

TO STUDY THE KNOWLEDGE ATTITUDE AND PRACTICE OF THE PHARMACOVIGILANCE AMONG THE SECOND PROFESSIONAL MBBS STUDENTS OF THE J. N. INSTITUTE OF MEDICAL SCIENCES, IMPHALOinam Joychandra Singh¹, Varkung Valte², Joymati Oinam³, Pritamjit R. K⁴**HOW TO CITE THIS ARTICLE:**

Oinam Joychandra Singh, Varkung Valte, Joymati Oinam, Pritamjit R. K. "To Study the Knowledge , Attitude and Practice of the Pharmacovigilance among the Second Professional MBBS Students of the J. N. Institute of Medical Sciences, Imphal". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 61, July 30; Page: 10619-10623, DOI: 10.14260/jemds/2015/1533

ABSTRACTS: OBJECTIVE: The aim and object of the present study is to assess the knowledge, attitude and practice of ADRs among the 2nd professional MBBS students and also to find out the ways for implementation of Pharmacovigilance Programme of India (PvPi). **MATERIAL AND METHOD:** The material is the pretested questionnaire on knowledge, attitude, and practice on Pharmacovigilance. The design of the study is cross sectional study. Percentage, proportions and means are used for descriptive statistics while the associations are calculated using corresponding tests for the associations. **RESULTS:** The knowledge of the students on Pharmacovigilance in connection with Over the Counter/self-medication (52%); minimum need of surveillance on marketing (74%); present surveillance on marketing as low as 60%; need of CME on ADRs along with Pharmacovigilance among student at least (64%) as the ADRs on elderly (57%), children(58%), Pregnancy (64%). Similarly out of 24 questions on Attitude, only 7 questions on Reporting, Multi National Company, Drug Controller of India, Disability and Compensation are selected for statistical analysis. The percentage of the students who has heard and seen ADRs 64.5. **CONCLUSION:** Most of the ADRs are avoidable if there is good communication and reports which plays a pivotal role in minimizing the ADRs. Drugs must be prescribed rationally and polypharmacy should be avoided as much as possible. To avoid the iatrogenic diseases, Pharmacovigilance is a matter of great concern for the health care providers and for the general mass too.

KEYWORDS: Adverse Drug Reactions (ADRs), Pharmacovigilance Programme of India (PvPi), Uppsala Monitoring Centre (UMC-WHO), Continuing Medical Education (CME), Over the Counter (OTC). Multi National Company (MNC), Drug Controller of India (DC- I).

INTRODUCTION: Even with the administration of right dose of the right medicine through the right route at the right time of the rightly diagnosed patient, the patient may have side effects and adverse drug reactions. As per the WHO, ADR is a response of a drug which is noxious/ unintended and which occurs at doses, normally used in man for the prophylaxis, diagnosis or therapy of disease and for the modification of physiological functions.¹ ADR is an increasing worldwide problem causing significant morbidity and mortality.

Therefore, monitoring of ADRs has become exceedingly important in today's practice of medicine particularly in a developing country like India. On the other hand, Pharmacovigilance is the activities relating to the detection, assessment, understanding and prevention of ADRs or any other drug related problems.¹ This is the application to both- marketing products and even those under clinical trial. Data collection, data processing and analysis are the pillars of Pharmacovigilance. The primary source of the ADRs is the spontaneous reporting of the health care professionals and even by the patients. Sometimes the drug may be withdrawn from the clinical trial and the market too.

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The Uppsala Monitoring Centre (UMC-WHO) Sweden is the international pharmacovigilance Centre where the international database of adverse drug reactions is maintained.² In India, the Pharmacovigilance (PvPi) programme is started with the aims of generating ADRs database.² Though there is a variety of illness and diseases; different methods of treatment and management, India is a mere contributor to the international ADRs database.³ This is nothing but an under reporting and negligence on the part of health care professionals.

MATERIALS & METHODS: The material is the pretested questionnaire on knowledge, attitude, practice on ADRs and PvPi. The design of the study is the cross sectional study.⁴ The setting and duration of the study is among the student of the 2nd professional MBBS students during the month of November 2014. The sample size is intended to cover all the students of 2nd professional MBBS students (94).The exclusion criteria are refusal to give consent, non-available or fail to return questionnaire in spite of the reminder and unable to attempt the questions. Percentage, proportions and means are used for descriptive statistics while the associations are calculated by using corresponding tests for the associations.⁵ The permission for the present study has been obtained from Institutional Ethical Committee.

OBSERVATIONS: There are 16 questions on knowledge but only 8 questions on ADRs, OTC/Self-medication, marketing, surveillance, CME and ADRs on selected population are selected for statistical analysis. The knowledge of the students on PvPi in connection with OTC/Self-medication(52%), need of surveillance on marketing (74%) but the surveillance on marketing may be low (60%), need of CME on ADRs along with PvPi (64%) as the ADRs on elderly (57%), children (58%), Pregnancy (64%). Similarly out of 24 questions on Attitude, only 7 questions on reporting, MNC, DC (I), Disability, and Compensation are selected for statistical analysis. The attitude of students towards the compensation on account of ADRs is only 15% as it is the responsibility of the prescribers in terms of rational use of drugs, OTC/self-medication, and surveillance. PvPi is very much useful to the MNC/DC (I) in view of the safety of the drugs during the marketing and post marketing surveillance and controlling the standards of the drugs under Drug and Cosmetics Acts. PvPi will be useful in prevention of disability due to ADRs as up to 70%. Likewise there are 15 questions on Practice only 10 questions on definition of Pharmacovigilance, ADR, OTC/ self-medication, Marketing, usefulness to the MNC, DC (I),rational use of drugs and prevention from disability is picked up for statistical analysis. Result of the data analysis is shown on Table.1.A Bar graph showing the different distribution of percentage of the students having the knowledge and attitude on ADRs, Rational use of drugs, Post marketing surveillance, PvPi, Initiative and willingness of reporting, CME and Compensation is presented for reference.

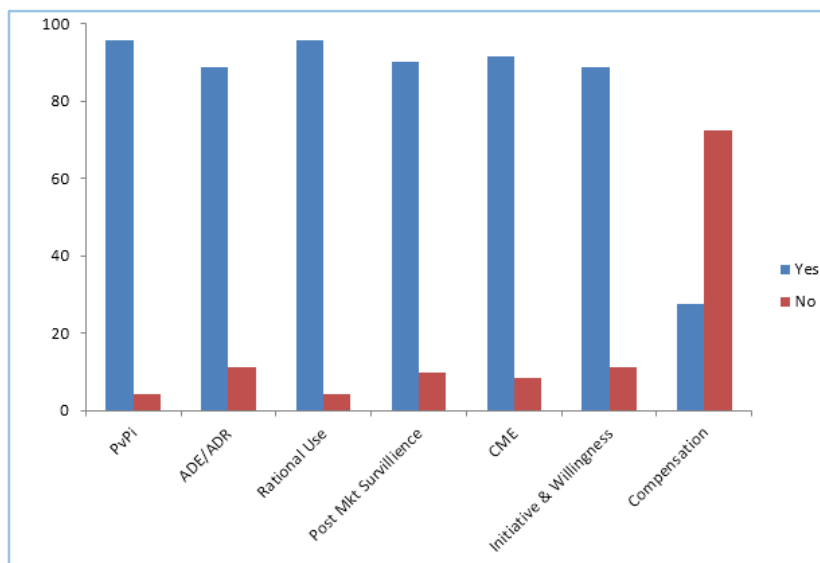
DISCUSSION: Utilising the knowledge and attitude on ADRs, the willingness of the prescribers in prescription writing, reporting and notification of the ADRs is not to the marks. ADRs on OTC/self-medication (54%), disability (73%) may be prevented by practicing the rational use of drugs, caring of prescription during buying/marketing. Over and above these observations, a statistical study on the Correlation between Knowledge and Practice; Attitude and Practice is done (Table II and III). While examining the usefulness of the PvPi to the MNCs and the DC (I), the significance level is value 0.87 (p-0.01), and value 0.23(p -0.05), the knowledge of students towards the practice on OTC and marketing is value 0.55(p-0.01) and value0.46 (p-0.01) shown as table II and III.

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These indicate knowledge, attitude and practice of the ADRs/ PvPi and also willingness /initiative of the health care providers towards the implementation of the PvPi and the chances of the compensation may be as low as below 27.5%. Extreme ages i.e., pediatric and geriatric are more vulnerable to drugs related ADRs due to age related pharmacokinetic and pharmacodynamic parameters and also due to polypharmacy and irrational use of drugs.⁵ Most of the ADRs may be avoided if there is good communication between the patients and health care providers. ADRs can be certainly minimized by considering the age related physiological changes and also pharmacokinetic/ pharmacodynamic factors before prescribing the drugs.⁵ Drugs must be prescribed rationally and their number may be kept to the minimum as much as possible.

Parameters	Yes	No
Knowing Definition of PvPi	95.7	4.3
Definition of ADR/ADE	88.8	11.2
Usefulness of ADR/ADE	95.7	4.3
Usefulness of Post Mkt	90.1	9.9
Compensation of ADR/ADE	27.5	72.5
Initiative & Willingness	88.8	11.2
Compensation	27.5	72.5

Table 1: Percentage Distribution of different Parameters



Bar Graph

Parameters	Value	Significance level
Usefulness of PvPi to MNC	0.87	0.01
Usefulness of PvPi to DCI	0.23	0.05

Table II: Correlation of Attitude and Practice on different Parameters

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Parameters	Value	Significance Level
Common with OTC	0.55	0.01
Marketing of Drugs	0.46	0.01

Table III: Correlation of knowledge and Practice on Different Parameters

CONCLUSION: On the basis of ADRs/ pharmacovigilance report many drugs were withdrawn from the market.³ Lot of works has to be done at the grass root level. Teaching on ADRs will be useful in educating the medical students/ doctors and the officials working in controlling and regulating the sale and supply of drug. The pharmacovigilance programme should be mandatory in each and every state health care institution (Govt. and Non-Govt.). Initiative and willingness of health care providers through voluntary reporting, after prescription event monitoring, computerized medical record linkage; dissemination of ADR data (Drug alerts, medical letters) with changing in labelling, statutory warning and, precaution will prevent many disabilities/ hazards due to ADRs.³ In short PvPi is a matter of great concern for the health care providers and the general mass too. It has an important role in the rational use of drugs as it provides the basis for assessing the safety of drugs.³

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