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Original Research Article

Knowledge, attitude and practice of pharmacovigilance among community pharmacists in Delhi, India

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ABSTRACT

Background: Lack of knowledge of Pharmacovigilance (PhV) and Adverse Drug Reactions (ADRs) reporting culture among the prescribers have been identified as major factors for under reporting of ADRs. In an attempt to increase the reporting many countries have allowed pharmacists to report ADRs. This study was planned to assess the knowledge, attitude and practices of PhV among community pharmacist in Delhi, India.
Methods: Cross sectional, questionnaire based study was conducted to evaluate the knowledge, attitude and practice of PhV among 200 community pharmacists of Delhi (west Delhi) India.
Results: Majority (74%) of the respondents felt that ADR reporting is necessary but only 9% were aware of existing PhV Program of India. Only 5% of pharmacists knew about elements of PhV. Forty percent (40%) of pharmacists did not know where to report ADRs and 26% felt that there is no need to report ADRs. Significant number (77%) of pharmacists felt that ADRs reporting will damage their image. 96% never try to find ADRs and in case if they get ADRs from patients, majority (95%) of them never report to anybody. Almost all (96%) of respondents cited busy schedule as the main reason for non-reporting and 86% said that it will be very convenient if ADRs are collected by someone from them.
Conclusions: Community pharmacists had positive attitude towards ADRs reporting but their knowledge and practice regarding PhV need to be improved. There is a need of regular training to increase their role in PhV.

Keywords: ADR reporting, Community Pharmacist, Pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) are one of the major causes of mortality, morbidity, unexpected hospitalization and increased cost of healthcare globally.[1-4] Amongst the total ADRs, 0.2% to 41.3% lead to emergency hospitalizations worldwide and 28.9% of these ADRs are avertable.[5] Several studies have reported that misuse and irrational prescribing of drugs account for majority of ADRs.[1-4] India is one of the largest drug consuming countries in the world with substantial irrational prescribing and therefore increased likelihood of development of ADRs.[6] Thus, early identification and reporting of ADRs is extremely important from health and economical point of view.

In India, activities related to the detection, monitoring and reporting of adverse events (AE) are growing since 1986.[7] Ministry of Health and Family Welfare, Government of India rechristened these activities as the Pharmacovigilance Program of India (PvPI) which became operational since July 2010.[8]

Under PvPI, the spontaneous reporting of ADRs is considered as the main mode of reporting. Early detection of signals for new, rare and serious ADRs is possible through spontaneous reporting of ADRs. It is also one of

the cheapest methods used worldwide for monitoring the safety of medicines. By spontaneous reporting system prescribers have contributed to the detection, monitoring, and reporting of AE experiences by the patients.[9,10]

Pharmacovigilance (PhV) programme plays a vital role in ensuring the patient's safety however; under-reporting is a one of the major problem in the success of PvPI. Till date over one lac Individual Case Safety Reports (ICSRs) have been submitted in WHO-vigibase from India but ADRs reporting rate is only 1% from India as compared to 5% from rest of the world.[11,12]

In an attempt to increase reporting, many countries have allowed hospital pharmacists, community pharmacists, nurses and even patients to report ADRs.[13]

Community pharmacists have an opportunity to detect possible ADRs as they are dealing with the counter prescriptions and hence they can help in management and reporting of the ADRs.[14,15] As per national data of 2014, total number of allopathic doctors is 9,38,861 and total number of registered pharmacists is 6,64,176.[16]

Therefore pharmacists can significantly contribute in PvPI by reporting ADRs. In a recent study, Kalaiselvan V et al. observed that majority of ADRs were reported by physicians (64.4%); followed by nurses (20.4%) and pharmacists (15.1%) in India.[11] So, why despite of huge number of pharmacists in India their participation in PvPI is very minimal? To find answer of this question we planned this study to evaluate knowledge, attitude and practice of PhV among community pharmacists.

METHODS

A cross-sectional questionnaire-based study was conducted on 200 community pharmacists of Delhi (west Delhi), India from June 2016 to September 2016. Structured pretested questionnaire based on the PvPI containing total 18 items to evaluate knowledge, perception and practices; was used. Participants were explained the purpose of study and were requested to complete and return the questionnaire form. Results were expressed in percentages.

RESULTS

All the 200 community pharmacists were registered with pharmacy council of India and providing their services in west Delhi, India.

Majority of them i.e. 92% and 91% respectively were not aware of elements of PhV and national programme related to ADRs reporting. In this study, 26% of community pharmacists opined that there is no need to report ADRs. Results have shown that 46% of respondents did not know about what to report and 40% of respondents did not know where to report ADRs (Table 1).

Amongst the total community pharmacists evaluated, 74% felt that ADRs reporting should be necessary (Table 2); though 95% of community pharmacists never reported any ADRs to anybody (Table 3).

In fact 96% of the respondents agreed that they have never tried to find ADRs. In case the pharmacists got ADRs through patients either they (70%) used to ask the patients to consult the prescribers or they (14%) used to change the brand of the drug without consulting prescribers (Table 3).

In our study 77% of respondents felt that ADRs reporting will spoil their image in general population. Busy schedule was cited by 96% of community pharmacists as a reason for not reporting ADRs and 86% felt that ADRs forms should be collected by someone from their pharmacy stores (Figure 1) (Table 2).

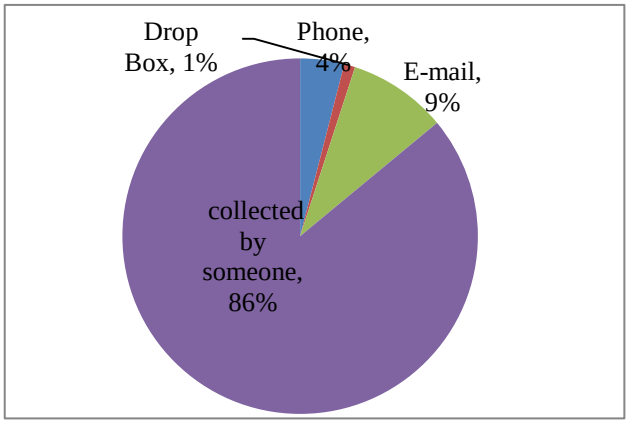

Figure 1: Preferred mode by community pharmacists to report ADRs.

DISCUSSION

Shift of pharmaceutical activities from west to east and availability of around 80,000 brands of drugs in the Indian market has lead to rapid growth of PhV.[17,18]

Hence, it is imperative to develop task force to monitor and report ADRs to ensure patient safety. A number of studies suggest that as pharmacists have a vast knowledge on drugs and therapeutics hence they can play a pivotal role in the identification, detection, prevention and management of ADRs.[11,19-21]

In our study only 17% respondents correctly defined ADR contrary to 69.7% of pharmacists in a study by Suyagh M et al.[22]

Regarding knowledge about reporting of ADRs, Nagaraju K et al. observed that 69% of pharmacists were not aware about the same; which was parallel with finding (66%) of our study.[23] Meta-analysis by Bhagavathula AS identified that the majority (81%) of pharmacists were unaware of PvPI in India.[18]

Table 1: Knowledge of pharmacist (N=200) towards Pharmacovigilance (PhV) and Adverse Drug Reaction (ADR) monitoring and reporting.

S. No.	Questions	Results (%)
1.	**Correct definition of Adverse drug reaction (ADR) is**:	
a.	A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis, or therapy, or for the modification of physiological function.	17
b.	Untoward medical occurrence(s) that may present during treatment with a pharmaceutical product and which does not necessarily have a causal relationship with treatment.	9
c.	Unwanted and unavoidable pharmacodynamic effects which can be predictable and occur at therapeutic doses.	26
d.	Harmful effect(s) of drug at any dose when taken for treatment purpose	48
2.	**Reporting of ADR is**:	
a.	Mandatory	9
b.	Voluntary	25
c.	No need to report	26
d.	Not know	40
3.	**What to report:**	
a.	serious adverse event (SAE)	19
b.	Adverse Event	3
c.	Adverse drug reaction (ADR)	20
d.	Side Effect	7
e.	All	5
f.	Not know	46
4.	**Whom to report ADRs**:	
a.	Indian Pharmacopeia Commission	3
b.	ADR monitoring centre of institution/hospital	6
c.	Treating physician	8
d.	Pharmaceutical company	20
e.	Any of the above	0
f.	No need to report	24
g.	Do not know	40
5.	**ADR reporting to be done for**:	
a.	Allopathic medicines	25
b.	Indian system of Medicine	2
c.	Medical devices	0
d.	All	7
e.	Not know	40
f.	No need to report	26
6.	**Do you know the name of national programme related to ADR reporting**? If yes please name it:	
a.	Yes (correct name)	9
b.	No	91
7.	**What are the elements of PhV?**	
a.	Detection, Assessment, Understanding, Prevention	5
b.	Diagnosis, Treatment, Monitoring	2
c.	Identification, Standardization, Prescription	1
d.	Do not know	92

Further like other authors as a reason of under-reporting, we found that 24% of pharmacists were in impression that ADRs reporting is not needed and 40% of pharmacists did not know where to report ADRs.[23,24] This finding is also consistent with the study from Saudi Arabia where lack of knowledge about PhV programme, where to report and how to report ADRs were revealed as major barriers in reporting of ADRs.[25] Result pertaining to knowledge of community pharmacists regarding ADRs monitoring and reporting system was in agreement with other national and international studies which found that majority of pharmacists were not aware of PhV programme and its elements.[16,22,23,26]

In this study, 74% of community pharmacists felt that reporting of ADRs should be necessary. Similarly Suyagh M. et al. and Prakasam A et al. found that majority of community pharmacists believe that reporting of ADRs should be necessary.[22,24] In consistence with our finding, Salim et al. reported that 55% of community pharmacists opined that by reporting ADRs patients will get benefits.[13]

Table 2: Attitude of pharmacists (N=200) towards ADRs monitoring and reporting.

S. No.	Questions	Results (%)
1.	**ADR reporting should be necessary?**	
a.	Yes	74
b.	No	26
2.	**Who get benefits from ADR Reporting?**	
a.	Doctors	10
b.	Nurses	0
c.	Pharmacist	5
d.	Patients	66
e.	Pharmaceutical company	8
f.	Health regulatory authorities	5
g.	All	6
3.	**Does ADR reporting spoil your image as a pharmacist?**	
a.	Yes	77
b.	No	23
	Do you need information on drug causing ADRs?	
4.	Yes (why)	21
a.	I. For future reference	15
	II. To inform patients	6
	No (why)	79
b.	I. Doctors will take care	60
	II. I have information on drug causing ADRs	19
5.	**Preferred ADRs Reporting system**:	
a.	Voluntary reporting	67
b.	Mandatory reporting	10
c.	Need base reporting	23
6.	**Preferred mode to report ADRs -**	
a.	Phone	4
b.	Drop Box	1
c.	E-Mail	9
d.	Should be collected by someone	86
7.	**Reason for not reporting:**	
a.	Busy Schedule	96
b.	Not very helpful for business	4

On asking for the need of information on drugs causing ADRs, 79% of community pharmacists denied because majority (60%) of them believed that it is doctor's responsibility to take care of and report ADRs. In contrast to our findings, many authors reported that majority of pharmacists were in favor of information on drugs causing ADRs and training on PhV.[13,22,24,27]

Similar to other studies in the past, we found that 66% of community pharmacists felt that patients will get benefit from ADRs reporting but majority of them never try to find ADRs (96%) and never reported ADRs (90%).[22,23] Contrary to 32.6% of participants in study by Prakasam et al, 77% of participants in our study felt that ADRs reporting will spoil their image in general public as well as create differences with prescribers. This could be one of the reasons for not reporting ADRs.[23]

Prakasam A. et al reported that 56.1% community pharmacists were in favour of online reporting of ADRs followed by surface mail (17.1%).[23] In our study community pharmacists (86%) opined that ADRs reporting forms should be collected by someone from them periodically as they are unable to report themselves because of busy schedule.

In contrast to Prakasam A. et al findings, our results showed that only 9% of participants were in favour of online reporting of ADRs and this finding is in parallel with findings of M. Suyagh et al.[22]

According to 96% of the pharmacists in this study, busy schedule was a vital factor for under-reporting of ADRs. For under reporting of ADRs same reason was cited by 26.67% of the community pharmacists of Malappuram, Kerala, India.[13]

Further legal problems or liabilities were considered as constrains in ADR reporting by many pharmacists.[13,22]

Table 3: Practices of pharmacists (N=200) towards ADRs monitoring and reporting.

S. No.	Questions	Results (%)
1.	**What you do to find ADRs:**	
a.	Only ask the patients	4
b.	Only ask the patient's relative	0
c.	All of the above	0
d.	Never try to find ADR	96
2.	**Have you ever dispensed the drugs for the treatment of ADRs:**	
a.	Yes	21
b.	No	14
c.	Do not know	65
3.	**Do you report ADRs:**	
a.	Yes	5
	If yes then report to whom?	
	I. Physician	4
	II. Authority	0
	III. Pharmaceutical company	1
b.	No	95
	If no then what you do for patients?	
	I. Change the drugs with other brands	14
	II. Ask patients to talk to prescriber	70
	III. Nothing	11
4.	**By which mode you report ADRs:**	
a.	Phone	3
b.	Drop Box	0
c.	E-Mail	2
d.	Manually	0
e.	Not reporting	95

In his study Salim M. et al. found that 45% of community pharmacists referred the patients who were suffering from ADRs to the physicians. In our study, 70% of community pharmacists were following the same practice. Further Salim M. et al. added that for the management of ADRs, community pharmacists either asked patients to stop the drug (20% cases) or gave another medicine to treat ADRs (10% cases).[13] In our study we also found that 21% of community pharmacists dispensed the drugs for treatment of ADRs. Further we observed that 14% of community pharmacists used to replace the ADRs causing drugs with drugs of different brands but of same chemical compound for the management of ADRs. Although in small percentage, this practice by community pharmacists in our study shows gross lack of knowledge regarding PhV.

CONCLUSION

In this study community pharmacists had positive attitude towards ADRs reporting but their knowledge and practice regarding PhV need to be improved. As community pharmacists have opportunity to detect a possible ADR because they are dealing with the counter prescriptions, hence they can help in the management and the reporting of the ADRs.

Awareness and regular training of the community pharmacists in the field of PhV will be very helpful in providing better patient care. To educate community pharmacists, activities like continuing medical education (CME), training programmes, seminars and conferences should be conducted regularly. Further convenient modes to collect ADRs and tools for periodic monitoring of ADRs reporting should be developed by the regulatory authority to stimulate the community pharmacists to be an essential part of PvPI.

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