



Assessment of Knowledge, Attitude and Practices of Adverse Drug Reaction Reporting among health care professionals in Pravara Rural Hospital, Ioni, Ahmednagar, Maharashtra, India

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Introduction

Adverse drug reactions (ADRs) are global problems of major concern. They are one of the common causes of morbidity and mortality in both hospital and community settings and affecting many with varying magnitudes; as well as leading to morbidity and mortality. Hence, proper monitoring of ADRs is a necessity.

World Health Organization (WHO) defines ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. According to a article, Worldwide, 95% of serious ADRs do not get reported to the health authorities.⁽¹⁾

It has been estimated that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization.

ADR spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of drug-induced risks. It may detect previously unrecognized adverse reactions and identify risk factors that predispose to drug toxicity and investigate causality.

Spontaneous reporting of ADRs has remained the cornerstone of pharmacovigilance and is important in maintaining patient safety. However, reporting of serious ADRs rarely exceeds 10%. Underreporting of ADRs is a common problem in pharmacovigilance programs.⁽²⁾

Assessment of awareness of Pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitude that are associated with high degree of underreporting.

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The Pharmacovigilance Programme of India (PvPI) like most others around the world suffers from underreporting of ADRs by the healthcare professionals; this can delay the detection of important ADRs. However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India.⁽³⁾

It is estimated that only 6–10% of all ADRs are reported⁽⁴⁾ This high rate of under-reporting can delay signal detection and consequently cause negative impact on the public health. Pharmacovigilance has constantly gained importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs⁽⁴⁾

Spontaneous reporting of ADRs has played a most important role in the detection of serious and unusual ADRs during marketing of the drug in actual practicing in the market. This has led to the withdrawal of many drugs in the past such as rofecoxib, cisapride, terfenadine, etc⁽⁵⁾ More than 75 drugs/ drug products have been removed from the market due to safety problems by Food and Drug Administration.⁽⁶⁾ A study by Lazarou described ADR's to be the 4th–6th largest cause of death in the USA⁽⁸⁾

Aim and Objectives

To assess the knowledge attitude and practices of health care Professionals towards ADR reporting in Pravara Rural Hospital. Ioni.

Material and Methodology

Study site: The study was conducted on all health care professionals working in PRH Ioni.

Study Design: The cross-sectional survey was conducted using a self-administered questionnaire given face-to-face by the researcher. The KAP questionnaires towards Pharmacovigilance and ADRs were developed from already published

articles and then it has been modify according to the need of the present study. Then questionnaire then validated by expert faculties from pharmacology and different clinical department of our institute. Few changes were made and the finalized KAP Questionnaires consisted of 12 questions: Q. No.01-06 were on knowledge, Q. No.07-09 were on attitude and Q.No.-10-12 were on practice aspects of Pharmacovigilance and ADRs reporting, respectively.

Study Criteria

After obtaining the verbal consent from the health care professionals the questionnaire form was distributed to them. The health care professionals was given enough time to respond to the questions. The filled in questionnaire was collected back immediately.

Eligibility Criteria

Inclusion Criteria

- Registered medical practitioners working in PRH Ioni during the study period.
- All resident doctors working in PRH Ioni during the study period.
- All staff nurses working in PRH Ioni during the study period.
- All pharmacists working in PRH Ioni during the study period.
- Medical interns.

Exclusion Criteria

- Health care workers not working in PRH Ioni during the study period or working before or after the study conducted.

Study procedure

- The following data will be collected in the questionnaire- based survey form and recorded in the excel sheet.
- After getting approval from the institutional committee ,verbal consent is taken from the participants', then questionnaire distributed to them after giving sufficient time to fill the form, questionnaire has been taken from them

Data collection Analysis

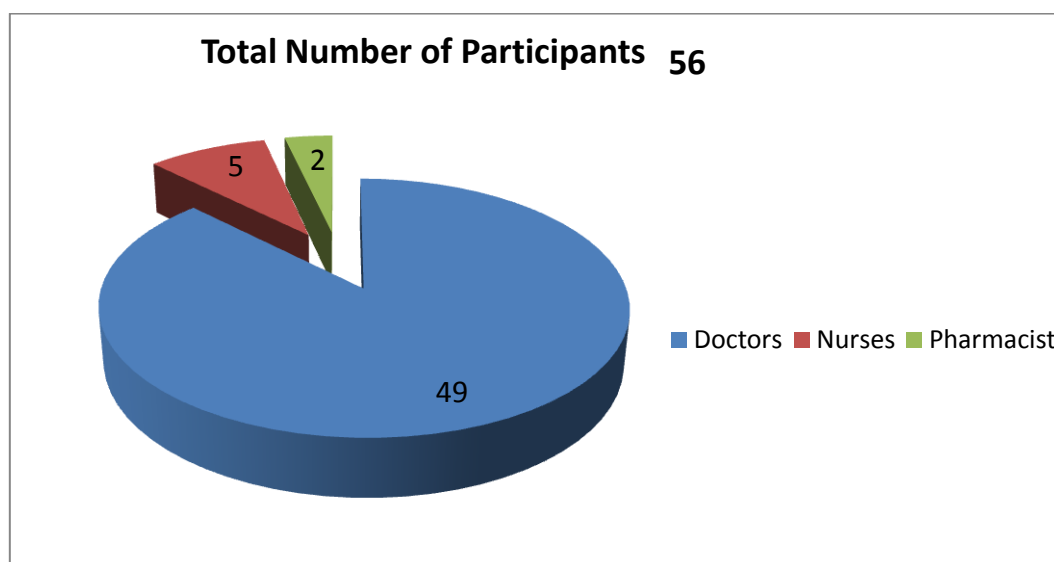
- The data will be collected by asking health care professionals to fill the questionnaire-based survey form.

The Data obtained from the study will be compiled, tabulated and analyzed by appropriate statistical methods.

Results

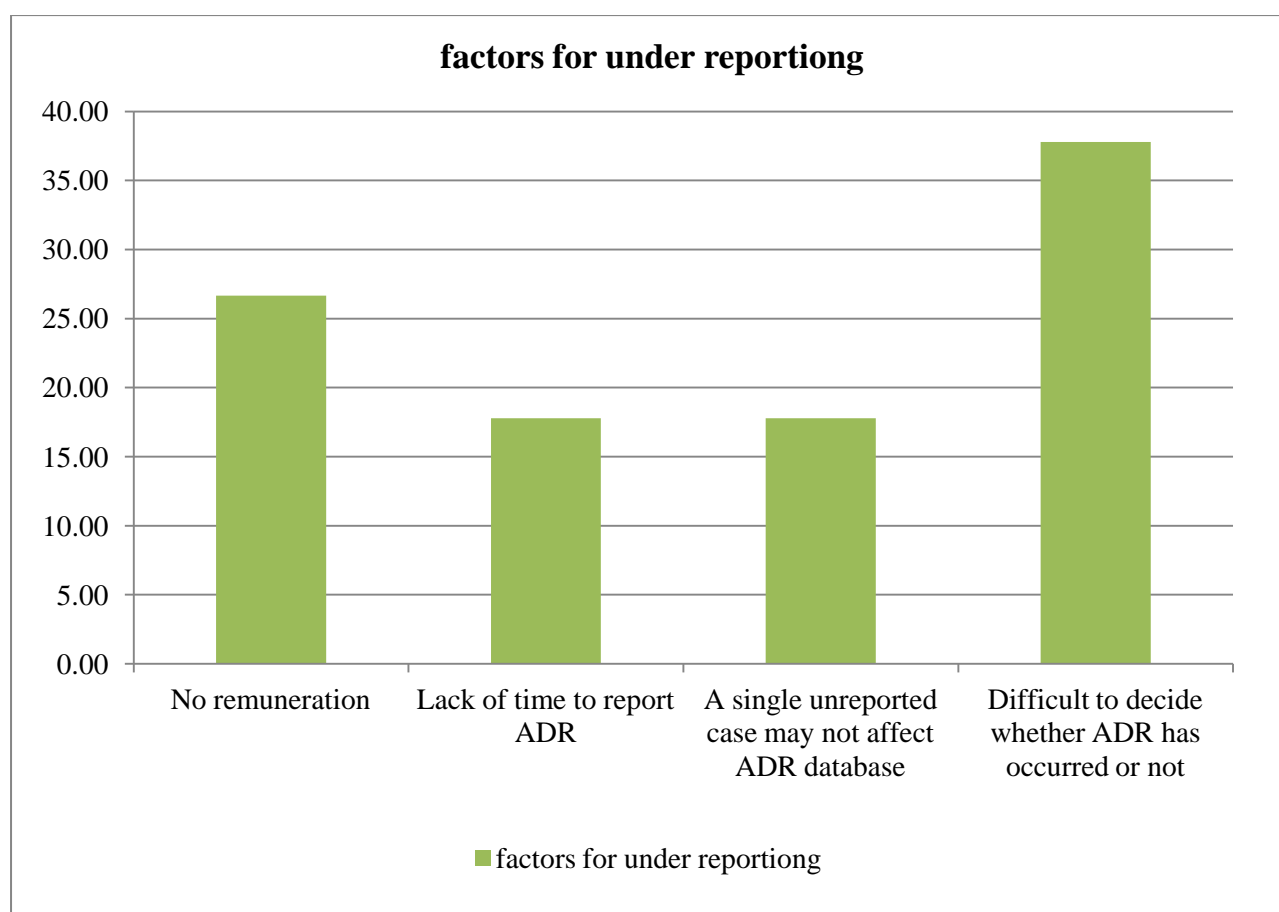
A total of 56 respondents answered the questionnaires, 31 male and 25 female health care professionals amongst which 49 doctors, 5 staff nurses and 2 pharmacists were involved in the study. 72.22 % of health care professionals knew

about ADR reporting, 64.81% were of opinion that all ADRs should be reported, 64.81% opined that all health care professionals are responsible for the ADR reporting. Of all the participants, 40% knew about pharmacovigilance committee working in the PRH Loni, 92.59% suggested that ADR reporting is necessary, 66.04% thought that ADR reporting is professional obligation for them, 88.68% felt that ADR reporting should be taught in details to health care professionals. Only 16.98% reported ADRs and 37.78% had not reported the ADR due to difficulty in deciding whether ADR has occurred or not.



Questions based on Knowledge	a)	b)	C)S	d)
1) Do you know about ADR reporting?	Yes 72.22 %	No 14.81 %	May be 11.11 %	Cant say 1.85%
2) Do you know what ADR you should report?	Expected 9.26 %	Unexpected 25.93 %	Serious 0.00 %	all of above 64.81%
3) The healthcare professional's responsible for ADR reporting in Pravara Rural Hospital?	Doctors 24.07 %	Nurses 9.26 %	Pharmacis t 1.85 %	All of the above64.81%
4) Is there any Pharmacovigilance Committee in your Institute?	Yes 40.00%	No 1.82 %	Not yet formed 0.00 %	Don't know 58.18 %
5)Where is the National Pharmacovigillance centre situated in India?	AIMS, Delhi 40.43 %	Gaziabad ,UP 36.17 %	KEM, Mumbai 10.64 %	PGI,Chndigar h 12.77 %
6) Where the international center for adverse drug reaction monitoring is located?	USA 42.22 %	UK 11.11 %	France 8.89 %	Sweden 37.78%

Questions based on Practice	a)	b)	c)	d)
1) Have you ever Reported ADR?	Yes 16.19%	No 69.81 %	Don't know where to submit the ADR reporting form 7.55 %	Don't know how to fill up the ADR reporting form 5.66 %
2) if yes, how many ADRs have you reported?	1 61.11 %	2 16.67 %	3 5.56 %	>=4 16.67 %
3) Which of the following factor discourage you from reporting ADR?	No remuneration 26.67 %	Lack of time to report ADR 17.78 %	A single unreported case may not affect ADR database 17.78 %	Difficult to decide whether ADR has occurred or not 37.78 %



Discussion

Worldwide, underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system. Amongst various factors knowledge, attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs⁽⁷⁾. Hence, this study was undertaken to evaluate the knowledge, attitude and practice of healthcare professionals on ADR reporting.

Adverse drug reaction reporting is a cornerstone of pharmacovigilance programme of India. Under-reporting may lead to more patients being exposed to the harmful effects of drugs. It is important for physicians to know which adverse effects to report, how and where to report an adverse drug reaction. Positive attitude and practice can improve adverse drug reaction reporting⁽⁸⁾. Karande Vitthal B..et.al study suggested that very few doctors having knowledge about existence of ADR reporting centre in the town similarly our

study also suggest that only 40.00% health care professionals were known about the presence of ADR reporting centre in the Pravara Rural Hospital,loni.⁽⁹⁾

A study by Datta Supratim, et.al. shows that A vast majority (97%) of the respondents shared the view that the reporting of ADR's was necessary, but only 63% considered it to be a professional obligation⁽⁸⁾ similarly our study shows that 92.59% health care professionals says that ADR reporting is necessary ,and 66.04% says that ADR reporting is professional obligation for them.It is an indication of a positive attitude toward the need to report, but a relative lack of commitment to do so⁽⁸⁾.

KAMTANE R, et.al. study 95.74% doctors stated that proper training should be provided to physicians for ADR reporting similar results were found in our study, 88.68% saying that pharmacovigilance should be taught in details⁽⁴⁾.

Bhagavathula A, et al. in their article of Health Professionals' Knowledge, Attitudes and Practices about Pharmacovigilance in India shows that 74.5%, health care professionals never reported any ADR to PV centers⁽¹⁰⁾ our study also suggesting that 69.81% health professionals never reported the ADR.

Conclusion

Participants reflected unsatisfactory knowledge on ADR reporting.

The prevalence of unsatisfactory practices and attitudes among these health care professionals contribute to failure of ADR reporting even if the ADR has identified.

Educational intervention strategies can be introduced in order to promote ADR reporting.

Implementing ADR reporting as a integral part of undergraduate internship, and postgraduate training.⁽¹¹⁾

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