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## Review Article

# Improvement of Data Quality of Spontaneous Adverse Drug Reaction Reporting Among Undergraduate Students: A Review

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## ABSTRACT

Background-Adverse Drug Reaction (ADR) reporting involving detection, evaluation, understanding and prevention of adverse effects or other medicine or vaccine related issues is fundamental to pharmacovigilance. Despite its importance, the spontaneous reporting of ADRs by undergraduate students and health care professionals often lacks sufficient data quality. Strengthening the quality of these reports is essential, as they provide critical insights into drug safety and ensures regulatory authorities to take prompt and necessary action to protect public health. Aim And Objective-To conduct a comprehensive review of different strategies to enhance the quality of ADR reporting among undergraduate students and identify factors influencing reporting accuracy. Material And Method- This review is based on analysis of quality of ADR reporting, from the literature gathered from Textbooks, PubMed, Google Scholar. Article from past 10 years were included to ensure the relevancy and timeless data. Reporting accuracy, completeness, frequency and time to report were the key variables analysed. DISCUSSION- It highlights challenges in ADR reporting, including lack of awareness regarding reporting channel, perceived complexities in reporting process and insufficient formal training and guidance, due to which undergraduate face difficulty in reporting ADRs and is impacting the overall quality. Conclusion- Overcoming barriers to ADR reporting requires a combination of educational training and practical experience. Recommendations include incorporating ADR reporting into the curriculum and providing students with practical opportunities through workshops, training sessions, and hand on clinical experience.

## INTRODUCTION

In modern healthcare, medications play a crucial role, ensuring safety and efficacy is essential to protect public health. ADRs, defined as harmful

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and unintended responses to drug administered, mainly occurring at normal doses used for prevention, diagnosis, treatment the modification of the physiological functions.<sup>1</sup> Pharmacovigilance is the science of detecting, assessing, understanding, and preventing adverse effects of medicines which relies heavily on spontaneous ADR reporting, where health care professionals voluntarily report suspected drug reaction.<sup>2</sup> ADR significantly contribute to patient mortality and morbidity, making effective pharmacovigilance crucial in clinical practice. Consequently, some ADRs, particularly rare or long-term effects, may only be evident once a drug is widely used in the general population. It is necessity of post marketing surveillance and the critical role of ADR reporting ingathering real data about drug safety.<sup>3</sup> Therefore, ADR reporting is vital for identifying, evaluating, and mitigating these risks. Health care professionals such as nurses, pharmacists, physicians, and others having direct interaction with patients and are often the first to notice adverse drug rection during treatment.<sup>4</sup> Their clinical observations can lead to identification of previously unknown adverse effects, improving patients' management and decision-making in-patient care. Furthermore, patients are also encouraged to report ADRs, foresting a collabrative approach to drug safety monitoring between healthcare providers and the public.<sup>5</sup> Guidelines and framework to support ADR reporting are established by the regulatory authorities, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These agencies rely on the comprehensive data from healthcare professionals, patients, and pharmaceutical companies to assess drug safety profile. Reports are carefully analysed to identify the pattern or emerging safety concerns that may require further investigation. When the significant safety issue arises, regulatory agencies can take corrective

actions such as updating drug labelling, issuing safety alerts, or, in severe cases, withdrawing a drug from the market.<sup>6,7</sup> Undergraduate students, particularly in pharmacy, nursing, MBBS interns in different departments, and junior doctors, represents a critical group of ADR reporting. The process of ADR reporting are challenging for them. Among undergraduate students, underreporting and poor quality of ADR reporting remains a significant issue. Factors leading to challenges in these region includes, lack of awareness, insufficient training, and the perceived complexities of the reporting process. Strengthening education and raising awareness about the importance of ADR reporting are crucial in overcoming these barriers.<sup>8</sup> Although tools such as ADR PvPI mobile app and electronic health record (EHR) systems are available in India but their adoption remains limited.<sup>9</sup> So, to Enhance the safety and reduce mortality, it is crucial to address underreporting and improve the quality of ADR reporting through a vigilant and efficient ADR reporting system.

### **Aim And Objective**

To conduct a comprehensive review of different strategies to enhance the quality of ADR reporting among undergraduate students and identify factors influencing reporting accuracy.

### **MATERIAL AND METHODS**

This review is based on analysis of quality of ADR reporting, from the literature gathered from Textbooks, PubMed, Google Scholar. Article from past 10 years were included to ensure the relevancy and timeless data. Reporting accuracy, completeness, frequency, and time to report were the key variables analysed. Studies examining the factors, influencing the quality of ADR reports, the role of undergraduate students in ADR reporting and educational interventions aiming



improvement of ADR reporting were selected. In addition, strategies to improve the aspects of ADR reporting, including training programs, awareness campaigns, were evaluated. The findings were synthesized to map the comprehensive overview of the current landscape and propose solutions for strengthening the ADR quality reporting.

### **Current Quality of ADR Reporting Among Undergraduate Students**

Several studies have highlighted that the current quality of ADR reporting among undergraduate students, particularly including nursing, pharmacy, dentistry, and medicines remains suboptimal despite increased awareness of importance of pharmacovigilance. Several studies highlight the gap in reporting accuracy, incomplete reports, insufficient patients' information, poor documentation, completeness, and consistency among students. It indicates a need for focused intervention to improve standards at the undergraduate levels. Study by García Abeijon P et al. (2023)<sup>10</sup> on main determinants of underreporting and found that ignorance (only serious ADRs need to be reported) in 86.2%, lack of interest, and other excuses) in 84.6%, complacency (the belief that only well tolerated drugs are allowed on the market) in 46.2%, diffidence (fear of appearing ridiculous for reporting merely suspected ADRs) in 44.6%, insecurity (it is nearly impossible to determine whether or not a drug is responsible for a specific adverse reaction) in 33.8%, and the absence of feedback in 9.2%. Patel PB et al. (2017)<sup>11</sup> compares ADR reporting patterns and quality between undergraduate medical students and physicians, identifying areas for improvement in student reporting practices. Similarly, many studies found that only 30% of ADR reports submitted by undergraduate students included all necessary patient details, such as age, medical history, and outcome. Furthermore, the content of

ADR reports is often unclear, with many students reporting adverse events using non-standard terminology, leading to inconsistent data. This inconsistency affects the quality and usefulness of the reports in pharmacovigilance databases. Similarly, a interventional study conducted by Sharma N et al. (2018)<sup>12</sup> to assess and enhance awareness about ADRs and strengthen reporting among medical undergraduates and found that didactic lecture in addition to case narrative enhanced awareness and may strengthen ADR reporting culture among the medical students.

### **Barriers To Effective ADR Reporting**

Several barriers contribute to the low level of ADR reports submitted by undergraduate students:

- **Lack of awareness and knowledge** – many healthcare professionals are unaware about the ADR reporting, role of drug safety, how to report it properly, limited understanding of what constitutes ADR reporting and inadequately trained in pharmacovigilance.
- **Uncertainty about causality** – many healthcare professionals have doubt whether the drug truly caused the adverse reaction or not. Some only reports, if there are certain.
- **Fear of legal or professional consequences** – Many health care professionals are concerned about the legal repercussions, or the damage to their reputations. For avoiding these blames individuals do not report.
- **Time constraints** - ADR reporting is seen as a time-consuming process, and the busy schedule and work load pressure makes the ADR reporting least priority.
- **Lack of feedback** – due to this reason, individual loses motivation to report in the future



- **Inadequate reporting system-** non friendly reporting platforms, absence of digital reporting mechanism, poorly designed reporting platforms also leads to inadequate reporting. Inadequate access to digital tools may too complicate ADR reporting.
- **Belief that one report will not make a difference-** a false perception that an individual report are insignificant in large pharmacovigilance system.
- **Insufficient institutional support-** lack of incentives and recognition for participation in reporting. There is no significant emphasis on the importance of ADR reporting fro hospital management or academic institution also.
- **Misconception-** a misconception is drawn in the society, that only serious or fatal ADRs should be reported. This leads to underreporting of mild and moderate but still important reactions.
- **Language and communication-** difficult to express or document ADR details clearly, mainly in multilingual regions or among students.
- **Regular workshops ad seminars-** short term training interactive seminar should be haled time to time led by pharmacovigilance experts it will improve the practical understanding and motivation. It can include case-based discussions, role playing to stimulate ADR reporting.
- **Continuing medical education (CME)-** It provides periodic updates to students and practitioners, reinforcing knowledge of pharmacovigilance system.
- **E-Learning modules-** flexible educational tools, online platforms and mobile apps offers self-paced learnings. E.g.: WHO's online pharmacovigilance courses.
- **Training programmes-** time to time training programme should be head by senior professionals and trained peers, which will promote collaborative learning culture.
- **Awareness Campaigns-** it includes quiz, poster competition, awareness weeks specifically focusing on ADR and pharmacovigilance. It will boost interest of students.

### **Educational Interventions to Improve Reporting**

Educational intervention is the key strategy for strengthening pharmacovigilance, mainly among healthcare professionals and students. Common educational interventions used are described below:

- **Integration of formal curriculum-**

undergraduate curriculum should include introducing pharmacovigilance and ADR reporting topics, which will lead to increased awareness and knowledge.

All the measures will lead to improved completeness and accuracy of reports, willingness ad confidence to report ADRs, and positive attitude towards ADR reporting. Manasa M et al (2023)<sup>13</sup> reported the impact of educational intervention through a learning module on pharmacovigilance had a significant impact on the overall knowledge of students about medicine safety. For instance, some studies implemented a pharmacovigilance training program that included case studies, role-playing, and hands-on ADR reporting exercises. Liyanage PH et al (2025)<sup>14</sup> introduced mobile app as an alternative solution of underreporting of ADRs. Many studies explored



the use of a mobile app designed to simplify ADR reporting among healthcare students.

### **Impact Of Faculty Support and Guidance in ADR Reporting**

Support and guidance of faculty plays a crucial role in enhancing ADE reporting practice, mainly among undergraduate students in medical fields. Faculty acts as a role model and also a prime source of information during lectures and trainings, leading to recognized importance of ADR reporting when emphasized consistently by faculty. Studies have shown that the students who received blame free environment and faculty encouragement are more likely to submit spontaneous ADR reports. When faculty provides guidance for completing ADR reporting forms during hospital rounds, it improved the accuracy and completeness of ADR reports. It reduces underreporting due to lack of confidence. Research and publication guidance in form of research appears, case reports and audits related to ADRs enhances academic involvement and professional development.

### **DISCUSSION**

The review findings highlight the critical role of improving the quality of adverse drug reaction reporting among undergraduate students. Several challenges, including inadequate trainings, lack of awareness and constraints related to time and motivation can be addressed for structured and targeted interventions. Educational strategies that focus on practical reporting exercise, clinical case study are important in improving students understanding of pharmacovigilance. Adopting user friendly technology can enhance the ease and accuracy of ADR reporting. Furthermore, Faculty support is essential to nurture a culture of pharmacovigilance among future healthcare professionals. Their regular guidance and

mentorship lead to better learning outcomes, improved reporting behaviour and greater integration of pharmacovigilance in clinical practice. Moreover, leveraging user friendly digital tools and reporting platforms can significantly improve the accuracy and conscience of reporting. Collaborative efforts between educational institutes, healthcare providers and regulatory authorities, are crucial part of establishing a sustainable and effective ADR reporting framework. This can bridge existing gaps by prompting standardization, supporting training initiatives, and integrative feedbacks.

### **CONCLUSION**

Enhancing the quality of ADR reporting among undergraduate students is key for strengthening pharmacovigilance system and promoting drug safety. These initiatives facilitated professional development of future healthcare providers by framing a strong foundation in pharmacovigilance practice and contribute to overarching goal of safeguarding patients' health. By empowering students with the knowledge, skills and tools necessary for ADR reporting, we enhance the quality of pharmacovigilance data along with a more responsible and safety conscious data generation by healthcare professionals. All these efforts together contribute to patients' safety, improved therapeutic outcomes and public health protection.

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