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## RESEARCH ARTICLE

# Knowledge, Attitude and Practice of Adverse drug reaction monitoring and Pharmacovigilance among various Healthcare Professionals in India.

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## ABSTRACT

**Objectives:** The aim of this study was to assess the knowledge, attitude and practice of healthcare professionals regarding adverse drug reaction [ADR] monitoring and pharmacovigilance [PV] in India. **Materials and Methods:** It was a questionnaire based cross sectional observational study. Data was collected with the help of data collection Google form that included the demographics and twenty two survey based questions. Data were analysed by using Microsoft Excel sheet, further analysed for results, including frequency, percentage, mean and standard deviation. **Result:** The questionnaire was filled by two hundred ten healthcare professionals in which 52.9 % were male and 47.10% of female. Most of the respondents were pharm d students (50.47%). Out of the total 91.4% responded to the definition of pharmacovigilance correctly. 87.6% participants said all ADR should be reported. 86.20% participants think Pharmacovigilance should be taught in detail to healthcare professionals. Most of the respondents (43.8%) always informed the patients about ADR while prescribing the medicines. **Conclusion:** Study revealed most of the participants have good knowledge about ADR and pharmacovigilance. Difficult to decide whether ADR occur or not and extra work load being major factors responsible for under reporting.


**Keyword:** Adverse drug reaction, Healthcare professionals, Pharmacovigilance, surveillance form, Suspected ADR.

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## INTRODUCTION

Any medicine in its standard therapeutic dose has the probability of origination of adverse reaction(s). Adverse drug reaction (ADR) is defined as any response to a drug which is virulent and unintended, transpires at doses normally employed on humans for prophylaxis, diagnosis, cure of any disease or for the tempering of physiological function (Ganesan et al., & Adhikari et al., 2017). It is one of the crucial issues of global concern, as ADRs being the significant contributor to the morbidity and mortality all over the world (Rai et al., 2015; Mala & Suresh, 2012; Radhakrishnan et al., 2011; Gupta et al., 2015). For motivating the health professionals to participate in spontaneous reporting, the Medical Council of India (MCI) took a step and has recommended to teach ADR monitoring to undergraduate students (Rai et al., 2015; Khan et al., 2013; Rehan et al., 2012). The responsibility of ADRs ranges from 0.3% to 11% among significant number of hospital admissions (Kaur et al., 2015). The Uppsala Monitoring Centre (UMC) in Sweden established by the world health organization (WHO) is responsible for maintaining the International database of the ADR reports (Arbind et al., 2013). Pharmacovigilance Programme of India (PvPI) was formed by combined efforts of central drug standard control organization (CDSCO) and government of India, which has been operational from July 2010 (Datta & Sengupta, 2015; Agarwal et al., & Srinivasan et al., 2017) . Approx. 202 ADR monitoring center are installed by the PvPI all over the India, with easier modes of reporting the ADR by the health care professionals as well as public, with the means like the toll free number, paper based ADR forms (Ganesan et al., 2017). Only 6-10% of all ADRs have been reported (Singh et al., 2013). For the success of this program, it is necessary for the healthcare professionals (HCPs) such as doctors, pharmacist, nurses to participate actively. To monitor known and unknown adverse effects of medicines, it is very necessary to have a practice of

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spontaneous reporting. ADRs reported from clinical trials, post marketing surveillance (PMS), and HCPs play the vital role in spontaneous reporting of ADRs Furthermore, it can play very importantly in the detection of fatal and new ADRs during marketing of the drug in actual practicing in the market. This practice led to a very successful withdrawal of many drugs in the past such as Rofecoxib, Cisapride, Terfenadine, etc. (Upaydhyay et al., 2015; Khan et al., 2013) An awareness of ADR aroused in the 18th century because of the formation of a chain of cluster of cases resulted due to use of some drugs (thalidomide disaster, sulfonamide disaster, etc.) (Garg et al., 2017) after which till now more and more attention is being paid which resulted in emergence of a new science so called PV (Nisa et al., 2018; Kaur et al., 2015). "Pharmacovigilance" programme, can be explained as the science and different activities relating to the assessment, detection, comprehension and preventary precautions of adverse effects or any other drug-related problems (Katekhaye et al., 2017). The major source of information in PV being Spontaneous ADR reporting schemes (Sen et al., 2017; Rai et al., 2015). National Adverse Drug Reaction Monitoring Centre which was initiated in 1987. Under this programme, all adverse drug reaction reports, received and assessed by Malaysian adverse drug reactions advisory committee (MADRAC) are forwarded to the central WHO Global Individual case safety report (ICSR) database, maintained by the UMC (Sivadasan et al., 2014). Despite the efforts of the Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) in establishing ADR monitoring centers in many hospitals in the major cities of India and the presence of a large number of tertiary care facilities, PV is still in its infancy in India (Kharkar & Bowalekar, 2012). In 2004 under WHO guideline government of India set up a national PV programme, with the national coordinating centre, located at Ghaziabad (Sharma et al., 2014). In 2013 PV promoted by WHO at country level. Among the top ten countries adding

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to global drug safety database India was at rank 7th. Total 181656 reports were received by PvPI through different sources such as ADR monitoring centre(AMCs), non-AMC and toll free helpline number, in between April 2011-March 2016. PvPI has generated helpline facility (Tel. No. 1800 1803 024) to make drug safety information available for Indian population. Beside suspected ADR reporting form, PvPI has generated medicine side effect reporting form for consumers/patients in their regional language (Bepari et al., 2019).

## METHODOLOGY

This was a questionnaire based cross-sectional observational study carried out with the concern of various health care professionals in India. Data was collected with the help of self-made data collection Google form which was produced with the help and insights of various previously published journals. The form comprised total of 22 questions, of which 7 questions were knowledge based, 9 questions were attitude based and 6 questions were practice based. Before proceeding to fill the form, the consent was seeked for their participation and for maintaining the confidentiality of the information provided. Before the commencement of the form filling participants were given a brief of the purpose of the study. The motto was to obtain information on the knowledge, attitude and practice of ADR and PV from healthcare professionals. The questionnaire was administered to various healthcare professionals from different states of India through different social and other platforms. Total of 210 entries were recorded in 2 month period of time. Collected data were analysed by using Microsoft Excel sheet, further analysed for analysis and results, including frequency, percentage, mean and standard deviation.

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## RESULT

A total of 210 healthcare professionals were participated in the survey. Maximum number of participants had their age group between 23 to 27 years, accounting to total of 59.04% of the total one. Mean age of participants was 23.74 ± 3 years. And majority of the participants in the survey were recorded to be male (52.9%). The Professional status of the participants being the maximum of Pharm D (50.47%) and minimum of nurses (4.76%). Demographic details of healthcare professionals are sum up in table I.

### Knowledge based information:

One hundred ninety two participants (91.4%) out of the total of 210 responded to the definition of PV correctly. Out of which majority being 52.08% were by pharm D's, then of pharmacist with 30.20%, doctors with 14.06% and the least were nurses with 3.64%. Most of the participants (75.2%) said CDSCO is responsible for ADR monitoring in which pharm d were 51.89% and doctor were 12.65% pharmacist were 31.01% and nurses were 4.43 %. 90% of the participants agreed with the awareness of PV programme of India. 81.4% participants said patients, pharmacist, nurses, doctors all can report an ADR, out of which 50% of pharm d, 29.65% of pharmacist, 17.44% of doctors and 2.90% of nurses. Out of total participants 87.6% (pharm d 54.09%, pharmacist 27.86%, doctors 13.66% and nurses 4.37%) said all ADR should be reported. Preclinical toxicity testing, clinical trials, spontaneous reporting by health care professionals and PMS all are the source for generating knowledge and information about ADR responded by health care professionals (pharm d 55.42%, pharmacist 28.31%, doctors 12.04% and nurses 4.21%). Most of the participants (64.1%) said ADR monitoring centre is nearby from her/him. Knowledge based information are tabulated in table II.

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| Table I: Demographic details of healthcare professionals (n=210) | |
|---|---|
| **Particulars** | **Frequency (%)** |
| Gender | |
| Female | 99 (47.1%) |
| Male | 111 (52.9%) |
| Mean age in years | 23.74 ± 3 |
| Age distribution (in years) | |
| 18-22 | 70 (33.33%) |
| 23-27 | 124 (59.04%) |
| 28-32 | 15 (7.14%) |
| >32 | 1 (0.47%) |
| Professional status | |
| Pharm-D | 106 (50.47%) |
| Doctors | 32 (15.23%) |
| Nurses | 10 (4.76%) |
| Pharmacist | 62 (29.52%) |

**Attitude based information:**

Total 210 participants responded to attitude based questions among which 86.20% said PV should be taught in detail to healthcare professionals. Most of the participants said that ADR reporting is a professional responsibility of a doctor. Out of total 64.8% participants said ADR reporting be compulsory (pharm d 50.36%, pharmacist 28.46%, doctors 16.78% and nurses 4.38%). If ADR reporting is compulsory then it should be reported to local ADR monitoring centre said by most of the participants. Total 94.7% participants expect a feedback from the ADR monitoring centre of which 51.26% were pharm d's. ADR reporting may be viewed as medical negligence is the greatest barrier for reporting ADR by physicians in India (45.2%), lack of attitude is the second most barriers (36.7%). Among total most of the healthcare professionals said extra work with no intensive is the first factor that discourage from reporting ADR (35.72%), difficult to decide whether ADR has occurred or not is the second most barrier (28.57%). If the reaction is serious then it may encourage reporting an ADR out of total (49.52%) HCP said that in which pharm D's were 40.30%, pharmacists were 34.61%, doctors were 20.19% and nurses were 4.80%. Mild adverse effect may discourage from reporting ADR

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(32.85%) participants said that, out of total 25.71% difficult to decide whether ADR has occurred or not is the second most region. Attitude based information are tabulated in table III.

**Practice based information:**

Majority of the respondents (67.8%) have not documented any suspected ADR surveillance form, only 32.2% have documented. Out of total 210 participants only 13.9% have published an ADR case reports in any medical journal in which pharm d were 17.92%, pharmacist were 8.06%, doctor were 18.75% and nurses were only 1%, most of the participants (86.1%) haven't published. Internet, scientific journals and reference books on drug information are the main source for gathering information for most of the HCP, among which internet seems to be most proficient one(29.5%). Most of the respondents (43.8%) always informed the patients about ADR while prescribing the medicines but it is seen that few of the respondents (37.6%) talked about the same with patients only sometimes. Among total 210 participants only 77(35.2%) come across an ADR in his/her clinical practice often, 20.5% sometimes. Most of the HCP (56.2%) have received training/ teaching on ADR monitoring among which pharm d's were 41.30%, pharmacist were 30.43%, doctors were 19.56% and nurses were 8.69%. 43.8% HCP doesn't receive any training regarding ADR monitoring. Practice based information are tabulated in table IV.

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## DISCUSSION AND CONCLUSION

This study revealed that most of the participants have good knowledge about PV and the resultant being that the knowledge about the same to Pharm Ds is comparatively higher than that of other healthcare professionals like Doctors and Nurses, while in a study done by (Kaur et al., 2015) the case was completely different as the result showed that the doctors had more knowledge than that of other health care professionals. The other knowledges about the same like the organizations involved in the responsibility for ADR monitoring is comparatively lesser with the Doctors (only 62.5%). In this study, 89.04% participants are aware of PV program of India, while in the study done by (Srinivasan et al., 2017) it was 83.1%. Further things like responsibility of reporting of an ADR, the nurses had lesser idea of such reporting practices (50%) as they are the people who are closely involved with the patient's business for a longer duration and they can play a key role in making the PV programs more effective. In this survey, 87.14% of HCP agreed that all ADR's need to be reported and all the HCP can report that (81.9%), while in the study of (Agarwal et al., 2017) 59% of them agreed with reporting all the ADRs and 50-60 % agreed with all the HCP can report them. Being the most significant figure among all the HCP, Doctors are comparatively lesser knowledgeable about ADR's generation. Knowledge about PV is important for HCP but only 30% nurses thinks PV should be taught on detail to Health Care Professionals. In this study, majority (88.09%) of participants think ADR reporting is professional responsibility, while in a study done by (Adhikari et al., 2017) 74% of participants think the same about the professional responsibility of HCP. Almost all the Doctors (100%) are aware about HCP's professional responsibility and it's compulsation regarding ADR reporting but they are unable to do so because of some barriers in way, like that may be misviewed as their medical negligence. In reporting any ADR, there are different factors

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responsible for the possibility of sources which may discourage and encourage the reporting process, the factors discouraging it is extra work with no incentive (35.72%) and difficult to decide whether ADR had occured or not (28.57%) and the reason for this is that, the drugs shows there were majority of participants with no formal training (84%) or attended any seminar on PV some mild adverse effect sometimes. While in the survey of Gupta et al,[6] the factors discouraging the ADR reporting were lack of time to report (23.8%) and, difficult to decide whether ADR had occurred or not (22.8%). If the reaction of the drug is serious then, it surely encourages the reporting. According to this survey, most of the HCP had received a formal training on PV (56.2%), while in the survey of (Datta el al., 2015) maximum of the participants didn't receive any training on PV. Maximum of the surveyer denied about documenting a suspected ADR in any surveillance form. It was also seen that the information what they gather regarding ADR's were mostly sources like internet with maximum percentage and then was the scientific journal. Despite being untrained with any formal teaching on ADR monitoring, the healthcare professionals always tend to inform and make them aware to their patients about ADR and it is also seen that they often come across an ADR in their clinical practice.

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| **Table II : Response to knowledge based questions** | | | | |
|---|---|---|---|---|
| **Questions** | **Doctors n=32** | **Pharm d n=106** | **Nurses n=10** | **Pharmacist n=62** |
| Which of the following best represents the definition for pharmacovigilance | | | | |
| Alertness about the safety and tolerability of prescribed medicine | 5 | 3 | 3 | 1 |
| The science and activities relating to detection, assessment, understanding and prevention of adverse drug. | 27 (84.37%) | 100 (94.33%) | 7 (70.00%) | 58 (93.55%) |
| Pre-marketing safety evaluation of drugs | 0 | 3 | 0 | 3 |
| Which organization in India is responsible for ADR monitoring | | | | |
| Indian Council of Medical Research (ICMR) | 7 | 5 | 1 | 6 |
| Medical Council of India (MCI) | 5 | 12 | 2 | 3 |
| Central Drugs Standard Control Organization (CDSCO) | 20 (62.5%) | 82 (77.36%) | 7 (70.00%) | 49 (79.03%) |
| National Accreditation Board for Hospitals and Healthcare Providers (NABH) | 0 | 2 | 0 | 3 |
| Don't know | 0 | 5 | 0 | 1 |
| Are you aware of the Pharmacovigilance Programme of India (PvPI) | | | | |
| Yes | 26 (81.25%) | 98 (92.45%) | 7 (70.00%) | 56 (90.32%) |
| No | 6 | 8 | 3 | 6 |
| Who can/ should report an ADR | | | | |
| Patients | 0 | 1 | 3 | 3 |
| Pharmacists | 1 | 17 | 0 | 7 |
| Nurses | 0 | 1 | 2 | 0 |
| Doctors | 1 | 1 | 0 | 1 |
| All of the above | 30 (93.75%) | 86 (81.10%) | 5 (50.00%) | 51 (82.26%) |
| Which ADRs should be reported | | | | |
| All ADR's | 25 (78.12%) | 99 (93.39%) | 8 (80.00%) | 51 (82.25%) |
| Only serious ADRs | 6 | 5 | 0 | 6 |
| ADRs to new drugs only | 1 | 2 | 0 | 4 |
| Don't know | 0 | 0 | 2 | 1 |
| How do you think the knowledge and information about ADRs are generated? | | | | |
| Preclinical toxicity testing | 0 | 0 | 0 | 2 |
| Clinical trials | 6 | 3 | 0 | 3 |
| Post marketing surveillance (PMS) studies | 4 | 3 | 0 | 3 |
| Spontaneous reporting of ADRs by health care professional | 2 | 6 | 0 | 7 |
| All of the above | 20 (62.50%) | 92 (86.81%) | 7 (70.00%) | 47 (75.81%) |
| Don't know | 0 | 2 | 3 | 0 |
| Is there any nearby ADR reporting and monitoring centre in your knowledge? | | | | |
| Yes | 17 (53.12%) | 66 (62.26%) | 4 (40.00%) | 47 (75.80%) |
| No | 15 | 40 | 6 | 15 |

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| **Table III: Response to Attitude based Questions** | | | | |
|---|---|---|---|---|
| **Questions** | **Doctors n=32** | **Pharm d n=106** | **Nurses n=10** | **Pharmacist n=62** |
| Do you think pharmacovigilance should be taught in detail to healthcare professionals | | | | |
| Yes | 26 (81.25%) | 100 (94.34%) | 3 (30.00%) | 52 (83.87%) |
| No | 5 | 4 | 0 | 7 |
| Don't know | 1 | 2 | 7 | 3 |
| Do you agree that ADR reporting is a professional responsibility of a doctor? | | | | |
| Yes | 32 (100%) | 94 (88.68%) | 3 (30.00%) | 56 (90.32%) |
| No | 0 | 12 | 7 | 6 |
| In your opinion should ADR reporting be | | | | |
| Legal | 7 | 21 | 1 | 12 |
| voluntary | 1 | 15 | 1 | 9 |
| compulsory | 23 (71.87%) | 69 (65.09%) | 6 (60.00%) | 39 (62.90%) |
| Remunerated | 1 | 1 | 2 | 2 |
| If yes, to whom should the reporting be done | | | | |
| Hospital Superintendent | 6 | 11 | 3 | 10 |
| State Drugs Controller | 2 | 6 | 0 | 1 |
| Local ADR monitoring centre | 18 (56.25%) | 61 (57.55%) | 7 (70.00%) | 46 (74.19%) |
| Drugs Control General of India (DCGI) | 6 | 28 | 0 | 5 |
| On reporting an ADR do you expect a feedback from the ADR monitoring centre | | | | |
| Yes | 30 (93.75%) | 101 (95.28%) | 7 (70.00%) | 59 (95.16%) |
| No | 2 | 5 | 3 | 3 |
| What is the greatest barrier for ADR reporting by physicians in India | | | | |
| Lack of attitude | 10 | 36 | 8 | 23 |
| Unsure about whom to report | 6 | 16 | 1 | 15 |
| Worried that it may be viewed as medical negligence | 16 (50.00%) | 54 (50.94%) | 1 (10.00%) | 24 (38.71%) |
| Select the factor(s) that discourage(s) you from reporting ADRs | | | | |
| Extra work with no incentive | 15 (46.87%) | 33 (31.13%) | 0 (0%) | 27 (43.55%) |
| Lack of time to report ADR | 8 | 19 | 1 | 16 |
| Difficult to decide whether ADR has occurred or not | 6 | 42 | 1 | 11 |
| Lack of access to ADR reporting form | 3 | 5 | 6 | 8 |
| A single unreported case may not affect ADR database | 0 | 7 | 2 | 0 |
| Which of the following may encourage you to report an ADR | | | | |
| If the reaction is serious | 21 (65.63%) | 42 (39.62%) | 5 (50.00%) | 36 (58.06%) |
| If the reaction is unusual | 3 | 19 | 2 | 5 |
| If the reaction is to a new product | 4 | 9 | 0 | 8 |
| If the reaction is certainly an ADR | 2 | 15 | 2 | 7 |
| If the reaction is well recognized for a particular drug | 2 | 21 | 1 | 6 |
| Which of the following may discourage you from reporting an ADR | | | | |
| Mild adverse effect | 14 (43.75%) | 23 (21.70%) | 4 (40.00%) | 28 (45.16%) |
| Well known reaction | 9 | 26 | 1 | 10 |
| Lack of time to report ADR | 4 | 7 | 0 | 7 |
| No remuneration for reporting | 0 | 6 | 0 | 6 |
| Difficult to decide whether ADR has occurred or not | 5 | 38 | 0 | 11 |
| A single unreported case may not affect ADR database | 0 | 6 | 5 | 0 |

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| Table IV: Response to Practice based Questions | | | | |
|---|---|---|---|---|
| **Questions** | **Doctors n=32** | **Pharm d n=106** | **Nurses n=10** | **Pharmacist n=62** |
| Have you ever documented a suspected ADR in any surveillance form | | | | |
| Yes | 6 | 51 | 3 | 8 |
| No | 26 (81.25%) | 55 (51.89%) | 7 (70.00%) | 54 (87.09%) |
| Have you ever published an ADR case report(s) in any medical journal | | | | |
| Yes | 6 | 19 | 1 | 5 |
| No | 26 (81.35%) | 87 (82.07%) | 9 (90.00%) | 57 (91.94%) |
| Where from do you gather information about ADRs | | | | |
| Colleagues | 3 | 3 | 1 | 9 |
| Text Book | 10 | 8 | 0 | 7 |
| Reference books on drug information | 6 | 23 | 2 | 16 |
| Scientific journals | 4 | 29 | 0 | 12 |
| Internet | 9 (28.15%) | 43 (40.56%) | 7 (70.00%) | 18 (29.03%) |
| While prescribing medicines, do you tell your patients about ADRs? | | | | |
| Always | 18 (56.25%) | 41 (38.67%) | 2 (20.00%) | 33 (53.23%) |
| Sometimes | 12 | 47 | 3 | 18 |
| Rarely | 2 | 11 | 4 | 9 |
| Never | 0 | 7 | 1 | 2 |
| How frequently do you ever come across an ADR in your clinical practice? | | | | |
| Very frequently | 7 | 19 | 1 | 12 |
| Often | 14 (43.75%) | 34 (32.07%) | 1 (10.00%) | 25 (40.32%) |
| Rarely | 5 | 21 | 1 | 12 |
| Sometimes | 5 | 26 | 1 | 11 |
| Never | 1 | 6 | 6 | 2 |
| Have you received any formal training/teaching on ADR monitoring? | | | | |
| Yes | 14 | 68 | 2 | 34 |
| No | 18 (56.25%) | 38 (35.85%) | 8 (80.00%) | 28 (45.16%) |

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