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PHARMACOVIGILANCE: ITS AWARENESS AND IMPACT- STUDY IN A TERTIARY CARE TEACHING MEDICAL COLLEGE IN CENTRAL INDIA

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Abstract

Pharmacovigilance is the subject that deals with the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems. Ecopharmacovigilance is the science & activity concerning detection, assessment, understanding and prevention of adverse effects or other problems related to the presence of pharmaceuticals in the environment, which affect human & other animal species. In the year 2004, Ministry of Health and Family Welfare, Govt. of India has set up National Pharmacovigilance Programme (NPP) with the aim to ensure the benefits of use of medicine and outweighs the risks and thus protecting the health of the people of the country. It was observed in our institution Pharmacovigilance Programme that the problems of underreporting and lack of awareness were prevalent in the community of health professionals. This study shows poor knowledge, attitude and practices of pharmacovigilance among medical professionals so that there is urgent need to improve the awareness of Pharmacovigilance among the healthcare professionals in the institute. Our ADR reporting should be intensively taught during undergraduate study, and this should be reinforced at the start of internships as well as periodically thereafter through continuous education programs.

Introduction:

The safety of patients and the safe use of medicines are high priorities in the modern world. The first practical international co-operation in drug monitoring started in 1968. The ideas came up as a consequence of the so-called thalidomide tragedy. In the 1960s it was discovered limb deformities in babies may occur if thalidomide is ingested by mothers during pregnancy. This incident became the modern starting point of a science focusing on patient problems caused by the use of medicines.

Pharmacovigilance, according to WHO is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems[1]. Newly emerging Ecopharmacovigilance is the subject that deals with the sources of entry of pharmacoceuticals into environment, consequences of environmental pollution by pharmaceuticals and its remedial measures[2]. It starts from the clinical stage and continues throughout the product life cycle of the drug, mainly divided as pre-marketing pharmacovigilance (that is clinical trial phase) and post-marketing pharmacovigilance. Pharmacovigilance is particularly concerned with adverse drug reactions (ADRs) which are defined as an unintentional noxious response by a drug that occurs at doses normally used for the prophylaxis, diagnosis, treatment of diseases and for the modification of physiological function[3].

In the year 2004, Ministry of Health and Family Welfare, Govt of India set up National Pharmacovigilance Programme (NPP) with the aim to ensure that the benefits of use of medicine and outweighs the risks and thus safeguard the health of the people of the country. India is now regarded as one of the countries where a vast number of new drugs are being introduced every year and also a 'big market for Generic Drugs, Clinical trials & Drug Discovery & Development', which throw up the challenges of monitoring ADRs over large population base in the country.

All medicines (pharmaceuticals and vaccines) as a rule have known or unknown side effects. However many adverse drug reactions (ADRs) are preventable but it demands a good knowledge of

pharmacology and good prescribing practices.[3]

It is important to monitor every undesirable effect of medicines to get any new information in relation to their ADR's profile. In a country like India with big population load, with vast ethnic diversity, differences in disease prevalence patterns among different regions, various systems of medicines like Ayurveda, Homeopathy, Unani & Allopathy and different socioeconomic status, it become important to have a proper pharmacovigilance and drug safety monitoring programme for the country. Collection of ADR's information and its analysis to reach a meaningful conclusion on the continued use of these medicines is the aim of Pharmacovigilance. The results thus obtained will be useful in changing the labeling of medicines indicating restriction in use or issue of statutory warning, precautions, or even withdrawal of the drug from the market. This also helps in educating doctors about ADRs, and in the official regulations of drug.

In India the whole programme is controlled by the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Govt. of India with the objectives of:

1. To monitor Adverse Drug Reactions (ADRs)
2. To increase awareness among health care professionals about the importance of reporting an ADR.
3. To have an eye on the benefit-risk profile on the use medicines in particular disease.
4. To create independent, evidence based recommendations regarding the safe use of medicines in the country.
5. To help the Drug control organization of the country to formulate safety related guidelines for the use of the medicines.
6. Exchange information with all key stakeholders.
7. Establishment of national center of excellence which works at par with global drug safety monitoring standards

The core data in the pharmacovigilance programme is generated through the identification & spontaneous reporting of

any suspected ADR by the healthcare professionals or in some countries by the consumer himself to their national pharmacovigilance centers or to the drug manufacturing company. The ADR report is almost submitted voluntarily. It is highly unfortunate that the ADR reporting is underreported in many countries including the developed countries and rarely exceeds 10% for the serious ADRs though the data vary greatly between countries and in relation to minor & serious ADRs. Overall underreporting of ADRs is a common problem in pharmacovigilance programs [5,6].

The overlooking of ADRs by the healthcare professionals is a common problem encountered in the pharmacovigilance programme. The reason for the problem may vary from the heavy workload, pathetic attitude towards ADR reporting, lack of knowledge about ADR reporting or the fear that reporting may affect their career.

After observing the Pharmacovigilance programme of our institution we found that the problems of underreporting and lack of awareness were prevalent in the community of health professionals. It was found that in the year 2012 only 30 ADRs were reported by the health professionals. This inspires us to conduct a study to know the awareness of Pharmacovigilance among health professionals of our institute. Aim of our study is to create awareness of pharmacovigilance among health professionals and to uncover the causes of underreporting. In this study we also aimed to know the suggestions to improve the ADRs reporting in our institute.

Material and Methods:

The present study is a randomized questionnaire-based survey, conducted at a 750-bedded tertiary care teaching hospital in Indore, India.

This questionnaire survey was conducted during March 2013 and approval from Institutional Ethical Committee was obtained prior to administering the questionnaire survey. The questionnaire, contains 16 questions regarding knowledge, attitude and practices of Pharmacovigilance and Ecopharmacovigilance along with suggestions to improve ADR reporting, was designed based on similar previous studies.[7, 8] Factors that discouraged reporting and demographics of participants were also included in questionnaire. Study

was done on health professionals (doctors, nursing staff & pharmacists) working in the medical college & hospital.

Pretesting of questionnaire was done on 5 randomized selected health professionals of the institute to identify any potential bias and mistakes. The name of the health professional was kept optional to avoid potential bias and to increase the number of responders but designation asked. The aim of study & questionnaire were discussed among the members of Pharmacovigilance committee and to the participants.

For submission of questionnaire time of 1 day was given and for those who had lost the questionnaire, we didn't resupplied the questionnaire. The information was recorded and analyzed using the Microsoft Excel worksheet (Microsoft Office 2010) and the ANOVA test. *P* value less than 0.05 was considered to be statistically significant.

Result:

The questionnaire was supplied to 200 health professionals and we got back 146 responses making a 73% of responses. The response rate was 56% among senior faculty members (Professor and Associate Professor), 84% among junior faculty members (assistant professor, senior resident and junior resident) and 92% were among paramedics (pharmacist and nursing staff).

The demographic profile of responders is shown in **table1**.

Awareness about pharmacovigilance based on our assumption of response to question number 1 of the questionnaire were calculated and it was found that 77% were aware and remaining 23 % were unaware. Awareness of pharmacovigilance among senior faculty members was 88.8%, junior faculty members 91.6%, while in paramedics were 59%. We did not include the responses of unaware respondents in further statistical analysis of questionnaire.

We assess the knowledge of respondents on the basis of question number 2-6 and gave maximum 10 marks. The mean knowledge of senior faculty members was 7, junior faculty members

were 8.5 and paramedical staff was 6.69. Knowledge of junior faculty was significantly higher ($p<0.05$) as compared to senior faculty. When we talked about existence of pharmacovigilance committee in the institute only 62.5% senior faculty and 23.07% paramedical staff knew that such a committee existed, while among junior faculty 81.8% were aware of pharmacovigilance committee. 87.5% senior faculty members, 91% junior faculty members and 77% paramedical staff thought that ADR reporting is a professional obligation.

Only 15% respondents receive training on how to report ADR to pharmacovigilance committee and 5% respondents had guided others on importance of ADR reporting but it is interesting that all respondents thinks that Pharmacovigilance should be taught in detail. Source of knowledge about ADRs of drugs of respondents are given in **table II**. Only 30% senior faculty and 25% paramedical staff had recorded ADRs while in case of junior faculty 45% had recorded ADRs.

It was found that none of the respondent were aware about the Ecopharmacovigilance.

Discussion

This study involved the paramedical staff (pharmacist and nurses) along with doctors. Doctors were divided into two groups, senior (Professor and associate professor) & juniors (assistant professor, senior resident and junior resident).

The paramedical staff has an important role in ADRs reporting, because they are close to the patient and are responsible for drug administration and recording side effects. Paramedics are also the first one to observe an ADR and can alert the responsible physician about possible ADRs without time gap. This shows the importance of encouraging the paramedics towards ADR reporting.[10]

This study has shown inadequate knowledge about ADRs and its reporting among doctors. A significant number (23%) of the respondents were not aware of the Pharmacovigilance. The cause may be the inefficient undergraduate training in pharmacovigilance. A major part of respondents had never come across ADRs

and it shows poor attitude towards ADRs reporting.

According to Inman[10]the reasons for under-reporting of ADRs can be complacency (belief that everyone know about serious ADRs as they are already documented during the introduction of drug into the market), diffidence (a belief that reporting is essential when there is a proof that ADR is caused by the use of a particular drug), financial incentives (any reward for reporting), ignorance (that only serious ADRs have to be reported), indifference (belief that a single ADR reporting would make no difference), legal aspects (fear of legal action) and lethargy (excuses that they have no time for ADR reporting or lack of interest).Some of these reasons were also documented in previous studies in India[12, 13]. In our study a major reason observed was ignorance which was also seen in a study conducted at Delhi[14]. A major part of all respondents did not know where to report an ADR while 42.36% junior faculty and 52.3% paramedical staff not know how to report ADR **(Table III)**. Lack of knowledge of where and how ADRs should be reported would automatically affect reporting, therefore, awareness programmes; through publicity, through notices & CMEs would appear necessary to improve ADR reporting among medical practitioners. It is satisfactory that almost all respondents think that ADR reporting is important but non aware respondents even did not know the importance of ADR reporting.

One important reason of underreporting was lack of access to ADR reporting form that's why about 65% of respondents suggested electronic option of ADR submission. (**Table IV**) A part of respondents were concerned that this reporting will generate extra work and some legal complication, so it is crucial to make proper counseling and training and encourage them to attend conferences and workshops on pharmacovigilance.

The various methods suggested by the respondents to improve ADR reporting are presented in **Table IV**.

Conclusion

This study shows poor knowledge, attitude and practices of pharmacovigilance and Ecopharmacovigilance among medical professionals so there is urgent need to improve the awareness of these among the healthcare professionals. The

questionnaire based studies have limitations of their own and it would be inappropriate to plan interventions based on the findings of some studies but present studies uncovers the importance of ADR reporting in the present scenario of ever increasing health conscious attitude and nature conservation attitude among different societies & countries. Our study suggest that ADRs & its reporting along with the importance of Ecopharmacovigilance should be included in the present medical curriculum which is followed in the country and intensively taught during undergraduate study, and this should be reinforced at the start of internships as well as periodically thereafter through CME.

Table I: Demographic Profile of study population

Age (years)	%	Male : Female
21-25	14	68:32
26-30	29	
31-35	25	
36-40	11	
>40	21	

Table II: Source of information about ADRs of new drugs

Sources	Senior faculty (frequency %)	Junior faculty (frequency %)	Paramedical Staff (frequency %)
MR/ Doctor	57.5	46.35	10
Internet	10	41	20
Books	35	59	53
Journals	35	45.8	11.5
Conferences/CME	37.5	46.35	11.5

Table III: Discouraging factors for not reporting ADR's

Factor	Frequency % Senior Doctors	Frequency % Junior Doctors	Frequency % Para medicals	Frequency % Not aware respondents
Did not know how to report	0	36.36	42.3	80
Not known where to report	37.5	59	42.3	80
Did not think it to be important	0	0	7.7	70.6
Managing the patient is more important than reporting ADR	25	31.8	46	0
Lack of access to ADR reporting form	37.5	40.9	23	0
Due to legal issue	25	9	26.9	0
Absence of fee for reporting	0	4.5	15.4	50.2
Concern that report will generate extra work	25	13.6	26.9	0
Concern that report may be wrong	0	4.5	7.7	0

Table IV: Suggested methods of improving ADRs reporting

Suggestions	Frequency % Senior Doctors	Frequency % Junior Doctors	Frequency % Para medicals	Frequency % Not aware respondents
Reporting of ADR to be made easy	87.5	81.8	38.46	23
Remuneration for ADR submission	62.5	45.5	11.53	53
Providing electronic option for submission	50	54.54	26.92	0
Making reporting mandatory	75	40.9	38.46	0
ADR reports to be kept confidentially	37.5	18.2	11.53	0
Provide toll free number for reporting	62.5	45.5	26.92	0
Make health professional more aware for ADR	62.5	68.2	69.23	85.6
Health care professional should be trained in ADR reporting	87.5	68.2	53.84	90
Having an ADR specialist in every department	25	22.72	38.46	75.2
Continuous medical education, training and refresher study	87.5	72.7	53.84	15.6

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Table II: Source of information about ADRs of new drugs

Sources	Senior faculty (frequency %)	Junior faculty (frequency %)	Paramedical Staff (frequency %)
MR/ Doctor	37.5	36.35	50
Internet	25	41	50
Books	75	59	23
Journals	25	31.8	11.5
Conferences/CME	37.5	36.35	11.5

Table III: Discouraging factors for not reporting ADR's

Factor	Frequency % Senior Doctors	Frequency % Junior Doctors	Frequency % Para medicals	Frequency % Not aware respondents
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