Original Article

Knowledge assessment in adverse drug reactions and reporting

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ABSTRACT

Objectives: In India, adverse drug reaction (ADR) monitoring activity is in infancy. This study was conducted to determine the pattern and extent of occurrence of ADRs in the hospital, to analyze the ADRs reporting behaviors in healthcare professionals (HCPs), to analyze the knowledge about ADRs in HCP, to analyze and compare the ADRs reported by HCP and to analyze the barriers involved in nonreporting of suspected ADRs. **Materials and Methods:** The study was carried out at Kovai Medical Center and Hospital (KMCH). A questionnaire containing 19 questions was distributed to the teaching faculties of pharmacy college, physicians, nurses, and students of the study setting. **Results and Conclusion:** The response rate of faculties, physicians, nurses, and students for the questionnaire in phase-I were found to be 66.67%, 40.00%, 66.67%, and 73.33%, respectively. But the response rates remarkably increased in phase-II when compared with phase-I study viz., 100% from faculties and students, 93.33% from physicians, and 86.67% from nurses. Almost all the participants said that ADR monitoring is done in their institution. Majority of the participants said that ADR should be reported if it causes both inconvenience and death to the patients. In our study, physicians (93%) knew the objectives of ADR monitoring very well in phase-II, when compared with phase-I study (75%), which was followed by faculties (83%), nurses (77%), and students (73%). Spontaneous reporting of ADRs is denoted by all faculties, 93% physician, 80% students, and 77% nurses in phase-II study. All participants in the phase-II survey knew any one method to monitor ADRs but in phase-I, 10% nurses and 9% students did not know about any method of monitoring ADR. Lack of knowledge about ADR reporting center is the mainstay in under-reporting or nonreporting of observed ADRs noted by only 6.67% of faculties, 19.23% nurses, and 10% students. The reason for underreporting was very much reduced in phase-II than in phase-I.

Key words: Adverse drug reactions, barriers, healthcare professionals, knowledge, underreporting

INTRODUCTION

India became a collaborating member of the World Health Organization-adverse drug reaction (WHO-ADR) monitoring program 30 years after its establishment. The pattern of drug use and ADRs in India is quite different due to the socio-economic, ethnic, nutritional, and other factors. The Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) have established ADR monitoring centers in many hospitals in major cities of India. Despite these efforts and the presence of a large number of tertiary care facilities, pharmacovigilance is still in its infancy. Gross under reporting of ADRs is a cause of concern, the reasons for which may be due to lack of trained staff and lack of awareness regarding detection, communication, and spontaneous monitoring of ADRs. ADRs may be under reported, since many physicians are not aware of importance of monitoring and reporting of ADRs.[1]

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Spontaneous reporting of ADRs would enhance monitoring and evaluation activities related to drug safety. To improve the pharmacovigilance activities in India, the Ministry of Health and Family Welfare had initiated the National Pharmacovigilance Program (NPP) on January 1, 2005, which was further reviewed in July 2010. This program is overseen by Central Drugs Control Organization (CDSCO), New Delhi. ADR reports will be collected at the monitoring centers, which will then be dispatched to the coordinating center as per the standard operating procedures. The coordinating center will conduct causality assessment and upload the reports into the pharmacovigilance software. Lastly, the integrated ADR data will be transmitted through vigiflow software interface into the Uppsala Monitoring Center's ADR database where signal processing can be carried out.[2]

Recently, the Medical Council of India has recommended teaching of ADR monitoring to the undergraduate (UG) students.[1] Primary objectives of the current prospective observational spontaneous reporting study were to study the pattern and extent of occurrence of ADRs in the hospital, to analyze the ADRs reporting behaviors in healthcare professionals (HCPs) (physicians, nurses, pharmacist of Kovai Medical Centre and Hospital; facultis and students of the KMCH college of pharmacy), to analyze the knowledge about ADRs in HCP, to analyze and compare the ADRs reported by HCP, and to analyze the barriers involved in nonreporting of suspected ADRs.

MATERIALS AND METHODS

Study site

The study was carried out at Kovai Medical Center and Hospital (KMCH), a 800-bed private corporate multi-specialty tertiary care hospital, which has all facilities under one roof. All departments of the hospital were included in this study, which has the potential of ADRs.

Study design

Prospective, observational, spontaneous reporting study with both active and passive methods: (a) Active method: Pharmacist actively looking for suspected ADRs and (b) Passive method: Stimulating prescriber to report suspected ADRs

Study period

The study was carried for a period of one year between July 2011 and June 2012.

Protocol of the study, which includes objectives, plan, and methodology, were submitted to the Chairman, Kovai Medical Center Research and Educational Trust (KMCRET) and KMCH and to the KMCH Ethics Committee. The authorization of Chairman and Medical Director were obtained to carry out the study. Ethical committee clearance was obtained from the KMCH Ethics Committee to carry out the study in the hospital patients (Ref. No: EC/AP/103/09-2009).

Inclusion criteria

Prescribers, nurses, pharmacists, patients, and their volunteers of the hospital were included in the study. Both the WHO and American Food and Drug Administration (FDA) definitions were used to describe the ADRs and to identify the patients. WHO defines ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for modification of physiological function." FDA defines adverse event as "any untoward medical occurrence associated with the use of a drug in human."

Exclusion criteria

ADR report of patients who develop an ADR due to accidental or intentional poisoning, ADR due to fresh blood or blood products, ADR due to over dose, patients with drug abuse, and intoxication were excluded from the study.

ADRs notification form

Separate ADRs notification form was designed that consists of all relevant data including patient's demographic details, all drugs patient received prior to onset of reaction, their route of administration, respective dosage, frequency, date of onset of reaction, and the patient's allergy status to drugs and foods, ADRs management, details of reporter, etc.

This form was made available in all nursing stations of the hospital and the out-patient areas for easy access to all HCP. It has 2-fold advantages; primarily to serve as an official medium of reporting back to the HCP with necessary information pertaining to the suspected ADRs reported. Secondly, it is to encourage their continuous reporting of suspected ADRs.

ADRs documentation form

A separate data entry format was specially designed for the documentation of suspected ADRs in the study. It contains patient's demographic details, past medical history, past medication history, reason for admission,

laboratory investigations like all blood and urine examinations, current diagnosis of the disease, name of the ADRs, description of the reaction, date of onset of reaction, name of the suspected drug in trade and generic name, dose (s) given, route and frequency of administration, date of therapy started and stopped, and indications of the drug. The ADRs treatment chart also included name of the drug (s), dose (s) prescribed, cost of the drug (s), number of days prescribed, and total cost of therapy.

Assessment of causality

The extent of relationship between suspected ADR and the drug therapy was assessed using the WHO Probability assessment scale.[3] It was further classified into: Certain: A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure, if necessary.

Probable/likely: A clinical event, including laboratory test abnormality, with a reasonable time sequence to the administration of drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.

Possible: A clinical event, including laboratory test abnormality, with a reasonable time sequence to the administration of drug, but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.

Unlikely: A clinical event, including laboratory test abnormality, with a temporal relationship to drug administration, which makes a causal relationship improbable, and in which other drugs, chemicals or underlying disease provide plausible explanations.

Conditional/unclassified: A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data is essential for a proper assessment or additional data is under examination.

Unassessable/unclassifiable: A report suggesting an adverse reaction that cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.

The causality relationship between a drug and suspected reaction was established by using the Naranjo's causality assessment scale,[4] further the causal relation is classified into definite, probable, possible, and unlikely.

It consists of 10 questions, Yes, No, and Not known are the three options, based on this Definite > or equal to 9, Probable 5-8, Possible 1-4, and Unlikely < or equal to 0 were determined.

Assessment of severity

Severity of the reaction was assessed by using the Modified Hartwig and Siegel Severity assessment scale[5] and the severity is broadly categorized into "mild," "moderate," and "severe" for each ADR. The suspected ADR is "mild" when "an ADR occurs but requires no change in treatment with the suspected drug" or the ADR requires that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS).

The suspected ADR is "moderate" when "the ADR requires treatment with the suspected drug be held, discontinued, or otherwise changed" and/or "an Antidote or other treatment was required. No increase in LOS" or "any level 3 ADR that increases LOS by at least 1 day," or "the ADR was the reason for the admission."

The suspected ADR is "severe" when "Any level 4 ADR that requires intensive medical care or the adverse reaction caused permanent harm to the patient or the adverse reaction either directly or indirectly led to death of the patient."

Assessment of preventability

All the reported ADRs were assessed for their preventability using the modified criteria of Schumock and Thornton's by Lau *et al.*,[6] and were categorized into "Definitely preventable," "probably preventable," and "not preventable."

Predisposing factors were assessed based on whether or not the patients had any of the predisposing factors quoted in the published literature as a risk.

Preparation and issue of alert card

All the patients who were admitted to the hospital due to an ADR were provided, whereever applicable,

with an "ALERT CARD," so as to prevent the future occurrence of similar ADRs in the patient. The alert card was designed to have patient name, age, sex, suspected drug and their reactions, severity of reactions, any other information if needed.

All the reported and evaluated suspected ADRs were documented in a suitably designed form and a feedback to each reporter was given using a "THANK YOU" note. It has 2-fold advantages; primarily to serve as an official medium of reporting back to the healthcare professional with necessary information pertaining to the suspected ADRs reported. Secondly, it as a method is to encourage their continuous reporting of suspected ADRs.

Preparation and implementation of questionnaire for the assessment of knowledge about ADRs and reason(s) for not reporting by HCP

A questionnaire was prepared and developed that contained 19 different questions; first 8 questions were focused to assess the knowledge about ADRs among HCP,[7] and the remaining 11 questions were focused to assess the reason for not reporting ADRs.

The first four set of questions were mainly focused to assess the basic knowledge like definition of ADRs, classification of ADRs, objectives of ADRs monitoring and reporting, monitoring methods, present status of ADRs monitoring in the study hospital, whether ADR monitoring should be done routinely for better patient care, ADR should be reported if it causes and ADR should be reported to, that is, when to report and where to report the suspected ADRs.

The last five set of questions were used to assess the reason for not reporting an ADRs, which includes: Not aware of correct reporting centers; do not have ADR reporting form; feeling that ADR was well known; not sure about the drug causing ADR; do not have set procedure for ADR reporting in their organization and aware of pharmacovigilance; report observed ADR; knew National Monitoring Center (NMC)/Regional Monitoring Center (RMC) as reporting centers; aware of ADR reporting center in Coimbatore; have phone number and address of NPP reporting in their organization; have set procedure of ADR reporting in their organization; nonreporting due to lack of knowledge about center; uncertain of drug causing ADR, feel all ADRs are well known and have ADR reporting form.

Assessment of knowledge about ADRs and reason(s) for not reporting by HCP

Prepared and developed questionnaire was distributed to the prescribers of the study hospital, teaching faculty of the institution and final year UG students of the study setting. The questionnaire was distributed twice, that is, before implementing the study in the hospital and after implementing the study with an interval of one year duration. In the mean time, ADRs notification form, and ADRs alert card, were prepared and implemented. Respondents were requested to fill the answer for the simple questions in front of the clinical pharmacist. Sufficient time was given to complete the questionnaire. Finally the filled questionnaire was collected for analyzing knowledge about ADRs and the reason for not reporting suspected ADRs.

Data analysis and interpretation

Collected data were analyzed for its appropriateness and suitability, characteristics of ADRs, nature and pattern of ADRs related hospital admission, differences in the severity of ADRs, management of ADRs, outcome of the management of ADRs, reporting behavior in HCP, knowledge about ADRs among HCP, barriers in reporting suspected ADRs. Interpretation was made for the collected data.

Statistical analysis

Statistical analysis was performed with SPSS software, version 17.0. P values < 0.05 were considered to be statistically significant. From the data analysis, results were obtained and conclusion was drawn. The collected ADRs datas were reported to the regional pharmacovigilance center and to the peripheral center.

RESULTS

In the current study, the severity of suspected ADRs were assessed by using the modified Hartwig and Siegel Severity assessment scale, it revealed that majority of the suspected ADRs were found to be moderate (n = 583; 61.37%). Mild ADRs were found to be 308 (32.42%), which is followed by severe ADRs. Lethal effects were observed in 4 (0.42%) of the study patients.

Causality assessment was used to describe the causal relationship between offending drugs and the reaction and it was done by using the Naranjo's causality assessment scale and showed that 20 (2.11%) ADRs were definitely related to drugs, 759 (79.89%) ADRs were probably related to drugs, 165 (17.37%)

ADRs were possibly related to drugs, and 6 (0.63%) ADRs were unlikely related to drugs.

Probability of the suspected ADRs was assessed by using the WHO probability assessment scale and revealed that 22 ADRs were certain, 758 ADRs were probable or likely, 160 ADRs were possible, 5 ADRs were unlikely, 5 ADRs were unassessable or unclassifiable and none of the ADRs were conditional or unclassified.

Preventability of the suspected ADRs was assessed by using the Schmock and Thornton criterion modified by Lau *et al.*, and showed that 384 (40.42%) ADRs were definitely preventable. Probably preventable ADRs were 294 (30.95%) and 272 (28.63%) ADRs were identified as not-preventable.

Management of ADRs in the study population shows that in 89.89% (n = 854) of patients, the offending drug was withdrawn, dose was altered in 10.11% (n = 96) of the patients.

In this prospective observational spontaneous reporting study, pharmacist played a major role in reporting the suspected ADRs. Pharmacist reported the most number of ADRs of about 40.18% (n = 493) of ADRs, next to pharmacist, nurses reported good percent of ADRs (n = 310; 25.26%) that is one-fourth of the ADRs and prescriber reported 13.04% (n = 160) of ADRs. Patients reported 7.82% (n = 96) of ADRs but more than this their volunteers reported 11.65% (n = 143) of ADRs. Other people reported only 2.04% (n = 25) of ADRs in this study [Table 1].

Regarding the mode of reporting of suspected ADRs (n = 1227), 1131 ADRs were reported through ADRs notification or reporting form, 46 ADRs were reported through referral mode, and 20 ADRs were reported through telephone; 30 ADRs were reported through direct contact with the pharmacist. A total of 1227 ADRs were reported, from these, 950 ADRs were accepted and the remaining reports were not accepted due of lack of information or the reactions were not coming under the category of ADRs.

In these accepted ADRs (n = 950), 887 ADRs were reported through ADRs notification or reporting form, 22 from referral mode and 12 ADRs reported through telephone. From 30 ADRs reported by direct contact, 29 ADRs were accepted [Table 2].

A questionnaire was developed to assess the knowledge about ADRs among the HCPs, teaching faculties, nurses, and students of the study settings. The developed questionnaire was distributed by direct approach with the HCPs, teaching faculties, nurses, and students, they were requested to fill and return the questionnaire. Enough time was given to fill the answer in the questionnaire and finally the filled or completed questionnaire were collected. The questionnaire was distributed two times, one at the time of beginning of phase-I study and the second at the end of phase-II study. The response rate was found out by dividing the number approached by number responded with filled questionnaire.

In phase-I, 30 faculties of the pharmacy college were approached and 20 responded well with the filled questionnaire, 20 physicians were approached and 8 responded well. Thirty nurses and 30 students were approached to fill the questionnaire, 20 nurses and 22 students responded with the filled questionnaire. The response rate of faculties, physicians, nurses, and students were found to be 66.67%, 40%, 66.67%, and 73.33%, respectively [Table 3].

In phase-II, 30 faculties of the pharmacy college were approached and all responded well with the filled questionnaire, 30 physicians were approached and 28 responded well. Equal number (n = 30) of nurses and students were approached to fill the questionnaire in phase-II, 26 nurses and 30 students responded and returned the filled questionnaire with response rate of 86.67% and 100%, respectively. The response rates remarkably increased in the phase-II when compared with phase-I study [Table 4].

Table 1: Status of reporters of ADRs

Reporter(s)	Number	Percent
Pharmacists	493	40.18
Prescribers	160	13.04
Nurses	310	25.26
Patients	96	7.82
Patient volunteers	143	11.65
Others	25	2.04
Total	1227	100.00

ADR=Adverse drug reaction

Table 2: Mode of reporting of suspected ADRs

Mode of reporting	Reported		Accepted	
	Number	Percent	Number	Percent
ADRs notification/ reporting form	1131	92.18	887	93.37
Referral	46	3.75	22	2.32
Telephone	20	1.63	12	1.26
Direct contact	30	2.44	29	3.05
Total	1227	100.00	950	100.00

ADR=Adverse drug reaction

The demographic study of respondents revealed that in phase-I study, 33 were male and 37 were female; 5 respondents were UG teachers and 15 were postgraduate (PG) teachers; 22 respondents were UG students and PG students were not included in this study. A total of 42 respondents were found to have UG qualifications and 28 were PGs.

A good response was observed in phase-II study, in which 72 respondents were male and 42 were female; only 4 were UG teacher and 26 were PG teachers. A total of 30 were UG students and PG students were not included. Respondents with educational qualification revealed that, 55 were UGs and 59 were PGs [Table 5].

A questionnaire was prepared to assess the knowledge about ADRs among HCP, which contains 19 different questions; the first 8 questions were focused to assess the knowledge about ADRs and the remaining 11 questions were focused to assess the reason for not reporting ADRs.

Table 3: Response for the questionnaires in phase-I

Status of respondents	Approached (*n*=110)	Responded (*n*=70)	Percentage of response
Faculties	30	20	66.67
Physicians	20	08	40.00
Nurses	30	20	66.67
Students	30	22	73.33

*P<0.001

Table 4: Response for the questionnaires in phase-II

Status of respondents	Approached (*n*=120)	Responded (*n*=114)	Percentage of response
Faculties	30	30	100
Physicians	30	28	93.33
Nurses	30	26	86.67
Students	30	30	100

*P<0.001

In phase-I study, 8 (40%) faculties, 3 (37.5%) physicians, 1 (5%) nurse, and 6 (27.27%) students wrote correct definition for ADRs. A total of 6 (30%) faculties, 1 (12.5%) physician, and 9 (40.90%) students classified the ADRs and none of the nurses classified correctly. Regarding the objectives of ADRs monitoring, 12 (60%) faculties, 6 (75%) physicians, 16 (80%) nurses, and 12 (54.5%) students noted that ADRs were monitored to identify quickly important or serious ones and give early warning to concerned authorities; 5 (25%) faculties, 2 (25%) physicians, 1 (5%) nurse, and 5 (22.72%) students reported that ADRs are monitored as an attempt to establish a cause–effect relationship between drug and reaction; 3 (15%) faculties and 3 (13.63%) students reported that ADRs monitoring were done to find out the incidence of particular reaction. Three (15%) nurses and 2 (9.09%) students replied that they do not know about the objectives of ADRs monitoring.

Regarding the monitoring methods of ADRs, 14 (70%) faculties, 7 (87.5%) physicians, 11 (55%) nurses, and 7 (31.81%) students noted the spontaneous reporting system is used for ADRs monitoring; 4 (20%) faculties, 6 (30%) nurses, and 11 (50%) students mentioned intensive monitoring for a particular drug; 1 (5%) faculty and 2 (9.09%) students mentioned cohort or case control study; Randomized trials was reported by 1 (5%) faculty, 1 (12.5%) physicians, and 1 (5%) nurse. A total of 2 (10%) nurses and 2 (9.09%) students do not know about the ADRs monitoring methods.

Twenty (100%) faculties, 8 (100%) physicians, 15 (75%) nurses, and 22 (100%) students knew the present status of ADR monitoring in the hospital. Only 5 (25%) nurses did not know about the present status of ADR monitoring in the hospital.

Table 5: Demographic details of the respondents in phase-I and phase-II

Demographic details	Faculties		Physicians		Nurses		Students		Total	
	Phase-I (*n*=20)	Phase-II (*n*=30)	Phase-I (*n*=08)	Phase-II (*n*=28)	Phase-I (*n*=20)	Phase-II (*n*=26)	Phase-I (*n*=22)	Phase-II (*n*=30)	Phase-I	Phase-II
Male	15	26	6	25	0	0	12	21	33	72*
Female	5	04	2	03	20	26	10	09	37	42*
UG teachers	5	04	0	0	0	0	0	0	5	4
PG teachers	15	26	0	0	0	0	0	0	15	26*
UG students	0	0	0	0	0	0	22	30	22	30*
PG students	0	0	0	0	0	0	0	0	0	0
Respondents with UG qualification	0	0	0	7	20	18	22	30	42	55*
Respondents with PG qualification	20	30	08	21	0	8	0	0	28	59*

*P<0.001

Twenty (100%) faculties, 8 (100%) physicians, 15 (75%) nurses, and 21 (95.45%) students answered 'Yes' for the question 'whether ADR monitoring should be done routinely for better patient care'. A total of 5 (25%) nurses and 1 (4.55%) answered 'No' for the same question.

One (5%) faculty, 1 (12.5%) physician, 1 (5%) nurse, and 2 (9.09%) students answered ADR should be reported if it causes inconvenience to the patient; 3 (15%) nurses replied it should be reported when it causes death of the patient; 19 (95%) faculties, 7 (87.5%) physicians, 16 (80%) nurses, and 20 (90.90%) students replied ADRs should be reported if it causes both inconvenience and death of the patient.

Three (15%) faculties, 3 (37.5%) physicians, 9 (45%) nurses, and 4 (18.18%) students mentioned that ADR should be reported to head of the unit or department, whereas 10 (50%) faculties, 3 (37.5%) physicians, 5 (25%) nurses, and 6 (27.27%) students mentioned it should be reported to department of pharmacy practice or pharmacology. National ADR monitoring center was reported by three (15%) faculties, two (10%) nurses, and four (18.18%) students but not even a single physician mentioned these centers. Four (20%) faculties, two (25%) physicians, two (10%) nurses, and seven (31.81%) students mentioned WHO-ADR monitoring cell (regional office) to report an ADR but 2 (10%) nurses and 1 (4.55%) student replied that they do not know where to report an ADR.

In the reason for not reporting of suspected or observed ADRs, 5 (25%) faculties, 2 (25%) physicians, 15 (75%) nurses, and 2 (9.09%) students responded that they were not aware of pharmacovigilance program. Fifteen (75%) faculties, 6 (75%) physicians, 5 (25%) nurses, and 20 (90.90%) students were aware about the pharmacovigilance program. Nine (45%) faculties, 6 (75%) physicians, 11 (55%) nurses, and 14 (63.63%) students replied that they will report the observed ADR. A total of 11 (55%) faculties, 2 (25%) physician, 9 (45%) nurses and 8 (36.36%) students did not report the observed ADRs.

Twelve (60%) faculties, 3 (37.5%) physicians, 17 (85%) nurses, and 12 (54.54%) students do not know about the NMC or RMC to report ADRs. Eight (40%) faculties, 5 (63.5%) physicians, 3 (15%) nurses, and 10 (45.45%) students have knowledge about the NMC or RMC as reporting centers. Eight (40%) faculties, 5 (63.5%) physicians, 2 (10%) nurses, and 14 (63.63%) students were aware of ADR reporting center in Coimbatore and the remaining participants were not aware about the reporting center.

Six (30%) faculties, two (25%) physicians, two (10%) nurses, and six (27.27%) students told that they have phone number and address of NPP reporting in their organization. Fourteen (70%) faculties, 2 (25%) physicians, 11 (55%) nurses, and 17 (77.27%) students mentioned that they have set procedure of ADR reporting in their organization. Each of 6 faculties and physicians, 9 nurses, and 16 students mentioned that they do not have a set procedure of ADR reporting.

Twelve (60%) faculties, 6 (75%) physicians, 18 (90%) nurses, and 16 (72.72%) students were not reporting the suspected ADR due to lack of knowledge about center. Seventeen (85%) faculties, 4 (50%) physicians, 16 (80%) nurses, and 17 (77.27%) students were uncertain about the drug causing ADR.

Two (10%) faculties, one (5%) nurse, and four (18.18%) students' feel that all ADRs are well known to them. Six (30%) faculties, four (50%) physicians, seven (35%) nurses, and seven (31.812%) students replied that they have ADR reporting form [Table 6].

We had a tremendous response from the participants for the questionnaire in the phase-II. In phase-II, 27 (90%) faculties, 21 (75%) physicians, 14 (53.85%) nurses, and 25 (83.33%) students wrote correct definition for ADRs. A total of 22 (73.33%) faculties, 24 (85.71%) physicians, 15 (57.69%) nurses, and 21 (70%) students wrote the exact classification of ADRs. Regarding the objectives of ADRs monitoring, 25 (83.33%) faculties, 26 (92.86%) physicians, 20 (76.92%) nurses, and 22 (73.33%) students reported that ADRs were monitored to identify quickly important or serious ones and give early warning to concerned authorities; 3 (10%) faculties, 2 (7.14%) physicians, 5 (19.23%) nurses, and 4 (13.33%) students reported that ADRs are monitored as an attempt to establish a cause–effect relationship between drug and reaction; 2 (6.67%) faculties, 1 (3.85%) nurse, and 2 (6.67%) students reported that ADRs monitoring were done to find out the incidence of particular reaction. One (3.33%) faculty and two (6.67%) students replied that they do not know about the objectives of ADRs monitoring.

Regarding the monitoring methods of ADRs, all 30 (100%) faculties, 26 (92.86%) physicians, 20 (76.92%) nurses, and 24 (80%) students noted that the spontaneous reporting system is used for ADRs monitoring; 2 (7.14%) physicians, 4 (15.38%) nurses, and 4 (13.33%) students mentioned intensive

Table 6: Assessment of knowledge about adverse drug reactions among healthcare professionals, faculties and students in phase-I

Questions	Answers	Faculties *n*=20 (%)	Physicians *n*=8 (%)	Nurses *n*=20 (%)	Students *n*=22 (%)
Definition	Correct	8 (40)	3 (37.5)	1 (5)	6 (27.27)
	Incorrect	6 (30)	1 (12.5)	9 (45)	13 (59.09)
	Partially correct	6 (30)	3 (37.5)	3 (15)	3 (13.63)
	Not attempted	0 (0)	1 (12.5)	7 (35)	0 (0)
Classification of ADRs	Correct	6 (30)	1 (12.5)	0 (0)	9 (40.90)
	Incorrect	8 (40)	3 (37.5)	3 (15)	3 (13.63)
	Partially correct	4 (20)	0 (0)	2 (10)	9 (40.90)
	Not attempted	2 (10)	4 (50)	15 (75)	1 (4.54)
Objectives of ADR Monitoring	Identify quickly important or serious ones and give early warning to concerned authorities	12 (60)	6 (75)	16 (80)	12 (54.5)
	Attempt to establish a cause-effect relationship between drug and reaction	5 (25)	2 (25)	1 (5)	5 (22.72)
	Find out the incidence of particular reaction	3 (15)	0 (0)	0 (0)	3 (13.63)
	Do not know	0 (0)	0 (0)	3 (15)	2 (9.09)
Monitoring methods	Spontaneous reporting	14 (70)	7 (87.5)	11 (55)	7 (31.81)
	Intensive monitoring for a particular drug	4 (20)	0 (0)	6 (30)	11 (50)
	Cohort or case control study	1 (5)	0 (0)	0 (0)	2 (9.09)
	Randomized trails	1 (5)	1 (12.5)	1 (5)	0 (0)
	Do not know	0 (0)	0 (0)	2 (10)	2 (9.09)
Present status of ADR monitoring in your hospital	Done	20 (100)	8 (100)	15 (75)	22 (100)
	Not done	0 (0)	0 (0)	5 (25)	0 (0)
ADR monitoring should be done routinely for better patient care	Yes	20 (100)	8 (100)	15 (75)	21 (95.45)
	No	0 (0)	0 (0)	5 (25)	1 (4.55)
ADR should be report if it causes	Inconvenience to the patient	1 (5)	1 (12.5)	1 (5)	2 (9.09)
	Death of the patient	0 (0)	0 (0)	3 (15)	0 (0)
	Both of the above	19 (95)	7 (87.5)	16 (80)	20 (90.90)
ADR should be report to	Head of the unit/dept	3 (15)	3 (37.5)	9 (45)	4 (18.18)
	Department of Pharmacy Practice/Pharmacology	10 (50)	3 (37.5)	5 (25)	6 (27.27)
	National ADR monitoring center	3 (15)	0 (0)	2 (10)	4 (18.18)
	WHO ADR monitoring cell (regional office)	4 (20)	2 (25)	2 (10)	7 (31.81)
	Do not know	0 (0)	0 (0)	2 (10)	1 (4.55)
	Reason for not reporting ADRs				
Aware of pharmaco-vigilance	Yes	15 (75)	6 (75)	5 (25)	20 (90.90)
	No	5 (25)	2 (25)	15 (75)	2 (9.09)
Report observed ADR	Yes	9 (45)	6 (75)	11 (55)	14 (63.63)
	No	11 (55)	2 (25)	9 (45)	8 (36.36)
Knew NMC/RMC as reporting centers	Yes	8 (40)	5 (63.5)	3 (15)	10 (45.45)
	No	12 (60)	3 (37.5)	17 (85)	12 (54.54)
Aware of ADR reporting center in Coimbatore	Yes	8 (40)	5 (63.5)	2 (10)	14 (63.63)
	No	12 (60)	3 (37.5)	18 (90)	8 (36.36)
Have phone number and address of NPP reporting in their organization	Yes	6 (30)	2 (25)	2 (10)	6 (27.27)
	No	14 (70)	6 (75)	18 (90)	16 (72.72)
Have set procedure of ADR reporting in their organization	Yes	14 (70)	2 (25)	11 (55)	17 (77.27)
	No	6 (30)	6 (75)	9 (45)	5 (22.72)
Nonreporting due to lack of knowledge about center	Yes	12 (60)	6 (75)	18 (90)	16 (72.72)
	No	8 (40)	2 (25)	2 (10)	6 (27.27)
Uncertain of drug causing ADR	Yes	17 (85)	4 (50)	16 (80)	17 (77.27)
	No	3 (15)	4 (50)	4 (20)	5 (22.72)
Feel all ADRs are well known	Yes	2 (10)	0 (0)	1 (5)	4 (18.18)
	No	18 (90)	8 (100)	19 (95)	18 (81.81)
Have ADR reporting form	Yes	6 (30)	4 (50)	7 (35)	7 (31.81)
	No	14 (70)	4 (50)	13 (65)	15 (68.18)

ADR=Adverse drug reaction

monitoring for a particular drug; 1 (3.85%) nurse and 1 (3.33%) student mentioned cohort or case control study; randomized trials was reported by 1 (3.85%) nurse and 1 (3.33%) student. No one made comment on 'do not know' about the ADRs monitoring methods.

All 30 (100%) faculties, 28 (100%) physicians, 22 (84.62%) nurses, and 25 (83.33%) students knew the present status of ADR monitoring in the hospital. Only four (15.38%) nurses and five (16.67%) students did not know about the present status of ADR monitoring in the hospital.

All 30 (100%) faculties, 28 (100%) physicians, 26 (100%) nurses, and 30 (100%) students answered 'Yes' for the question 'whether ADR monitoring should be done routinely for better patient care.' Two (6.67%) faculties, 2 (7.69%) nurses and 3 (10%) students answered ADR should be reported if it causes inconvenience to the patient; 2 (6.67%) faculties, 4 (15.38%) nurses, and 2 (6.67%) students noted it should be reported when it causes death of the patient; 26 (86.67%) faculties, 28 (100%) physicians, 20 (76.92%) nurses, and 25 (83.33%) students answered ADRs should be reported if it causes both inconvenience and death of the patient.

Ten (33.33%) faculties, 2 (7.15%) physicians, 5 (19.23%) nurses, and 10 (33.33%) students answered that ADR should be reported to head of the unit or department, whereas 20 (66.67%) faculties, 10 (35.71%) physicians, 10 (38.46%) nurses, and 30 (100%) students replied it should be reported to department of pharmacy practice or pharmacology. National ADR monitoring center was reported by 25 (83.33%) faculties, 25 (89.29%) physicians, 15 (57.69%) nurses, and 25 (83.33%) students. All 30 (100%) faculties, 28 (100%) physicians, 15 (57.69%) nurses, and 28 (93.33%) students mentioned WHO-ADR monitoring cell (regional office) to report an ADR but 2 (6.67%) students replied that they do not know where to report an ADR.

In the reason for not reporting of suspected or observed ADRs in phase-II study, only 2 (7.69%) nurses and 3 (10%) students did not have awareness of pharmacovigilance program. But all thirty (100%) faculties, 28 (100%) physicians, 24 (92.31%) nurses and 27 (90%) students were aware about the pharmacovigilance program. All our respondents agreed they will report the observed ADR. All 30 (100%) faculties, 28 (100%) physicians, 22 (84.62%) nurses, and 25 (83.33%) students have knowledge about the NMC or RMC as reporting centers but 4 (15.38%) nurses and 5 (16.67%) students mentioned they do not know about reporting centers.

All 30 (100%) faculties, 28 (100%) physicians, 23 (88.46%) nurses, and 28 (93.33%) students were aware of ADR reporting center in Coimbatore but 3 (11.548%) nurses and 2 (6.67%) students were not aware of ADR reporting center in Coimbatore to report the observed ADRs. Ten (33.33%) faculties, 5 (17.86%) physicians, 6 (23.08%) nurses and 8 (26.67%) students told they don't have phone number and address of NPP reporting in their organization. Twenty (66.67%) faculties, 23 (82.14%) physicians, 20 (76.92%) nurses and 22 (73.33%) students told they have phone number and address of NPP reporting in their organization.

Two (6.67%) faculties, 6 (21.43%) physicians, 3 (11.54%) nurses, and 11 (36.67%) students mentioned that they do not have set procedure of ADR reporting in their organization. Twenty-eight (93.33%) faculties, 22 (78.57%) physicians, 23 (88.46%) nurses, and 19 (63.33%) students mentioned that they have set procedure of ADR reporting in their organization. Two (6.67%) faculties, five (19.23%) nurses, and three (10%) students were not reporting the suspected ADR due to lack of knowledge about center. Twelve (40%) faculties, 15 (57.69%) nurses, and 15 (50%) students were uncertain about the drug causing ADR.

Eighteen (60%) faculties, 22 (78.57%) physicians, 14 (53.85%) nurses, and 14 (46.67%) students' felt that all ADRs are well known to them. All 30 (100%) faculties, 28 (100%) physicians, 26 (100%) nurses, and 30 (100%) students replied that they have ADR reporting form and none of the participants mentioned that they do not have ADR reporting form to report the suspected of observed ADRs [Table 7].

DISCUSSION

In this study, the severity assessment of suspected ADRs by modified Hartwig and Siegel scale shows, majority of the suspected ADRs were moderate (n = 583; 61.37%), followed by mild (n = 308; 32.42%) and severe (n = 55; 5.79%). These observations were consistent with other studies, the severity of ADRs was either moderate (urticaria, abnormal LFT) or severe (neutropenia).[8] Most of the ADRs (96.5%) were moderately severe while three cases were severe in nature and were preventable. At least one in five patients was admitted to the hospital due to severe ADRs and a small portion (0.07%) of patients died in

Table 7: Assessment of knowledge about adverse drug reactions among healthcare professionals, faculties, and students in phase-II

Questions	Answers	Faculties *n*=30 (%)	Physicians *n*=28 (%)	Nurses *n*=26 (%)	Students *n*=30 (%)
Definition	Correct	27 (90)	21 (75)	14 (53.85)	25 (83.33)*
	Incorrect	0 (0)	0 (0)	5 (19.23)	2 (6.67)
	Partially correct	3 (10)	4 (14.29)	7 (26.92)	3 (10)
	Not attempted	0 (0)	3 (10.71)	0 (0)	0 (0)
Classification of ADRs	Correct	22 (73.33)	24 (85.71)	15 (57.69)	21 (70)*
	Incorrect	2 (6.67)	0 (0)	4 (15.38)	3 (10)
	Partially correct	4 (13.33)	3 (10.71)	7 (26.92)	6 (20)
	Not attempted	2 (6.67)	1 (3.57)	0 (0)	0 (0)
Objectives of ADR monitoring	Identify quickly important or serious ones and give early warning to concerned authorities	25 (83.33)	26 (92.86)	20 (76.92)	22 (73.33)*
	Attempt to establish a cause-effect relationship between drug and reaction	3 (10)	2 (7.14)	5 (19.23)	4 (13.33)
	Find out the incidence of particular reaction	2 (6.67)	0 (0)	1 (3.85)	2 (6.67)
	Do not know	1 (3.33)	0 (0)	0 (0)	2 (6.67)
Monitoring methods	Spontaneous reporting	30 (100)	26 (92.86)	20 (76.92)	24 (80)*
	Intensive monitoring for a particular drug	0 (0)	2 (7.14)	4 (15.38)	4 (13.33)
	Cohort or case control study	0 (0)	0 (0)	1 (3.85)	1 (3.33)
	Randomized trails	0 (0)	0 (0)	1 (3.85)	1 (3.33)
	Do not know	0 (0)	0 (0)	0 (0)	0 (0)
Present status of ADR monitoring in your hospital	Done	30 (100)	28 (100)	22 (84.62)	25 (83.33)*
	Not done	0 (0)	0 (0)	4 (15.38)	5 (16.67)
ADR monitoring should be done routinely for better patient care	Yes	30 (100)	28 (100)	26 (100)	30 (100)*
	No	0 (0)	0 (0)	0 (0)	0 (0)
ADR should be report if it causes	Inconvenience to the patient	2 (6.67)	0 (0)	2 (7.69)	3 (10)
	Death of the patient	2 (6.67)	0 (0)	4 (15.38)	2 (6.67)
	Both of the above	26 (86.67)	28 (100)	20 (76.92)	25 (83.33)*
ADR should be report to	Head of the unit/dept	10 (33.33)	2 (7.14)	5 (19.23)	10 (33.33)
	Department of Pharmacy Practice/Pharmacology	20 (66.67)	10 (35.71)	10 (38.46)	30 (100)*
	National ADR monitoring center	25 (83.33)	25 (89.29)	15 (57.69)	25 (83.33)
	WHO ADR monitoring cell (regional office)	30 (100)	28 (100)	15 (57.69)	28 (93.33)*
	Do not know	0 (0)	0 (0)	0 (0)	2 (6.67)
	Reason for not reporting of ADRs				
Aware of pharmaco-vigilance	Yes	30 (100)	28 (100)	24 (92.31)	27 (90)*
	No	0 (0)	0 (0)	2 (7.69)	3 (10)
Report observed ADR	Yes	30 (100)	28 (100)	26 (100)	30 (100)*
	No	0 (0)	0 (0)	0 (0)	0 (0)
Knew NMC/RMC as reporting centers	Yes	30 (100)	28 (100)	22 (84.62)	25 (83.33)*
	No	0 (0)	0 (0)	4 (15.38)	5 (16.67)
Aware of ADR reporting center in Coimbatore	Yes	30 (100)	28 (100)	23 (88.46)	28 (93.33)*
	No	0 (0)	0 (0)	3 (11.54)	2 (6.67)
Have phone number and address of NPP reporting in their organization	Yes	20 (66.67)	23 (82.14)	20 (76.92)	22 (73.33)*
	No	10 (33.33)	5 (17.86)	6 (23.08)	8 (26.67)
Have set procedure of ADR reporting in their organization	Yes	28 (93.33)	22 (78.57)	23 (88.46)	19 (63.33)*
	No	2 (6.67)	6 (21.43)	3 (11.54)	11 (36.67)
Non reporting due to lack of knowledge about center	Yes	2 (6.67)	0 (0)	5 (19.23)	3 (10)
	No	28 (93.33)	28 (100)	21 (80.77)	27 (90)*
Uncertain of drug causing ADR	Yes	12 (40)	0 (0)	15 (57.69)	15 (50)
	No	18 (60)	28 (100)	11 (42.31)	15 (50)
Feel all ADRs are well known	Yes	18 (60)	22 (78.57)	14 (53.85)	14 (46.67)
	No	12 (40)	6 (21.43)	12 (46.15)	16 (53.33)*
Have ADR reporting form	Yes	30 (100)	28 (100)	26 (100)	30 (100)*
	No	0 (0)	0 (0)	0 (0)	0 (0)

ADR=Adverse drug reaction, RMC=Regional monitoring center, NMC=National monitoring center, NPP=National pharmacovigilance program

emergency department.[9] We observed some distinct findings from other studies that a higher percentage of patients with severe ADRs were male (44%) compared with patients with mild ADRs (38% male).[9] The degree of severity was minor in 72.9% of the reports, moderate in 22.4%, severe in 4.4%, and fatal in 0.3% (4 cases).[10]

In our study, 4 (0.42%) lethal effects were observed; among these, 3 (0.32%) from female and 1 (0.11%) from male patients, which is in contrast to a study that showed 28 (2.3%) patients died as a direct result of the index ADRs and gastrointestinal bleeding was responsible for 15 (54%) deaths, while aspirin individually or in combination with other drugs was implicated in 17 (61%) deaths.[11]

Causality assessment was used to describe the causal relationship between offending drugs and the reaction and it was done by using the Naranjo's causality assessment scale and shows that 20 (2.11%) ADRs were definitely related to drugs, 759 (79.89%) ADRs were probably related to drugs, 165 (17.37%) ADRs were possibly related to drugs, and 6 (0.63%) ADRs were unlikely related to drugs. Similar findings were noted from other studies also, most of the reported ADRs belonged to the category of probable (70%) followed by possible in 30% of the cases.[12] All ADRs were found to be probably related to the antibiotic administration.[13] Causality assessment revealed that no reactions were certain or definite, 9 were probable, and 52 were possible reactions.[14]

Probability of the suspected ADRs were assessed by using the WHO probability assessment scale and revealed that 22 ADRs were certain, 758 ADRs were probable or likely, 160 ADRs were possible, 5 ADRs were unlikely, 5 ADRs were unassessable or unclassifiable, and none of the ADRs were conditional or unclassified. This is in contrast to a study wherein causality assessment showed 46% possible, 23% probable, and 29% were unassessable because the drug was unknown.[15]

Preventability of the suspected ADRs was assessed by using the Schumock and Thornton criterion modified by Lau *et al.,* and showed that 384 (40.42%) ADRs were definitely preventable, among these, 256 (26.95%) ADRs were present in female and 128 (13.47) in male patients; probably preventable ADRs were 294 (30.95%) in which 198 (20.84%) ADRs were identified in female and 96 (10.11%) ADRs in male patients; 272 (28.63%) ADRs were identified as not-preventable and it was observed in 183 (19.26%) female and 89 (9.37%) male patients. These findings were similar to a study, of 316 reported ADRs, majority (56%) of the reactions were predictable and 33% of the reactions were preventable.[12] The findings were different from other studies in which a majority of ADRs were not preventable (n = 57; 79%).[15] None of the ADRs were definitely probable, 84 ADRs were probably preventable, and 12 ADRs were not preventable.[16]

In our study, management of ADRs shown that in 89.89% (n = 854) of patients, the offending drug was withdrawn, and in 10.11% (n = 96) of patients the dose was altered. In one study, the suspected drug was withdrawn in 90% of the cases, while no change was made with the suspected drug in 9% of the cases, and dose was altered in 1% of the case.[12] A total of 56% of ADRs were managed by withdrawing the drug and altering the dose, 43.75% of ADRs were treated with other drugs in another study.[16]

In this prospective observational spontaneous reporting study, pharmacist played a major role in reporting the suspected ADRs. Pharmacist reported the most number of ADRs, in this study it was around 40.18% (n = 493) of ADRs, next to pharmacist, nurses reported good percent of ADRs (n = 310; 25.26%), that is, one-fourth of the ADRs and prescriber reported 13.04% (n = 160) of ADRs. Patients reported 7.82% (n = 96) of ADRs, whereas their volunteers reported 11.65% (n = 143) of ADRs. Other people reported only 2.04% (n = 25) of ADRs. Similar findings were observed where clinical pharmacist reported 257 (45.6%) of the ADRs, nurses reported 204 (36.2%), and physicians reported 85 (15.1%) of the ADRs. The remaining 18 (3.2%) were reported by the patient or family members.[17] Out of 65 ADRs reported, 42 (64.6%) were identified and reported by physicians and nurses, while the remaining 23 (35.4%) were identified and reported by clinical pharmacists.[18]

Regarding the mode of reporting of suspected ADRs (n = 1227), 1131 ADRs were reported through ADRs notification or reporting form, 46 ADRs were reported through referral mode, and 20 ADRs were reported through telephone. Thirty ADRs were reported through direct contact with the pharmacist. A total of 1227 ADRs were reported, from these, 950 ADRs were accepted and the remaining reports were not accepted due to lack of information or the reactions did not fall under the category of ADRs.

In these accepted ADRs (n = 950), 887 ADRs were reported through ADRs notification or reporting form, 22 from referral mode, and 12 ADRs reported through telephone. From the 30 ADRs reported by direct contact, 29 ADRs were accepted.

Lack of knowledge in ADR assessment, monitoring, and reporting among HCPs results in heavy economic burden on healthcare delivery systems in many countries. The under reporting of ADRs leads to under estimation of occurrence, severity and nature of rare types of ADRs, and it adversely affects the quality of life of patients.

We developed a questionnaire to assess the knowledge about ADRs among HCPs and to identify the barrier in reporting of suspected ADR. We had a tremendous and very good response for the questionnaire survey in phase-II study when compared with phase-I study.

In phase-I study, 40% faculties wrote correct definition of ADRs and in phase-II the percentage increased to 90, this shows the ability of teaching faculties toward improving and updating their knowledge and the interest in patient care. Next to faculties, students have much knowledge about ADR (83%) followed by physicians (75%) and nurses (54%) in phase-II study. A total of 85% physicians and 73% faculties were able to classify the ADRs in phase-II, this percentage was increased from 12.5% and 30%, respectively, in phase-I.

Similar findings were observed in a study, about 68% of the nurses did not even know the correct definition of the term "pharmacovigilance" and most of the nurses in the study (79.0%) were not aware of what kind of ADR should be reported.[19] In another study, the overall knowledge of ADRs and pharmacovigilance activity was found poor in UG medical students.[20]

In our study, physicians (93%) knew the objectives of ADRs monitoring very well in phase-II, when compared with phase-I study (75%), which is followed by faculties (83), nurses (77%), and students (73%). Another study stated that identifying previously unreported ADR was the most important goal for ADR reporting, in before and after the interventions of the study.[21]

Lacking suspicion of an ADR could be a problem. There are doctors who believe that it is necessary to confirm the ADRs and do not report anything if they are not completely sure about the causality assessment of ADR. A problem in reporting is to establish a causality relationship between several drugs taken by patients and suspicions of adverse reactions.[22]

Spontaneous reporting of ADRs is very essential in the current scenario, which was mentioned by all faculties, 93% physicians, 80% students, and 77% nurses in phase-II study. All participants in the phase-II survey knew any one method to monitor ADRs but in phase-I, 10% nurses and 9% students did not know about any method of monitoring ADRs.

Almost all faculties and physicians know the present status of ADR monitoring in the hospital in both the phases. A total of 25% of nurses in phase-I; 15.38% of nurses and 16.67% of students in phase-II reported that ADR monitoring is not done presently at the hospital, this is due to the fact that newly appointed nurses and fresher's in the pharmacy course do not know much about the routine work in the hospital.

All the faculties, physicians in phase-I, and all respondents in phase-II mentioned that ADR monitoring should be done routinely for better patient care and it is essential for improving the health outcome of the patients.

All of our physicians stated that ADR should be reported if it causes both inconvenience and death of the patient, because they know well about the necessity of ADR reporting when compared with faculties, students, and nurses. Almost all of our respondents know very well, where to report an ADR but only 7% of the students do not know the reporting center.

Lack of reporting is the main underlying cause to have reduced quality of life of the patients, after experiencing and seeing a mild or moderate form of ADRs. Under-reporting of ADR may be associated with poor knowledge, attitudes, and practices to pharmacovigilance.[23]

In the current study, awareness about pharmacovigilance was created through regular monitoring of patients and their profiles with other HCPs, providing pamphlets, hand outs, and thank you note to the reporter. In phase-II study, most of our participants were aware of pharmacovigilance program when compared with the phase-I study. Only two (7.69%) nurses and three (10%) students were not aware of pharmacovigilance program in phase-II study.

Consistent with our study, most doctors know about the pharmacovigilance program, but there are few

who still do not. Many doctors are not acquainted with the objectives and potential usefulness of the pharmacovigilance program. Many doctors think that barriers to contact and access to people working in the hospital pharmacovigilance system are an important problem in spontaneous reporting. A lack of reporting cards or forms for reporting is another problem that doctors described.[22]

All our participants in the phase-II accepted and reported the observed ADRs to the reporting centers. Majority of the participants know the NMC or RMCs to report the suspected or observed ADRs, but four (15.38%) nurses and five (16.67%) students did not know the NMC or RMCs to report the suspected or observed ADRs. All our faculties and physicians were aware of reporting centers in Coimbatore to report the observed ADRs, only 11% nurses and 7% students did not know the correct reporting centers.

Only 19 (45.2%) of the clinicians were aware of the existence of a pharmacovigilance center and only 6 of them had reported ADRs to the Pharmacovigilance Centre. Only 28 (66.7%) felt that ADR reporting was necessary.[24] This finding was similar to our study in phase-I, but the awareness of clinicians or physicians increased in phase-II. Similar finding was observed in another study, in that 89% of responders were aware of existence of ADR reporting and monitoring system at their hospital.[25]

Many of our study participants told that the organization has phone number and address of the NPP, and has set procedure for reporting ADR in the organization; the percentage was considerably increased from phase-I to phase-II. But in one study, 43 (41.35%) nurses agreed that their organization do not have set procedure of reporting ADR.[26]

Lack of knowledge about ADR reporting center is the mainstay in under-reporting or nonreporting of observed ADRs noted by only 6.67% of faculties, 19.23% nurses, and 10% students. The reasons for under-reporting was very much reduced in phase-II; 40% faculties, 58% nurses, and 50% students told that they were not sure or uncertain about drug causing ADRs, this indicates in depth of knowledge of drugs and their reactions are needed in these groups.

A consistent result was found in one study and states that the reasons for not reporting ADRs given by nurses were uncertainty about causal drug (49.04%), ADR is well known (40.38%), unawareness of ADR reporting centers (83.65%).[26] The physicians and nurses in this private hospital have insufficient knowledge about pharmacovigilance and ADRs reporting.[27] Education interventions also should be targeted at student pharmacists, who have been found to have inadequate knowledge of ADR reporting.[28]

A study showed that the most frequently mentioned barrier in reporting the ADRs is to assume that ADRs are already known or were uncertain about the causal relationship between the ADRs and the drug, and the reporting procedure being too time-consuming.[29] The major barrier to ADR reporting was lack of knowledge about ADR reporting processes. To increase ADR reporting rates, some participants suggested that educational interventions are needed from organizations and academia.[30]

Spontaneous reporting system of the pharmacovigilance program has contributed significantly to improve the ADR reporting rates worldwide. Nurses' attitude toward ADRs report and their practice need major changes. Education and training can have a strong influence on knowledge and attitude toward reporting.[24]

Most of participants answered 'No' for the question, 'feel all ADRs are well known?' at phase-I, but in phase-II the percentage was reduced much and most of them told 'Yes'. Increase of knowledge about ADRs among the HCPs increased the percentage of answering as 'Yes'.

In phase-I, only little percentage of the study participants reported that they have ADR reporting form to report the suspected or observed ADRs. But in phase-II, all of our study participants have ADRs reporting form and answered 'Yes' (100%).

This highlights the need for encouraging medical practitioners to report suspected ADRs and therefore there is a greater potential for the pharmacists to increase reporting rate of ADRs by creating awareness and educating the medical practitioners about the importance of reporting of ADRs. Underreporting of ADRs is a problem that should be taken seriously and given higher priority with regard to increasing the amount of knowledge.[31]

The pharmacist is a key member of the healthcare team and is often the patient's main point of contact for health information and guidance. Continuing education and knowledge exchange are important tools for the pharmacists and most respondents, indicating that they keep abreast of ADR-related

information through various sources. Pharmacists are particularly well equipped to recognize and report ADRs, the entire focus of pharmacy training is almost exclusively on drugs, while knowledge of drugs form a relatively small proportion of clinicians and nurses training.[32]

The deficit in knowledge regarding ADRs and Pharmacovigilance need the urgent attention on priority basis, not only for the success of the Pharmacovigilance program but also for the better clinical management of the patients, in general.[20]

The pharmacovigilance program should take strong steps to motivate physicians and other HCPs for ADR reporting in order to increase the numbers.[33] There is an urgent need to do more research to improve the understanding of barriers to report ADRs and overcome them.

CONCLUSION

ADRs are significant causes of morbidity and mortality and contribute to the incidence of adverse events, resulting in increased healthcare costs. It is important to motivate HCPs to understand their role and responsibility in the detection, management, documentation, and reporting of suspected ADRs and all essential activities for optimizing patient safety.

Pharmacists plays a central role in drug safety by contributing to the prevention, identification, documentation, and reporting of suspected ADRs. All HCPs have roles to play in maintaining a balance between a medicine's benefit and risk.

The reporting of ADRs need continuous stimulation. It is important to achieve the development of a positive attitude toward pharmacovigilance among HCPs, including pharmacists, so that ADRs reporting becomes an accepted and understood routine. Research into pharmacist ADRs reporting has shown that those who undergo training are more likely to report and that continued educational initiatives are needed for the multidisciplinary team to sustain a successful ADRs monitoring and reporting program. It is essential that programs aimed at increasing ADRs surveillance include processes that are user friendly and lack negative associations. Many studies on ADRs monitoring and reporting in India are necessary.

Prospective studies always employ trained professionals to detect ADRs, HCPs especially clinicians or physicians working in the emergency department are responsible for identifying ADRs. Since new drugs are entering into the market at a rapid rate, it is impractical for any physician to be familiar with all the drugs and identify countless associated ADRs, especially when working in stressed environment. Poor recognition could account for the low estimation of the incidence of ADRs-related hospital visit as noted in a German study that more than half of the preexisting ADRs were not recognized by either the admitting or attending physician.[9] Hence, early detection or identification of an ADR is the predominant factor in preventability, and effective interventions aimed at improving ADRs identifications are warranted.

Patients were also considered responsible for the development of avoidable ADRs. Reasons for the improper use of prescribed medication may include poor understanding of instructions given by physicians during the consultation, by pharmacist at the time of dispensing, or contained in product information leaflets. Improved patient education would help minimize these patient attributable ADRs. Dose adjustment according to the needs of individual patients and therapeutic drug monitoring can help to minimize these ADRs, and pharmacogenetics has the potential to identify patients at an increased risk of such problems. A thorough knowledge of ADRs and a well established ADRs reporting system will help to reduce the occurrence and the cost of avoidable ADRs-related admissions.

A limitation of the study was that the rate of ADR-related hospitalization was probably an underestimate because of underreporting or misclassification, because all ADRs possibly were not identified. The actual number of ADRs in the study population might also have been higher than the number of ADRs detected and reported during hospitalization because of relatively short LOS in our hospital.

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