ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE RELATED TO PHARMACOVIGILANCE AMONG THE HEALTHCARE PROFESSIONALS IN A TEACHING HOSPITAL IN CENTRAL INDIA: AN QUESTIONNAIRE STUDY

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ABSTRACT

Aim: The present cross sectional questionnaire survey was conducted with an aim of assessing the knowledge, attitude and practice related to pharmacovigilance among the healthcare professionals in a teaching hospital located in central India region. Materials and Methods: To assess the demographic details of the healthcare professionals, their knowledge, attitude and practices towards pharmacovigilance and ADR reporting; a predesigned, structured, close-ended 18 item questionnaire was used. Results: A total of 392 questionnaires were distributed among the healthcare professionals. It was found that only 38.01% healthcare professionals comprising of 54.43% medical, 38.01% nursing and 19.01% dental professionals were aware regarding the existence of pharmacovigilance program of India. While, only 40.56% healthcare professionals felt that ADR monitoring centre should be established in every hospital. Similarly, very few healthcare professionals...
professionals i.e. 6.12% have ever reported ADR to pharmacovigilance centre. **Conclusion:** The results of our study indicate that majority of the healthcare professionals had a poor knowledge and attitude about pharmacovigilance. There was a huge gap between the ADR experienced and ADR reported by the healthcare professionals especially among dentist and nursing staff. It has been advised that the healthcare professionals; especially dental and nursing, should be trained properly on ADR reporting to improve the current scenario in the pharmacovigilance programme of the country.

**KEYWORDS:** Pharmacovigilance, Healthcare professionals, adverse drug reactions, ADR reporting.

**INTRODUCTION**

Safety and efficacy are the two major concerns about a drug. The efficacy of a drug can be quantified with relative ease; the same cannot be said about safety. This is because, the adverse effect of a drug may be uncommon (but very serious) and many patients may be affected or subjected to a potential risk before the relationship with the drug is established.\(^{[1,2]}\)

According to Barker, there are three possible actions of drug: the one you want, the one you don’t want, and the one you don’t know about.\(^{[3]}\)

Adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function”.\(^{[4]}\)

Adverse Drug Reactions (ADRs) are an imperative public health crisis striking a substantial fiscal burden on the society and health-care systems. It is one of the significant basis of hospitalization varying between 5- 20%.\(^{[3,5-7]}\) Furthermore, according to Uppsala Monitoring Centre (UMC, WHO), Sweden; which maintains the international database of the adverse drug reaction reports, only 6-10% of all the ADRs are reported.\(^{[8]}\) Hence, the detection, recording and reporting of adverse drug reactions becomes vital and health experts should be encouraged to execute this appropriately to ensure safer usage of medicines. For this purpose, the concept of pharmacovigilance has been taken place.

WHO defines pharmacovigilance as “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related
problems”.[9] In an effort to strengthen the pharmacovigilance in India, government has initiated pharmacovigilance programme of India (PvPI). Similarly, the Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have established ADR monitoring centres in many hospitals in major cities of India.[10] Despite these efforts and the presence of a large number of tertiary care facilities, pharmacovigilance is still in its infancy. The major reason behind this is poor understanding of the healthcare professionals towards the existing pharmacovigilance program.[11]

In India, the gross under reporting of ADRs is a cause of concern, the reasons for which may be due to lack of trained staff and lack of awareness regarding detection, communication and spontaneous monitoring of ADRs among the healthcare professionals (physicians, nurses, pharmacist, and dentists).[12,13]

There is a requirement for constant training and enactment of regulations for ADR reporting among healthcare professionals. Previous reported study has found that underreporting of ADR is related with shortcomings in the knowledge and attitude among healthcare professionals.[14,15]

It is important for healthcare professionals to know how to report and where to report an ADR. The active participation of healthcare professionals in the pharmacovigilance program can improve the ADR reporting.[16]

Therefore, the present study was contemplated and done to assess the knowledge, attitude and practices of the healthcare professionals working in a teaching hospital located in Central India region regarding ADRs reporting, to get an insight into the reasons for non-reporting and to suggest possible ways of improving spontaneous reporting based on our findings.

MATERIALS AND METHODS

Study design and settings: A cross sectional questionnaire survey was conducted in People’s university, Bhopal, Madhya Pradesh, India.

Source of data: The required information for the study was obtained from all the available healthcare professionals (medical, dental and nursing professionals) of People’s university, Bhopal, Madhya Pradesh, India.
Study period: The study was conducted for a period of 2 months from October 2014 to December 2014.

Ethical approval: The ethical approval was obtained from the ethical committee before the commencement of study.

Selection criteria: All the available healthcare professionals’ i.e. medical, dental and nursing professionals who gave their informed consent and who were working at the hospital during the study period were included in the study. The healthcare professionals who did not respond were excluded from the study.

Sample size: A total of 392 subjects including 169 medical, 142 dental and 81 nursing professionals participated in the study.

Assessment & structure of a questionnaire: To assess the demographic details of the healthcare professionals, their knowledge of pharmacovigilance, attitudes towards pharmacovigilance, and their practice on ADR reporting; a predesigned, structured, close-ended 18 item questionnaire, which had been designed based on the primary objective of the study was used. The interview was conducted in English. To design a questionnaire; earlier studies for assessing KAP of ADR reporting were also reviewed. [11,16-18]

The details of the questionnaire are as follows.

a. Knowledge related questions: The assessment of participant’s knowledge of pharmacovigilance included 5 questions (items) on Definition and purpose of Pharmacovigilance, responsibility of reporting ADRs, knowledge of National Pharmacovigilance Programme, and regulatory body responsible for monitoring ADRs.

b. Attitude related questions: The assessment of participant’s attitudes towards pharmacovigilance included 4 questions (items) on necessity of reporting ADRs, teaching of pharmacovigilance, prevention of ADR, and opinion about ADR monitoring centre.

c. Practice related questions: The assessment of participant’s practice on ADR reporting included 8 questions (items) on experience of ADRs, Report to pharmacovigilance centre, ADR reporting form, training to report ADRs, reporting of serious adverse event, identification of rare ADRs, methods to monitor ADRs of new drug, presence of pharmacovigilance Committee in institute.
d. One question was asked to determine the reasons for underreporting, i.e. factors discouraging from reporting ADRs.

Pilot study: A preliminary pilot pretesting of the questionnaire was done on 20 randomly selected healthcare professionals of the institute. The purpose behind this was to know the practical and communication difficulties while surveying. Also the pilot testing allowed us to modify the ambiguous and unsuitable questions. The reliability and internal consistency of the questionnaire based on Cronbach alpha coefficient was between 0.7 and 0.8. Furthermore, the questionnaire after its final drafting was reviewed by subject experts in the field of Clinical Pharmacology as regards the face validity, content validity and the relevance and comprehensiveness.

Method of collection of Data: All the subjects (medical, dental and nursing professionals) who were available at the time of survey were approached personally by the principal investigator. The subjects were asked to respond to each item according to the response format provided in the questionnaire. Response format included multiple choice questions in which the subjects were asked to choose an appropriate response from provided list of options. The investigator recorded the responses of the subjects in the printed format. The completed response format was carefully checked by the investigator.

Statistical analysis: All the obtained data was entered into a personal computer on Microsoft excel sheet and analyzed using Statistical Package for Social Science (SPSS, IBM, Chicago, USA) version 20. The variables were characterized by their frequencies, and differences between groups were assessed by using Chi-square tests. The statistically significant level was set at less than 0.05 with confidence interval of 95%.

RESULTS
A total of 392 questionnaires were distributed among the healthcare professionals who comprised of a highest of 169 (43.11%) medical professionals followed by 142 (36.22%) dental and 81 (20.66%) nursing professionals. The most of the healthcare professionals were males i.e. 64.54% compared to 35.45% females. Furthermore, the mean age of the study participants was 33.67 years. (Table 1)
Table 1: Showing demographic details of the study subjects.

<table>
<thead>
<tr>
<th>Demographic details</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>253 (64.54%)</td>
</tr>
<tr>
<td>Females</td>
<td>139 (35.45%)</td>
</tr>
<tr>
<td>Mean age (in years)</td>
<td>33.67±11.14</td>
</tr>
<tr>
<td>Age distribution (in years)</td>
<td></td>
</tr>
<tr>
<td>19-25</td>
<td>59 (15.05%)</td>
</tr>
<tr>
<td>26-30</td>
<td>144 (36.73%)</td>
</tr>
<tr>
<td>31-35</td>
<td>112 (28.57%)</td>
</tr>
<tr>
<td>36-40</td>
<td>41 (10.45%)</td>
</tr>
<tr>
<td>&gt;40</td>
<td>36 (9.18%)</td>
</tr>
</tbody>
</table>

**Assessment of pharmacovigilance related knowledge**

While assessing the knowledge of the healthcare professionals on pharmacovigilance, it was found that a highest of 70.14% medical and 69.13% nursing professionals gave correct response regarding the definition of pharmacovigilance compared to 42.95% dental professionals. The difference among healthcare professionals was statistically significant (p=0.001).

According to 59.43% healthcare professionals who included 66.27% medical, 59.25% nursing and 51.40% dental professionals; the most important purpose of pharmacovigilance is to identify a safety of the drug. The difference among healthcare professionals was statistically significant (p=0.002).

Only 48.72% healthcare professionals who comprised of 68.63% medical, 35.91% dental and 29.62% nursing professionals believed that ADR reporting is a professional obligation for them. The difference among the healthcare professionals was statistically significant (p=0.001).

Similarly, only 38.01% healthcare professionals comprising of 54.43% medical, 38.01% nursing and 19.01% dental professionals were aware regarding the existence of
pharmacovigilance program of India. Furthermore, only few i.e. 28.57% healthcare professionals including 51.47% medical, 12.67% dental and 8.64% nursing professionals were aware that the regulatory body responsible for monitoring ADRs in India is Central Drugs Standard Control Organization (CDSCO). The differences among the healthcare professionals were statistically significant (p=0.001). (Table 2)

Table 2: Showing pharmacovigilance related knowledge of the healthcare professionals.

<table>
<thead>
<tr>
<th>Knowledge related Questions</th>
<th>Medical professionals n (%)</th>
<th>Dental professionals n (%)</th>
<th>Nursing professionals n (%)</th>
<th>Total N (%)</th>
<th>Statistical inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct response</td>
<td>Incorrect response</td>
<td>Correct response</td>
<td>Incorrect response</td>
<td>Correct response</td>
<td>Incorrect response</td>
</tr>
<tr>
<td>Define pharmacovigilance</td>
<td>118 (70.14%)</td>
<td>50 (29.86%)</td>
<td>61 (42.95%)</td>
<td>61 (57.05%)</td>
<td>56 (69.13%)</td>
</tr>
<tr>
<td>The most important purpose of pharmacovigilance is</td>
<td>112 (68.27%)</td>
<td>57 (31.73%)</td>
<td>73 (51.40%)</td>
<td>40 (48.59%)</td>
<td>46 (59.25%)</td>
</tr>
<tr>
<td>The healthcare professionals responsible for reporting ADRs in a hospital are</td>
<td>116 (68.43%)</td>
<td>53 (31.57%)</td>
<td>51 (35.52%)</td>
<td>51 (64.88%)</td>
<td>24 (29.62%)</td>
</tr>
<tr>
<td>Do you know the existence of Pharmacovigilance Programme in India?</td>
<td>92 (54.49%)</td>
<td>77 (45.51%)</td>
<td>27 (19.02%)</td>
<td>115 (80.98%)</td>
<td>36 (43.03%)</td>
</tr>
<tr>
<td>In India which regulatory body is responsible for monitoring ADRs?</td>
<td>87 (51.49%)</td>
<td>82 (48.52%)</td>
<td>16 (12.63%)</td>
<td>124 (67.32%)</td>
<td>37 (44.94%)</td>
</tr>
</tbody>
</table>

Assessment of pharmacovigilance related attitude

While assessing the pharmacovigilance related attitude of the healthcare professionals it was found that a total of 75.51% healthcare professionals comprised of 81.06% medical, 72.53% dental and 69.13% nursing professionals; agreed that reporting of ADR is necessary. Overall, 82.39% healthcare professionals i.e. 89.34% medical, 78.87% dental and 74.07% nursing professionals were of the view that pharmacovigilance should be taught in detail to healthcare professionals. The differences among the healthcare professionals were statistically significant (p=0.004).
In continuation with this, only few i.e. 23.97% healthcare professionals including 47.33% medical, 7.04% dental and 4.93% nursing professionals have read articles on prevention of ADRs. Furthermore, only 40.56% healthcare professionals felt that ADR monitoring centre should be established in every hospital. This difference among healthcare professionals were statistically significant (p=0.001). (Table 3)

Table 3: Showing pharmacovigilance related attitude of the healthcare professionals.

<table>
<thead>
<tr>
<th>Attitude related Questions</th>
<th>Medical professionals n (%)</th>
<th>Dental professionals n (%)</th>
<th>Nursing professionals n (%)</th>
<th>Total n (%)</th>
<th>Statistical reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think reporting of adverse drug reaction is necessary?</td>
<td>Yes  137 (11.06%)</td>
<td>Yes 31 (10.59%)</td>
<td>Yes 39 (27.46%)</td>
<td>Yes 26 (10.89%)</td>
<td>X² value= 5.27 p value 0.017</td>
</tr>
<tr>
<td>Do you think Pharmacovigilance should be taught in detail to healthcare professionals?</td>
<td>Yes 355 (83.40%)</td>
<td>Yes 18 (10.05%)</td>
<td>Yes 39 (21.12%)</td>
<td>Yes 115 (55.56%)</td>
<td>X² value= 10.71 p value 0.004</td>
</tr>
<tr>
<td>Have you anytime read any article on prevention of adverse drug reactions?</td>
<td>Yes 90 (47.13%)</td>
<td>Yes 18 (14.59%)</td>
<td>Yes 39 (39.93%)</td>
<td>Yes 17 (17.17%)</td>
<td>X² value= 19.03 p value 0.001</td>
</tr>
<tr>
<td>What is your opinion about establishing ADR monitoring center in every hospital?</td>
<td>Yes 101 (59.76%)</td>
<td>Yes 68 (40.23%)</td>
<td>Yes 41 (28.87%)</td>
<td>Yes 77 (55.06%)</td>
<td>X² value= 46.76 p value 0.001</td>
</tr>
</tbody>
</table>

**Assessment of pharmacovigilance related practices**

On assessing the Pharmacovigilance related practices it was found that only 52.29% healthcare professionals who included 61.53% medical, 64.19% nursing and 34.50% dental professionals have experienced ADRs in patient during their practice. Similarly, very few healthcare professionals i.e. 6.12% have ever reported ADR to pharmacovigilance centre. Highest among them were the medical professionals (14.20%). While, none of the dentist and nursing professionals have never reported the ADRs. The differences between healthcare professionals were statistically significant (p=0.001).

Furthermore, it was observed that only 40.82% medical, 4.93% nursing and 3.52% dental professionals have ever seen the ADR reporting form. In accordance with this, it was found that only 37.86% medical, 16.04% nursing and none of the dental professionals have been
trained on reporting on ADR. The differences among the healthcare professionals were statistically significant (p=0.001). (Table 4)

Table 4: Showing pharmacovigilance related practices among the healthcare professionals.

<table>
<thead>
<tr>
<th>Practice related/Questions</th>
<th>Medical professionals n (%)</th>
<th>Dental professionals n (%)</th>
<th>Nursing professionals n (%)</th>
<th>Total N (%)</th>
<th>Statistical inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ever experienced adverse drug reactions in your patient during your professional practice?</td>
<td>104 (61.53%)</td>
<td>49 (34.50%)</td>
<td>52 (64.19%)</td>
<td>205 (52.29%)</td>
<td>X² Value = 28.39; P value = 0.001</td>
</tr>
<tr>
<td>Have you ever reported adverse drug reaction (ADR) to the pharmacovigilance center?</td>
<td>24 (14.20%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>24 (6.12%)</td>
<td>X² Value = 33.73; P value = 0.001</td>
</tr>
<tr>
<td>Have you ever seen the ADR reporting form?</td>
<td>69 (40.82%)</td>
<td>5 (3.52%)</td>
<td>4 (4.93%)</td>
<td>78 (19.89%)</td>
<td>X² Value = 81.71; P value = 0.001</td>
</tr>
<tr>
<td>Have you ever been trained on how to report ADR?</td>
<td>64 (37.86%)</td>
<td>0 (0.0%)</td>
<td>13 (16.04%)</td>
<td>77 (19.64%)</td>
<td>X² Value = 70.94; P value = 0.001</td>
</tr>
</tbody>
</table>

Additionally, a highest of 95.66% healthcare professionals agreed that there is no pharmacovigilance committee in their institution. While exploring the factors discouraging from reporting ADRs it was found that 70.42% dental and 66.27% medical professionals felt it difficult to decide whether the ADR has occurred or not. On the other hand, 83.95% nursing professional had lack of time to report the ADR. (Figure 1 & 2)

Figure 1: Showing response of the healthcare professionals in relation to the presence of Pharmacovigilance Committee in the Institute.
DISCUSSION

During the developmental phase of a drug a good deal is known about its therapeutic activity but rather less about its safety because the clinical trials are conducted in a controlled environment in a lesser number of patients and subjects. Once a drug gains entry into the market it will be prescribed by hundreds of doctors to thousands of patients belonging to different age groups. The scenario is complicated when there are ethnic variations, presence of co-morbid conditions and concomitant medications. During this phase only unusual and rare ADRs are encountered. So, if we have a system which can help us determine any new information available in relation to their safety profile can be critically useful. And since there are considerable social and economic consequences of ADRs, there is a need to engage healthcare professionals, in a well-structured program to build synergies for monitoring ADRs. ADR reporting is of prime importance in the success of any pharmacovigilance program. So the cross-sectional questionnaire survey was conducted with the intention of assessing the outlook of prescribers towards ADRs and pharmacovigilance. The current study was conducted in a central India region which included a total of 392 healthcare professionals i.e. 169 (43.11%) medical, 142 (36.22%) dental and 81 (20.66%) nursing professionals. The Response rate reported in our study was highest (100%) than that reported in other studies.
It was observed that the awareness about ADR among all the healthcare professionals was very low. In fact, one of the major findings of our study is that the percentage of awareness among the dental and nursing staff was surprisingly negligible. This indicates a serious issue of concern and immediate measures should be taken regarding this as both these professionals are an integral part of our healthcare system.

Most of the healthcare professionals (75.51%) accepted that reporting ADR is necessary and pharmacovigilance should be taught in detail to healthcare professionals. These findings are in correlation with findings of a study conducted by Gupta et al. [11]

Only 38.01% healthcare professionals knew the existence of pharmacovigilance programme of India (PvPI). Whereas only few i.e. 28.57% healthcare professionals knew that in India the Central Drugs Standard Control Organization (CDSCO) is a regulatory body responsible for monitoring ADRs. These findings are lower compared to other studies conducted among the healthcare professionals. [11]

According to the outcomes of our research, healthcare professionals’ practice towards ADR reporting was far below expectation. We observed that there was a huge gap between the ADR experienced (52.29%) and ADR reported (6.12%) by the healthcare professionals. These findings are similar to those reported by WHO [8] and with other studies conducted by Aziz et al. [22], Herdeiro et al. [23] and Okezie et al. [24] More alarming, however, is the fact that the dentists and nursing staff have never reported a single case of ADR while working in the institution.

It was noticed that the participants in our study could not utilize their knowledge to conduct proper ADR reporting since they had lack of training in this regard. We found that only 19.64% healthcare professionals were trained on how to report ADR. Similarly, a survey conducted in UAE revealed that only 5.5% of doctors received training on ADR reporting. [25] This shows that there is an urgent need for all stakeholders to come together to ensure proper implementation of pharmacovigilance program.

The hallmark finding of our study was to know that dentists were never been trained on ADR reporting. This finding was very discouraging for us as the role of dentist becomes critical to ensure safe and effective oral care.
Nwokike\cite{26} in his study suggested that attention should shift from spontaneous reporting by health care workers to self-report or patient initiated reporting of ADRs; encouraging healthcare professionals to self-report incidences of personal experiences of ADR may motivate them into engaging in pharmacovigilance activities after graduation.

Furthermore, in relation to ADR reporting we also identified the various possible factors responsible for underreporting. These determinants of underreporting include no remuneration, difficulty in deciding whether ADR has occurred or not, Lack of time, belief that a single unreported case may not affect ADR database, lack of training, and unawareness regarding the ADR reporting form etc. Similar factors were identified by studies conducted by Gupta et al\cite{11}, and Showande et al.\cite{27}

Many Indian studies have indicated that there is a gradual increase in the knowledge and attitude of the healthcare professionals towards pharmacovigilance,\cite{14,15,16,18} but unfortunately it seems that the actual practice of ADR reporting is still deficient.

It has been reemphasized that there is a positive correlation between training of pharmacovigilance and reporting ADR by healthcare professionals.\cite{11} Factors such as the unawareness about the method to decide the causal relationship between the ADR can only be removed by regular training.\cite{16} The significance of adverse event monitoring and reporting can be increased through academic interference. This will ultimately help in improving the efficiency of pharmacovigilance program in India.

We recommend that hospital managements, pharmaceutical companies, drug regulatory agencies should pay a significant contribution towards educating doctors on ADR monitoring and reporting. Along with this; few more suggestions were advised by previous researches. These include: Inclusion of pharmacovigilance in the undergraduate (UG) curriculum for healthcare professionals,\cite{15} Perseverance of pharmacovigilance center,\cite{28} establishing a network of doctors for ADR reporting,\cite{29} Easy accessibility to ADR reporting forms,\cite{30} Promotion of patient self-reporting\cite{31} and Regular e-mail update on the safety of drugs.\cite{32}

Limitations of the study include; results are of only a single hospital (institution) and those inherent to questionnaire-based studies such as subjective response and recall bias. It would be logical to extend this study to other teaching hospitals, private practitioners, members of allied fields, students of medical and associated streams to enable us generalize our findings.
CONCLUSION

In conclusion, the results of our study indicate that majority of the healthcare professionals had a poor knowledge and attitude about pharmacovigilance. There was a huge gap between the ADR experienced and ADR reported by the healthcare professionals especially among dentist and nursing staff. Similarly, a clear-cut correlation between training of pharmacovigilance and reporting ADR was found. Furthermore, majority of the respondents agreed that reporting of ADR is necessary and awareness that pharmacovigilance should be taught in detail to the healthcare professionals. It has been advised that the healthcare professionals; especially dental and nursing, should be trained properly on ADR reporting to improve the current scenario in the pharmacovigilance programme of the country.

REFERENCES


