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

Under

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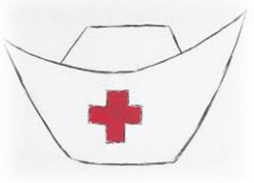
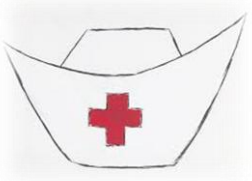
Background



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



Nurses are known to have an important role in ADR reporting and constitute a potentially valuable source for spontaneous ADR reports in hospitals.

Thus, the opinions and attitudes of hospital nurses on the difficulties of reporting of ADRs and the ways to solve them are very important.

Rational

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 .

Such effects can best be identified by pharmacy professionals, physicians and nurses because of their close proximity with their patients.

Objectives

- 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 – Descriptive Study
- Study Population – Nurses in Jaipur
- Sampling – Non Probability Sampling
- Sample Size- 100 Nurses
- Study Duration – 3 Months
- Data Collection Technique- Semi Structured Questionnaire

Reliability testing

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

Since the Cronbach's alpha was more than 0.5.
Therefore, the questionnaire is reliable.

FINDINGS

Male – 37
Female – 63

Mean age – 30 yrs
Max Age- 50yrs
Min Age – 23yrs

Average experience- 6 yrs

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%**

10% nurses are aware about the ADR reporting system in India

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.

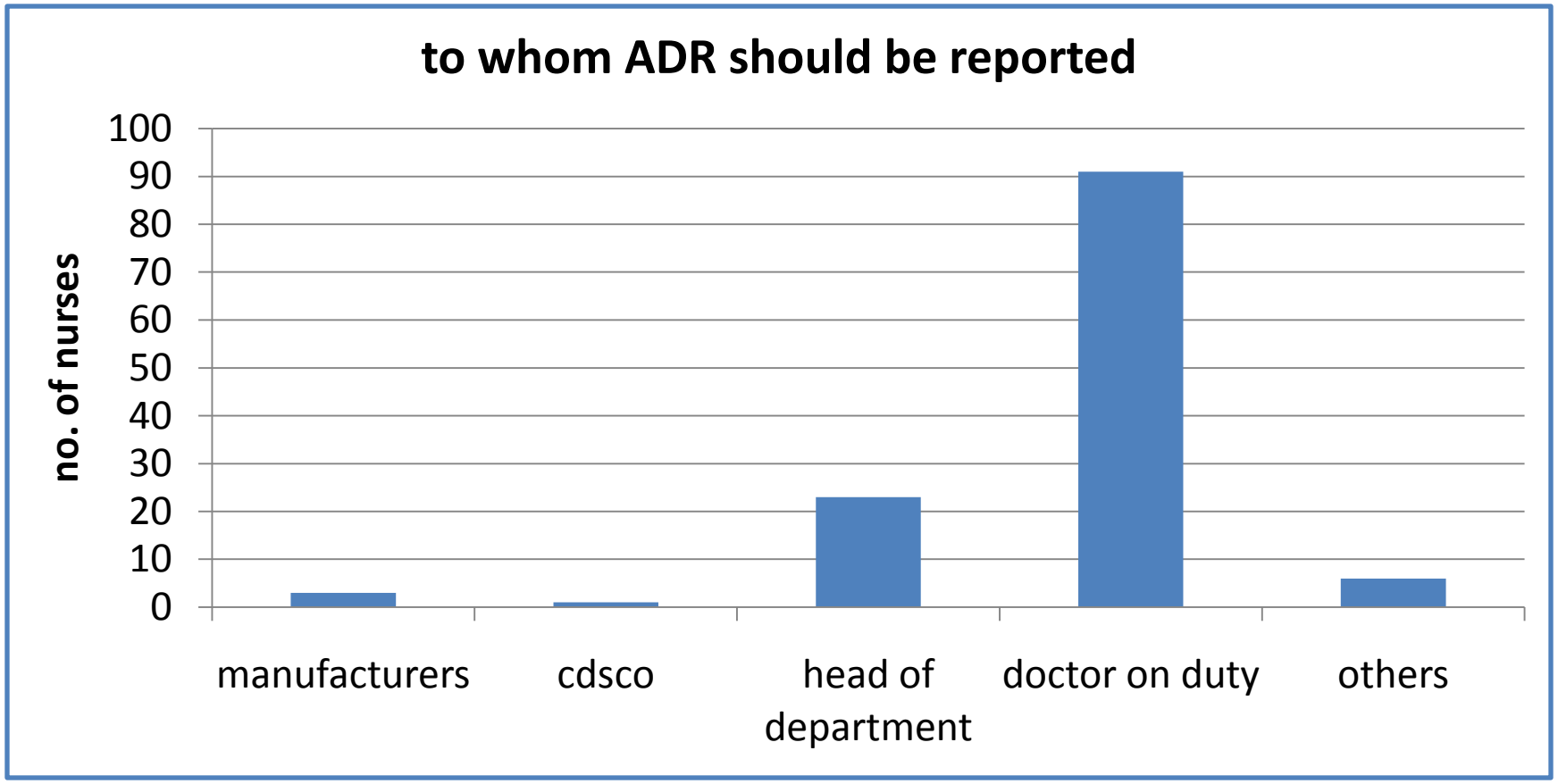
How often they report ADRs?

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	

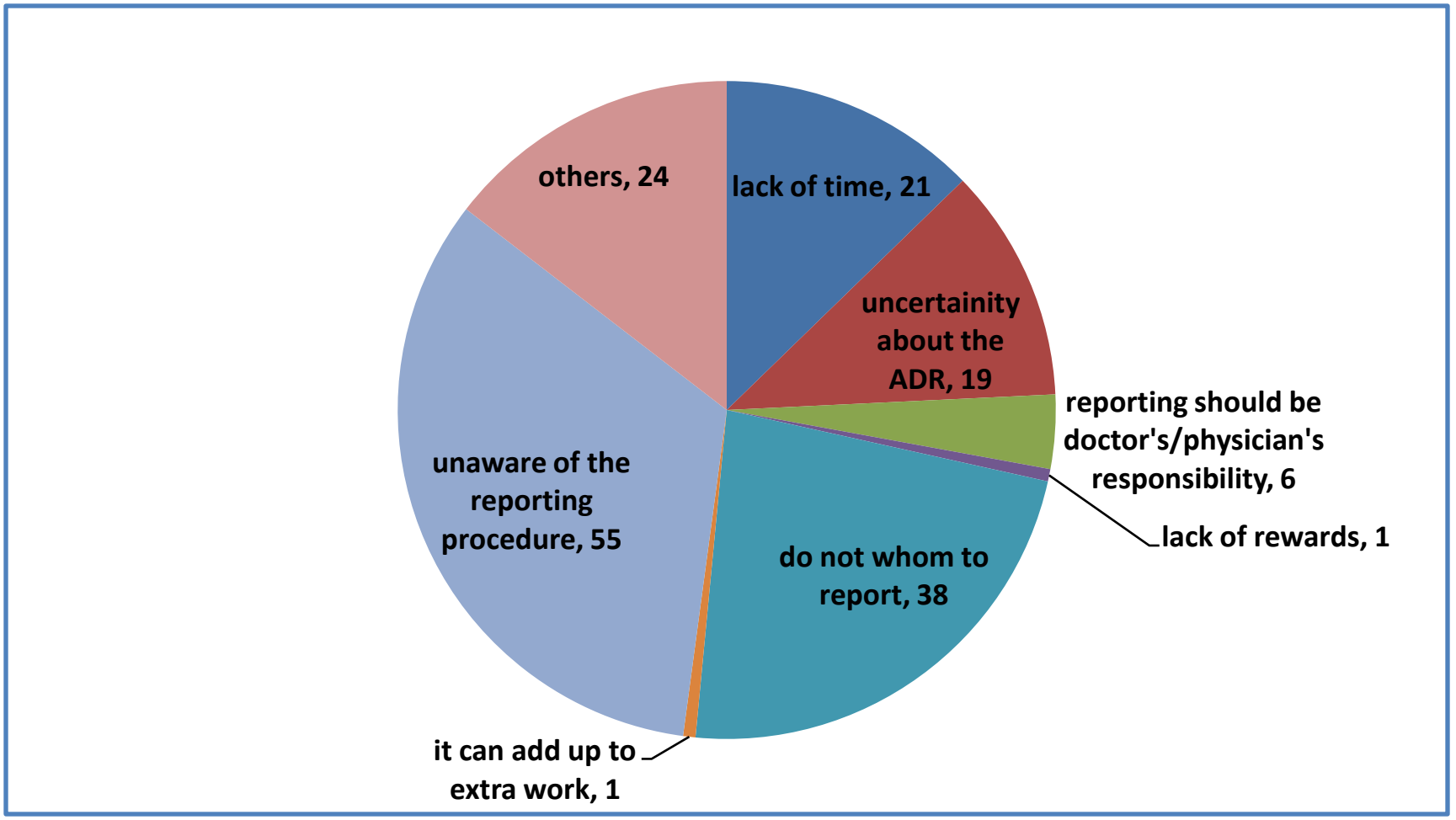
Only 44.4% respondents report ADRs usually and around 41% report sometimes.

Only 88% respondents advise the patients about the drug-drug interaction and drug-food interaction.

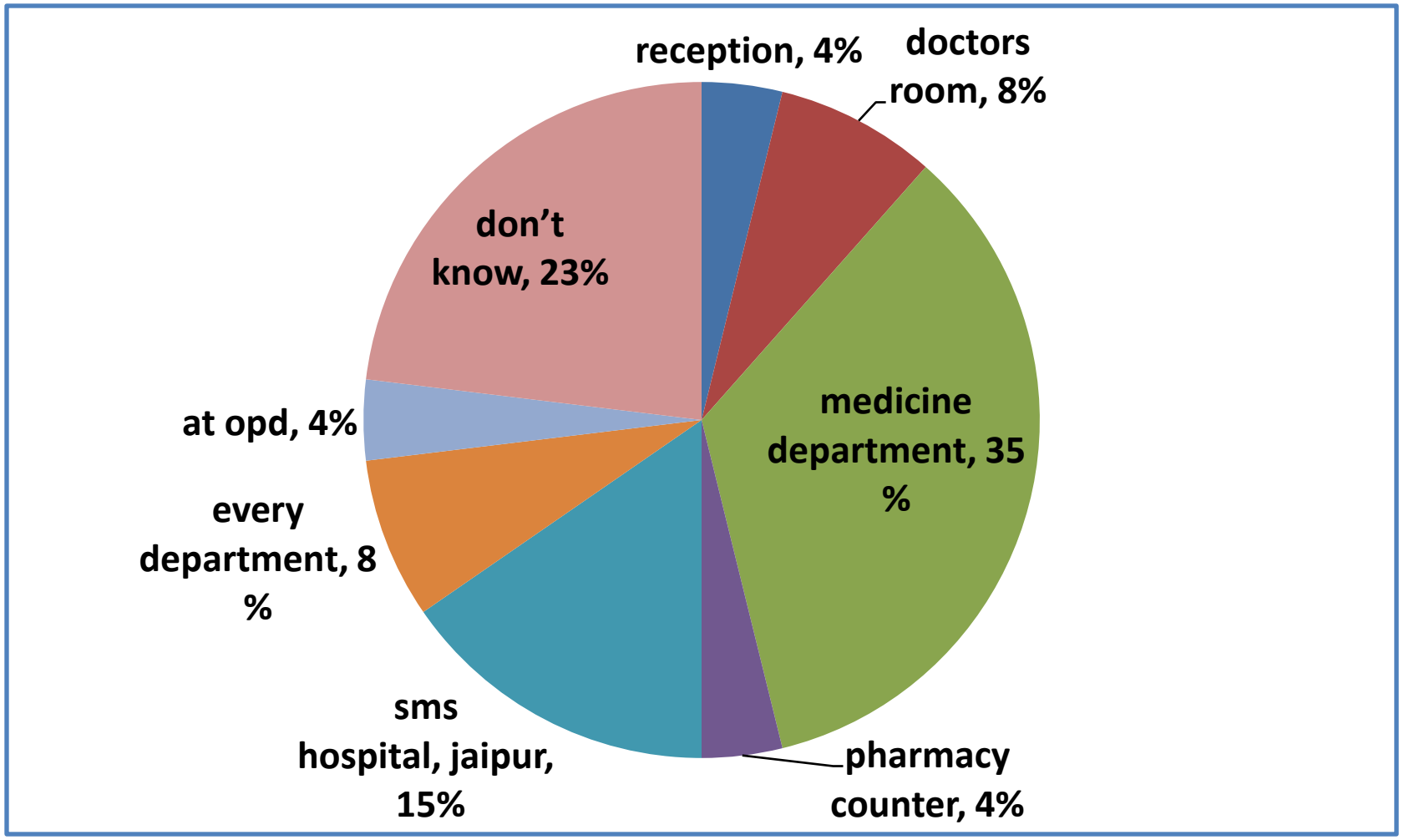
To whom ADRs should be reported?



Reasons of irregular reporting

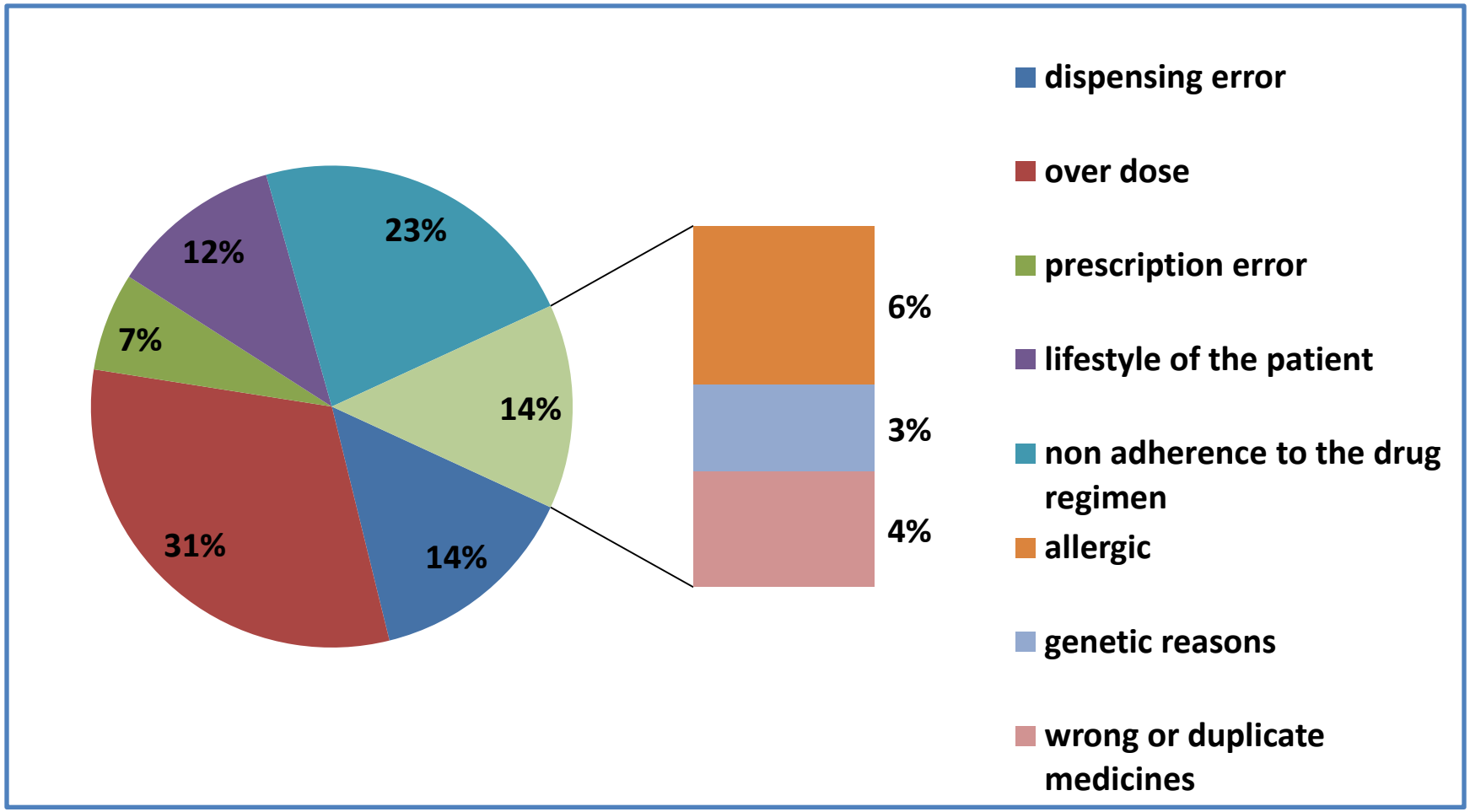


Where is ADR reporting form available in your hospital

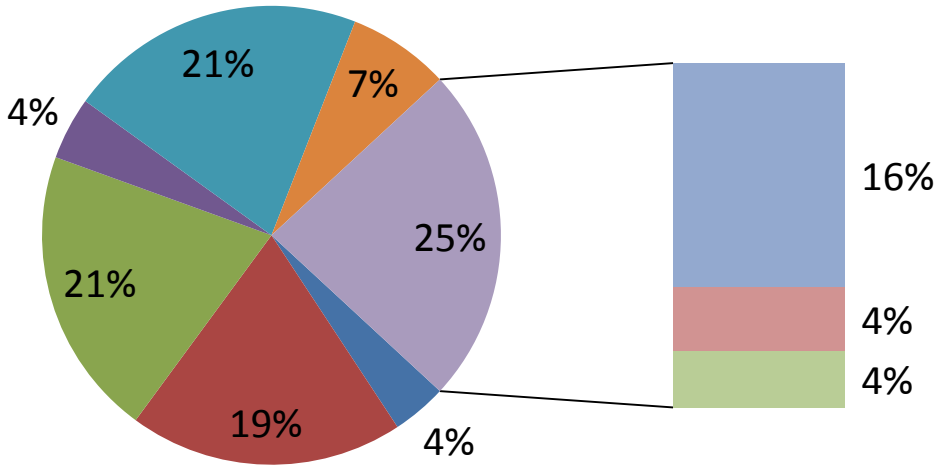


- 94% nurses agreed that the ADRs are well documented by the pharmaceutical companies in their patient information leaflet.
- Only 12% of the respondents had undergone training or workshop specifically to report ADR.
- The training period varied from 1 day to around 1 month.
- Only 28% respondents were aware about it about the mandatory period of reporting.
- only 4 responses mentioned that every health professional and patient is responsible for explaining patients about side effects of drugs they are given.
- Rest stated that the doctors are the sole responsible for explaining things to patients
- 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

Possible reasons of ADRs



Possible ways to promote ADR reporting



- drug information centre assistance
- workshops and seminars regarding ADR identifiaction and reporting
- encouraging all health professionals to report
- ADR information sheet for OPD and IPD
- training to report an ADR
- encouraging patients to report
- Developing a system within hospital to report an ADR
- increase awareness among the people
- media coverage

Factor Analysis				
	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.				

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

Suggestions

- Each hospital should build local ‘Pharmacovigilance Unit’ for collection of ADR reporting forms.
- Unit should periodically supply ADRs forms to physicians and collect ADR forms from hospitals by sending representatives.
- Hospitals can develop a system within the hospital, which will be help the professionals to report without burdening any one
- A contact number of vigilance center or pharmacovigilance unit can be displayed
- Periodical meetings of experts from PvPI with doctors should be arranged to boost reporting.
- Pharmacovigilance workshops for health care professionals should be initiated.
- Facilitate ADR reporting by SMS, e-mail, fax and phone.
- Incorporation of pharmacovigilance in the syllabus of UG and PG courses of medicine.
- Associating ADR reporting with incentives.

References

- Guideline for Adverse Drugs Reaction (ADR) Monitoring,2nd Edition, September 2008, DACA, Addis Ababa, Ethiopia.
- WHO, A Guideline to detecting and reporting adverse drug reactions, Geneva, 2001.
- Gupta SK. Pharmacovigilance: current status & future challenges. Indian Journal of Medical Specialities 2013;4(1):1-4.
- Pharmacovigilance programme of India for assuring drug safety. Available at http://www.cdsco.nic.in/pharmaovigilance_intro.htm#goal&objectives. Accessed 1 October 2013.
- 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.
- Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. Lancet. 2000;356:1255–9. [PubMed: 11072960]
- World Health Organization. International drug monitoring: The roleof National Centres. Report No: 498. Geneva, Switzerland, 2006
- NCC pharmacovigilance programme of India. Available at http://ipc.nic.in. Accessed 1 October 2013.
- National Pharmacovigilance Protocol, Ministry of Health & Family Welfare, Government of India pg 17-18
- Indian Pharmacopoeia Commission, report 2014
- 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
- Backstrom M, Ekman E, Mjorndal T. Adverse drug reaction reporting by nurses in Sweden. Eur J ClinPharmacol. 2007;63(6):613–8. [PubMed]
- 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
- 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.
- Inman WH: Attitudes to adverse drug-reaction reporting. Br J ClinPharmacol 1996, 41:433–435.
- 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

Annexure

Have you heard the term Adverse Drug Reaction (ADR)? (interview ends if answer is “No”)	Yes -1	No -2	
Is adverse drug reaction is same as side effect?	Yes -1	No -2	Don’t Know -3
Have you heard about ADR reporting system in India? If “Yes” where is its central office in India _____	Yes -1	No -2	
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	
Approximately how many patients with ADR, did you see in the last 12 months?			
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	
Have you reported any ADRs?	Usually -1	Some time - 2	Rarely/ Never -3

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		
How often do you give advice to your patients on possible drug- drug or drug- food interactions?	Usually - 1	Sometimes -2	Never - 3
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		
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		

ADR reporting to be practiced regularly	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting ADR is part of duty of Health professional	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting about 'drug safety' is important	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting drug safety is important for the health care system	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
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
Only ADR of prescribed drugs need to be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
ADR related with non-prescribed drugs need not to be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4

Only ADR that cause persistent disability should be reported	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting ADR is part of health care	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting ADRs improves quality of patient care	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
One report of ADR makes no difference	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting is not useful to the patient	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
Reporting creates additional work load	Strongly agree -1	Agree -2	Disagree - 3	Strongly disagree -4
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
Is ADRs of marketed drugs are well documented by Pharmaceutical companies in their ‘Patient information leaflet’?			Yes(1)	No(2)
Have you had undergone any workshop/training specifically related to ADR reporting? If answer is “no” skip to ee			Yes(1)	No(2)
What was the duration of the training?				
Where was the training held?				

Do you know about mandatory ADR reporting time period? If yes, please mention mandatory time period _____	Yes(1)	No(2)
Where Regional office for reporting ADR is located?		
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	
Do you think the above responsible person is reporting efficiently?	1. Yes 2. No 3. Sometimes 4. Other, please specify _____	
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 _____	
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	

Any Questions??