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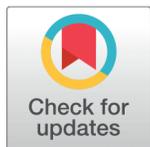
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## Evaluation of Awareness of Knowledge, Attitude and Practices of Nursing Students on Monitoring and Reporting of Adverse Drug Reactions in a Tertiary Care Hospital

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### Abstract

To assess the Knowledge, Attitude and Practices of nursing students on monitoring and reporting of adverse drug reactions in a tertiary care hospital. This questionnaire based study was conducted in a tertiary care hospital on 85 Prefinal and final year nursing students. The study instrument was a pre designed questionnaire which included the Knowledge of the ADRs reporting, the attitudes towards the reporting, and the factors which could hinder the reporting. The students were given an educative and interactive session for clearance of their understanding about Pharmacovigilance. The post-session questionnaire was also completed to assess their understanding. A total of 85 students participated. The median knowledge, attitude scores before the intervention were 42.5%, 46.6% respectively. After the intervention the scores increased significantly to 89.4%, 98.8% respectively.

**Keywords:** Adverse Drug Reactions; Pharmacovigilance; Questionnaire; Knowledge Attitude and Practices; Nursing students

### Introduction

WHO defined adverse drug reactions (ADRs) as, any noxious, unintended and undesired effect of a drug which occurs at the doses which are used in humans for prophylaxis, diagnosis or therapy of disease or modification of physiological

function. <sup>(1)</sup> ADRs are one the major drug related problems associated with pharmacotherapy and important public health problem imposing economic burden on the society and health care systems and one of the causes of hospitalization varying between 5-13%. <sup>(2)</sup>

Modern approaches and newer strategies have changed the way in which diseases are being treated and prevented. In spite of all their benefits, adverse effects due to medicines are common cause of morbidity and mortality worldwide.<sup>(3)</sup>

Pharmacovigilance is the science which relate to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.<sup>(4)</sup> Spontaneous and voluntary reporting system is one of the basic methods for post-marketing surveillance and is most effective method of acquiring ADR information especially new and serious ADRs.<sup>(5)</sup> Under reporting of ADR is very common, as it accounts for up to 90-95% and is the major shortcoming of spontaneous reporting system. It is also known to delay early detection of ADRs & can increase associated morbidity and mortality.<sup>(2,6)</sup> Health care professionals (HCPs) have contributed enormously to the detection, monitoring and reporting of these adverse events experienced by the patients. Among HCPs nurses spend more time in patient care, and they play an important role in monitoring, detection and reporting of adverse event (AE).<sup>(3)</sup> They observe the effects and adverse reactions of medicines after administration and take interventions as per consultant's advice.<sup>(7)</sup> Knowledge and Attitude of nurses towards reporting of ADRs play a significant role in spontaneous reporting system.<sup>(2)</sup> In order to improve the participation of HCPs in spontaneous reporting, it might be necessary to design strategies that modify both intrinsic (Knowledge, Attitude, Practice) and extrinsic (Relationship between HCPs and their patients, the health system and the regulators) factors. Knowledge, Attitude and Practices regarding ADR reporting has not been studied extensively in India and more so among nurses.<sup>(8)</sup> Hence we planned to conduct this questionnaire basestudy among nursing students of our college.

### Methodology

This questionnaire based study was conducted in a tertiary care hospital. It was conducted on 85 prefinal and final year nursing students posted in various departments. Consent was taken before starting the study. The study instrument was a pre designed questionnaire which was structured to obtain information on the Knowledge of the ADRs reporting, the attitudes towards the reporting, and the factors which could hinder the reporting among the nursing students. Suggestions on the possible ways to improve the ADR reporting were also taken in the form of feedback. The students were requested to complete the questionnaire and to return it within one day. The students were given an educative and interactive session for their understanding about pharmacovigilance. The post-session questionnaire was also completed to assess their understanding

### Results

A total of 85 nursing students studying in prefinal and final year, working in various departments participated in the study. It was found that average age of the students was 20.36 years. The questionnaire sheet consisting of 27 questions were distributed to students and all were duly filled, returned back with a response rate of 100%. The average time taken to complete the questionnaire was 30 min and the mean score of completeness of the questionnaire was 24.6 out of 27. The questionnaire was divided into 3 sections of Knowledge (8 questions), Attitude (3 questions) & Practice (1question) remaining questions were not considered for analysis. All the calculation was done by using EPI info software. Table 1 Shows pretest and post-test knowledge scores about Adverse drug reactions (ADRs).

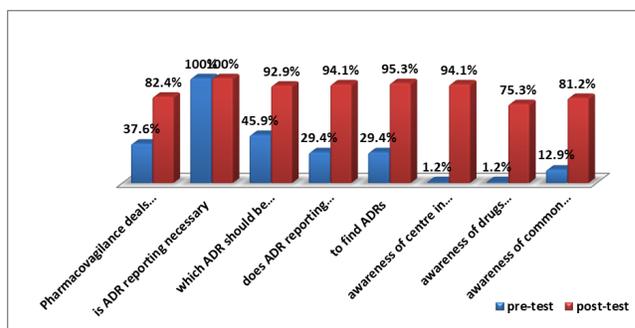


Fig 1. Comparison of percentages pretest & posttest knowledge about ADRs

Initially only 37.6% of the students were aware about what Pharmacovigilance deals with. Among the students 45.9% stated that they would like to report all forms of ADRs, while 54.1% said that they would like to report only serious forms of ADRs and 29.6% said they would like report ADRs caused by new drug. Most respondents however, did not emphasize on reporting of ADRs to herbal & non-allopathic medicines, unknown ADRs to old drugs, ADRs to vaccines. About ADR reporting centre, only 1.2% students knew that regional reporting centre is located in JSS medical college Mysore. After the educative intervention 100% of the students said that ADR reporting is necessary. 70.6% said that ADR reporting damages the professional image, and they will find ADRs by asking patients and their relatives, by monitoring the patient records. Only about 1.2% of students were aware about drugs banned due to ADRs and 12.9% were aware about common ADRs along with medicines causing them. After the educative intervention 82.4% of the students knew that what pharmacovigilance deals with. 92.9% of the students were of the opinion that they would like to report all forms of ADRs irrespective of seriousness, drugs (old/new). 94.1% said ADR reporting do not damages professional image. 94.1% were aware about location of ADR reporting center is in

**Table 1. Comparison of pretest & post test knowledge scores of ADRs**

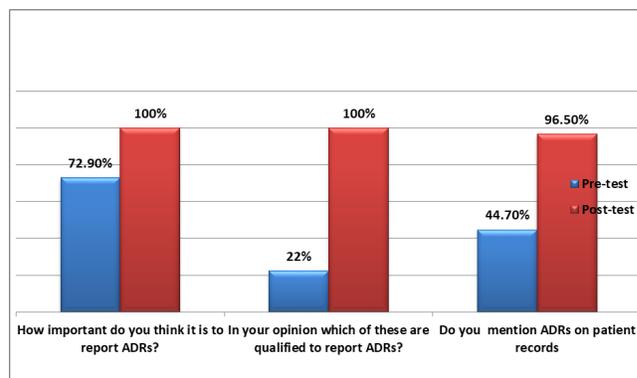
| Knowledge questions  | Pre test                     |              | Post test                  |              |
|--|------------------------------|--------------|----------------------------|--------------|
|  | Right answer                 | Wrong answer | Right answer               | Wrong answer |
| Pharmacovigilance deals with   | 32(37.6%) (all of the above) | 53(62.4%)    | 70(82.4%) All              | 15(17.6%)    |
| Is ADR reporting necessary   | 85(100%) (yes)               | 0%           | 85(100%) Yes               | 0%           |
| Which ADR should be reported   | 39(45.9%) (all)              | 46(54.1%)    | 79(92.9%) All forms        | 6(7.1%)      |
| ADR reporting damages professional image                             | 60(70.6%) (No )              | 25(29.4%)    | 80(94.1%) No               | 5(5.9%)      |
| To find ADRs   | 60(70.6%)                    | 25(29.4%)    | 81(95.3%) all of the above | 4(4.7%)      |
| Are you aware of any centre in Karnataka where you can report ADRs.? | 1(1.2%), JSS Mysore          | 84(98.8%)    | 80(94.1%) JSS Mysore       | 5(5.9%)      |
| Awareness of drugs banned due to ADRs?                               | 1(1.2%) Aware                | 84(98.8%)    | 64(75.3%) Aware            | 21(24.7%)    |
| Awareness about common ADRs along with medicines can cause them?     | 11(12.9%) Aware              | 74(87.1%)    | 69(81.2%) Aware            | 16(18.8%)    |

JSS medical college Mysore, Karnataka. 75.3% knew drugs banned due to ADRs and 81.2% students listed common ADRs and drugs causing them.

Table 2 shows Pretest and post-test Attitude scores towards reporting of ADRs. Initially 72.9% of the respondents thought that it is very important to report ADRs. Only 22.3% were knowing all (physician, nurse, dentist, physiotherapists, pharmacist, patients, health workers) can report ADRs, whereas 57% said only physician, 49% said only nurses and 61.8% said only pharmacist can report ADRs. Only 44.7% of the respondents were of opinion to mention ADRs always on patient records. 100% of the respondents said that it is very important to report ADRs and they were aware that any medical and paramedical professional such as physician, nurse, dentist, physiotherapists, pharmacist, patients, and health workers can report ADRs. 96.5% said that they will always mention ADRs on patient records from then onwards.

**Table 2. Pretest & post test attitude scores toward reporting of adverse drug reactions**

| Attitude questions   | Pre test     |              | Post test    |              |
|--|--------------|--------------|--------------|--------------|
|  | Right answer | Wrong answer | Right answer | Wrong answer |
| How important do you think it is to report ADRs?             | 62 (72.9%)   | 23 (27.1%)   | 85 (100%)    | 0            |
| In your opinion which of these are qualified to report ADRs? | 19 (22.3%)   | 66 (77.6%)   | 85 (100%)    | 0            |
| Do you mention ADRs on patient records                       | 38 (44.7%)   | 47 (55.3%)   | 82 (96.5%)   | 3 (3.5%)     |



**Fig 2.** Comparison Of Percentages Pretest & Post Test attitude towards reporting of ADRs

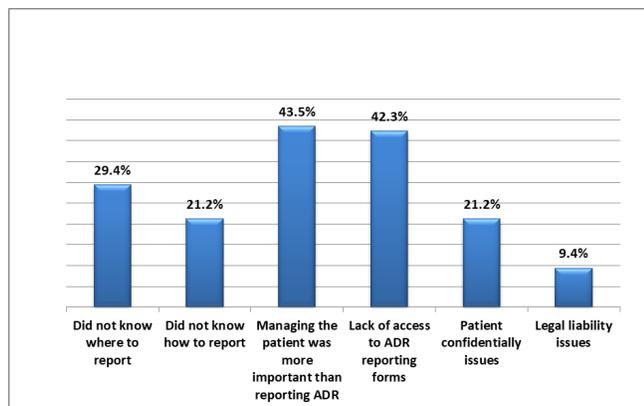
Table 3 shows the reasons given by the students for not reporting ADRs. The major factors that could discourage from reporting as perceived were, lack of knowledge on how (44.2%), where (49.4%) to report ADRs, lack of easy access to ADR reporting forms (42.3%), managing the patient was most important than reporting ADR (43.5%), and patient confidentiality issues (21.2%). The median knowledge, attitude scores before the intervention were 42.5%, 46.6% respectively. After the intervention the scores increased significantly to 89.4%, 98.8% respectively.

### Discussion

ADR is a very important and essential component of Pharmacovigilance systems worldwide and is essential part of safety surveillance of marketed drugs. Studies have been done previously to evaluate the knowledge, attitude and practices of

**Table 3. Practical factors affecting reporting of adverse drug reactions**

| Question  | Did not know where to report | Did not know how to report | Managing the patient was more important than reporting ADR | Lack of access to ADR reporting forms | Patient confidentially issues | Legal liability issues |
|---|------------------------------|----------------------------|--|---------------------------------------|-------------------------------|------------------------|
| Factors that discourage you from reporting ADRs | 25 (29.4%)                   | 18 (21.2%)                 | 37 (43.5%)   | 36 (42.3%)                            | 18 (21.2%)                    | 8 (9.4%)               |



**Fig 3.** Practical factors that discourages reporting of ADRs

nursing students in various colleges before & after an educational awareness. The present study was conducted among the pre-final and final year nursing students. An overall response rate was 100%. From the results, it was noticed that knowledge on the definition of Pharmacovigilance was low. The student's knowledge on the location of the centre for adverse drug reaction reporting was very poor. The present study result concurs with earlier reports of similar studies.<sup>(9-11)</sup> Less than half of the students opined that they would report all the ADRs observed by them. This was similar to the responses obtained in a study done in northern Italy.<sup>(12)</sup> Where the doctors considered all suspected reactions to any marketed drug and all serious suspected ADRs as worth reporting. Some of them also said that they would report only serious ADRs or ADRs to new drugs which is similar to a study done in Nigeria and Mumbai the respondents would mainly report ADRs to either new drugs or serious ADRs to established drugs.<sup>(13,14)</sup> Spontaneous reporting of ADRs by patients and healthcare personnel, other than doctors, is practiced in many parts of the world.<sup>(15-17)</sup> This was not recognized by the respondents in our study, less than half identified patients, physiotherapists, nurses, pharmacists, and dentists to be capable of reporting ADRs. These findings were also observed in the Mumbai study where respondents did not identify nurses and pharmacists as qualified reporters. This again indicates a lack of awareness of the principles and practice of Pharmacovigilance among the respondents.<sup>(12)</sup>

In our study ADR reporting was considered to be very important by a large majority of the respondents, the reasons for reporting, as cited by a majority of the respondents were, improving the safety of the patients and identifying new ADRs which is similar to a study conducted on prescribers. The reasons for reporting ADRs, as reported by Biriell and Edwards, are a desire to contribute to medical knowledge, identifying a previously unknown ADR, reactions to new drugs, and severity of the ADR.<sup>(18)</sup>

Even as ADR reporting was considered to be important by a large majority of the respondents, the actual reporting was very low. Just 8% of the respondents stated that they had reported an ADR previously. Similarly, the Mumbai study also cited similar findings of under-reporting of ADR to any of the national ADR monitoring centers (2.9%) in spite of 72.9% of the respondents considering it important.<sup>(14)</sup> Various studies from developed countries like UK & the US have shown higher rate of ADR reporting & relatively higher awareness & knowledge about Pharmacovigilance among HCPs.<sup>(19-21)</sup> In a recent study conducted among pharmacists regarding knowledge & attitude towards herbal medicine the median knowledge scores improved after the educational intervention.<sup>(22)</sup> The overall median knowledge, attitude & the total scores improved significantly after the awareness. Difference in scores of knowledge & attitude were noted among certain groups of respondents before & after the awareness.<sup>(23)</sup> Similarly in our study also median knowledge, attitude & the total scores improved significantly after the awareness session.

Only few students were aware that nurses are also important health care professionals to report ADR. This suggests that Pharmacovigilance topic is either not incorporated sufficiently or not incorporated in the curriculum and there is need of information regarding the topic among these students. Educational training programs on the topic can enhance their knowledge and perception as recommended by different researchers.<sup>(24,25)</sup> The results of the present study showed that most of the students had the positive perception towards ADR reporting. But only very few of the participants perception was that pharmacist is one of the most important health care personnel to report ADR. These findings are similar to the results of healthcare professionals in other studies.<sup>(26-30)</sup> Under-reporting of ADRs is a worldwide

phenomenon and this has been established from previous studies.<sup>(31-34)</sup> The determinants of under-reporting of our study are management of patient was more important than reporting, lack of access to reporting forms, not knowing how to and where to report this is similar to previous studies.<sup>(35-37)</sup> The effect of intervention on retention of information was not assessed as the knowledge, attitude and practice assessment is yet to be conducted among the same respondents after few months. Further such studies will help in voluntary reporting of adverse drug reactions which can enhance the of Pharmacovigilance program in India.

## Conclusion

The intervention was effective in improving the nursing student's knowledge, attitude towards ADRs & Pharmacovigilance. Further such studies will help in voluntary reporting of adverse drug reactions which can enhance the of Pharmacovigilance program in India.

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