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RESEARCH ARTICLE

Knowledge, attitude and practice of ADR reporting among clinical residents: A rural medical college survey

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ABSTRACT

Introduction*:** Pharmacovigilance practices have persistently suffered from under-reporting of ADRs by the clinicians. The present study was done to assess the knowledge, attitude and practices of clinical residents towards ADR reporting to provide insight into the reasons for this under-reporting. ***Methodology*:** A 21 item semi-structured questionnaire was used to evaluate the knowledge, attitude and practices of 81 clinical residents towards ADR reporting. Statistical analysis was done using non-parametric tests. ***Results*:** All the residents were familiar with the term "ADR" and more than 80% of the residents were aware of the professionals supposed to report ADR, nearest regional pharmacovigilance center and its regulatory bodies. Even though 80.6% residents had witnessed ADR, 76.7% failed to report them and of those who reported ADR only 33.3% reported it to the proper authority. The two most common reported barriers were "difficulty in deciding whether ADR has occurred or not" (38.3%) and "Lack of time to report ADRs" (37.2%). Around eighty five percent acknowledged being taught ADR reporting in the undergraduate CPT teaching. However, only around twenty four percent experienced such training during their internship and post-graduation. Only 58.3% felt that reporting an ADR is a professional obligation. ***Conclusions: Although the clinical residents are good enough in knowledge about ADR reporting, they are not willing to put this knowledge into practice due to various perceived barriers and dismal attitude towards the whole process of reporting of ADRs. The relentless efforts towards proper training and creating awareness among the clinical residents will surely improve the pharmacovigilance practices.

Key words: ADR reporting, Pharmacovigilance, Clinical residents

INTRODUCTION:

With the healthcare policies becoming patient centered, patient safety is emerging as a pivotal determinant in the health technology assessment including the drugs.[1] Voluntary adverse drug reaction (ADR) reporting schemes have been in place in the developed countries since early sixties. These surveillance systems enable physicians and pharmacists to report suspected ADRs and thus act as a tool to identify new ADRs and risk factors predisposing to recognized ADRs. ADRs account for 0.2%-24% of hospital admissions,[2,3,4,5] and 3.7% of patients have fatal ADRs.[4] Even though it's common to experience these adverse drug reactions during clinical work they are seldom reported.[6] For instance, one report mentions that only 4–7% of episodes of drug-associated anaphylaxis were reported to the national reporting centre.[7,8]

The situation is not very different in India.[9] Drug Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) has established ADR monitoring centers in many hospitals in the major cities of India. Despite these efforts, pharmacovigilance is still in its infancy. Insight into reasons for under-reporting should enable national reporting centers to take appropriate measures to increase reporting rates and hence the western literature has frequently pondered for reasons of under-reporting of ADRs.[10,11] An earlier attitudinal survey of ADR reporting showed that the lack of availability of report forms and shortage of time were important reasons for non-reporting.[12] A survey conducted among general practitioners (GPs) revealed that lack of training and unfamiliarity with the national reporting centre was the most important reason for not reporting an ADR.[13]

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However, the literature is relatively silent over the attitudes of Indian doctors towards the ADR reporting, the reasons for low reporting and deficits in training if any. Moreover due to the socio-cultural, economic, ethnic, nutritional and other factors, the pattern of drug use and ADRs in India is quite different.[14] Hence we planned to survey clinical resident, the major workforce of Indian medical colleges, about their knowledge, attitude and practice about ADR reporting. Any insight into the reasons for under-reporting of ADRs in this significant group of doctors will go a long way in improving the prompt ADR reporting and pharmacovigilance database, thereby improving the safety profile of various therapies.

METHODOLOGY:

This was a cross-sectional questionnaire-based study performed in a rural medical college of central India. After a prior approval from the institutional ethics committee, 81 residents from various medical and surgical branches of the institute were requested to participate in the study. After agreeing to participate and signing the written informed consent form, the residents were handed over a 21 item semi-structured questionnaire. This questionnaire was inspired by the work of Oshikoya et al.[15] and Tobaiqy et al.[16] and had 21 questions pertaining to the knowledge, attitude and practice about the ADR reporting inclusive of 4 items assessing training deficits if any. (Appendix 1) Most of the questions were objective and mostly required a "yes" or "no" response. The residents were asked to return the forms at their earliest convenience within the next 3 days. Results were later analyzed by nonparametric statistical tests.

RESULTS

Initially 81 residents consented to participate in the study. The residents were given reminders to return the completed forms. However only 72 residents returned the completed questionnaire and the remaining 9 residents stated lack of time as the main reason for not completing of the questionnaire.

Table 1: Demographic profile of the study population

Age		**Gender (male/female)**		**Clinical Experience after graduation**	
21-25 yrs	2.7%	Males	55.5%	≤ 3 yrs	58.4%
26-30 yrs	91.7%	Females	44.5%	4-6 yrs	38.8%
31-35 yrs	5.6%	Male:Female ratio	1.25:1	≥ 7 yrs	2.8%

Majority of the respondents were in the age group of 26-30yrs (91.7%), with only 2.7% and 5.6% in the age groups of 21-25yrs and 31-35yrs respectively. Although males were slightly higher in number (55.5%), the difference in the distribution of males and females in the study group was not found to be significant. As the study group was postgraduate residents, majority of them had recently passed their graduation and as a result 97.2% of the subjects had less than 7 yrs of clinical work experience. (Table No.1)

Table No.2: Knowledge about ADR reporting

Questions	Responses (percentage)
Heard of the term "ADR" before	100%
Could define "pharmacovigilance" correctly	50%
Knowledge about the professionals responsible for ADR reporting in a hospital	80.6%
Aware about the pharmacovigilance program of India	11.1%
Aware of the nearest regional pharmacovigilance centre	80.5%
Knew about the CDSCO as the regulatory body responsible for the monitoring of the ADRs.	80.5%

The ADR term was familiar to all the residents and 80.6% of the residents were also aware that doctors, pharmacists and nurses, all of the professionals are responsible for the ADR reporting. There was a good awareness of the nearest regional pharmacovigilance centre (80.5%) and also regarding CDSCO as the regulatory body responsible for the monitoring of the ADRs (80.5%). Even though 50% of them could define pharmacovigilance correctly, 88.9% of the residents are not aware of the pharmacovigilance program of India. (Table No. 2)

Table No. 3: Attitude towards ADR reporting

Questions	Responses (percentage)
ADR reporting is a professional obligation	58.3%
ADRs are avoidable	69.4%
ADRs are predictable	58.3%
Knowledge of pharmacovigilance is required by medical graduates	80.5%
Good knowledge of Clinical Pharmacology and Therapeutics (CPT) teaching about ADR would have improved its reporting	77.7%
Most important factor discouraging the ADR reporting	
Non-remuneration for ADR reporting	14.3%
Lack of time to report ADRs	37.2%
A single unreported case may not affect the ADR database	10.2%
Difficult to decide whether ADR has occurred or not	38.3%

Despite a high proportion of people knowing of the professionals responsible for ADR reporting (80.6%), only 58.3% felt that it is a professional obligation. 69.3% of the respondents felt that the ADRs are avoidable and 58.3% of them felt that the ADRs are predictable. A large percentage of the respondents agreed that Knowledge of pharmacovigilance is required by medical graduates (80.5%) and they also felt that a good knowledge of Clinical Pharmacology and Therapeutics (CPT) teaching about ADR would have improved its reporting (77.7%). The two most common reasons responsible for discouraging the residents from reporting ADR were "difficulty in deciding whether ADR has occurred or not" (38.3%) and "Lack of time to report ADRs" (37.2%). The other reasons cited for not reporting ADRs are "non-remuneration for ADR reporting" by 14.3% and 10.2% felt that a single unreported case may not affect the ADR database.

Table No. 4: Practice of ADR reporting

Questions	Responses (percentage)
Witnessed any ADR	80.6%
Reported the ADR	33.3%
Reporting of ADR was done to	
ADR monitoring committee of the hospital	25%
National Pharmacovigilance Center	8.3%
Head of the department	66.7%
Most likely cause of the ADR	
Drug-drug	20.6%
Medication error	10.5%
Idiosyncratic reaction	68.9%
Witnessed ADR ultimately led to	
No hospitalization	10.3%
Short hospitalization	48.3%
Prolonged hospitalization	17.2%
Morbidity	20.8%
Death	3.4%

Even though 80.6% residents had witnessed ADR during their clinical work, 76.7% failed to report them. Of those who reported ADR only 33.3% reported the ADR to the proper authority such as ADR monitoring committee or National Pharmacovigilance center and 66.7% of them reported it to their Head of the department. (Table No. 4)

Table No.5: Training of ADR reporting

Questions	Responses (percentage)
Were taught ADR reporting in undergraduate CPT teaching	84.9%
ADR reporting was discussed during the internship training	24.8%
Trained how to report ADRs after internship	24.1%
Can fill the ADR form independently	5.3%

A large number of residents (84.9%) acknowledged being taught ADR reporting during their undergraduate days as a part of CPT teaching. However only 24.8% accepted that the same was again discussed during the internship training and only 24.1% were trained during their post-graduation. Only 5.3% were confident enough to fill the ADR form independently.

DISCUSSION:

The under-reporting of ADR has been a matter of concern world-over and has been an active area of research with number of western investigators contemplating the reasons for this under-reporting. The bio-ethnic, cultural and economic differences of India from rest of the countries, made us study the knowledge, attitude and practice of ADR reporting among the Indian residents. When the knowledge of the residents was assessed, everybody had heard of the term ADR and more than 80% of the subjects were aware of the professionals responsible for ADR reporting and the nearest regional pharmacovigilance center. The same number of respondents also accepted that knowledge of pharmacovigilance is required by medical graduates. The study showed that the residents had a relatively good theoretical know-how about ADR reporting. These findings of existence of good theoretical knowledge about ADR reporting are in consonance with other similar Indian studies where-in good knowledge was demonstrated among medical practitioners[17] and pediatricians[18]. However, unfortunately this good theoretical know-how was not leading to a good ADR reporting in practice.

Even though 80.6% of the residents had witnessed and identified an ADR, a staggering 86.2% did not feel the need to report it to the proper authority. This rate of underreporting is at par with studies done earlier.[19,20] Of the ADRs witnessed, majority of them (66.7%) were reported to the heads of the department instead of the ADR monitoring committee or the national pharmacovigilance center implying inadequate practical knowledge pertaining whom to report an ADR. These findings of our study replicate the findings from some previously done studies.[9,20,21] Most of them even felt that ADR's are predictable and avoidable. Only a little more than half of the people accepted that ADR reporting is a professional obligation. This kind of dismal attitude towards ADR reporting among the clinical residents could be one the most important reasons for the under-reporting of ADRs.

Various authors have tried to identify the barriers in proper reporting of ADRs. In our study among the reasons for under-reporting of these ADRs, three quarters of them felt that "Lack of time for ADR reporting" and "Difficult to decide whether ADR has occurred or not" are the main reasons for underreporting of ADRs. The rest quarter felt that non-reporting of a single database will not affect the database and that there should be proper remuneration for ADR reporting to motivate them. In a study done by Williams et al.[22], "lack of time" was reported by around 34.7% of the doctors as the main reason for not reporting ADRs. Other reasons reported by them were "not knowing whether the ADR has occurred cause of the drug used", "ADR being too well known or trivial to report" and "reporting ADR being a very bureaucratic procedure". Another study by Kamtane et al. also showed that busy schedule is one the main reasons for not reporting ADR (54%) among other reasons such as not knowing how to report (58%) and feeling that one report shouldn't matter (48%). [23]

A Spanish study has also shown that lack of time and problems with ADR diagnosis are the two main reasons for low-reporting of ADRs. The study further went on to identify the solutions to improve the ADR reporting.[24] The solutions cited by the author such as defining the kind of ADR(S) which should be reported, facilitating an easy contact and quick access to the hospital pharmacovigilance system, facilitating information and support for reporting and providing feedback of pharmacovigilance activities are universal and applicable to all the societies. Reducing the bureaucratic procedures will surely improve the attitude of the reporting clinicians as it will simplify the procedure and also be quick to save the time. Proper feedback of the ADR reporting is one the most neglected but important solution for improving ADR

reporting. Various studies have been done displaying the role of giving feedback to the reported ADR's.[25,26,27]

One fact that has clearly come forward is that a significant proportion of the residents felt that a Good knowledge of Clinical Pharmacology and Therapeutics (CPT) teaching about ADR would have improved its reporting, implying lack of perceived training by the clinical residents. However on objectively asking regarding their undergraduate training in ADR reporting, more than eighty percent of the residents accepted that they had been trained in ADR reporting during under-graduate days. In contrast only around 20 percent accepted that they were further trained during internship and during their post-graduate training. This clearly demonstrates that although ADR reporting is given importance during under-graduate teaching, it is ripped off its significance during the internship and post-graduate training. The result is that only 5.3% residents felt that they were confident enough to fill up the ADR form independently.

This study highlights that other than the routine factors responsible for the under-reporting of ADRs, there is huge lack of re-enforcement of ADR reporting training after completing graduation and this could be responsible for the low awareness and dismal attitude of the clinical residents during their post-graduation towards ADR reporting. ADR reporting although taught during graduation should be frequently re-enforced during internship and thereafter through continuing medical education.[27,28,29]

CONCLUSION:

The current study highlights that although the clinical residents are good enough in knowledge about ADR reporting, they are not willing to put this knowledge into practice due to various perceived barriers and dismal attitude towards the whole process of reporting of ADRs. Considering the low reporting rate, there is an urgent need to improve the attitude towards ADR reporting by considering various problems stated by the residents. Further, although there is no significant reported deficit in under-graduate teaching of ADR reporting, the same has to be re-enforced during internship and post-graduation period by way of integrated teaching of pharmacology with various disciplines. The relentless efforts towards proper training and creating awareness among the clinical residents will surely improve the pharmacovigilance practices.

DISCLOSURE:

The authors report no conflict of interest that might bias the outcome of the paper.

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