The comparative evaluation of knowledge, attitude, and practice of different health-care professionals about the pharmacovigilance system of India

Asmatanzeem Bepari, Shaik Kalimulla Niazi, Ishrat Rahman, Asmabi Makandar Dervesh

Department of Basic Health Sciences, College of Medicine, Princess Nourah bint Abdulrahman University, 1Department of Preparatory Health Sciences, Riyadh Elm University, 2Department of Basic Health Sciences, College of Dentistry, Princess Nourah bint Abdulrahman University, Riyadh, Saudi Arabia, 3Department of Biochemistry, Prakash Institute of Medical Sciences and Research, Urun-Islampur, Islampur, Sangli, Maharashtra, India

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Abstract

In India, the under-reporting of adverse drug reactions (ADRs) by health professionals is recognized as one of the leading reasons of poor ADR signal detection. The knowledge of ADRs and positive attitude of health-care professionals toward ADRs reporting is vital for decreasing the irrational use of an inappropriate pharmacy. The present study was directed to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance (PV) among the physicians, nurses, and pharmacists of a teaching tertiary care hospital of India. A structured questionnaire was designed using previous studies and standardized. Questions were categorized into three groups: Group 1 tested the knowledge (K1–K8), Group 2 tested attitude (A1–A6), and Group 3 tested the level of practice of PV (P1–P5) of the participant. Such 250 questionnaires were distributed to different health-care professionals of VIMS, Ballari. The participants were graded in three categories as poor, unsatisfactory, and satisfactory depending on the mean score. The data were interpreted by calculating the frequencies, one-way ANOVA and Scheffe’s test. Furthermore, factors that discourage them from taking part in the PV program were recorded. A total of 182 questionnaires were statistically analyzed. It was found that KAP of PV among doctors, nurses, and pharmacists was unsatisfactory. Our study showed that knowledge, attitude, and level of practice of PV among doctors, nurses, and pharmacists stand inadequate. Educational interventions periodically can improve these parameters of PV.

Key words: Adverse drug reaction, attitude, knowledge, pharmacovigilance, practice

INTRODUCTION

Adverse drug reaction (ADR) is defined according to the World Health Organization (WHO) as any response to a medicinal product which is harmful and unintended and which occurs at doses ordinarily utilized in man for prophylaxis, diagnosis or therapy of disease, or the modification of physiological function.[1] ADRs are associated with drug-related patient morbidity by causing a prolonged length of hospital stay, higher economic burden, and sometimes mortality. They are a common and often preventable cause of hospital admission. The worldwide incidence of ADR incidence driving to emergency hospitalization varies from 0.2% to 41.3%, while 28.9% of these ADRs are preventable.[2] In 2012, a meta-analysis showed that 52% of ADR-related emergency hospitalizations and 45% of ADRs in inpatients were preventable.[3] Moreover,

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more than 50% of approved drugs are linked with some adverse effects that are not recognized before their approval for clinical use." Therefore, detection and monitoring of ADRs are of vital importance for patient safety.

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. It is an arm of patient care and monitoring. It intends to getting the best outcome from treatment with medicines. The objectives of PV are rapid identification of adverse drug events, identification of possible causal relationships between an adverse event and medicine following the introduction of a new drug or drug combination, assessment of these signals to evaluate causality, clinical relevance, frequency and distribution of ADRs, in particular, population groups. These objectives compare the safety of different medicines, clearly identify the risk factors, and contribute to the assessment of both effectiveness and risk of medicines. It provides timely communication and recommendations to regulatory authorities, clinicians, and the public. Therefore, PV is an essential component of patient care and the rational use of medicines.

The WHO promotes PV at the country level. In the year 2013, India’s contribution to the WHO–Uppsala Monitoring Centre’s global drug safety database (Vigibase) was 2%. India was 7th in rank among the top ten countries adding to global drug safety database. Among Asian countries, India is the only country possessing more than 1 lakhs ICSRs in Vigibase. A total of 181,656 reports were received at the National Coordination Centre (NCC)- PV Programme of India (PvPI) during April 2011–March 2016 from various sources, i.e., ADR Monitoring Centres (AMCs), non-AMC, and through toll-free helpline number. The spontaneous ADR reporting is the mainstay of the Indian drug safety evaluation in the postapproval phase.

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. PvPI have also increased its reach to other National Health Programmes within the country. The national coordinating center has collaborated with the Revised National Tuberculosis Control Programme and National Aids Control Organization to observe the safety of drugs used in their programme. However, India does not have a robust database on ADRs and has to depend on data from Western countries to make recommendations relating to banning and suspension of drugs. Therefore, all health-care institutes such as medical, dental, pharmacy, nursing, and paramedical associated with patients care to require collective and continued efforts to encourage ADR reporting by providing safe and effective medication. Furthermore, including a chapter on PV in the education curriculum of medicine, pharmacy, nursing could create the raising of ADR reporting among young scholars. Thus, the present study was conducted to assess the knowledge, attitude, and practice (KAP) of PV among doctors, nurses, and pharmacists to know the current status of the adverse drug reporting system in India.

Objectives of the study

The objective of the study

To study the assessment of the Knowledge, Attitude and Practice of Pharmacovigilance among the physicians, nurses, and pharmacists of a teaching tertiary care hospital of India.

Specific objectives

1. To evaluate the knowledge of PV among the physicians, nurses, and pharmacists of teaching tertiary care hospital of India
2. To assess the attitude toward PV among the physician, nurses and pharmacists of teaching tertiary care hospital of India
3. To assess the level of practice of PV among the physician, nurses, and pharmacists of teaching tertiary care hospital of India
4. To compare the results of each group of health-care profession.

MATERIALS AND METHODS

Study design

It was a cross-sectional, noninterventional, questionnaire-based study.

The study setting

The study was carried at Vijayanagara Institute of Medical Sciences, Ballari, Karnataka. The ethical approval from Institutional Review Board of the institution was obtained before the start of the study.

Sample selection criteria

Inclusion criteria

The nonprobability convenience sample of the physician, nurses, and pharmacists working at Vijayanagara Institute of Medical Sciences, Ballari, Karnataka, who give their informed consent were included in the study.

Exclusion criteria

Participants who do not give their consent will be excluded from the study.

Structure of a questionnaire

A structured, questionnaire designed based on the primary objective of the study was used. A questionnaire was designed after a detailed review of relevant literature. The questionnaire composed of four parts: Section I comprised
demographic information. Section II comprised eight knowledge questions designed with multiple choice options. Section III consists of six attitudes. Finally, Section IV has five practice-related questions. Score of 1 was assigned to the correct answer and 0 to the wrong answer. Furthermore, factors that discourage them from taking part in the PV program were recorded. The participants were graded in three categories as poor, unsatisfactory, and satisfactory depending on the mean score.

Such 250 questionnaires were distributed among doctors, nurses, and pharmacists of Vijayanagara Institute of Medical Sciences, Ballari. The participants were graded in three categories as poor, unsatisfactory, and satisfactory depending on the mean score.

Data collection
The study was carried between May and July 2016. Two hundred and fifty questionnaires were distributed among doctors, nurses, and pharmacists of Vijayanagara Institute of Medical Sciences, Ballari and their responses were obtained. A total of 182 returned questionnaires were statistically analyzed, thus giving a response rate of 72.5%. Among the respondents, 58.79% were doctors, 35.16% were nurses, and only 6% were pharmacists.

Data analysis
The data were coded using Microsoft Excel and analyzed using the SPSS version 16.0 (Chicago, SPSS Inc.). Descriptive statistics were carried out to evaluate the KAP score of the participants. ANOVA test was performed to determine if there was a difference in the mean KAP score between doctors, nurses, and pharmacists and between sexes. It was followed by post hoc Scheffe’s multiple comparison tests. The statistical significance was determined at a $P = 0.05$ and a 95% confidence interval.

RESULTS
The results of the study are tabulated in Tables 1-7. The outcomes were analyzed statistically, and tests of significance were found out.

Table 1 shows descriptive statistics indicating that the mean KAP scores of doctors, nurses, and pharmacists. Figure 1 explains the level of knowledge was unsatisfactory in 56.1% of doctors, 48.4% of nurses, and 54.5% of pharmacists. The evaluation of mean attitude score toward PV of doctors, pharmacists and doctors were unsatisfactory in 57.9%, 63.6%, and 64.1%, respectively. The level of practice score of PV among nurses, pharmacists, and doctors was poor in 93.8%, 72.7%, and 89.7%.

Table 2 represents the ANOVA test, and Table 3 represents post hoc Scheffe’s test for multiple comparisons between the groups.

**DISCUSSION**

The primary requirement of PV is the reporting of suspected ADRs. The postmarketing safety studies have been shown to be very critical in recognizing possible risk factors correlated with the use of new drugs in the general population, and the participation of health professionals is essential in reporting suspected ADRs to strengthen signal detection.

Many determinants are associated with the ADR under-reporting among the health-care professionals. However, to improve the reporting rate, it is crucial to educate health-care professionals regarding ADR reporting/PV properly. The recent analysis conducted on 90 AMCs working under PvPI highlighted that 68% of the doctors, 80% of nurses, and 81% of the pharmacists are unaware of PvPI in India. The lack of information regarding the existence of PvPI may be a significant deterrent to ADR reporting. In Bisht et al. intervention study, more than 50% of the continuing medical education (CME) attended doctors were unaware of the presence of PvPI.
Moreover, it was noted that a portion of the health professionals (28.7%) was not interested in reporting suspected ADRs. This attitude showcases the passive attention of some of the health professionals neglecting the significance of reporting ADRs. Evidence from numerous national and international studies suggested that laziness,

| Table 2: ANOVA test of significance for comparison among the groups of each health-care professionals |
|-----------------------------------------------|
| Sum of squares | Df | Mean square | F | Significance |
|-----------------|----|-------------|---|--------------|
| **Mean_K_Score** | | | | |
| Between groups | 12.223 | 2 | 6.112 | 3.877 | 0.022* |
| Within groups | 282.150 | 179 | 1.576 | | |
| Total | 294.374 | 181 | | | |
| **Mean_A_Score** | | | | |
| Between groups | 0.501 | 2 | 0.250 | 0.200 | 0.819 |
| Within groups | 223.879 | 179 | 1.251 | | |
| Total | 224.379 | 181 | | | |
| **Mean_P_Score** | | | | |
| Between groups | 4.064 | 2 | 2.032 | 3.788 | 0.024* |
| Within groups | 96.029 | 179 | 0.536 | | |
| Total | 100.093 | 181 | | | |

*The statistical significance

| Table 3: Post hoc Scheffe’s test for multiple comparisons |
|-----------------------------------------------|
| Dependent variable | Mean difference (I-J) | SE | Significance | 95% CI |
|-------------------|----------------------|----|--------------|--------|
| **Mean_K_Score** | | | | Lower bound | Upper bound |
| Nurse | | | | | |
| Pharmacist | 0.05682 | 0.40979 | 0.990 | −0.9547 | 1.0683 |
| Doctors | −0.51752* | 0.19839 | 0.035* | −1.0072 | −0.0278 |
| Pharmacist | | | | | |
| Nurse | −0.05682 | 0.40979 | 0.990 | −1.0683 | 0.9547 |
| Doctors | −0.57434 | 0.39753 | 0.354 | −1.5556 | 0.4069 |
| Doctors | | | | | |
| Nurse | 0.51752* | 0.19839 | 0.035* | 0.0278 | 1.0072 |
| Pharmacist | 0.57434 | 0.39753 | 0.354 | −0.4069 | 1.5556 |
| Mean_A_Score | | | | | |
| Nurse | | | | | |
| Pharmacist | −0.12500 | 0.36503 | 0.943 | −1.0260 | 0.7760 |
| Doctors | 0.07126 | 0.17672 | 0.922 | −0.3650 | 0.5075 |
| Pharmacist | | | | | |
| Nurse | 0.12500 | 0.36503 | 0.943 | −0.7760 | 1.0260 |
| Doctors | 0.19626 | 0.35411 | 0.858 | −0.6778 | 1.0703 |
| Doctors | | | | | |
| Nurse | −0.07126 | 0.17672 | 0.922 | −0.5075 | 0.3650 |
| Pharmacist | −0.19626 | 0.35411 | 0.858 | −1.0703 | 0.6778 |
| Mean_P_Score | | | | | |
| Nurse | | | | | |
| Pharmacist | −0.17472 | 0.23907 | 0.766 | −0.7648 | 0.4154 |
| Doctors | 0.26709 | 0.11574 | 0.073 | −0.0186 | 0.5528 |
| Pharmacist | | | | | |
| Nurse | 0.17472 | 0.23907 | 0.766 | −0.4154 | 0.7648 |
| Doctors | 0.44180 | 0.23191 | 0.166 | −0.1306 | 1.0143 |
| Doctors | | | | | |
| Nurse | −0.26709 | 0.11574 | 0.073 | −0.5528 | 0.0186 |
| Pharmacist | −0.44180 | 0.23191 | 0.166 | −1.0143 | 0.1306 |

*The statistical significance. SE: Standard error, CI: Confidence interval
diffidence, insecurity, and overloading were some of the factors for under-reporting of ADRs by health-care professionals.\textsuperscript{[14,16]}

In this study, we estimated the KAP of PV among three different groups of health-care professions of doctors, nurses, and pharmacists.

The mean knowledge score of the pharmacists and nurses (2.88 and 2.82) was lower than that of the doctors (3.39). Only 31.8% knew the definition of PV. About 65.93% of the participants were unaware that PV is related to blood transfusion-related, herbal, medical devices, and vaccines associated ADRs, in addition to drug-related problems. Many (70.88%) did not know when the National PV Program of India had officially started. Only 21.4% of the respondents identified the WHO ADR collection database, Vigibase. Several (97.35%) were lacking information about the number of centers present under the National PV Program.

The mean attitude score of the doctors, nurses, and pharmacists was 2.8, 2.88, and 3.0 and was found to be unsatisfactory. Few (36.8%) of the participants were of the opinion of the requirement of PV center in every hospital. Almost 55.5% of the respondents agreed that ADR reporting is not necessary. A vast majority (91.4%) think that nonmedical person is not allowed to report ADR.

### Table 4: Factors discouraging to take part in pharmacovigilance program

| Factors discouraging to take part in PV program | Nurse | Pharmacist | Doctors |
|------------------------------------------------|-------|------------|---------|
| Not knowing how and where to report            | 12.5  | 72.7       | 59.8    |
| Patient confidentiality issues                 | 9.4   | 9.1        | 8.4     |
| A single unreported case a not affect ADR database | 54.7 | 0          | 9.3     |
| Difficult to decide whether ADR had occurred or not | 23.4 | 18.2       | 22.4    |

ADR: Adverse drug reaction, PV: Pharmacovigilance

### Table 5: Knowledge related responses of pharmacovigilance from study participants

| Question                                      | Correct response                                                                 | Nurse (64), n (%) | Pharmacist (11), n (%) | Doctors (107), n (%) |
|-----------------------------------------------|----------------------------------------------------------------------------------|-------------------|------------------------|----------------------|
| Are you aware of term PV                      | Yes                                                                              | 62 (96.90)        | 10 (90.90)             | 91 (85.00)           |
| PV is defined as                               | Detection, assessment, understanding, and prevention of adverse drug effects      | 17 (26.60)        | 2 (18.20)              | 39 (36.40)           |
| The aim of PV is to assess                    | Safety over efficacy                                                            | 41 (64.10)        | 8 (72.70)              | 92 (86.00)           |
| PV include                                    | All are correct (drug, blood, herbal, vaccines, and medical devices related      | 24 (37.50)        | 2 (18.20)              | 36 (33.60)           |
| The PV Program of India was officially launched in the year | 2010                                                                            | 9 (14.10)         | 2 (18.20)              | 42 (39.30)           |
| The international center for ADR monitoring is located in | Sweden                                                                         | 12 (18.80)        | 5 (45.50)              | 41 (38.30)           |
| Which of the following is the “WHO online databases” for reporting ADR’s? | Vigibase                                                                       | 16 (25.00)        | 2 (18.20)              | 21 (19.60)           |
| There are how many ADR monitoring Centres in India? | 179                                                                             | 3 (4.70)          | 0 (0.00)               | 1 (0.90)             |

WHO: World Health Organisation, ADR’s: Adverse drug reactions, PV: Pharmacovigilance

### Table 6: Attitude related responses of pharmacovigilance from study participants

| Questions                                         | Correct answer | Nurse, n (%) | Pharmacist, n (%) | Doctors, n (%) |
|---------------------------------------------------|----------------|--------------|-------------------|---------------|
| What is your opinion about establishing ADR monitoring centre in every hospital? | Should be in every hospital | 19 (29.70) | 4 (36.40) | 44 (41.10) |
| Do you think reporting of ADRs is necessary?      | Yes | 29 (45.30) | 8 (72.70) | 44 (41.10) |
| Do you think PV should be taught in detail to health-care professionals? | Yes | 37 (57.80) | 7 (63.60) | 93 (86.90) |
| Have you ever been come across educational session in specific about PV? | Yes | 57 (89.10) | 7 (63.60) | 69 (64.50) |
| Have you any time read any article on prevention of ADR’s? | Yes | 37 (57.80) | 2 (18.20) | 41 (38.30) |
| Nonmedical person can report ADR to a nearby healthcare professional? | Yes | 3 (4.70) | 0 (0.00) | 7 (6.50) |

ADR’s: Adverse drug reactions, PV: Pharmacovigilance
The mean practice score of the doctors (2.47) was lower than nurses (2.73), and pharmacists (2.91) and the majority were on the poor scale. A considerable number (50.5%) were not aware of the most common causality assessment scale, Naranjo scale for ADRs. Around 30% of the participants did not know to diagnose augmented ADR. While considering the factors discouraging them from taking part in PV, the higher number of participants said that they do not know how to and where to report, in similar with a study carried out by Desai et al. who reported that 70% of their study participants did not know where to report the suspected ADRs.[17]

The above observations indicated that serious measures have to be taken to implement the regular reporting of ADRs among doctors, nurses, and pharmacists. To facilitate the culture of reporting and creating awareness among health professionals, CME, workshops, conferences, posttraining reminders such as periodic E-mails and SMS alerts should be conducted. This will reduce the ignorance of ADR reporting, as the perception that only serious ADRs are to be reported is one of cause for under-reporting of ADRs.[18] Other measures would be providing active workers for busy clinicians and incentives to promote the reports on ADRs. As “lack of financial incentives” and lack of time are also the reasons for under-reporting of ADRs,[19,20]

The simplification of the ADR reporting process might encourage healthcare professionals to report ADRs in India. Importantly, executing ADR reporting online is also recommended. NCC-PvPI has developed an advanced version of the Android mobile app “ADR PvPI” which is an enabler for all health-care professionals and consumers to instantly report ADRs on September 29, 2017.[21]

The other possible measure is to implement ADR reporting as an integral part of undergraduate, internship and postgraduate training. A cross-sectional, questionnaire-based, multicentric study which was performed on six various medical colleges in Gujarat revealed that the overall awareness of PV was poor in undergraduate medical students.[22] Research which was conveyed at a pediatric tertiary care center in Bengaluru suggested that educational interventions and the development of the facilities would help in enhancing the reporting rate.[23] The academic knowledge on PV, the National PV Programme and its centers and ADR monitoring should be included in the undergraduate syllabus. The exact practical knowledge can be gained by visiting a PV center and by observing its functioning. During internship and the postgraduate training, they should be obtaining, interpreting and reporting ADRs, along with posting in the PV centers. They should be familiarized with the ADR reporting and the methods for estimating the causality and the severity of ADRs. CME meetings and other education programs can help in sensitizing them.

CONCLUSION

Now, the need for an adequate PV system has been recognized more than ever, to assure the safe use of medicines. PV is being taught to some degree in theory, but the knowledge on the practical method is lacking. The existing academic curriculum should be amended to incorporate the application of PV in the medical practice. Experience of learning about PV should start early in the professional training of health-care professionals. The medical, nursing, and pharmacy students who are aware of PV are sure to understand that all medicines can cause ADRs. Moreover, they, by participating in the National PV Programme, can discover the adverse effects which result from the drug use in the population. This will decrease the irrational use of medicines and emphasis should be executed on the ADR detection and reporting.

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