

RESEARCH ARTICLE

Impact of educational intervention on health-care professional's behaviors toward adverse drug reactions reporting – A study of tribal belt of central India

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ABSTRACT


Background: Adverse drug reactions (ADRs) are one of the most significant causes of mortality; hence, it must be reported. Very few studies were done, including educational intervention and even fewer in a tribal area of world, especially in India. **Aims and Objectives:** We planned this study to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance (PVG) and ADR reporting of health-care professionals (HCPs) of tertiary care hospital of the central tribal belt in India before and after an educational intervention. **Materials and Methods:** A cross-sectional descriptive KAP pre- and post-questionnaire based study was conducted on a total of 164 participants, including doctors and nurses working in Tertiary Care Hospital, Ratlam, India. A predesigned structured questionnaire with multiple-choice questions was used for pre-test and post-test along with the intermediate educational session. Furthermore, the practice of ADR reporting was assessed over a month's time. The data were analyzed using descriptive statistics and Fisher's exact test was done to compare the difference in correctness for each question. **Results:** In the pre-test, about 73.77% of the doctors and 11.65% of the nurses knew what is PVG, while the post-test response rocketed to 100% in doctors and 98.06 % in nurses ($P < 0.001$). The overall knowledge and attitude of doctors and nurses were low initially and it improved significantly ($P < 0.001$) after the educational intervention. Furthermore, ADRs reported increased from 0 to 10 ($P < 0.001$) during the follow-up practice of 1 month of the study. **Conclusions:** Educational intervention is a reinforcement tool to improve the KAP of the ADR reporting of HCPs. Furthermore, more awareness and cooperation by the HCPs are required to deal with the prevalent under-reporting of the ADRs in tribal region of India.

KEY WORDS: Pharmacovigilance; Adverse Drug Reaction Reporting; Health-care Professionals; India; Tribal

INTRODUCTION

Our advancement and knowledge in the field of medicine are ever-expanding. Yet, a few hurdles continue to interrupt

our journey toward better health – most of which can be prevented by imparting knowledge, inculcating the right attitude, and encouraging the right practices among the health-care professionals (HCPs) and the masses. Adverse drug reactions (ADRs) are among the significant cause of morbidity and mortality worldwide.^[1] The WHO defines ADR as “any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.”^[2] The practice of monitoring ADRs and drug safety is pharmacovigilance (PVG). The WHO defined the term PVG as “The pharmacological science and activities relating to the

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detection, assessment, understanding, and prevention of the adverse effects, or any other drug-related problems.”^[3] ADR incidence has been reported to range from 5.9% to 22.3% of all emergency department admissions.^[4] The major limitation associated with the spontaneous ADR reporting system is underreporting.^[5] It is estimated that only 6–10% of all ADRs are reported.^[6] India rates below 1% in terms of ADR reporting.^[7] ADRs increase the cost of healthcare and this emphasizes the importance of timely ADR reporting in a developing country like India. One hundred and fifty ADR monitoring centers (AMCs) were established in various medical institutions/hospitals across India to monitor and collect ADR reports under National Coordinator Centre-PVG Programme of India.^[8] However, underreporting of ADR is still very high among HCPs due to a lack of knowledge and awareness.^[9] Ratlam district lies in the tribal belt of central India. There was a grave lack in the incidences of ADR reporting studies and data in Ratlam which indicated a lack of awareness. The nurses and doctors are the backbone of the health industry and their knowledge, attitude, and practice (KAP) related to ADR reporting is thus crucial. Therefore, this research work was planned to not only get the data for the present situation but also educate them about ADR reporting and PVG.

MATERIALS AND METHODS

Type of Study and Study Design

It was a cross-sectional descriptive KAP questionnaire-based study which was conducted from July 2019 to September 2019.

Study Population and Selection Criteria

The intended study participants were all the doctors and nurses who were working in a tertiary care hospital of the tribal belt in India during the study period and who were willing to participate in the study and gave their written informed consent.

Data Collection Procedure

The study was done in a pre- and post-educational session survey using a questionnaire of KAP for ADR reporting. The subjects were first given the pre-test questionnaire that they had to attempt based on their previous knowledge. Then, an interactive educational session was conducted by the trained faculty of PVG. After this session, the post-test questionnaire was given to the subjects, and then all participants were instructed to report ADR to the department of pharmacology of the studied site. Then, regular follow-up of any ADR reporting in our hospital was done for 1 month. After 1 month, the post-test questionnaire containing practice-related questions was given to all the study participants.

Study Instrument

A predesigned structured questionnaire with multiple-choice questions (MCQs) adapted from the previous studies was used for our study.^[9-14] The questionnaire was modified which suited our new medical college and hospital. The modified questionnaire content was pre-tested in four nurses and four doctors (who were not included as participants of the study) and re-modified. The final modified questionnaire was administered to willing respondents. The modified questionnaire divided into three parts. The first part related to questions pertaining to KAP of the professionals. It contains 19 MCQs for knowledge, 10 for attitude, and 3 for practice. The second part contains open-ended questions regarding the factors that encourage and discourage spontaneous ADR reporting by the HCPs (to be filled after the educational intervention) over a month's time. The third part contains demographics of HCPs such as sex, qualification, designation, specialty (only for the doctors), and work experience.

Statistical Analysis

The data were collected and entered in MS Excel 2010 and analyzed using descriptive statistics. To measure changes in the knowledge and attitude toward PVG among the HCPs between pre- and post-educational intervention and to evaluate the impact of effectiveness, the Fisher's exact test was used to compare the difference in correctness for each question. To see the practice of PVG in nurses, correctness was analyzed in percentage. All statistical calculations were performed using Graphic Pad, a web-based epidemiological, and statistical calculator. The significance was assessed at a 5% level of significance ($P < 0.05$) with 95% confidence interval.

Ethical Consideration

Ethical approval was obtained from the Institutional Ethics Committee (IEC) of the studied tertiary care center (Ethics Committee Registration Number: ECR/1192/Inst/MP/2019). The approval number of this study is Government Medical College (GMC) RATLAM/2019/IEC/Approval/002, dated 20/05/2019. Written informed consent was obtained from each participant before enrollment in the study.

RESULTS

A total of 164 HCPs participated in the study. Out of these, 37% (61) were doctors and 63% (103) were nurses. Of the resident doctors, the numbers of junior residents were more than that of senior resident. Similarly, more junior nurses (73%) participated in the study than senior nurses (27%). The details of the demographic data are given in Table 1.

For the assessment of knowledge of the doctors and nurses regarding PVG and ADR reporting, 19 MCQs were used

that encompassed questions relating to knowledge about PvPI, ADR reporting forms, what types of ADRs must be reported, etc. There was a highly significant ($P < 0.001$) improvement in the knowledge of both doctors and nurses after the educational intervention. The doctors had better pre-test knowledge than nurses. The detailed analyses of the change in knowledge before and after the session conducted are mentioned in Tables 2 and 3 for the doctors and nurses, respectively. The doctor's median score of pre-intervention was 9 (range 3–15) and post-intervention was 16 (range 10–19), and nurses median score of pre-intervention was 0 (range 0–3) and post-intervention was 18 (range 12–19); it showed improvement in both groups ($P < 0.0001$). A comparison of educational intervention between doctors and nurses demonstrated more improvement in nurses compared to doctors.

An array of 10 questions were used to assess the attitude of the HCPs regarding PVG and ADR reporting with questions related to the importance of ADR reporting, whether it

should be mandatory, whether any monetary reward should be associated with it, etc. In general, the pre-test attitude of the doctors was better than that of the nurses. There was a positive increase in attitude after the educational session. Most of the participants thought that some monetary reward must be given for spontaneous ADR reporting. The detailed analysis of the change in attitude before and after the educational intervention is given below in Tables 4 and 5 for the doctors and nurses, respectively.

There were three questions to assess the practice of ADR reporting of the HCPs. These questions strived to assess whether the participants have ever reported an ADR during practice in our hospital, ever been trained, and ever read any article regarding ADR prevention. Although there was an overall increase in practice-related aspects of the HCPs but the increase in ADR reporting even after 1 month was very less. Only 10 of the 61 doctors reported an ADR and none of the nurses reported any ADR even after being educated about it. Even out of the doctors who reported an ADR, the maximum reports were from the dermatology department followed by pediatrics and then obstetrics and gynecology departments. The detailed analysis of the change in practice before and after the educational intervention is given below in Tables 6 and 7 for the doctors and nurses, respectively.

The most frequent reasons that discouraged ADR reporting for the doctors and nurses were lack of time since managing patient was more important. The doctors did also emphasize that lack of access to ADR reporting forms at the point of time of reporting is crucial.

Among the factors that would encourage ADR reporting, the most frequently chosen response by the doctors was the availability of an assistant for reporting (since there is lack of time) and reward in monetary form.

DISCUSSION

Our entire study focused on not only assessing the KAP of the HCPs but also on educating them regarding PVG and ADR reporting and then assess whether this intervention put any impact upon the KAP or not. Out of the study participants, among the doctors, majorities were faculty doctors and junior doctors and among the nurses, junior nurses were dominating. This is similar to one other study done in south India.^[11] Senior nurses and doctors participated less probably due to the high workload upon them.

The pre-test knowledge of the doctors was much better than that of the nurses. Although the nurses were lacking the knowledge before the educational session, after the session, their response improved more than the increase of the doctors. This is in contrast with another study done in south India.^[11] As observed during the educational intervention, almost none

Table 1: Demographic data of the study participants

Characteristics	n=164 (%)
Male/Female (nurses)	4:99
Male/Female (doctors)	44:17
Designation	Doctors (n=61)
	Faculty = 38 (62)
	Resident doctors = 23 (38)
	Nurses (n=103)
	Senior nurses = 28 (27)
	Junior nurses = 75 (73)
Specialization of the doctors	General medicine = 7
	General surgery = 6
	Anesthesia = 6
	Obs. and Gyne = 6
	Pediatrics = 5
	Orthopedics = 4
	Community medicine = 4
	Pharmacology = 4
	Ophthalmology = 3
	TB and chest = 2
	ENT = 2
	Psychiatry = 2
	Microbiology = 2
	Pathology = 2
Forensic medicine = 2	
Dentistry = 2	
Dermatology = 2	

n: Total number (% - percent)

Table 2: Assessment of knowledge toward pharmacovigilance, pre- and post- educational intervention of doctors

Questions related to knowledge	Knowledge of doctors				P-value
	Pre-test correct response		Post-test correct response		
	n=61	%	n=61	%	
Are you aware of the national pharmacovigilance program of India?	45	73.77	61	100.00	0.001
In India, which regulatory body is responsible for monitoring ADRs?	11	18.03	40	65.57	0.001
From where can you get the ADR reporting form?	28	45.90	30	49.18	0.001
Do you have free and easy access to ADR reporting forms?	18	29.51	51	83.61	0.001
To whom do you report ADR?	18	29.51	46	75.41	0.001
Who all can report an ADR?	48	78.69	60	98.36	0.001
Out of the options given, in your knowledge, how many of these drugs are known to cause ADRs?	47	77.05	52	85.25	0.001
Are you aware of any drugs banned due to ADRs?	34	55.74	50	81.97	0.001
Are you aware of the ADR reporting center near you?	8	13.11	43	70.49	0.001
Are you aware of national reporting center in India?	5	8.20	45	73.77	0.001
Are you aware of main international reporting center?	2	3.28	26	42.62	0.001
Who gets benefit of reporting ADR?	46	75.41	59	96.72	0.001
ADR reports should be sent to AMC within how many days of suspected ADR?	34	55.74	55	90.16	0.001
Does your hospital have an ADR monitoring center?	15	24.59	50	81.97	0.001
Do you think ADR underreporting is prevalent India?	51	83.61	56	91.80	0.001
According to you, which ADRs should be reported?	46	75.41	55	90.16	0.001
According to you, which ADRs should be reported?	52	85.25	58	95.08	0.001
According to you, which ADRs should be reported?	51	83.61	61	100.00	0.001
An ADR is said to be serious if the patient outcome is?	37	60.66	61	100.00	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

of the nurses and only a few doctors had heard of or used the ADR reporting app.

In the pre-test, about 73.77% of the doctors and 11.65% of the nurses knew what is PVG, while the post-test response rocketed to 100% in doctors and 98.06% in nurses when a similar question was asked: In one other studies done on nurses the percent increased from 30.6% to 99%^[9] and 27% to 90%.^[10] In another study done on doctors, it was from 55.2% to 98.9%^[12]

In the doctors, questions related to the location of national and international reporting centers and from where to avail the ADR reporting form had very less percentages of correct responses in the pre-test while the response in the post-test increased, same as in other studies^[9,13,15] and different from other study.^[11] Questions like what all ADRs should be reported and what are serious ADRs had a high percentage of correct response even in the pre-test and the post-test correct response increased till 100%.

Among the nurses, in the pre-test mostly all questions had a low correct response % but in the post-test these percentages increased massively and touched 90–100% for most of the questions. The finding is almost similar to another study done in the nearby area of the present study, but the sample size of

the said study was less (number of nurses-30) in contrast to our study ($n = 103$).^[10]

The same goes with attitude related questions. Among the doctors, the pre-test attitude was good, and it improved in the post-test, whereas in the nurses, the pre-test attitude was poor, and it improved to a greater extent in the post-test, same as another study.^[9-11]

However, in practice related section, the nurses were far behind and even after an entire month, no ADRs were reported by the nurses even though a proper follow-up was done by face-to-face interaction and through other messaging apps. The doctors showed some improvement in this regard and reported a few ADRs, but still the number of reported ADRs was not satisfactory as the majority of the doctors complained of lack of time to report an ADR due to the magnanimous workload. The studied hospital is located in a tribal belt and is the only tertiary care hospital in this area, and therefore, it is met with a huge load of patients from neighboring villages. There is no ADR MC (AMC) in our study place, and therefore, the status of KAP of the nurses and doctors here was not good, this is very different from a study done in a teaching hospital that had an AMC.^[11]

The practice of the ADR reporting by the HCPs is reportedly poorer than expected in most of the studies done whether or

Table 3: Assessment of knowledge toward pharmacovigilance, pre- and post- educational intervention of nurses

Questions related to knowledge	Knowledge of nurses				P-value
	Pre-test correct response		Post-test correct response		
	n=103	%	n=103	%	
Are you aware of the national pharmacovigilance program of India?	12	11.65	101	98.06	0.001
In India, which regulatory body is responsible for monitoring ADRs?	0	0.00	98	95.15	0.001
From where can you get the ADR reporting form?	4	3.88	85	82.52	0.001
Do you have free and easy access to ADR reporting forms?	2	1.94	102	99.03	0.001
To whom do you report ADR?	0	0.00	99	96.12	0.001
Who all can report an ADR?	6	5.83	99	96.12	0.001
Out of the options given, in your knowledge, how many of these drugs are known to cause ADRs?	4	3.88	16	15.53	0.001
Are you aware of any drugs banned due to ADRs?	4	3.88	60	58.25	0.001
Are you aware of the ADR reporting center near you?	0	0.00	87	84.47	0.001
Are you aware of national reporting center in India?	0	0.00	97	94.17	0.001
Are you aware of main international reporting center?	0	0.00	82	79.61	0.001
Who gets benefit of reporting ADR?	16	15.53	97	94.17	0.001
ADR reports should be sent to AMC within how many days of suspected ADR?	0	0.00	92	89.32	0.001
Does your hospital have an ADR monitoring center?	18	17.48	94	91.26	0.001
Do you think ADR underreporting is prevalent India?	0	0.00	103	100.00	0.001
According to you, which ADRs should be reported?	2	1.94	98	95.15	0.001
According to you, which ADRs should be reported?	2	1.94	103	100.00	0.001
According to you, which ADRs should be reported?	2	1.94	103	100.00	0.001
An ADR is said to be serious if the patient outcome is?	6	5.83	103	100.00	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

Table 4: Assessment of attitude toward pharmacovigilance, pre- and post- educational intervention of doctors

Questions related to attitude	Attitude of doctors				P-value
	Pre-test correct response		Post-test correct response		
	n=61	%	n=61	%	
How important do you think it is to report ADRs?	58	95.08	61	100.00	0.001
Do you think pharmacovigilance should be taught in detail to health-care professionals?	55	90.16	61	100.00	0.001
In your opinion, should there be an ADR monitoring center in every hospital?	57	93.44	61	100.00	0.001
According to you, should a clinician/nurse be aware of ADRs due to particular drugs before administering?	57	93.44	61	100.00	0.001
According to you, should one have a suspicion of possible ADR during treatment or diagnosis?	56	91.80	61	100.00	0.001
In your opinion, can ADR reporting by one person make a significant contribution to betterment of health care of society?	51	83.61	61	100.00	0.001
In your opinion, should ADR reporting in the hospital by health-care professional be voluntary?	41	67.21	58	95.08	0.001
In your opinion, should ADR reporting in the hospital be mandatory?	53	86.89	61	100.00	0.001
Should there be any financial reward for ADR reporting?	20	32.79	25	40.98	0.001
Do you think it is your social responsibility to report ADRs?	55	90.16	61	100.00	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

not an intervention was involved.^[10-25] Underreporting is still prevalent even after educating the HCPs, although regular follow-up, asking for suggestions and providing assistance

proved to be useful in increasing the ADR reporting within the short span of time that we had for our study. Still, after several studies done in the various parts of the world and all-over India

Table 5: Assessment of attitude toward pharmacovigilance, pre- and post- educational intervention of nurses

Questions related to attitude	Attitude of nurses				P-value
	Pre-test correct response		Post-test correct response		
	n=103	%	n=103	%	
How important do you think it is to report ADRs?	36	34.95	99	96.12	0.001
Do you think pharmacovigilance should be taught in detail to health-care professionals?	6	5.83	103	100.00	0.001
In your opinion, should there be an ADR monitoring center in every hospital?	89	86.41	101	98.06	0.001
According to you, should a clinician/nurse be aware of ADRs due to particular drugs before administering?	93	90.29	96	93.20	0.001
According to you, should one have a suspicion of possible ADR during treatment or diagnosis?	90	87.38	95	92.23	0.001
In your opinion, can ADR reporting by one person make a significant contribution to betterment of health care of society?	96	93.20	98	95.15	0.001
In your opinion, should ADR reporting in the hospital by health-care professional be voluntary?	56	54.37	103	100.00	0.001
In your opinion, should ADR reporting in the hospital be mandatory?	65	63.11	102	99.03	0.001
Should there be any financial reward for ADR reporting?	77	74.76	45	43.69	0.001
Do you think it is your social responsibility to report ADRs?	67	65.05	100	97.09	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

Table 6: Assessment of practice of pharmacovigilance, pre- and post-educational intervention of doctors

Questions related to practice	Practice of doctors				P-value
	Pre-test correct response		Post-test correct response		
	n=61	%	n=61	%	
Have you ever reported any ADR during your practice in our hospital?	0	0.00	10	16.39	0.001
Have you ever been trained on how to report ADRs?	14	22.95	61	100.00	0.001
Have you ever read any article on prevention of adverse drug reactions?	26	42.62	47	77.05	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

Table 7: Assessment of practice of pharmacovigilance, pre- and post-educational intervention of nurses

Questions related to practice	Practice of nurses				P-value
	Pre-test correct response		Post-test correct response		
	n=103	%	n=103	%	
Have you ever reported any ADR during your practice in our hospital?	0	0.00	0	0.00	-
Have you ever been trained on how to report ADRs?	0	0.00	103	100.00	0.001
Have you ever read any article on prevention of ADRs?	0	0.00	11	10.68	0.001

n: Total number (% - percent). ADR: Adverse drug reaction

ADR reporting remains to be prevalently poor. Some measures that can be suggested to improve the current status may be easier reporting methods: Promotion and encouraging the use of the ADR reporting app since the world is digitalizing this method can prove to be very handy. Other suggestions include making ADR reporting mandatory and regular workshops and follow-ups to keep the process in motion.

Limitations of the Study

The main limitation we had was of the time we had for the study. Due to the scarcity of time, we could only assess

ADR reporting for 1 month. The results could have been better had we had more time. Second, ours' is a new college, and therefore, the general awareness and practice of ADR reporting were very less. This also pertains to the fact that the studied site lies in the tribal belt of central India. All this made conducting the study a grueling job.

Strength of the Study

This was one of the very first studies done in a tribal area of central India. We not only collected data but also educated the HCPs regarding the PVG and ADR reporting. Due to all

this, the ADR reporting in the studied site improved from an initial state of zero reporting to at least 10 reports in the 1 month we had for our study. At present, there is no AMCs or center of PVG in the studied district and our new medical college looks forward to becoming one and our study served as the first step toward this goal.

CONCLUSIONS

After this entire study, we conclude that the initial knowledge and attitude of the doctors and nurses was low, but it immensely improved after the educational intervention. This suggests that the problem of ADR under-reporting can be dealt by two important mode, first with the educational interventions and second by determination if we work meticulously and if the HCPs together take up the responsibility of ADR reporting, we might reach to our goal after all the doctors and nurses are the supporting pillars of our health-care industry and they have to understand that only they can do.

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