A STUDY ON NURSES FOR THEIR KNOWLEDGE, ATTITUDE & PRACTICE FOR ADR REPORTING IN TERTIARY CARE HOSPITALS IN JAIPUR DISTRICT

Dissertation
at
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Under the Guidance of
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MBA Pharmaceutical Management
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INSTITUTE OF HEALTH MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

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TO WHOMSOEVER MAY CONCERN

This is to certify that Shalini Attkan student of MBA in Pharmaceutical Management from IIHMR University, Jaipur has undergone internship training at The IIHMR University from February,2015 to May, 2015.

The Candidate has successfully carried out the study designated to him during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all her future endeavors.

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This is to certify that the Ms. Shalini Attkan student of MBA Pharmaceutical Management 2nd year Batch (2013-15), IIHMR University, Jaipur is been working as field investigator for the project title "A study of key stakeholders for their knowledge, attitude & practice for Adverse Drug Reaction reporting in tertiary care hospitals in Jaipur District" from a period of 10th February 2015 to 12th May 2015. She is been involved in the preparation of tools, approval of hospitals and data collection in two major tertiary care hospitals in Jaipur district.

She has successfully carried out her part of work during this period. I wish her success for her future.

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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **'A study on Nurses for their Knowledge, Attitude & Practice for ADR Reporting in tertiary care hospitals in Jaipur District'** and submitted by Shalini Attkan Enrollment No. IIHMR/MBAPM/2013-15/05-204 under the supervision of Mr. Abhishek Dadhich for award of MBA Pharmaceutical Management of the university carried out during the period from February, 2015. to May, 2015 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

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Abstract

Title - A study on Nurses for their Knowledge, Attitude & Practice for ADR Reporting in tertiary care hospitals in Jaipur District

Author name- Shalini Attkan

Background

This study is about adverse drug reactions reporting. The purpose is to understand the possible gap in ADR reporting system. The possible gap in the knowledge, attitude and practice, so that the system can be understood.

Objectives

- a. To test the knowledge regarding adverse drug reactions reporting among nurses
- To analyze the current practice of ADR reporting
- To test the attitude of nurses towards ADR reporting
- To identify current gap in knowledge and practices related to ADR reporting of marketed drugs in hospitals in Jaipur

Method

The study was a descriptive study. The sampling was done in hospitals of Jaipur, targeting only nurses. The data was collected using a semi structured questionnaire. The data was collected through direct interview. The data was stored, cleaned and analyzed in MS Excel.

Conclusion

The study revealed that there is a strong need of training and creating awareness about the ADR reporting in Jaipur. The Nurses are a very important part on healthcare system. Their role in patient care is irreplaceable and if they are initiated and encouraged to report, we can notice a very significant change in ADR reporting pattern.

It was noticed that the knowledge inflow from the authorities and in curriculum is not standardized. The ADR reporting is the need of hour, especially in India where multi pharmacy, self-medication is a common practice. Due to these reasons there are cases of resistance and abuse of drugs which may lead to high chances of ADR. From the above study, it can be concluded that there is a gap in system, execution of such major project and knowledge flow from the top to each and every healthcare professional

Acknowledgement

I have taken efforts in this project. However, it would not have been possible without the kind support and help of The IIHMR University, Jaipur, my institute, project guide and colleagues. I would like to extend my sincere thanks to all of them.

I would also like to extend my gratitude towards my mentor Mr. Abhishek Dadhich, Assistant Professor, The IIHMR University who helped me out throughout the project.

I would like to express my gratitude towards my Project Guide, Mr. Rahul Sharma, Assistant Professor,The IIHMR University for his kind support for his kind co-operation and encouragement which helped me in completion of this project in time.

My thanks and appreciations also go to my family, my colleagues, and students of MBA PM 05 who have willingly supported me throughout the project.

SHALINI ATTKAN

Executive Summary

This study is about adverse drug reactions reporting. Safety and efficacy are the two major concerns about a drug. Efficacy of a drug can be estimated with relative ease but the same is not true for ADR. The adverse effect of a drug may be uncommon (but very serious) and many patients may be affected or subjected to a potential risk before the relationship with the drug is established.

Thus the role of ADR reporting becomes a lifesaver for other patients suffering from same conditions.

This study includes nurses. The purpose is to understand the possible gap in ADR reporting system. The possible gap in the knowledge, attitude and practice, so that the system can be understood.

Recent published data suggest the less number of ADR cases reported by various PV centers in major cities compared to rest of the world (Indian Pharmacopoeia Commission, report) (Report, May 2014) which indicate low awareness/ knowledge/ inadequate practice of ADR reporting is the region.

The objectives of the study are to:

- a. To test the knowledge regarding adverse drug reactions reporting among nurses
- To analyze the current practice of ADR reporting
- To test the attitude of nurses towards ADR reporting
- To identify current gap in knowledge and practices related to ADR reporting of marketed drugs in hospitals in Jaipur

It is a descriptive study. The tertiary care hospitals including private and public hospitals along with teaching and non-teaching hospital were taken under the study for the ADR in marketed drugs.

A pretested questionnaire was used by the investigating team which will be available in English and Hindi. Questionnaire was semi structured.

If participant agreed to participate in the study only then he/she was included in the study, with an informed consent form.

The data was collected, stored, screened and cleaned before analyzing.

Benefits involved in the study are the assessment of the quality of the reporting system included in the facility. The possible gap in the system will can be highlighted and thus can be resolved.

This study has helped in providing an insight about the ADR reporting system in Jaipur. The study revealed that there is a strong need of training of adverse drug reaction (ADR) reporting in Jaipur. Nurses being a very important and integral part of healthcare system, they should be given specific training regarding ADR reporting, it can be very beneficial.

Other possible way to promote ADR reporting is to develop a system within the hospital to report ADR, so that it would not be a burden to only doctors or physicians or nurses or pharmacists. All three are an integral part of patient care and hence developing a system and not burdening one would be a better option to promote ADR.

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Acronyms

1	ADR	Adverse Drug Reaction
2	WHO	World Health Organization
3	AIIMS	All India Institute of Medical Sciences
4	PvPI	Pharmacovigilance Programme of India
5	ICH	International Conference on Harmonization
6	CDSCO	Central Drugs Standard Control Organization
7	PV Centre	Pharmacovigilance Centre
8	NPP	National Pharmacovigilance Programme

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Introduction

Safety and efficacy are the two major concerns about a drug. Efficacy of a drug can be estimated with relative ease but the same is not true for ADR. Adverse drug reaction is noxious and unwanted reaction to drugs at dose used in humans for diagnosis, treatment or prophylaxis. It is unintended effects of a medicine including idiosyncratic effects which occur during its proper use. They differ from accidental or deliberate excessive dosage or drug maladministration. This shows that in addition to the pharmaceutical properties of the drugs the characteristics of the patients predisposes an adverse drug reaction. Detection, recording and reporting of adverse drug reaction is of vital importance and health professionals are thus encouraged to perform this properly.[1]

Adverse drug reaction reporting system is an area of drug information that has been given little attention yet. It is possible that drugs produce initially unanticipated effects (adverse or potentially useful) after their approval for marketing[2]. Such effects can best be identified by pharmacy professionals, physicians and nurses because of their close proximity with their patients.

Pharmacovigilance as defined by the World Health Organization (WHO) is 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. The Pharmacovigilance Programme of India was initiated by the Government of India on 14.7.2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Co-Ordination Centre for monitoring Adverse Drug Reactions (ADR) in the country for safe-guarding Public Health. This is essentially due to the absence of a vibrant ADR monitoring system and also due to a lack of the reporting culture among the health care professionals[3]. One of the important long term goals of this programme is to develop reporting culture amongst healthcare professionals and make ADR reporting mandatory for healthcare professionals.[4]

Nurses are known to have an important role in ADR reporting and constitute a potentially valuable source forspontaneous ADR reports in hospitals.[5] Thus, the opinions and attitudes of hospital nurses on the difficulties of reporting of ADRs and the ways to solve them are very important.

Literature Review

Edwards IR, (2000), has states in his research work,' Adverse drug reactions: Definitions, diagnosis, and management' An adverse drug reaction can be defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." Such reactions are currently reported by use of WHO's Adverse Reaction Terminology, which will eventually become a subset of the International Classification of Diseases. Adverse drug reactions are classified into six types (with mnemonics): dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure). ADRs contribute to a significant number of morbidity and mortality all over the world. ADR can be seen in clinical practice with both new as well as marketed medicines.

WHO, (2006) has stated in' International drug monitoring: The role of National Centres' , To improve safety, patients and health care providers have failed in learning from the previous mistakes. It has been noticed that the health care professionals or health-care organizations do not share what they have learnedwhen an investigation has been carried out. As a consequence, the same mistakesoccur repeatedly in many settings and patients continue to be harmed by preventableerrors. One solution to this problem is reporting: by the doctor, nurse, or other providerwithin the hospital or health-care organization, and by the organization to a broaderaudience through a system-wide, regional, or national reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and,within a hospital or other health-care organization, a measure of progress towardsachieving a safety culture. At a minimum, reporting can help identify hazards andrisks, and provide information as to where the system is breaking down. This canhelp target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

The ADR reporting can be either voluntary or obligatory as per WHO (ICH) guidelines, but such process is not followed properly in practice keeping in view the low number of reporting in developing and underdeveloped nations (**WHO, 2006**). Spontaneous reporting of ADR is

commonly practiced method for monitoring of ADR. Healthcare practitioners have an important role in Pharmacovigilance and Adverse drug reactions (ADR) reporting.

National Pharmacovigilance Protocol, Ministry of Health & Family Welfare, Government of India, defines what to report, who should report and where to report. The National Pharmacovigilance Programme (NPP) encourages reporting of all suspected drug related adverse events, including those suspected to have been caused by herbal, traditional or alternative remedies. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem.

The programme particularly solicits reports of:

- ALL adverse events suspected to have been caused by new drugs and 'Drugs of current interest' (List to be published by CDSCO from time to time)
- ALL suspected drug interactions
- Reactions to any other drugs which are suspected of significantly affecting a patient's management, including reactions suspected of causing:
- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

The prescribed 'Adverse Drug Event Reporting Form' should be used for the purpose of National Pharmacovigilance Programme. Any health care professionals (Doctors including Dentists, Nurses, and Pharmacists) can report suspected adverse drug events.After completion the form should be returnedor forwarded to the same Pharmacovigilance Centre from where it was received. Reporting can be done to any one of the country vide Pharmacovigilance Centres nearest to the reporter.

Indian Pharmacopoeia Commission, report, May 2014, Recent published data suggest the less number of ADR cases reported by various PV centers in major cities compared to rest of the

world which indicate low awareness/ knowledge/ inadequate practice of ADR reporting is the region.

According to **Hanafi (2012),** in his research paper,' Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting., Hospital nurses could play an important role in ADRs reporting, because they are close to the patient and havegood knowledge of health criteria, symptoms, drugs and ADRs. Given their unique position in drug administrationand recording side effects, nurses are well placed to monitor the patients' response to drugs. They are often thesource in alerting the responsible physician about possible ADRs. There is thus a logical reason to involve nursesand encourage them to contribute in ADR reporting system.[5,13]

Goyal, (2013), To Assess the Attitude, Knowledge and Practices of Medical Professionals About Adverse Drug Reactions and Their Reporting in a Teaching Hospital staed in his work, Spontaneous ADR reporting is fundamental to medical Drug safety surveillance. Though, this system is Inexpensive and easy to operate and encompasses All drugs and patient populations, including special Groups but substantial under-reporting and inability To calculate the incidence of ADRs are the inherent Disadvantages of this system.3,4 Under-reporting can Lead to long delays between marketing and detection regulatory action of an adverse reaction.

John (2014), observed in his work, '.: Reporting of adverse drug reactions: an exploratory study among nurses in a teaching hospital'. Among the health care providers, nurses are in aunique position to monitor and report ADRs. Knowledgeand attitude of nurses towards reporting of ADRs play a significant role in the spontaneous reporting system.Several factors influence reporting behavior among health care providers such as; financial incentives for reporting; fear of litigation; belief that serious ADRs are well documented; uncertainty of an ADR, a singleADR report may not contribute and lack of interest or lack of time[16].The factors that hinder reporting among the nurseswere; uncertainty of the ADRs (49.5%); concern thatthe report may be wrong (46.2%) and inadequate knowledge of the ADR reporting procedure (45%).

Arunmali S. et al. 2007, Adverse drug reaction monitoring in a secondary care hospital in South India said in his work, Under-reporting of ADR by doctors is well known, and inIndia also, the spontaneous ADR reporting system has producedlower rates of reporting. Clinical pharmacy was introduced to the hospital in 1998 but the ADR monitoring and reporting programme was not

introduced until 2004because pharmacovigilance was poorly developed in ourcountry. At the same time, as part of the routine clinicalpharmacy services, ADR monitoring was done by the clinicalpharmacists in the hospital without further documentation and reporting.

Rationale

The benefits involved in the study are the assessment of the quality of the reporting system included in the facility. The possible gap in the system will can be highlighted and thus can be resolved.This study will help in providing an insight about the ADR reporting system in Jaipur, which will be beneficial for the hospitals and patients also.

Objectives

The objectives of the study are to:

- To test the knowledge regarding adverse drug reactions reporting among nurses
- To analyze the current practice of ADR reporting
- To test the attitude of nurses towards ADR reporting
- To identify current gap in knowledge and practices related to ADR reporting of marketed drugs in hospitals in Jaipur

Research Methodology

Study design - This was a descriptive study which targeted the nurses working in tertiary care hospitals in Jaipur.

Source of data- primary and secondary data was used to carry out this study. Secondary data was collected by research articles, journals, books and internet. The primary data was collected using a tool.

Sampling - The non-probability sampling was done. The study was explained to the respondent and if they agreed, only then they were included in the study. The consent form was duly signed if the respondent agreed to be a part of this study.

Total samples of 102 respondents were received from the selected group of hospitals. The study was of duration of 3 months.

Tools - The tool used for study was a semi structured questionnaire, which had questions based on knowledge, practice and attitude.

Pretesting - A pretesting was done on 20 samples to test the validity and reliability of the questionnaire. After pretesting, a final draft of questionnaire was finalized.

Analysis plan - The data was recorded using Microsoft excel and was analyzed quantitatively as well as qualitatively using Microsoft excel and SPSS 16.0

Analysis

The questionnaire was pretested for the reliability testing. The reliability of the tool was analyzed by SPSS 16.0 using Cronbach alpha.

As the Cronbach alpha was achieved 0.7, this shows that the tools is reliable and is validated. The data was further analyzed.

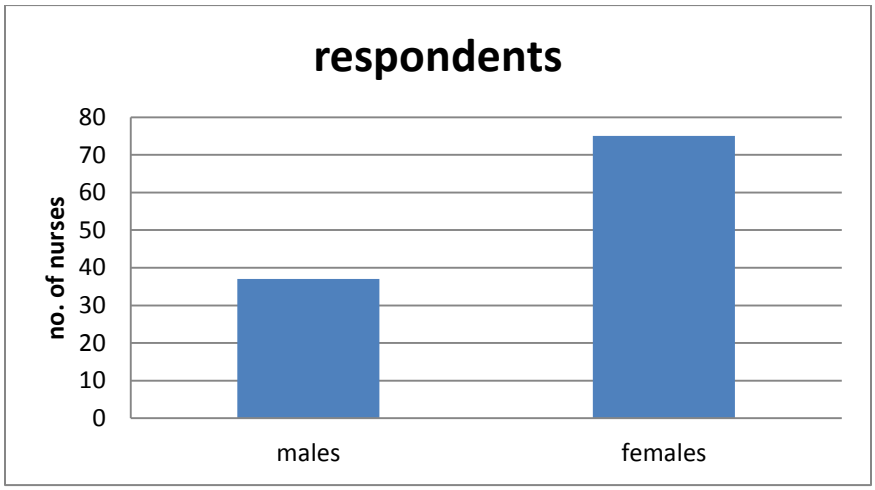
Table 1: Reliability testing

Reliability Statistics

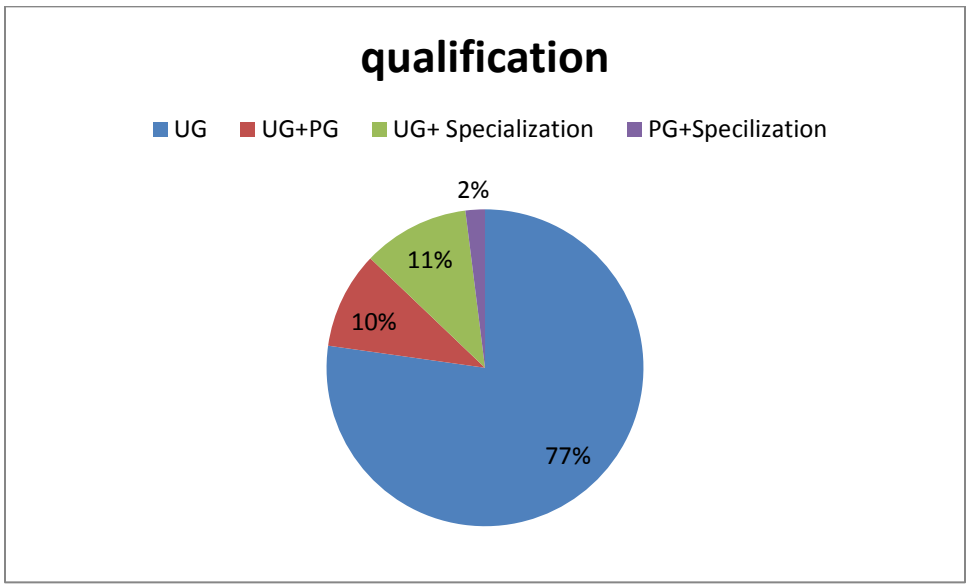
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.735	.711	14

Out of 102 respondents 37 were males and 65 were females. Since the number of male nurses are usually less, so the there is a difference in the number of respondents. No discrimination based on gender was done.

Figure 1: Gender of respondents



The average age of respondents is 30 yrs with range of 33 and maximum age of 50yrs, with average experience of 6 yrs .Figure 2: qualification of respondents



The majority of the respondents were graduates only, i.e. 77%, 11% were graduates with specialization, 10% were post graduates and only 2% were post graduates with specialization.

Have you heard the term Adverse Drug Reaction (ADR)? 100% respondents knew what an ADR is.

Is adverse drug reaction is same as side effect? 87.9% respondents knew that the adverse drug reaction is not same as side effects, whereas 5.1% nurses think that ADRs and side effects are same and there are 7.1% nurses who didn't know about it.

Table 2: knowledge about ADR and side effects

Is adverse drug reaction same as side effects		
response	data	percent
yes	5	4.9%
no	89	87.3%
don't know	8	7.8%

Have you heard about ADR reporting system in India? Out of 102 respondents, only 10% nurses are aware about the ADR reporting system in India.

Have you ever encountered patient with ADR in your clinical practice, in the last 12 months? If "Yes", Approximately how many patients with ADR, did you see in the last 12 months? In last 12 months, only 39.1% nurses have encountered patients with ADRs with average 6 patients and maximum 17 patients. 41.4% records the ADR they have encountered in either patient's file or register.

How often you report any ADRs? 44% said that they usually report and 41% said sometimes report. This is however a preferable practice that these respondents are usually reporting the ADR and the frequency of those nurses who do no report is comparatively less, i.e. only 14%. This shows that there is a scope of improvement and attitude changing training. These professionals can be trained to report regularly, hence there will be an increase in spontaneous reporting. There is a need to bring the reporting culture in regular practice.

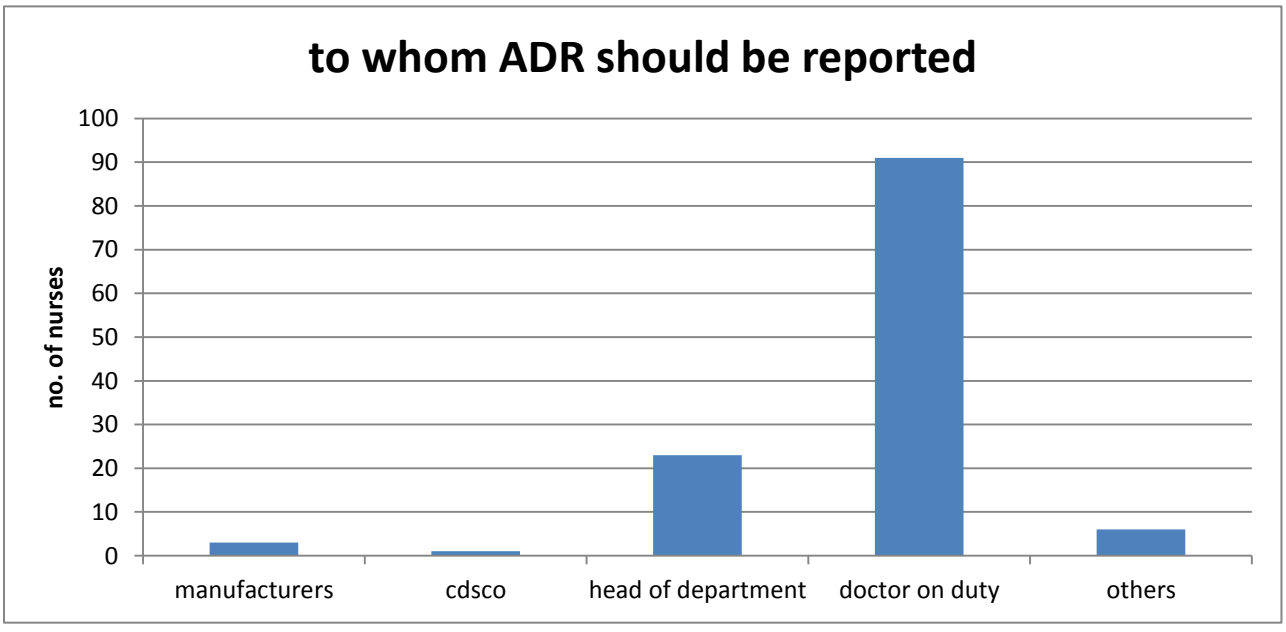
Table 3: Frequency of reporting ADR

Report_ADR

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Usually	44	44.4	44.4	44.4
	Sometimes	41	41.4	41.4	85.9
	rarely/never	14	14.1	14.1	100.0
	Total	99	100.0	100.0	

To whom ADRs should be reported? This question was asked and 94.9% respondents responded that they report to doctors on duty and only 24% responded head of department. There was no respondents who had reported to PvPi regional centre.

Figure 3: to whom ADR should be reported

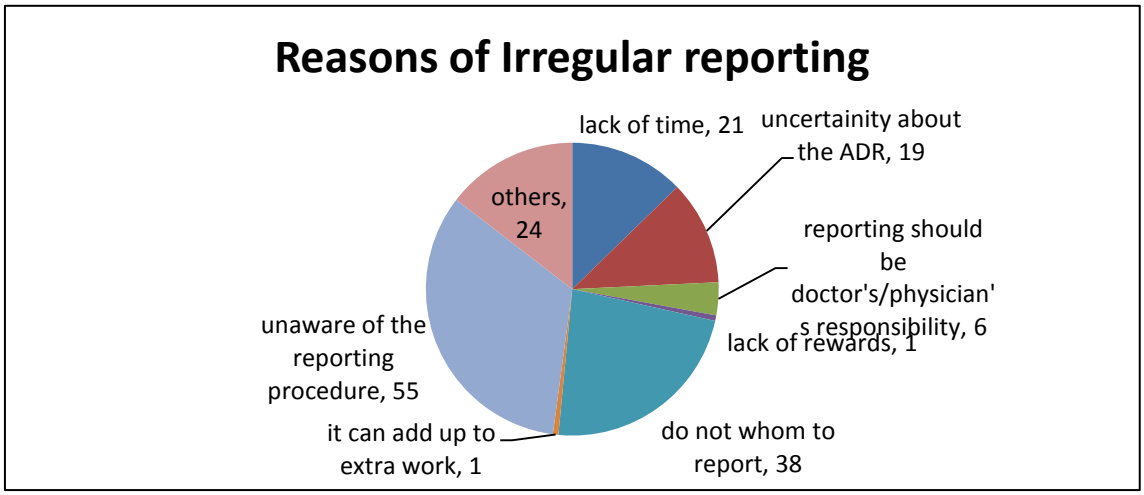


How often do you give advice to your patients on possible drug- drug or drug- food interactions?

There are 88% respondents who admit that they have been advising the patients about the drug-drug interaction and drug-food interaction. This shows that the respondents have been trying to reduce chances of any kind of side effects and ADR.

According to you, what are the main reasons of irregular reporting of ADRs? 54% respondents admitted that the main cause of irregular reporting is due to unawareness of the reporting procedure. Another majority of respondents said that they do not know whom to report. lack of time with professionals seems to be another reason why there is irregular reporting.

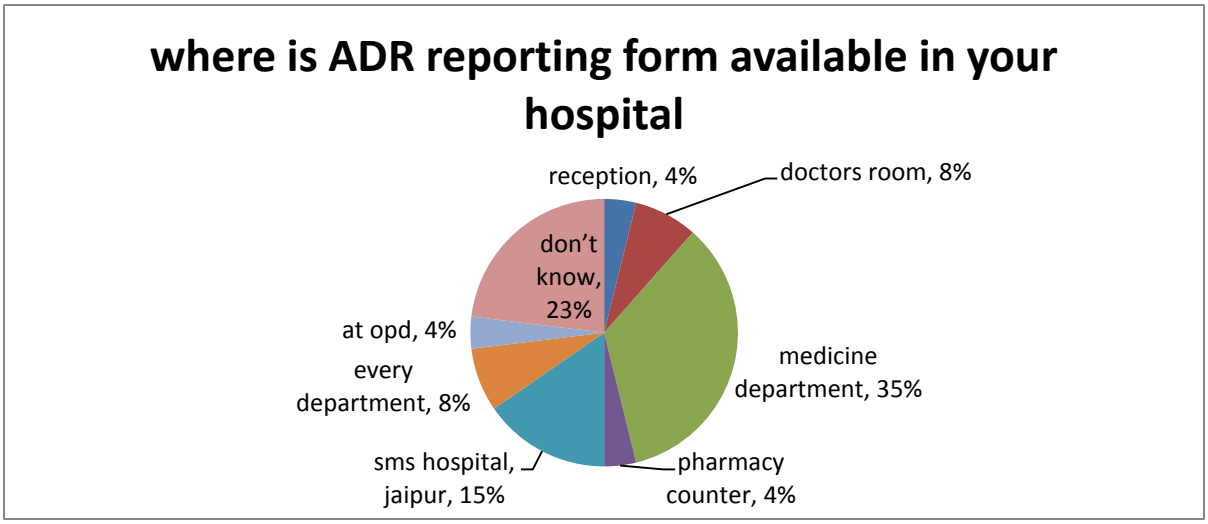
Figure 4: Reasons of irregular reporting



This shows a need of training and increasing awareness among nurses. As nurses are the closest in taking care of medical needs of a patients, training them can prove to be a great step in ADR reporting.

Is the ADR reporting form available in your organization? 75% of nurses were not aware of the fact that ADR reporting form is available within their hospital. Only 25% knew about the forms and only some of them knew where the form would be available. There was a variety of answers clearly depicting lack of knowledge.

Figure 5: Availability of ADR reporting form



Is ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'? They admitted that the ADRs are well documented by the pharmaceutical companies in their patient information leaflet, about 94% nurses agreed. Some of them even mentioned that these leaflets are sometimes very useful to them and they think that ADRs and precautions are well documented.

Have you had undergone any workshop/training specifically related to ADR reporting? Only 12% of the respondents had undergone training or workshop specifically to report ADR. The training period varied from 1 day to around 1 month. Even about the mandatory period of reporting only 28% respondents were aware about it.

When asked about the regional ADR reporting centre only 4 respondents answered correctly.

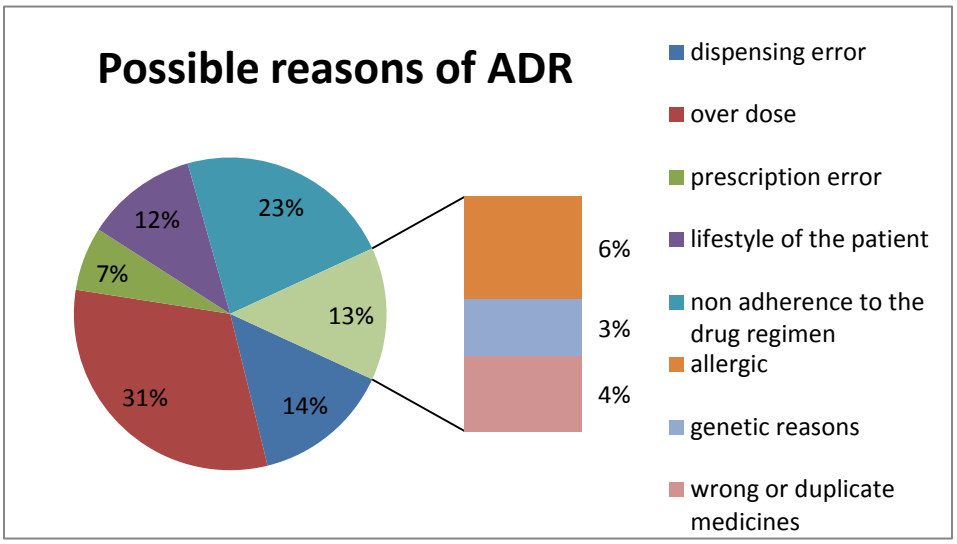
Who do you think is primarily responsible for explaining the patients about side effects of drugs they are given? When a question regarding the responsibility of explaining patients about side effects of drugs they are given was asked, only 4 responses mentioned that every health professional and patient is responsible. They clearly stated that whoever is giving the medicine to a patient is responsible for explaining patients about the possible side effects and prevention. Rest stated that the doctors are the sole responsible for explaining things to patients. This shows that there is a need of attitude changing workshop, so that as a health professional even they know that it their responsibility too. 95% respondents said that the responsible person is doing their job efficiently.

What is your source of information about ADR? When asked about the sources of information regarding the ADR reporting, 88% replied that their only source of information is doctors. 25% said standards text books and 8% mentioned that they got to know about the ADR

with experience on patients and 12% mentioned pharmacists has been helpful in explaining ADRs to them.

What possible factor (s) do you think predispose(s) a patient to ADR? There was a very blurred image of the possible factors that can predispose a patient to ADRs in respondents' mind. Major section of the respondents said that ADR happens due to the non compliance of the patients.

Figure 6: Possible reasons of ADR

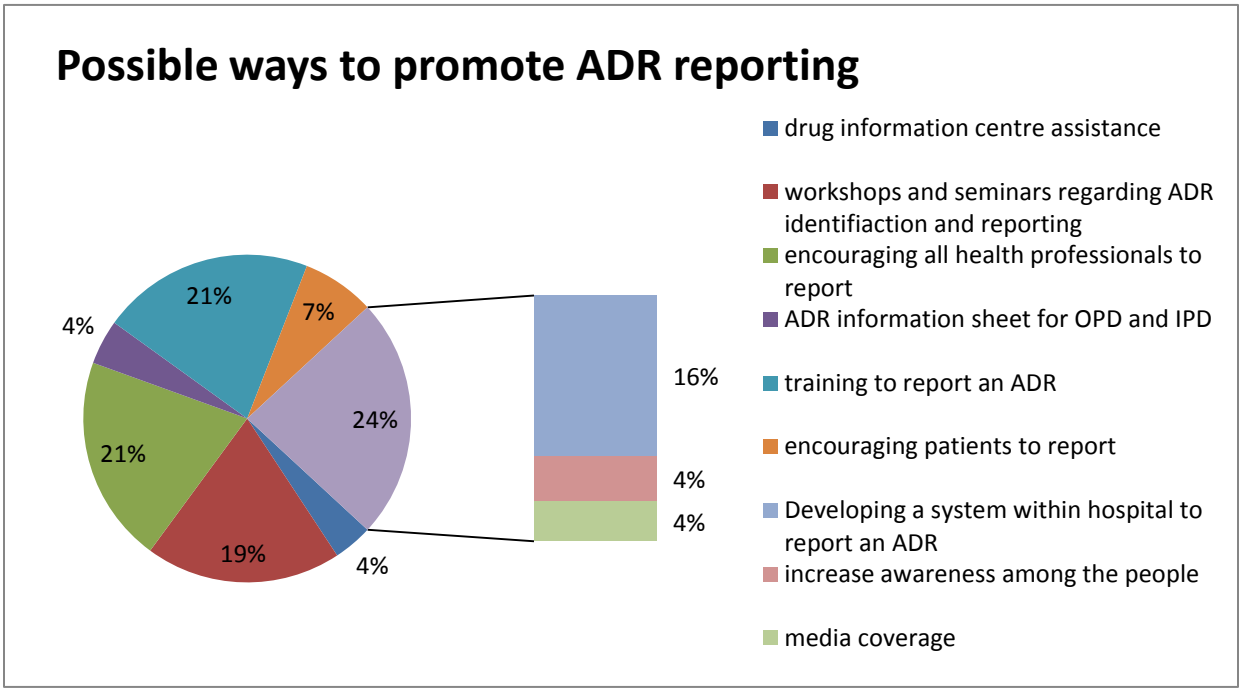


They mentioned that patient does not follow the drug regimen and they are exposed to ADRs. Over dose and dispensing error are other reasons for ADRs. There were many responses which were not at all related to ADRs but still are considered to be a reason of ADRs, such as alcohol consumption, life style of patient, diseases like diabetes, etc.

PvPI is taking many measures to promote ADR reporting in India, there are regional reporting centres all over in India, some respondents were not even aware that their own hospital is a regional centre of ADR reporting. There were however many innovative ideas to promote ADR reporting in India. Encouraging all health professionals and patients to report ADR was a priority with all.

They also mentioned that the training regarding ADR reporting and workshops and seminars will be very beneficial for all. Another reply which was taken as a possible solution to this problem of irregular or under reporting is that a system should be developed within hospital to report ADR.

Figure 7: Possible ways to promote ADR reporting



On attitude measuring scale, most of the respondents were found to a have a positive or inclination towards reporting ADR. They understood the importance of ADR reporting.

Factor Analysis

Table 4: Table showing factor analysis

Component Matrix[a]

	Component			
	1	2	3	4
ADR reporting to be practiced regularly	.629			
reporting ADR is a part of duty of health professionals	.784			
reporting about 'drug safety' is important	.762			
reporting drug safety is important for the health care	.764			
there is a need to be sure that ADR is related to the drug before reporting	.703			
only adr of prescribed drugs need to be reported		.581		
ADR related with non-prescribed drug need not to be reported				
only ADR that causes persistent disability should be reported	.680			
reporting ADR is a part of health care	.730			
reporting ADRs improves quality of patient care	.617			.564
one report of ADR makes no difference		.621		
reporting is not useful to the patient		.615		
reporting creates additonal workload			.718	

Extraction Method: Principal Component Analysis.

a. 4 components extracted.

Factor analysis shows that there can be three major factors. The first one can be named as the duty of health professional to report ADR, second will be the importance of even a single report and third one as additional work load. The value above 0.5 shows their importance and also that these values significantly contributes to the importance of ADR reporting and attitude of professionals.

Table 5: Correlating knowledge about ADR reporting system with frequency of reporting ADR

Correlations

		knowledge about ADR reporting system	Report ADR
knowledge about ADR reporting system	Pearson Correlation	1	.290**
	Sig. (2-tailed)		.004
	N	98	98
Report ADR	Pearson Correlation	.290**	1
	Sig. (2-tailed)	.004	
	N	98	99

**. Correlation is significant at the 0.01 level (2-tailed).

Knowledge about ADR reporting system was correlated with the frequency of reporting. A significant positive correlation was found.

Conclusion

The study revealed that there is a strong need of training and creating awareness about the ADR reporting in Jaipur. The Nurses are a very important part on healthcare system. Their role in patient care is irreplaceable and if they are initiated and encouraged to report, we can notice a very significant change in ADR reporting pattern.

It was noticed that the knowledge inflow from the authorities and in curriculum is not standardized. The ADR reporting is the need of hour, especially in India where multi pharmacy, self-medication is a common practice. Due to these reasons there are cases of resistance and abuse of drugs which may lead to high chances of ADR. From the above study, it can be concluded that there is a gap in system, execution of such major project and knowledge flow from the top to each and every healthcare professional

Discussion

There are gaps between knowledge and ADRs reportingamong doctors working in a teaching hospital. Thesegaps need to be filled by improved training and awareness in pharmacovigilance

at various levels of healthcare system. Attitudinal changes would becritical for a long-term improvement of ADR reporting.This may have important implications in terms of public health, if knowledge and attitudes are viewedas potentially modifiable factors.

Suggestions for Improvement in ADR Reporting

The data revealed that the nurses are closely related to patients in IPD and in day care. Therefore if there is need to educate nurses more about ADRs and reporting ADRs. Workshops, seminars, training or CMEs may prove to be a good option to improve ADR reporting scenario in India and nurses can be a useful to achieve this aim.

Educating them regarding the identification of ADR, notifying about ADR to doctors, and reporting procedure is highly recommended.

Improving the ADR reporting in India will be achieved only when every health professional understands their role in reporting and how they can be very useful in improving healthcare system. It can only be done through rigorous awareness and promotion programme and providing assistance in initial stages and follow up in next stages.

1. Each hospital should build local 'Pharmacovigilance Unit' for collection of ADR reporting forms.
2. Unit should periodically supply ADRs forms to physiciansand collect ADR forms from hospitals by sending representatives.
3. Hospitals can develop a system within the hospital, which will be help the professionals to report without burdening any one
4. A contact number of vigilance center or pharmacovigilance unit can be displayed
5. Periodical meetings of experts from PvPI with doctors should be arranged to boost reporting.
6. ADR drop boxes should be introduced at strategic locationsin hospitals.
7. Pharmacovigilance workshops for health care professionalsshould be initiated.
8. Facilitate ADR reporting by SMS, e-mail, fax andphone.
9. Incorporation of pharmacovigilance in the syllabus of UG and PG courses of medicine.
10. Associating ADR reporting with incentives.
11. Felicitation of physicians for maximum ADR reportingin a year.

12. Positively changing the mindset of physicians, so that ADR reporting becomes an accepted and understoodroutine.
13. The Government of India may pass a law for making ADR reporting mandatory for physicians.

References

1. Guideline for Adverse Drugs Reaction (ADR) Monitoring,2nd Edition, September 2008, DACA, Addis Ababa, Ethiopia.
2. WHO, A Guideline to detecting and reporting adverse drug reactions, Geneva, 2001.
3. Gupta SK. Pharmacovigilance: current status & future challenges. Indian Journal of Medical Specialities 2013;4(1):1-4.
4. Pharmacovigilance programme of India for assuring drug safety. Available at http://www.cdsco.nic.in/pharmaovigilance_intro.htm#goal&objectives. Accessed 1 October 2013.
5. Hall M, McCormack P, Arthurs N, Feely J. The spontaneous reporting of adverse drug reactions by nurses. Br J ClinPharmacol. 1995;40(2):173–5.
6. Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. Lancet. 2000;356:1255–9. [PubMed: 11072960]
7. World Health Organization. International drug monitoring: The roleof National Centres. Report No: 498. Geneva, Switzerland, 2006
8. NCC pharmacovigilance programme of India. Available at http://ipc.nic.in. Accessed 1 October 2013.
9. National Pharmacovigilance Protocol, Ministry of Health & Family Welfare, Government of India pg 17-18
10. Indian Pharmacopoeia Commission, report 2014
11. Hanafi S, Hayatshahi A,Gholami K, Javadi M.Knowledge, attitudes and practice of nurse regarding adverse drug reaction reporting, Iran J Nurs Midwifery Res. 2012 JanFeb; 17(1): 21–25. PMCID: PMC3590690
12. Backstrom M, Ekman E, Mjorndal T. Adverse drug reaction reporting by nurses in Sweden. Eur J ClinPharmacol. 2007;63(6):613–8. [PubMed]
13. GoyalM, Bansal M, Yadav S, Grover V,Kanwal P, To Assess the Attitude, Knowledge and Practices of Medical Professionals About Adverse Drug Reactions and Their Reporting in a Teaching Hospital, Indian Journal of Clinical Practice, Vol. 24, No. 3, August 2013
14. John et al.: Reporting of adverse drug reactions: an exploratory study among nurses in a teaching hospital, Ajman, United Arab Emirates. DARU Journal of Pharmaceutical Sciences 2012 20:44.
15. Inman WH: Attitudes to adverse drug-reaction reporting. Br J ClinPharmacol 1996, 41:433–435.
16. R. Arulmani, S.D. Rajendran& B. Suresh Adverse drug reactionmonitoring in a secondary care hospital in South India, Br J ClinPharmacol / 65:2 / 210–216

ANNEXURES

Questionnaire

Serial Number	
Gender	Male -1 / Female -2
Age (in full completed years)	
Qualification	UG-1 / UG+PG-2 / UG+Other specialization-3 / PG+Other specialization-4
Department	
Years of Experience	

a.	Have you heard the term Adverse Drug Reaction (ADR)? (interview ends if answer is "No")	Yes -1	No -2	
b.	Is adverse drug reaction is same as side effect?	Yes -1	No -2	Don't Know -3
c.	Have you heard about ADR reporting system in India? If "Yes" where is its central office in India _____	Yes -1	No -2	
d.	Have you ever encountered patient with ADR in your clinical practice, in the last 12 months? (interview ends if answer is "No")	Yes -1	No -2	
e.	Approximately how many patients with ADR, did you see in the last 12 months?			
f.	Do you record the ADRs encountered in your practice? If "Yes" Where did you record the ADR encountered in your practice?	Yes -1	No -2	
g.	Have you reported any ADRs?	Usually -1	Sometime - 2	Rarely/ Never -3
h.	To whom ADRs should be reported? (Multiple answers are possible)	1. Manufacturers 2. Ministry of Health 3. DCGI 4. DTC of respective health facility 5. CDSCO (Central Drugs Standard Control Organization) 6. Head of department 7. Doctor on duty		
i.	How often do you give advice to your patients on possible drug- drug or drug- food interactions?	Usually - 1	Sometimes -2	Never - 3
j.	According to you, what are the main causes of irregular reporting of ADRs? (Multiple answers are possible)	1. Lack of time 2. Uncertainty about the ADR 3. Reporting should be doctors/physicians' responsibility 4. Lack of rewards 5. Do not know whom to report 6. It can add up to extra work 7. Unaware of the reporting procedure 8. Others, please specify		
k.	According to you, what are the possible ways to promote ADR reporting in India? (Multiple answers are possible)	1. Drug information centre assistance 2. Workshops and seminars regarding ADR identification and reporting 3. Encouraging all health professionals to report		

		4. ADR information sheets for OPD and IPD 5. Training to report an ADR 6. Encouraging patients to report 7. Developing a system within hospital to report an ADR 8. Others, please specify			
l.	ADR reporting to be practiced regularly	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
m.	Reporting ADR is part of duty of Health professional	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
n.	Reporting about 'drug safety' is important	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
o.	Reporting drug safety is important for the health care system	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
p.	There is a need to be sure that ADR is related to the drug before reporting	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
q.	Only ADR of prescribed drugs need to be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
r.	ADR related with non-prescribed drugs need not to be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
s.	Only ADR that cause persistent disability should be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
t.	Reporting ADR is part of health care	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
u.	Reporting ADRs improves quality of patient care	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
v.	One report of ADR makes no difference	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
w.	Reporting is not useful to the patient	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
x.	Reporting creates additional work load	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
y.	Is the ADR reporting form available in your organization? If answer is "Yes", Where ADR reporting forms are available in your organization?			Yes -1	No -2
z.	Is ADRs of marketed drugs are well documented by Pharmaceutical companies in their 'Patient information leaflet'?			Yes(1)	No(2)
aa.	Have you had undergone any workshop/training specifically related to ADR reporting? If answer is "no" skip to ee			Yes(1)	No(2)

bb.	What was the duration of the training?		
cc.	Where was the training held?		
dd.	Do you know about mandatory ADR reporting time period? If yes, please mention mandatory time period _____	Yes(1)	No(2)
ee.	Where Regional office for reporting ADR is located?		
ff.	Who do you think is primarily responsible for explaining the patients about side effects of drugs they are given?	1. Pharmacists 2. Physicians/ Doctors 3. Nurse 4. Patient 5. Others, please specify	
gg.	Do you think the above responsible person is reporting efficiently?	1. Yes 2. No 3. Sometimes 4. Other, please specify _____	
hh.	What possible factor (s) do you think predispose(s) a patient to ADR? (Multiple answers are possible)	1. Dispensing error 2. Over dose 3. Prescription error 4. Life style of the patient 5. Non adherence to the drug regimen 6. Other, please specify _____	
ii.	What is your source of information about ADR? (Multiple answers are possible)	1. National drug formulary and STG 2. Standard text books 3. Notes from the training 4. Pharmacists 5. Doctors 6. Other, please specify	