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ORIGINAL ARTICLE

Integrating a Pharmacovigilance and Response Unit Team for a Better Adverse Drug Reaction Reporting and Management: Insights from a Prospective Cross-Sectional Study

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ABSTRACT

Objectives: The multidisciplinary team approach improves adverse drug reaction (ADR) reporting and management. Our study aims to integrate a pharmacovigilance (PV) and Response Team within the general medicine department to improve ADR reporting and management.

Materials and Methods: We conducted a prospective cross-sectional study for seven months in four general medicine wards. We proposed a PV and response unit team (PRUT), comprising a nursing student, and a Doctor of Pharmacy (intern). After the team received interventional educational training, we integrated them with the physician and head nurse of each general medicine inpatient ward. We then evaluated the effectiveness of the team in ADR reporting and management using a feedback survey.

Results: In this study, comorbidities (30.69%) and polypharmacy (≥5 drugs) (26.25%) were major predisposing factors. Among drug-related problems in 125 patients, inappropriate drug use (28.80%) and unclear dose timing (21.60%) were predominant. Gastrointestinal disorders were common (44.73%), with dose adjustment being the top management strategy (36.84%). Over 71% supported the PRUT for improving patient safety and reducing medication errors, noting high effectiveness in consultation (85.92%) and in reducing the ADR reporting burden (87.32%). There is a statistically significant association between the level of agreement on the effectiveness of PRUT among healthcare professionals ($p<0.01$). Most healthcare professionals agreed on PRUT's effectiveness without any reports of low agreement levels.

Conclusion: The PRUT effectively reported and managed ADRs. A multidisciplinary approach improves ADR reporting and management.

Keywords: Adverse drug reaction, pharmacovigilance, inappropriate drug use, dose adjustment, polypharmacy, pharmacovigilance, and response unit team

INTRODUCTION

Adverse drug reaction (ADR) management is crucial in reducing patient morbidity, minimizing healthcare costs, and improving the quality of medical care. Initiatives for ADR monitoring and reporting are instrumental in protecting patient safety by providing essential insights into drug efficacy and safety, initiating risk management strategies, and quantifying ADR occurrences.[1, 2] The primary responsibility of detecting, documenting, and reporting ADRs falls upon healthcare professionals (HCPs) -namely medical doctors, nurses, and pharmacists.

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Their vigilance in daily practices is crucial for ADR prevention, as research suggests that adherence to current medical protocols and the evaluation of potential ADR risk factors could significantly reduce ADR incidences.[3]

Risk communication, a cornerstone of ADR management, involves educating patients, their families, and healthcare colleagues about the dangers of specific medications, aiming to reduce exposure to potential adverse drug effects. Despite its significance, studies highlight a gap in effectively communicating medication-related risks to patients at the time of discharge. This represents a crucial area that needs improvement in ADR communication strategies.[4] This observation highlights the important need for improved risk communication methods to strengthen patient safety and care standards.

In response to such challenges, a Dutch study explored the feasibility and impact of integrating Junior-Adverse Drug Event Managers (J-ADEMs), comprising medical students, within hospital settings to supervise and report ADRs. The findings indicated that the J-ADEM framework effectively enhances ADR detection and management, supports physicians in reporting tasks, and provides students with helpful pharmacovigilance (PV) expertise.[5]

Furthermore, extensive research in India has thoroughly reported ADR patterns, severities, causality, and organ-specific impacts, highlighting the importance of such studies.[6,7] However, the integration of specialized ADR management teams within the Indian healthcare context remains unexplored. Our study aims to fill this gap by evaluating the practicality and efficacy of a multidisciplinary ADR management team within a general medicine inpatient department. This innovative approach seeks to strengthen patient safety and elevate the standard of care through refined ADR management and reporting protocols.

MATERIALS AND METHODS

Study setting and duration

The study was conducted in four in-patient departments of General Medicine for a duration of seven months (01/04/2023 to 30/11/2023).

Study participants

Third-year Nursing students and sixth-year Doctor of Pharmacy internship students.

Sampling technique

We employed the judgmental sampling technique because it helps to select participants with expertise or characteristics that are important to the research study.[8]

PV and Response Unit Team (PRUT)

The PRUT team contains a nursing student and a Pharm.D intern. The Pharm.D intern must spend six months in the general medicine department, while nursing students will visit the hospital regularly as part of the curriculum. The competent team coordinates with the attending physician and the head nurse of the respective general medicine inpatient wards. The primary responsibility of the nursing student is to collect the best possible patient medication history and to update the intern and physician on clinical and objective measures. The primary responsibility of the Pharm.D intern is to evaluate the predisposing factors of ADRs and to conduct prescription auditing.

If the Pharm.D intern finds any medication errors and drug therapy problems, then these issues will be communicated to the nursing student and physician. If the team observes any ADR, they will inform the physician and report it on the ADR form recommended by the PV Programme of India (PvPI). In case of any discrepancy in filling out the ADR form, they will contact the PV associate in the nearby ADR Monitoring Center to clarify it. The team, with the help of the physician, will prepare a management plan and implement it effectively.

Educational training for the team

We adapted and developed an educational training module for the team from previous studies.[9,10] The training was carried out for four weeks, and each module included a 45-minute lecture. We covered the basics of PV, ADR reporting, case-report-based ADR reporting, identifying predisposing factors, taking the best possible medication history, and a real-life practical demonstration. We then estimated the knowledge and competency of the students using a questionnaire, which contained a few multiple-choice questions, fill-in-the-blank answers, and one case study.

PRUT impact survey

We framed a predetermined questionnaire with 10 statements to evaluate the impact of PRUT on patient safety, PV, and healthcare practice. The statements covered the effectiveness of the PRUT in improving ADR reporting, the role of collaboration among HCPs, the reduction in medication errors, the importance of prescription audits, the understanding of PV, proactive patient safety measures, the quality of ADR surveillance, the effectiveness of consultations for validating ADRs, the impact on ADR reporting burden, and the overall necessity of the PRUT in healthcare. We used a three-point Likert scale for each response, with a score of 3 for "Agree," a score of 2 for "Neutral," and a score of 1 for "Disagree." The maximum score was 30, whereas the minimum score was 10. Scores ranging from 25 to 30 indicate a high level of agreement with the effectiveness and importance of the PRUT, whereas a score between 16 and 24 represents a moderate level of agreement, and a score of 10 to 15 indicates a low level of agreement.

Validity and reliability of the survey questionnaire

We assessed the content validity of the questionnaire by involving one PV associate and a physician specialized in pharmacology. Each expert evaluated whether the statements accurately reflected the constructs of interest. They rated the relevance of each statement on a 4-point scale, where 1 represented "not relevant" and 4 indicated "highly relevant." After both experts completed their evaluations, we calculated the Content Validity Index (CVI), following the guidelines of Polit and Beck.[11] We considered statements with a CVI of 0.80 or higher to be acceptable, indicating that they were relevant and

valid for assessing the impact of the PRUT on patient safety, PV, and healthcare practice.

Given that Streiner[12] recommends a minimum sample size of 30 for a reliable estimate of Cronbach's alpha, we conducted a pilot test with 30 HCPs. We then used Cronbach's alpha to assess the internal consistency of the questionnaire and obtained a value of 0.85, indicating strong internal consistency among the items. This result confirmed that the questionnaire reliably measured the intended constructs.

Pharmaceutical Care Network Europe (PCNE) classification of drug-related problems (DRPs)

We used the PCNE classification of DRPs in our study.[13] The classification contains three primary domains for problems, nine primary domains for causes, and five primary domains for interventions. It also contains the acceptance of the intervention proposals and the status of DRP.

Study procedure

Initially, we explained the aim and objectives of our study to nursing students and Pharm.D interns and identified the interested candidates. Fourteen nursing students and 18 Pharm.D intern students were willing to participate. We then screened their preliminary knowledge of PV with a questionnaire containing a few multiple-choice questions. Post-screening, we started a four-week educational training module for these students. After the educational training module, 12 out of 14 nursing students and 13 out of 18 Pharm.D interns were eligible to form a team (PRUT). We then divided them into pairs, consisting of one nursing intern and one Pharm.D intern, for each general medicine inpatient ward. Additional nursing students and Pharm.D interns were also used when required (Figure 1). To carry out their primary roles and responsibilities, we introduced the new team to the head nurse and attending physician in the respective wards.

Statistical analysis

Socio-demographic details, including age, gender, comorbidities, smoking and alcohol history, and clinical details, including past medical history, previous drug allergies, drug-related problems, previous and current ADRs, and predisposing factors for ADRs, were collected. Feedback on the impact of PRUT from physicians and nurses was also gathered. The qualitative data were represented as frequencies and percentages, whereas the quantitative data were represented as means and standard deviations where appropriate. The chi-square test was used to assess the association between the HCPs level of agreement on the effectiveness of PRUT. A p value <0.05 was considered statistically significant. Jeffrey's Amazing Statistical Programme (version 0.18.3) was used for statistical analysis.

Ethical approval

The study was approved by the Vignan Institute of Pharmaceutical Technology Ethical Committee (approval number: VIPT/IEC/359/2023, date: 28.03.2023). We obtained written informed consent from the participants who were willing to participate. We assured the participants of the confidentiality of the data.

RESULTS

Table 1 outlines the socio-demographic details of the patients (n=358). The majority of patients fall between 56 and 70 years of age group (37.7%), followed by those in the age group 41-55 years (24.68%). Males are more predominant (58.38%) than females. The most common comorbidities in our study were hypertension (26.7%) and diabetes mellitus (23.99%). Among 101 patients who reported ADRs, nausea and vomiting were the most frequent (32.67%), followed by severe itching (20.79%). Pantoprazole (32.48%) was the most frequently prescribed past medication, followed by metformin and glimepiride (18.98%).

Table 2 highlights the identified predisposing factors (n=720) among the patients. The most common predisposing factor was comorbidity (30.69%), followed by polypharmacy (26.25%) and age (18.47%). As illustrated in Table 3, the most common drug-related problem identified among the patients in our study was an inappropriate drug (28.80%), followed by unclear timing or omission of dose instructions (21.60%), and unavailability of the prescribed drug (18.40%).

Table 4 summarises the ADRs (n=76) identified among the patients. Gastrointestinal disorders are the most commonly reported ADRs, occurring in 44.73% of the patients. Dermatological reactions, including skin rash and itching, are the second most frequent, affecting 34.21% of patients. Respiratory system-related ADRs, such as dry cough and breathlessness, are observed in 14.47% of cases, while musculoskeletal reactions, including myalgia and pedal edema, are reported in 6.58% of patients. The most frequently employed management strategy was dose adjustment (36.84%), followed by symptomatic treatment (15.79%) and withdrawal of the offending drug (15.79%) (Table 5).

Table 6 outlines the impact of PRUT survey results conducted among 41 healthcare professionals. A significant majority (87.8%) observed an improvement in ADR surveillance since its implementation. Additionally, 85.3% agreed that the consultation process within the PRUT is effective in assessing the severity and validity of suspected ADRs, and the same percentage

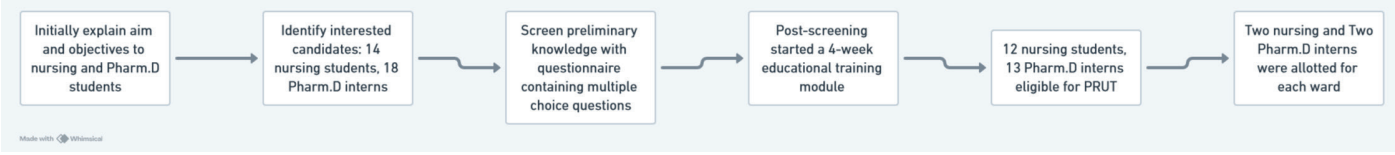

Figure 1. Study procedure for selecting the eligible participants for including in PRUT

PRUT: Pharmacovigilance and response unit team

Table 1. Socio-demographic and clinical details of the patients (n=358)

S. no.	Characteristic	Frequency (%)
1	**Age (in years)**	
	<10	05 (1.39)
	11-25	34 (9.49)
	26-40	51 (14.24)
	41-55	89 (24.86)
	56-70	135 (37.70)
	>70	44 (12.29)
2	**Gender**	
	Male	209 (58.38)
	Female	149 (41.62)
3	**Comorbidities (n=221)**	
	Gastrointestinal disorders	18 (8.14)
	Musculoskeletal disorders	19 (8.60)
	Thyroid disorders	21 (9.50)
	More than two comorbidities	51 (23.07)
	Diabetes mellitus	53 (23.99)
	Hypertension	59 (26.70)
4	**Previous drug allergies (n=7)**	
	Diclofenac	4 (57.14)
	Cefixime	3 (42.86)
5	**Previous drug related ADRs (n=101)**	
	Stevens Johnson syndrome	2 (1.98)
	Weight gain	8 (7.92)
	Weakness/fatigue	9 (8.91)
	Injection site reaction	10 (9.90)
	Skin rash	18 (17.82)
	Severe itching	21 (20.79)
	Nausea and vomiting	33 (32.67)
6	**Past medications (n=274)**	
	Nifedipine	12 (4.38)
	Levothyroxine	16 (5.84)
	Amlodipine	19 (6.93)
	Ibuprofen	19 (6.93)
	Aceclofenac and paracetamol	28 (10.22)
	Metoprolol	39 (14.23)
	Metformin and glimepiride	52 (18.98)
	Pantoprazole	89 (32.48)

S. no.: Serial number, ADRs: Adverse drug reactions

considered the PRUT an essential component of healthcare for ensuring drug safety and efficacy. Most respondents (82.9%) also emphasized the importance of pharmacists' role in prescription audits and acknowledged the PRUT's contribution to proactive patient safety by categorizing patients based on their ADR predisposition. Overall, the feedback highlights strong support (85.3%) for PRUT's positive impact on patient care and safety. However, a chi-square test for independence showed that there was no significant association between the profession and level of agreement on PRUT team effectiveness (p=0.40). The chi-square test and survey both show that physicians and nurses largely agree on the effectiveness of PRUT. There are no significant differences in their perceptions, with both groups consistently expressing high agreement on PRUT's positive impact in areas like patient safety and ADR reporting.

DISCUSSION

We observed alignment with findings on common predisposing factors in two studies.[14,15] In contrast, one study highlighted polypharmacy as the predominant predisposing factor.[16] As people age, the occurrence of comorbid conditions increases, leading to the need for multiple medications, a situation known as polypharmacy. Advanced age is associated with changes in the body that affect how drugs are processed, increasing the risk of ADRs. These changes include reduced heart function, lower kidney filtration, and smaller liver size, which impact how drugs are absorbed, metabolized, distributed, and eliminated from the body.[17]

When individuals have multiple health conditions at the same time, the overall effectiveness of treatments often does not

Table 2. Predisposing factors identified among the patients (n=720)

S. no.	Predisposing factor	Frequency (%)
1	Impaired/abnormal liver function	37 (5.14)
2	Impaired/abnormal renal function	39 (5.42)
3	Previous drug related ADR	101 (14.03)
4	Age	133 (18.47)
5	Polypharmacy (≥5 drugs)	189 (26.25)
6	Comorbidities	221 (30.69)

S. no.: Serial number, ADR: Adverse drug reaction

Table 3. ADRs identified among the patients (n=125)

S. no.	Drug related problem	Frequency (%)
1	No indication for drug	09 (7.20)
2	Inappropriate combination of drugs	13 (10.40)
3	Dosage regimen not frequent enough	17 (13.60)
4	Prescribed drug not available	23 (18.40)
5	Dose timing instructions unclear or missing	27 (21.60)
6	Inappropriate drug	36 (28.80)

S. no.: Serial number, ADRs: Adverse drug reactions

Table 4. Adverse drug reactions identified among the patients (n=76)

S. no.	Organ system	Adverse drug reaction	Frequency (%)
1	Musculoskeletal	Myalgia (2), pedal edema (3)	05 (6.58%)
2	Respiratory	Dry cough (8), breathlessness (3)	11 (14.47)
3	Dermatology	Skin rash (8), itching all over the body (3), itching over hands (2), erythema (5), pruritis (4), fixed drug eruption (2), and urticaria (2)	26 (34.21)
4	Gastrointestinal Disorders	Nausea and vomiting (12), abdominal discomfort (3), abdominal pain (4), diarrhea (5), and constipation (5), and gastritis (8)	34 (44.73)

S. no.: Serial number

Table 5. Management strategies for ADRs

S. no.	Management strategy	Frequency (%)
1	Preventive measures	07 (9.21%)
2	Monitoring and supportive care	08 (10.52)
3	Switching medications	09 (11.84)
4	Withdrawal of the offending drug	12 (15.79)
5	Symptomatic treatment	12 (15.79)
6	Dose adjustment	28 (36.84)

S. no.: Serial number, ADRs: Adverse drug reactions

Table 6. Feedback survey of physician and nurse perceptions on the effectiveness of PRUT (n=41)

S. no.	Question	Agree n (%)	Disagree n (%)	Neutral n (%)
1	Do you believe that the PRUT enhances patient safety by improving ADR reporting?	33 (80.5)	5 (12.2)	3 (7.3)
2	Do you agree that the collaboration between physicians, pharmacists, nurses, and PV associates in the PRUT leads to more comprehensive patient care?	32 (78)	5 (12.2)	4 (9.8)
3	Have you found that the PRUT's efforts have led to a noticeable reduction in medication errors in your practice?	33 (80.5)	5 (12.2)	3 (7.3)
4	Is the pharmacist's role in conducting prescription audits crucial for identifying potential drug interactions and incorrect dosages?	34 (82.9)	4 (9.8)	3 (7.3)
5	Have the PRUT's activities improved your understanding of PV and its importance in clinical practice?	31 (75.6)	4 (9.8)	6 (14.6)
6	Do you agree that the PRUT promotes a proactive approach in patient safety by categorizing patients based on their predisposition to ADRs?	34 (82.9)	3 (7.3)	4 (9.8)
7	Have you observed an improvement in the quality of ADR surveillance since the implementation of the PRUT in your facility?	36 (87.8)	3 (7.3)	2 (4.9)
8	Is the consultation process with the physician and nurses within the PRUT effective in validating the severity and validity of suspected ADRs?	35 (85.3)	4 (9.8)	2 (4.9)
9	Do you agree that the PRUT significantly decreases the burden of ADR reporting and management for nurses and physicians, allowing them to focus more on patient care?	33 (80.5)	5 (12.2)	3 (7.3)
10	Overall, do you believe that the PRUT is an essential component of the healthcare system for ensuring drug safety and efficacy?	35 (85.3)	4 (9.8)	2 (4.9)

S. no.: Serial number, PRUT: Pharmacovigilance and response unit team, ADR: Adverse drug reaction, PV: Pharmacovigilance

meet expectations. As people age, treatments also tend to be less effective. Polypharmacy, the use of multiple medications, poses a major challenge in clinical practice because it can cause drug interactions that reduce the effectiveness of treatments. Even though each medication is prescribed to treat a specific condition, using many drugs together can complicate the patient's health outcomes due to such interactions.[18] This situation emphasizes the importance of careful monitoring and evaluation of all prescribed medications by HCPs. Such oversight is necessary to balance the benefits of each drug against the risks of polypharmacy.

The team identified 125 drug therapy problems in total. The most common issue was the prescription of inappropriate drugs, which made up 28.80% of the problems. This was followed by unclear or missing dose timing instructions (21.60%) and the unavailability of prescribed drugs (18.40%). These findings are consistent with previous research, where three studies, numbered 19-21, also reported inappropriate drug prescriptions as the most frequent drug therapy problem.

The prescription of inappropriate drugs in public hospitals may stem from several factors. These include limited access to updated drug information, high patient-to-physician ratios that lead to rushed clinical decisions, and the absence of standardized treatment protocols. Additionally, a lack of adequate training on current pharmacotherapy guidelines among HCPs contributes to this issue. Donnenberg et al.[22] emphasize the need for improving prescribing skills and integrating clinical pharmacology education into medical training.

The team identified a significant gap in the physicians' knowledge regarding established guidelines for prescribing potentially inappropriate medications to the elderly, such as the Screening Tool of Older Person's Prescriptions criteria and the American Geriatrics Society Beers criteria. One clear example of this was the prescription of glimepiride to elderly patients. Glimepiride is generally not recommended for older adults due to the increased risk of prolonged hypoglycemia, a serious condition.[23] Despite this, the PRUT team found instances where glimepiride had been prescribed to elderly patients.

In this study, gastrointestinal-related ADRs were the most common, accounting for 44.73%, followed by dermatological reactions at 34.21%. This result is consistent with the findings of Singh et al.[24], who reported a similar pattern. However, two other studies identified dermatological reactions as the most frequent ADRs.[25,26]

The prevalence of ADRs is closely related to the presence of specific diseases within a patient group and the medications used to treat them. For example, in the general medicine department involved in this study, many patients were treated with drugs known for causing gastrointestinal side effects, such as non-steroidal anti-inflammatory drugs commonly used for pain management. This may explain the higher reporting of gastrointestinal-related ADRs in these cases.[27] On the other hand, the increased use of medications like antibiotics and antiepileptics, which are often associated with dermatological reactions, points to a different pattern of ADR prevalence, as noted by two studies.[28,29] Elderly patients with multiple comorbidities are especially vulnerable to gastrointestinal complications, which can be linked to the challenges of polypharmacy and the use of drugs affecting the gastrointestinal system.

In this study, dose adjustment was the most frequently used strategy for managing ADRs, accounting for 36.84% of cases. This finding differs from two studies 7; 28, which found that adding another medication or discontinuing the offending drug was a more common approach for managing ADRs. This variation highlights the different management strategies that can be used in specific clinical contexts. Dose adjustment is crucial in managing ADRs. Jiang et al.[30] emphasized that modifying the dosing regimen or discontinuing the suspected drug is a common approach in clinical practice. Precision dosing, which considers patient-specific factors and biomarkers, can help prevent ADRs.[31] However, healthcare providers must have access to detailed dosage information, especially regarding lower effective doses, to make informed dose adjustments and reduce ADR occurrence.[32]

The positive response observed in this study may be due to a reduced burden on physicians, who often face time constraints because of their demanding patient care duties. Gupta et al.[33] found that 73% of physicians cited time constraints as a major reason for underreporting ADRs. Other contributing factors to underreporting included limited awareness of reporting protocols, reluctance to report known reactions, and fear of legal consequences.[33] Mwakawanga et al.[34] also reported that fewer HCPs) participated in ADR reporting, viewing the process as difficult, time-consuming, and unnecessary for every ADR. In contrast, the PRUT team in this study successfully addressed these issues by reporting 76 ADRs, highlighting the value of a multidisciplinary approach to PV.

The effectiveness of a team approach involving medical students was demonstrated by Reumerman et al.,[5] who created the JJ-ADEM team. This group of medical students (from 1st to 6th year) was responsible for reporting and managing ADRs in inpatients. The J-ADEM approach proved beneficial, as physicians were supported in ADR reporting, patients received better care, and students gained valuable PV experience.

Patidar et al.[35] involved physicians, pharmacists, and nurses in spontaneous reporting method where they actively searched for suspected ADRs. A passive method also encouraged prescribers to report any suspected ADRs. All physicians were briefed on the study and the harmful effects of ADRs, which led to increased reporting. Reminders were regularly sent to ensure consistent reporting throughout the study.[35] This setting differs from the current study's environment, which is a 35-bed internal medicine ward in a private hospital. The previous study was conducted in an 800-bed public hospital with four general medicine wards, each with an average capacity of 15 beds, where physicians managed both inpatient and outpatient care. PV sensitization efforts, such as lectures, workshops, and induction programs, had a positive impact on ADR reporting.[36] These programs improved the completeness of ADR forms

between 2018 and 2020. However, no such programs have been conducted in the current hospital for the past five years.[36]

Study limitations

The study has several limitations. The region where the study was conducted, which is home to over 150 pharmacy colleges and 250 nursing colleges, offers easy access to a large pool of students. This advantage may not be present in other regions. Both the Doctor of Pharmacy and the new Bachelor of Pharmacy curricula have now incorporated PV concepts. To further improve ADR reporting, it would be beneficial to include a mandatory two-month PV training at a nearby public hospital as part of the Bachelor of Pharmacy curriculum. Other limitations include the small sample size and the limited generalizability of the findings. Furthermore, the lack of baseline data on medication errors, drug therapy problems, and ADR reports required the study to rely on feedback surveys to evaluate the effectiveness of the PRUT.

CONCLUSION

The PRUT effectively reported and managed the ADRs. Most physicians and nurses also had a high level of agreement on the effectiveness of this team. Incorporating mandatory PV activities for nursing and pharmacy students in nearby public hospitals can improve the reporting and management of ADRs.

Ethics

Ethics Committee Approval: The study was approved by the Vignan Institute of Pharmaceutical Technology Ethical Committee (approval number: VIPT/IEC/359/2023, date: 28.03.2023).

Informed Consent: Informed consent was obtained.

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Footnotes

Authorship Contributions

Concept: V.K.M., Design: V.K.M., S.R.Y., Data Collection or Processing: V.K.M., S.S.S.A., C.R.V.S.K., Analysis or Interpretation: V.K.M., S.S.S.A., C.R.V.S.K., S.R.Y., Literature Search: V.K.M., S.S.S.A., C.R.V.S.K., S.R.Y., Writing: V.K.M., S.S.S.A., C.R.V.S.K., S.R.Y.

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