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Assessment of Knowledge, Attitude and Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India

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Abstract: *The Study entitled "Assessment of Knowledge, Attitude and perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India" was designed to assess the awareness of Pharmacovigilance and ADR reporting, and to evaluate the impact of an educational intervention. A validated (pilot study) self administered (KAP) Knowledge, attitude, perception survey questionnaire was used in the study. This prospective knowledge attitude practice (KAP) questionnaire study, of 6 month duration included a total of 225(90%) participants out of 250. An interactive educational intervention was designed for all participants of pre-KAP questionnaire survey. The impact of effectiveness of educational intervention among the pharmacy students was evaluated by means of post-KAP questionnaire survey. The paired t-test and chi-square test in GraphPad InStat was used for statistical calculation. The overall response rates between pre intervention and post intervention was statistically significant (P< 0.001) shows effectiveness of educational intervention for improving awareness of pharmacovigilance and ADR reporting among the participants. The study concluded that imparting the knowledge and awareness of Pharmacovigilance among the pharmacy students by means of continuous educational intervention would bring up updated knowledge and practice in drug safety and rational use.*

Keywords: *ADR reporting, Continuous Pharmacy Education, KAP questionnaire, Pharmacovigilance, Pharmacy Students.*

I. Introduction

The safety of patients and the safe use of medicines are high requisitions in the modern world. In 1968, the first practical international co-operation in drug monitoring was established. The ideas came up as a consequence of the so called thalidomide tragedy. In the 1960's it was discovered that if thalidomide is ingested by mothers during pregnancy limb deformities in babies may occur. This incident became the modern starting point of a science focusing on patient problems due to medicinal use. Medication safety is a more significant issue, because of immense competition among pharmaceutical manufacturers; medicinal products may be registered and marketed in many countries simultaneously. As a result, adverse reactions may not always be readily identified and so are not monitored systematically.

Pharmacovigilance is a systematic and structured process for the monitoring and detection of adverse drug reactions (ADRs) in a given context [1]. Pharmacovigilance has constantly grown its importance in last 15 years, relating to the absolute amount of adverse drug reactions (ADRs) and to the fact of several hospital admissions are due to ADRs [4, 5]. Pharmacovigilance is an arm of patient care and surveillance. It aims at getting the best outcome from treatment with medicine.Adverse drug reactions (ADRs) are common causes of morbidity and mortality in both hospital and community settings. Adverse drug reactions (ADRs) are global problems of major concern. They affect both children and adults with varying magnitudes; causing morbidity and mortality [2-3, 7-8]. ADRs are responsible for about 5% to 20% of hospital admissions [2, 3].

World Health Organization (WHO) defines Pharmacovigilance "as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems [6].Definitions of Adverse Drug Reactions (ADR) exist, including those of the World Health Organization (WHO) [6], Karch and Lasagna and the Food and Drug Administration (FDA).

World Health Organization (WHO) defines ADR as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function".

Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare professionals as well as attitude that are associated with high degree of underreporting [9-14].Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The Pharmacovigilance Programme of India (PvPI) like most others around the world suffers from underreporting of ADRs by the healthcare professionals; this can delay the detection of important ADRs.However, the Indian national Pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India [15].

Assessment of awareness of Pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions.Although previous studies indicated that pharmacists are pivotal players in ADR monitoring and reporting, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries, drug regulatory bodies responsible for assessing ADRs [16, 17].

As drug experts, pharmacists should be equipped with the skills to prevent, identify, and resolve drug related problems and counsel patients on drug therapy [18]. The involvement of pharmacists in pharmacovigilance programs is considered to be vital.Modern Pharmacists consider Pharmaceutical care as their prime focus and play an important role in patient care. Ensuring the safe use of drugs is a combined responsibility of the healthcare team that includes Doctors, Nurses, Pharmacists and other supporting staff [19].

As future pharmacy practitioners, pharmacy students need to be well trained on how to recognize, prevent and report ADRs. Therefore, the aim and objective of this study was to evaluate the perceptions of and knowledge about Pharmacovigilance and ADR reporting among pharmacy students at pharmacy colleges in South India by an interactive educational module as an intervention.

II. Methodology

2.1 Study design and site:

The six months prospective Knowledge Attitude Practice (KAP) Questionnaire based study was carried out in one of the reputed pharmacy institute of Andhra Pradesh, Raghavendra Institute of Pharmaceutical Education and Research, Andhra Pradesh, India, from January to June 2013.

2.2 Study sample:

A total of 225 students participated in the study, and they comprised of 111 male and 114 females. The study criteria included students of M.Pharmacy(Pharmaceutics, Pharmacology & Analysis Departments), Pharm.D (Doctor of Pharmacy) both regular(IV, V, and VI) and post baccalaureate (PB), and final year students of B.Pharmacy.

2.3 Design of Questionnaire:

The questionnaire was a 30 item inventory titled Standard KAP Questionnaire, the items were generated from the literature and adaptation from previous studies and a two step validation process was followed for its accuracy and uniqueness.

Initially, the questionnaire comprised of 36 inventories, modified to 30 in final by 02 step validation process.

In step 01, Questionnaire Validation three pharmacy lecturers with experience in drug use research and ADR reporting studies were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire (limitations on questionnaire was a feedback which was rectified by eliminating 6 questions which was felt more complex for the participants). The observations and comments of the lecturers were taken in to the account.

In step 02, Questionnaire validation to test the validity and reliability of the questionnaire, the survey form was pilot tested by administering it to sample of 15 pharmacy students who did not participate in the study. The overall Cronbach's alpha value calculated was 0.72, which required no further modifications in questionnaire.

The final KAP questionnaire (Annexure - 01) consisted of 30 questions out of which:

Section A: Includes 20 questions related to basic knowledge and information about pharmacovigilance.

Section B: Includes 05 questions related to student's attitude.

Section C: Includes 05 questions related to perception regarding identification of ADR and reporting nature.

2.4. Data collection:

Initially Pre-KAP questionnaire was administered and briefed to all participants about the purpose of the study and asked to submit the same. The Pre-KAP questionnaire was analyzed question wise and their percentage value was calculated. An interactive educational intervention was designed separately for all participants of Pre-KAP questionnaire survey in order to facilitate the transfer of knowledge of pharmacovigilance program. The educational intervention consisted of a theoretical presentation on what is pharmacovigilance, adverse drug reactions, history of pharmacovigilance, classification of ADRs, incidence of ADRs, mechanism of ADRs, role of HCP (health care professionals in-specific pharmacists), reporting of

suspected adverse drug reaction followed by economic and epidemiological importance of reporting the ADRs and its effect on patient safety and Classification of ADRs (i.e. in terms of causality assessment, seriousness and severity, ADR reporting cards from various countries, ADR alert cards). After the interactive educational intervention program on pharmacovigilance, all participants of Pre-KAP questionnaire in the study was administered with Post-KAP questionnaire and it was analyzed, question wise and their responses were documented.

2.5. Data Analysis and Statistics:

The filled KAP questionnaires were evaluated as per the study objectives. The various parameters such as sex distribution, professional status, educational qualifications, and the KAP scores were analyzed. The data obtained were entered in Microsoft excel spread sheet and evaluated.To measure changes in the awareness of pharmacovigilance among the pharmacy students between pre-intervention and post-intervention and to evaluate the impact of effectiveness of educational intervention among the pharmacy students, the chi-square test was used to compare the difference in correctness for each question.All results attained were entered in Microsoft excel and the statistical calculations were executed using GraphPad Instat Version 3.06. The level of statistical significance was set at $p<0.05$.

III. Results

The present study involved 225 (90%) pharmacy students out of 250, who participated and responded. Demographic details of the participants involved in the study was categorized based on gender distribution, educational qualification, and professional status, the results of which were thoroughly analyzed and reported in Table. 1.

Table. 1. Demographic detail of the participants

S. no	Demographic details	No. of Participants (n = 225)		
01	Gender Distribution	Male 111 (49.3%)	Female 114 (50.7%)	
02	Education Qualification	No. of students (n = 225)	Gender distribution	
			Male	Female
	A. B. Pharmacy	69 (30.67%)	27 (39.1%)	42 (60.8%)
	B. M. Pharmacy	55 (24.44%)	22 (40%)	33 (60%)
	C. Pharm. D	79 (35.11%)	45 (56.9%)	34 (43.1%)
	D. Pharm. D (*post baccalaureate*)	22 (9.78%)	17 (77.3%)	05 (22.7%)
03	Professional Status	Pharmacy Students		

The response of the study was evaluated by administering a standard KAP Questionnaire to all the 225 participants, to assess their knowledge attitude and perception/practice towards pharmacovigilance and ADR reporting by comparative study between Pre-KAP & Post-KAP percentage of positive responses.

All the values and percentage of positive and negative responses for the KAP questionnaire, (Pre-KAP & Post-KAP) comprising of 30 questions was evaluated and tabulated in Table. 2.

Table. 2. Knowledge, attitude, perception of pharmacy students towards Pharmacovigilance& ADR reporting Questionnaire before & after educational intervention.

Q. no	K A P Items	Pre – KAP responses (%) N = 225	Post – KAP responses (%) N = 225	*p- value*
01.	Pharmacovigilance is the study that relates to			
	Safe, effective, appropriate and economic use of medicines	13 (5.88%)	03 (1.33%)	
	Therapeutic drug monitoring	25 (11.11%)	05 (2.22%)	
	Detection, assessment, understanding & prevention of adverse effects*	174 (77.33%)	209 (92.88%)	<0.001
	All.	13 (5.88%)	08 (3.55%)	
02.	The functions of Pharmacovigilance are:			
	Detection and study of ADRs.	63 (28%)	26 (11.55%)	
	Measurement of risk and effectiveness of drug use.	11 (4.88%)	13 (5.77%)	
	Dissemination of ADR information and education	11 (4.88)	13 (5.77%)	
	All of the above.*	140 (62.2%)	173 (76.83%)	<0.001

03.	Pharmacovigilance includes:			
	Drug related problem.	32(14.2%)	26 (11.55%)	
	Herbal products	19(8.44%)	11 (4.9%)	
	Medical devices & vaccines.	40(17.77%)	26 (11.55%)	
	All.*	134 (59.55%)	162 (72%)	0.007
04.	National Pharmacovigilance Programme (NPP) of India was officially inaugurated in the year:			
	Ghaziabad, 2002	21 (9.33%)	04 (1.77%)	
	Mumbai, 2008	18 (08%)	06 (2.66%)	
	New Delhi, 2004*	154 (8.44%)	212 (94.22%)	<0.001
	Kolkata, 2006	32 (14.22%)	03 (1.33%)	
05.	National pharmacovigilance program in India is governed by:			
	CDSCO under the aegis of Health and Family Welfare*	14 (6.22%)	225 (100%)	<0.001
	Medical Council of India & ICMR	33 (14.66%)	00	
	Pharmacy Council of India	157 (9.77%)	00	
06.	Pharmacovigilance program in India comprises of how many members			
	17	16 (7.11%)	08 (3.55%)	
	13	193 (85.77%)	13 (5.77%)	
	10*	13 (5.77%)	201 (89.33%)	<0.001
	11	03 (1.33%)	03 (1.33%)	
07.	The International centre of Adverse Drug Reaction monitoring is located in			
	United States of America	97 (43.11%)	03 (1.33%)	
	France	27 (12%)	00	
	Australia	49 (21.7%)	00	
	Sweden*	52 (23.11%)	222 (98.66%)	<0.001
08.	AIIMS New Delhi is a:			
	Peripheral pharmacovigilance centre.	13 (5.77%)	02 (0.88%)	
	Zonal pharmacovigilance centre.*	25 (11.11%)	209 (92.88%)	<0.001
	Regional pharmacovigilance centre.	94 (41.77%)	05 (2.22%)	
	National pharmacovigilance centre.	93 (41.33%)	09 (4.0%)	
09.	Hierarchy of Pharmacovigilance centers in India comprises of following:			
	Zonal, regional & peripheral.*	86 (38.22%)	184 (81.77%)	<0.001
	Peripheral, zonal & regional	41 (18.22%)	11 (4.88%)	
	Regional, zonal & peripheral.	65 (28.88%)	12 (5.33%)	
	None of the above	33 (14.66%)	18 (8.0%)	
10.	One among these is a regional pharmacovigilance centre:			
	Kasturba Hospital Manipal.	11 (4.88%)	02 (0.88%)	
	JIPMER, Pondicherry*	13 (5.77%)	211 (93.77%)	<0.001
	JSS Medical College & Hospital, Mysore	90 (8.44)	04 (1.76%)	
	CMC, Vellore.	111 (49.33%)	08 (3.55%)	
11.	The order ADR report submission is:			
	PPC – RPC – ZPC*	54 (24.0%)	162 (72.0%)	<0.001
	RPC – PPC – ZPC	69 (30.66%)	21 (9.33%)	
	ZPC – RPC – PPC	32 (14.22%)	24 (10.66%)	
	Any order.	70 (31.11%)	18 (8.0%)	
12.	Peripheral centers in National Pharmacovigilance India			
	27	76 (33.77%)	46 (20.44%)	
	26	45 (20.0%)	67 (29.77%)	
	28*	56 (24.88%)	140 (62.22%)	<0.001
	29	48 (21.33%)	28 (10.66%)	
13.	The chairman of Pharmacovigilance program in India			
	DCGI (Drug Controller General of India).*	54 (24.0%)	188 (83.55%)	<0.001
	Scientific Director, Indian Pharmacopeia Commission, Ghaziabad.	111 (49.33%)	23 (10.22%)	
	Nominee of Director General, ICMR	34 (15.11%)	10 (4.44%)	
	Nominee of Pharmacy Council of India	26 (11.55%)	04 (1.76%)	
14.	ADR reporting form are periodically reviewed by			
	National Advisory Committee.*	66 (29.33%)	175 (77.77%)	<0.001
	National Co-coordinating Committee.	78 (34.66%)	56 (24.88%)	
	Steering Committee	25 (37.77%)	18 (08)	
	All of the above	56 (24.88%)	24 (10.66%)	
15.	According to Wills & Brown, how many types of ADRs are classified			
	06	54 (24.0%)	36 (16.0%)	
	07	33 (14.66%)	21 (9.33%)	
	08	87 (38.66%)	19 (8.44%)	
	09*	51 (22.66%)	149 (66.22%)	<0.001

16.	Match the following ADRs: Streptomycin – Phocomelia Thalidomide – Psychosis Ofloxacin – Deafness			
	ii, i & iii.	49 (21.77%)	25 (11.11%)	
	iii, ii & i	65 (28.88%)	11 (4.88%)	
	iii, i & ii.*	76 (33.77%)	189 (84%)	<0.001
	None of the above.	35 (15.55%)	00	
17.	ADRs which are independent can be treated:			
	By withdrawing the drug.*	146 (64.88%)	203 (90.22%)	<0.001
	By reducing the dose	54 (24.0%)	18 (8.0%)	
	Replacing the medications.	25 (11.11%)	04 (1.77%)	
	All of the above	00	00	
18.	Augmented drug reaction is			
	Dose dependent, common in occurrence, rarely fatal.*	129 (57.33%)	197 (87.55%)	<0.001
	Dose independent, comparatively rare in occurrence, more fatal.	87 (38.66%)	28 (12.44%)	
	Both of above.	05 (2.22%)	00	
	None of the above	04 (1.76%)	00	
19.	Which one of the following is the "WHO online databases" for reporting ADRs			
	ADR advisory committee.	86 (38.22%)	11 (4.88%)	
	Medsafe	19 (8.44%)	9 (4.0%)	
	Vigibase.*	57 (25.33%)	199 (88.44%)	<0.001
	Med watch	63 (28.0%)	06 (2.66%)	
20.	Match the ADR reporting system to the respective countries: Yellow card - India Green card - Australia ADR reporting form - UK Blue card - Scotland			
	iii, iv, i ii*	45(20%)	178(79.11%)	<0.001
	iv. iii, ii, i	62(27.55%)	32(14.22%)	
	ii, i, iii, iv	106(47.11%)	25(11.11%)	
	i, ii, iii, iv	12(5.33%)	10(4.44%)	
21.	The health care professionals responsible for ADR reporting in a hospital is/are:			
	Doctor	57(25.33%)	01(0.44%)	
	Pharmacist	146(64.88%)	19(8.44%)	
	Nurses	12(5.33%)	00	
	All of the above*	10(4.44%)	205(91.11%)	<0.001
22.	Do you think reporting is a professional obligation to you			
	Yes*	90(40%)	187(83.11%)	<0.001
	No	76(33.77%)	32(14.22%)	
	Don't Know	53(23.55%)	00	
	Perhaps	06(2.66%)	06(2.66%)	
23.	What is your opinion about establishing ADR monitoring centre in every hospital:			
	Should be in every hospital.*	115(51.11%)	185(82.22%)	<0.001
	One in a city is sufficient	70(31.11%)	12(5.33%)	
	Not necessary in every hospital	45(20%)	27(12%)	
	Depends on bed size	05(2.22%)	01(0.44%)	
24.	Do you think reporting of ADRs is necessary			
	Yes*	205(91.11%)	225(100%)	<0.001
	No	20(8.88%)	00	
25.	Do you think Pharmacovigilance should be taught in detail to healthcare professionals:			
	Yes*	215(95.55%)	224(99.55%)	0.014
	No	10(4.44%)	01(0.44%)	
26.	Have you ever come across with an ADR			
	Yes*	69(30.66%)	135(60%)	<0.001
	No	156(69.33%)	90(40%)	
27.	Have you ever been came across educational session in specific about pharmacovigilance:			
	Yes*	76(33.77%)	225(100%)	<0.001
	No	149(66.22%)	00	

28.	Have you anytime read any article on prevention of ADRs:			
	Yes*	18(8%)	20(8.88%)	0.865
	No	207(92%)	205(91.11%)	
29.	Have you ever been trained on how to report ADRs:			
	Yes*	47(20.88%)	225(100%)	<0.001
	No	178(79.11%)	0	
30.	Non medical person can report ADR to a nearby Healthcare professional			
	Yes*	58(25.77%)	221(98.22%)	<0.001
	No	167(74.22%)	04(1.77%)	

Correct Response*

P < 0.001- (comparison between the pre- KAP and Post- KAP responses).

From the above Results, it was analyzed that the response rate was statistically more significant with a p- value of p<0.001 for most of all the questions.

IV. Discussion

To the best of our knowledge, this was the first study in India that evaluated the knowledge, attitude, perception and practice of Pharmacovigilance among the pharmacy students, in a pharmacy Institute of South India (Andhra Pradesh). The study among the pharmacy students (UG, PG and Pharm.D) showed an overall response rate of 90%, this numeral can be regarded as very high, especially when compared with those of other studies on the same topic carried out among pharmacy students. The response rate attained was within the accepted range for survey research. In order to maximize the response rate and minimize response bias, the questionnaire was administered personally to the participants by the facilitator [20, 21].

The study showed that participants (pharmacy students) who attended the interactive educational intervention session on Pharmacovigilance and ADR reporting were much satisfied, and considered more effective and valuable.In our study, one focus of educational intervention was to increase the participant's (pharmacy students) awareness to Pharmacovigilance topics, regulatory body responsible for monitoring of ADRs, and the International- scenario on Pharmacovigilance. This educational intervention program encouraged the participants (pharmacy students) to pursue career in Pharmacovigilance as their future perspective.

This was demonstrated by an increase in the positive response in pre and post-KAP Questions (1 to 20) of the standard KAP questionnaire. Evidently, the documented results of question 05, was 6.22% to 100% after the intervention, which strongly suggested pharmacists are in need of information regarding the Pharmacovigilance Program of India (PVPI).

Question 13 from table 02 shows that 24% before pre-KAP to 83.55% post-KAP suggests that there is great need to create awareness and promote the governing authorities of PVPI, India. Question 07 & 08 from table 02 framed to obtain the information about the International and National scenario on ADR reporting system, where there was an increased positive response rate of 23.11% before to 98.66% after the educational intervention program as pre-KAP and post-KAP values respectively & 11.11% before to 92.88% after the intervention. The result strongly suggests educating pharmacy students about the reporting systems of ADRs both of National and International standards [21]. The study secondarily focused on improvising the approach on Pharmacovigilance and ADR reporting among the pharmacy students, which was attained to the optimum best by comparing the positive responses of both pre-KAP and post-KAP values and it was statistically significant. Question 21and 24 of table 02 emphasized on role of health care professionals on ADR reporting, for which the comparativeness with educational intervention in between pre-KAP and post-KAP defined effective and statistically significant.

Question 21 from table 02 showed that 4.44% before pre-KAP to 91.11% post-KAP strongly suggests that there is a great need to create promotion and awareness on ADR reporting among pharmacy students. The study finally focused on assessing the perception and practice of Pharmacovigilance and ADR reporting in the participants (pharmacy students), which was attained to an optimum best with 90% overall, with an exceptional of statistical insignificant response for question 28, which strongly suggests that students and professionals of pharmacy field to attend regularly the continuing pharmacy education programs on Pharmacovigilance [22]. Question 26 from table 02 shows response rate from 30.66% pre-KAP to 60% post-KAP which strongly suggests that the information, updation and practical knowledge on ADR were deficit.

Question 27 and question 29 from table 02 shows that there was reduced exposure on pharmacovigilance and ADR reporting from participants, due to lack in availability of facilitators expertise in delivering education sessions on pharmacovigilance. This study overcomes the above mentioned limitation to satisfactorial extent, with significant positive and statistical responses.

V. Conclusion

In conclusion, the results of the present study demonstrates that an educational intervention can increase awareness of pharmacovigilance among the participants (pharmacy students) and incorporate this gained knowledge of pharmacovigilance for opting career and routine clinical practice.

This study has important limitation that the number of students participated in this study was relatively small considering the number of students currently enrolled in the study site. Therefore, these results may not necessarily be extrapolated to all pharmacy students and pharmacy Institute. We recommend that several such studies of similar kind should be conducted among other Institutions so as to develop strategies to improve the knowledge, attitude and perception of pharmacovigilance in India.

This survey on pharmacovigilance and ADR reporting among pharmacy students in south India suggests that the pharmacy students in this country may lack in-depth understanding of the facts about ADR reporting and may need more information on the National Pharmacovigilance System and ADR reporting process. Pharmacy student's education should include topics related to the methods of detecting, preventing, and reporting of ADRs to enable and play vital role in prevention of ADRs through their interactions with both prescribers and patients.

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Annexure 1

KAP (Knowledge, Attitude &Perception) Questionnaire

01. Pharmacovigilance is the study that relates to:
- ☐ Safe, effective, appropriate and economic use of medicines.
- ☐ Therapeutic drug monitoring.
- ☐ Detection, assessment, understanding & prevention of adverse effects.
- ☐ All.

02. The functions of Pharmacovigilance are:
- ☐ Detection and study of ADRs.
- ☐ Measurement of risk and effectiveness of drug use.
- ☐ Dissemination of ADR information and education.
- ☐ All of the above.

03. Pharmacovigilance includes:
- ☐ Drug related problem.
- ☐ Herbal products
- ☐ Medical devices and vaccines.
- ☐ All.

04. National Pharmacovigilance Programme (NPP) of India was officially inaugurated in the year:
- ☐ Ghaziabad, 2002
- ☐ New Delhi, 2004
- ☐ Mumbai, 2008
- ☐ Kolkata, 2006

05. National pharmacovigilance programme in India is governed by:
- ☐ CDSCO under the aegis of Health and Family Welfare.
- ☐ Medical Council of India & ICMR.
- ☐ Pharmacy Council of India.
- ☐ None of the above.

06. Pharmacovigilance programme in India comprises of how many members:
- ☐ 17
- ☐ 13
- ☐ 10
- ☐ 11

07. The International centre of Adverse Drug Reaction monitoring is located in:
- ☐ United States of America
- ☐ Australia
- ☐ France
- ☐ Sweden

08. AIIMS New Delhi is a:
- ☐ Peripheral pharmacovigilance centre.
- ☐ Zonal pharmacovigilance centre.
- ☐ Regional pharmacovigilance centre.
- ☐ National pharmacovigilance centre.

09. Hierarchy of Pharmacovigilance centres in India comprises of following:
- ☐ Zonal, regional & peripheral.
- ☐ Peripheral, zonal& regional.
- ☐ Regional, zonal& peripheral.
- ☐ None of the above.

10. One among these is a regional pharmacovigilance centre:
- ☐ Kasturba Hospital Manipal.
- ☐ JIPMER, Pondicherry.
- ☐ JSS Medical College & Hospital, Mysore.
- ☐ CMC, Vellore.

11. The order ADR report submission is:
☐ PPC – RPC – ZPC.
☐ RPC – PPC – ZPC.
☐ ZPC – RPC – PPC. ☐ Any order.

12. Peripheral centres in National Pharmacovigilance India:
☐ 27 ☐ 26 ☐ 28 ☐ 29

13. The chairman of Pharmacovigilance programme in India:
☐ DCGI (Drug Controller General of India).
☐ Scientific Director, Indian Pharmacopeia Commission, Ghaziabad.
☐ Nominee of Director General, ICMR.
☐ Nominee of Pharmacy Council of India.

14. ADR reporting form are periodically reviewed by:
☐ National Advisory Committee.
☐ National Co-ordinating Committee.
☐ Steering Committee.
☐ All of the above.

15. According to Wills & Brown, how many types of ADRs are classified:
☐ 6 ☐ 7 ☐ 8 ☐ 9

16. Match the following ADRs:
i. Streptomycin – Phocomelia
ii. Thalidomide – Psychosis
iii. Ofloxacin – Deafness
☐ ii, i & iii.
☐ iii, ii & i.
☐ iii, i & ii.
☐ None of the above.

17. ADRs which are independent can be treated:
☐ By withdrawing the drug.
☐ By reducing the dose.
☐ Replacing the medications.
☐ All of the above.

18. Augmented drug reaction is:
☐ Dose dependent, common in occurrence, rarely fatal.
☐ Dose independent, comparatively rare in occurrence, more fatal.
☐ Both of above.
☐ None of the above.

19. Which one of the following is the "WHO online databases" for reporting ADRs:
☐ ADR advisory committee.
☐ Medsafe.
☐ Vigibase.
☐ Med watch.

20. Match the ADR reporting system to the respective countries: (write the number in appropriate boxes)

i.	Yellow card	☐	India
ii.	Green card	☐	Australia
iii.	ADR reporting form	☐	United Kingdom
iv.	Blue card	☐	Scotland

21. The health care professionals responsible for ADR reporting in a hospital is/are:
☐ Doctor ☐ Pharmacist ☐ Nurses ☐ All of the above

22. Do you think reporting is a professional obligation to you:
☐ Yes ☐ No ☐ Don't Know ☐ Perhaps

23. What is your opinion about establishing ADR monitoring centre in every hospital:
☐ Should be in every hospital.
☐ One in a city is sufficient.
☐ Not necessary in every hospital.
☐ Depends on bed size.

24. Do you think reporting of ADRs is necessary:
☐ Yes ☐ No

25. Do you think Pharmacovigilance should be taught in detail to healthcare professionals:
☐ Yes ☐ No

26. Have you ever come across with an ADR:
☐ Yes ☐ No

27. Have you ever been trained on how to report Adverse Drug Reaction:
☐ Yes ☐ No

28. Have you anytime read any article on prevention of ADRs:
☐ Yes ☐ No

29. Have you ever been trained on how to report ADRs:
☐ Yes ☐ No

30. Non medical person can report ADR to a nearby Healthcare professional:
☐ Yes ☐ No

Participant's details:

Name of the student	
Gender	
Professional status	
Educational qualification	