

## Knowledge, attitude and practice of pharmacovigilance towards adverse drug reactions reporting among health care professionals (nurses) in a tertiary care teaching hospital in Eastern India: an observational study

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### ABSTRACT

**Background:** Nursing staffs spend most time in patient care and are bedside caregivers. To expect voluntary reporting of adverse reactions, it is essential that they possess proper knowledge, right attitude and practice reporting. Therefore, the present study was aimed to assess the Knowledge, Attitude and Practice of Pharmacovigilance towards ADRs reporting.

**Methods:** A prospective, cross sectional, observational, questionnaire-based survey was conducted among nurses in a tertiary care teaching hospital in Eastern India. Questionnaire containing 15 questions was used to assess knowledge, attitude and practice. The questionnaire was administered to 150 nurses. Analysis of data was done using statistical software..

**Results:** The response rate in our study was 86.67%. Nurses have good knowledge of pharmacovigilance and adverse reaction. However, only 10% have reported an adverse reaction in our study. This shows that in spite of having a good knowledge of reporting, nurses have poor attitude, which is reflected by a low reporting rate. Nurses opined that taking patient care is of prime importance than report an adverse reaction. This corroborates the low reporting rate in our set up.

**Conclusions:** Majority of nurses have good knowledge on pharmacovigilance and adverse drug reaction. The concern remains on the low reporting rate. Continuous training programmes, and reminders likely to enhance the voluntary reporting from the nursing staffs.

**Keywords:** Adverse reaction, KAP, Nurses, Pharmacovigilance

### INTRODUCTION

The thalidomide disaster paved the way for World Health Organization (WHO) to initiate globalization of pharmacovigilance studies through establishment of global drug monitoring. WHO-approved national pharmacovigilance centres collect case reports and send to the Global database, at Uppsala, Sweden.<sup>1</sup> WHO defines Pharmacovigilance as “The science and activities which

are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems”.<sup>2</sup> This improves the safety profile, for use in diverse category of patient population. Pharmacovigilance Programme of India (PvPI), initially started functioning in 2010 from AIIMS, Delhi and later from Indian Pharmacopoeia Commission (IPC), Ghaziabad, in 2011, for better implementation and matching global standards in safety data.<sup>3</sup> Studies revealed that ADRs are leading to

hospitalization and constitute a significant economic burden on patients in India.<sup>4-6</sup> WHO defines “adverse reactions as harmful and unintended responses to a drug and which occur with doses normally used in humans for prophylaxis, diagnosis or treatment of a disease or modifying a physiological function”.<sup>7</sup> Studies conducted in several parts of India have estimated the incidence of suspected adverse reactions to be nearly 2% to 3% among hospitalized patients.<sup>8,9</sup> A recent systematic review estimated the median incidence of adverse reactions that led to hospitalization and those that developed during hospitalization as 2.85% and 6.34% respectively.<sup>10</sup> Under-reporting by health professionals is a major problem in India.<sup>11</sup>

Nursing staffs spend most time in patient care and are bedside caregivers, and have a vital role in recognizing, and reporting of adverse event. For voluntary reporting of adverse reaction from nurses, it is essential that they should possess proper knowledge, right attitude. Therefore, the present study was done to evaluate the Knowledge, Attitude and Practice of Pharmacovigilance towards reporting amongst nursing staff in a Teaching Hospital in Eastern India.

## METHODS

### Study design

This study was a prospective, cross-sectional, observational, questionnaire - based study. The questionnaire was newly designed, based on the similar studies that have been conducted previously and was modified to make it relevant in our set up and was tested for its content validity.<sup>12-15</sup> A questionnaire was prepared to assess knowledge, attitude toward pharmacovigilance, practice of reporting, identify the reasons of non-reporting and to evaluate the methods to improve the reporting rate. The study was conducted after receiving the approval from the Institutional Ethics Committee of IMS and SUM Hospital, Bhubaneswar.

### Study setting and time period

The study was conducted in nursing staffs of IMS and SUM Hospital, Bhubaneswar. The study was conducted from 01/02/2019 to 28/02/2019, i.e., for one month.

### Study questionnaire

The importance of the study and instructions on how to fill the questionnaire were explained to each respondent. Participants willing to be a part of the study, voluntarily agreed to sign the informed consent form. The questionnaire consists of demographic characteristics of the participants, knowledge of pharmacovigilance, attitude towards reporting, and practice of reporting, and also included questions on factors affecting non-reporting, and methods to improve the reporting rate. The participants were given 30 mins to provide the necessary information.

The response to each question was scored as 0 for incorrect and 1 for correct in knowledge question, 0 for disagree (non-favourable) and 1 for agree in attitude questions, and 0 for No and 1 for Yes in practice questions.

### Study participants

Nurses working in different clinical departments of IMS & SUM Hospital Bhubaneswar were included in the study. The questionnaire was administered to 150 nurses. Those who were not willing to participate, not submitting the form on time and incomplete responses were not included in present study.

### Statistical analysis

The information was tabulated and analysed using the Microsoft Excel worksheet (Microsoft Office 2013). Frequency of response was calculated in percentage and presented as percentage (%) of respondents. Mean score and standard deviation were calculated for responses of knowledge, attitude and practices using SPSS version 20.0v (IBM Corp., Armonk, NY, USA).

## RESULTS

Total 150 questionnaires were administered to nursing staffs, 130 forms were returned, and analysed as per the inclusion criteria. 86.67% was the response rate. A total of 10 Auxiliary Nurse Midwifery (ANM), 79 General Nursing Midwifery (GNM) and 41 B.Sc. Nursing staff were included in the study (Table 1).

**Table 1: Demographic profile of study population categorized by qualification.**

Parameters	ANM	GNM	B.Sc. Nursing
Mean Age (Mean±SD)	23.8±3.42	24.0±2.82	24.07±3.04
Male: Female	5:5	7:72	4:37
Total Nursing staff	10	79	41

**Table 2: Mean score of respondents categorized by qualification.**

Qualification	Knowledge (Mean±SD)	Attitude (Mean±SD)	Practice (Mean±SD)
ANM	0.675 ±0.168	0.625 ±0.270	0.675 ±0.168
GNM	0.637 ±0.238	0.696 ±0.157	0.637 ±0.238
B.Sc. Nursing	0.693 ±0.215	0.631 ±0.233	0.693 ±0.215

The mean score of knowledge and practice was lowest in the GNM group and highest in the B.Sc. Nursing group. The mean score of attitudes was lowest in the ANM group

and highest in the GNM group. Maximum adverse reactions were reported by the B.Sc. Nursing staff in present study (Table 2).

GNM nurses were more aware of the Indian agency involved in drug safety issues, adverse reaction collaborating centres, type of reactions to be reported,

healthcare professionals are responsible for reporting, and there is no legal consequence for reporting. B. Sc qualified nurses were more aware of adverse reaction definition, meaning of PvPI. However, only 5% of GNM nurses have ever reported, which is the lowest amongst study groups (Table 3).

**Table 3: Knowledge, attitude, practice of reporting ADR based on qualification.**

Knowledge, attitude and practice related questions	(ANM) Correct Response N (%)	(GNM) Correct Response N (%)	(B.Sc. Nursing) Correct Response N (%)	p value
Pharmacovigilance definition	9 (90)	57 (72.15)	34 (82.92)	0.143
International ADR centre	5 (50)	46 (58.22)	20 (48.78)	0.705
Indian agency involved in ADR	6 (60)	49 (62.02)	17 (41.46)	0.143
ADR definition	9 (90)	67 (84.81)	37 (90.24)	0.389
Meaning of PvPI	8 (80)	65 (82.27)	39 (95.12)	0.044*
National ADR centre	7 (70)	55 (69.62)	26 (63.41)	0.906
Which ADR to be reported	8 (80)	67 (84.81)	31 (75.61)	0.702
HCPs responsible for ADR reporting	9 (90)	74 (93.67)	36 (87.80)	0.883
ADR centre in each hospital	8 (80)	75 (94.94)	33 (80.49)	0.107
Is reporting of ADR necessary	7 (70)	69 (87.34)	27 (65.85)	0.044*
Is there legal consequence of ADR reporting	9 (90)	75 (94.94)	35 (85.36)	0.502
Trained on how to report ADR	10 (100)	70 (88.61)	37 (90.24)	0.378
Seen ADR reporting form	10 (100)	70 (88.61)	37 (90.24)	0.378
Confidentiality to be maintained	6 (60)	60 (75.95)	29 (70.73)	0.599
Ever reported an ADR	1 (10)	4 (5.06)	8 (19.51)	0.036*

\*Significant (calculated by Chi-square test), ADR – Adverse Drug Reaction, HCPs – Health care professionals, PvPI – Pharmacovigilance program of India, KAP – Knowledge, Attitude, Practice

**Table 4: Assessment of knowledge about ADR reporting.**

Knowledge related questions	Correct response N (%)	Incorrect response N (%)
Definition of pharmacovigilance	100 (76.9)	30 (23.1)
Location of International ADR collaborating centre	71 (54.6)	59 (45.4)
Agency in India involved in ADR (drug safety) issues	72 (55.4)	58 (44.6)
Definition of ADR	113 (86.9)	17 (13.1)
Meaning of PvPI	112 (86.2)	18 (13.8)
ADR and PV national coordination centre location	88 (67.7)	42 (32.3)
Which ADR should be reported	106 (81.5)	24 (18.5)

Total 76.9% of the respondents knew the definition of pharmacovigilance, 54.6% knew the location of International ADR collaborating centre, 55.4% knew the name of the agency involved in drug safety issues in India.

The meaning of adverse reaction and PvPI was correct in 86.9% and 86.2% of the study population, respectively. 67.7% and 81.5% could correctly identify the location of national coordination centre, the type of reactions which should be reported, respectively (Table 4).

Total 91.5% responded that healthcare professionals should report an adverse reaction, 89.2% were of the opinion that adverse reaction reporting centre should be established in each hospital, 79.2% agreed that reporting is necessary and 91.5% disagreed that there is a legal consequence of reporting (Table 5).

Total 90% of the respondents had undergone training on reporting. 73.1% were of the opinion that confidentiality is to be maintained while reporting and only 10% have ever reported in present study (Table 6).

Total 49.2% responded that taking care of patients is more vital than reporting. 22.3% did not know how to report and 5.4% did not know where to report. 10% think that reporting is not important.

Total 6.9% and 6.2% feel that no remuneration and legal liability are the factors in nonreporting (Table 7).

**Table 5: Assessment of attitude about ADR reporting.**

Attitude related Questions	Agreed N (%)	Disagreed N (%)
Healthcare professionals responsible for ADR reporting	119 (91.5)	11 (8.5)
Establishing ADR centre in each hospital	116 (89.2)	14 (10.8)
Is reporting of ADR necessary	103 (79.2)	27 (20.8)
Is there legal consequence for ADR reporting?	11 (8.5)	119 (91.5)

**Table 6: Assessment of practice about ADR reporting.**

Practice related Questions	Yes N (%)	No N (%)
Trained on how to report ADR	117 (90)	13 (10)
Seen an ADR reporting form	117 (90)	13 (10)
Confidentiality to be maintained while reporting an ADR	95 (73.1)	35 (26.9)
Ever reported an ADR	13 (10)	117 (90)

**Table 7: Factors affecting nonreporting of an ADR.**

Factors	Respondents N (%)
Did not know how to report	29 (22.3)
Did not know where to report	07 (5.4)
Did not think is important to report	13 (10)
Taking care of patients is more vital than reporting	64 (49.2)
No remuneration	09 (6.9)
Legal liability	08 (6.2)

**Table 8: Different methods to increase reporting of ADRs.**

Methods to increase reporting ADR	Respondents N (%)
Conducting training/workshops/CME	60 (46.2)
Providing acknowledgement receipt to the reporter	24 (18.5)
Appreciation of the reporter	28 (21.5)
Reminders and increased awareness from the ADR monitoring committee	18 (13.8)

Total 46.2% suggested conducting training, workshops, 21.5% need appreciation for reporting, 18.5% seek acknowledgement receipt and 13.8% need increased awareness from the ADR monitoring committee in the form of reminders for improving the rate of spontaneous reporting (Table 8).

## DISCUSSION

Nurses spend maximum time with the patients in delivering quality healthcare, and probably the first to alert the physician on adverse reactions. There are very few studies done only on nursing population in India. Thus, an important reason to include nurses in present study and encourage them for contribution to the reporting system.<sup>16,17</sup> The response rate in present study was 86.67% against 63%, 65% and 67.33% in study done at Mangalore, Delhi and Perambalur, respectively.<sup>18-20</sup>

### Assessment of knowledge

Total 76.9% knew the meaning of pharmacovigilance, as compared to 68.27%, 62.4%, 38.6% and 44.34% by Amrita P et al, Gupta SK et al, Patil AP et al, Kumari S et al, respectively.<sup>19-22</sup> International ADR collaborating centre was known to 54.6%, as compared to 41.6%, 1.48% and 17.39% by Gupta SK et al, Patil AP et al, and Kumari S et al, respectively.<sup>20-22</sup> 55.6% knew the agency in India, which is involved in drug safety issues, as compared to 78.2% and 28.26% by Gupta SK et al, and Kumari S et al, respectively.<sup>20,22</sup>

The meaning of adverse reaction was known to 86.9%, as compared to 51.92% by Amrita P et al.<sup>19</sup> The meaning of PvPI was known to 86.2%, against 75.2% and 79.77% by Gupta SK et al, and Patil AP et al, respectively.<sup>20,21</sup> National adverse reaction collaborating centre was known to 67.7% against only 0.99% by Patil AP et al.<sup>21</sup> The type of adverse reaction to be reported is known to 81.5%, as compared to only 15.2% by Hanafi S et al.<sup>23</sup>

### Assessment of attitude

Total 91.5% responded that health care professionals are responsible for reporting, as compared to 93.25%, 91%, and 80.2% by Scandashree K et al, Hajebi G et al, and Gupta SK et al, respectively.<sup>18,20,24</sup> 89.2% believed that establishing a reporting centre is necessary in each hospital, as compared to 74.3% and 70.86% by Gupta SK et al, and Kumari S et al, respectively.<sup>20,22</sup> Total 79.2% responded that reporting is necessary, which was quite low as compared to 97.1%, 97%, 90.59%, 90%, 94% by Amrita P et al, Gupta SK et al, Patil AP et al, Kumari S et al, and Ganesan S et al, respectively.<sup>19-22,25</sup>

### Assessment of practice

Total 90% were previously trained on reporting, as compared to 53.5%, 70% and 5% by Gupta SK et al, Kumari S et al, and Ganesan S et al, respectively.<sup>20,22,25</sup>

90% have seen a reporting form as compared to 58.4% by Gupta SK et al.<sup>20</sup> Total 73.1% stated that confidentiality is to be maintained while reporting as compared to 62.37% by Patil AP et al.<sup>21</sup>

Only 10% have reported, as compared to 11.1%, 90.38%, 22.8%, 92%, 25% and 45% by Scandashree K et al, Amrita P, Gupta SK et al, Hajebi G et al, Ganesan S et al, and Adiga SMN respectively.<sup>18-24,25,26</sup> In Amrita P et al, and Hajebi G et al, study, nurses have reported 79.81% and 56% of ADR to the physicians respectively.<sup>19,24</sup>

### **Factors affecting nonreporting of an ADR**

Total 22.3% did not know how to report, 5.4% did not know where to report and 10% does not find any necessity to report, as compared with 27.27%, 25.45%, 5.45% by Adiga SMN, respectively.<sup>26</sup>

About 49.2% replied that taking care of patients is more vital than making report which was quite high compared to 23.8% by Gupta SK et al.<sup>20</sup> This corroborates the low reporting rate of adverse reaction in our hospital. 38.26% by Kumari S et al, and 63.63% by Adiga SMN replied lack of time for nonreporting.<sup>22,26</sup> 6.9% replied no remuneration for nonreporting as compared with 51.98%, 31.7%, and 23.47% by Scandashree K et al, Gupta SK et al, and Kumari S et al, respectively.<sup>18,20,22</sup> 6.2% stated legal liability for nonreporting as compared to 14.5% by Adiga SMN.<sup>26</sup>

### **Methods to increase response for voluntary reporting**

Total 46.2% in present study require more training and workshop, as compared to 92.31% by Amrita P et al.<sup>19</sup> Acknowledgement to the reporter and appreciation of the reporter was reported by 18.5% and 21.5% of the study population. 13.5% suggested for reminders and awareness as compared to 82.5% by Adiga SMN.<sup>26</sup> Majority of nurses require training programmes, reminders to improve the spontaneous reporting rate.

### **CONCLUSION**

Majority of nurses have good knowledge on pharmacovigilance and adverse reaction. The concern remains on the low reporting rate. This can be due to their poor attitude towards reporting. Continuous training programmes, and reminders likely to enhance the voluntary reporting from our nursing staffs.

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