Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital

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ABSTRACT

Background: Lack of knowledge of pharmacovigilance (PhV) and adverse event (AE) reporting culture among the healthcare providers have been identified as major factors for under reporting of AE in developing countries. Hence, this study was planned to assess and compare the knowledge, attitude, and practices (KAP) of resident doctors and nurses about PhV and AE reporting.

Material and Methods: This cross-sectional, questionnaire-based study was conducted to compare KAP of 100 doctors and 100 nurses on PhV and AE reporting.

Results: All the respondents felt that AE reporting is necessary and two-thirds were aware of the existing PhV Program of India. Significantly, higher proportion of doctors had correct understanding regarding PhV (P<0.05) and knew what should be reported (P<0.05) but nurses (75%) knew better about where to report (P<0.001). Significantly (P<0.001), more doctors (98%) felt that the patients are benefited by reporting AE. Nurses (96%) felt the need for information on drugs causing AE and their management strategy (P<0.001).

Conclusion: Resident doctors and nurses had good knowledge and awareness on AE reporting and PhV but their practices need to be improved.

KEY WORDS: Adverse drug reactions, attitude, knowledge, nurses, pharmacovigilance, practices, resident doctors

Introduction

Modern approaches and newer medicines have changed the way in which diseases are treated and prevented. However, in spite of all their benefits, adverse effects due to medicines are common cause of morbidity and mortality. In a recent systematic review done by Taché et al., it was observed that the median adverse drug event (ADE) prevalence rate for retrospective studies was 3.3% vs. 9.65% for prospective studies. The median preventable ADE rate for ambulatory care-based studies was 16.5%, as compared to 52.9% for hospital-based studies. Healthcare professionals (HCPs) have contributed enormously to the detection, monitoring, and reporting of these events experiences by the patients.

In India, activities related to the detection, monitoring, and reporting of adverse events (AE) are growing since the inception in 1986. As a result of the funds from the World Bank, the program got its invigorating push in 2004 as the
National Pharmakovigilance (PhV) Program. This World Bank support continued till 2009 and was then taken over by the Ministry of Health and Family Welfare, Government of India which rechristened it as the PhV program of India which became operational since July 2010.\[7]\) Besides modern medicines, in India there are other systems of traditional medicines like Ayurveda, Siddha, Unani, and Homeopathy which are practiced for medical care. Efforts have been made by the Department of Ayurveda, Unani, Siddha, Homeopathy, and the Ministry of Health and Family Welfare to instigate PhV program in their systems as well. Apart from this, PhV has been included in the medical undergraduate and postgraduate pharmacology curriculum in many medical colleges in India. To inculcate the culture of PhV activities, the Medical Council of India (MCI) has made it mandatory to have functional PhV unit in each medical college. In view of this, our institution has included PhV in the medical teaching curriculum in pharmacology and is also one of the ADR monitoring centers (AMC) under the PhV program of India. These efforts may develop knowledge and attitude among the future HCPs toward PhV and ultimately may translate into increase in the adverse drug reaction (ADR) reporting.

Several studies were conducted in different countries to assess the knowledge, attitude, and practices (KAP) of the HCPs. Rehan et al.\[8\] reported that 82% of prescribers were aware about AE reporting systems. In Nigeria, 42.9% of doctors and 35% of nurses had knowledge regarding ADR reporting.\[9\] Whereas in China, only 2.7% of doctors and 1.6% of nurses had correct knowledge of ADRs.\[9\] It can be concluded from such observations that both the doctors and nurses lacked adequate KAP on monitoring, detection, and reporting of AE. It can also be inferred that nurses had marginally less KAP than the doctors, since nurses spend more time in patient care; it was hypothesized that nurses can play an important role in monitoring, detection, and reporting of AE. With this background, we evaluated and compared the KAP of doctors and nurses in PhV. Case records of the inpatients were also screened retrospectively in the medical record department (MRD) for the reported ADRs.

**Materials and Methods**

A cross-sectional questionnaire-based study conducted on 100 resident doctors and 100 staff nurses of our institution from March 2011 to September 2011. Prior approval was taken from the Institutional Ethics Committee to conduct the study. Structured pretested questionnaire contained 7 items to check knowledge, 11 for attitude, and 5 to study practices. In addition, space was provided to give suggestions and furnish any additional information.

Participants were explained the purpose of study and were requested to complete and return the questionnaire immediately. Data were analyzed using SPSS 17 software. Comparison between KAP data obtained from resident doctors and nurses was performed using Chi-square test. \(P<0.05\) was considered as significant.

One thousand case sheets of patients submitted to the MRD during the study period were randomly retrieved and scrutinized for documentation of AE. These case sheets belonged to the in-patient wards from where resident doctors and nurses were included in the study.

**Results**

All the resident doctors and nurses enrolled from different medical and surgical disciplines, viz. medicine, surgery, obstetrics and gynecology, pediatrics, ophthalmology, oto-rhino laryngology, and dermatology completed the questionnaire.

Two-third of the respondents from both the categories were aware of the existing PhV program in the country, but only 35% of the resident doctors and 27% of nurses chose the correct definition of ADR. Resident doctors had significantly \((P<0.05)\) better knowledge on the elements of PhV and “what to report.” On the other hand, two-third of the nurses (75%) had significantly \((P<0.001)\) better knowledge about “whom to report” an ADR \([Table 1]\). Knowledge of resident doctors and nurses with regard to what is serious AE, for which ADR reporting should be done and about the national PhV system, was found to be almost similar \([Table 1]\). Regarding the attitude, all the resident doctors and nurses opined that ADR reporting is necessary. Significantly, higher proportion (96%; \(P<0.001\)) of nurses were of the impression that the information on the frequently used medicines causing ADRs and their management strategies should be available in the wards and OPDs \([Table 2]\).

Both resident doctors (53%) and nurses (60%) felt the need of mandatory PhV while voluntary/spontaneous system was felt necessary by resident doctors, 38% and nurses, 25% \((P<0.05)\) and need-based system by 7% and 15%, respectively.

Resident doctors significantly \((P<0.05)\) outnumbered the nurses (67%) in suggesting that PhV for newer drugs as well as old drugs is necessary. Nurses preferred ADR monitoring should be done for new drugs and vaccines \([Table 2]\). Majority of respondents (resident doctors, 93%; nurses, 82%; \(P<0.05\)) desired regular feedback on the submitted ADEs.

Regarding the mode of reporting ADRs, both resident doctors (47%) and nurses (45%) preferred telephone followed by drop box. Among the resident doctors and nurses who suggested drop box as mode of reporting, majority of them suggested nursing station in wards and OPDs as a suitable place for its location. Resident doctors (73%) and nurses (78%) felt that reporting ADRs will not harm their professional image among the colleagues and patients \([Table 2]\).

Both categories respondents (resident doctors, 96%; nurses, 91%) mentioned that attending conferences and continuing medical education (CMEs) and other similar activities would be a means toward improving the understanding of PhV and majority of them (resident doctors, 31%; nurses, 45%; \(P<0.05\)) felt the need to conduct such activities periodically on a quarterly basis \([Table 2]\).

In comparison to the nurses, resident doctors (67% \([P<0.05]\)) enquired about the occurrence of any untoward outcome of pharmacotherapy frequently \([Table 3]\). Majority of the respondents (resident doctors, 87%; nurses, 89%) mentioned that they had monitored and reported ADRs of minor, moderate, and/or severe intensity. Resident doctors (40%) mentioned that ADRs are routinely discussed during the rounds, whereas only few of the nurses (9%) reported such discussions \([Table 3]\). Nearly half of all the respondents (doctors, 45%; nurses, 55%; \(P<0.05\)) mentioned that they record the observed ADRs in patient’s case record \([Table 3]\). However, screening of case records revealed that the ADRs
were not mentioned in any of the case record. More nurses (73%; \( P<0.001 \)) than the doctors (49%) had reported ADRs to the treating consultant/surgeon [Table 3].

**Discussion**

In India, PhV is rapidly growing with the shift of pharmaceutical activities (i.e., new drug development and clinical trials) from west to east. Hence, it is imperative to develop task force to handle trials and patient care as per ICH-GCP \([11]\) guidelines to ensure patient safety. A number of studies suggest that physicians’ attitude toward ADR reporting is a significant determinant of the reporting rate. \([10,12]\) Results pertaining to knowledge of the resident doctors and nurses in this study were encouraging. Both doctors and nurses were aware of the local hospital-based and national level activities related to the PhV program. In contrast to this, surveys conducted on the healthcare professionals of nine European Union member states, \([13]\) Canada, \([14]\) Malaysia, \([15]\) and Nigeria \([16]\) have shown that the majority of them had an inadequate knowledge about ADRs and PhV. In this study, resident doctors and nurses opined that ADR reporting is necessary and majority of resident doctors \((P<0.001)\) felt that it benefits health care professionals, patients, and health regulatory authorities [Table 2].

A previous study done by Rehan \textit{et al.}\([8]\) in 2002 reported that KAP about ADRs of the medical students and prescribers at LHMC, New Delhi, India was inadequate and needed further improvement. Subsequently in a span of 8 years, this study has shown some improvement in their KAP. The probable reason for such improvement could be due to the reasons that the department of pharmacology organized several continuing medical education (CME), symposia, and group discussions with the prescribers, which probably has reinforced the concept of PhV. Apart from this, they were encouraged to attend 3 days International Conference on PhV organized by the department of pharmacology. Also PhV is taught to the undergraduate students in this institution as two didactic lectures of 1 hour duration each followed by a clinical exercise in which each student is asked to detect, collect, and analyze two cases of ADRs during

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**Table 1:**

| Questions                                                                 | Doctors |   | Nurses |   |
|---------------------------------------------------------------------------|---------|---|--------|---|
| Definition of ADR: An adverse drug reaction (ADR) is “a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man” | 35      | 65| 27     | 73|
| Knowledge about national ADR reporting systems                            | 71      | 29| 73     | 27|
| Knowledge about elements of PhV (detection, assessment, understanding, prevention) | 87      | 13| 73*    | 27|
| ADR reporting to be done for: Allopathic medicines                        | -       | 10|- 12    |   |
| Indian system of medicine                                                 | -       | 7 | - 9    |   |
| Medical devices                                                           | -       | 8 | - 8    |   |
| All                                                                       | 75      |   | 71     |   |
| What is a serious adverse event (SAE)? A SAE is any event that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly or requires intervention to prevent permanent impairment or damage | 73      | 27| 64     | 36|
| “What to report”                                                          | -       | 5 | - 8    |   |
| Adverse event: An adverse event or experience is defined as “any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with the treatment.” | -       | 5 | - 8    |   |
| ADRs                                                                      | -       | 8 | - 7    |   |
| Side effect                                                               | -       | 9 | - 13   |   |
| All                                                                       | 73      |   | 61*    |   |
| Whom to report ADRs                                                       | -       |   | -      |   |
| National PhV center                                                       | -       |   | -      |   |
| ADR monitoring center of institution                                       | -       |   | -      |   |
| Treating physician (in case of nurses)                                    | -       |   | -      |   |
| Any of the above                                                          | 33      |   | 75***  |   |
| Kept personally for future reference                                      | -       | 47| - 25   |   |
| Do not know                                                               | -       |   | 20     |   |

* \(P<0.05; \* P<0.01; \*** P<0.001 \) calculated by Chi-square test

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Table 2:
Comparison of attitude of resident doctors (N = 100) and nurses (N = 100) toward monitoring and reporting ADRs

| Questions                              | Doctors % | Nurses % |
|----------------------------------------|-----------|----------|
| Is ADR reporting necessary?            | 100       | 100      |
| Who benefits from ADR reporting?       | 2         | 10       |
| HCPs                                   | 2         | 14       |
| Patients                               | 5         | 8        |
| Health regulatory authorities          | 3         | 8        |
| All                                    | 98        | 82***    |
| Does ADR reporting damage professional image? |        |          |
| Yes                                    | 27        | 22       |
| No                                     | 73        | 78       |
| Is there need of information on drug causing ADRs and their risk management strategies? | |          |
| Yes                                    | 80        | 96***    |
| No                                     | 20        | 4        |
| Preferred ADRs reporting system        | 38        | 25*      |
| Voluntary                              | 55        | 60       |
| Mandatory                              | 7         | 15       |
| Pharmaceutical products to be monitored for ADRs? | |          |
| New drug                               | 30        | 67*      |
| Old drug                               | 5         | 9        |
| Medical devices                        | 4         | 9        |
| Vaccines                               | 5         | 15*      |
| Do conference/workshops on PhV improve reporting? | |          |
| Yes                                    | 96        | 91       |
| No                                     | 4         | 9        |
| Suggested frequency of ADR conference/workshops | |          |
| Three monthly                          | 31        | 45*      |
| Six monthly                            | 27        | 33       |
| Once in a year                         | 29        | 16*      |
| Once in 3 years                        | 13        | 6        |
| Expectations from the submitted ADRs?  | 93        | 82*      |
| Feed back                              | 7         | 2        |
| Publication                            | 0         | 16       |
| Preferred mode to report ADRs          | 47        | 45       |
| Phone                                  | 31        | 31       |
| Drop box                               | 13        | 11       |
| E-mail                                 | 9         | 13       |
| Personal visit                         | 21.5      | 22.6     |
| If opted drop box its preferred location (N=31) | |          |
| Ward/OPD                               | 6         | 4        |
| AMC                                    | 1         | 3.8      |
| Nearby chemist                         | 2.5       | 0.7      |

*P<0.05; **P<0.01; ***P<0.001 calculated by Chi-square test

Table 3:
Comparison of practices of resident doctors (N=100) and nurses (N=100) toward ADR monitoring and reporting

| Questions                                | Doctors % | Nurses % |
|------------------------------------------|-----------|----------|
| To find ADRs?                            |           |          |
| Only ask from patients                   | 9         | 17       |
| Only ask from patient’s relative         | 11        | 14       |
| Only monitor the patient’s reports       | 13        | 20       |
| All of the above                         | 67        | 49*      |
| What you do with ADRs                    |           |          |
| Report to center/treating physician (nurses) | 49      | 73***    |
| Do not inform to anybody as it is routine part of the treatment | 51      | 27***    |
| Which severity of ADRs do you report?    |           |          |
| Minor: no therapy required               | -         | -        |
| Moderate: required therapy               | -         | -        |
| Severe: life-threatening                 | 13        | 11       |
| All                                      | 87        | 89       |
| Is there any routine discussion on ADRs? |           |          |
| Yes                                      | 40        | 9***     |
| No                                       | 60        | 91       |
| Do you mention the ADRs on the patient’s record? | |          |
| Always                                  | 45        | 55*      |
| Once in a while                          | 42        | 30*      |
| Never                                   | 11        | 15       |
| Managed it without mentioning            | 2         | 10       |

*P<0.05; **P<0.01; ***P<0.001 calculated by Chi-square test

In this study, knowledge of the resident doctors about “what to report” was better (P<0.05) than nurses. Doctors usually have more knowledge of the disease and medicines, which helps understand and analyze the appearance of the ADRs. On this basis, a good clinician considers suspected ADRs as one of the differential diagnosis. Probably, this was the reason for their better knowledge about “what to report.”

Nurses knowledge about “where to report” ADRs was better (P<0.001) than resident doctors. Significant difference in reporting behavior of the doctors and nurses has been observed, which may be due to the lack of tradition or habit.[9,10] In countries where nurses are participating in the ADR reporting scheme, studies have shown that they indeed contribute positively toward promoting ADR reporting.[19] Nurses, through their close contact with the patients and their behavior of maintaining patient-related daily report book, can be a key source of information on ADRs.

In this study, nearly half of all the surveyed respondents mentioned that they always record the observed ADEs in their clinical ward postings. The reports were discussed in six sessions of 2 h duration in small groups. Several other studies have also shown that improving knowledge and awareness of ADRs among the HCPs increase spontaneous reporting.[15-18]
patient’s case record but screening of such records did not reveal it [Table 3]. It may be possible that nurses recorded them in the treatment books but did not transfer these into the patient’s case sheet. To ensure that ADEs are recorded in the case sheet, we have suggested that hospital authorities add a box in the red color on the front page of the case sheet stating “Did you encounter any ADR-Yes/No,” which will be mandatory to be filled by the treating physician and/or nurses before submitting it to the MRD. This may encourage the discussion of ADE during the clinical rounds, which is currently not always done.

In this study, both resident doctors (55%) and nurses (60%) felt that PhV should be a mandatory practice to ensure patient safety. Contrary to this in another study, doctors preferred voluntary reporting (86.8%) over mandatory reporting (13.7%).[19] The strategies suggested by the resident doctors and nurses to enhance ADR reporting in this study were giving feedback on the reported ADEs to the prescribers and organizing CMEs, etc. [Table 2]. Drug information and feedback to the doctors have shown improvement in ADR reporting.[20]

Conclusion

In this study, resident doctors and nurses had adequate knowledge and awareness of ADR reporting and PhV, but their practices regarding reporting ADRs need to be improved.

References

1. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. JAMA 1998;279:1200-5.
2. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. JAMA 1997;277:301-6.
3. Taché SV, Sönnichsen A, Ashcroft DM. Prevalence of adverse drug events in ambulatory care: A systematic review. Ann Pharmacother 2011;45:977-89.
4. Edwards I, Olsson S. WHO: global monitoring. In: Mann RD, Andrew E, editors. Pharmacovigilance. Chichester: John Wiley & Sons; 2002. p. 169-82.
5. Ahmad SR. Adverse drug event monitoring at the Food and Drug Administration. J Gen Intern Med 2003;18:57-60.
6. Kulkarni RD. Reporting systems for rare side effects of non-narcotic analgesics in India. Problems and opportunities. Med Toxicol 1986;1 Suppl:1:110-3.
7. Gupta YK. Ensuring Patient Safety - Launching the New Pharmacovigilance Programme of India. Pharmatimes 2010;42(6):21-26.
8. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Natl Med J Ind 2002;15:24-6.
9. Fadare JO, Enwere OO, Atilalabi AO, Chedi BA, Musa A. Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in Northern Nigeria. Trop J Pharm Res 2011;10:235-42.
10. Li G, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. Chin Med J (Engl) 2004;117:856-61.
11. ICH (International Conference on Harmonisation). Guideline for good clinical practice, 1996. Available from: http://www.ich.org. Last assessed 17.10.2011.
12. Belton KJ. Attitude survey of adverse drug-reaction reporting by health care professionals across the European Union. The European Pharmacovigilance Research Group. Eur J Clin Pharmacol 1997;52:423-7.
13. Nichols V, Thériault-Dubé I, Touzin J, Delilea JF, Lebel D, Bussières JF, et al. Risk perception and reasons for noncompliance in pharmacovigilance: A qualitative study conducted in Canada. Drug Saf 2009;32:579-90.
14. Aziiz Z, Siang TC, Badarudin NS. Reporting of adverse drug reactions: Predictors of under-reporting in Malaysia. Pharmacoepidemiol Drug Saf 2007;16:223-8.
15. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res 2011;3:1064-9.
16. Wallace SM, Suveges LG, Gesy KF. Adverse drug reaction reporting part I: a survey of pharmacists and physicians in Saskatchewan. Drug Inf J 1995;29:571-9.
17. Suveges LG, Gesy KF, Wallace SM, Blackburn JL, Appel WC. Adverse drug reaction reporting part II: evaluation of the Saskatchewan pilot project for a regional reporting program in Canada. Drug Inf J 1995;29:581-9.
18. Scott HD, Thacher-Renshaw A, Rosenbaum SE, Waters WJ Jr, Green M, Andrews LG, et al. Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project. JAMA 1990;263:1785-8.
19. Sencan N, Altminkaynak M, Ferah I, Ozyildirim A, Ceylan ME, Clark MP. The knowledge and attitude of physicians and nurses towards adverse event reporting and the effect of pharmacovigilances trained: A hospital experience. Hacettepe University Journal of the Faculty of Pharmacy 2010;30:25-40.

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