

Original Research Article

## **A study on pharmacovigilance awareness among the healthcare professionals in a tertiary hospital, Imphal**

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**Abstract:** Spontaneous adverse drug reaction (ADR) reporting by health professionals is the corner stone of ADR monitoring activity of National Pharmacovigilance Programme. Present study was designed to assess the knowledge, attitude and practices (KAP) of healthcare professionals about Pharmacovigilance in a tertiary hospital, Imphal. A questionnaire based cross-sectional study for a period of one month was conducted among resident doctors, post graduate trainees, MBBS interneers, B.Sc. nursing interneers and staff nurses in RIMS hospital, Imphal. A total of 577 participants were included in the study. Out of 577 participants, 64.5% of the participants knew what Pharmacovigilance was and 66.95% of the participants realised the importance to identify drug safety. Only 35.9% of the participants correctly identified scope of Pharmacovigilance and 74.9% accepted ADR reporting as professional obligation. 96.9% of the participants agreed that Pharmacovigilance should be taught to every healthcare professional. 71.2% of the participants had noticed ADRs during the practice but only 12.7% of them reported the reactions to ADR monitoring centre. The study demonstrated that deficiencies in the knowledge of Pharmacovigilance should be improved among health care professionals. Despite the positive attitude towards Pharmacovigilance, there was huge gap between ADR detected and ADR reporting by the healthcare professionals.

**Keywords:** Adverse drug reaction, Pharmacovigilance, Attitude, Knowledge, Practices, Healthcare professionals.

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### **INTRODUCTION**

All drugs are capable of producing adverse effects. Whenever a drug is given a risk is taken. Adverse effects may develop promptly or after prolonged medication or after stoppage of the drug. The documented incidence of ADRs in various clinical settings ranges from 10-25% [1]. In preclinical trials, result of drug safety and efficacy in animals may not be appropriate to extrapolate in human. Clinical trials are conducted under strictly controlled conditions and usually involve small sample size. The special category subjects e.g. children, elderly, pregnant etc. are included in the later phase. Aggressive marketing strategies and efforts to launch under-evaluated products simultaneously in many countries have increased the risk of ADRs. The preference of many practitioners and patients to newer products over the established ones, increasing accessibility to over-the-counter (OTC) drugs and underreporting of the adverse reactions make the assessment of ADR very difficult [2].

Thus, it is important to identify adverse drug events as early as possible and prevent them to ensure the well-being of the patients. Pharmacovigilance, the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems [1] is an important step for ensuring safety of patients. The monitoring of adverse drug event during treatment is of utmost importance in Pharmacovigilance. Spontaneous reporting of ADRs by the health professionals is the corner stone of the monitoring activity and as such their contribution towards detection of adverse drug reactions – known and unknown is a key to the success of the National Pharmacovigilance Programme [3, 4].

The present study was taken up to assess the knowledge, attitude and practices of pharmacovigilance among the healthcare professionals in a tertiary health care centre in a North-Eastern state of India.

**MATERIALS AND METHODS**

**Study Setting:**

The study was conducted at Regional Institute of Medical Sciences (RIMS) Hospital, a tertiary care centre in Imphal, Manipur, India after getting approval of the Research Ethics Board, RIMS, Imphal.

**Study Design:**

The study was a cross-sectional, non-interventional, observational, questionnaire-based study.

**Study Duration:**

The study was done for a period of one month from September to October, 2016.

**Study Population:**

The study was conducted among the health care professionals - resident doctors, post graduate trainees, MBBS internees, and B.Sc. nursing internees and staff nurses of RIMS, Imphal Manipur. Those who were not willing to participate and those who were on leave during the study period were not included in the study.

**Sampling, Sample size and Data collection:**

Sampling was not done as it was intended to cover all available resident doctors, post graduate trainees, internees and staff nurse in RIMS. All study

participants were contacted directly, explained the purpose of the study and then questionnaires were distributed. Participants were given one hour to fill up the questionnaires. Out of 661 questionnaires distributed, 577 filled up questionnaires were able to be collected.

**Data analysis:**

The data obtained were analysed using Statistical Package for Social Science (SPSS, IBM) version 21. Descriptive statistics like frequencies, percentages were used for baseline characteristics of different variables. Chi square ( $X^2$ ) test was used for testing statistical significance. P value < 0.05 was considered significant.

**RESULTS**

**Response rate:**

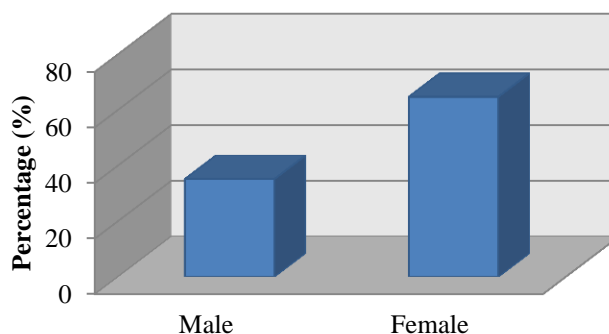
A total 661 questionnaires were distributed among the health care professionals and 577 questionnaires were collected. Response rate is 87.29%.

**Demographic details:**

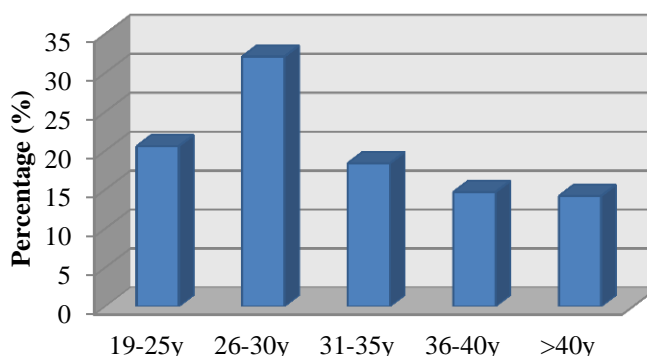
The respondents comprised of staff nurses (52.9%), post graduate students (32.1%), MBBS internees (9.5%), resident doctors and B.Sc. nursing internees. Last two groups contributed 5.5% of the total respondents. The most of health care professionals were female (64.8%) [Table 1, Figure 1, 2, 3].

**Table 1: Demographic details of the study subjects (n=577)**

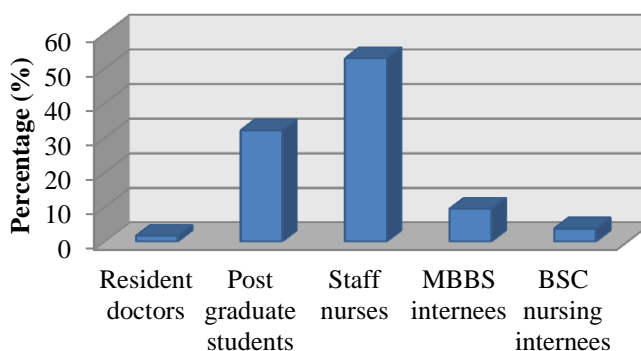
Demographic details	Frequency (%)
<b>Gender</b>	
Male	203 (35.2)
Female	374 (64.8)
<b>Age distribution (Years)</b>	
19-25	119 (20.6)
26-30	185 (32.1)
31-35	106 (18.4)
36-40	85 (14.7)
>40	82 (14.2)
<b>Distribution of healthcare professionals</b>	
Resident doctors	10 (1.7)
Post graduate students	185 (32.1)
Staff nurses	305 (52.9)
MBBS Internees	55 (9.5)
B.Sc. nursing internees	22 (3.8)



**Fig 1: Demographic detail of gender**



**Fig 2: Demographic detail of age (Years)**



**Fig 3: Demographic detail of health care professionals**

**Pharmacovigilance-related Knowledge:**

Regarding the responses to the questions - definition, most important purpose and scope of Pharmacovigilance, the correct responses were obtained from 64.5%, 66.9% and 35.9% of the respondents respectively [Table-2]. 49% of the respondents had no idea that medical device was also included in scope of Pharmacovigilance.

84.2%, 58.4% and 68.3% of the respondents knew about the persons responsible for ADR reporting in hospital, existence of Pharmacovigilance Programme of India (PvPI) and ADR Monitoring Centre (AMC) in their institute respectively. The differences of correct responses among different groups were statistically significant [Table-2].

Regarding partners involved in Pharmacovigilance, criteria for serious adverse events and centre for reporting ADR, 32.9% of the respondents had good knowledge about partners involved, 48.2% about the serious adverse events and 29.5% about the centre for reporting ADR. The statistical analysis revealed significance differences among the respondents in their knowledge relating to the above questionnaires [Table-2]. However, 42.3% of the respondents had no idea about consumer and media were partners in Pharmacovigilance. 23.2% of the respondents did not know that hospitalization and prolongation of hospital stay due to ADR were among the criteria for serious adverse events. Majority of the

respondents (58.4%) preferred the nearest AMC as the reporting centre.

61.7% of the respondents had idea about the timeline to report a serious adverse event. For

identification of rare ADRs, 50.3% of the respondents gave correct answer. Knowledge of different groups of respondents regarding the above two questionnaires were significantly different [Table-2].

**Table 2: Correct responses for knowledge related questions and statistical inference**

Questions	A	B	C	D	E	Overall % knowledge	Statistical inference
Define pharmacovigilance	7 (70)	124 (67)	36 (65.5)	191 (62.6)	14 (63.2)	64.5	$X^2=1.146$ $P > 0.05$
Most important purpose of pharmacovigilance	3 (30)	125 (67.6)	38 (69.1)	206 (67.5)	14 (63.6)	66.9	$X^2=6.468$ $P > 0.05$
Healthcare professionals responsible for ADR reporting in hospital	10 (100)	147 (79.5)	37 (67.3)	270 (88.5)	22 (100)	84.2	$X^2=25.300$ $P < 0.001$
Scope of Pharmacovigilance	4 (40)	75 (40.5)	15 (27.3)	103 (33.8)	10 (45.5)	35.9	$X^2=15.028$ $P > 0.05$
Idea about existence of PvPI	8 (80)	110 (59.5)	22 (40)	188 (61.6)	9 (40.9)	58.4	$X^2=13.759$ $P < 0.01$
Partners in Pharmacovigilance	4 (40)	78 (42.2)	20 (36.4)	78 (25.6)	10 (45.5)	32.9	$X^2=21.133$ $P < 0.01$
A serious adverse event include	9 (90)	109 (58.9)	19 (34.5)	129 (42.3)	12 (54.5)	48.2	$X^2=52.868$ $P < 0.001$
Time line for serious adverse event reporting	4 (40)	78 (42.2)	28 (50.9)	232 (76.1)	14 (63.6)	61.7	$X^2=61.256$ $P < 0.001$
Clinical trial phase for identification of rare ADRs	7 (70)	131 (70.8)	28 (50.9)	121 (39.7)	3 (13.6)	50.3	$X^2=58.302$ $P < 0.001$
Centre for ADR reporting	4 (40)	66 (35.7)	22 (40)	70 (23)	8 (36.4)	29.5	$X^2=17.189$ $P < 0.05$
Idea about existence of AMC in your Institute	8 (80)	129 (69.7)	30 (54.5)	217 (71.1)	10 (45.5)	68.3	$X^2=12.055$ $P < 0.05$

Note: A- Resident doctors; B- Post graduate students; C- MBBS internees; D- Staff nurses; E- B.Sc. nursing internees; Figures in the parenthesis show %

**Pharmacovigilance-related Attitude:**

The study showed that 96% of the respondents felt ADR reporting as a necessity, and 74.9% of the respondents agreed that the reporting should be a professional obligation. Majority of the respondents (96.9%) suggested that Pharmacovigilance should be

taught and 91% felt the need of training to every healthcare professional to improve ADR reporting. But only 58.4% of the respondents had thought of sparing time for ADR reporting. 88.7% of the respondents opined that AMC should be established in every teaching hospital [Table-3].

**Table 3: Positive responses of attitude related questions and statistical inference**

Questions	A	B	C	D	E	Overall % attitude	Statistical inference
Professional obligation towards ADR reporting	6 (60)	147 (79.5)	32 (58.2)	236 (77.4)	11 (50)	74.9	$X^2=19.638$ $P < 0.01$
Regarding necessity of ADR reporting	10 (100)	180 (97.3)	51 (92.7)	296 (97)	17 (77.3)	96	$X^2=23.807$ $P < 0.001$
Pharmacovigilance should be taught to every healthcare professional	10 (100)	178 (96.2)	51 (92.7)	301 (98.7)	19 (86.4)	96.9	$X^2=15.081$ $P < 0.01$
Ever thought of sparing time for reporting ADRs?	4 (40)	86 (46.5)	22 (40)	219 (71.8)	6 (27.3)	58.4	$X^2=51.196$ $P < 0.001$
Regarding need of ADR monitoring centre in every teaching hospital	9 (90)	156 (84.3)	43 (78.2)	286 (93.8)	18 (81.8)	88.7	$X^2=18.538$ $P < 0.05$
Need of training on Pharmacovigilance to improve ADR reporting	9 (90)	164 (88.6)	51 (92.7)	286 (93.8)	15 (68.2)	91	$X^2=18.284$ $P < 0.01$

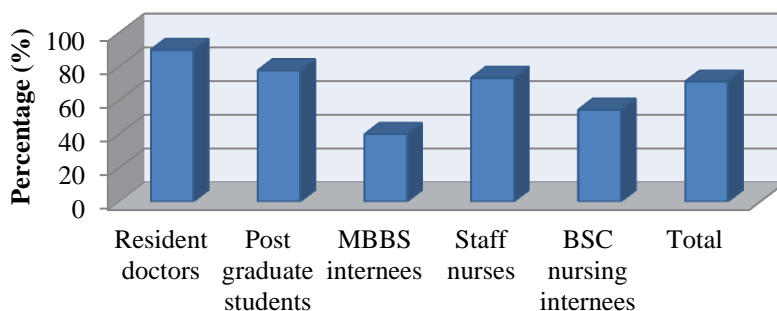
Note: A-Resident doctors; B- Post graduate students; C- MBBS internees; D- Staff nurses; E- B.Sc. nursing internees; Figures in the parenthesis show %

**Pharmacovigilance-related Practice:**

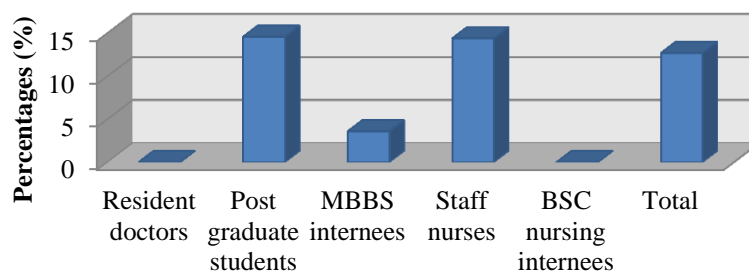
71.2% of the respondents had seen ADRs in their patients [Figure-4] and most of them (95%) had encountered less than 6 ADRs per week. Remaining 1% and 4% of the respondents had seen more than 10 and 6-10 ADRs per week respectively. 31.7% of the respondents had seen ADR reporting form and only 12.7% of the respondents had reported ADR. No ADR had so far been reported by resident doctors and B.Sc.

nursing interneees [Figure-5]. 71.8% of the respondents preferred Telephone or Mobile apps or E Mail to personal submission (25.6%) for ADR reporting to ADR centre [Table-4].

For under reporting of ADRs, 61.4% of the respondents thought that ignorance about ADR reporting was the main factor rather than difficulty to diagnose ADRs (24.3%).



**Fig 4: ADR noticed in patient by health care professionals**



**Fig 5: ADR reported to AMC by health care professionals**

**Table 4: Positive responses of practice related questions and statistical inference**

Questions	A	B	C	D	E	Overall % practice	Statistical inference
Have you ever seen ADRs in your patient during your professional practice?	9 (90)	144 (77.8)	22 (40)	224 (73.4)	12 (54.5)	71.2	$X^2=35.554$ $P < 0.001$
Have you ever seen the ADR reporting form?	5 (50)	55 (29.7)	4 (7.3)	117 (38.4)	2 (9.1)	31.7	$X^2=28.472$ $P < 0.001$
Preference of Telephone/ Mobile apps/E-mail to report ADRs to ADR centre	6 (60)	150 (81.1)	30 (54.5)	215 (70.5)	13 (59.1)	71.8	$X^2=32.069$ $P < 0.001$
Have you ever reported ADR to Pharmacovigilance centre?	0	27 (14.6)	2 (3.6)	44 (14.4)	0	12.7	$X^2=10.181$ $P < 0.05$

Note: A-Resident doctors; B- Post graduate students; C- MBBS interneees; D- Staff nurses; E- B.Sc. nursing interneees; Figures in the parenthesis show %

**DISCUSSION**

In our study, it is found that the awareness about Pharmacovigilance among all the health-care professionals is average. But most of them are not aware of the scope (64.1%), the partners involved (67.1%) in Pharmacovigilance and the centres for ADR

reporting (70.5%). This indicates a serious issue of concern, and immediate measures should be taken to improve the knowledge of Pharmacovigilance among health care professionals. Most of the respondents opine that ADR reporting is necessary and it should be a professional obligation. They also feel that opening of

ADR monitoring centre in every teaching hospital and training on Pharmacovigilance will improve ADR reporting. But only 58.4% of the participants spare time for reporting ADRs encountered in their practice and this is an area where every health professional can do improvements by realising professional responsibilities towards patient care. The ADR reporting by only 12.7% of the participants despite reasonably good knowledge

about the existing AMC (68.3%) and encountered ADRs (71.2%) is an indication that there is huge gap between ADRs experienced and reporting. The lack of understanding regarding the knowledge, attitude and practices of Pharmacovigilance in our study and some other studies conducted in India can be acknowledged [Tables-5, 6, 7].

**Table 5: Comparison of knowledge-related questions with results (%) of published studies from India**

	F	G	H	I	J	K	L
Define Pharmacovigilance	64.5	60.2	62.4	80	61.4	44.34	55.2
Most important purpose of Pharmacovigilance	66.9	59.43	66.3	41	59.6	40.86	28.3
Healthcare professionals responsible for ADR reporting in hospital	84.2	48.72	80.2	NA	57.5	52.6	94.2
Do you know the existence of PvPI	58.4	38.01	75.2	NA	NA	NA	NA

Note: F- Our study; G- Bhopal [5]; H- Perambalur [3]; I- Nalhar [4]; J- Lucknow [6]; K- Delhi [7]; L- Manipal [8].

**Table 6: Comparison of attitude-related questions with results (%) of published studies from India**

	F	G	H	I	J	K	L
Do you think ADR reporting is a professional obligation for you	74.9	48.72	69.3	NA	53.5	52.6	89.4
Do you think reporting of ADR is necessary	96	75.51	97	90	73.2	90	91.8
Do you think knowledge of Pharmacovigilance should be taught to every healthcare professional	96.6	82.39	92.1	79	71.9	87.82	94.1
What is your opinion about establishing ADR monitoring centre in every teaching hospital	88.7	40.56	74.3	55	38.2	70.86	70.6

Note: F- Our study; G- Bhopal [5]; H- Perambalur [3]; I- Nalhar [4]; J- Lucknow [6]; K- Delhi [7]; L- Manipal [8].

**Table 7: Comparison of practice-related questions with results (%) of published studies from India**

	F	G	H	I	J	K	L
Have you ever seen adverse drug reactions in your patient during your professional practice	71.2	52.29	64.4	80	NA	54.34	100
Have you ever seen the ADR reporting form	31.7	19.89	58.4	NA	NA	NA	NA
Have you ever reported ADR to the Pharmacovigilance centre	12.7	6.12	22.8	15	27.63	NA	NA

Note: F- Our study; G- Bhopal [5]; H- Perambalur [3]; I- Nalhar [4]; J- Lucknow [6]; K- Delhi [7]; L- Manipal [8].

Regarding the improvement of ADR reporting, we could collect various suggestions from the participants. These include

- Workshops, seminars, CMEs on Pharmacovigilance
- ADR education to public via radio, TV, newspaper, etc.
- To inform ADRs via phone, Email, SMS to AMC
- Pharmacovigilance classes in medical training
- Coordination of health care staffs

- Surveillance of ADR

**CONCLUSION**

The results of our study indicate that the majority of the health-care professionals have average knowledge, positive attitude about Pharmacovigilance and understand the importance of ADRs reporting. However, the ADR reporting rate is very low. Majority of the participants feel that there is need for Pharmacovigilance awareness programmes for all

health professionals and public to improve ADR reporting.

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