

Assessment of awareness towards pharmacovigilance programme of india and reporting of adverse drug reactions among nurses in a tertiary care hospital

Atul Jain¹, Arpita Singh^{1*}, Ajay Kumar Verma², Maneesh Soni¹

¹Department of Pharmacology,
Dr. Ram Manohar Lohia
Institute of Medical Sciences,
Lucknow, Uttar Pradesh, India

²Department of Pulmonary &
Critical Care Medicine, King
George's Medical University
Lucknow, Uttar Pradesh, India

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***Correspondence to:**

Dr. Arpita Singh,
Email: drarpitasingh21@gmail.com

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ABSTRACT

Background: The success of PvPI depends upon spontaneous reporting of ADRs by health care professionals especially nurses as 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 hindrance in the path of this programme. So, to assess the awareness, attitude and practices of nurses regarding PvPI and ADR reporting this study was undertaken.

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

Results: After analysing the questionnaire, it was observed that, despite satisfactory level of awareness and interest of the nurses to participate in this programme, still there is meagre ADR reporting practices among the nurses.

Conclusions: Lack of reporting culture and improper communication is the root of problem which should be overcome in future by proper training for patient safety.

Keywords: Awareness, Adverse drug reactions, Nurses, Pharmacovigilance Programme of India

INTRODUCTION

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.¹

The core purpose of pharmacovigilance is to enhance patient care and generate the evidence-based information on safety of medicines. It is increasingly gaining significance in pursuit of safe-guarding public health by

monitoring and prevention of adverse drug reactions. The mission 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.²

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.”³

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.⁴

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. Of these, 17 receive information from the Revised National Tuberculosis Control Programme (RNTCP), 20 from the HIV control programme on Anti-retroviral therapy (ART) and 6 are designated Bedaquiline centres (now scaled up to 19 sites). As the outcome of cases under RNTCP is highly affected by ADRs.⁵

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.

Pharmacovigilance Programme of India (PvPI) is also collaborating with WHO-UMC, Sweden, for International Drug Monitoring Program by exchange of scientific information through different software tools.⁶

The PvPI spontaneous reporting form is available for health care professionals and for consumer, separately.⁷

In PvPI, nurses can play an important role by early detection of ADR, identification of the causative drug and by encouraging and counselling patients to report ADR voluntarily. Pharmacovigilance in India has been growing day by day, but there are challenges like underreporting of ADRs due to ignorance, communication gap and lack of reporting culture that need to be developed in years to come.⁸

METHODS

It was a cross-sectional, questionnaire-based study, conducted among nurses of the hospital. Study was approved by the Institutional Ethics Committee.

A total of 147 nurses participated in the study, out of which 130 nurses responded while 17 participants had not filled the form properly, so these were excluded from the study.

The 12-items questionnaire feedback form provided by Indian Pharmacopoeia Commission (IPC) was used for this study, to assess the awareness of nurses towards

pharmacovigilance programme and Adverse Drug Reaction (ADR) reporting practices.⁹

After explaining the questionnaire (Annexure I) forms were distributed to the participants. The participants were given 15 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 147 nurses. 17 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 32.25 years. 79.23% were females while 20.76 % were male participants.

Assessment of awareness about pharmacovigilance programme of India (PvPI) and ADR reporting

Table 1: Assessment of awareness about pharmacovigilance programme of India (PvPI) and ADR reporting.

Questions		
1) Have you ever heard about PvPI?		
Yes 91.53% (119)	No 8.46% (11)	
2) Are you aware that the mission of PvPI is to monitor ADRs and promote safe use of medicines?		
Yes 90.76% (118)	No 9.23% (12)	
3) Are you aware about PvPI helpline (1800-1180-3024) toll free to report any suspected ADRs after the use of Medicines?		
Yes 80.76% (105)	No 19.23% (25)	
4) Are you aware about specifically designed format of PvPI for reporting of ADRs		
By Health care professionals	By patients/ consumers	By mobile application
76.92% (100)	27.69% (36)	2.30% (3)
5) Are you aware of ADRs monitoring Centre (AMC) in your region?		
Yes 74.61% (97)	No 25.38% (33)	

There were 91.53% (119) participants who have heard about PvPI while 8.46% (11) have not heard about it previously. 90.76% (118) participants were aware about mission of PvPI i.e. to monitor adverse drug reactions and promoting safe use of drugs, while 9.23% (12) were unaware. 80.76% (105) participants were aware of PvPI toll free helpline no. (18001803024) for reporting any suspected adverse drug reactions while 19.23% (25) participants were not aware. 76.92% (100) participants were aware of designated format of PvPI for reporting ADRs by health care professionals, 27.69% (36) were aware of ADR reporting format by patients/consumers/relatives of patient/care givers (available in different languages at PvPI website while

only 2.30% (3) participants were aware of ADR reporting through ADR mobile app. 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.

Assessment of attitude of participants towards PvPI and ADR reporting

There were 96.92% (126) participants who think that ADRs are an important health concern while only 3.07% (4) participants do not think so. It is 76.1% (99) participants have never seen any medicine safety promotional material prepared by PvPI while 23.85% (31) participants have seen such material before. Only 15.38% (20) participants found it useful while the remaining 8.46% (11) did not think them useful or had not commented anything about its usefulness. 51.53% (67) participants have interacted with PvPI personal (Pv associate) while 48.46% (63) participants never interacted with any such person. 36.15% (47) participants agree that this interaction provided them with valuable information on medicine safety while 15.38% (20) participants did not agree with any such benefit of interaction.

Table 2: Assessment of attitude of participants towards PvPI and ADR reporting.

Questions	
(1) All medicines can cause side effects/ADRs, do you think this is an important concern?	
Yes 96.92% (126)	No 3.07% (4)
(2) Have you seen any medicine safety promotional materials prepared by PvPI?	
Yes 23.84% (31)	No 76.15% (99)
If yes, did you find it useful?	
Yes 15.38% (20)	No 8.46% (11)
(3) Have you ever interacted with any PvPI personnel?	
Yes 51.53% (67)	No 48.46% (63)
If yes, does he/she provide any value addition in medicines safety?	
Yes 36.15% (47)	No 15.38% (20)

Assessment of ADR reporting practices among nurses

There were 83.84% (109) participants were of the view that they sometimes experience or notice ADRs after use of medicines, 6.92% (9) participants noticed ADRs very commonly while 9.23% (12) participants quoted that they never experienced or noticed ADRs after use of medicines. 79.23% (103) participants informed the concerned doctor or nurse (their co-worker) after experiencing or noticing any ADRs after use of medicine, 18.46% (24) participants reported it to the nearest AMC while 2.30% (3) participants did nothing and no participant (0%) informed the drug company or manufacturer of the drug which caused the suspected ADR. 60% (78) participants attended an awareness programme regarding reporting of suspected side effects of medicine or ADRs after its use while 40%

(52) participants did not attended any such session. 96.15% (125) participants were interested in participating in the medicine safety initiatives of PvPI while only 3.84% (5) participants were not interested in any such initiatives.

Table 3: Assessment of ADR reporting practices among nurses.

Questions			
(1) Have you experienced/noticed side effects/ADRs after use of medicines?			
Never 9.23% (12)	Very commonly 6.92% (9)	Sometimes 83.84% (109)	
(2) When experienced/noticed any ADR what you did?			
Nothing 2.30% (3)	Informed Nurse/Doctor 79.23% (103)	Informed drug company/manufacturer 0% (0)	Informed AMC/ADR Monitoring centre 18.46% (24)
(3) Have you ever attended any awareness programme regarding reporting of suspected side effects of medicines/ADRs after use?			
Yes 60% (78)		No 40% (52)	
(4) Would you like to participate in medicine safety initiatives of PvPI?			
Yes 96.15% (125)		No 3.84% (5)	

DISCUSSION

As nurses are in close contact with indoor patients throughout the treatment, they can observe the adverse effects of medicine at its earliest onset, therefore the present study was undertaken to assess the awareness of nurses about Pharmacovigilance Programme of India and ADR reporting in a tertiary care hospital. Underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system and awareness level of health care professionals including nurses regarding the Pharmacovigilance Programme and ADR reporting plays a significant role in it.

A total of 130 nurses were assessed in this cross-sectional, questionnaire-based study. The 12- items questionnaire feedback from provided by IPC was used for this study.

The mean age of participants were 32.25 years with 79.23% (103) females and 20.76% (27) males. The questionnaire for assessment of awareness about PvPI and ADR reporting included questions like- knowledge regarding PvPI and its mission i.e. to monitor ADRs and promoting safe use of drugs, awareness regarding toll free helpline no. of PvPI for reporting any suspected ADRs, awareness regarding designated format of PvPI for reporting ADRs by health care professionals, by patients or consumers and by mobile application. Out of 130 participating nurses, 91.53% (119) have heard about PvPI, 90.76% (118) were aware about its mission, 80.76% (105) know about the toll-free helpline no. and 76.92% (100)

were aware about designated format of PvPI for health care professionals for reporting ADRs. 74.61% (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 nurses in this study was higher than other similar studies.¹⁰⁻¹²

The questionnaire for assessment of attitude of participating nurses towards PvPI and ADR reporting included questions like- attitude of nurses towards ADRs as important health concern, their attitude towards medicine safety promotional material prepared by PvPI and their interaction with PvPI personnel (Pv associate).

About 96.92% (126) nurses think ADRs to be important health concern while 3.07% (4) participating nurses 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 15.38% (20) found it useful while remaining 8.46% (11) 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, 51.53% (67) nurses have interacted with PvPI personnel (Pv associate) while 48.46% (63) never interacted with any such person. Only 15.38% (20) participants agree that this interaction provided them with valuable information on medicine safety.

The questionnaire for assessment of ADR reporting practices among nurses 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. 83.84% (109) participating nurses were of the view that they sometimes experience or notice ADRs after use of medicines while 6.92% (9) experienced or notice them very commonly. 79.23% (103) nurses informed the concerned doctor or nurse (their co-workers) after any ADRs on use of medicines while 18.46% (24) reported them to AMC. These findings 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 96.15% (125) 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 despite having an operational Pharmacovigilance system and satisfactory level of awareness among the participating nurses under reporting and poor quality of spontaneous ADR reporting practices

is a major problem. Thus, there is a need for generating spontaneous reports as a sustained practice by sensitization and training programmes. 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. There are few limitations of our study like only nurses were included since we thought for the need of assessing them separately as they are the ones who usually get the first-hand information regarding occurrence of ADRs after use of medicines in indoor patients. Also, our study is confined to our AMC with limited participants. So, further studies of larger scale are needed for assessing the possible challenges and their solutions for the long term success of this programme.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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ANNEXURE I

Pharmacovigilance Programme of India (PvPI)

National Coordination Centre

INDIAN PHARMACOPOEIA COMMISSION



Ministry of Health and Family Welfare, Government of India

SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.

Tel No: 0120- 2783392, 2783400, 2783401 Fax: 0120-2783311

E-mail: pvpi.ipc@gov.in; ipclab@vsnl.net, Web: www.ipc.gov.in

No. MM/YY/No (Filled by NCC-PvPI)

Feedback Form for Stakeholders

PvPI appreciate your effort to complete this feedback form. Your honest feedback will help us to strengthen the programme and enable us to improve our standards of monitoring medicine safety.

(Please tick (✓) the appropriate box)

Doctor **Nurse** **Pharmacist** **Patient** **Others** **(Please specify)**

1. All medicines can cause side effects/Adverse Drug Reactions (ADRs). Do you think this is an important health concern?

Yes No

2. Have you experienced/noticed side effects/ Adverse Drug Reactions (ADRs) after use of medicines?

Never Very Commonly Sometimes

3. When experienced/noticed any Adverse Drug Reaction (ADR) what did you do?

Nothing Informed Nurse/Doctor

Informed Drug Company/Manufacturer Informed ADR Monitoring Centre

4. Have you ever heard about Pharmacovigilance Programme of India (PvPI)?

Yes No

5. Are you aware that the mission of Pharmacovigilance Programme of India (PvPI) is to monitor Adverse Drug Reactions (ADRs) and promote safe use of medicines?

Yes No

6. Are you aware about PvPI helpline (1800-180-3024) (Toll free) to report any suspected Adverse Drug Reactions (ADRs) after the use of medicines?

Yes No

7. Have you ever attended any awareness programme regarding reporting of suspected side effects of medicines/ Adverse Drug Reactions (ADRs) after use?

Yes No

8. Are you aware about specifically designed format of PvPI for reporting Adverse Drug Reactions (ADRs)?

By Healthcare Professional

By Patients/Consumers/Relatives of Patient/Care givers (available in different languages at PvPI website - www.ipc.gov.in)

Through ADR Mobile App

9. Are you aware of Adverse Drug Reactions (ADRs) Monitoring Centre in your region?

Yes No

10. Would you like to participate in medicine safety initiatives of PvPI?

Yes No

11. Have you seen any medicine safety promotional materials prepared by PvPI?

Yes No

If yes, did you find it useful?

Yes No

12. Have you ever interacted with any PvPI personnel?

Yes No

if Yes, please share your experience:

a) Does he/she provide any value addition in medicines safety?

.....
.....

b) What role do you expect from him/her to improve the medicines safety?

.....
.....

Your comments/suggestions to improve our services:

.....
.....
.....

Personal details:

Name:
Address:
Name of premises/building/village.....
Road/street.....
Area
Locality.....
District.....State.....Pin.....
Email:
Phone/Mobile No.:.....

Date:

Signature

Kindly send feedback to pvpi.ipc@gov.in; ipclab@vsnl.net

Thank you for your feedback.

Your assistance in completing this form is greatly appreciated.