Nirma Univ J Pharm Sci; 2017, 4(1) 41-50

ISSN 2348 –4012

RESEARCH ARTICLE

STUDY ON PERCEPTION OF PHYSICIANS TOWARDS ADVERSE DRUG REACTION REPORTING - A SURVEY IN INDIA

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Abstract:

Background:

Ongoing assessment for a positive risk–benefit profile of any medicinal product is an important aspect of lifecycle management; it is also a regulatory requirement. Important stakeholders in this process of pharmacovigilance (PV) are the patients, healthcare practitioners, pharmaceutical companies and regulatory agencies. Despite the regulations for post-marketing drug safety monitoring being well-defined, the rate of reporting of adverse drug reaction (ADR) by the healthcare community continues to be inordinately low.

Objective:

To understand the awareness of and patterns of ADR reporting amongst healthcare practitioners in a major city of India.

Materials and methods:

This was a questionnaire-based cross-sectional survey involving 53 physicians of various specialties from Ahmedabad. Data collected was analysed descriptively to evaluate the awareness and understanding of physicians on ADR reporting.

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Results:

About 68% of the participating physicians were unaware of the PV reporting requirements or regulations in the country. Only 5.67% prescribers had reported a drug-related event at least once to the nearest ADR monitoring centre in the last six months from this survey.

Conclusion:

Underreporting of ADR is a major concern for the success of the PV program in India, which directly impacts public health. Spontaneously reported ADRs (SADRs) is the most commonly used methodology to gather data on a drug's safety profile. For the number of SADR to realistically reflect the observed ADRs in practice, a greater thrust in bringing awareness amongst the medical community on PV requirements and available infrastructure is the need of the hour.

Keywords- Pharmacovigilance, physicians, spontaneous reports, India

INTRODUCTION

Spontaneous reporting of adverse events (AEs) by the healthcare practitioners, the patient or caregiver is the most widely used and recommended tool to monitor the safety of a marketed medicines. Data form the USFDA lists Adverse drug reactions (ADRs) popularly known as side effects as the 4th leading cause of death in the developed world. Adverse drug reactions (ADRs) not only account for market withdrawals but also for changes in labels or introduction of new-labeled warnings for prescription drugs. (1)

While the drug may have undergone extensive clinical testing during development and its safety profile largely known, the very nature of it being done on a limited number of patients in controlled trial conditions precludes many of the rare AEs being detected. Once marketed, medicines are not used under the same conditions as clinical trials. They are used by a larger number of patients across a range of age groups, who have varied lifestyles, comorbid conditions, or are taking several medicines simultaneously. Common and predictable side effects are characterized during the development phase of the drug, but idiosyncratic or rare side effects may only be known once the medicine is used by a large number of patients under actual conditions of use. In addition, some side effects might not get discovered until the medicine has been used over a long period of time or even after stopping treatment. It is therefore imperative that the safety of medicines is monitored even after they are marketed so as to identify any formerly unknown information on side effects and, if required, vital action can be taken to protect public health.

The process of reviewing the safety of medicines following their authorization is known as Pharmacovigilance [2]. India, which is also one of the members of the WHO Programme for International Drug Monitoring has a formal system of Pharmacovigilance run as the Pharmacovigilance programme of India (PvPI) under whose aegis ADR monitoring centres have been set up across the country to monitor medicinal safety [3]. One of the ways regulatory authorities monitor the safety of medicines is by collecting and analysing spontaneous reports of suspected side effects from health professionals, patients or consumers called 'spontaneous adverse drug reaction reports' (SADR) [2]. The success of this widely used and recommended method is totally dependent on the contribution of health professionals and consumers to ensure that the observed side effects are adequately reported and recorded for analysis. In reality the program is plagued by underreporting in most parts of the world were such initiatives are run. WHO recommends a reporting rate of 200 events per million people per year as being adequately representative; most developed countries have a reporting rate of 130 and India around 40. While the reporting rate of SADRs in India has significantly gone up in the last few years, it contributes to less than 2% of the reported events in VigiBase, the WHO global safety data base hosted by Uppsala Monitoring Centre, and is disproportionate to the country's vast population and medicine consumption.

Underreporting of SADRs by physicians is considered one of the major obstacles in the success of the Pharmacovigilance Programme of India; thus having a negative impact on the public health [4]. Hence the present study was undertaken to evaluate the perception of physicians towards ADR reporting in India, and their awareness towards available resources.

MATERIALS AND METHODS

A questionnaire-based cross-sectional survey was performed for this study. The study questionnaire was designed and pre-validated with clinical practitioners on the answerability and information value of the questions Knowledge and perception based questionnaire (containing 9 questions was designed to obtain the information about knowledge regarding ADR reporting system in India and perception of ADR reporting (Appendix-1). More than one answer was allowed in some questions.

In the first question, the participating physicians were inquired about the average number of patients they had examined in last 6 months and in the second about the number of side effects seen amongst these. The response to the first two questions was based of their day-to-day practice. The next question sought their response on the usual course of action if a drug related AE was encountered and this included the option of changing medication, reducing the dose, informing the patient or reporting possibilities. The succeeding two questions were perception based asking about physician's choice on recipient of their ADR reporting information whether they would report to pharmacist, medical representative and senior medical

representative or nearest PV cell. The other question was asked to them on the ideal way according to them to manage these AEs by options like informing the patient and managing the event, informing the company and/or informing the regulatory authority. The practitioners were also asked about the number of ADRs they have reported in last 6 months and if reported, to whom, Medical representative or the regulatory authority (PV cell). And the last three questions were knowledge based inquiring whether the physician knew about the location of the nearest PV cell, and reporting mode options (phone, fax, e-mail, in person, Not Applicable) if they report to a PV cell and the minimum requirements to report an ADR.

The study population surveyed involved medical practitioners from varied specialties from Ahmedabad. A total of 60 questionnaires were distributed to medical doctors, excluding the practitioners involved in the pre-validation. Those who were not willing to participate or did not return the questionnaire within the given time were excluded from the study. The completion of the questionnaire by respondents was taken as their consent to participate in the study. Hence, out of 60 questionnaires, only 53 were taken into consideration.

The information was recorded and analysed using simple descriptive statistics with use of graphs and figures to interpret and report the results of this survey. In order to preclude any potential bias, the disclosure of name of the responder was made optional.

RESULTS

Total of 53 responses were taken into consideration for this survey from Ahmedabad, which is one of the larger cities in India. All the responders were practitioners from various medical specialties including family physicians, consultant physicians, paediatricians, dermatologists, gynaecologists, E.N.T specialists, ophthalmologists, neurologists, critical care and emergency medicine specialists, anaesthetists, cardiologists and pulmonologists.

Over the past 6 months, 41.51% of the doctors had seen more than 500 patients 33.96% practitioners had consulted around 200 - 500 patients; 15.10% doctors examined 100-200 patients and rest of the physicians had about 50-100 patients [Table 1].

For the surveyed physicians, 30% doctors observed more than 6 cases of suspected AE in the last six months, 26.42% doctors observed 2 to 5 cases of ADRs, while the rest of the group (43.40%) did not observe more than 1 ADR [Table 2].

Table 1: Average number of patients seen and number of side effects encountered by practitioners in last 6 months.

Parameter	Range	Response	% Response
(A) No. of patients seen	50-100	5	9.43
	101-200	8	15.10
	201-500	18	33.96
	More than 500	22	41.51
(B) No. of side effects encountered	0-1	23	43.40
	2-5	14	26.42
	6-10	8	15.10
	More than 10	8	15.10

Table 2:- Opinion on ideal way of handling these events.

Way to Handle These Events	Response	% Response
Informing the patient and managing the event	23	43.40
Informing the patient and managing the event + Informing the company	7	13.21
Informing the patient and managing the event + Informing the company + Informing the regulatory authority	23	43.40

The action taken in response to the adverse effects for most of them was replacing or modifying treatment [Chart 1]; and doctors had different preferences for reporting ADRs [Chart 2]; less than 4% responded that they would report the event to the PV cell [Chart 3].

The awareness of the nearest PV cell or the available of modes of reporting as well knowledge on the minimum requirements of reporting were lacking amongst the larger number of respondents.

Out of 53, 36 practitioners were totally unaware about the location of the nearby PV cell. 43% of the practitioners were ignorant about the means by which they can report an ADR; an additional 17% thought it is necessary to report the ADR in person [Chart 4].

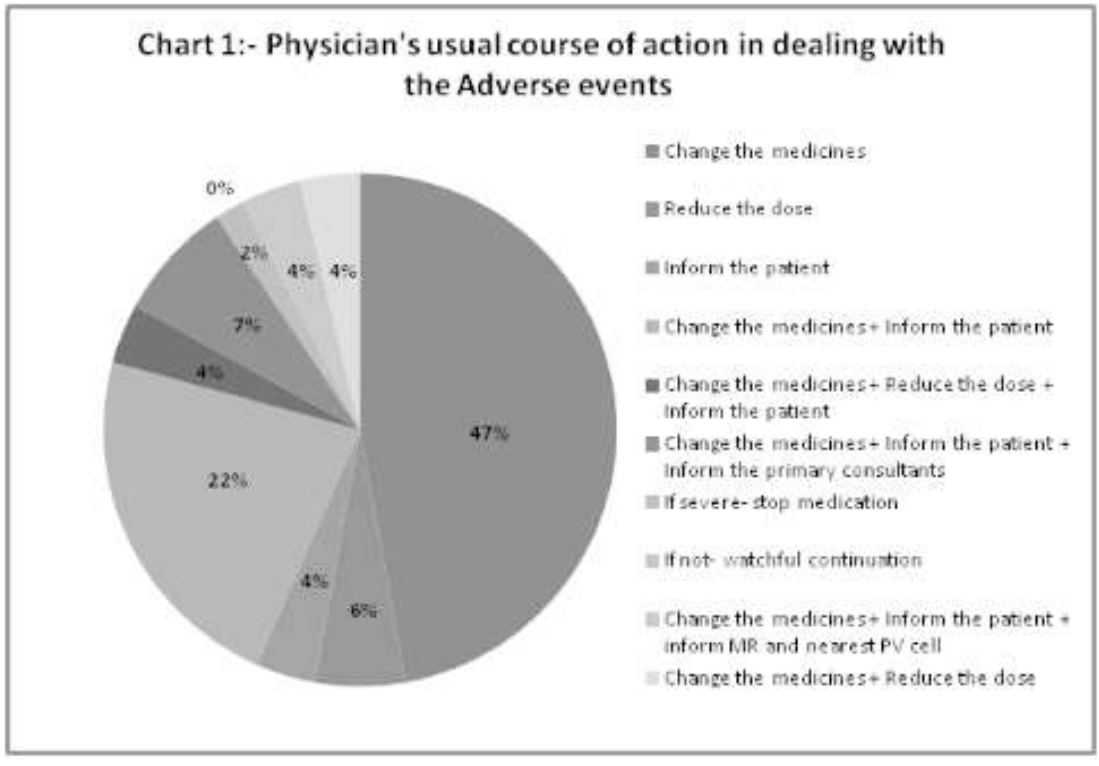


Chart 1:- Physician's usual course of action in dealing with the Adverse events
47%
6%
4%
22%
4%
7%
2%
4%
4%
0%
Change the medicines
Reduce the dose
Inform the patient
Change the medicines+ Inform the patient
Change the medicines+ Reduce the dose + Inform the patient
Change the medicines+ Inform the patient + Inform the primary consultants
If severe- stop medication
If not- watchful continuation
Change the medicines+ Inform the patient + inform MR and nearest PV cell
Change the medicines+ Reduce the dose

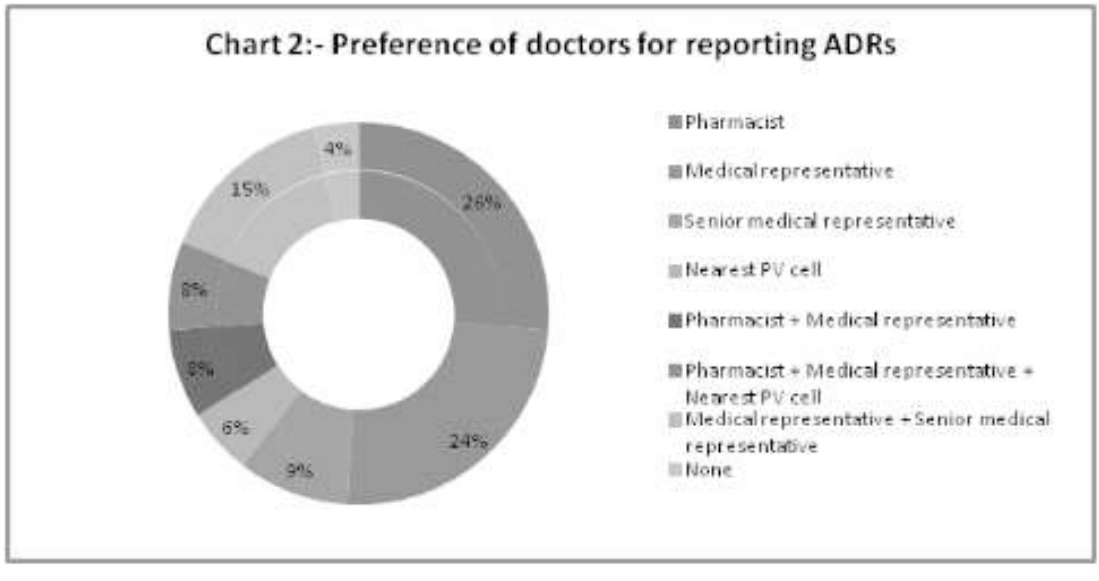
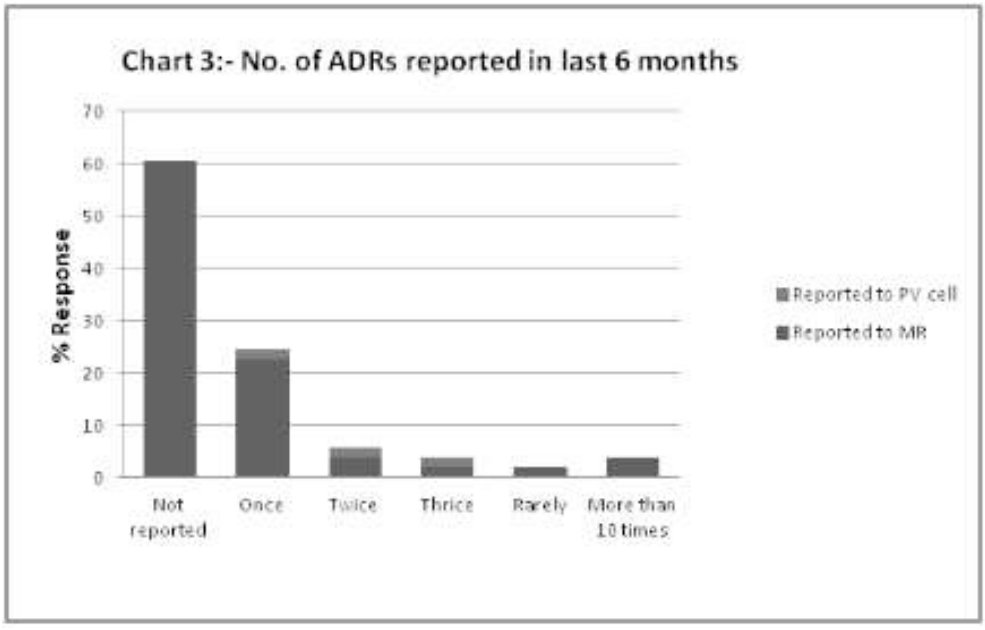
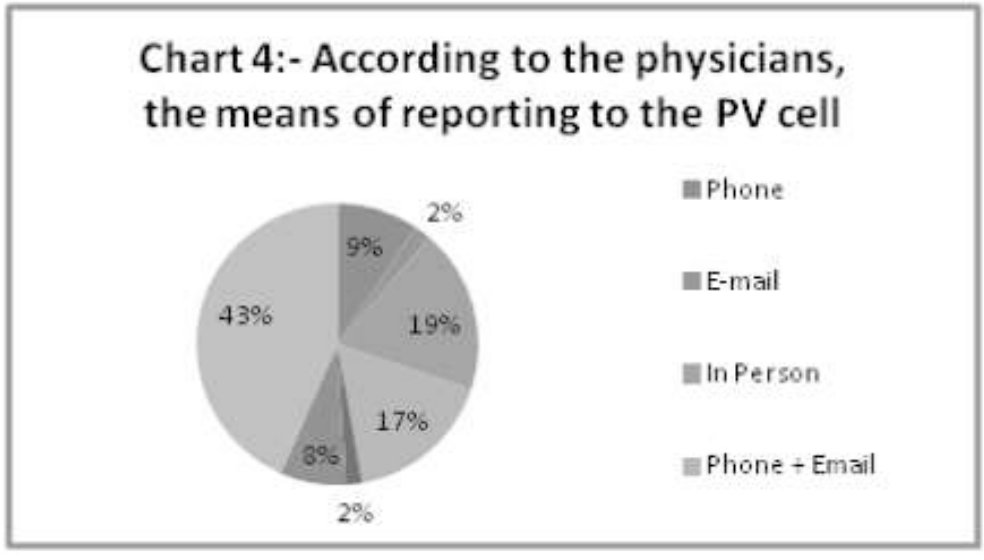


Chart 2:- Preference of doctors for reporting ADRs
26%
24%
9%
6%
9%
6%
15%
4%
Pharmacist
Medical representative
Senior medical representative
Nearest PV cell
Pharmacist + Medical representative
Pharmacist + Medical representative + Nearest PV cell
Medical representative + Senior medical representative
None





Also the minimum requirements to report an ADR were unknown to 77.36% physicians. According to several of the physicians, observation of rash, itching, breathing difficulties, severe life threatening/anaphylactic ADR were the reporting requirements for an ADR.

DISCUSSION AND CONCLUSION

Globally, drug regulators are placing increased thrust on robust safety monitoring mechanisms for pharmacovigilance. The PvPI program of India has also taken great strides in this regard with the National Coordination

Centre in Ghaziabad and zonal offices as well as almost 150 ADR monitoring cells around the country.

A dedicated help line number, a web-based ADR reporting form and a mobile application form easily available modes of reporting suspected ADRs to the health authority. These ADRs once reported and assessed are further data based in the WHO repository Vigibase, thus not only adding value on safe guarding national health but contributing to global efforts in PV.

However, the overall strength of any system lies in its weakest link. Multiple studies and repeatedly demonstrated the low reporting rates of ADR form the healthcare and patient communities. (5, 6, 7, 8)

Our survey with its limited regional population corroborated these findings with majority of respondents, who were all practicing physicians being inadequately unaware of the need of watchful assessment and reporting.

Studies earlier than ours have cited various reasons for this phenomenon, which include complacency, insecurity and legal issues, case series publication, diffidence, professional responsibility, lethargy and financial incentives to report. The results in our survey point to lack of awareness and knowledge on pharmacovigilance amongst our respondents. (5, 6, 7, 8)

These include their own responsibility to detect and report, the minimum requirements of reporting, and the existence of the PVPI function.

Training and awareness program amongst the medical community on the needs of PV, their own reporting responsibilities, the structure and functioning of PVPI and information on the minimum requirements of ADR reporting is the need of the hour to ensure the PVPI mission of protecting national health form adverse effects of medicines can indeed be upheld.

ACKNOWLEDGEMENTS

We hereby take the opportunity to thank all the physicians who took part in the survey willingly and also the physicians who validated and advised us on designing the survey form.

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