An Observational Study of the Knowledge, Attitude and Practice of ADR Reporting among the Junior Doctors of Jawaharlal Nehru Institute of Medical Sciences (JNIMS), Imphal

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ABSTRACT

BACKGROUND

One of the health problems which is associated during the management of a patient with series of drugs is ADR/ADE. Therefore, the aim of the present study was to find out the activities for improving the reporting of ADRs/ADEs. The data on the KAP is collected on a pre-tested questionnaire.

METHODS

This is a non-interventional cross-sectional study. The questionnaire was prepared after referring the questionnaires of previous studies. Out of 120 questionnaires distributed, only 100 questionnaires were received back. Descriptive statistics is used for analysing the data.

RESULTS

The response on the questionnaire is 83.3%. Seventy-nine (79) participants knew the definition of ADR/ADE. Eighty-eight (88) participants want to report the ADRs of the marketed drugs irrespective of new or old. Seventy-five (75) participants know about PvPI. Ninety (90) participants do not consider all the OTC and Herbal drugs are safe. Seventy-two (72) participants do not know the establishment of a Pharmacovigilance centre at the Department of Pharmacology, JNIMS. Only 55.6% of the participants oblige to report the ADRs as a professional health care provider. 58% of the participants opine to conduct a regular CME program on ADR/Pharmacovigilance. 63.2% participants state that maximum ADRs are seen among dermatological, paediatric and elderly patients. 58.2% of the participants express their opinion about the occurrence of ADRs/ADEs with irrational prescription, polypharmacy, foods, drinks etc. 44% participants have the attitude of reporting ADRs/ADEs but only 10% participants perform the actual reporting with careful observations on patients' behaviour. Most of the ADRs/ADEs are avoidable if there is good communication and reporting.

CONCLUSIONS

A regular awareness programme on ADR/ADE along with CME program and also online reporting facilities is necessary for promotion of reporting of the ADR/ADE. Therefore, the drug should be prescribed rationally, and polypharmacy should be avoided as much as possible.

KEY WORDS

ADR, PvPI, Polypharmacy, OTC, Herbal, Participants

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BACKGROUND

The Adverse Drug Reaction (ADR) or Adverse Drug Effect (ADE) is a health problem which is not strictly noticed and detected by the health-care providers. That is why there is many casualties and hospital admissions. ADR is defined according to the World Health Organisation as any response to a medical product which is harmful and unintended and which occurs at doses ordinarily utilized in man for prophylaxis, diagnosis or therapy of disease, or for the modifications of physiological function.^{1,2}

On the other hand, Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. It is an arm of patient care and monitoring the status of the drugs. It intends to get the best outcome from treatment with medicines. The objectives of pharmacovigilance are rapid identification of adverse drug events, identification of possible causal relationships between an adverse event and medicine following the introduction of a new drug or drug combination, assessment if these signals to evaluate causality, clinical relevance, frequency and distribution of ADRs/ADEs in particular population groups. These objectives compare the safety of different medicines, clearly identify the risk factors and contribute to the assessment of both effectiveness and risk of medicines.^{1,2} ADRs/ADEs are associated with drug-related patient morbidity by causing a prolonged length of hospital stay, higher economic burden and sometimes mortality. They are a common and often preventable cause of hospitalisation. There are many reasons for under-reporting of the ADR/ADE by the health-care providers voluntarily or as an obligation.³ 4, 5 the reporting of ADR/ADE is under the aegis of Pharmacovigilance is made compulsory. Owing to the current trend of under-reporting, Drug Controller of India under the supervision of Indian Pharmacopoeia Commission, launched a National Program on ADR/ADE implementing the Pharmacovigilance Program of India (PvPI) in 2014.^{4,5,6} Even though there is establishment of many ADR/ADE reporting centres as Zonal, divisional and peripheral centres all over the country under the close inspection of the various agents, ADR/ADE is still under-reporting.^{7,8,9,10}

PvPI (Pharmacovigilance program of India) has generated helpline facility with the toll-free number 1800 1803 024 to make drug safety information available for the Indian population as a whole. Besides suspected ADR/ADE reporting form, PvPI has generated medicine side-effect reporting form for consumers and patients in their regional or local language. However, India does not have a robust database on the ADRs/ADEs and has to depend on data from Western countries to make recommendations relating to banning and suspicion of any drugs whether new or old.³

Objectives

To study the Knowledge, attitude and practice (KAP) of the Junior Doctors of JNIMS about the ADR reporting and also to find out an activity for better ADR/ADE reporting.

METHODS

Study Design and Setting

It is a cross-sectional, non-interventional, questionnaire-based study conducted at Jawaharlal Nehru Institute of Medical Sciences (JNIMS) as an awareness program during the establishment of AMC centre in the Department of Pharmacology. Junior Doctors who gave their consent were included in the study. Accordingly, 120 junior doctors have given their consent for participation in the study.

Designing of Questionnaire

The questionnaire was designed on the basis of primary objective of the study by referring questionnaires used by previous investigators.^{4,5,6,7,8,9,10,11,12,13,14} It has three parts- Knowledge-10 questions, Attitude-10 Questions and Practice-10 questions.

Procedure

A briefing was done about the questionnaire and time factors for answering the questionnaire i.e., 10 minutes. Otherwise the answers on the questionnaire was excluded from the study. Accordingly, 120 questionnaires were distributed to 120 junior doctors (35 interns, 10 medicine residents, 10 surgery residents, 13 obstetrics & gynaecology residents, 15 dermatology residents, 15 paediatric residents, 14 casualty medical officers and 8 orthopaedic residents).

Data Analysis

Descriptive statistical analysis was carried out to evaluate the KAP of the participants through SPSS (version 26) and Microsoft Excel.

RESULTS

Though there was distribution of 120 questionnaires, only 100 questionnaires were received back. Therefore, the data was analysed on the basis of the answers of 100 questionnaires. The results were examined and analysed as below i.e., Table 1 to Table 5.

The frequency and percentage of participants who knew the definition of ADR is 79% the existence of Adverse drug monitoring centre (AMC) in JNIMS is 28% and the implementation of PvPI in INDIA is 75% (Table-1).

Parameter	Frequency	Percentage
ADR definition	79	79
AMC existence in JNIMS	28	28
PvPI existence in India	75	75

Table 1. Knowledge

The frequency and percentage of ADR reporting among the participants were new drugs (88%), serious ADR (88%), professional obligation (76%) and single ADR not significant (24%). (Table-2).

The frequency and percentage of junior doctors who considered commonly reported ADRs were associated with various conditions are as, dermatological/paediatric (34%),

patient taking multiple drugs i.e., polypharmacy (47%), patient taking drugs along with foods and drinks (44%) and elderly people taking OTC, unprescribed and herbal drugs (27%). (Table-3)

Parameter	Frequency	Percentage
New Drugs	88	88
Serious ADR	88	88
Professional Obligation	76	76
Single ADR is not significant	24	24

Table 2. ADR Reporting

Parameter	Frequency	Percentage
Dermatological/Paediatric	34	34
Elderly	27	27
Polypharmacy	47	47
Food & Drinks	44	44

Table 3. ADR Commonly Seen

There were many reasons for under-reporting of ADRs. 32% participants opined there was lack of time in filling up the form; 41% participants were not able to identify the correct ADRs. 48% of the Junior Doctors preferred or wished to hide their identity as there was many risky behaviours of the patients. (Table-4)

Parameter	Frequency	Percentage
Hiding identity	48	48
Lack of ADR form filling time	32	32
Correct ADR may not be possible as it is not visible all the time	41	41

Table 4. Reasons for Under-Reporting of ADR

25% participants received training; 88% participants opined the need of Awareness program on ADR/PvPI. 87% participants suggested the inclusion of ADR/PvPI in the teaching curriculum of PGs and UGs. (Table-5)

Parameter	Frequency	Percentage
Training	25	25
Need of Awareness	88	88
Pharmacovigilance in UGs and PGs teaching	87	87

Table 5. Awareness and Training of ADR

DISCUSSION

The present study is a part of awareness program of ADR reporting and existence of an AMC under PvPI at the Dept. of Pharmacology, JNIMS. The responses on the questionnaire of Knowledge is encouraging. This finding is also observed in another study of Sarfaraz Alam Khan et al.¹⁵ Most of the doctors (90%) know that all Herbal/Allopathic/OTC drugs are not safe but only twenty-eight (28) doctors opine that the ADRs associated with these products need to be reported. This is in support of another study by O Joychandra Singh et al.¹⁶ As the Indian market is flooded with many newly marketed drugs, OTC and Herbal drugs, the single ADR reporting of any type/class of drug is recommended. Further, eighty-eight (88) doctors express their desire of reporting the ADR of newly marketed drug because all ADRs associated with the particular new drug were not observed at the time of approval for clinical uses. These findings support the report and findings of many investigators Oinam Joychandra Singh et al.¹⁶, Mansij Biswas et al.¹⁷ Even though the ADR form is complex (78% participants), the doctors being lethargic or citing lack of time for ADR filling (32% participants),

insignificance of single report (24% participants) and hiding identity (42% participants), forty-four (44) doctors have the attitude of reporting the ADR. These observations support those of investigators Chetna K Desai et al,⁷ Supratim Dutta et al,⁸ Vishal R Tandon et al,⁹ Rabina Mulchandani et al.¹⁰

If there is serious ADR (88% participants) and ADR of a new drug (88% participants) majority of the doctors felt that the reporting of ADR is a professional obligation. These findings are almost similar to the findings of previous investigators Chetna K Desai et al,⁷ S Sre Akshaya Kalyani et al,¹⁴ Mansij Biswas et al.¹⁷ The attitude of 24% participants who have the attitude of not reporting single ADR needs to be changed. 72% of participants felt that ADR from the OTC/Herbal/non-allopathic products need not be reported. The opinion of these 72 participants may be changed towards the reporting that all medicine/drug are not 100% safe. These findings is almost similar to the findings of many investigators Chetna K Desai et al, Supratim Dutta et al, Vishal R Tandon et al, Rabina Mulchandani et al and also with the National Program PvPI. 41% participants was not able to fill up the ADR form due to lack of time, not able to identify the correct ADR (32% participants) and also want to hide the identity of the reporters (48% participants). Most of the participants observe the ADRs among the patient/people with poly-pharmacy (47% participants), among elderly patients (27% participants), dermatology/paediatric (34% participants) and sometimes with food/drinks (49% participants) Such type of findings were also found as those of previous studies S Sre Akshaya et al,¹⁴ Mansij Biswas et al.¹⁷ Anal Modi et al.¹⁸

Only 25% participants receive adequate training on ADR and 75% doctors know the implementation of PvPI and 28% participants know the existence of AMC in JNIMS. Therefore, 88% participants opine that the reporting of ADR will increase if there is wide awareness program on ADR and PvPI. Such findings also support the findings of previous investigators Sandeep Kumar Gupta et al, Chetna K Desai et al,⁷ Rabina Mulchandani et al,¹⁰ Sandeep Kumar Gupta et al,¹³ S Sre Akshaya Kalyani et al,¹⁴ Sarfaraz Alam Khan et al,¹⁵ O Joychandra Singh et al.¹⁶ 87% Doctors express their opinion about the inclusion of a topic on PvPI in the teaching curriculum of UG and PG and also a regular CME to be conducted.

CONCLUSIONS

A significant gap pertaining to knowledge, attitude and practice related to ADR/ADE and Pharmacovigilance activities exists. The identified inadequate knowledge, training of Health care professional, their attitude and perception and problem with organised reporting system at the facility level are the main hurdles. Poor reporting of the ADR/ADE is essentially due to the absence of vibrant ADR/ADE monitoring system and also inadequacies in reporting culture among the health care professionals.

The reporting rate of ADR/ADE could be improved with proper and extensive training about pharmacovigilance in health care professionals. The investigators suggest a large-scale awareness programme with regard to pharmacovigilance among the medical students for better

understanding of ADR/ADE and its reporting. Special emphasis of Pharmacovigilance in medical curriculum and its incorporation in medical internship is required to bring more awareness about the rational usage of drugs; there by minimising the adverse drug event or adverse drug reaction on other drug-related problems. The process of reporting should be made as seamless, hassle-free, convenient and less time consuming as possible.

Recommendations for Better Reporting of ADRs

1. Wide and effective awareness programmes on ADR and pharmacovigilance at various levels of health-care providers involving policymakers and health authorities.
2. ADR and pharmacovigilance should be included in teaching curriculum.
3. Spontaneous and voluntarily reporting of ADR to the AMC centre through print and electronic media.

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