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"A prospective study of pharmacovigilance awareness among consumers of healthcare services in a tertiary care hospital of Jharkhand"

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Abstract
Background: *The access to healthcare is the primary right of the citizen. One of the important things to achieve such objective is by reporting of the adverse reactions by medications. In India the existing system for monitoring ADRs depends on spontaneous reporting from health professionals as a main source of information. Consumer's knowledge and perception towards adverse drug reactions & there reporting can play an important role in ensuring a healthy lifestyle and proper use of medicines.*
Aim & Objective: *a)To get the knowledge regarding ADR & pharmacovigilance among consumers of healthcare service,s b)To aware the consumers about the Adverse Drug Reaction & its reporting system*
Methods: *Every third patient or their attendant in the different wards & OPDs of RIMS, Ranchi were interviewed using a structured questionnaire. These documents were properly signed by the participants. We interviewed a total of 100 participants from 10/10/2019 to 19/10/2019.*
Results: *Most of the participants knew about the ADRs but very few knew about its reporting system i.e pharmacovigilance. Many participants had wrong concept about ADRs & pharmacovigilance.*
Conclusion: *From this survey we can conclude that consumers of healthcare services are aware of ADRs but since they did not know the reporting system these ADRs are not reported. This is a major cause of ADR underreporting. However participants are willing to report ADRs if they know what to report & where to report.*
Keywords: *Adverse drug reaction, Pharmacovigilance, ADR reporting system, Pharmacovigilance Programme of India*

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I. Introduction

The access to healthcare is the primary right of the citizen. To fulfill the objective to safeguard the health of general public, Pharmacovigilance program of India (P_vPI) was launched on 14th July, 2010.[1] Pharmacovigilance is defined by the World Health Organization (WHO) as 'the science and activities related to the detection, understanding, assessment and prevention of adverse drug reactions and any other problems which are related to drugs.[2] One of the important things to achieve such objective is by reporting of the adverse drug reaction (ADR). WHO defines an ADR as 'any response to a drug that is noxious and unintended, and that occurs at doses which are used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose.[3] ADRs are a major cause for morbidity and mortality.[4] ADRs entail a significant burden on healthcare facilities, increasing the length of hospital stay, and requiring sometimes additional investigations and drug therapies for the treatment of symptoms and diseases caused to the patient.[5] ADRs account for 5–10% of all hospital admissions.[6]

The National Coordination Centre-PvPI was launched as a WHO Collaborating Centre for Pharmacovigilance in Public Health Programs and Regulatory Services on 30 October 2017. The event also witnessed the launch of "National Strategic Plan for Scale up of Pharmacovigilance in India".

"We believe in India" is the tagline used by the PvPI on its website. It also ensures a place where all citizens have right to access medical facility, where medicines are affordable for the entire population & where all healthcare professionals & patients can report ADRs as a concern of safety.

The major challenge related to pharmavigilance in India is underreporting of ADRs. There are several explanations for this including deficiency of medical professionals, inadequate nationwide awareness of pharmavigilance etc. In developing countries like India, lack of basic facilities and easy going procedures results in under-reporting of ADRs which is a serious concern.

In India the existing system for monitoring ADRs depend on spontaneous reporting from health professionals which is the main source of information. Consumer's knowledge and perception towards adverse drug reactions & their reporting can play an important role in pharmacovigilance program of India & ensuring a healthy lifestyle with proper use of medicines.[7] Here in our study we focused on majority of the consumers of healthcare who come to Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, a tertiary care hospital.

II. Material & Methods

Participants were interviewed using a structured questionnaire[8,9]. This questionnaire was prepared by keeping the knowledge of the previous studies done regarding the consumers of different places. Name, gender, age, any addiction & address were noted. The documents were properly signed by the participants.

Study Design: Systematic random sampling**,** i.e every third patient or their attendant in the different wards & OPDs of RIMS, Ranchi

Study Location: Rajendra Institute of Medical Sciences, Ranchi, A tertiary care hospital of Jharkhand

Study Duration: 10th October 2019 to 19th October 2019.

Sample size: 100 participants

Inclusion criteria:

- All age group
- Either sex
- Attendants of the patients (if Pediatric or Geriatric group)

Exclusion criteria:

- Seriously ill patients
- Uncooperative patients

III. Results

A total of 100 participants were interviewed which also included the attendants of the pediatric & geriatric patients. Since a total of 100 participants were taken, so the absolute numbers in the result also shows the percentage (%) values. Out of 100, 46 were females & 54 were male participants. Among them all were addicted to some kind of substances eg. Bidi, Cigarette, Tobacco or Alcohol (Tadi). 67% of participants were educated below 10th class. 16% participants were educated to intermediate level. 17% participants were graduates or pursuing graduation. Participants were explained that they should choose most suitable option for their views, opinion and their understanding about adverse drug reaction & pharmacovigilance.

Table 1: Participants understanding about Adverse Drug Reaction/Aushadhi Dushprabhav:

Harmful response after taking a medicine at normal doses	**33**
Side effects experienced after taking medicine	**58**
Any undesired effects experienced after taking a medicine	**02**
Don't know	**07**

According to Table 1, 93% participants know that the adverse reaction or event can happen by taking medication. 33% said that it is harmful response after taking normal dose of medicine. Whereas others think that it is side effect or undesired effect of medication. 7% participants did not know anything about ADRs.

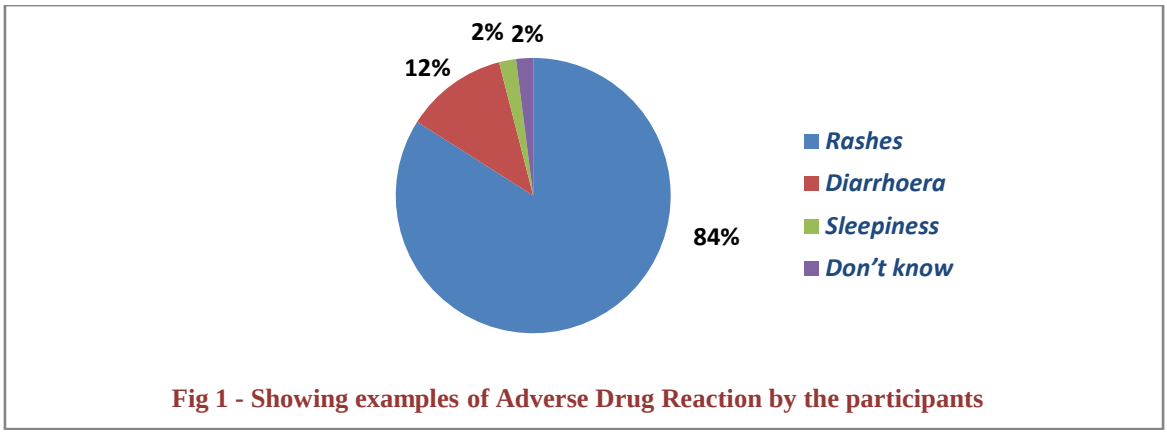

Fig 1 - Showing examples of Adverse Drug Reaction by the participants

Fig 1 shows that most participants said that rashes are the adverse reaction of most of the drugs. Diarrhea after taking a medicine is an ADR according to 12% participants. 2% participants did not know anything about this. However there are 62% participants who experienced ADR of any form at home either themselves or in their relatives.

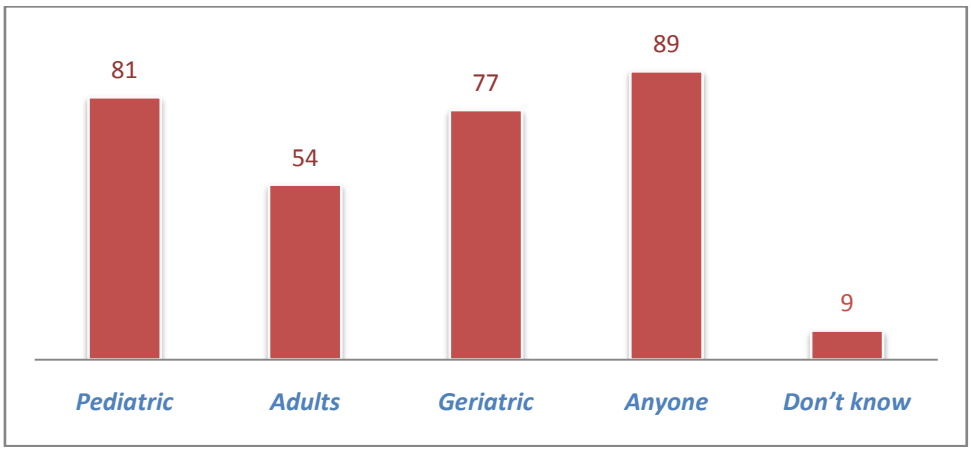

Fig 2: Participant's knowledge about vulnerable group of people who are more likely to develop ADRs:

According to Fig 2, it can be seen that most participants (89%) think that ADR can happen to anyone. However, most common age groups are pediatric (81%) & geriatric (77%).

Table 2: Participant"s perception about the purpose of adverse drug reaction reporting:

To strengthen safety of drug	**37**
To prevent recurrence of adverse drug reactions	**42**
Just to fulfill requirements	**00**
To help the doctor easily diagnose the illness	**21**

In our study, when we questioned about pharmacovigilance knowledge, only few (11%) participants responded that there is a system for adverse reaction reporting. However many participants had wrong concept about pharmacovigilance. Table 2 shows that 42% participants think that it is to prevent further ADR, 37% think that it is to strengthen drug safety, & others (21%) think that it will help the doctor to diagnose a condition.

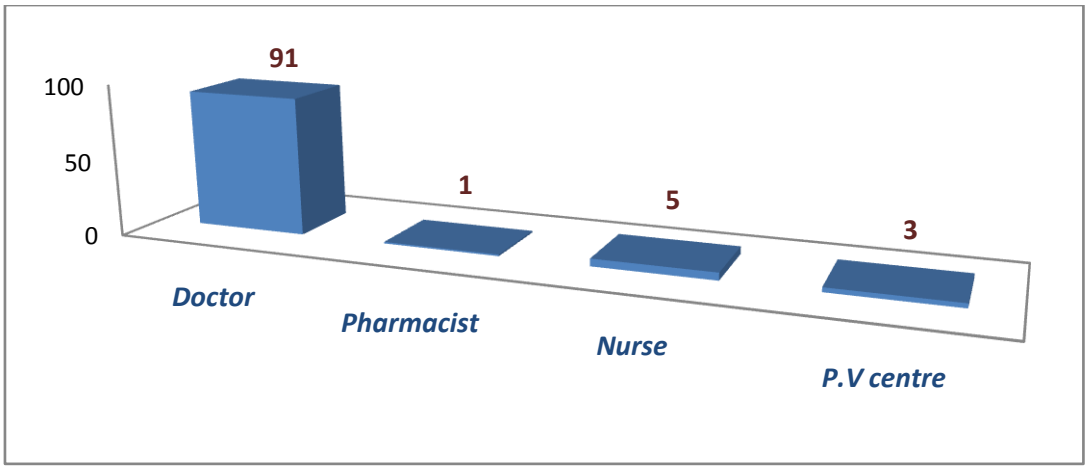

Fig 3: Participants thinking about the person to whom ADRs should be reported

As shown in Fig 3, every participant thinks that ADRs should be reported. 91% participants think that ADRs should be reported directly to the doctor. 5% think it should be reported to the nursing staff. 3% think that if ADR should be reported to the pharmacovigilance centre.1% think that if ADR should be reported to the pharmacist from where they purchased the medicine.

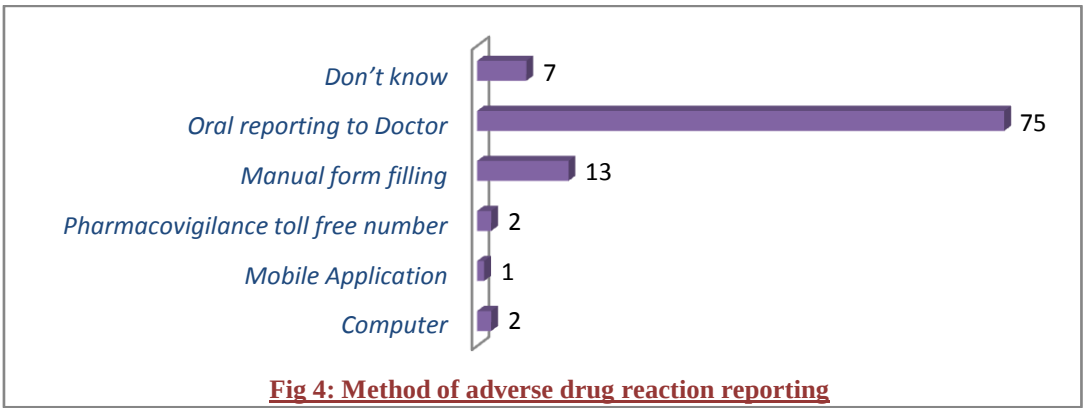

Fig 4: Method of adverse drug reaction reporting

Fig 4 shows that 75% participants think that most easy method to report ADR is direct oral reporting to doctor. 13% are willing to do that by manual form filling if they get the form. In the era of computer & mobile applications only 2% & 1% participants are willing to do ADR reporting via these methods respectively. 2% participants have heard about the pharmacovigilance toll free number. There are 7% participants who did not know anything about reporting methods.

Table 3: Participant's perception about effective way to educate the consumer regarding ADR reporting:

By Doctor/Pharmacist	**74**
Label over Prescription slip	**13**
Label on medicine leaflet	**02**
Awareness campaign	**06**
Newspaper article/Hoarding's about ADRs/Pharmacovigilance	**05**
Any other medium	**00**

The participants think that most people are not aware of the system of ADR reporting. So we asked for the effective methods to aware general public about the ADR reporting. As depicted in Table 3, 74% people think that it must be done by treating doctor or by the pharmacist. 13% think that label over prescription slip will be encouraging. 6% think that awareness campaign by government or non-government organization will be useful. 5% think that newspaper article & hoardings are a good measure to educate mass about ADR/pharmacovigilance. 2% participants said that label on medicine leaflet will be useful.

Table 4: Participants opinion about pharmacovigilance:

	Yes	No
Do you think that the adverse drug reaction reporting system is beneficial to the public	**87**	**13**
Do you think that it is necessary to aware consumers about an adverse drug reaction reporting system	**74**	**26**
If you know about adverse drug reaction reporting centre at RIMS, Ranchi, would you like to report by coming there?	**93**	**07**

Table 4 shows the participants opinion about pharmacovigilance. It shows that 87% participants think that ADR reporting is beneficial to the general public. 74% participants think that it is necessary to aware consumers about adverse drug reaction reporting system. 93% participants are willing to report ADRs at the ADR reporting centre in future.

IV. Discussion

In our study we found that most of the consumers of healthcare services are aware of adverse drug reaction. Most participants experienced some kind of ADRs but they rarely reported. They come to the hospital only when the reaction was severe or life threatening. Very few participants had knowledge of pharmacovigilance or ADR reporting system.

A study done in Malaysia shows that the goal is not achieved even after many years of pharmacovigilance in Malaysia. The consumer reporting of suspected ADRs must be introduced to improve their pharmacovigilance system.[8] This can be an important information source for clinical practice, to overcome under reporting & to promote consumer rights.[9]

A study done in Nepal found that Consumer reporting will be a good initiative for the Pharmacovigilance.[10] Their result was also similar to ours as their respondents had knowledge about ADRs but awareness of its reporting was lacking.

Tandon et al in 2015 explained underreporting of ADRs in India. The results of the study suggest that lack of knowledge and awareness about PvPI, lethargy, insecurity, workload, and lack of proper training in PV were some factors responsible for underreporting.[11] In a similar type of study, ignorance in 95%; diffidence in 72%; lethargy in 77%; indifference and insecurity in 67%; and complacency in 47% of subjects were held responsible for under-reporting.[12]

Jose & Rafeek in 2018 found that underreporting of ADRs is the major challenge related to PV in India.[13] There are several explanations for this including deficiency of medical professionals, inadequate nationwide awareness of PV. They suggested that all the health care providers including rural areas, should be given awareness about PV. ADR reporting was found to be on a higher percentage by physicians than pharmacists and health care providers.

Kalaiselven in 2019 found that despite PvPI achievements, the programme intends to continue with the same passion to meet its challenges, like creating awareness in the country's population, with special attention to disease-specific ADRs.[14] Confidence about the PvPI in the healthcare providers & consumers is essential. They should know that the programme intended to build trust between the physician and the patient, thereby increasing patient safety.[15]

Though the organizations regarding pharmacovigilance are doing tremendous work to aware the general public & to enhance the reporting, but still consumers are not reaching the system.

V. Conclusion

This study gives us an idea about knowledge & thinking of pharmacovigilance among consumers of healthcare in a tertiary care hospital of Jharkhand. Here we conclude that awareness about ADR is fair but consumers are unaware of pharmacovigilance. So, awareness among the consumers must be increased by various possible means.

In this study we promoted pharmacovigilance by providing them ADR form, toll free number & the address of ADR monitoring centre in our hospital. We also convinced the participants to report any type of ADR in future.

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