

ASSESSMENT OF ADR DETECTION, REPORTING AWARENESS, AND RISK PERCEPTION AMONG PHARMACY STUDENTS: A CROSS-SECTIONAL INSTITUTIONAL STUDY

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ABSTRACT

Adverse drug reactions (ADRs) are an important concern in healthcare and can contribute to patient morbidity, mortality, increased healthcare costs, and prolonged hospital stay. Pharmacovigilance plays an important role in identifying, monitoring, assessing, and preventing adverse effects associated with medicines. ADR reporting is an important part of pharmacovigilance because it helps in detecting safety problems that may not be identified during clinical trials. Pharmacy students are future healthcare professionals and should have adequate knowledge about ADR detection, reporting procedures, and pharmacovigilance systems. The present study was conducted to assess ADR detection knowledge, reporting awareness, risk perception, and reporting practices among pharmacy students. A descriptive cross

sectional institutional study was conducted among 400 pharmacy students over a period of three months. A structured, self-administered questionnaire was used for data collection. The questionnaire consisted of four sections covering demographic characteristics, ADR detection knowledge, ADR reporting awareness, and risk perception and reporting practices. The findings showed that 77.3% of respondents correctly identified the definition of an ADR, while 82.5% were aware of the WHO definition of ADR. About 71.5% were aware of ADR classification types and 77.8% reported that they could identify clinical signs of common ADRs. However, only 63.7% were familiar with causality assessment scales. Regarding reporting awareness, 81.3% recognized that ADR reporting is important for patient safety,

69.5% knew where ADRs could be reported in India, and 72.3% were familiar with the Pharmacovigilance Programme of India (PvPI). However, misconceptions were observed regarding who can report ADRs and the appropriate reporting timeframe. Regarding practice, 60.9% of students had observed an ADR during clinical practice, whereas 53% had reported an ADR. ADR Monitoring Centres were the most commonly used reporting channel. A large majority of respondents, 81%, supported mandatory pharmacovigilance and ADR reporting training in the pharmacy curriculum. The study indicates that pharmacy students have generally good basic knowledge and awareness regarding ADRs, but gaps remain in practical reporting knowledge and reporting behaviour. Regular pharmacovigilance education, practical ADR reporting exercises, clinical exposure, and awareness programmes may help improve ADR reporting practices among pharmacy students.

KEYWORDS: Adverse drug reactions; Pharmacovigilance; ADR reporting; Pharmacy students; Risk perception; Patient safety; PvPI.

INTRODUCTION

An adverse drug reaction (ADR) is a harmful and unintended response associated with the use of a medicinal product at normally used doses. ADRs are an important public health concern because they can result in patient discomfort, additional treatment, prolonged hospital stay, increased healthcare expenditure, and in severe cases, disability or death.

ADRs may occur even when medicines are prescribed and used correctly. Therefore, continuous monitoring of medicines is required to maintain patient safety.

Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or other medicine-related problems. Although medicines are evaluated for safety and efficacy during clinical trials, some adverse effects may not be identified before marketing. Clinical trials usually involve a limited number of participants and are conducted for a relatively short period. Rare reactions, delayed reactions, drug interactions, and reactions occurring in specific patient populations may therefore become evident only after a medicine is widely used.

ADR reporting is one of the important components of pharmacovigilance. Healthcare professionals can identify suspected ADRs during routine clinical practice and report them through appropriate reporting systems. Proper reporting provides useful information for

identifying potential safety signals and helps in improving the safe use of medicines.

In India, the Pharmacovigilance Programme of India (PvPI) provides a national system for monitoring ADRs. ADR Monitoring Centres support the collection and assessment of suspected ADR reports. Knowledge about these systems is important for pharmacy students because pharmacists have an important role in medication safety and patient care.

Pharmacy students receive theoretical education in pharmacology, pharmacy practice, therapeutics, and pharmacovigilance. However, theoretical knowledge may not always result in actual reporting behaviour. Students may recognize an ADR but may be uncertain about whether it should be reported, who can report it, where it should be reported, or how the reporting form should be completed.

Previous studies have also identified a gap between knowledge and practice in ADR reporting. Studies among healthcare professionals and pharmacy students have shown that although many participants have positive attitudes toward ADR reporting, practical reporting remains inadequate. Lack of training, uncertainty about reporting procedures, limited clinical exposure, and misconceptions regarding reporting responsibilities can contribute to under-reporting.

Therefore, assessing the knowledge and reporting practices of pharmacy students is important. Identifying gaps at the student level may help educational institutions introduce suitable interventions before students enter professional practice.

The present study was conducted to assess ADR detection knowledge, awareness of ADR reporting systems, risk perception, and reporting practices among pharmacy students. The study also aimed to identify areas where pharmacovigilance education can be strengthened.

ADR DETECTION AND KNOWLEDGE AMONG PHARMACY STUDENTS

The study included 400 pharmacy students. The majority of respondents were in the 21–23-year age group, accounting for 58.5% of the participants. Students below 20 years accounted for 33.35%, while 7.5% were aged 23–25 years and 0.7% were aged 26 years or above. Male students represented 55.8% and female students represented 44% of the study population.

Most participants were B.Pharm students, representing 72.8% of the sample. Pharm.D students accounted for 13%, D.Pharm students for 10%, and M.Pharm students for 4.2%.

Third-year students represented the largest academic group at 47%, followed by fourth-year students at 24.5%.

Regarding the basic definition of ADR, 77.3% correctly identified an ADR as a harmful and unintended response to a drug at normal therapeutic doses. However, 11.7% considered ADR to be a medication error, 5.8% considered it drug abuse, and 5.2% considered it drug overdose. This indicates that although most students understood the basic definition, some confusion between ADRs and other medication-related problems was present.

A majority of the participants were aware of the WHO definition of ADR. About 82.5% responded that they were aware of the WHO definition, whereas 17.5% were not familiar with it. This suggests that basic theoretical knowledge regarding ADRs was relatively good among the study population.

Awareness of ADR classification was reported by 71.5% of respondents. The classification of ADRs into different types is useful for understanding the nature, predictability, and timing of adverse reactions. However, 28.5% of students reported that they were not aware of ADR classification types, showing that further teaching may be useful.

When students were asked about therapeutic categories that are commonly associated with ADRs, 59.4% answered yes, while 17.1% answered no and 23.4% selected maybe. This indicates that knowledge regarding high-risk therapeutic categories such as antibiotics, anticoagulants, and NSAIDs was not uniform among the respondents.

About 77.8% of respondents stated that they could identify clinical signs of common ADRs such as anaphylaxis, hepatotoxicity, and nephrotoxicity. This is an important finding because early recognition of clinical signs is necessary for appropriate management and reporting of suspected ADRs.

Familiarity with causality assessment scales was reported by 63.7% of students, while 36.3% were not familiar with them. Causality assessment is useful in evaluating the possible relationship between a suspected drug and an adverse reaction. The findings indicate that practical pharmacovigilance concepts such as causality assessment require additional attention during pharmacy education.

Awareness of Type A and Type B ADRs was reported by 74.8% of students. Although this

demonstrates a good theoretical understanding among most respondents, 25.2% were not familiar with these classifications.

About 77.8% of participants stated that they knew the essential information required for ADR documentation, including patient details, drug name, description of the reaction, and outcome. Another 72% reported that they could identify drug-drug interactions and contraindications that may precipitate ADRs. These findings suggest that most students possess basic knowledge required for recognizing and documenting suspected ADRs.

AWARENESS OF ADR REPORTING AND PHARMACOVIGILANCE

Awareness of the importance of ADR reporting was high among the study participants. A total of 81.3% of respondents stated that ADR reporting is crucial for patient safety, whereas 18.8% were not aware of its importance. This shows that most pharmacy students understand the role of ADR reporting in improving medication safety.

About 69.5% of participants knew where ADRs could be reported in India, including the PvPI National Coordination Centre and ADR Monitoring Centres. However, 30.5% did not know the appropriate reporting locations. This indicates that general awareness of pharmacovigilance is reasonably good, but practical knowledge of the reporting system is still incomplete.

A total of 72.3% of respondents were familiar with the Pharmacovigilance Programme of India established by CDSCO, while 27.7% were not aware of it. PvPI awareness is important because it provides the national framework for monitoring suspected ADRs in India.

About 71.5% of participants reported familiarity with the structure of the suspected ADR reporting form. The remaining 28.5% were not familiar with the form. This finding suggests that although a majority of students know about ADR reporting forms, nearly one-third may require practical training in completing and submitting them.

One important gap was observed regarding who can report ADRs. About 41.5% believed that all healthcare professionals can report ADRs, while 28.7% correctly identified that everyone, including patients, can report ADRs. However, 16.5% believed that only pharmacists could report ADRs and 9.3% believed that only doctors could report them. These findings show that misconceptions regarding reporting responsibility are still present.

The respondents also showed uncertainty regarding the reporting timeframe for serious

ADRs. About 32.5% selected within 15 days, 31.3% selected within 24 hours, and 26.8% selected within 7 days. Another 9.5% reported that they did not know the appropriate timeframe. The variation in responses demonstrates the need for clearer practical education regarding ADR reporting procedures.

RISK PERCEPTION TOWARDS ADRs

Risk perception is an important factor influencing ADR reporting behaviour. Students who understand the possible harm caused by ADRs may be more willing to identify and report suspected reactions.

The study showed that a large proportion of students recognized ADR reporting as an important component of patient safety. This positive perception is encouraging because a good attitude toward pharmacovigilance can support better reporting practices.

However, the findings also suggest that knowledge and perception do not always translate into action. Some students who were aware of ADRs and pharmacovigilance had not reported an ADR. This may be related to limited clinical exposure, uncertainty regarding the reporting process, or lack of confidence in completing a report.

More than half of the participants also recognized ADR under-reporting as an important problem. This indicates that students are aware that the number of ADR reports received through pharmacovigilance systems may not represent the actual number of ADRs occurring in clinical practice.

The study also found strong support for including mandatory pharmacovigilance and ADR reporting training in the pharmacy curriculum. A total of 81% of respondents supported mandatory training, while only 19% did not support it.

This finding is important because students themselves recognize the need for additional practical training.

Pharmacovigilance education should therefore include practical examples rather than being limited to theoretical lectures.

ADR REPORTING PRACTICES AMONG PHARMACY STUDENTS

Clinical exposure provides students with an opportunity to identify suspected ADRs. In the present study, 60.9% of respondents reported that they had observed an ADR during clinical practice, while 39.1% had not. This indicates that ADRs were encountered by a considerable proportion of students during their clinical exposure.

Despite this exposure, only 53% of participants reported that they had reported an ADR. Nearly half of the students, 47%, had not reported an ADR. This finding demonstrates an important gap between observing an ADR and actually reporting it.

The difference between ADR observation and reporting is important from a pharmacovigilance perspective.

Identification alone does not contribute to the pharmacovigilance database unless the suspected reaction is documented and reported through an appropriate reporting pathway.

Among those who reported ADRs, ADR Monitoring Centres were the most commonly used reporting channel, accounting for 37%. Hospitals accounted for 31%, while 19.5% reported through PvPI. Online reporting systems accounted for 5.2% and other methods for 7.3%.

These findings indicate that ADR Monitoring Centres and hospitals play an important role in facilitating ADR reporting among pharmacy students. Greater awareness of online reporting systems and other available reporting mechanisms may further improve reporting accessibility.

IMPORTANCE OF PHARMACOVIGILANCE EDUCATION

The findings of the study indicate that pharmacy students possess good basic knowledge regarding ADRs. However, practical knowledge remains less consistent. Knowledge about ADR definitions, classifications, clinical signs, and documentation was generally satisfactory, whereas knowledge regarding reporting responsibilities and timelines showed greater variation.

This knowledge-practice gap has also been observed in previous studies. Yawson *et al.* reported that healthcare professionals may have good awareness and positive attitudes toward ADR reporting while actual reporting remains lower. Similarly, studies among pharmacy students have identified limitations in familiarity with practical ADR reporting procedures.

Rasel *et al.* reported that pharmacy students demonstrated awareness and positive perceptions

toward ADR reporting but required greater exposure to practical reporting systems. The present findings show a similar pattern, with a majority recognizing the importance of ADR reporting but only 53% reporting an ADR.

Educational interventions may therefore play an important role in improving reporting behaviour. Previous work has shown that structured educational programmes can improve knowledge regarding ADR reporting. Elkalmi *et al.* reported improvement in pharmacist knowledge following educational intervention, supporting the value of targeted pharmacovigilance education.

Pharmacy education should include practical sessions on identifying suspected ADRs, collecting relevant patient and medication information, documenting the reaction, assessing causality, completing ADR reporting forms, and understanding the available reporting pathways.

Clinical postings can also be used to improve students' exposure to real ADR cases. Students can be encouraged to discuss suspected ADRs with clinical pharmacists, physicians, and other healthcare professionals. This approach can help students develop confidence in recognizing and reporting suspected reactions.

Awareness programmes and workshops conducted in collaboration with ADR Monitoring Centres may also be useful. Such programmes can demonstrate the actual ADR reporting process and reduce uncertainty among students.

ROLE OF PHARMACY STUDENTS AND FUTURE PHARMACISTS IN PHARMACOVIGILANCE

Pharmacy students are future members of the healthcare team and can contribute significantly to medication safety. Their education should prepare them to identify potential ADRs, communicate suspected reactions to healthcare professionals, educate patients, and participate in pharmacovigilance activities.

Pharmacists are closely involved in medicine selection, dispensing, counselling, medication review, and monitoring. Therefore, they may encounter information about suspected ADRs during different stages of patient care.

Improving ADR reporting knowledge during student education can help develop good

professional habits. Students who receive practical training before graduation may be more confident in reporting ADRs after entering hospital, community, clinical, or pharmaceutical practice.

The present study also demonstrates that students themselves support greater pharmacovigilance education. Since 81% supported mandatory pharmacovigilance and ADR reporting training, curriculum-based intervention may be well accepted by students.

CONCLUSION

The present study assessed ADR detection, reporting awareness, risk perception, and reporting practices among 400 pharmacy students. Overall, the participants demonstrated a good level of basic knowledge regarding adverse drug reactions. Most students were able to identify the definition of an ADR, recognize the WHO definition, identify common clinical signs, and understand basic ADR classification.

Awareness of pharmacovigilance was also relatively good. A large majority recognized the importance of ADR reporting for patient safety, while many were familiar with PvPI and ADR Monitoring Centres. However, important gaps were observed in practical aspects of ADR reporting, including reporting responsibilities and reporting timelines.

The most important finding was the difference between ADR exposure and reporting practice. Although 60.9% of students had observed an ADR during clinical practice, only 53% reported having reported an ADR. This suggests that knowledge and clinical exposure do not always lead to actual reporting behaviour.

The strong support for mandatory pharmacovigilance education, reported by 81% of participants, shows that students recognize the need for additional training. Practical pharmacovigilance education, clinical case discussions, ADR reporting exercises, causality assessment training, and direct exposure to ADR Monitoring Centres may help improve the confidence and reporting practices of pharmacy students.

Strengthening ADR reporting skills during pharmacy education may contribute to better pharmacovigilance practice in the future and ultimately support safer use of medicines and improved patient care.

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