Improvement of Knowledge, Attitude and Perception of health care workers about ADRs, a pre and post clinical pharmacists' interventional cohort study

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Title:

Improvement of Knowledge, Attitude and Perception of health care workers about ADRs, a pre and post clinical pharmacists' interventional cohort study

Short title: ADR and KAP study

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Abstract

Purpose: Health care workers have an essential role in detection, assessment and spontaneous reporting of adverse drug reactions and accordingly improvement of their related knowledge, attitudes and perception is essential. The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude and perception about adverse drug reactions in a teaching referral hospital, Tehran, Iran.

Method: Changes in knowledge, attitude and perception of health care workers of Imam teaching hospital, were evaluated before and after clinical pharmacists interventions including workshops, meetings and education.

Results: From the 100 participated subjects, 82 of them completed the study. Fifty one percent of the health workers have been aware of Iranian Pharmacovigilance Center at ministry of health before intervention and after that all of the participants knew this center. About awareness and detection of adverse drug reactions in patients, 69(84.1%) of health care workers recognized at least one and following interventions it was improved to 73 (89%). Only 7 (8.5%) subjects of participants have reported adverse drug reactions in before intervention phase that were increased significantly to 18 (22%) after intervention.

Conclusion: Clinical Pharmacists' interventions were successful in improvement of health care workers' knowledge, attitude, and practice about adverse drug reactions and spontaneous reporting, in Imam teaching hospital.

Article Summery

Article focus: The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude and perception about adverse drug reactions in a referral teaching hospital, Tehran, Iran.

Key massages:

-Our results showed that 91.5% of health care workers of Imam teaching hospital that participated in the study never reported any ADR, and 49% were not even aware of Iranian Pharmacovigilace Center.

-Identifying previously unrecognized ADRs was the most important goal for ADR reporting in before and after the interventions phases of the study.

- Regarding this study results, it was suggested that health systems must to have training programs for their workers about importance and how to detect, gather, analyze, report and fallow-up ADRs in the hospital and Provide online and telephone line accesses to facilitate ADRs reporting system.

Strengths and limitation of this study:

-To the best of our knowledge this is the first survey in Iran that have evaluated clinical pharmacists' interventions in improvement of the health care professionals' knowledge, attitudes and perceptions regarding ADR.

- The most important limitation of our survey was incomplete filled questionnaires.

Introduction

Adverse drug reactions (ADR) are a major cause of morbidity and mortality around the world[1]. These also have enormous economic burden on health care systems [2, 3]. Pharmacovigilance studies are more important for evaluating medication safety following drugs marketing [4]. Spontaneous ADR reporting by yellow cards is the corn stone of national and international drug safety evaluation in the post marketing phase. Health care workers, especially medical practitioners are the principal contributors of ADR reports[5]. Health care professionals' knowledge, attitudes and perception about ADR spontaneous reporting systems have central role in improvement of medication safety[1,5,-6]. There are some concerns about ADR spontaneous reporting by health care 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[1,5-7]. World Health Organization 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 4,967 reports per year were sent to the Iranian Pharmacovigilance Center (IPC)[6]. The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude and perception about adverse drug reactions in a referral teaching hospital, Tehran, Iran.

Method

In this study, changes in knowledge, attitude and perception of health care workers of Imam teaching hospital, were evaluated before and after clinical pharmacists interventional cohort study in the Imam Khomeini Complex hospital during one year period. To assess knowledge, attitude and perception of

health care workers about ADR a validate questionnaire [1] was used. In the first phase of the study, the clinical pharmacists (3 persons) attended in different medical wards and asked health care workers to participate in the study and fill the questionnaire. Clinical pharmacists' interventions included training workshops (providing lectures and group discussion) and continuous providing information at the hospital general morning report section (every other day) about ADRs, their importance, seriousness, preventability, necessity of reporting, and spontaneous reporting system and its advantages. In the workshop they learned to fill a yellow card and emphasized on reporting any suspected reaction regardless of uncertainty about the causality. After three months the same questionnaire were filled again. Then all the data analyzed by Statistical Package for Social Sciences (SPSS) software version 16.0 for Windows. Results were reported as frequency and for comparing the before and after intervention's data, we used Crosstabulation and Chi- Squre. Values less than 0.05 were considered as significant.

Results

From 100 participated health care workers, 82 questionnaires 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 one (1.2%) pharmacist participated in the study. Average age of them was 30.9 years with standard deviation of 6.7 years. Mean and median of practice experience of health care workers included in the study were 9.9 and 9 years, respectively.

Fifty one percent (n=42) of the health care workers were aware of IPC at Iranian ministry of health before interventions and after that all of the participants knew this center. Four people (4.9%) had attended in an ADR workshop prior to this

study. Sixty nine (84.1%) of subjects had recognized at least one ADR in their practice period and following interventions 73 (89%) of cases have identified ADR. Only 7 (8.5%) people have reported ADR in first step that increased significantly to 18 (22%) by the interventions (P<0.001).

Two (2.4%) responders have sent the reported ADR to IPC in Tehran, 1(1.2 %) to Food and Drug Organization in another city of Iran, 1 (1.2 %) to the manufacture, and 4 (4.9%) to hospital's ADR center before the interventions and after that reporting to IPC increased to 17 (20.7%) of cases (P<0.001).

Doubt about occurrence of an ADR that was caused underreporting, didn't alter with the interventions significantly (63.4% vs. 69.5%). Sources of suspected ADR without reporting were shown in table 1. The interventions had considerable impact to reduce causes of underreporting including did not know how to report (p = 0.002), yellow card not available(p = 0.039), lack of enough information about the patient(p < 0.0001).

All types of ADR that might promote health care professionals for reporting them were improved significantly after clinical pharmacists' interventions (Table 2).

The next question was about health care workers' perception of ADR and spontaneous ADR reporting goals. As it was indicated in table 3 our interventions had a significant effect on the participants' total perception about ADR spontaneous reporting.

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

Regarding their attitude for reporting ADRs the question was; in which of the fallowing conditions (carbamazepine induced agranulocytosis, hypoglycemia

following use of a new hypoglycemic agent, a new statin induced myalgia, weight loss following fluoxetin therapy in a young women, amoxicillin induced skin rash, pedal edema following amlodipine therapy, bronchospasm following use of new beta blocker, and a new antiepileptic induced paresthesias) you will fill the yellow card? Only reporting of serious reactions such as carbamazepine induced agranulocytosis was improved by clinical pharmacists' interventions.

The options for ADR reporting have been indicated in table 5. Yellow card, online, telephone and fax were frequent preferred methods in that order for ADRs reporting in this study (Table 6). Clinical pharmacists' interventions improved participants' perception in cases which had no idea about ADRs reporting methods.

Discussion

To the best of our knowledge this is the first survey in Iran that have evaluated clinical pharmacists' interventions in improvement of the health care professionals' knowledge, attitudes and perceptions regarding ADR. ADR under-reporting among health care workers is a problem in this regard.

Our results showed that 91.5% of health care workers of Imam teaching hospital that participated in the study never reported any ADR, and 49% were not even aware of IPC being at first phase of the study and obviously improved after interventions. Iranian pharmacists are more aware about IPC (6) that may be related to pharmacists more information about drugs and whole ADR point.

Before the clinical pharmacists' interventions a little (2.4%) of responders sent ADR reports to IPC at the Ministry of Health and after that all of reports have set to this center. It shows that interventions improve participant information regarding the center responsible for analyzing and managing of their reports. In previous research in Shiraz, Iran[1], 11% of the reports were sent to this center.

The majority of health care workers in present survey never reported an ADR that is comparable with other studies [4,6,8]. In the first phase the main reasons

of under reporting 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 studies [9-15] that assess causes of under reporting ADRs, there are not many of them which evaluating these barriers in hospitals. In a study performed in a tertiary teaching hospital in Barcelona / Spain results have been similar to our study that have illustrated lack of time to report due to the workload of clinical practitioners 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 [9]. The main problems in other studies are similar to these data and included uncertain association, too trivial to report, too well known to report, yellow card unavailability, lack of time, and not knowing how to report[10-15]. In this regard clinical pharmacists of Imam Hospital decided to have interventions to improve these problems.

This is clear that all kind of ADR related to all drugs have not been reported sufficiently. In present study serious and unusual reactions, unrecognized ADR, and reactions to a new product were expressed more important ADR for reporting by the participants. This was as the same as other studies' results[16-20]. We found only one study in Turkey that the idea of reporting all kind of ADRs was more often among pharmacist than reporting only serious and unexpected reactions [21]. After the study's interventions as was shown in the result section, believe of all kind of reactions reporting have been increased significantly.

Identifying previously unrecognized ADRs was the most important goal for ADR reporting in before and after the interventions phases of the study. This

was also reported by other studies [22,23]. Regarding the influence of the clinical pharmacists' interventions on modifying health care workers' practice, just reporting carbamazepine induced agranulocytosis shown a significant change, that is indicated reporting of a serious reaction.

The preferred method to report ADRs was yellow card followed by online report in both before and after the interventions, while in previous study in Iran, Phone was the ideal method fallowing yellow cards for pharmacists[1].

The most important limitation of our survey was incomplete filled questionnaires; consequently we couldn't enroll all 100 questionnaires for the analysis.

Regarding this study results, it was suggested that health systems must to have training programs for their workers about importance and how to detect, gather, analyze, report and fallow-up ADRs in the hospital and Provide online and telephone line accesses to facilitate ADRs reporting system.

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

Authorship:

Hossein khalili**:** Clinical pharmacist of the hospital and provided educational programs for the participants to the study and manuscript revision.

Niayesh Mohebbi: Data gathering and manuscript preparation.

Narjes Hendoiee: Data gathering.

Abbas-Ali Keshtkar: Study design and statistical analysis.

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Conflict of interest: There is not any competing interest for all authors about present work.

Founding: We have not any founding resource.

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Table 1 - Causes of suspected ADR without reporting

Reason	Before intervention	After intervention	P value
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 don't 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

Table 2 - Reactions characteristics that might encourage health care professionals to report

Factor	Before intervention	After intervention e	P value
A serious reaction	53(64.6)	74(90.2)	<0.001
Unusual reaction	38(46.3)	66(80.5)	<0.001
Reaction of a new product	36(43.9)	46(56.1)	0.02
Reaction not reported before for a particular drug	36(43.9)	66(80.5)	<0.001
Reaction is well recognized for a particular drug	8(9.8)	31(37.8)	<0.001
Any reaction (serious or non-serious, well-known or new) to an old or new product	7(20.7)	26(31.7)	0.004

Table 3 - Health care workers' perception of ADR and spontaneous reporting purposes, before and after intervention.

Purpose	Before intervention	After intervention	P value
To enable safe drugs to be identified	36(43.9)	46(56.1)	0.02
To measure the incidence of ADR	39(47.6)	57(69.5)	<0.001
To identify factors which might predispose to ADR	35(42.7)	58(70.7)	<0.001
To identify previously unrecognized ADRs	56(68.3)	70(85.4)	<0.001
To compare ADRs for drugs in similar therapeutic classes	36(43.9)	52(63.4)	<0.001
To compare ADRs of same drug from different drug companies	44(53.7)	44(53.7)	1

Table 4- Believes about spontaneous reporting, before and after intervention

Believes about spontaneous reporting	Before intervention	After intervention	P value
Professional responsibility	55(67.1)	60(73.2)	0.12
Felt that one report can not modify the health-care system	6(7.3)	6(7.3)	1
All serious ADRs were recognized before drug marketing	3(3.7)	1(1.2)	0.5
Completely aware of what should be reported	4(4.9)	8(9.8)	0.06
Yellow-cards are too complicated	19(23.2)	18(22)	1

Table 5 – Health care workers' attitude for reporting; some instances of ADR

Event	Category of reaction	Report before the intervention	Report after the intervention	P value
Carbamazepine induced agranulocytosis	serious	30(36.6)	74(90.2)	<0.001
Hypoglycemic coma of a new diabetes medication	Serious for a new drug	48(58.5)	45(54.9)	0.72
Myalgia with a new statin	New drug	19(23.2)	20(14.2)	1
Weight loss after 8 week of fluoxetine	well recognized for a particular drug	69(7.3)	13(15.9)	0.14
Rash with amoxicillin after 6 days	well recognized for a particular drug	18(22)	12(14.6)	0.33
Foot edema after 4 month amlodipine	well recognized for a particular drug	19(23.2)	18(22)	1
Pain and tingling of tongue after two weeks of a new anti- seizure	Reaction not reported before for a particular drug	33(40.2)	40(48.8)	0.34
Bronchospasm in an asmatic patient after the first administration of a beta-blocker	Serious well recognized for a particular drug	33(40.2)	29(35.4)	0.63

Table 6- Health care workers' preferred method of reporting

Preferred method	Before intervention	After intervention	P value
Yellow Card	29(32)	34(45.1)	0.09
Telephone	18(24.3)	16(21.6)	0.21
Fax	1(1.4)	0	0.33
Online	21(28.4)	23(31.1)	0.45
None	5(6.8)	1(1.4)	0.02

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	3-4
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	4
		(*b*) Describe any methods used to examine subgroups and interactions	4
		(*c*) Explain how missing data were addressed	4
		(*d*) If applicable, explain how loss to follow-up was addressed	4
		(*e*) Describe any sensitivity analyses	4
Results			4

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	5
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	5
		(c) Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	Report numbers of outcome events or summary measures over time	5-6
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	8

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	8

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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Title:

Improvement of Knowledge, Attitude and Perception of health care workers about ADR, a pre and post clinical pharmacists' interventional study

Short title: ADR and KAP study

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Abstract

Purpose: Health care workers have a main role in detection, assessment and spontaneous reporting of adverse drug reactions and improvement of their related knowledge, attitudes and perception is essential. The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude and perception of health care workers about adverse drug reactions in a teaching referral hospital, Tehran, Iran.

Method: Changes in knowledge, attitude and perception of health care workers of Imam teaching hospital about adverse drug reactions 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. Fifty one percent of the health workers have been aware of Iranian Pharmacovigilance Center at ministry of health before intervention and after that all of the participants knew this center. About awareness and detection of adverse drug reactions in patients, 69(84.1%) of health care workers recognized at least one and following interventions it was improved to 73 (89%). Only 7 (8.5%) subjects of participants have reported adverse drug reactions in before intervention phase that were increased significantly to 18 (22%) after intervention.

Conclusion: Clinical Pharmacists' interventions were successful in improvement of health care workers' knowledge, attitude, and perception about adverse drug reactions and spontaneous reporting, in our hospital.

Article Summary

Article focus: The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude and perception about adverse drug reactions in a referral teaching hospital, Tehran, Iran.

Key messages:

-Our results showed that 91.5% of health care workers of the hospital never reported any ADR, and 49% were not even aware of Iranian Pharmacovigilace Center.

-Identifying previously unrecognized ADRs was the most important goal for ADR reporting in before and after the interventions phases of the study.

- Regarding the study results, it was suggested that health systems must to have training programs for their workers about importance, detection, analysis, reporting and fallow-up of ADRs in the hospital and Provide online and telephone line accesses to facilitate ADRs reporting system.

Strengths and limitation of this study:

-To the best of our knowledge this is the first survey in Iran that have evaluated clinical pharmacists' interventions in improvement of the health care professionals' knowledge, attitudes and perceptions regarding ADR.

- Our study was done in a single center with small sample size and short duration between pre and post interventions participants' assessment.

Introduction

Adverse drug reactions (ADR) are a major cause of morbidity and mortality around the world and have high economic burden on health care systems [1-3]. Pharmacovigilance studies are more important for evaluating medication safety following drugs marketing [4]. Health care workers, especially medical practitioners are the principal contributors of ADR reports [5]. Health care professionals' knowledge, attitudes and perception about ADR have central role in improvement of patients' safety [1,5,6]. There are some concerns about ADR spontaneous reporting by health care 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 [1,5-7]. World Health Organization 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 4,967 reports per year were sent to the Iranian Pharmacovigilance Center (IPC) [6].

Continuous education of health care workers about pharmacovigilance by oral presentations, verbal reminders, providing ADR newsletters by e-mail, 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 health care workers especially nurses and physicians were proposed for improvement of knowledge and attitude of heath care workers about ADRs (8-10).

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

Method

In this study, changes in knowledge, attitude (perspective toward ADR and way of understanding or awarenessof saying and doing about that) and perception (the ADR) of health care workers of 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 health care workers about ADR a validate questionnaire [1] was used. The questionnaire consisted of a total of 15 Questions (5 questions for each of the knowledge, attitude and perception). Multiple choice questions about ADR definition, goals and importance of pharmacovigilance, and types of drugs induced reactions that must be reported was 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 (3 persons) attended in different medical wards of the hospital and invited from all health care workers (medical students, nurses, physicians and pharmacist) to participate in the study. From whom those had enough time and were happy with our program schedule asked to fill the questionnaire. Then the participants were invited to attend in an educational program (clinical pharmacists' interventions) in the hospital. Clinical pharmacists' interventions included training workshops (providing lectures and group discussion, 3 hours per week for 4 consecutive weeks) and continuous providing information at the hospital morning case report section (every other day for one month) about ADR importance, seriousness, preventability, necessity of reporting, and spontaneous reporting system and its advantages. In the workshop they learned to fill a yellow card and emphasized on reporting any suspected reaction regardless of uncertainty about the causality. After three months the same questionnaire were filled again by the participants in the educational programs. 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 analyzed by Statistical Package for Social Sciences (SPSS) software version 16.0. Results were reported as frequency and for comparing the before and after intervention's results, we used Crosstabulation and Chi- Squre test. Values less than 0.05 were considered as significant.

Results

From 136 health care workers that were positive for our invitation, only 100 persons attended in the educational programs regularly and from them 82

questionnaires 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 one (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 standard deviation of 6.7 years.

Fifty one percent (n=42) of the health care workers were aware of IPC at Iranian ministry of health before interventions and after that all of the participants knew this center. Four people (4.9%) had attended in an ADR workshop prior to this study. Sixty nine (84.1%) of subjects had recognized at least one ADR before and following interventions 73 (89%) of cases have identified ADR. Only 7 (8.5%) people have reported ADR before intervention that was increased significantly to 18 (22%) by the interventions (P<0.001).

One of question was designed to determine center that ADRs were reported previously by the participants. Two (2.4%) responders had sent the ADR reports to IPC in Tehran, 1(1.2 %) to Food and Drug Organization in another city of Iran, 1 (1.2 %) to the manufacture, and 4 (4.9%) to hospital's ADR center before the interventions and after that, reporting to IPC increased to 17 (20.7%) of cases (P<0.001).

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

All types of ADR that might promote health care professionals for reporting them were improved significantly after clinical pharmacists' interventions (Table 2).

The next questions were about health care workers' perception about ADR and spontaneous ADR reporting goals. As it was 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%) of 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 fallowing conditions (carbamazepine induced agranulocytosis, hypoglycemia following use of a new hypoglycemic agent, a new statin induced myalgia, weight loss following fluoxetine therapy in a young women, amoxicillin induced skin rash, pedal edema following amlodipine therapy, bronchospasm following use of new beta blocker, and a new antiepileptic induced paresthesia) 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 frequent preferred methods for ADRs reporting in this study respectively (Table 6).

Discussion

To the best of our knowledge this is the first survey in Iran that have evaluated clinical pharmacists' interventions in improvement of the health care workers' knowledge, attitudes and perceptions regarding ADR.

Our results showed that 91.5% of health care workers of our hospital that participated in the study never reported any ADR, and 49% of them were not even aware of IPC at first phase of the study and obviously improved after interventions. Iranian pharmacists are more aware about IPC (6) that may be related to pharmacists' more education about drugs' safety.

Before the clinical pharmacists' interventions a little (2.4%) of responders sent ADR reports to IPC at the Ministry of Health and after that all of reports have set to this center. It shows that interventions improve participant information regarding the center that is responsible for analyzing and managing of their reports. In previous research in Shiraz, Iran [1], 11% of the reports were sent to IPC.

The considerable numbers of health care workers in present study never reported an ADR that is comparable with other studies [4,6,11]. 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 studies [12-18] 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 present study serious and unusual reactions, unreported ADR at 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 [19-23]. We found only one study in that the idea of reporting all kind of ADRs was more often selected by pharmacist than reporting only serious and unexpected reactions [24]. After the study's interventions, believe of reporting of 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 [25,26]. Regarding the influence of the clinical pharmacists' interventions on modifying health care 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 [1].

Our study was a single center 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 incomplete filled questionnaires that consequently we couldn't enroll all 100 questionnaires for the analysis.

Educational program including workshops, oral presentations, group discussion, designing ADR newsletters in hospitals, providing information about pharmacovigilance for health care workers by mail, e-mail, 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 health care workers knowledge, attitude and perception about ADRs (7-10).

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

Authorship:

Hossein khalili and Simin Dashti-Khavidaki**:** Clinical pharmacists of the hospital and provided educational programs for the participants to the study and manuscript revision.

Niayesh Mohebbi: Data gathering and manuscript preparation.

Narjes Hendoiee: Data gathering and provided educational program for the participants to the study.

Abbas-Ali Keshtkar: Study design and statistical analysis.

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Table 1 – Reasons that cause ADR not be reported

Reason	Before intervention	After intervention	P value
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 don't 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

Table 2 - Reactions characteristics that might encourage health care professionals to report

Factor	Before intervention	After intervention e	P value
A serious reaction	53(64.6)	74(90.2)	<0.001
Unusual reaction	38(46.3)	66(80.5)	<0.001
Reaction of a new product	36(43.9)	46(56.1)	0.02
Reaction not reported before for a particular drug	36(43.9)	66(80.5)	<0.001
Reaction is well recognized for a particular drug	8(9.8)	31(37.8)	<0.001
Any reaction (serious or non-serious, well-known or new) to an old or new product	7(20.7)	26(31.7)	0.004

Table 3 - Health care workers' perception about ADR and spontaneous reporting systems' goals, before and after intervention.

Goal	Before intervention	After intervention	P value
To enable safe drugs to be identified	36(43.9)	46(56.1)	0.02
To measure the incidence of ADR	39(47.6)	57(69.5)	<0.001
To identify factors which might predispose to ADR	35(42.7)	58(70.7)	<0.001
To identify previously unrecognized ADRs	56(68.3)	70(85.4)	<0.001
To compare ADRs for drugs in similar therapeutic classes	36(43.9)	52(63.4)	<0.001
To compare ADRs of same drug from different drug companies	44(53.7)	44(53.7)	1

Table 4- Believes about spontaneous reporting, before and after intervention

Believes about spontaneous reporting	Before intervention	After intervention	P value
Professional responsibility	55(67.1)	60(73.2)	0.12
Felt that one report can not modify the health-care system	6(7.3)	6(7.3)	1
All serious ADRs were recognized before drug marketing	3(3.7)	1(1.2)	0.5
Completely aware of what should be reported	4(4.9)	8(9.8)	0.06
Yellow-cards are too complicated	19(23.2)	18(22)	1

Table 5 – Health care workers' attitude for reporting; some instances of ADR

Event	Category of reaction	Report before the intervention	Report after the intervention	P value
Carbamazepine induced agranulocytosis	serious	30(36.6)	74(90.2)	<0.001
Hypoglycemic's coma of a new diabetes medication	Serious for a new drug	48(58.5)	45(54.9)	0.72
Myalgia with a new statin	New drug	19(23.2)	20(14.2)	1
Weight loss after 8 week of fluoxetine	well recognized for a particular drug	69(7.3)	13(15.9)	0.14
Rash with amoxicillin after 6 days treatment	well recognized for a particular drug	18(22)	12(14.6)	0.33
Foot edema after 4 month amlodipine treatment	well recognized for a particular drug	19(23.2)	18(22)	1
Pain and tingling of tongue after two weeks of a new anti- seizure therapy	Reaction not reported before for a particular drug	33(40.2)	40(48.8)	0.34
Bronchospasm in an asthmatic patient after the first administration of a beta-blocker	Serious well recognized for a particular drug	33(40.2)	29(35.4)	0.63

Table 6- Health care workers' preferred method for reporting of ADR

Preferred method	Before intervention	After intervention	P value
Yellow Card	29(32)	34(45.1)	0.09
Telephone	18(24.3)	16(21.6)	0.21
Fax	1(1.4)	0	0.33
Online	21(28.4)	23(31.1)	0.45
None	5(6.8)	1(1.4)	0.02