

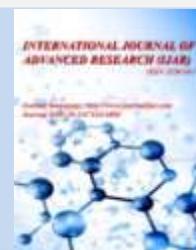


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### RESEARCH ARTICLE

#### EVALUATION OF THE FEEDBACK ON PHARMACOVIGILANCE BASIC AWARENESS PROGRAM AMONGST THE MEDICAL POST GRADUATE RESIDENTS OF A RURAL TEACHING HOSPITAL

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#### Abstract

**Introduction:** The World Health Organization (WHO) defines an Adverse drug reaction (ADR) as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. Adverse drug reactions (ADRs) are a major clinical problem and are main cause of death and serious disease in patients and a key cause of drug attrition in the pharmaceutical industry, as nearly more than 90% of drug molecules do not succeed in preclinical/clinical studies due to a deficiency of safety and efficacy. The chief reasons for withdrawal of already approved drugs are cardiovascular and hepatic adverse effects. The main goal was, our future healthcare providers should have basic pharmacovigilance knowledge, how to detect and prevent ADRs in order to rationally reporting ADRs and preventing serious health problems. The main aim was to sensitize all the health care providers regarding Pharmacovigilance activities.

**Materials & Method:** The present retrospective and observational study was initiated by collecting necessary information about the Pharmacovigilance awareness program conducted during July 2017. The participants (n=47) were second year MD/MS/Diploma post graduate students (Medical), residents of Dhiraj Hospital attached to Smt. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidyapeeth an Institution deemed to be University, Piparia.

**Results & Discussion:** The participants (n=47) rated the quality of presentations and content from excellent to good for both the sessions. With regard to the usefulness of the sessions, it was also rated from excellent to very good. They felt both the sessions were interactive, interesting & useful in all aspects. The quality of presentation was rated as good to excellent. All 47 (100 %) participants reported that it was an excellent workshop with good interactive session and interesting group activity. Majority of participants, 23 (48.93%) found that the workshop would help them to value add in their patient care in future, which implied that workshop was beneficial to convey the importance of national programme to the participants. Forty six (97.87%) participants said that they will like to attend this type of workshop in future also.

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The resource persons through interactive sessions, had given an overview on Pharmacovigilance, which was followed by hands on technique, how to fill ADR forms and group discussions, at the end of each workshop feedback forms were distributed to all participants. Pharmacovigilance workshops were conducted to generate awareness regarding ADR reporting amongst doctors is essential to promote the rational and safe use of medicines.

**Conclusion:** Feedback from the post graduate healthcare professionals plays a key role in the reassurance and augmentation of the quality and their understanding on their role in pharmacovigilance and hands on training in ADR form filling group activity. Further, the study implies that workshop was beneficial to convey the importance of national programme to the participants.

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### **Introduction:-**

The World Health Organization (WHO) defines an Adverse drug reaction (ADR) as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function [1]. Adverse drug reactions (ADRs) are a major clinical problem and are main cause of death and serious disease in patients and a key cause of drug attrition in the pharmaceutical industry, as nearly more than 90% of drug molecules do not succeed in preclinical/clinical studies due to a deficiency of safety and efficacy. The chief reasons for withdrawal of already approved drugs are cardiovascular and hepatic adverse effects. The main goal was, our future healthcare providers should have basic pharmacovigilance knowledge, how to detect and prevent ADRs in order to rationally reporting ADRs and preventing serious health problems [2,3]. Feedback from the post graduate healthcare professionals plays a key role in the reassurance and augmentation of the quality and their understanding on their role in pharmacovigilance and hands on training in ADR form filling group activity.

To encourage ADR reporting amongst healthcare professionals and to ensure patient safety in India, the **Pharmacovigilance Programme of India (PvPI)** was initiated in 2010 by the Central Drugs Standard Control Organization, New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India [4]. More pharmacovigilance awareness programmes are required to develop better understanding and awareness of ADR reporting among healthcare professionals. The main aim of the present study was to sensitize post graduate residents regarding Pharmacovigilance activities [5-10].

### **Materials & Method:-**

The present study was retrospective and observational study. After obtaining prior approval from the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC) and from AMC centre, SBKSMIRC, Piparia, the present observational study was initiated by collecting necessary information retrospectively, about the PV program conducted in July 2017.

The pharmacovigilance state level workshop was organized for second year MD/MS/Diploma post graduate students of 2016 batch and various faculties of medical college, in July 2017. The participants (n=47) were Medical Post Graduate residents and faculties of Smt. B. K. Shah Medical Institute & Research Centre, Sumandeep Vidyapeeth an Institution deemed to be University, Piparia; were from Pharmacovigilance awareness workshop conducted by Dept. of Pharmacology, SBKS MI&RC, SVDU. As the study was retrospective, consent was taken from the AMC centre to use the participants' feedback form data. Descriptive analysis was performed to assess the feedback of the workshop, its best feature, potential drawbacks and areas for improvement.

Based on perception towards 'Pharmacovigilance basic understanding and training on how to fill ADR forms' PV workshop; **feedback form** was distributed to them in the form of hard copy. It included information such as **General information of the participants** such as name, qualification, contact details, designation, subject speciality, name of institute were collected in the feedback format that was distributed to all the participants attending the workshop at the end of the day. Further, **evaluation of the PV workshop sessions** were done based on

questionnaire pertaining to lectures delivered in each session of the workshop, session one was on topic "Pharmacovigilance- an overview", and session two topic was on "How to fill ADR forms". Also, the facility of the venue chosen, hospitality, AV aids were also asked to tick appropriate any one option from excellent, very good, good, average and below average to chose. PV workshop also included **participants' group activity i.e. hands on training to fill up the ADR form**, as one of the interactive session, hence, questions related to usefulness and future outcomes were also asked in the feedback form. These data was collected and entered in Microsoft excel sheet and further statistical analysis was carried out. All calculations were performed using statistical software SPSS version 21.0 computer-based. Data were analyzed by using appropriate analytical tests like chi-square test, t test, or percentile, P values was considered to be significant if less than or equal to 0.05 ( $p \leq 0.05$ ).

### Results and Discussion:-

Total number of participants were forty seven (**n=47**). The participants rated the quality of presentations and content from excellent to good for both the sessions. Session one was on topic "Pharmacovigilance- an overview" and session two topic was on "How to fill ADR forms". With regard to the usefulness of the sessions, it was also rated from excellent to very good. They felt both the sessions were interactive, interesting & useful in all aspects. The quality of presentation was rated as good to excellent.

#### Assessment by participants through feedback form:

Out of total 47 participants (n=47), overall they remarked to be well informative. The students who participated were also given chance to express their views in person, who mentioned that the programme was very interesting and helped them to gain good knowledge about the subject.

The scoring method, scoring from 5 to 0, wherein, 5-excellent, 4-very good, 3-good, 2-aveerge, 1-below average, 0-not useful was employed for statistical analysis. Also, the rating method from Excellent, Very Good, Good, Average and below average was used for evaluation of scientific sessions, where the participants were asked to tick appropriate box. Some questions related to group activity, future aspects were evaluated by either answering from options **YES / NO**.

Feedback was also taken from the participants regarding improvement of their understanding in Pharmacovigilance, improvement of their skills regarding how to fill ADR form, and Value to their patient care in India in future.

Thirty one (**65.95%**) participant had come to know about the workshop by circular, **05 (10.63%)** by organizer and while **10 (21.27%)** participants by colleagues. Forty four (**93.61%**) participant remarked that the workshop was satisfactory.

#### The quality of presentation and the content of two interactive sessions:

The overall evaluation of **session one**, regarding the quality of presentation and its content of topic on Basic of Pharmacovigilance was rated as good to excellent. Out of **47 participants**, **30 (63.82%)** rated the quality of presentation as excellent & **17 (36.17%)** as very good. The presentation content was rated as excellent by **21 (44.68%)**, very good by **24 (51.06%)** and good by **02 (4.25) %**.

Regarding **session two**, on topic hands on technique, how to fill ADR forms; out of **47 participants**, **24 (51.06%)** rated the quality of presentation as excellent, **20 (42.55%)** as very good and **03 (6.38%)** as good, whereas the content was rated as excellent by **22 (46.80%)**, very good by **20 (42.55%)** and good by **04 (8.51%)**.

#### The usefulness of the sessions:

With regard to the usefulness of the sessions, **23 (48.93%)** rated session I as excellent, **23 (48.93%)** very good and below average **01 (2.12%)**. However, the session II was rated as excellent by **24 (51.06%)**, **20 (42.55%)** as very good and **03 (6.38%)** as good.

All **47 (100 %)** participants reported that it was an excellent workshop with good interactive session and interesting group activity. They admitted that the faculties were clear in conveying the essentials of hands on training. They felt both the sessions covered important and useful aspects of pharmacovigilance.

Majority of the participants **23 (48.93%)** felt that their understanding of the subjects was very well improved (scores of 5), and **22 (46.80%)** felt that their understanding of the subjects was improved (scores of 4). Nobody (**0%**) reported absolute non improvement in understanding of the subject.

Similarly, nearly half of participants **22 (46.80%)** of participants reported that their skill had greatly improved (scores of 5), while **20 (42.55%)** of participants found to be improved (scores of 4) in improvement of their skill.

Majority of participants, **23 (48.93%)** found that the workshop would help them to value add in their patient care in future (score of 5 and 4). This implied that workshop was beneficial to convey the importance of national programme to the participants.

#### Hospitality at Workshop:

The evaluation was done by scoring method. Majority of the participants 18 (38.29%) found the service of registration as excellent & 24 (51.06) found it to be satisfactory (score of 3 and 2). Majority 14 (29.78%) of participants found the breakfast as excellent & 19 (40.42%) said it to be satisfactory (score of 3 and 2). The venue with audio/visual aids was found to be excellent by 16 (34.04%) and 20 (42.55%) as satisfactory by participants.

#### The group activity of hands on technique on how to fill ADR forms:

The group activity regarding was found to be excellent by **46 (97.87%)** of the participants.

#### Future interest in Pharmacovigilance:

Forty six (**97.87%**) participants said that they will like to attend this type of workshop in future also. However, **01 (2.12%)** participant did not reply. However majority of the participants have not mentioned how often they would like to attend this type of workshop in future.

**Table no. 1:-** Assessment of resource persons:

Scores n (%) (n=47)							
Session I	5	4	3	2	1	NR	Total
Quality of presentation	<b>30 (63.82)</b>	<b>17 (36.17)</b>	--	--	--	--	47 (100)
Content	<b>21 (44.68)</b>	<b>24 (51.06)</b>	<b>02 (4.25)</b>	--	--	--	47 (100)
Usefulness	<b>23 (48.93)</b>	<b>23 (48.93)</b>	--	--	<b>01 (2.12)</b>	--	47 (100)

Scores n (%)							
Session II	5	4	3	2	1	NR	Total
Quality of presentation	<b>24 (51.06)</b>	<b>20 (42.55)</b>	<b>03 (6.38)</b>	--	--	--	47 (100)
Content	<b>22 (46.80)</b>	<b>20 (42.55)</b>	<b>04 (8.51)</b>	--	--	<b>01 (2.56)</b>	47(100)
Usefulness	<b>24 (51.06)</b>	<b>20 (42.55)</b>	<b>03 (6.38)</b>	--	--	--	47(100)

**5-excellent, 4-very good, 3-good, 2-average, 1-below average, 0- not useful, NR = No Reply**

**Table no. 2:-** Improvement in understanding Pharmacovigilance:

Scores n (%)							
5	4	3	2	1	0	NR	Total
<b>23 (48.93)</b>	<b>22 (46.80)</b>	<b>02 (4.25)</b>	--	--	--	--	<b>47(100)</b>

**Table no. 3:-** Improvement in understanding skills to fill ADR form:

Scores n (%)							
5	4	3	2	1	0	NR	Total

22 (46.80)	20 (42.55)	05 (10.63)	--	--	--	--	47(100)
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**Table no. 4:-** Perception towards value for patient care in future:

Scores n (%)							
5	4	3	2	1	0	NR	Total
23 (48.93)	20 (42.55)	03 (6.38)	--	--	--		47 (100)

**Table no. 5:-** Perception towards Hospitality & registration:

Scores n (%)				
3	2	1	NR	Total
18 (38.29)	24 (51.06)	04 (8.51)		47(100)

**Table no. 6:-** Perception towards audiovisual facilities:

Scores n (%)				
3	2	1	NR	Total
16 (34.04)	20 (42.55)	08 (17.02)	--	47(100)

3 - Excellent, 2 - Satisfactory, 1- Not Satisfactory, NR = No Reply

**Table no. 7a:-** Understanding in Group activity – Hands on technique:

Yes (%)	No (%)	NR (%)	Total (%)
46 (97.87)	01 (2.12)		47(100)

**Table no. 7b. Faculties conveying skill – Hands on technique:**

Yes (%)	No (%)	NR (%)	Total (%)
47 (100)	-		47(100)

**Table no. 8:-** Future perception about attending PV programme:

Yes (%)	No (%)	NR (%)	Total (%)
46 (97.87)	-	01 (2.12)	47(100)

**Conclusion:-**

Feedback from the post graduate healthcare professionals plays a key role in the reassurance and augmentation of the quality and their understanding on their role in pharmacovigilance and hands on training in ADR form filling group activity. Further, the study implies that workshop was beneficial to convey the importance of national programme to the participants.

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