Study of Awareness of Pharmacovigilance among Health Care Professionals & Medical Students attached to a Tertiary Care Hospital in Andhra Pradesh, India.

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Research Article
Subject: Pharmacology

Abstract:
Adverse Drug Reactions are under reported by health care professionals due to lack of awareness. The aim of our study was to know the awareness on pharmacovigilance among healthcare providers and medical students attached to a teaching hospital. We undertook a questionnaire based study to evaluate the awareness of pharmacovigilance among participants like nursing staff, Final M.B.B.S., students, House surgeons, postgraduates, senior residents and Assistant Professors attached to Government General Hospital, Guntur. They were asked to complete the questionnaire with 15 questions related to pharmacovigilance and A.D.R reporting and the answers were analyzed. Out of 240 participants 180(75%) had awareness of pharmacovigilance. 110 (46%) have come across A.D.R and 160(67%) felt that reporting is necessary. 175 (73%) disagreed that serious A.D.Rs were documented by the time the drug is released into market and impossible to detect whether the drug is responsible for ADR. 120(50%) participants wanted to report only if they were sure of the ADR. Only 75(31%) knew about Adverse Drug Reaction Monitoring centre (A.M.C) established in Government General Hospital in June 2013. The reasons for under reporting as per our study were lack of time and difficult to decide whether A.D.R occurred or not. Even though study reveals good awareness about pharmacovigilance among Health care providers, still better reporting can be encouraged by educating them to utilize the assistance of Adverse Drug Reaction Monitoring centers in identifying the ADRs.

Key words: Adverse Drug Reaction, Health Care Professionals, Pharmacovigilance.

Introduction:
As per World Health Organization, A.D.R is any noxious, unintended and undesired effect of the drug which occurs at doses used in humans for the prophylaxis, diagnosis or therapy of a disease or the modification of physiological state [1]. Pharmacovigilance is defined as science and activities related to detection, assessment, understanding and prevention of adverse drug reactions or any drug related problem. Studies have shown that ADRs are an important cause of hospital admissions [2]. The use of medicines for therapy has being and will continue to be associated with side effects and sometimes harmful adverse drug reactions. A monitoring & surveillance of ADRs will be helpful to reduce the morbidity & mortality among patients. ADRs are associated with large number of hazards leading to increased economic burden both for the individual and also for the community [3]. Under reporting is a major limitation for drug safety surveillance [4]. As per the pharmacovigilance newsletter the incidence of ADRs reported increased since 2010 in India indicating the progress of reporting [5]. Assessment of awareness of pharmacovigilance among health care professionals is said to be important to find the reason for under reporting of adverse drug reactions[6].

Material and Methods:
This was a cross sectional, observational, questionnaire based study done among health care professionals and medical students. Study was conducted for 3 months from June 2014 to August 2014. A Questionnaire containing 15 questions was designed and validated to know the knowledge and awareness about pharmacovigilance and ADR reporting. Total 250 questionnaires were prepared.
and distributed to 250 subjects. After taking consent the participants were asked to answer the questions and return the Questionnaire. Out of 250, 10 Questionnaires were incomplete and eliminated while evaluating the results. The results were evaluated graphically with the help of Microsoft excel sheet.

Out of 240 participants 14 were Assistant professors, 46 senior residents and post graduates, 91 house surgeons, 54 final year medical students and 35 were nursing staff of Government General Hospital attached to Guntur Medical College, Guntur, AP, India.

**Observations & Results:**
Out of 240 participants, 180 (75%) had awareness of pharmacovigilance. Among them 12 (86%) were assistant professors (A.P), 77 (85%) house surgeons, 33 (72%) senior residents (SR) and post graduates (PG), 39 (72%) final year students and 19 (54%) nursing staff.

**Graph 1:**

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Pharmacovigilance awareness

<table>
<thead>
<tr>
<th>Professional</th>
<th>Present</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asst Prof</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Sr. Residents &amp; PGs</td>
<td>33</td>
<td>13</td>
</tr>
<tr>
<td>House surgeons</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Final MBBS</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>19</td>
<td>16</td>
</tr>
</tbody>
</table>
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Awareness on the healthcare professionals responsible for reporting ADR in hospital. 200 out of 240 (83%) knew who all can report. Of them all the assistant professors (100%), 86 (95%) HS, 36 (78%) PGs and SRs, 41 (76%) final year students and 23 (66%) nursing staff knew who can report.

**Graph 2:** Who can report ADR?

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Graph 2: Who can report ADR?

<table>
<thead>
<tr>
<th>Professional</th>
<th>Known</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asst Prof</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Sr. Residents &amp; PGs</td>
<td>36</td>
<td>10</td>
</tr>
<tr>
<td>House surgeons</td>
<td>86</td>
<td>5</td>
</tr>
<tr>
<td>Final MBBS</td>
<td>41</td>
<td>13</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>23</td>
<td>12</td>
</tr>
</tbody>
</table>
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110 participants out of 240 (46%) have come across ADRs. 100% of APs, 63% (29), 38% (35) HS, 33% (18) final year M.B.B.S., students and 40% (14) nursing staff reported that they have come across ADRs.
83% (199) felt that reporting ADR is necessary. All APs (100%), 89% (81) HS, (48) final year M.B.B.S., students, 74% (34) SRs and PGs and 63% (14) nursing staff felt that it is necessary to report ADRs.

All APs and most of the HSs (92%), 70% SRs and PGs, 71% nursing staff, 50% final year M.B.B.S., students disagreed that really serious ADRs were documented at the time of marketing. 73% of participants said that it is impossible to detect whether the drug is responsible for the ADR. Out of them 12 APs, 35 PG & SRs, 90 HSs, 36 final MBBS students and 23 nursing staff disagreed that it is impossible to detect whether the drug is responsible for the ADR. 120 (50%) will report only if they were sure about the cause of ADR.

Graph 4: Is Reporting ADR necessary? Yes

Graph 5: Participants who will report only if sure of cause of ADR

Reporting ADR - Puts Career at risk. 201 (83%) participants thought that ADR reporting will not put one’s career at risk. All APs, 43 SRs and PGs, 62 HS, 30 nursing staff, 52 final year M.B.B.S., students Expresed that reporting will not put one’s career at risk.

Graph 5: Reporting ADR-Career at risk

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181 (75%) participants said they will report only serious/unexpected ADRs

**Participants who agree to report only serious/unexpected ADRs**

<table>
<thead>
<tr>
<th>Participants</th>
<th>Asst Prof</th>
<th>Sr. Residents &amp; PGs</th>
<th>House surgeons</th>
<th>Final MBBS</th>
<th>Nursing staff</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agree</strong></td>
<td>[Graph showing distribution]**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disagree</strong></td>
<td>[Graph showing distribution]**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Discouraging factors for reporting.** 10 APs, 16 SRs and PGs, 13 nursing staff expressed lack of time, while 42 HS and 32 final year M.B.B.S. students expressed difficulty in deciding about ADR as the discouraging factors for reporting.

<table>
<thead>
<tr>
<th>Discouraging factors for reporting</th>
<th>No remuneration</th>
<th>lack of time</th>
<th>single unreported</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>[Graph showing distribution]**</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

133 participants thought that reporting is not a professional obligation. 8 APs, 34SRs and PGs, 47HS, 25 nursing staff and 19 final year M.B.B.S., students felt that reporting ADRs is not a professional obligation.

49% participants were aware of reporting system in India. 102 participants knew CDSCO as the regulatory body. 99 participants thought ICMR as the regulatory body. 42% knew that there is a pharmacovigilance committee. 31% knew that there is an AMC in the hospital started in July 2013 at G.G.H, Guntur.

**Discussion:**

The incidence of ADRs is worldwide and the aim of PvPI is to ensure rational therapy by encouraging the adverse drug reaction reporting. This can be done by assessing the awareness among professionals who are basically involved in delivery of health care. Our study aims at evaluating the knowledge of pharmacovigilance and ADR reporting among health care professionals and finding out the reasons for under reporting.

Out of 240 participants, 180 (75%) had awareness of pharmacovigilance. Awareness is more among assistant professors and less among nursing staff. As per the study conducted by Mohamed M.M. Abdel-latif, Basel A Abdel-wahhab, knowledge and awareness of adverse drug reactions and pharmacovigilance practices among health care professionals in Al-madinah Al-munawwarah, Kingdom of Saudi Arabia 2014 [7] the awareness was 39.6%. 46% of total participants have come across ADRs. Of them all (100%) A.Ps, 95% H.Ss, 78% SRs and P.Gs, 76% final MBBS students and 66% nursing staff have come across ADRs. This is consistent with the study of Rajesh A kamtane, V Jayawardhani On “Knowledge, attitude and perception of physicians towards adverse drug...
reaction reporting. A pharmacoepidemiological study." 2012 [6]. 83% of participants thought reporting necessary. Khan SA et al in their study on “Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study” 2013 [8] showed that 95.6% knew that serious reactions should be reported. 12 A.Ps, 35 PG & SRs, 90 HSs, 36 final MBBS students and 23 nursing staff disagreed that it is impossible to detect whether the drug is responsible for the ADR. 120 participants agreed to report only if they were sure that ADR was due to the use of a particular drug. 49% participants were aware of reporting system in India. 102 participants knew CDSCO as the regulatory body. 99 participants thought ICMR as the regulatory body. 42% knew that there is a pharmacovigilance committee and 31% knew that there is an AMC in the hospital started in 12. Among the factors discouraging, difficulty in deciding whether ADR has occurred or not was felt by 102 participants. 72 (30%) participants felt lack of time and 29 thought no remuneration as the reason for not reporting. In the study conducted by Rajesh A kamtane, V Jayawardhani On “Knowledge, attitude and perception of physicians towards adverse drug reaction reporting. A pharmacoepidemiological study,” [6]. They concluded that 57.44% felt busy schedule and 40.4% lack of incentives as discouraging factors for under reporting.

Conclusion:

Present study revealed good awareness about pharmacovigilance and ADR reporting among healthcare providers in the hospital attached to our medical college. Though AMC was started in 12th June 2013, awareness about its existence was only 31%. The major discouraging factors for under reporting as per our study were lack of time and difficulty in detecting that the ADR was due to a particular drug. Better reporting can be encouraged by educating the health care professionals to utilize the assistance of A.M.C in identifying the ADRs.

Acknowledgement:

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References:

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