Improvement of knowledge, attitude and perception of healthcare workers about ADR, a pre- and post-clinical pharmacists’ interventional study

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ABSTRACT

Purpose: Healthcare workers have a main role in detection, assessment and spontaneous reporting of adverse drug reactions (ADRs), and improvement of their related knowledge, attitude and perception is essential. The goal of this study was evaluation of clinical pharmacists’ interventions in improvement of knowledge, attitude and perception of healthcare workers about ADRs in a teaching referral hospital, Tehran, Iran.

Method: Changes in knowledge, attitude and perception of healthcare workers of Imam teaching hospital about ADRs were evaluated before and after clinical pharmacists’ interventions including workshops, meetings and presentations.

Results: From the 100 participated subjects, 82 of them completed the study. 51% of the health workers have been aware of the Iranian Pharmacovigilance Center at the ministry of health before intervention and after that all the participants knew this centre. About awareness and detection of ADRs in patients, 69 (84.1%) healthcare workers recognised at least one, and following interventions, it was improved to 73 (89%). Only seven (8.5%) subjects have reported ADRs in before intervention phase that were increased significantly to 18 (22%) after intervention.

Conclusion: Clinical pharmacists’ interventions were successful in improvement of healthcare workers’ knowledge, attitude and perception about ADRs and spontaneous reporting in our hospital.

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of morbidity and mortality around the world and have high economic burden on healthcare systems.1–3 Pharmacovigilance studies are more important for evaluating medication safety following drugs marketing.4 Healthcare workers, especially medical practitioners, are the principal contributors of ADR reports.5 Healthcare professionals’ knowledge, attitudes and perceptions about ADR have central role in improvement of patients’ safety.1,5–6 There are some concerns about ADR spontaneous reporting by healthcare workers, including ADR importance, do not know how to report and fill the yellow cards, doubt about adverse effect and suspicious drug, lack of time, fear...
of legal problems, avoiding paper works and unavailable yellow card.\textsuperscript{1} 5–7 WHO standards show that the best spontaneous reporting rate is over 200 reports per 1 000 000 populations per year. Consequently, in Iran with a population of over 70 million, it is expected to have at least 14 000 reports per year that unfortunately only 4967 reports per year were sent to the Iranian Pharmacovigilance Center (IPC).\textsuperscript{6}

Continuous education of healthcare workers about pharmacovigilance by oral presentations, verbal reminders, providing ADR newsletters by email, mailing and direct distribution for hospital staff, advertisement, increased accessibility of yellow cards, attending of pharmacist in the medical wards and involving actively in education and training of healthcare workers especially nurses and physicians were proposed for improvement of knowledge and attitude of healthcare workers about ADRs.\textsuperscript{8–10}

The goal of this study was evaluation of clinical pharmacists’ interventions in improvement of knowledge, attitude and perception about ADRs in a referral teaching hospital, Tehran, Iran.

\textbf{METHOD}

In this study, changes in knowledge, attitude (perspective towards ADR and way of saying and doing about that) and perception (awareness or understanding of the ADR) of healthcare workers of the Imam Khomeini Complex Hospital (a tertiary referral hospital with 1200 beds that is affiliated to Tehran University of Medical Sciences, Tehran, Iran) about ADRs were evaluated before and after clinical pharmacists’ interventional study. Based on WHO definition, ADR was considered as any noxious, unintended and undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis or therapy. To assess knowledge, attitude and perception of healthcare workers about ADR, a validate questionnaire\textsuperscript{1} was used. The questionnaire consisted of a total of 15 questions (five questions for each of the knowledge, attitude and perception). Multiple-choice questions about ADR definition, goals and importance of pharmacovigilance and types of drug-induced reactions that must be reported were used for evaluation of the participants’ knowledge. For evaluation of attitude and perception, some cases with drug-induced ADRs were designed and asked from the participants to determine which of them must be reported.

In the first phase of the study, the clinical pharmacists (three persons) attended in different medical wards of the hospital and invited from all healthcare workers (medical students, nurses, physicians and pharmacist) to participate in the study. From whom those had enough time and were happy with our programme schedule asked to fill the questionnaire. Then, the participants were invited to attend in an educational programme (clinical pharmacists’ interventions) in the hospital. Clinical pharmacists’ interventions included training workshops (providing lectures and group discussion, 3 h/week for four consecutive weeks) and continuously providing information at the hospital morning case report section (every other day for 1 month) about ADR importance, seriousness, preventability, necessity of reporting and spontaneous reporting system and its advantages. In the workshop, they learnt to fill a yellow card and emphasised on reporting any suspected reaction regardless of uncertainty about the causality. After 3 months, the same questionnaire was filled again by the participants in the educational programmes. Effects of clinical pharmacists’ interventions in improvement of knowledge, attitude and perception of the participants about ADR were evaluated by comparing their responses to the questions before and after interventions. All data were analysed by Statistical Package for Social Sciences (SPSS) software V.16.0. Results were reported as frequency, and for comparing the before and after intervention’s results, we used cross tabulation and $\chi^2$ test. Values <0.05 were considered as significant.

\textbf{RESULTS}

From 136 healthcare workers that were positive for our invitation, only 100 persons attended in the educational programmes regularly and from them 82 questionnaires were invited to participate in the study. From whom those had enough time and were happy with our programme schedule asked to fill the questionnaire. Then, the participants were invited to attend in an educational programme (clinical pharmacists’ interventions) in the hospital. Clinical pharmacists’ interventions included training workshops (providing lectures and group discussion, 3 h/week for four consecutive weeks) and continuously providing information at the hospital morning case report section (every other day for 1 month) about ADR importance, seriousness, preventability, necessity of reporting and spontaneous reporting system and its advantages. In the workshop, they learnt to fill a yellow card and emphasised on reporting any suspected reaction regardless of uncertainty about the causality. After 3 months, the same questionnaire was filled again by the participants in the educational programmes. Effects of clinical pharmacists’ interventions in improvement of knowledge, attitude and perception of the participants about ADR were evaluated by comparing their responses to the questions before and after interventions. All data were analysed by Statistical Package for Social Sciences (SPSS) software V.16.0. Results were reported as frequency, and for comparing the before and after intervention’s results, we used cross tabulation and $\chi^2$ test. Values <0.05 were considered as significant.

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|}
\hline
\textbf{Reason} & \textbf{Before intervention} & \textbf{After intervention} & \textbf{p Value} \\
\hline
Uncertain association between reaction and drug & 18 (22) & 17 (20.7) & 1 \\
Unimportant to report & 13 (15.9) & 11 (9) & 0.30 \\
Well known that do not need to be reported & 21 (25.6) & 16 (19.5) & 0.23 \\
Unaware of the existence of a national ADR reporting system & 17 (20.7) & 15 (18.3) & 0.62 \\
Did not know importance of reporting & 12 (14.6) & 10 (12.2) & 0.69 \\
Did not know how to report & 20 (24.4) & 12 (14.6) & 0.02 \\
Lack of time & 11 (13.4) & 16 (19.50) & 0.18 \\
Lack of financial reimbursement & 2 (2.4) & 2 (2.4) & 1 \\
Fear of legal liability & 2 (2.4) & 2 (2.4) & 1 \\
Yellow card not available & 16 (19.5) & 9 (11) & 0.04 \\
Reporting system is too technical & 18 (9.8) & 14 (4.9) & 0.12 \\
Not enough information from the patient & 82 (100) & 3 (3.7) & 0.0001 \\
\hline
\end{tabular}
\caption{Reasons that cause ADR not be reported}
\end{table}

ADR, adverse drug reaction.
were filled out both before and after intervention with same name. The questionnaires that were filled only in one phases of the study were excluded. Thirty-five men and 47 women including 7 (8.5%) physicians, 31 (37.8%) residents, 26 (31.7%) interns, 17 (20.7%) nurses and 1 (1.2%) pharmacist participated in the study. We had not any intention to invite senior or junior of the wards and based on the demographic data of the study we had participants from the both groups. Average age of the participants was 30.9 years with SD of 6.7 years.

Fifty-one per cent (n=42) of the healthcare workers were aware of the IPC at Iranian ministry of health before interventions and after that all the participants knew this centre. Four people (4.9%) had attended an ADR workshop prior to this study. Sixty-nine (84.1%) subjects had recognised at least one ADR before, and following interventions, 73 (89%) cases have identified ADR. Only seven (8.5%) people have reported ADR before intervention that was increased significantly to 18 (22%) by the interventions (p<0.001).

One of the question was designed to determine centre that ADRs were reported previously by the participants. Two (2.4%) responders had sent the ADR reports to the IPC in Tehran, one (1.2%) to the Food and Drug Organization in another city of Iran, one (1.2%) to the manufacture and four (4.9%) to hospital’s ADR canter before the interventions and after that reporting to the IPC increased to 17 (20.7%) cases (p<0.001).

Doubt about occurrence of an ADR did not alter with the interventions significantly (63.4% vs 69.5%). Reasons that caused the participants did not report ADR are shown in table 1. The interventions had considerable impact to reduce causes of under-reporting, including did not know how to report (p=0.002), yellow card not available (p=0.039) and lack of enough information about the patient (p<0.0001).

All types of ADR that might promote healthcare professionals for reporting them were improved significantly after clinical pharmacists’ interventions (table 2).

The next questions were about healthcare workers’ perception about ADR and spontaneous ADR reporting goals. As it is indicated in table 3, our interventions had a significant effect on the participants’ total perception about ADR spontaneous reporting.

Responders’ perception about spontaneous reporting was not improved significantly following the clinical pharmacists’ interventions (table 4). Fifty-five (67.1%) and 60 (73.2%) subjects believed that it is a professional responsibility at pre- and post-interventional phases of the study, respectively.

Regarding the participants’ attitude for reporting ADRs, the question was, in which of the following conditions (carbamazepine-induced agranulocytosis, hypoglycaemia following use of a new hypoglycaemic agent, a new statin-induced myalgia, weight loss following fluoxetine therapy in a young women, amoxicillin-induced skin rash, pedal oedema following amiodipine therapy, bronchospasm following use of new β blocker and a new antiepileptic-induced paraesthesia) you will fill the yellow card? Only reporting of serious reactions such as carbamazepine-induced agranulocytosis was improved by clinical pharmacists’ interventions.

The participants’ preferred systems to report an ADR have been indicated in table 5. Yellow card, online, telephone and fax were frequently preferred methods for ADRs reporting in this study, respectively (table 6).

### Table 2 Reaction characteristics that might encourage healthcare professionals to report

<table>
<thead>
<tr>
<th>Factor</th>
<th>Before intervention</th>
<th>After intervention</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A serious reaction</td>
<td>53 (64.6)</td>
<td>74 (90.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Unusual reaction</td>
<td>38 (46.3)</td>
<td>66 (80.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reaction of a new product</td>
<td>36 (43.9)</td>
<td>46 (56.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>Reaction not reported before for a particular drug</td>
<td>36 (43.9)</td>
<td>66 (80.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reaction is well recognised for a particular drug</td>
<td>8 (9.8)</td>
<td>31 (37.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Any reaction (serious or non-serious, well known or new) to an old or new product</td>
<td>7 (20.7)</td>
<td>26 (31.7)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

### Table 3 Healthcare workers’ perception about ADR and spontaneous reporting systems’ goals, before and after intervention

<table>
<thead>
<tr>
<th>Goal</th>
<th>Before intervention</th>
<th>After intervention</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>To enable safe drugs to be identified</td>
<td>36 (43.9)</td>
<td>46 (56.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>To measure the incidence of ADR</td>
<td>39 (47.6)</td>
<td>57 (69.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>To identify factors which might predispose to ADR</td>
<td>35 (42.7)</td>
<td>58 (70.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>To identify previously unrecognised ADRs</td>
<td>56 (68.3)</td>
<td>70 (85.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>To compare ADRs for drugs in similar therapeutic classes</td>
<td>36 (43.9)</td>
<td>52 (63.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>To compare ADRs of same drug from different drug companies</td>
<td>44 (53.7)</td>
<td>44 (53.7)</td>
<td>1</td>
</tr>
</tbody>
</table>

ADRs, adverse drug reactions.
DISCUSSION

To the best of our knowledge, this is the first survey in Iran that have evaluated clinical pharmacists’ interventions in improvement of the healthcare workers’ knowledge, attitudes and perceptions regarding ADR. Our results showed that 91.5% of healthcare workers of our hospital that participated in the study never reported any ADR and 49% of them were not even aware of the IPC at the first phase of the study and obviously improved after interventions. Iranian pharmacists are more aware about the IPC that may be related to pharmacists’ more education about drugs’ safety.

Before the clinical pharmacists’ interventions, a little (2.4%) of the responders sent ADR reports to the IPC at the ministry of health and after that all the reports have set to this centre. It shows that interventions improve participant information regarding the centre that is responsible for analysing and managing of their reports. In previous research in Shiraz, Iran, 11% of the reports were sent to the IPC.

The considerable numbers of healthcare workers in the present study never reported an ADR that is comparable with other studies. In the first phase of the study, the main reasons of under-reporting of ADR were in order of had not enough information from the patient, too well known to report, did not know how to report, uncertain association and being unaware of the existence of a national ADR reporting system.

Although there are many studies12-18 that assess some causes of under-reporting ADR, a little of them have evaluated these barriers in hospitals. Results of a study performed in a tertiary teaching hospital in Barcelona/Spain are similar to our study, and lack of time to report an ADR due to the workload of clinical practitioners was detected as the most important reason to ADR under-reporting. Other causes of under-reporting in that study were lack of information about the spontaneous reporting system, unavailability of yellow cards, doubt of ADR causality assessment and lack of patient confidentiality.12 Other reasons for under-reporting of an ADR in other studies were diagnosed as uncertain association, too trivial to report, too well known to report, yellow card unavailability, lack of time and not knowing how to report.13-18

In the present study, serious and unusual reactions, unreported ADR before and reactions to a new product were selected as more important ADR for reporting by the participants. These are as the same as other studies’ results.4 19-22 We found only one study in that the idea of reporting all kind of ADRs was more often selected by healthcare workers in the present study in Shiraz, Iran.10

Table 4 Believes about spontaneous reporting, before and after intervention

<table>
<thead>
<tr>
<th>Believes about spontaneous reporting</th>
<th>Before intervention</th>
<th>After intervention</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional responsibility</td>
<td>55 (67.1)</td>
<td>60 (73.2)</td>
<td>0.12</td>
</tr>
<tr>
<td>Felt that one report cannot modify the healthcare system</td>
<td>6 (7.3)</td>
<td>6 (7.3)</td>
<td>1</td>
</tr>
<tr>
<td>All serious ADRs were recognised before drug marketing</td>
<td>3 (3.7)</td>
<td>1 (1.2)</td>
<td>0.5</td>
</tr>
<tr>
<td>Completely aware of what should be reported</td>
<td>4 (4.9)</td>
<td>8 (9.8)</td>
<td>0.06</td>
</tr>
<tr>
<td>Yellow cards are too complicated</td>
<td>19 (23.2)</td>
<td>18 (22)</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 5 Healthcare workers’ attitude for reporting, some instances of adverse drug reaction

<table>
<thead>
<tr>
<th>Event</th>
<th>Category of reaction</th>
<th>Report before the intervention</th>
<th>Report after the intervention</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine-induced agranulocytosis</td>
<td>Serious</td>
<td>30 (36.6)</td>
<td>74 (90.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypoglycaemia’s coma of a new diabetes medication</td>
<td>Serious for a new drug</td>
<td>48 (58.5)</td>
<td>45 (54.9)</td>
<td>0.72</td>
</tr>
<tr>
<td>Myalgia with a new statin</td>
<td>New drug</td>
<td>19 (23.2)</td>
<td>20 (14.2)</td>
<td>1</td>
</tr>
<tr>
<td>Weight loss after 8 weeks of fluoxetine</td>
<td>Well recognised for a particular drug</td>
<td>69 (7.3)</td>
<td>13 (15.9)</td>
<td>0.14</td>
</tr>
<tr>
<td>Rash with amoxicillin after 6-day treatment</td>
<td>Well recognised for a particular drug</td>
<td>18 (22)</td>
<td>12 (14.6)</td>
<td>0.33</td>
</tr>
<tr>
<td>Foot oedema after 4-month amlodipine treatment</td>
<td>Well recognised for a particular drug</td>
<td>19 (23.2)</td>
<td>18 (22)</td>
<td>1</td>
</tr>
<tr>
<td>Pain and tingling of tongue after 2 weeks of a new anti-seizure therapy</td>
<td>Reaction not reported before for a particular drug</td>
<td>33 (40.2)</td>
<td>40 (48.8)</td>
<td>0.34</td>
</tr>
<tr>
<td>Bronchospasm in an asthmatic patient after the first administration of a β blocker</td>
<td>Serious well recognised for a particular drug</td>
<td>33 (40.2)</td>
<td>29 (35.4)</td>
<td>0.63</td>
</tr>
</tbody>
</table>
pharmacist than reporting only serious and unexpected reactions. After the study’s interventions, beliefs of reporting all drug-related reactions have been increased significantly.

Identifying previously unreported ADR was the most important goal for ADR reporting in before and after the interventions of the study. This was also reported by other studies. Regarding the influence of the clinical pharmacists’ interventions on modifying healthcare workers’ perception about ADR, just reporting carbamazepine-induced agranulocytosis showed a significant change, which indicated reporting of a serious reaction.

The preferred method to report an ADR was yellow card followed by online report in both before and after the interventions. In previous study in Iran, phone was the selected method for ADR reporting by pharmacists. Our study was a single-centre study with small sample size and short duration between pre- and post-clinical pharmacists’ interventions participants’ evaluation. It seems that the consequence of the interventions will be pale over time. Another limitation of our survey was incompletely filled questionnaires that consequently we could not enrol all 100 questionnaires for the analysis.

Educational programme including workshops, oral presentations, group discussion, designing ADR newsletters in hospitals, providing information about pharmacovigilance for healthcare workers by mail, email, verbal reminders, advertisement and continuous education of nurses, physicians and pharmacists about ADRs, regular attending of pharmacists in the medical wards and involving actively in patient’s pharmaceutical care are essential for improving healthcare workers knowledge, attitudes and perceptions about ADRs.

In conclusion, clinical pharmacists’ interventions can improve knowledge, attitude and perception of healthcare workers about ADR that is a great issue of importance regarding pharmacovigilance and public health.

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**Contributors** HK and SD-K: clinical pharmacists of the hospital and provided educational programmes for the participants of the study and revised the manuscript. NM: data gathering and manuscript preparation. NH: data gathering and provided educational programme for the participants of the study. A-K: study design and statistical analysis.

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