



ORIGINAL RESEARCH PAPER

Pharmacology

STUDY OF KNOWLEDGE OF ADVERSE DRUG REACTION REPORTING SYSTEM AND PHARMACOVIGILANCE PROGRAMME AMONG MEDICAL STUDENTS IN TERTIARY CARE CENTRE HOSPITAL

KEY WORDS: Awareness, Adverse drug reactions, medical student, Pharmacovigilance Programme of India

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ABSTRACT

BACKGROUND: PvPI depends upon spontaneous reporting of ADRs by health care professionals they are usually first contact persons for patients in case of ADRs after use of medicines. Underreporting of ADRs due to inadequate reporting culture among health care professionals is the main problem in the path of this programme. So, to the awareness of knowledge and identification of ADR and practices of medical students regarding PvPI and ADR reporting this study was undertaken.

METHODS: It was a questionnaire-based cross-sectional, study in which 130 medical student responded. The feedback form provided by Indian Pharmacopoeia Commission (IPC) was used to assess the awareness towards pharmacovigilance programme and Adverse Drug Reaction (ADR) reporting practices using 12-items questionnaire.

RESULTS: After analysing the questionnaire, it was observed that, despite satisfactory level of knowledge, awareness and interest of the medical students regarding ADR reporting system, still there is problem in ADR reporting practices and PvPI system among the medical students.

CONCLUSIONS: Knowledge of ADR reporting and PvPI system among medical students can improve the outcome of ADR reporting for betterment of patients safety.

INTRODUCTION

Adverse Drug Reaction is “A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.”

A study in India reported overall incidence of 9.8% ADRs including 3.4% of total hospital admissions and 3.7% ADRs developed during hospital stay.

Pharmacovigilance (PV) is the science and activities relating to the detection, monitoring, assessment, understanding and prevention of adverse effects or any other drug-related problem from any pharmaceutical products.

The purpose of pharmacovigilance is to enhance patient care and develop the evidence-based information on safety of medicines. PvPI significance in pursuit of safe-guarding public health by monitoring and prevention of adverse drug reactions. The motive of PvPI is to safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

The Pharmacovigilance Programme of India (PvPI) was initiated in July 2010 by Central Drugs Standard Control Organization (CDSCO) under the aegis of Ministry of Health and Family Welfare (MoHFW) to safeguard health of Indian population. On 15th April 2011, Indian Pharmacopoeia Commission (IPC) took over as NCC. NCC-PvPI started with 22 ADR Monitoring Centres (AMCs) in the initial phase and currently has 250 centres across the country.

Pharmacovigilance Programme of India (PvPI) has established procedures and tools for collection, assessment, and interpretation of safety issues. Suspected ADR reporting formats are standardized for the reporting of adverse events. Communication of information includes a PvPI website, e-mails and a dedicated toll-free helpline. In addition, the PvPI publishes a periodic newsletter with updates on activities and information which is widely disseminated. Medical students can play a important role by early detection of ADR , identification of the causative drug.

Pharmacovigilance in india has been growing now, but there are challenges like underreporting of ADR due to ignorance, communication gap and lack of knowledge of health professionals and reporting culture that need to be developed in coming years.

METHODS

It is a cross sectional, questionnaire based study, conducted among medical students of the hospital.

Study was approved by the Institutional Ethics Committee. Atotal of 150 medical students participated in the study, out of which 130 responded while 20 participants had not filled the form properly, so these were excluded from the study. The 12 item questionnaire feedback form provided by the Indian Pharmacopoeia Commission (IPC) was used for the study, to assess the awareness of medical students toward Pharmacovigilance programme and ADR reporting practices.

After explaining the questionnaire (Annexure 1) forms were distributed to the participants.

The participants were given 20 minutes time to complete the questionnaire form, after which they were collected. This was done to avoid bias and maximize the response rate. Results were analysed through Microsoft Excel 2007.

RESULTS The 12- items questionnaire feedback form provided by IPC was given to 150 students. 20 forms were inadequately filled and hence were excluded from the analysis. 130 forms were duly filled giving a response rate of 88.43%. The mean age of participants was 22.5 years. 62.5 % were male while 37.5 % were female participants.

Table 1 Awareness of PvPI and ADR reporting in medical students

| SN. NO. | QUESTION | YES | NO |
|---------|---|-----------|------------|
| 1 | Have you ever heard about PvPI | 73.07(95) | 26.92(35) |
| 2 | Are you aware that the mission of PvPI is to monitor ADRs and promote safe use of medicines | 66.15(86) | 33.84(44) |
| 3 | Are you aware about PvPI helpline(1800-1180- 3024) toll free to report any suspected ADRs after the use of medicines. | 23.07(30) | 76.30(100) |
| 4 | Are you aware about specifically designed format of PvPI for reporting of ADR | 61.53(80) | 38.47(50) |
| 5 | Are you aware of ADR monitoring center AMC | 74.6(97) | 25.38(33) |

There were 73.07% (95) participants who have heard about PvPI while 26.92% (35) have not heard about it previously. 66.15% (86) participants were aware about mission of PvPI i.e. to monitor adverse drug reactions and promoting safe use of drugs, while 33.84% (44) were unaware. 23.07% (30) participants were aware of PvPI toll free helpline no. (18001803024) for reporting any suspected adverse drug reactions while 76.30% (100) participants were not aware. 61.53% (80) participants were aware of designated format of PvPI for reporting ADRs by health care professionals, 38.47% (50) were aware of ADR reporting format by patients/consumers/relatives of patient/care givers (available in different languages at PvPI). 74.61% (97) participants were aware of Adverse Drug Reaction Monitoring Centre (AMC) in their region while 25.38% (33) were not aware of it.

TABLE 2 Assessment of knowledge of participant towards PvPI and ADR reporting

| Sn no | Questions | Yes | No |
|-------|---|------------|-----------|
| 1 | All medicines can cause side effects, do you think it is important concern. | 81.53(106) | 18.46(24) |
| 2 | Have you seen any medicine safely promotional material prepared by PvPI ? | 23.84(31) | 76.15(99) |
| 3 | If yes did you find it useful? | 38.70(12) | 61.29(19) |
| 4 | Have you ever interacted with any PvPI personnel? | 43.07(56) | 56.92(74) |
| 5 | If yes, does he/she provide any value addition in medicines safety? | 57.14(32) | 42.85(24) |

There were 81.53% (106) participants who think that ADRs are an important health concern while 18.46% (24) participants do not think so. It is 23.84% (31) participants have never seen any medicine safety promotional material prepared by PvPI while 76.15% (99) participants have seen such material before. Only 38.70% (12) participants found it useful while the remaining 61.29% (19) did not think them useful. 43.07% (56) participants have interacted with PvPI personal (Pv associate) while 56.92% (74) participants never interacted with any such person. 57.14% (32) participants agree that this interaction provided them with valuable information on medicine safety while 42.85% (24) participants did not agree with any such benefit of interaction.

TABLE 3 ADR reporting practices among medical students

| Sn no | Questions |
|-------|---|
| 1 | Have you ever experienced/ noticed side effect/ADRs after use of medicines? Never 24.6%(32). Very common 9.2%(12). Sometimes 66.15%(86) |
| 2 | When experienced /noticed any ADR what you do? Nothing 8.46%(11) Informed to AMC/ADR monitor 91.5%(119) |
| 3 | Have you ever attended awareness program regarding reporting of ADR Yes 60%(78). No 40%(52) |
| 4 | Would you like to participate in medicine safety initiative of PvPI? Yes 86.15%(112). No 13.84%(18) |

There were 66.15% (86) participants were of the view that they sometimes experience or notice ADRs after use of medicines, 9.2% (12) participants noticed ADRs very commonly while 24.6% (32) participants quoted that they never experienced or noticed ADRs after use of medicines. 91.5%(119) participants informed to AMC /ADR monitor while 8.46%(11) did nothing. 60% (78) participants attended awareness programme regarding reporting of ADR while 40%(52) Participants did not show interest and 86.15% (112) participants showed interest in attending medicine safety initiative of PvPI.

DISCUSSION

ADR is a well-recognized problem associated with spontaneous ADR reporting system and awareness level of health care professionals like medical students regarding the Pharmacovigilance Programme.

Total 150 of medical students were included in questionnaire, out of which 130 medical students were assessed in this cross-sectional, questionnaire-based study. The questionnaire feedback form provided by IPC was used for this study which 12 questions are asked.

The mean age of participants were 22.5 years with 62.5% (81) males and 37.5% (49) females. The questionnaire for assessment of knowledge about PvPI and ADR reporting system.

Out of 130 participating medical students, 73.07% (95) have heard about PvPI, 66.15% (86) were aware about its mission, 23.07% (30) only knew about the toll-free helpline no. and 61.53% (80) were aware about designated format of PvPI for health care professionals for reporting ADRs. 74.6% (97) participants were aware of AMC in their region while 25.38% (33) were not aware of it. These findings suggest that awareness level of participating medical students in this study was higher than other similar studies .

The questionnaire for assessment of knowledge of participating medical students towards PvPI and ADR reporting included questions like- towards ADRs as important health concern, their knowledge towards medicine safety promotional material prepared by PvPI and their interaction with PvPI personnel (Pv associate). About 81.53% (106) students think ADRs to be important health concern while 18.46% (24) participating students did not think so. This finding is similar to another such study. (13,14)

76.15% (99) participants have never seen any medicine safety promotional material prepared by PvPI while 23.85% (31) participants have seen such material before. Out of these, only 38.70% (12) found it useful while remaining 61.29% (19) did not find it useful or did not comment anything about its usefulness. A similar trend has been reported in another study. (15) According to our study, 43.07% (56) students have interacted with PvPI personnel (Pv associate) while 56.92% (74) never interacted with any such person. Only 57.14% (32) participants agree that this interaction provided them with valuable information on medicine safety.

The questionnaire for ADR reporting practices among medical students included questions like- how frequently they have noticed ADRs after use of medicines, what they did after experiencing or noticing any ADRs after use of medicines, whether they have attended any awareness programme regarding reporting of suspected side effects of medicines or ADRs after use and finally whether they are interested in participating in the medicine safety initiatives of PvPI. 66.15% (86) participating students were of the view that they sometimes experience or notice ADRs after use of medicines while 9.2% (12) experienced or notice them very commonly. 91.5% (119) students informed the concerned doctor/AMC after any ADRs on use of medicines while 8.46% (11) not reported to AMC. These finding were on higher side than other similar studies. (16-18)

60% (78) participants attended an awareness programme regarding ADR reporting in the past, which is more than another similar study while 86.15% (112) participants were interested in participating in PvPI and ADR reporting in future which is similar to the previous study. (19)

CONCLUSION

This study concluded that inspite of knowledge of drug interactions and drug reactions medical students need more awareness about ADR reporting system and Pharma covigilance system.

ADR reporting practices is a major problem. Health professionals need motivation, knowledge, awareness and sensitisation and training programmes for PvPI and ADR reporting systems.

There should be motivation for reporting such as giving credit to reporter for good quality work or other added incentives, for increasing quality ADR reporting practices.

Limitations of our study are that only medical students were included in this study, we need awareness and knowledge of ADR and reporting system among the nurses, paramedical staff and other health workers also and our study is confined to our AMC with limited participants.

So, we need frequent training and sensitisation programme in a larger scale for implementation of PvPI reporting system and ADR reporting system for better outcome of patients safety among health care professionals.

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