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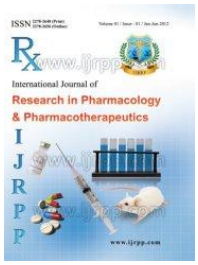

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Impact of educational intervention on knowledge, attitude, perceptions of pharmacovigilance and adverse drug reactions in fifth term medical students and their feed back

Harish. G. Bagewadi[*1], Venkatadri.T.V[2], Swapna. R. Nayaka[3]

**[1]Asst. Professor, [2]Professor & HOD, [3]Asst. Professor - Department of Pharmacology, MVJ Medical College & Research Hospital, Bangalore, India -562114*

***Corresponding author: Harish. G. Bagewadi**

E-mail id: harish2957@gmail.com

ABSTRACT

Aim of the study-The Study was designed to assess the awareness of Pharmacovigilance and Adverse Drug Reaction (ADR's) reporting and to evaluate the impact of an educational intervention.

Materials and methods-This was a questionnaire based pre- and post-test educational interventional study. Students were given handouts containing information about pharmacovigilance and ADR's reporting one week before the educational intervention. A pre-validated 20-point questionnaire on (KAP) Knowledge, attitude, perceptions about Pharmacovigilance and Adverse Drug Reaction (ADR's) Reporting was distributed to 5th term medical students (n=47). An interactive educational intervention (Power point presentation) was designed. The chi-square test and unpaired paired t-test was used for statistical calculation.

Results- The overall response rates were expressed as percentages, Mean±SD. The Knowledge, attitude and perceptions of pharmacovigilance and adverse drug reactions when compared before (pre-KAP) and after (post-KAP) the educational intervention, the correct response rates were found to be statistically significant (P<0.001).The feedback from the students was encouraging, handouts before the lecture classes helped them to easily grasp the pharmacovigilance and adverse drug reactions concepts better during lectures.

Conclusion-The study concluded that imparting the knowledge about pharmacovigilance and ADR's reporting promotes drug safety and rational use of medicines in future.

Keywords: Continuous medical education, Pharmacovigilance, ADR's reporting, KAP questionnaire.

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 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 [1,2]. 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. ADRs are responsible for about 5% to 20% of hospital admissions [3, 4]. World Health Organization (WHO) defines ADR's 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 [5-10]. Assessment of awareness of Pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Ensuring the safe use of drugs is a combined responsibility of the healthcare team that includes Doctors, Nurses, Pharmacists and other supporting staff [11]. As future medical practitioners, medical 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 knowledge, attitude and the perceptions about Pharmacovigilance and ADR's reporting among medical students at medical college in south India by an interactive educational module as an intervention.

MATERIALS AND METHODS

The study was conducted at MVJ medical college and research hospital, Bangalore. Permission was duly taken from Institutional Ethics Committee to conduct the study. This was a prospective, knowledge, Attitude and Practice (KAP) questionnaire based study. Fifth term (n=47) medical students, were participated in the study. Before the educational intervention was conducted, students were given handouts containing information about pharmacovigilance and ADR's reporting one week before the intervention. Semi-structured, pre-validated, questionnaire was used for data collection as a research tool. A structured questionnaire was designed after minor modifications from the work of V. Lokesh Reddy et al [12] and Radhakrishnan Rajesh et al [13]. The KAP questionnaire (Annexure -01) consisted of 20 questions about pharmacovigilance and ADR's reporting nature. Out of which, 11 questions were related to knowledge, 05 questions were related to attitude, 04 questions were related to perception. The correct responses were scored 1 point and wrong responses were given zero point for knowledge related questions and practice related questions. The attitude related questions were scored based upon the participant's degree of agreement using Likert scale. The score was as following; "0"– strongly disagree, "1" – disagree, "2"- uncertain, "3"- agree and "4"-strongly agree. In order to preclude any potential bias, the disclosure of name of the responder was made optional.

Before the start of educational intervention, initially all the students were briefed about the purpose of the study, student's consent was taken; later pre-KAP questionnaire was administered and asked to submit the same. An interactive educational intervention was designed in the form of power point presentation for one hour by trained faculty to all participants of Pre-KAP questionnaire survey in order to facilitate the transfer of knowledge of pharmacovigilance and ADR's reporting. The educational intervention consisted of a theoretical presentation on what is pharmacovigilance, its main objectives, adverse drug reactions reporting, Vigiflow database, classification of ADRs, incidence of ADRs, role of health care professionals, reporting of suspected adverse drug reaction followed by economic and epidemiological importance of reporting the ADRs and its effect on patient safety and causality assessment of ADRs. 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.

The filled KAP questionnaires were evaluated as per the study objectives, the KAP scores were analyzed. The data obtained were entered in Microsoft excel

spread sheet and evaluated. The impact of effectiveness of educational intervention on the awareness of pharmacovigilance and ADR's reporting among the 5th term medical students is evaluated. The chi-square test and unpaired t 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 Graph Pad Instat. The p value ($p<0.05$) was considered to be statistically significant.

RESULTS

All the answers are expressed in terms of numbers, percentages, and Mean±SD, for the KAP questionnaire (Pre-KAP & Post-KAP) comprising of 20 questions was evaluated and tabulated in Table.1, 2, 3, 4 and Figure 1.

Question 01 of table 01, emphasized on the role of health care professionals in ADR's reporting, for which the comparativeness with educational intervention in between pre-KAP (40.4%) and post-KAP (89.4%) revealed effectiveness of educational intervention with statistically significance ($p<0.0001$).In our study it was demonstrated by an increase in the correct responses for pre and post KAP question 02, table 01 in defining pharmacovigilance, from 44.7% before to 85.1% after the intervention. Question 03 from table 01 was framed to obtain the information about objectives of pharmacovigilance where in pre-KAP (25.5%) and post-KAP (76.6%) and statistically significant ($p<0.0001$) correct responses were evident after educational programme. This data suggests that continuing educational intervention is an important tool for increasing all health care professionals' awareness to pharmacovigilance. Based on our study results and the finding of Cosentino et al [14] and Figueras et al [15] recommend including "pharmacovigilance" as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program to all health care professionals.

Question 04 from table 01 was framed to obtain the information about the international center for reporting of ADR's and Question 06 from table 01, about databases on ADR's reporting system, it was found that there was an increased positive response rate of 19.2% as pre-KAP to 80.9% post-KAP and 21.3% as pre-KAP to 65.7% post-KAP after the educational intervention program respectively. The result strongly suggests that students were greatly influenced by the educational intervention regarding the reporting systems of ADRs both of national and international standards which is in accordance with earlier study by Suveges LG et al [16].

Question 05 from table 01, was framed to obtain the causality assessment of an ADR's, we could see drastic increased positive response of 17.1% before to 74.5% and after the educational intervention. Question 07 from table 01 is designed to know the information about rare ADR's found in clinical trials, we observed that increased positive response of 23.4% before to 70.2% after the educational intervention which points to create more awareness about phases of clinical trials and safety of medicines in medical students.

The study also focused on assessing the attitude of medical students on ADR's reporting in question 14 and 15 table no.2, which reveled to be 51.7% before pre-KAP to 89.4% post-KAP, 36.2% before pre-KAP to 85.1% post-KAP respectively, which strongly suggests that students need to undergo educational sessions on ADR's reporting [17].

The study is focused on assessing the perceptions of ADR's reporting centers in question 17 table no.3, which revealed to be 25.5% before pre-KAP to 91.5% post-KAP, which also points to the importance of impact of educational interventions on Pharmacovigilance in accordance with earlier study by Scolt HD et al [17].

Question 18 table no 03, highlights on communication of safety information between all health care professionals which can minimize the risk of marketed medicines, observed to be 34.1% before pre-KAP to 85.1% post-KAP, students were made aware that communication among other health care professionals is important. Question 19 from table 03, showed that 27.7% before pre-KAP to 80.9% post-KAP depicts to change the perceptions of students where rational use of medicines is the need of the hour by educational interventions.

Question 20 from table 03, to read an article (online /newspaper/Magazine) about ADR's in near future revealed to be 34.1% before pre-KAP to 74.5% post-KAP, this type of enthusiasm, motivation gained

among students after educational intervention was a very positive response to be acknowledged.

Table.1. Knowledge of Pharmacovigilance& ADR's reporting before & after educational intervention.

Q.no	Knowledge questions	Pre–KAP Score n (%)	Post-KAP Score n (%)	p-value
1.	The healthcare professionals responsible for reporting ADR's in a hospital is/are- **a)** Doctor **b)** Pharmacist **c)** Nurses **d)** All of the above*	19 (40.4)	42 (89.4)	p<0.0001
2.	Define Pharmacovigilance? **a)** The science of monitoring ADR's in the Hospital **b)** The process of improving the safety of Drugs **c)** The detection, assessment, understanding & prevention of adverse effects* **d)** The science of detecting the type & incidence of ADR'S after drug is marketed.	21 (44.7)	40 (85.1)	p<0.0001
3.	The important objective of Pharmacovigilance is **a)** To identify safety of drugs* **b)** To calculate incidence of ADR's **c)** To identify predisposing factors to ADR's **d)** To identify ADR's occurring at high doses	12 (25.5)	36 (76.6)	p<0.0001
4.	The international center for adverse drug reaction monitoring is located in: **a)** Unites States of America **b)**Australia **c)** Canada **d)** Sweden*	9 (19.2)	38 (80.9)	p<0.0001
5.	Which of the following scales is commonly used to assess the causality of an ADR's? **a)**Hartwig scale **b)** Naranjo algorithm*	8 (17.1)	35 (74.5)	p<0.0001

	c) Schumock & Thornton scale **d)** Karch & Lasagna scale			
6.	Which one of the following is the 'WHO online database' for reporting ADRs? **a)** ADR's advisory committee **b)** Med safe **c)** Vigibase* **d)** Med watch	10 (21.3)	31 (65.7)	p<0.0001
7.	Rare ADRs can be identified in the following phase of a clinical trial: **a)** phase-1 clinical trials **b)** phase-2 clinical trials **c)** phase-3 clinical trials **d)** phase-4 clinical trials*	11 (23.4)	33 (70.2)	p<0.0001
8.	Select the correct (ADR's and its causative drug) option: **a)** Phocomelia- Streptomycin **b)** Hemolytic anemia- Thalidomide **c)** HPA axis suppression - Ofloxacin **d)** Cleft lip- Phenytoin*	16 (34.1)	35 (74.5)	p<0.0001
9.	Select the correct (ADR's and its causative drug) option **a)** Yellowish discoloration of teeth- Isotretinoin **b)** Ebstein's cardiac anomaly- Warfarin **c)** Neural tube defects- Valproic acid* **d)** depressed nose, hand defects- Lithium	18 (38.3)	33 (70.2)	p<0.0001
10.	Regarding classification of ADR's, the correct option is: **a)** Type A is predictable, dose related **b)** Type B is Unpredictable, dose unrelated **c)** Both a) and b) are correct*	14 (29.8)	36 (76.6)	p<0.0001

	d) None of the above			
11.	It is important to report ADRs leading to- **a)** Hospitalization **b)** congenital abnormality **c)** patient death **d)** All of the above*	26 (55.3)	37 (78.7)	p<0.0001

Table. 2. Attitude of Pharmacovigilance & ADR's reporting before & after educational intervention.

Q.no	Attitude questions	Pre–KAP Score n(%)	Post–KAP Score n(%)	p- value
12.	Do you agree that ADR's reporting system would benefit patient care? -Strongly agree*	30 (63.8)	46 (97.8)	p<0.0001
13.	Would you suspect ADRs when drug is administered in normal dose? -Strongly agree*	18 (38.3)	44 (93.6)	p<0.0001
14.	Reporting of all ADRs for a new drug is essential? -Strongly agree*	24 (51.7)	42 (89.4)	p<0.0001
15.	Do you agree reporting of adverse drug reaction is necessary? -Strongly agree*	17 (36.2)	40 (85.1)	p<0.0001
16.	Do agree Pharmacovigilance should be taught in detail to healthcare professionals? -Strongly agree*	22 (46.8)	38 (80.9)	p<0.0001

Table.3. Perception of Pharmacovigilance and ADR's reporting before & after educational intervention.

Q.no	Perceptions questions	Pre–KAP Scores n(%)	Pre–KAP Scores n(%)	p- value
17.	Is it important to know national, international centers for ADR's monitoring? -Yes*	12 (25.5)	43 (91.5)	p<0.0001
18.	Communication of safety information between all health care professionals can minimize the risk of	16 (34.1)	40 (85.1)	p<0.0001

	marketed medicines? -Yes*			
19.	Can ADR's monitoring help to promote rational use of medicines? - Yes*	13 (27.7)	38 (80.9)	p<0.0001
20.	Would you like to read an article (online /newspaper/Magazine) about ADR's in future? -Yes*	16 (34.1)	35 (74.5)	p<0.0001

Correct Response*, P<0.001 (comparison between the pre- KAP and Post- KAP responses).

Figure 1: Mean KAP scores of responders-Overall level of knowledge, attitude and perceptions among the participants. (n=47)

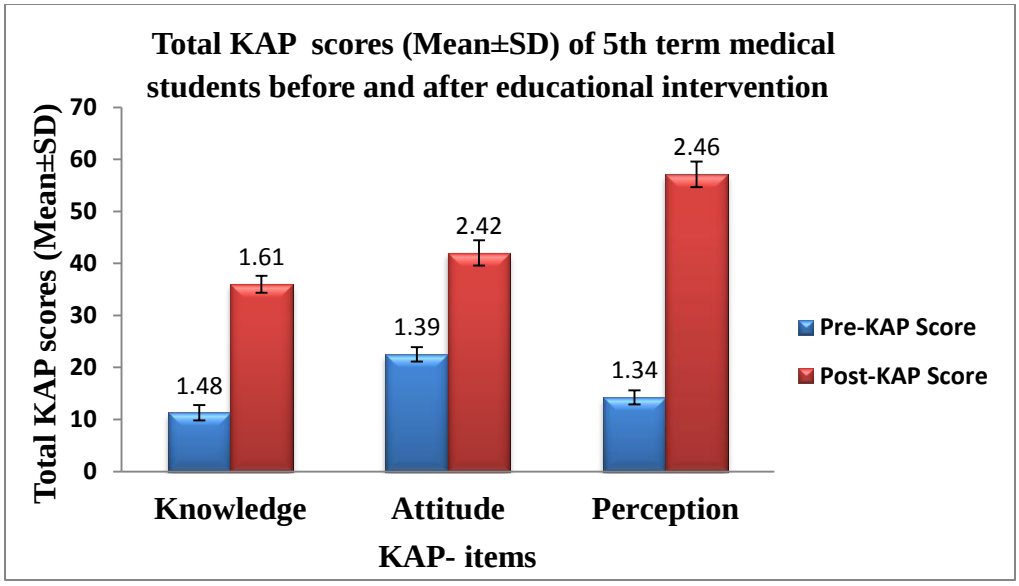

Table.4. Student Feedback regarding Educational intervention on Pharmacovigilance and Adverse drug reactions reporting

Students opinions:	**Response**	**n (%)**
1. Sought information about Objectives of Pharmacovigilance-	Yes*	37 (90.2)
2. Sought information about Vigiflow database for adverse drug reactions monitoring-	Yes*	32 (90.2)

3. Sought essential information required while reporting an ADR's-	Yes*	40 (87.8)
4. Sought information about different types of ADR's-	Yes*	42 (44.0)
5. The hand-outs before the lecture helped us to grasp the ADR's monitoring and Pharmacovigilance concepts during lecture better-	Yes*	38 (80.5)
6. Handouts before every Pharmacology lecture class helps to absorb concepts better-	Yes*	35 (90.2)
7. The photo images showing some examples of (ADR's and its causative drug) during lecture were informative-	Yes*	41 (75.6)

n- Number of Yes*responses, (%) - percentage of responses

Annexure. 01

This questionnaire is anonymous and aimed at assessing the best instructional methods to facilitate your learning of Pharmacology.

- Please mark tick (√) for the most correct single option to the best of your knowledge.
- Ensure all the questions are answered.
- All the information provided would be treated with utmost confidentiality.

1. The healthcare professionals responsible for reporting ADR's in a hospital is/are-

a)□Doctor **b)**□Pharmacist **c)** □Nurses **d)** □All of the above

2. Define Pharmacovigilance?

a)□The science of monitoring ADR's happening in a Hospital

b) □The process of improving the safety of Drugs

c)□The detection, assessment, understanding & prevention of adverse effects

d)□The science detecting the type & incidence of ADR's after drug is marketed.

3. The important objective of Pharmacovigilance is

a)□To identify safety of drugs **b)** □To calculate incidence of ADR's

c)□To identify predisposing factors to ADR's **d)**□To identify ADR's occurring at high doses

4. The international center for adverse drug reaction monitoring is located in:

a) □Unites States of America **b)** □Australia **c)** □Canada **d)** □ Sweden

5. Which of the following scales is commonly used to assess the causality of an ADR's?

a□) Hartwig scale **b)** □ Naranjo algorithm

c) □ Schumock and Thornton scale **d)** □Karch and Lasagna scale

6. Which one of the following is the 'WHO online database' for reporting ADRs?

a)□ADR's advisory committee **b)** □Med safe **c)**□Vigibase **d)**□Med watch

7. Rare ADRs can be identified in the following phase of a clinical trial:

a)□phase-1 clinical trials **b)**□phase-2 clinical trials

c) □ phase-3 clinical trials **d)** □phase-4 clinical trials

8. Select the correct (ADR's and its causative drug) among the following:

a) □Phocomelia- Streptomycin **b)**□ Hemolytic anemia- Thalidomide

c)□ HPA axis suppression - Ofloxacin **d)** □Cleft lip- Phenytoin

9. Select the correct (ADR's and its causative drug) option:

a) □Yellowish discoloration of teeth- Isotretinoin **b)**□ Ebstein's cardiac anomaly- Warfarin

c)□Neural tube defects- Valproic acid **d)**□depressed nose, hand defects- Lithium

10. Regarding Classification of ADR's, the correct option is:

a) □ Type A is predictable, dose related **b)** □Type B is Unpredictable, dose unrelated

c) □Both a) and b) are correct **d)**□None of the above

11. It is important to report ADRs leading to-

a)□Hospitalization **b)**□congenital abnormality

c)□patient death **d)**□All of the above

Attitude: Please mark tick (√) for your correct answer.

12. Do you agree that ADR's reporting system would benefit patient care?

□ strongly agree/ □agree/ □uncertain/ □disagree/ □strongly disagree

13. Would you suspect ADRs when drug is administered in normal dose?

□strongly agree/ □agree/ □uncertain/ □disagree/ □strongly disagree

14. Reporting of all ADRs for a new drug is essential?

□strongly agree/ □agree/ □uncertain/ □disagree/ □strongly disagree

15. Do you agree reporting of adverse drug reaction is necessary?

□strongly agree/ □agree/ □uncertain/ □disagree/ □strongly disagree

16. Do agree Pharmacovigilance should be taught in detail to healthcare professionals?

□strongly agree/ □agree/ □uncertain/ □disagree/ □strongly disagree

Practice: Please mark tick (√) for your correct answer.

17. Is it important to know national, international centers for ADR's monitoring?

-Yes□ / NO□

18. Communication of safety information between all health care professionals can minimize the risk of marketed medicines? -Yes□ / NO □

19. Can ADR's monitoring help to promote rational use of medicines? -Yes□/ NO□

20. Would you like to read an article (online /newspaper/Magazine) about ADR's in future?

-Yes□/ NO□

Signature-

DISCUSSION

The study showed that medical students who attended the interactive educational intervention on Pharmacovigilance and ADR's reporting were much satisfied and considered more effective and valuable. In our study, one focus of educational intervention was to increase the medical students awareness to Pharmacovigilance, regulatory bodies responsible for monitoring of ADR's, types of ADR's. This was demonstrated by an increase in the correct responses in pre and post-KAP questions (1 to 20) about pharmacovigilance and ADR's reporting with statistical significance ($p<0.0001$), after the educational intervention highlighting the impact on its effectiveness.

Questions 08 and 09 from table 01 are framed to obtain the knowledge about ADR's and its causative drug which medical students, physicians must know to promote safe and rational use of medicines. The response rate is 34.1% as pre-KAP to 74.5% post-KAP and 38.3% as pre-KAP to 70.2% post-KAP respectively, after the educational intervention program. Question 10 from table 01, shows response rate from 29.8% pre-KAP to 76.6% post-KAP which strongly suggests that the information about different types of ADR's, and question 11 from table 01, infers about when to report ADR's and practical knowledge on ADR's from 55.3% pre-KAP to 78.7% post-KAP improved enormously after educational intervention. Question 12 from table 02, showed that 63.8% before pre-KAP to 97.8% post-KAP, and Question 13 from table 02 showed that 38.3% before pre-KAP to 93.6% post-KAP strongly suggests that there is a great need to create awareness on attitude aspect of ADR's reporting among medical students can be done by continuous medical education programs on pharmacovigilance.

In figure 01, the total Pre-KAP scores on knowledge (11.3 ±1.48), attitude (22.5±1.39), perception (14.25 ±1.34) when compared to total post- KAP scores on knowledge (36 ±1.61), attitude (42±2.42), perception (57.12 ±2.46) respectively, the overall increase in correct response rate with statistical significance ($p<0.0001$) was observed after educational intervention.

Earlier studies by Suveges LG et al and Scolt HD et al [16-17] has also shown that enhancing knowledge, attitude, and perception of improving awareness can increase the number of ADR's reports. This study conducted by Chatterjee et.al[18] which stated that a main reason for under reporting of ADRs was the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported. However, in a similar educational interventional program in pharmacovigilance study of Li Q, Zhang et al [19] showed that educational intervention improved awareness of pharmacovigilance on knowledge, attitudes, practice of healthcare professionals.

The feedback from the students was encouraging and positive. The hand outs before the lecture classes helped them to understand the concepts better and potentiated easy grasping habits during lecture hours. Students are of the opinion that handouts when given before every Pharmacology lecture would help them to absorb concepts better during lecture classes. The photo images showing some examples of (ADR's and its causative drug) during lecture class, made students to learn ADR's causality effectively and to assess benefit/risk ratio of marketed medicines.

This study has two important limitations. Firstly, the study period was too short. Secondly, the study findings could not be applied to the wider community medical students and other health care professionals as the study was restricted to 5^{th} term medical students in department of Pharmacology, MVJ Medical College and Research hospital, Bangalore. Therefore we recommend that several such studies of similar kind should be conducted among wider community medical students as well as to all types of health care professionals so as to develop strategies to improve the knowledge, attitudes, practice of pharmacovigilance in India and globally.

CONCLUSION

In conclusion, the results of the present study demonstrate that an educational intervention can increase awareness of pharmacovigilance, ADR's reporting among the medical students and inculcate in their future clinical practice. The medical students would be made aware about benefit- risk ratio of safety of marketed medicines and importance of communication with various health care professionals in pharmacovigilance.

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