised in other institutional VigiFlow studies. It suggests that institutional documentation practices are broadly satisfactory. However, a small but consistent share of ICSRs still needs closer review at the point of entry. This would help maximise their value for signal detection in VigiBase.^{8,10}

Antimicrobials were the leading suspect drug class in the study (24.0%). This finding matches the wider Indian and international literature. Antimicrobials were also the most common class in a Northern Indian tertiary hospital (33%), a Karwar-based study, Chennai pharmacovigilance-centre series and in a Chhattisgarh teaching hospital (32.3%).²⁰⁻²³ This pattern likely reflects two things. First, the high volume of antimicrobial prescribing in Indian tertiary hospitals. Second, the tendency of beta-lactams, glycopeptides and fluoroquinolones to cause easily recognisable skin and gastrointestinal reactions which clinicians are primed to report.

The second and third most common classes in the study were antineoplastic/chemotherapeutic agents (13.1%) and cardiovascular drugs (11.4%). These reflect the case-mix of a high-volume referral hospital with dedicated oncology, radiology and non-communicable disease services. This differs from mainly medicine-ward studies where antihypertensives and analgesics rank second after antimicrobials.^{20,23} This shows that the specialty mix of the reporting hospital strongly shapes the drug-class pattern observed. Antitubercular drugs made up 4.0% of implicated classes in the study. This is a smaller share than

in some hospital-based Indian studies, where antitubercular therapy was the second most common cause of ADRs.¹² This is not surprising. The institution also handles a large number of oncology, psychiatry and general-medicine ADRs. This dilutes the relative share of any single programme. Radiocontrast media (2.7%) and antifungal agents (3.7%) were also notably represented. Both are plausible, given our centre's large radiology and haemato-oncology caseload. Radiocontrast-associated hypersensitivity reactions include rash and itching. In one case they caused a fatal anaphylactoid reaction to iohexol. These reactions are an actionable target for pre-procedure risk assessment and premedication protocols in high-risk patients.

Gastrointestinal disorders (27.4%) and skin and subcutaneous tissue disorders (25.1%) were the two most affected SOC in the study. This closely matches the pattern reported by Lhamo et al from a Northern Indian tertiary facility. Gastrointestinal (34.5%) and cutaneous (32%) reactions were similarly the leading SOC in their study.²⁰ This similarity across different Indian tertiary centres is notable. It suggests that gastrointestinal and skin reactions are the most visible and easily reportable ADR types in routine practice. This likely reflects two factors. First, their high background frequency with commonly prescribed antimicrobial, antitubercular and analgesic drugs. Second, how easy they are to recognise clinically.

This contrasts with for example subtle blood or biochemical changes which may only be found through active laboratory monitoring. Causality assessment in the study was mostly "probable/likely" (73.4%) and "possible" (25.7%) on the WHO-UMC scale. The Naranjo scale gave near-identical results. This pattern was also seen by Yadav et al (75.1% probable) and the Ballari cohort (60% probable, remainder possible).^{11,14} No report in the dataset was rated "certain". This was also reported in several similar Indian studies.¹¹ This likely reflects a practical

difficulty. The strict WHO-UMC requirement for a positive rechallenge is hard to meet in routine care. Re-exposing a patient to a drug that caused a reaction is rarely ethical or clinically justified. The severity pattern in the study was mostly mild (63.4%) and moderate (29.8%). Severe reactions occurred in only 6.8% of cases. This matches previous Indian studies, where most ADRs were also graded mild-to-moderate.^{14,20}

The 8 fatal reports (0.9%) in our study were concentrated in two groups. These were oncology patients on multi-agent chemotherapy and one patient who received intravenous radiocontrast medium. This is similar to the 3.16% fatality rate reported by Vemuri et al. That study had a comparable share of antineoplastic and radiocontrast-related ADRs.¹² A dedicated study of anticancer drugs from North India reached a similar conclusion. It found these drug classes to be an important source of serious and life-threatening reactions, needing close inpatient monitoring.²⁴

In contrast to most other Indian series, most ADRs in the study (820, 88.6%) were judged preventable using the Schumock and Thornton criteria. This is considerably higher than the roughly 26-31% preventable share reported by Lhamo et al.²⁰ It is also higher than the 12-26% preventable range typically reported in other Indian studies.²³ This difference may partly reflect genuine differences in prescribing practice at our institution.

However, it may also reflect the retrospective chart-based nature of the preventability assessment. Reviewers sometimes classified reports as preventable when supporting clinical detail was incomplete, such as documented dose checks, allergy history or drug-interaction screening. This large preventable share is nonetheless an important, actionable finding. It suggests that structured interventions-such as electronic dose-checking, allergy-history verification and closer therapeutic drug monitoring-could meaningfully reduce the ADR burden at our institution. This finding and its limitations, are discussed further.

Overall, the findings suggest that a substantial share of ADRs reported at our institution may be avoidable. This is based on the high preventable proportion found on Schumock and Thornton assessment. This points to actionable gaps in routine prescribing practice. These include dose selection, allergy screening and drug-interaction monitoring for widely used antimicrobial, antineoplastic and cardiovascular drugs.

Alongside this, continued structured surveillance remains important for high-risk drug classes. These include chemotherapy, radiocontrast media and antitubercular therapy. Our findings reinforce the value of VigiFlow-based institutional surveillance. This surveillance can help identify which drug-reaction pairs need the closest clinical attention. It can also guide targeted, preventive interventions.

Limitations

This study has several limitations. These are common to its retrospective spontaneous-reporting design. First, as with all spontaneous reporting systems, the data are subject to under-reporting and reporting bias. The frequencies we describe reflect reporting patterns, not true rates in the population. Authors had no denominator population such as total prescriptions or admissions during the study period. Because of this, we could not calculate incidence or prevalence rates. Secondly 5.0% of retrieved ICSRs lacked enough documentation of the suspect drug and reaction to allow analysis. Authors excluded these reports. We therefore cannot describe the true pattern of ADRs among these incomplete reports. Our hospital has dedicated oncology, tuberculosis and psychiatry services. Because of this, our findings may not apply to primary or secondary care settings.

CONCLUSION

This was a five-year retrospective study of VigiFlow data from a large North Indian tertiary care hospital. Antimicrobials, antineoplastic agents and cardiovascular drugs were the leading suspect drug classes. Gastrointestinal and skin reactions were the most frequently affected system organ classes. Most ADRs were rated probable or possible in causality and mild-to-moderate in severity. Notably, a large majority (88.6%) were judged preventable on Schumock and Thornton assessment. This suggests that a substantial share of the ADR burden at our institution may be avoidable through more rigorous dose selection, allergy screening and drug-interaction monitoring.

Nonetheless, a small but clinically important share of severe and fatal reactions occurred. These were concentrated among oncology and radiocontrast drugs. This finding shows the need for continued vigilant monitoring in these high-risk groups. Reducing the 5% burden of incomplete ICSRs is a further practical, achievable goal. This can be done through point-of-reporting documentation checks and regular feedback of institutional ADR patterns to prescribers. Together, these steps, alongside targeted preventive interventions would strengthen pharmacovigilance practice at our institution.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Verma V, Kushwaha A, Chugh PK, Saini HS. Pattern of adverse drug reactions reported through VigiFlow at a tertiary care teaching hospital in North India: a retrospective analysis. *Int J Basic Clin Pharmacol* 2026;15:1350-7.