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Approach And Practice of Pharmacovigilance and Adverse Drug Reaction Reporting Method

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Abstract

The most serious ADRs lead to hospitalization, and hospital stays can lead to further ADRs. Hence, HCPs and hospitals can play a significant role in minimizing ADR-related morbidity and mortality. HCPs can play multiple roles by carefully reviewing the full patient history, particularly the drug allergy and drug-drug interaction history, to avoid any unwanted ADRs. In addition, reporting ADRs to the responsible office at their hospital or the regulatory authority is a pharmacovigilance approach that can be used to minimize ADRs because reporting ADRs can increase HCPs' awareness of reactions, which could result in the avoidance of particular drugs, thus reducing the harm associated with reactions to particular drugs. Several drugs have been withdrawn from the market as a result of HCPs reporting ADRs. However, understanding the knowledge and practice of health care professionals regarding ADR reporting is very important for enhancing the reporting of ADRs. Therefore, the present study is undertaken to determine the current status of ADR reporting and also to investigate knowledge and attitude of particularly nursing staffs towards pharmacovigilance and ADR reporting.

Key words: Pharmacovigilance, Adverse drug reaction, WHO, National Pharmacovigilance Centre (NPC)

World Health Organization characterizes adverse drug reaction as any reaction to a medication which is harmful and unintended, and which happens at measurements typically utilized as a part of man for prophylaxis, analysis or treatment of illness or for the alteration of physiological capacity.[1] Antagonistic medication responses are negative outcomes of medication treatment.[2] They are one of the main sources of grimness and mortality. It has been assessed that around 2.9-5.6% of all clinic affirmations are because of ADRs and upwards of 35% of hospitalized patients encounter an ADR amid their hospitalization.[3] An unconstrained revealing of ADRs has remained the foundation of pharmacovigilance and is imperative in keeping up tolerant wellbeing.[4] In India, all social insurance experts including specialists, medical caretakers, and drug specialists can report an ADR by filling an ADR type of the Central Drugs Standard Control Organization.[5] The dynamic interest of social insurance experts in the pharmacovigilance program can enhance the ADR revealing.[6]

The ADR revealing rate in India is underneath 1% contrasted with the overall rate of 5%.[7] One reason for low reporting rate in India might be an absence of learning and sharpening towards pharmacovigilance and ADR among health care professionals (HCPs). The examination likewise demonstrated that the normal cost associated with treating these ADRs was INR 900/ - per patient.[8]In India, Pharmacovigilance is still in early stage and there exists very limited knowledge about this discipline.[9]Inadequate funds, lack of trained staff, and lack of awareness about detection, communication, and spontaneous monitoring of ADRs may be the reason, gross underreporting of ADRs is a cause of concern.[10]

The market today is flooded with an enormous number of drugs for various ailments. The Pharmaceutical industries are busy innovating testing and manufacturing new drugs day in and day out, such that 45 drugs gained FDA approval in 2015 and 41 new drugs were launched in 2014 every year on anaverage.[11] Before the drugs are marketed, they undergo stringent measures to assess their safety profile; still, certain unusual, rare, serious adverse drug reactions may go undetected at this level. This applies more to newer drugs which may lead to severe adverse drug reactions which may not have come to light yet owing to a short spanof their use. ADRs (adverse drug reactions) are responsible for about 5 % to 20% of hospital admissions.[12]About 2.9% ADRs lead to hospitalization and approximately 6.3% ADRs develop while one is in the hospital.[13] One third of these ADRs are preventable.[14]

In India, National Pharmacovigilance Centre (NPC) has been formed which is an active participant in the on-going activities of UMC and in the past years, the PV programme has gained momentum such that the reporting rates from India have increased from 0.5% to 2%, still these figures are very low as compared to other countries.[15]All healthcare professionals can report an ADR by filling an ADR reporting form provided by CDSCO (Central Drug Standard Control Organization). Still, under reporting is highly prevalent. An important part in this under reporting is played by the lacunae in the knowledge (especially lack of knowledge of how and whom to report about ADRs) and attitude of various health care professionals towards monitoring and reporting of ADRs.[16] The success of a PV program depends upon the active involvement of the healthcare professionals such as doctors, pharmacists, nurses and can greatly reduce the burden on limited health care resources in developing countries like India.[17]

Increasing health professional and student participation in national medication reporting programs remains an important goal in promoting safe health care practices. Opportunities for improvement in pharmacy curricula and practice sites toward interactive experiences with reporting programs should be continually evaluated.[18] Thus, early identification of ADRs is extremely important for both government and non-government health care organizations.

Pharmacovigilance (PV)

Pharmacovigilance is concerned with only two outcomes: safety and efficacy. Does a drug work and is it safe? It touches on almost every aspect of the drug lifecycle - from preclinical development to post-market surveillance - making it one of the most fundamental functions within a life science company.

Pharmacovigilance – also known as drug safety - is a broad term that describes the collection, analysis, monitoring and prevention of adverse effects in drugs and therapies. It is a completely scientific and process-driven area within pharma.

The definition of an adverse event is any reaction within a patient's body caused by a drug/candidate molecule – a side effect. A serious adverse event is a life-threatening side effect that causes hospitalisation, incapacity, permanent damage or, in extreme cases, the death of a patient. Adverse event reporting is mandatory for all clinical research investigators, even if the side effects are only suspected.

The role of pharmacovigilance is to determine which adverse events cross the line of a drug's efficacy. In other words, analysing which side effects are worth the risk to patients compared with how effective they are at treating a disease. For instance, chemotherapy is known to cause some very serious side effects but when faced with life-threatening cancer, these side effects are considered acceptable given the potential to cure a patient. However, if a drug used to cure a headache caused similar side effects, the risk to the patient would be considered too great and the benefit not substantial enough to justify the potential damage.

Main areas of pharmacovigilance

Pharmacovigilance is a huge and encompassing discipline, but we can broadly divide pharmacovigilance into four main sub-specialisms:

Operations

Surveillance

Systems

Qualified Person for Pharmacovigilance (QPPV)

QPPVs jobs are mainly concerned with marketed drugs and those about to be authorised, but as QPPVs are considered by many to be subject matter experts, their expertise is utilised across the discipline and wider business. These senior pharmacovigilance roles will only be held by very experienced professionals and their focus is to understand, plan for and advise upon the regulations and requirements that companies must adhere to across the EU. This is a highly strategic appointment and one of great importance.

Fortunately for drug safety professionals, there are several pharmacovigilance jobs available to them due to the different types of companies within life sciences, including global pharmas,

small pharmas, generics companies, drug safety consultancies and health authorities. Each offers slightly different opportunities but in every case, there is plenty of scope for professionals to progress their pharmacovigilance career.

Importance of pharmacovigilance

Pharmacovigilance is arguably the most essential function within a life science company. To develop, manufacture and commercialise a drug a company must adhere to strict regulations. Many of these regulations will focus on the patient's safety and the added benefit to the patient derived from the drug. This, in a nutshell, is the mission of drug safety and highlights why this discipline plays such acentral and important role within pharmaceuticals.

Patient safety and continuous vigilance

By definition, drug safety ensures that a patient's safety and wellbeing is safeguarded throughout the entire drug development lifecycle, including when the drug is readily available on the market. Indeed, drugs are continuously monitored forother side effects on patients, and any new data is collected and reported to health authorities on a regular basis. While other areas focus on improving patient lives in everything that they do, no other department has such a sharp focus on patient safetyas an end-point.

- ✓ Power and authority
- ✓ Keeping it moving
- ✓ Adverse event reporting
- ✓ Individual Case Safety Report (ICSR)
- ✓ Coding of adverse events
- ✓ Seriousness determination
- ✓ Expedited reporting
- ✓ Clinical trial reporting
- ✓ Spontaneous reporting
- ✓ Aggregate reporting

Other reporting methods

Some countries legally oblige spontaneous reporting by physicians. In most countries, manufacturers are required to submit, through its Qualified Person for Pharmacovigilance (QPPV), all of the reports they receive from healthcare providers to the national authority. Others have intensive, focused programmes concentrating on new drugs, or on controversial drugs, or on the prescribing habits of groups of doctors, or involving pharmacists in reporting. All of these generate potentially useful information. Such intensive schemes, however, tend to be the exception.

Study tools

The study questionnaire was prepared for incorporating participant'sdemographic details like age, gender and designation and working experiences. In KAP, Knowledge part of the questionnaire included sixteen questions that were used
to measure the knowledge of nurses related to ADR and pharmacovigilance such as definition, awareness, purpose of ADR, PV, reporting system, regulatory body etc. The attitude part comprised of eight questions about their thoughts and views related to ADR and reporting. Attitudes related questions were developed in 5-point likert scale. The practice part of questionnaire included three questions such as type, nature, methods for ADR reporting. Finally the fifth section was limited to two questions with the help of which factors encouraging and discouraging to nurses to report ADR were determined.

Data collection

A structured pretested questionnaire was prepared. After pilot-scale testing, the questionnaire was modified. After obtaining approval from IEC and hospital authority, a questionnaire was distributed to nursing staffs. articipants were explained about the purpose of the study. Those who showed interest to participate in the study were requested to fill the questionnaire in 30 min with ensured confidentiality. The responses to the questionnaire were analyzed, categorized and presented in percentages.

1. RESULTS

Table 1: Gender wise distribution of participants

Gender	Total no of participantsn= 151(%)
Female	144(95.3%)
Male	7(4.63%)

Table 2: Age wise distribution of participants

Age group in years	Total no of participantsn= 151 (%)
16-20	0
21-25	112(74.1%)
26-30	26(17.2%)
31 and above	13(8.6%)

Table 3: Experience wise distribution of participants

Working Experience in years	Total no of participantsn=151 (%)
<1	2(1.3%)
1-5	132(87.4%)
6-10	10(6.6%)
11-15	0
16-20	0
>21	7(4.6%)

Table 4: Grade/Rank wise distribution of participants

Designation	Total no of participantsn=151(%)
Beginner/junior	3(1.9%)
Nurse	139(92%)
Senior Nurse	1(0.6%)
Nurse specialist	5(0.3%)
Senior nurse specialist	2(0.1%)
Head of nurse	1(0.6%)

Table 5: Awareness status

Awareness status	Total no of participantsn=151(%)
Have you attended any program/seminar relate to PV	
Yes	147(97.3%)
No	4(2.6%)

Table 6: Knowledge towards ADR/PV

S.No	Question regarding knowledge	Respondent response n= 151(%)
1	Pharmacovigilance	
	a) The science of monitoring ADR's happening in a hospital	94 (62.2%)
	b) The process of improving the safety of drugs	21(13.9%)
	c) The detection, assessment, understanding and prevention of adverse effects	30(19.8%)
	d) The science detecting the type and incidence ofADR after the drug is marketed	2(1.3%)
	e) Do not know	4(2.6%)
2	ADR	
	a) Noxious and unintended response to drug and occurs at doses normally used in man or animalfor prophylaxis, diagnosis or therapy of disease	64 (42.3%)
	b) Noxious and unintended response to drug andoccurs	21 (13.9%)

	at doses normally used in man for prophylaxis, diagnosis and therapy of disease c) Any untoward medical occurrence that may present during treatment with a medicine butwhich does not necessarily have a causal relationship with this treatment d) Any adverse reaction identified in regulatory documents such as investigators brochures or product monograph occurring within the expectedfrequency Do not know	46 (30.4%) 15 (9.9%) 5 (3.3%)
S.No	**Question regarding knowledge**	**Respondent response n= 151 (%)**
3	Are you aware of any formal reporting system available in other countries a) Yes b) No	116(76.8%) 35(23.1%)
4	Are you aware of any drug that has been banned in the world due to ADR? a) Yes b) No c) Do not know	18(11.9%) 23(15.2%) 110(72.8%)
5	Have you ever shared information about ADRs with anyone? a) Yes b) No	8(5.3%) 143(94.7%)
6	Where is an international centre for adverse effect reaction monitoring located? a) Sweden b) Germany c) USA d) Do not know	12(7.9%) 28(18.5%) 65(43%) 46(30.4%)
7	Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions? a) Arthritis b) Renal failure c) Visual impairment d) All of these e) Do not know	24(15.8%) 64(42.3%) 16(10.5%) 5(3.3%) 42(27.8%)
S.No	**Question regarding knowledge**	**Respondent response n= 151 (%)**
8	Are you aware of any of the below reporting centre or system in India where you can report ADR? a) Madras Medical College, Chennai b) Christian Medical College, Vellore c) PSG institute, Coimbatore d) Govt. Kilpauk Medical College, Chennai e) Ministry of health f) No centre for reporting Do not know	43(28.4%) 5(3.3%) 0(%) 50(33%) 41(27.1%) 0(%) 12(7.9%)
	Identify the types of ADR's? a) Type A, B, C, D, E, F and G b) Type 1, 2, 3, 4, 5, 6 and 7	0(%) 0(%) 0(%)

9	c) Known, unknown and common, uncommon d) Reversible and irreversible Do not know	0(%) 151(100%)
10	Which one of the following is the WHO online databasefor reporting ADR's? a) ADR advisory committee b) Med safe c) Vigibase d) Med watch e) Do not know	 64(42.3%) 24(15.8%) 12(7.9%) 30(19.8%) 21(13.9%)
11	From which sources do you gather information about ADRs to new drugs? a) Textbooks b) Journals c) Internet d) Medical representatives e) Seminars/conferences	 15(9.9%) 2(1.3%) 23(15.2%) 3(1.9%) 78(51.6%)
S.No	**Question regarding knowledge**	**Respondent response n= 151 (%)**
	f) Direct mail brochures g) All of the above	0(%) 30(19.8%)
12	Side effects like headache, fever and vomiting shouldnot be reported? a) Strongly agree b) Agree c) Disagree d) Strongly disagree	 21(13.9%) 84(55.6%) 40(26.4%) 6(3.9%)
13	What to report: a) Serious adverse event (SAE) b) Adverse Event c) Adverse drug reaction (ADR) d) Side Effect e) All f) Not know	12(7.9%) 8(5.2%) 32(21.1%) 84(55.6%) 9(5.9%) 6(3.9%)
14	Which ADR should be reported a) All serious ADRs b) ADRs to herbal and non-allopathic drugs c) ADRs to new drugs d) ADRs to vaccines e) Unknown ADRs to odd drugs f) All of the above	123(81.4%) 0(%) 0(%) 0(%) 14(9.2%) 14(9.2%)
15	In India which Regulatory body is responsible for monitoring of ADR's? a) Central Drugs Standard Control Organization* b) Indian Institute of sciences c) Pharmacy Council of India d) Medical Council of India	 4(2.6%) 57(37.7%) 68(45%) 22(14.5%)
S. No	**Question regarding knowledge**	**Respondent response n= 151 (%)**
	Pharmacovigilance includes a) Drug related problems b) Blood related products	67(44.3%) 0(%) 23(15.2%)

16	c) Herbal products All of the above	61(40.3%)

Table 7: Attitude towards ADR reporting

Attitude towards ADR	Total no of participants n= 151 (%)			
	Stronglyagree	Agree	Disagree	Strongly disagree
ADR reporting necessary	126(83.4%)	25(16.5%)	0(%)	0(%)
ADR reporting should bemandatory	136(90%)	15(9.9%)	0(%)	0(%)
ADR reporting increasepatient safety	131(86.7%)	20(13.2%)	0(%)	0(%)
ADR is time consuming	110(72.8%)	25(16.5%)	8(5.2%)	8(5.2%)
Do you think it is necessary toconfirm that an ADR is related to a particular drug before reporting it?	8(5.2%)	131(86.7%)	12(7.9%)	0(%)
Education programs havepositive effect on ADRs reporting	148(98%)	3(1.9%)	0(%)	0(%)
Consulting the physician isimportant before report an ADR	63(41.7%)	53(35%)	35(23.1%)	0(%)
With my present knowledge, Iam very well prepared to report any ADRs notice in myfuture practice.	8(5.2%)	84(55.6%)	10(6.6%)	49(32.4%)
Do you think Pharmacovigilance should betaught in detail to healthcare professionals?	151(100%)	0(%)	0(%)	0(%)

Table 8: Practice towards ADR reporting

Practice	Yes	No
Have you reported any ADR	89(59%)	62(41%)

Table 9: Distribution of nature of ADR

Nature of ADR reported	Total no. of participants n= 89 (%)
Severe	84(94.3%)
Moderate	26(29.2%)
Mild	51(57.3%)
All of the above	0(%)

Table 10: Practice towards ADR prevention

Practice	Yes	No
Have you done any intervention to prevent ADRs	0(%)	89(58.9%)

Table 11: Distribution of ADR reporting centre

ADR reporting centre by respondents	Total no. of participants n= 151(%)
Colleagues/ immediate reporting	119(78.8%)
Head of department	20(13.2%)
Ministry of health	0(%)
Do not know	12(7.9%)

Table 12: Distribution of preferred methods of ADR reporting

Preferred methods to reportADR	Total no. of participants n=151(%)
Direct contact	139(92%)
Post	0(%)
Telephone	12(7.9%)
Mail/website	0(%)

Table 13: Distribution of factors responsible for ADR reporting

Factors that encourage you toreport ADRs	Total no. of participants n=151(%)
Seriousness of reaction	9(6%)
Unusualness of reaction	0(%)
Involvement of new drug	0(%)
Confidence in diagnosis of ADR	0(%)
All of above	142(94%)

Table 14: Factors that hinder ADR Reporting

Factors that discourage you to report ADRs	Total no. of participants n= 151 (%)
Did not know how to report	14(9.2%)
Do not think it important	3(1.9%)
Managing patient was more important	30(19.8%)
Lack of access to ADR reporting form	23(15.2%)
Patient confidentiality issue	54(35.7%)
ADR reporting is physicians' duty	0(%)
Reporting is time consuming	13(8.6%)
Legal liability issue	2(1.3%)
All of above	12(7.9%)

Discussion:

The objective of the study was to assess the knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staffs. The study was conducted in the multi speciality hospitals at Chennai. 300 participants were randomly approached for collecting the data. Out of 300, 150 were responded.

In present study total 300 questionnaires were distributed among nursing staffs who were working in different private multi speciality hospitals at Chennai. Out of 300 questionnaires, 151 were filled and return back it. In table 1, majority of study participants were female nursing staffs 144(95.3%) than male 7(4.63%). Similarly, women were found to be more interested in participating in surveys investigating drug safety issues.[26] Age wise distribution of study participants were presented in Table 2. 112 (74.1%) study participants were present in the age group of 21-25 years, 26 (17.2%) participants in 26-30 years and least participants were 13(8.6%) in age group of 31 and above. In previous study eighty-four percent of the participants were between20 and 40 years of age which is similar to our study report. Therefore, young HCPs are likely more enthusiastic about ADR reporting systems.[26]In previous study male health care professionals were higher than female which is inconsistent with our study report. In table 3, majority of study participants 132(87.4%) had working experienceof 1-5 years than 10(6.6%) had 6-10 years. Only 7(4.6%) nursing staffs had greater than 21 years of experience and 2(1.3%) participants had less than 1 years of experience which mean fresher. None of the participants were present in between 11-15 and 16-20 years of experience. More than half (54%) of the study participants were at the early stages of their professional careers (up to five years of experience), which might explain the limited knowledge and awareness of the ADR reporting system. However, many participants had more years of experience, and these participants had more knowledge regarding the ADR reporting system.

In table 4, 139(92%) participants had designation as nurse, 5(0.3%) as nurse specialists, 3(1.9%) as beginners/juniors, 2(0.1%) as senior nurse specialists andeach 1(0.6%) as head of nurse and senior nurse. In another study by Ahmad et al., among 151 nursing staffs, 147(97.3%) have attend seminars/programmes related to pharmacovigilance and others

4(2.6%) have didn't attend any programmes. Training professionals with prior exposure to pharmacovigilance practices could result in betteroutcomes.[37] Strengthening the regular education and training of HCPs about pharmacovigilance and ADR reporting is a very important step towards improving the safety and quality of life of patients Alshammariet al., (2015). There were 16 questions assessing knowledge regarding ADR. As shown in table 6, 30(19.8%) and 21 (13.9%) knew about the term pharmacovigilance and ADRs respectively, 151(100%)don't knew about the types of ADR. Among respondents, 12(7.9%) knew where the International Centre for adverse drug reaction monitoring is located. Only 18(11.9%) were aware of the drugs that are banned due to ADR whereas 64(42.3%) knew the major risk factor for the occurrence of ADR. A small proportion of respondent 41(27.1%) knew where to report ADR in India and only 116(76.8%) knew about the formal reporting system in other countries. The majority of respondents 143(94.7%) did not share information regarding ADR to anyone, whereas 78(51.6%) respondents gathered information about ADR through the seminars, 15(9.9%) from textbooks, journals 2(1.3%), medical representative 3(1.9%), internet 23(15.2%) and all of the above 30(19.8%) respectively. None had collected from direct mail brochures. Among respondents, 21(13.9%) believed that side effects like a headache, vomiting and fever should never be reported. Only a small proportion of the respondents were aware of WHO online database for reporting ADR 12(7.9%). In India, 4(2.6%)
knew about which Regulatory body is responsible for monitoring of ADR's. 67(44.3%) knew about pharmacovigilance which includes drug related problems.

Knowledge regarding ADR is very important when it comes to reporting ADR. It is very important for physicians as well as pharmacists to possess great knowledge of ADR and procedure of reporting ADR. The results showed that health care professionals have poor knowledge regarding ADR reporting which is in correspondence with studies conducted in other different cities of Pakistan which include Lahore, Abbottabad and Hyderabad, all these studies show poor knowledge of physicians and pharmacists regarding ADR reporting.[38,39] Similar studies carried out in India showed poor knowledge of physicians and pharmacists regarding ADR.[40]A study carried out inIndia reveals that 41.6% were aware of the International Centre for ADR monitoring.[41]On the other hand, the studies conducted in India by Ghoshet al., and Gupta et al., showed that the healthcare professionals have high knowledge regarding ADR reporting but still the poor practice of ADR.

Many respondents could not identify the most appropriate source of information on ADR. According to the previous study, 31.9% physicians and pharmacists refer to the internet, 18.4% textbooks, 12.7% journals and 4.7% to seminars.[24] Attitude towards ADR reporting were presented in table 7. Majority ofparticipants had given response as strongly agree for the questions like ADR reporting necessary 126(83.4%), ADR reporting should be mandatory136(90%), ADR reporting increase patient safety 131(86.7%), ADR is time consuming 110(72.8%), Education programs have positive effect on ADRs reporting 148(98%), Do you think Pharmacovigilance should be taught in detail to healthcare professionals 151(100%) and least for Consulting the physician is important before report an ADR63(41.7%). Since most of the physicians and pharmacists consider ADR reporting is necessary, they should overcome the obstacles in reporting ADR and report ADR voluntarily, whenever they encountered and should consider ADR reporting as their professional obligation.[24.] 131(86.7%),84(55.6%) had given response as agree for the questions Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it and With my present knowledge, I am very well prepared to report any ADRs notice in my future practice. Meanwhile 49(32.4%) given response as strongly disagree for I am very well prepared to report any ADRs notice in my future practice. This clearly shows that most of the nursing staffs had very good attitude towards ADR reporting and pharmacovigilance. Study by Desai et al.,showed that 97.3% in India believe that ADR reporting increase patient safety.

59% of nursing staffs have reported ADR and 41% have never reported any ADR. Out of 89

ADR, 84(94.3%) were found to be severe, 51(57.3%) were mild and 26(29.2%) were moderate. None of the nursing staffs had ever done any interventions to prevent ADRs. The ADR reporting practice among physicians and pharmacists was far below than expectations. ADR has not been reporteddespite encountering ADR in their daily practice. One of the important findings of this study is the majority of respondents 88.3%never reported ADR. Only 11.7% reported ADR and those who have reported ADR did not report to the proper place, only9.1% respondents report ADR to the Ministry of Health.[24]

Out of 151 participants, 119(78.8%) replied that ADR reporting center were colleagues/ immediate reporting, 20(13.2%) said head of department, 12(7.9%) said do not know. Itis evident from the study that physicians and pharmacists are not encouraged by their workplace to report ADR. The majority statedthat their workplace does not encourage them to report ADR and does not provide any information regarding ADR reporting. Alarge proportion of respondent stated that they have never been trained for reporting ADR.[24]Furthermore, different healthcare professions were compared in this study, and pharmacists (77%) were found to be better informed regarding the NPC's location; most physicians and nurses thought the NPC existed within the Ministry of Health. Knowledge, awareness, and practice are interrelated but might not always bereciprocal. In our study, a quite encouraging percentage (73%) of HCPs were aware of the ADR reporting system at their workplace; however, only 27% of the HCPs were able to report ADRs.95% of the participants responded that they would report ADR reactions for both old and newly marketed agents.[26] Among 151 nursing staffs, most of them 139(92%) had reported that direct contact as preferred method to report ADR and rest 12(7.9%) reported as telephone. Furthermore, only 22% of the participants were aware that the NPC was located at the SFDA. However, this lack of knowledge is not a major concern because HCPs can report ADRs online or viae-mail, postal mail, fax or phone, and all of these routes are accepted by the NPC as reporting methods. Distribution of factors responsible for ADR reporting is presented in table 12. 142(94%) reported as all of the above such as seriousness of reaction, unusualness of reaction, involvement of new drug, confidence in diagnosis of ADR. The remaining 9(6%) had reported as seriousness of reaction. Our study report is highly correlate with Nisha et al.[24]

Factors that discourage the respondents to report ADR include patient confidentiality issue 54(35.7%) and managing patient was more important 30(19.8%). Some stated that lack of access to ADR reporting form 23(15.2%), did not know how to report 14(9.2%), reporting is time consuming13(8.6%), all of above 12(7.9%), do not think it important 3(1.9%), legal liability issue 2(1.3%). One of the findings of previous study is that lack of knowledge on how, where and whomto report ADR is one of the main reasons which discourages physicians and pharmacists to report ADR.[24]Whereas studies carried out in India by Shah et al., revealed that lack of time is the main reason that discourages healthcareprofessionals to report ADR. Previous studies around the world by Adhikaryet al., and Abubakaret al., emphasised great importance in providing awareness regarding ADR reporting and education interventions have a positive impact on increasing awareness regarding ADR reporting among healthcare professionals. Therefore it is very important to provide education and training to improve ADR reporting system. According to a study by Bishtet al., in India, the healthcare professionals who have received educational training regarding ADR reporting had adequate knowledge of pharmacovigilance and improved awareness regarding ADR. Proper education and training should be provided to healthcare professionals at regular interval to increase their knowledge regarding ADR reporting. Some other studies also confirmed that educational interventions lead to an increased awareness about ADR reporting (Li et al.,2004, Rajesh et al., 2011).[9,] Knowledge and awareness of ADR reporting alone is not sufficient, and an emphasis on the practical involvement of HCPs in ADR reporting is required.

One of the main limitations, number of participants is very less. The findings should not be extrapolated to nursing staffs in other hospitals. It is necessary to extend this type of study to other hospitals in India to obtain more generalizable results. Knowledge and perception may

vary on other locations. Therefore, its findings cannot be generalized to the whole country.

CONCLUSION

The study discloses that nursing staffs have poor knowledge and poor practice but good in attitude towards ADR reporting. Even though they have reported more number of severe ADRs, they didn't perform any further interventions to prevent it. The major factor which discourages them from reporting ADR is a patient confidentiality issue and managing patient was more important. Seriousness of reaction, unusualness of reaction, involvement of new drug, confidence in diagnosis of ADR was the factors that encourage nursing staffs to report ADR. Based on the outcomes of the present study following recommendations are concluded. ADR reporting forms should be freely available in all hospitals asit can improve the reporting rates of ADR in the country. ADR reporting should be mandatory for all healthcare professionals. Each hospital should have a database on ADR which should be considered by healthcare professionals. The nursing syllabus curriculum needs to be revised to include ADR and pharmacovigilance. Continuous education programme and workshop want to be conducted regularly relate to how and where to report ADR.

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