

RESEARCH ARTICLE

Knowledge, practice, and attitude toward adverse drug reaction reporting among interns at a tertiary health care centre

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Received: September 21, 2017; **Accepted:** November 11, 2017

ABSTRACT

Background: Adverse drug reactions (ADRs) are an important public health problem in terms of mortality, morbidity as well as costs. However, studies worldwide have shown gross under-reporting with a rate of just 6–10%. Knowledge and attitude of health-care professionals about ADR greatly influence the extent of reporting. Educational interventions such as lectures, CMEs on pharmacovigilance (PvG) have proven to improve the rate of reporting. Hence, this study was conducted among new interns to assess their awareness, attitude, and practice patterns toward ADR reporting. **Aims and Objectives:** (1) To assess the knowledge and awareness regarding ADR reporting, (2) to assess attitude and practice patterns, and (3) to assess barriers to reporting among interns. **Materials and Methods:** A validated questionnaire based cross-sectional study was conducted among the medical interns in a tertiary health care center. Data were assessed by frequency, percentage. Statistical analysis was performed using SPSS version 22. **Results:** Of the 100 interns in the study, more than 80% were aware about who can report an ADR and the type of ADR. 90% knew that ADR can occur with drugs, vaccines and herbal products too. However, 52% did not know about the PvG center or reporting system in the hospital. Only 20% had reported an ADR, the common drug being penicillin. 97% had never filled the ADR notification forms. **Conclusion:** Knowledge regarding ADRs was found to be adequate with the positive and right attitude toward reporting, but the actual reporting practice was found to be poor and needs to be improved. Hence, it is essential to include lectures on ADR and PvG, hands-on training, CMEs and interactive workshops in the MBBS curriculum, to promote reporting of ADRs, particularly among interns.

KEY WORDS: Knowledge; Attitude; Practice; Interns; Adverse Drug Reaction

INTRODUCTION

Adverse drug reactions (ADRs) are an important public health problem in terms of mortality, morbidity as well as costs.^[1,2] Spontaneous reporting of ADRs by health-care

professionals (HCP) plays a major role in establishing the frequency of occurrence of known ADRs, detection of new, serious, and even unknown reactions. Studies worldwide have shown gross under-reporting with a rate of just 6–10%.^[3] The Government of India launched the pharmacovigilance (PvG) program of India in 2010.^[4] The Indian pharmacopoeia commission has been the national coordinating center since 2014, and nearly 173 ADR monitoring centers have been identified. India's contribution to the WHO global individual case safety reports database is 3%.^[5] According to a systematic review, the most important reasons for underreporting are inadequate knowledge and poor attitude among the HCPs.^[6]

Access this article online	
Website: www.njppp.com	Quick Response code
DOI: 10.5455/njppp.2018.7.0937311112017	

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Interns are an integral part of the health care and delivery system. They are the link between the consultants and patients and thus have an important role in ADR reporting in hospitals. Thus, their level of awareness regarding ADRs, beliefs, opinions, and attitudes toward reporting, the difficulties of spontaneous reporting of ADRs that they face will have an impact on the rate of reporting. A meta-analysis has shown that 45% of ADRs in inpatients were preventable.^[7] Several studies have highlighted that educational interventions improve the quantity and quality of ADRs.^[8-12] The inclusion of ADR related topics and PvG in the MBBS curriculum would enable to improve the knowledge among students who are the future doctors. Several medical colleges in India have included topics on PvG as part of the MBBS curriculum. Knowledge, attitude, practice (KAP)-based educational intervention is an important tool to reduce under-reporting of ADRs.^[13] This study thus would help to assess the impact of the educational intervention and also enable to suggest modalities for further improvement of the rate of reporting.

The following were the objectives of the study:

1. To assess the knowledge and awareness regarding ADR reporting.
2. To assess attitude and practice patterns.
3. To assess barriers to reporting among interns.

MATERIALS AND METHODS

We conducted a prospective questionnaire-based cross-sectional study at PES Institute of Medical Sciences and Research, Kuppam. The study was approved by the Institutional Ethics Committee. About 100 medical interns were chosen by convenient sampling, and they participated in the study after verbal assent.

Study tool: A pre-validated questionnaire^[3] was used to assess KAP and barriers to ADR reporting. The questionnaire was given to interns during an internship orientation session and collected after 30 min. The questionnaire was designed to assess the demographic details (age, sex, and specialty), their knowledge, attitudes, and practice pattern toward PvG. There were 24 questions in all (14 related to knowledge, 7 related to attitude and 4 to assess practice).

Statistical Analysis

We used descriptive statistics to summarize demographic data and to assess the response among interns to identify knowledge, attitude of ADR reporting. Collected data were assessed by frequency, percentage. Data were entered using Epi data version 3.1, statistical analyses were performed using Statistical Package for the Social Sciences version 22.0 software (SPSS Inc, Chicago, IL, USA).

RESULTS

Assessment of knowledge on ADR reporting and ADR burden: A total of 100 interns participated in the study. There were 10 questions to assess the awareness regarding PvG objective and importance about the type of ADR which can be reported, personnel who can report and also about serious ADR.

47% interns opined that the aim of PvG is patient safety while 46% were of opinion it is drug safety. 63% opined that reporting ADRs will help to create awareness among other HCP. Only 13% said doctors can report, 81% were aware that nurses, doctors, and pharmacists can report ADRs. 90% knew that it is necessary to report all types of ADR's. Figure 1 shows the knowledge on serious ADR. 90% of interns were aware that ADRs can occur with drugs, vaccines, and herbal products. 55% were of the opinion that all adverse reactions are not known by the time the drug is marketed. Table 1 summarized the response to other knowledge related questions.

Attitude Questions Regarding ADR Reporting

- A1: One should be certain of the ADR due to particular drug.
 A2: One should have a suspicion of possible ADR during treatment.
 A3: ADR reporting by one person can make a significant difference to the community.
 A4: ADR reporting in the hospital by HCP should be voluntary.
 A5: ADR reporting in the hospital should be mandatory.
 A6: ADR reporting in the hospital should be financially rewarded.

About 36% felt that one should be very certain of ADR due to a particular drug to report it to the PvG team. While 58% said that strong suspicion is adequate to report. 79% were of the opinion that ADR reporting by one person will make a difference to ADR database. Regarding making ADR reporting mandatory in hospital, 62% agreed while 29% felt it should be voluntary, and 5% opined that financial remuneration would be a better option.

Practice: Although 82% interns were aware of hospital PvG center a majority had never reported an ADR. 84% said they rarely come across an ADR and 71% said that only in suspected cases, ADR would be considered as a differential diagnosis. Only 3% could correctly identify the ADR notification forms. Only 20% had reported an ADR, and the most common drug was penicillin. After reporting an ADR, 40% said they would document the ADR in a file and also issue an alert card. Other responses are shown in Table 2.

Barriers to reporting: Ignorance about the ADR reporting system was the most common reason for not reporting as

52% were unaware. Confidence about accurately diagnosing an ADR was an important detriment to reporting as 36% said they could not diagnose. Excessive workload leading to time constraints was another reason in 19% interns; while 14% commented on lack of forms to report.

Role of PvG team: The interns showed a yearning to learn more about PvG and when asked about their expectations from the ADR monitoring team gave the following response as shown in Figure 2.

DISCUSSION

Interns play a pivotal role in providing quality health care. The very purpose of the internship is training and developing high professional standards.^[14] The importance of ADR reporting cannot be overemphasized. It is well known that ADRs are among the leading causes of morbidity and mortality. Knowledge, attitude, and practice of reporting thus are important to safeguard patient safety. In our study, we found that majority of interns were aware of the types of ADRs, what to report, who can report, importance of reporting, objective of PvG. Compared to studies conducted elsewhere in India, we found that the awareness was better.^[8,9] The reason for the improved level of awareness could be due to the inclusion of topics on PvG in the MBBS curriculum.

Adequate knowledge is very essential to inculcate the right attitude among interns. In our study 79% were of the opinion that ADR reporting even by one person will definitely make a difference to the database, highlighting that the interns had a positive attitude toward reporting. Other studies in India showed slightly lower percentage.^[15] Furthermore, 62% felt reporting should be mandatory as it decreases the morbidity and costs to the patient, this finding is similar to many other studies.^[15] Only 29% said voluntary reporting while 5% wished for financial incentives. Clearly over the past few years, there is an increasing positive attitude toward PvG.

The practice patterns, however, showed a very poor trend. 20% of interns had come across an ADR, but only 3% could correctly identify the reporting forms. The practice pattern as studies have shown across the globe is alarmingly poor. Only 6.5% doctors had reported at least one ADR in 6 months in an Italian study.^[16] Likewise in another study at Saudi 88.8% had never reported, submitted, or identified any ADR reports.^[17] According to a systematic review^[18] in 2016 based on 28 studies three-quarters (74.5%, 95% confidence interval 67.9–81.9; *P* < 0.001) of the sample declared that they never reported any ADR to PV centers.

Lack of training on how to report ADRs was the most important reason for under-reporting, similar to the low percentage of training imparted to health-care professionals in previously reported studies from Indore^[19] and Trivandrum.^[20] Reporting

Table 1: Awareness among interns on ADR and pharmacovigilance

Parameters	Frequency (%)
Frequency of ADRs	
Never come across	1
Rarely	84
Frequently	14
Drugs banned/withdrawn	
Rofecoxib	90
Phenylpropanolamine	48
Awareness of AMC in hospital	
Know	83
Don't know	13

ADR: Adverse drug reaction

Table 2: Procedure practiced in case of an ADR

Procedure practiced	Frequency (%)
Document the ADR in the patient file	44
Document and issue an alert card	40
Caution the patient about the reaction	37
Wanted to issue an alert card but card not available	7

ADR: Adverse drug reaction

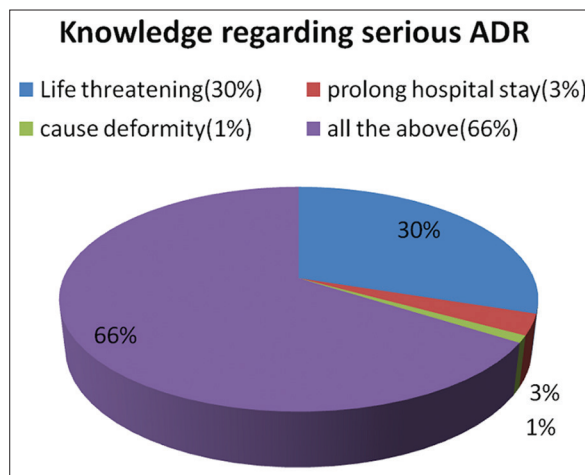


Figure 1: Awareness of serious adverse drug reactions among interns

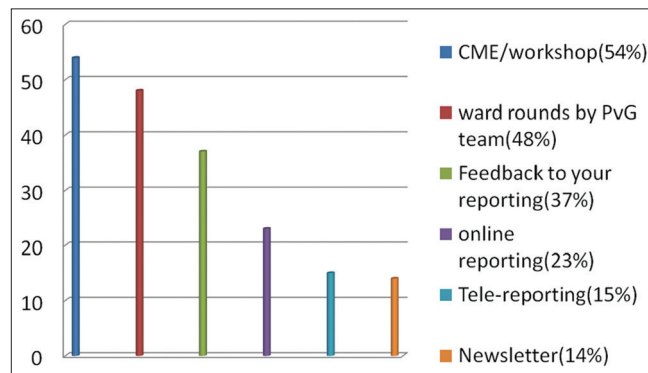


Figure 2: Expectations of interns from the pharmacovigilance team

a certain number of ADRs during an internship can be made mandatory to promote reporting culture.

This finding clearly highlights the need for regular and repeated educational interventions particularly regarding how to identify and how to report ADRs. Most of the medical colleges in India have incorporated lecture classes on ADR and PvG, but the practical application of that knowledge seems to be lacking. Very few colleges have practical exercises on ADR in their curriculum presently. Incorporation of clinical cases particularly to discuss ADRs and hands-on training of documenting and reporting should be made a mandatory practical exercise in pharmacology curriculum.

Low confidence in diagnosing an ADR has been found to be one of the detriments. Good knowledge about drugs, drug interactions and adverse effects of drugs would improve the confidence in making a diagnosis.^[21] This again emphasizes the necessity to integrate pharmacology teaching with clinical subjects in MBBS Phase III.^[21,22] Context learning has been proven to be more effective than sequential learning.^[21-23] The present curriculum in pharmacology could be revised and appraised to incorporate more recent, relevant and practically applicable syllabus. Internship is meant to orient and equip the MBBS graduates to apply all the theoretical knowledge into actual clinical practice. A mandatory log of procedures, techniques are to be completed by them during the 1 year period. Inclusion of ADR reporting, as one of the mandatory practices, would help in inculcating the culture of reporting ADRs. Educational interventions such as CMEs, conferences, training workshops on PvG for students, interns and HCPs would thus improve the rate of reporting.

Limitations

The sample size was limited to only 100 interns, and so results cannot be extrapolated to all interns. Being a single center study results cannot be generalized. The actual impact of educational intervention in the form of an increase in the rate of reporting could not be assessed in this study.

CONCLUSION

Knowledge regarding ADRs was found to be adequate in the majority of interns. They also had the right and positive attitude, however, the actual reporting practice was found to be poor and needs to be improved. Integrating pharmacology in MBBS Phase III and updating the curriculum to facilitate application of knowledge to practice is the need of the hour. Educational interventions for all HCPs should be conducted at repeated and regular intervals particularly training workshops on how to report ADRs will improve both quality and rate of reporting.

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How to cite this article: Leena A, Jose M. Knowledge, practice, and attitude toward adverse drug reaction reporting among interns at a tertiary health care centre. Natl J Physiol Pharm Pharmacol 2018;8(4):465-469.

Source of Support: Nil, **Conflict of Interest:** None declared.