KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTH CARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTION REPORTING IN A SOUTH INDIAN TEACHING HOSPITAL

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ABSTRACT

Adverse drug reactions (ADRs) are one of the common causes of morbidity and mortality. Hence doctors and nurses should have adequate knowledge about identification, treatment and reporting of ADRs. To assess the knowledge, attitude and practice of health care professionals towards ADR reporting, a cross-sectional, observational, questionnaire-based study among doctors and nurses working in a South Indian teaching tertiary hospital was carried out. The questionnaire was given to 300 health care professionals including consultants, postgraduates and nurses. Of the total 250 respondents, 24.8% were consultants and 35.2% were postgraduates, while the rest 40% were nurses. The mean KAP score for consultants, postgraduates and nurses was 27.21 ± 4.69, 23.33 ± 4.99 and 14.60 ± 5.05 respectively. The most important factor for doctors not reporting an ADR was lack of time to look for an ADR (86%) and to fill an ADR form (68.7%) whereas, for nurses the correctness of an ADR was the primary concern (41%). Hence, training and motivation of health care professionals towards ADR reporting is of utmost importance for success of pharmacovigilance programme and in minimizing ADR related morbidity and mortality.

Key words: Adverse drug reaction, pharmacovigilance, ADR reporting.

INTRODUCTION

No drug is without risk and all medicines have side effects, some of which can be fatal. An adverse drug reaction is defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from
future administration and warrants prevention or specific treatment, or alteration of the
dosage regimen, or withdrawal of the product.¹ Unintended, harmful reactions to medicines
are among the leading causes of death in many countries. Adverse drug reactions (ADRs)
also lead to huge financial burden to patients as well as the country because of
hospitalization, surgery and loss of productivity.²³ Most of the ADRs are preventable. The
risk of harm can be minimized by ensuring that prescribed medicines are of good quality,
safe, effective and used by the right patient in the right dose at the right time. To achieve this,
the health care providers should be aware of possible adverse reactions associated with a drug
and the ways to minimize them.

In order to promote the awareness and to monitor the adverse drugs reactions, the Central
Drugs Standard Control Organization (CDSCO), Directorate General of Health Services in
collaboration with Indian Pharmacopeia Commission, Ghaziabad has initiated a nation-wide
pharmacovigilance (PhV) programme for protecting the health of the patients by assuring
doctor safety. The programme is coordinated by the Indian Pharmacopeia Commission,
Ghaziabad as a National Coordinating Centre (NCC). Pharmacovigilance Programme of
India (PvPI) was launched in July 2010. Even though huge initiatives are being taken at the
higher levels to tackle the ADR related problems, success cannot be achieved unless the
health care providers themselves get involved in the programme whole heartedly. One of the
methods for ADR monitoring is spontaneous reporting by health care professionals. This
method is easy to operate and inexpensive. It encompasses all drugs and patient populations.
However, under-reporting and failure to calculate the incidence of ADRs are some of the
disadvantages of this method.¹⁴⁻⁶ A knowledge, attitude and practice (KAP) analysis may
help us in understanding the reasons for under-reporting and in developing strategies for
improving ADR monitoring as well as reporting. Knowledge, attitude, and practice regarding
ADR reporting have not been studied extensively in India. Spontaneous reporting by the
health care professionals at this hospital was initiated way back in the year 2004. Hence it
was thought worthwhile to assess their KAP regarding ADR reporting.

MATERIAL AND METHODS

This was a cross-sectional, observational, questionnaire-based study which evaluated the
KAP among doctors and nurses working in a South Indian Teaching Hospital, which is one of
the ADR monitoring centres approved by the Pharmacovigilance Programme (PvP),
Government of India. The study was carried out after obtaining institutional ethics committee
clearance. Letter no-IEC 299/2012. All health care professionals (doctors and nurses) working in the hospital during the study period were included in the study after obtaining an informed consent. The health care professionals who were not willing to participate were excluded from the study.

For the purpose of the study, a questionnaire designed to assess the KAP of doctors and nurses was used. It consisted of a total of 20 questions. Among those questions, (Qs: 1 to 11) were related to the ‘knowledge’, (Qs: 12 to 16) were related to ‘attitude’ and the remaining (Qs: 17 to 20) were related to the ‘practice’ aspects. The questionnaire was designed using the previous set by similar studies, to obtain information regarding the demographics of the respondents, knowledge regarding the ADR reporting system, attitude and practice of ADR reporting, and the factors that encourages and discourages reporting. The questionnaire was designed in such a way that the answers are not mutually exclusive. More than one answer was allowed in some questions. Each correct answer and each positive response was given a score of ‘1’ whereas the negative response or wrong answer was given a score of ‘0’.

Anova followed by Tukey’s test was used to analyse mean KAP scores and level of significance was set at $p<0.05$. Chi square test was used to compare practice scores. SPSS software version 15.0 was used for all statistical analysis.

RESULTS
The questionnaire was given to 300 health care professionals including consultants, postgraduates and nurses. Among the total 300 health care professionals given the questionnaire, only 83.3% (n=250) provided their responses. Of the total respondents (250), 24.8% (n=52) were consultants and 35.2% (n=88) were postgraduates, while the rest 40% (n=100) were nurses. The mean KAP score of nurses, post graduates and consultants are given in Table I. For the purpose of comparison, we have grouped the consultants and postgraduates as clinicians/doctors and compared them with the nurses. Most of the clinicians (90%) knew the definition of ADR and were able to correctly define pharmacovigilance but only half the nurses knew the definition of both ADR and pharmacovigilance. Surprisingly less than one third of the doctors (30%) and less than one-fourth of the nurses (21%) had the knowledge regarding the initiation of the pharmacovigilance programme (PvP) in the country and about the National Pharmacovigilance Programme centre (Table II&III).

According to the respondents, commonest adverse drug reaction (56.7%) was gastrointestinal adverse effects (nausea, vomiting and diarrhoea) followed by skin (34%) which included
rashes. Most common group of drugs responsible for these adverse effects were analgesics (43.7%) followed by antimicrobials (37.8%). About 19.4% of the doctors and nearly 64% of the nurses failed to name the drugs withdrawn from the market due to adverse reactions caused by the drugs.

Most of the respondents opted internet (83.3%) as the preferred source to gather information about ADRs to a new drug followed by journals (78.7%), textbook (83.3%), drug advertisement (31%) and seminars (26%). This suggests that a lot of the respondents depend on several sources to acquire knowledge of an ADR to a new drug (Figure 1). Majority of the doctors (98.7%) knew that they can report an ADR but in contrast only 75% of nurses were aware that nurses could also report ADRs. Among others, respondents considered that patients (64%), pharmacists (60.8%) and health workers (49.3%) could also report an ADR. Unfortunately only 34.7% of doctors and 16.7% of nurses knew where to report an ADR noted in this hospital. Most of the nurses opined that ADR reporting was essential (96.8%) and should be made mandatory (94.8%). Although 95.3% of the clinicians considered ADR reporting were essential, only 52.7% of them agreed that it should be made mandatory. There are numerous factors that discourage doctors and nurses from reporting an ADR. A few important ones were framed in our questionnaire and the response to those questions is shown in Figure 2. The most important factor for doctors was lack of time to look for an ADR (86%) and to fill an ADR form (68.7%) whereas, for nurses the correctness of an ADR was the primary concern (41%). More than one third of nurses (37.3%) did not know how to report an ADR.

Majority of the respondents (91%) felt that improving patient safety was the prime reason for reporting an ADR. Identification of newer adverse drug effects, recognition of relatively safer drugs and detection of the incidence of ADRs were considered as the other important reasons for reporting an ADR. Reporting of the adverse drug reactions was low among the clinicians and in particular nurses. Out of 250, about 70% of the respondents (54.7% of clinicians and 86% of nurses) admitted that they have not reported any ADR. The reasons for not reporting an ADR is illustrated in Figure 2. A total of 153 respondents (109 clinician and 44 nurses) had come across an adverse drug reaction and 123 respondents (82 clinician and 41 nurses) have prevented the occurrence of an ADR. Most of the clinicians (98.3%) and about 84% of the nurses had read articles about adverse drug reactions. The practice score of nurses was significantly lower than doctors (Table IV).
Table I: Knowledge, attitude and practice score of health care professionals

<table>
<thead>
<tr>
<th>Profession</th>
<th>Knowledge (Max 23)</th>
<th>Attitude (Max 13)</th>
<th>Practice (Max 4)</th>
<th>Total KAP (Max 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultants</td>
<td>16.60 ± 3.63</td>
<td>7.81 ± 1.50</td>
<td>2.81 ± 1.20</td>
<td>27.21 ± 4.69</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>13.78 ± 3.71</td>
<td>7.88 ± 2.09</td>
<td>1.67 ± 1.47</td>
<td>23.33 ± 4.99*</td>
</tr>
<tr>
<td>Nurses</td>
<td>7.87 ± 3.39</td>
<td>5.56 ± 2.31</td>
<td>1.17 ± 1.05</td>
<td>14.60 ± 5.05*</td>
</tr>
</tbody>
</table>

*p<0.001. values expressed as Mean (SD) score

Table II. Percentage of doctors answering knowledge related questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>Correct Answer</th>
<th>Wrong Answer</th>
<th>No Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is an Adverse Drug Reaction (ADR)</td>
<td>90</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>What is Pharmacovigilance</td>
<td>87.3</td>
<td>12</td>
<td>0.7</td>
</tr>
<tr>
<td>Year in which PV activities was started in our country</td>
<td>30</td>
<td>54.3</td>
<td>16.7</td>
</tr>
<tr>
<td>Location of the National PV Coordinating Centre</td>
<td>30</td>
<td>57.3</td>
<td>12.7</td>
</tr>
<tr>
<td>The location of WHO Centre for International Drug Monitoring</td>
<td>63.3</td>
<td>20.7</td>
<td>16</td>
</tr>
<tr>
<td>Scales used to establish the causality assessment of an adverse drug reaction</td>
<td>74.7</td>
<td>8</td>
<td>17.3</td>
</tr>
</tbody>
</table>

Table III. Percentage of Nurses answering knowledge related questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>Correct Answer</th>
<th>Wrong Answer</th>
<th>No Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is an Adverse Drug Reaction (ADR)</td>
<td>62</td>
<td>34</td>
<td>4</td>
</tr>
<tr>
<td>What is Pharmacovigilance</td>
<td>52</td>
<td>44</td>
<td>4</td>
</tr>
<tr>
<td>Year in which PV activities was started in our country</td>
<td>21</td>
<td>52</td>
<td>27</td>
</tr>
<tr>
<td>Location of the National PV Coordinating Centre</td>
<td>7</td>
<td>76</td>
<td>17</td>
</tr>
<tr>
<td>The location of WHO Centre for International Drug Monitoring</td>
<td>6</td>
<td>82</td>
<td>12</td>
</tr>
<tr>
<td>Scales used to establish the causality assessment of an adverse drug reaction</td>
<td>53</td>
<td>18</td>
<td>29</td>
</tr>
</tbody>
</table>
Fig 1: Sources of information about ADRs to a new drug

Fig 2: Factors that discourage from reporting an ADR

Table IV: Practice score of doctors and nurses

<table>
<thead>
<tr>
<th>Designation</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postgraduate</td>
<td>28</td>
<td>15</td>
<td>17</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Consultants</td>
<td>4</td>
<td>6</td>
<td>9</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Nurses</td>
<td>33</td>
<td>31</td>
<td>22</td>
<td>14</td>
<td>0</td>
</tr>
</tbody>
</table>

DISCUSSION

The present study was a questionnaire based study which assessed the KAP of doctors and nurses towards ADR and pharmacovigilance. The study showed that most of the doctors had good knowledge about definitions of ADR and PhV, however many nurses were ignorant of it. Most of the doctors and nurses were unaware of the pharmacovigilance programme of
India and its coordinating centre. In our study, doctors had a good knowledge while nurses had poor idea about ADRs. Similar results were observed in other studies\textsuperscript{9-12} from India in which doctors had adequate knowledge. Certain literature reports also revealed\textsuperscript{8,13-16} that health care professionals had poor knowledge about ADRs and PhV.

Only 34.7\% of the doctors and 16.7\% of nurses knew where to report an ADR. The department of Pharmacology, KMC, Manipal has been functioning as the peripheral ADR reporting centre since 2011 and the department has been constantly conducting CMEs and workshops on PhV but inspite of these efforts, most of the health care providers were unaware about it. In a study conducted in China,\textsuperscript{17} 71\% of the physicians did not know where and how to report an ADR whereas in a study conducted in Nepal,\textsuperscript{7} 61\% of physicians knew the location of the regional PhV centre. In India, a study conducted in Mumbai\textsuperscript{9} and Mysore,\textsuperscript{10} 50\% and 89\% of respondents respectively knew about reporting center.

Majority of the respondents relied on varied sources for obtaining information on ADRs but the most common source was internet followed by journals and textbooks. In another study\textsuperscript{8}, textbooks were stated as most common source (80.4\%) followed by journals (54.2\%) and internet (50\%). Most of the nurses felt reporting an ADR should be made mandatory while only half of the clinicians of the agreed to that. In the study\textsuperscript{7} conducted by Palaian et al, 70.8\% of the health care providers (doctors, nurses and pharmacists) felt that ADR reporting should be made mandatory. However in other studies, respondents felt that only serious ADRs or those related to new drugs should be reported.

Doctors as well as nurses felt that the most common reason for reporting an ADR was improvement of patients’ safety. Next common reason was considered as identification of newer ADRs. Similar results were seen in study conducted by Desai et al.\textsuperscript{8} Though majority of respondents felt that reporting of ADRs was essential, reporting was low, 54.7\% of the clinicians and 86\% of the nurses had never reported an ADR. In another study,\textsuperscript{8} only 15\% of respondents had reported an ADR previously. Majority of doctors stated that lack of time was the prime reason for not looking for an ADR and filling an ADR form while the nurses were concerned about the correctness of an ADR. The common reasons for not reporting are usually the same in all studies.

Our study shows that both clinicians and nurses are ignorant of various aspects of adverse drug reactions. Continuous sensitization of health care professionals towards ADR reporting
and PvP is required to improve their KAP. The study showed significantly lower KAP scores for nurses compared to clinicians. Nurses should be trained adequately because they are in closer contact with the patients and an ADR would probably come to their notice first. In addition to this pharmacist should also take active part in reporting of ADRs and training the doctors and nurses about possible ADRs. As a step towards overcoming these challenges, the reporting and data acquisition of ADRs on hospital website has been introduced by our PhV centre. Though the study has the inherent limitations that are associated with any other KAP study but we have tried to project the overall knowledge, attitude and practice of the doctors and nurses in our hospital.

In conclusion, setting up an ADR reporting centre is just a step forward to ensure patient safety. However, for success of PvP, it is of paramount importance to adequately train and motivate health care professionals towards ADR reporting.

REFERENCES


