

Lack of Awareness of Pharmacovigilance among Young Health-care Professionals in India: An Issue Requiring Urgent Intervention

Abstract

Background: Young healthcare professionals (HCPs) are the pillar of healthcare system. The objective of the present study was to assess the knowledge, attitude, and practices of young HCPs regarding adverse drug reactions (ADRs) reporting. **Methods:** This cross-sectional questionnaire-based study was conducted on young HCPs in a tertiary care teaching hospital of North India. The study instrument was semi-structured, prevalidated questionnaire. The responses obtained were compared among doctors and nursing professionals. **Results:** We obtained response from 84 HCPs (61 doctors and 23 nurses). The mean age of the doctors and nurses was 25.0 ± 2.4 versus 26.3 ± 3.4 years, respectively. No significant difference was observed in questions related to definition of ADR, components of pharmacovigilance (PV), who can report ADRs and medications for which ADRs are to be reported. Only 9.8% doctors and 26.1% nurses were aware of ADR reporting system in India, of which 6 (26%) nurses and none of the doctors were aware of its name. About 16.4% doctors as compared to 61% nurses admitted to have reported an ADR ($P < 0.001$). The main discouraging factor in ADR reporting was time constraint while lack of knowledge was also highlighted by the HCPs. More nurses as compared to doctors (78.3% vs. 49.2%, $P = 0.01$) were of the opinion that holding continuing medical education/workshop could encourage reporting. **Conclusion:** There is an urgent need to increase awareness about PV among young HCPs, and adequate interventions should be instituted to encourage PV practices.

Keywords: Adverse drug reactions, knowledge attitude and practices pharmacovigilance, Pharmacovigilance Programme of India

Introduction

Pharmacovigilance (PV) activities are essential to ensure patient safety and must be encouraged at all health-care institutes.^[1,2] However, lack of awareness, training, and underreporting of adverse drug reactions (ADRs) are the major hindrances in the successful implementation of PV programmes.^[3,4]

To encourage ADR reporting culture and to ensure patient safety in India, the pharmacovigilance programme of India (PvPI) was initiated in 2010 by the Central Drugs Standard Control Organization, New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India.^[5]

A recent study conducted on 90 ADR monitoring centers (AMCs) in India reported that the majority of health-care professionals (HCPs), i.e., 68% of the doctors, 80% of nurses, and 81% of

pharmacists were not aware of the national ADR reporting system of India (PvPI).^[6] However, another knowledge, attitude, and practices (KAP) study from South India, involving 318 HCPs (46.2% doctors, and 53.8% nurses), found that the participants had good knowledge regarding PV and no significant difference was found in the knowledge and attitude between doctors and nurses. However, the practices of ADR reporting were better among doctors as compared to nurses.^[7] Hence, more studies are required, in view of the conflicting results, to have better understanding of KAP among HCPs.

Young HCPs are the major workforce of a health-care system and are the most important target for the successful implementation of any health-care program including PV. Thus, it is vital to assess their KAP regarding PV. This will help in developing the adequate knowledge, attitude and practice of PV in this important section of HCPs. There are many PV

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studies available on the assessment of KAP among doctors; however, the studies addressing the same in young HCPs are lacking. Hence, the present study was aimed to assess the KAP of ADR reporting among young doctors and nursing professionals in a tertiary care teaching hospital in North India.

Methods

This was a cross-sectional questionnaire-based KAP study, conducted on young HCPs in a tertiary care teaching hospital of North India. The study was approved by the Institutional Ethics Committee vide reference no. GMCH/TA-I (19-D)/2013/41663.

The study instrument was semi-structured, pre-validated questionnaire consisting of 15 items. Initially, the 20 questions were framed to assess the KAP regarding PV among young HCPs. This 20 items questionnaire was administered to 10 potential participants and 4 pharmacologists to get their inputs. Subsequently, the questionnaire was modified to include 15 questions. Out of 15 questions, 7 questions addressed knowledge, 4 questions each addressed the attitude and practices of ADR reporting and PV. Out of total 15 questions, three were open ended which were intended to get more insight. We included only young doctors (interns and residents) and nursing professionals. We excluded the faculty members and undergraduate MBBS students since many KAP studies involving them are available in literature. We administered the final questionnaire to 100 young HCPs. They were given sufficient time to understand and fill the questionnaires. The responses obtained from young HCPs were collated and entered into excel sheet for analysis. The responses were compared among doctors and nursing professionals.

Statistical analysis

The data were represented as numbers and percentages (%). Data regarding age was represented as mean \pm standard deviation. The data were analyzed using statistical software SPSS Statistics for Windows, Version 17.0.

(Chicago: SPSS Inc). Categorical data were analyzed using Chi-square test or Fisher exact test (wherever applicable). Continuous variables were analyzed using *t*-test. $P < 0.05$ were considered as statistically significant.

Results

Out of 100 administered questionnaires, 84 were returned back by the HCPs and were included in the final analysis. Out of 84 respondents, 39 (46.4%) were male, and 45 (53.6%) were females. Age of male and female respondents was 25.56 ± 2.6 and 25.26 ± 2.9 , respectively ($P = 0.82$). Out of all HCPs, 61 (72.6%) were doctors, and 23 (27.4%) were nursing professionals. The age of the doctors and nursing professionals was 25.07 ± 2.4 and 26.30 ± 3.4 , respectively ($P = 0.07$). The responses obtained were segregated into knowledge, attitude, and practices.

Most of the HCPs were aware about the definition of an ADR (69%), components of PV (92.9%), who can report ADR (86.9%), ADR for which medication are to be reported (89.3%), who benefits from ADR reporting (89.3%) and to whom ADRs are to be reported (67.9%). However, there was lack of knowledge regarding the ADR reporting system of India, as only 14.3% of HCPs were aware of this. The comparative analysis between doctors and nursing professional regarding knowledge has been shown in Table 1.

Most of the respondents were of the opinion that ADR reporting is necessary (89.3%). Nearly 45.2% of the respondents thought that workshops/continuing medical education (CME) can improve ADR reporting. Regarding factors discouraging ADR reporting, lack of time was reported as the most common factor (51.2%). Significantly more doctors (65.6%) as compared to nurses (13%) reported lack of time as a discouraging factor ($P < 0.001$). Other factors reported were damage to professional image (9.5%) and fear of medicolegal complications (10.7%) while lack of knowledge of ADR reporting process was acknowledged by 9.5% of HCPs. Regarding factors which could encourage

Table 1: Responses for questions assessing knowledge

Question	Number of respondents (%)			P
	Total correct responses (both doctors and nursing professionals) (n=84)	Correct response (doctors) (n=61)	Correct response (nursing professionals) (n=23)	
Definition of an ADR	58 (69)	41 (67.2)	17 (73.9)	0.55
Awareness of ADR reporting system in India	12 (14.3)	6 (9.8)	6 (26.1)	0.06
Components of PV	78 (92.9)	56 (91.8)	22 (95.7)	0.54
Who can report ADRs	73 (86.9)	51 (83.6)	22 (95.7)	0.14
ADR of which medication to be reported	75 (89.3)	55 (90.2)	20 (87)	0.67
To whom ADR should be reported	57 (67.9)	38 (62.3)	19 (82.6)	0.07
Who benefits from ADR reporting	75 (89.3)	53 (86.9)	22 (95.7)	0.25

Responses represented as number and percentages in brackets. ADRs: Adverse drug reactions; PV: Pharmacovigilance

ADR reporting, 57.1% of HCPs were of the opinion that by creating awareness through CME/workshops could help while 41.7% of HCPs opined that making the ADR reporting process easier could be useful. Interestingly, 18% doctors and none of the nurses felt that providing incentives will encourage ADR reporting ($P = 0.029$). Comparative analysis between doctors and nursing regarding attitude has been shown in Table 2 (serial no. 1 and 2) and Figures 1 and 2.

In our study, only 4.8% of HCPs had ever attended a CME/Workshop on PV and 28.6% of HCPs had reported an ADR. Significantly more nurses, as compared to doctors, had reported an ADR ($P < 0.001$). Regarding the preferred mode of ADR reporting, E-mail was the most preferred mode (38.1%) followed by phone (34.5% total; 52.2% nurses vs. 27.9% doctors, $P = 0.03$), drop box (27.4%) and visit to ADR monitoring center (10.7%). Majority of the HCPs wanted the drop box to be located in the outpatient department (OPD)/ward (63.1%) Comparison between practices among doctors and nursing professionals is given in Table 2 (serial no. 3 and 4) and Figures 3 and 4.

Although 12 HCPs (six doctors and six nurses), admitted to have knowledge about ADR reporting system in India, subsequent analysis showed that none of the doctors and all 6 nurses were aware of the term PV or PvPI. This difference

was statistically significant. ($P < 0.001$). Surprisingly, two doctors were aware of ADR reporting system of the United States but not that of India. Seven doctors and one nursing professional felt that there is lack of knowledge regarding the process of ADR reporting. One doctor highlighted the issue of difficulty of reporting and nonavailability of ADR reporting forms. Two nursing professionals thought that ADR reporting process seems to be a long drawn process with no clear-cut outcome.

Discussion

We undertook this survey on young HCPs with the intent to “catch them young.” This would sensitize the important group of HCPs about PV so that they are knowledgeable and motivated enough to report ADRs encountered during their routine clinical practice and promoting the safe and effective use of medicines.

We evaluated the knowledge, attitude, and practices of PV among young HCPs, i.e., MBBS interns and resident doctors and young nursing professionals. We found that the majority of the HCPs were aware of the basic knowledge about PV and ADR reporting; however, 31% were not aware of the definition of an ADR while 32% were ignorant regarding whom to report ADRs. No significant difference was found among doctors and nurses with respect to these questions [Table 1]. These findings are in agreement with

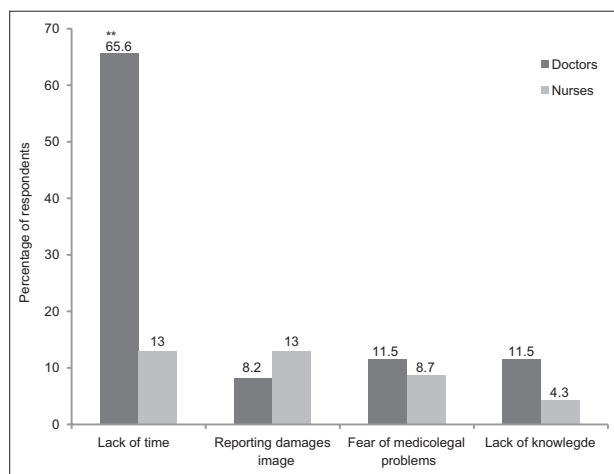


Figure 1: Bar diagram depicting factors discouraging adverse drug reaction reporting. ** $P < 0.001$

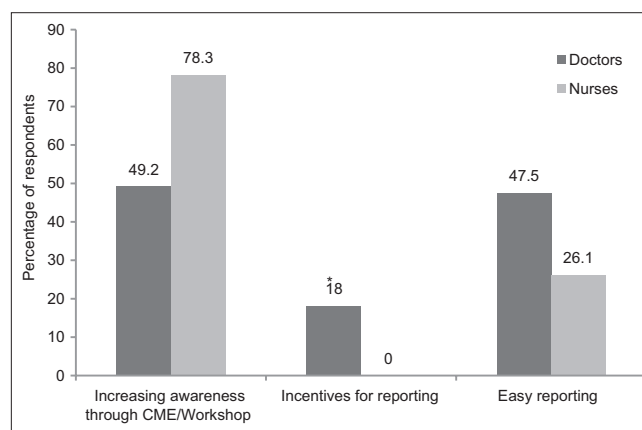


Figure 2: Bar diagram depicting factors encouraging adverse drug reaction reporting. * $P < 0.05$

Table 2: Responses for questions addressing attitude and practices

Question	Number of respondents (%)			P
	Total positive responses (both doctors and nursing professionals) (n=84)	Positive response (doctors) (n=61)	Positive response (nursing professional) (n=23)	
Is ADR reporting necessary?	75 (89.3)	53 (86.9)	22 (95.7)	0.25
Can workshops/CME improve ADR reporting?	38 (45.2)	29 (47.5)	9 (39.1)	0.49
Have you ever attended CME/workshop on PV	4 (4.8)	2 (3.3)	2 (8.7)	0.3
Have you reported an ADR*	24 (28.6)	10 (16.4)	14 (60.9)	<0.001

*Positive response means actually reported ADR. Responses represented as number and percentages in brackets. ADR: Adverse drug reaction; CME: Continuing medical education; PV: Pharmacovigilance

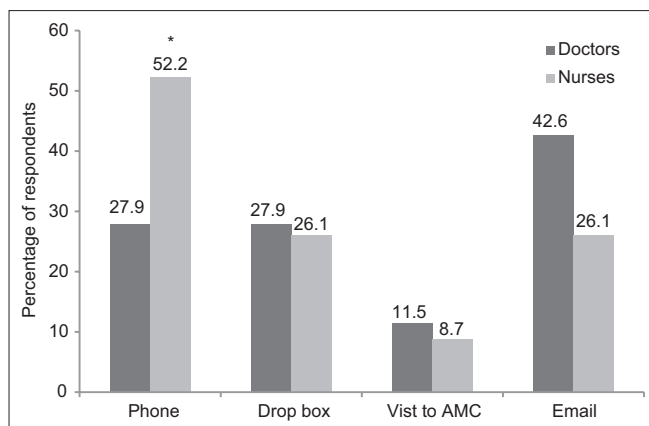


Figure 3: Bar diagram depicting preferred mode of adverse drug reaction reporting. * $P < 0.05$

the studies done by Ganesan *et al.*,^[7] Gupta *et al.*^[8] and Rehan *et al.*^[9]

However, there was a poor knowledge regarding the ADR reporting system of India. Only 12 (14.3%) of HCPs (six doctors and six nurses) admitted to be aware of the ADR reporting system in India, interestingly, all six nurses and none of the doctors were able to name it ($P < 0.001$). This finding is contrary to the studies done by Gupta *et al.*^[8] and Rehan *et al.*,^[9] who reported awareness regarding PvPI in 75.2% and 72% of HCPs, respectively. However, they did not find any significant difference between the knowledge of doctors and nurses. A study by Hardeep *et al.*^[10] reported that only 59% doctors were aware of the national ADR reporting system. Another study done by Necho and Worku^[11] also reported the poor knowledge among HCPs regarding ADR reporting system; however, they did not compare the responses among doctors and other HCPs. A systematic review and meta-analysis by Bhagavathula *et al.*^[12] of 18 studies done in India revealed that 55.6% of HCPs were unaware of the existence of national PV program. Our study differs from the existing studies in revealing very poor knowledge regarding the national ADR reporting system where 100% of the doctors and 74% of the nursing professionals were unaware of the same.

Despite being located in a modern city in North India and in close to one of the North zonal center of PvPI, poor knowledge of young HCPs, especially doctors at our center, reflects on the inadequacy of the program in generating awareness regarding ADR reporting. It could also be due to the absence of an AMC in our institute. Many of the medical colleges are still devoid of AMC, although they have PV committees. The PV committees in medical colleges need to be actively involved in promoting PV activities.

In our study, most HCPs felt that ADR reporting is necessary. This is in concordance with the study done by Vora and Barvaliya^[13] Less than half of the HCPs (45.2%) felt the need of conducting workshops/CME to improve the

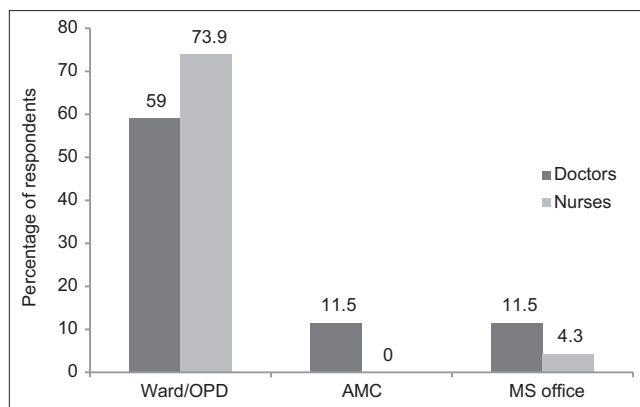


Figure 4: Bar diagram depicting preferred location of drop box

ADR reporting while in the study by Rehan *et al.*,^[9] more than 90% of HCPs were of the same opinion.

We found that lack of time was the major factor discouraging ADR reporting described by the HCPs (51%). As compared to nurses, significantly more number of doctors reported lack of time as discouraging factor for ADR reporting (65.6% vs. 13%, $P < 0.001$), [Figure 1]. Possible reason for this difference could be the hectic schedule of young doctors, mainly residents. Other factors reported were fear of medicolegal complications, damage to professional image, and lack of knowledge. Chatterjee *et al.*^[14] and Raza and Jamal^[15] also reported the lack of time as important factor for not reporting ADRs. Other factors such as nonavailability of ADR reporting forms, lack of clear-cut outcome (feedback from the authorities) of the reported ADRs were also mentioned by HCPs.

Among the factors encouraging ADRs, 57.1% of HCPs felt that conducting workshops/CME on PV will be helpful and 41.7% felt that ADR reporting process should be made easier [Figure 2]. 18% doctors and none of the nurses felt that providing incentives for ADR reporting could be helpful for this purpose. Studies by Bhagavathula *et al.*,^[12] and Kamtane and Jayawardhani^[16] and Amedome and Dadson^[17] also found that giving financial incentives may encourage reporting of ADRs. Hence, steps should be taken to make the ADR reporting process easier and more feasible. Policies to give incentives which are not monetary in nature may be framed, for example, academic appreciation certificates/awards and giving points by the medical council equivalent to CME points.

We came across very poor PV practices among young HCPs. Surprisingly, only 4.8% had ever attended a workshop/CME on PV, although the majority of them opined that attending workshop/CME could encourage ADR reporting. This reflects the lack of motivation and lackadaisical attitude toward PV in them, and it seems that they are yet to accept the culture of ADR reporting. Katekhaye *et al.*^[18] in their study also reported that most

of the doctors (68.7%) had never attended a workshop/CME on PV while in our study, only 2 doctors (3.3%) had attended a workshop/CME.

In our study, only 28.6% of HCPs had ever reported an ADR. Interestingly, significantly greater proportion of nursing professionals as compared to doctors had reported ADRs (60.9% vs. 16.4%, $P < 0.001$). The possible reason for this difference could be that nursing professionals have more patient exposure at early stage of their training as compared to young doctors. Our study is in disagreement with the studies done by Ganesan *et al.*^[7] and Tandon *et al.*^[6] where significantly more number of doctors, as compared to nurses (52% vs. 25%, $P < 0.001$ and 95.9% vs. 4.1%, $P < 0.001$), respectively, reported an ADR. However, the above studies were not exclusively done on young doctors and nurses. Our study is in agreement with Rehan *et al.*,^[9] who found a significant difference between the number of nurses and doctors who had ever reported an ADR (73% vs. 49%, $P < 0.001$). A study by Srinivasan *et al.*^[19] also reported poor practices of ADR reporting by the HCPs where majority (66.5%) had never reported an ADR; however, this study did not analyze the difference between the doctors and nurses.

These findings underscore the importance of providing practical and hands-on training to undergraduate medical students regarding filling the ADR reporting forms and the ADR reporting process. ADR reporting must be integrated into the teaching curriculum as a part of vertical integration. It must be taught in theory and practical and exercises may be given to them in their examination. Similarly, adequate training and sensitization of clinicians is of paramount importance, so that they do not consider ADR reporting as theoretical and unrealistic activity.

Nichols *et al.*^[20] in their study listed the important obstacles for reporting ADRs and reasons for underreporting by the HCP. They mainly pointed out that PV is seen as an unrealistic ideal, reporting authority being perceived as 'virtual and remote', HCPs are not concerned with PV and they are uncertain about their scope and role in ADR reporting.

In our study, the respondents preferred using E-mail, phone, and dropbox for ADR reporting over visiting AMC. Majority of the respondents wanted drop box to be located in the OPD/Wards for easy and timely reporting. Possible reason for this difference could be the remote locations of AMCs (mainly in pharmacology departments). In our institute, absence of an AMC could be the major factor behind the above preferences. In addition, the reporting using phone, E-mails and dropbox would be time-saving which is an important factor determining the ADR reporting. It also gives an insight into the preferences of young HCPs for using web-based (SMS apps, E-mails, etc.) technology for ADR reporting.

Strengths of our study

We focused on young HCPs who are the pillars of our health-care system, and hence, the most important group to be targeted for sustained improvement in ADR reporting in future. This study has highlighted certain weaknesses and challenges in the current ADR reporting practices. The data obtained from this study is contradictory to the claimed success of the current PV program. The possible reason may be the unawareness of the physicians/practicing HCPs regarding the knowledge of ADR reporting and PvPI which is mainly discussed and disseminated within the pharmacology/pharmacy fraternity.

Limitations of our study

Our study is limited by small sample size because we mainly focused on young HCPs (interns, resident doctors, and young nursing professionals). Because of small sample size, we were unable to perform the subgroup analyses. The authenticity of certain responses obtained could not be validated and there is a need to add some qualitative objectives which could be validated at a later stage. This can be addressed by designing further studies.

Conclusion

We can conclude from our study that the young HCPs had adequate knowledge about the ADRs but lack knowledge about the ADR reporting system in India. Their casual attitude and poor ADR reporting practices, especially among young doctors, raise the need for urgent interventions for motivation and training toward PV and ADR reporting. Ongoing PV activities must be revisited and strengthened in our institute. Undergraduate Medical/Paramedical students should be sensitized at an early stage of their courses. PV can be included into their theory, and practical curriculum and hands-on exercises must be given to them for adequate training. Existing PV activities must be strengthened to take a practical shape by involving the practicing physicians and those directly linked with patient care.

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Conflicts of interest

There are no conflicts of interest.

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