Section: Pharmacology

Original Research Article

PREVALENCE OF ADR REPORTING IN TERTIARY HOSPITAL- A CROSS-SECTIONAL STUDY

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) are a major cause of morbidity and mortality worldwide. Spontaneous ADR reporting by healthcare professionals plays a crucial role in pharmacovigilance and patient safety. However, underreporting remains a significant challenge in healthcare settings. The objective is to assess the awareness of ADR reporting among healthcare professionals, identify barriers to ADR reporting, and suggest measures to improve the ADR reporting system in a tertiary hospital. **Materials and Methods:** A cross-sectional study was conducted among healthcare professionals in a tertiary hospital over a period of three months. Data were collected using a structured questionnaire comprising items related to awareness, reporting practices, barriers, and suggestions for improving ADR reporting. The collected data were analyzed using descriptive statistics and expressed as frequencies and percentages. **Results:** The study revealed that a majority of participants were aware of ADR reporting and recognized its importance in ensuring patient safety. Most participants knew where ADRs should be reported within the hospital. Despite this awareness, ADR reporting practices were hindered by several barriers, including lack of time, lack of awareness, uncertainty regarding the reporting process, and fear of legal consequences. The findings further indicated that regular training and workshops, simplification of the reporting process, provision of feedback on reported ADRs, and institutional support were the most frequently suggested measures to enhance ADR reporting. **Conclusion:** Healthcare professionals demonstrated satisfactory awareness regarding ADR reporting; however, several barriers continue to contribute to underreporting. Strengthening educational interventions, simplifying reporting procedures, and providing regular feedback may improve ADR reporting practices and enhance pharmacovigilance activities, ultimately contributing to improved patient safety in tertiary healthcare settings.

INTRODUCTION

Adverse Drug Reactions (ADRs)—defined by the World Health Organization as any noxious, unintended, and undesirable effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy—represent a significant global public health challenge.[1] Despite the rigorous clinical trial processes that drugs undergo prior to market approval, these trials are often limited by restricted sample sizes, short durations, and the exclusion of vulnerable populations (such as the elderly, pregnant women, and patients with comorbidities). Consequently, rare or long-term safety signals frequently remain undetected until a drug is exposed to the wider, more heterogeneous population in real-world clinical practice.[2]

Pharmacovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects, serves as the critical safety net for post-marketing surveillance. In a tertiary care setting, where patients often present with

complex disease profiles, polypharmacy, and high-acuity needs, the risk of ADRs is inherently amplified.[1] Effective ADR reporting is the backbone of a robust pharmacovigilance system; it enables the identification of safety trends, facilitates regulatory interventions, and directly improves patient outcomes by reducing medication-related morbidity and mortality.[3]

However, despite its clinical importance, the reporting of ADRs remains suboptimal, characterized by significant under-reporting across various healthcare settings.[4] This discrepancy between the actual incidence of adverse events and the documented reports suggests critical gaps within the existing pharmacovigilance framework. Addressing these gaps requires a nuanced understanding of the professional landscape, including current levels of awareness among healthcare providers, the institutional and systemic barriers that discourage reporting, and the often-overlooked role of patient education in identifying and reporting medication-related harm.[5]

This study aims to bridge these gaps by evaluating the prevalence of ADR reporting within a tertiary hospital environment. Through a comprehensive assessment of professional awareness, identification of systemic barriers, and an exploration of patient-centric reporting strategies, this research intends to provide actionable insights. The ultimate goal is to propose evidence-based improvements to the ADR reporting system, fostering a culture of safety that prioritizes proactive monitoring and enhanced patient care.

MATERIALS AND METHODS

Study Design: This study was conducted as a prospective, observational, cross-sectional, questionnaire-based study. This design was selected to capture real-time data regarding the incidence and reporting patterns of Adverse Drug Reactions (ADRs) within the clinical environment.

Study Setting: The study was carried out at the Government General Hospital, Vijayawada. This tertiary care setting provided a diverse patient population and complex medication regimens for observation.

Study Population: The study population consisted of in-patients admitted to the various wards of the Government General Hospital, Vijayawada, who met the inclusion criteria during the study period.

Study Duration: The total duration of the study was two months.

Data Collection: Data were collected using a multi-method approach, including:

Active Surveillance: Daily monitoring of inpatient medication charts and clinical notes.

Survey/Questionnaire: Structured questionnaires administered to healthcare professionals (HCPs) to assess awareness, identify barriers to reporting, and gather suggestions for system improvements.

Hospital Records: Review of patient case files for documented ADRs and medication history.

Study Procedure: The study employed a multidisciplinary spontaneous (voluntary) reporting program. This procedure relied on the concurrent detection of suspected ADRs by the research team and voluntary reporting by clinical staff. The prospective nature of the study allowed for the real-time identification and documentation of adverse events as they occurred during the hospital stay.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of Siddhartha Medical College and Government General Hospital, Vijayawada, under the approval reference number IEC SMC GGH 2024 AP/278. Informed consent was obtained from all participants prior to their inclusion in the study, and all data were handled in accordance with the ethical guidelines for biomedical research.

Selection Criteria

Inclusion Criteria

- Patients of either sex and any age.
- Patients who experienced an ADR during their hospital admission within the two-month study period.

Exclusion Criteria

- Outpatients.
- Patients with ADRs resulting from intentional or accidental poisoning.
- ADRs attributed to the administration of blood or blood products.
- Cases involving drug overdose, drug abuse, or intoxication.
- Adverse events classified under material vigilance (e.g., medical device failures).

Data Analysis

The data collected from the questionnaires and hospital records were coded, tabulated, and analyzed using statistical software (such as Microsoft Excel or SPSS). Categorical data were expressed as frequencies and percentages. Descriptive statistics were employed to summarize the demographic characteristics of the study population, the prevalence of Adverse Drug Reactions (ADRs), and the identified barriers to reporting. The results were organized to address the primary and secondary objectives, providing a clear overview of ADR reporting trends and areas for potential system improvement within the hospital.

Statistical Analysis

The data collected during the study were compiled, coded, and entered into a spreadsheet (e.g., Microsoft Excel). The statistical analysis was performed using descriptive statistics to summarize the findings. Continuous variables were expressed as mean and standard deviation, while categorical variables—such as the prevalence of Adverse Drug Reactions (ADRs), the distribution of reactions by demographic groups, and the barriers identified by healthcare professionals—were expressed as frequencies and percentages.

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RESULTS

I. Demographic Profile of Healthcare Professionals Involved in ADR Reporting at a Tertiary Care Hospital:

Years of Experience

Most participants had 0–5 years of experience (93%), followed by 6–10 years (6%) and 11–15 years (1%). This indicates that the study population predominantly comprised individuals with limited professional experience, such as undergraduates, postgraduates, or other junior healthcare professionals. The distribution of participants according to years of experience was shown in [Figure 1].

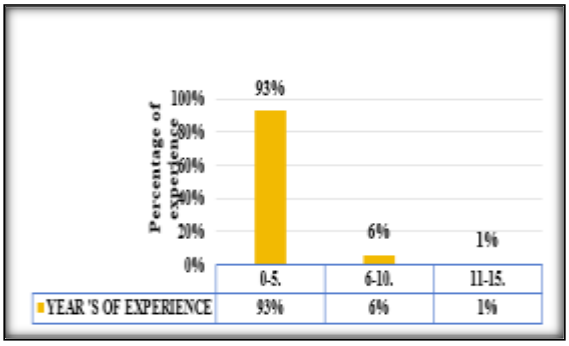

Figure 1: Years of Professional Experience of ADR Reporters in a Tertiary Hospital

Data were expressed as numbers (N)and percentage (%)

Age distribution

The majority of participants were in the 21–25 years' age group (59%), followed by 26–30 years (24%) and 15–20 years (20%). A smaller proportion of participants belonged to the 31–35 years (5%) and 35–40 years (1%) age groups. These findings indicate that the study population was predominantly composed of young adults, particularly those in their early twenties. The age-wise distribution of participants is presented in [Figure 2].

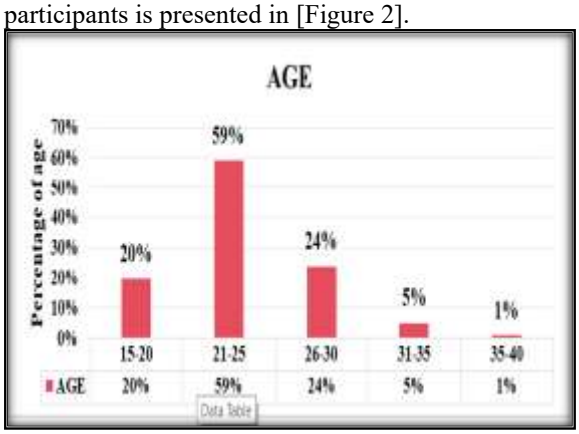

Figure 2: Age Distribution of ADR Reporters in a Tertiary Hospital

Data were expressed as numbers(N)and percentage (%)

Gender distribution

Among the participants, 59% were female and 41% were male. This indicates a higher representation of female healthcare professionals in the study population. The gender-wise distribution of participants was presented in [Figure 3].

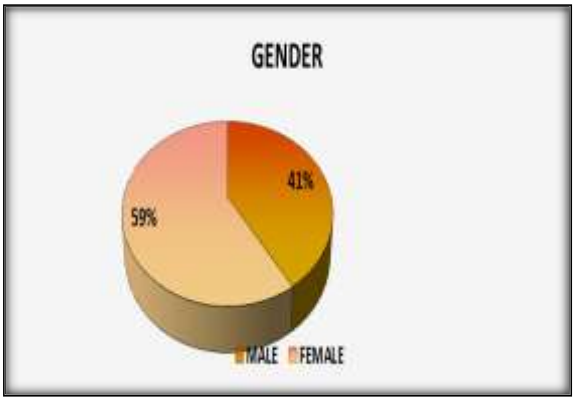

Figure 3: Gender Distribution of ADR Reporters in a Tertiary Hospital

Data were expressed as numbers(N) and percentage (%)

Overall, the respondents were mainly young, early-career individuals, with a strong representation from the 15–30-year age range and a female majority. This demographic pattern should be considered when interpreting the findings, as the results may largely reflect the views of younger and less experienced participants.

II. Assessment of Awareness Regarding ADR Reporting Among Healthcare Professionals.

Figure 4: Training on ADR Reporting Among Healthcare Professionals

Data were expressed as numbers(N) and percentage (%)

Among the participants, 47% reported having received training on ADR reporting, whereas 53% had not received any such training. This indicates that more than half of the healthcare professionals lacked formal training in ADR reporting.

The findings suggest a gap in ADR-related training among healthcare professionals. Since a majority of respondents had not undergone ADR reporting training, there is a need for regular educational

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programs, workshops, and awareness initiatives to improve knowledge and strengthen pharmacovigilance practices within the hospital. The distribution of participants according to ADR training status is shown in [Figure 4].

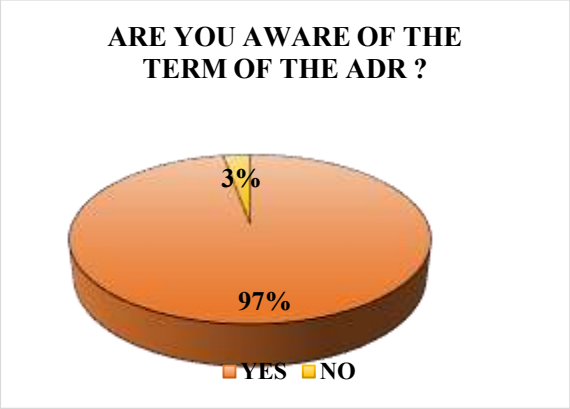

Figure 5: Awareness of the Term "Adverse Drug Reaction (ADR) Among Healthcare Professionals
Data were expressed as numbers(N) and percentage (%)

The majority of participants (97%) reported that they were aware of the term Adverse Drug Reaction (ADR), while only 3% indicated that they were not aware of the term. This demonstrates a high level of basic awareness regarding ADRs among healthcare professionals.

The findings indicate that awareness of the concept of ADRs is widespread among healthcare professionals in the tertiary care hospital. However, awareness alone may not necessarily translate into effective ADR reporting practices, highlighting the importance of continued training and practical guidance on pharmacovigilance activities. The distribution of participants based on their awareness of the term ADR is shown in [Figure 5].

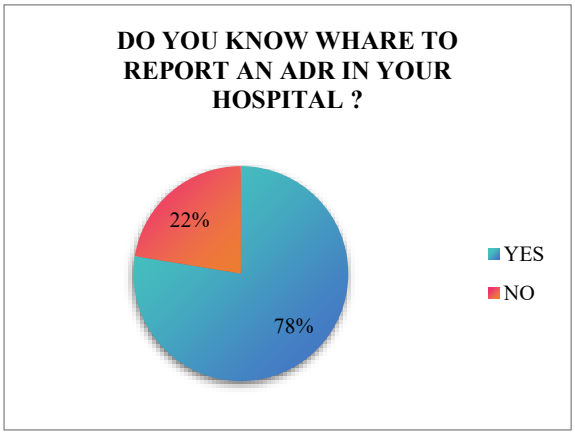

Figure 6: Awareness of ADR Reporting Location Among Participants
Data were expressed as numbers(N) and percentage (%)

The pie chart shown in [Figure 6] illustrates the distribution of participants based on their awareness of where to report an Adverse Drug Reaction (ADR) in their hospital. Among the participants, 78% were aware of the ADR reporting location, whereas 22% were not aware. The results indicate that the majority of participants (78%) had knowledge of the ADR reporting system in their hospital. However, the remaining 22% lacked this awareness, suggesting the need for further educational and awareness initiatives to improve ADR reporting knowledge among all participants.

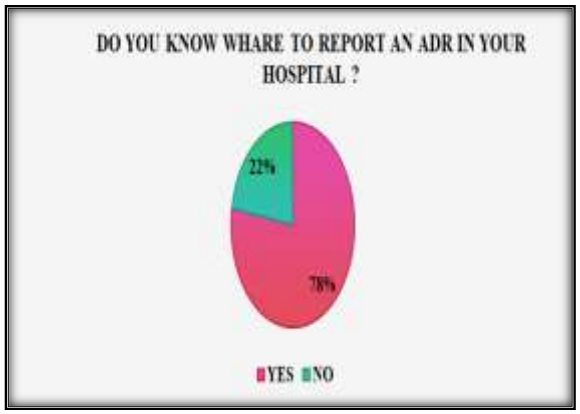

Figure 7: Participants' Perception of the Importance of ADR Reporting for Patient Safety
Data were expressed as numbers(N) and percentage (%)

The pie chart shows in [Figure 7] documented, among the participants, 80% strongly agreed and 19% agreed that ADR reporting is important for patient safety, while only 1% remained neutral.

The results indicate an overwhelmingly positive perception of ADR reporting among participants, with 99% either strongly agreeing or agreeing that ADR reporting is important for patient safety. This reflects a high level of awareness regarding the role of ADR reporting in enhancing patient care and safety.

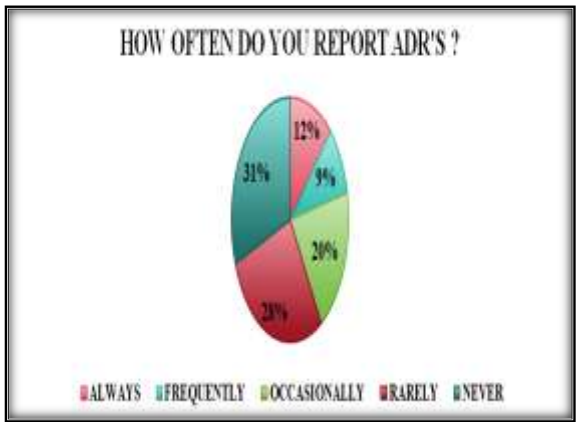

Figure 8: Frequency of ADR Reporting Among Participants
Data were expressed as numbers(N) and percentage (%)

The frequency of ADR reporting among participants revealed that 12% always reported ADRs, 9% frequently reported ADRs, 20% occasionally

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reported ADRs, 28% rarely reported ADRs, and 31% never reported ADRs, as shown in [Figure 8]. The findings indicate that ADR reporting was infrequent among the majority of participants, with 59% reporting ADRs rarely or never. In contrast, only 21% of participants reported ADRs always or frequently, suggesting the need for measures to improve regular ADR reporting practices, as shown in [Figure 8].

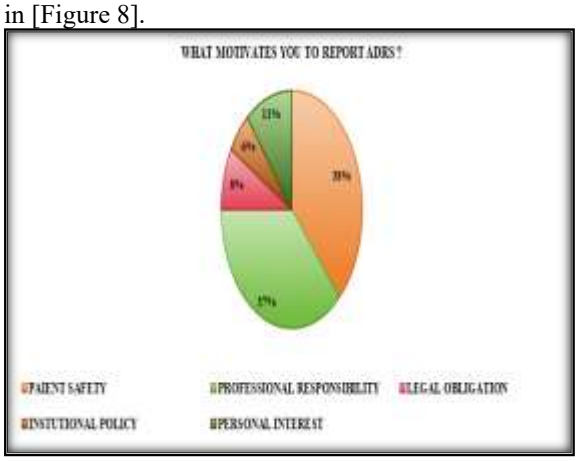

Figure 9: Factors Motivating Participants to Report Adverse Drug Reactions (ADRs)
Data were expressed as numbers(N) and percentage (%)

The factors motivating participants to report ADRs included patient safety (38%), professional responsibility (37%), institutional policy (11%), legal obligation (8%), and other factors (6%), as shown in [Figure 9].
The findings indicate that patient safety and professional responsibility were the primary motivators for ADR reporting among participants, accounting for 38% and 37%, respectively. Institutional policy, legal obligation, and other factors contributed less to ADR reporting motivation, as shown in [Figure 9].

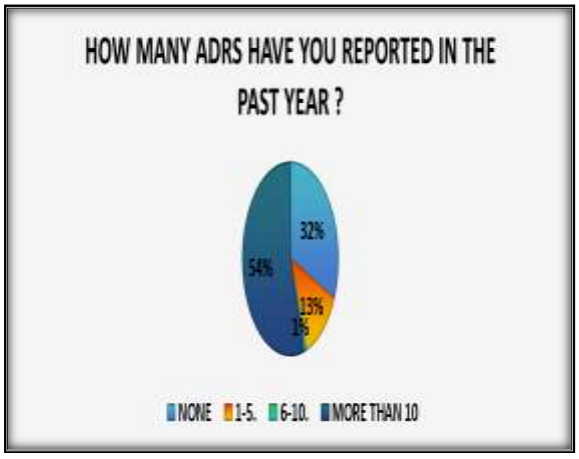

Figure 10: Number of Adverse Drug Reactions (ADRs) Reported by Participants in the Past Year
Data were expressed as numbers(N) and percentage (%)

The number of ADRs reported by participants in the past year showed that 32% had reported no ADRs, 13% had reported 1–5 ADRs, 1% had reported 6–10 ADRs, and 54% had reported more than 10 ADRs, as shown in [Figure 10].
The findings indicate that more than half of the participants (54%) reported more than 10 ADRs in the past year, while 32% had not reported any ADRs. A smaller proportion reported 1–5 ADRs (13%) and 6–10 ADRs (1%), reflecting variability in ADR reporting practices among participants, as shown in [Figure 10].

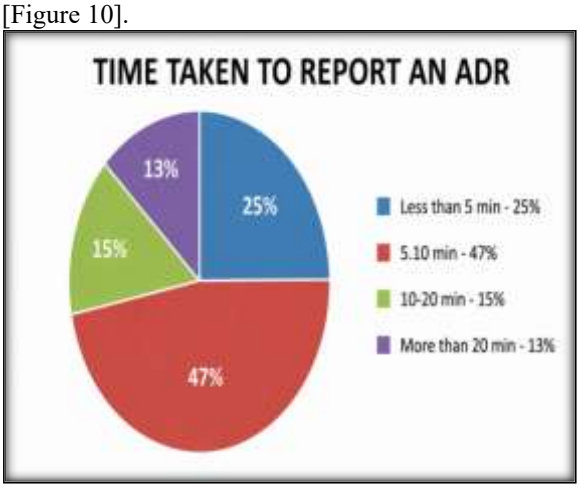

Figure 11: Time Taken by Participants to Report an Adverse Drug Reaction (ADR)
Data were expressed as numbers(N) and percentage (%)

The time taken by participants to report an ADR showed that 25% required less than 5 minutes, 47% required 5–10 minutes, 15% required 10–20 minutes, and 13% required more than 20 minutes, as shown in [Figure 11].
The findings indicate that the majority of participants (72%) were able to report an ADR within 10 minutes, while 28% required more than 10 minutes. This suggests that ADR reporting was relatively time-efficient for most participants, as shown in [Figure 11].

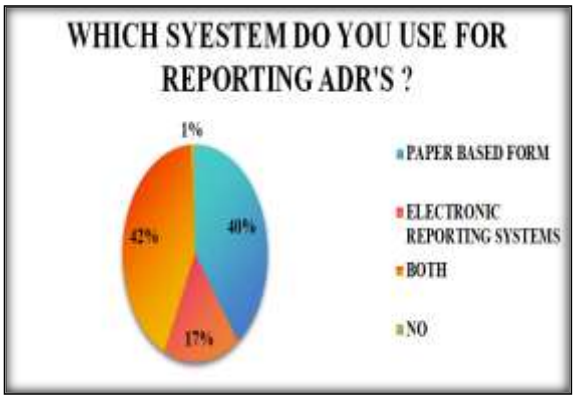

Figure 12: ADR Reporting Systems Used by Participants
Data were expressed as numbers(N) &percentage (%)

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The ADR reporting systems used by participants showed that 40% used paper-based forms, 17% used electronic reporting systems, 42% used both paper-based and electronic systems, and 1% did not use any reporting system, as shown in [Figure 12].

The findings indicate that the use of both paper-based and electronic reporting systems was the most common method among participants (42%), followed closely by paper-based forms alone (40%). Electronic reporting systems alone were used by a smaller proportion of participants (17%), while only 1% reported not using any ADR reporting system, as shown in [Figure 12].

III. Identify barriers to ADR Reporting

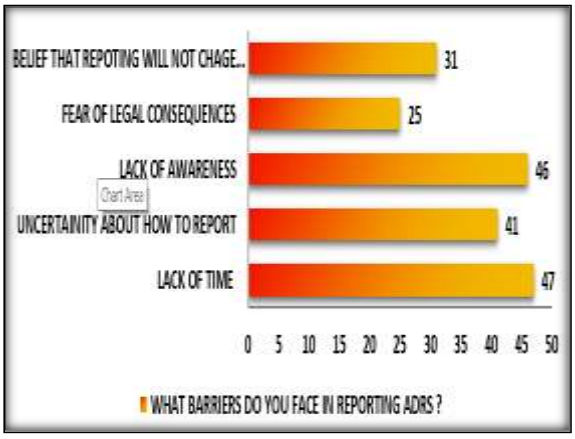

Figure 13: Barriers Faced by Participants in Reporting Adverse Drug Reactions (ADRs)

Data were expressed as numbers(N) and percentage (%)

The barriers faced by participants in reporting ADRs included lack of time (47%), lack of awareness (46%), uncertainty about how to report (41%), belief that reporting would not change anything (31%), and fear of legal consequences (25%), as shown in [Figure 13].

The findings indicate that lack of time and lack of awareness were the most commonly reported barriers to ADR reporting among participants, accounting for 47% and 46%, respectively. Uncertainty about the reporting process was also a significant barrier (41%), while belief that reporting would not make a difference and fear of legal consequences were reported less frequently, as shown in [Figure 13].

IV. Suggestions for improving the ADR reporting System.

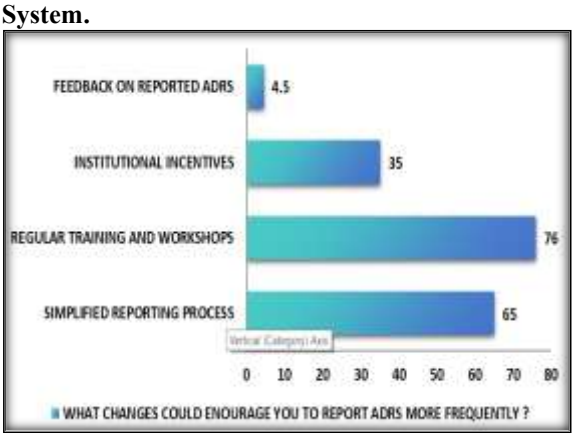

Figure 14: Changes suggested by participants to encourage more frequent ADR Reporting

Data were expressed as numbers(N) and percentage (%).

The changes suggested by participants to encourage more frequent ADR reporting included regular training and workshops (76%), a simplified reporting process (65%), feedback on reported ADRs (45%), and institutional incentives (35%), as shown in [Figure 14].

The findings indicate that regular training and workshops were the most preferred strategy to enhance ADR reporting among participants (76%), followed by simplifying the reporting process (65%). Feedback on reported ADRs and institutional incentives were also considered important measures by 45% and 35% of participants, respectively, as shown in [Figure 14].

DISCUSSION

The present study demonstrated a satisfactory level of awareness regarding ADR reporting among healthcare professionals. Most participants were aware of the importance of ADR reporting for patient safety and knew where ADRs should be reported within the hospital. These findings are consistent with those reported by Bhagavathula et al. (2022), who found that healthcare professionals had good knowledge and positive attitudes toward pharmacovigilance and ADR reporting. Similarly, Alshammari et al. (2023) reported that healthcare professionals recognized the significance of ADR reporting in improving medication safety, although certain knowledge gaps persisted.[6-7] The relatively high awareness observed in the present study may reflect increased emphasis on pharmacovigilance programs and continuous professional education.

The present study documented lack of time, lack of awareness, uncertainty regarding the reporting process, and fear of legal consequences as major barriers to ADR reporting. Lack of time and insufficient awareness were the most frequently reported obstacles. Similar findings were reported by Alwhaibi et al. (2020), who observed that inadequate

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knowledge of reporting procedures and workload-related constraints significantly contributed to underreporting of ADRs. Likewise, Alshammari et al. (2023) found that uncertainty about reporting methods and insufficient training were among the major barriers affecting spontaneous ADR reporting.[7-8] These findings indicate that despite improvements in awareness, practical and educational challenges continue to limit ADR reporting practices.

In the present study, participants suggested regular training and workshops, simplification of the reporting process, feedback on reported ADRs, and institutional incentives as measures to improve ADR reporting. Regular training and workshops emerged as the most preferred strategy. These findings are in agreement with Alwhaibi et al. (2020), who reported that educational interventions and continuous professional training significantly improved ADR reporting behavior among healthcare professionals. Similarly, Bhagavathula et al. (2022) emphasized that periodic training, feedback mechanisms, and easy-to-use reporting systems are essential for strengthening pharmacovigilance activities.[6-7] Therefore, implementing regular educational programs and simplifying reporting procedures may substantially improve ADR reporting rates and enhance patient safety.

CONCLUSION

The present study demonstrated that healthcare professionals possessed a satisfactory level of awareness regarding adverse drug reaction (ADR) reporting and recognized its importance in ensuring patient safety. Most participants were aware of the ADR reporting system and its role in pharmacovigilance.

Despite the adequate level of awareness, several barriers to ADR reporting were identified. Lack of time, lack of awareness, uncertainty about the reporting procedure, and fear of legal consequences were the major factors contributing to underreporting of ADRs among healthcare professionals.

To enhance ADR reporting practices, participants recommended regular training and workshops, simplification of the reporting process, timely feedback on reported ADRs, and institutional support. Implementing these measures may improve the frequency and quality of ADR reporting, strengthen pharmacovigilance activities, and ultimately contribute to improved patient safety and healthcare outcomes.

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