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Original Research Article

To Measure Patients (Consumers) Knowledge and Awareness of Pharmacovigilance, as well as their Involvement in Reporting Adverse Drug Reactions

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Conflict of interest: Nil

Abstract

Background: The purpose of the current study was to conduct drug safety monitoring in tertiary care hospitals with established patient education programmes for adverse drug reactions (ADRs) and to evaluate the role of patients (consumers) in ADR reporting.

Methods: Total 300 patients were enrolled in this study. The subject was chosen using the simple random sampling procedure. The study, which was 6 months long, followed patients from the departments of paediatrics and medicine at Dr. Ulhas Patil Medical College and Hospital in Jalgaon. The study staff has direct contact with the participants. Information was gathered using a Case Recorded Form that Involves an ADR Reporting Form, and then Causality Analysis was used to analyse it (WHO and Naranjos Scale). Consumer data is collected for the test arm (Patients). Information gathered from healthcare professionals makes up the control arm. Data from Consumers and Healthcare Professionals were Converted into Generic Names on ATC (Anatomical Therapeutic Chemical Classification system).

Results: More women than men have information about diseases. More educated people than uneducated people knew about diseases. Consumer reports of reactions revealed that 50% were moderate, 25% were mild, and the remaining 25% were severe. Only 12.33% of patients are aware of their drug regimen. 1.10% was reported the ADR. 4.33% of patients told their doctor about their ADR. 2% of patients reported having an ADR. Fifteen ADRS were determined to be Probable, seven to be Possible, and one to be a Definite Type by the causality assessment. Five patients sent us serious ADRs. More serious ADRs are reported by healthcare professionals than by patients. According to the finding, consumer reporting of dermatological ADR was simpler.

Conclusion: Reporting an adverse drug reaction (ADR) involves both the prescribing physician, Patients (consumer) and the delivery pharmacist. It is collaborative.

Keywords: Reporting Adverse Drug Reactions, Knowledge, Attitude, and Healthcare Professionals.

Introduction:

In terms of morbidity, mortality, and cost, adverse drug reactions (ADRs) constitute a recurring and significant issue in healthcare [1]. ADRs are a major issue for patients and all healthcare professionals [2]. Although taking them as prescribed, patients nevertheless experience negative effects from [3]. Using a variety of channels, including as the mail, internet, and telephone[4], the FDA's programme for postmarketing surveillance gathers clinical data about medications from consumers and health-care providers. Health care professionals, patients, and others must all participate in the process of identifying ADEs. AERS comprises over 2.5 million adverse event reports that were generated by healthcare professionals or laypeople [5]. and Because there aren't many established scientific standards for data collecting, the data in the database may not be thorough, and the conclusions drawn may be challenging to understand[6]

The prudent prescription of drugs is crucial to drug safety[7]. Winterstein *et a l*meta-findings's analysis's revealed that 59% of ADRs are avoidable [8]. Research have shown that mistakes made during the prescription procedure were the cause of approximately half of preventable ADRs. A significant portion of these mistakes, like prescribing the incorrect dosage or substance, frequently happen as a result of a lack of knowledge regarding the medication, the patient, or both[9].

According to Lazarou *et al* estimation's [10]. ADRs were the fourth to sixth leading cause of death in the US. The introduction of numerous very dangerous substances as medications during the past two or three decades has increased the importance of detecting adverse drug reactions (ADRs). Health care providers should be well-versed in drug safety.

A lot of work is needed to gather ADR data that may result from safety surveillance of billions of therapeutically active drugs, either alone or in combinations, because there are very few active ADR monitoring centres in India. Pharmacovigilance is a crucial component of medication therapy. However, it is not frequently used in Indian hospitals[11]. Adverse medication reactions have been linked to numerous studies as a major factor in significant morbidity and mortality. Studies have shown that the occurrence of ADR can range from 0.15% to 30%[12]. Older patients and those who are hospitalised are believed to be more vulnerable to ADRs than the general adult population (16.6% vs. 4.1%). There haven't been many reports on ADR monitoring in India; this may be because ADR monitoring is still developing in this countryA national pharmacovigilance programme has been launched by the Central Drug Standard Control Organization (CDSCO) under the supervision of the Directorate General of Health Services (DGHS). Despite these attempts, the prescribers' spontaneous reporting is weak. Widespread underreporting of ADRs is concerning; in fact, 51% of major ADRs associated with commercially available medications went undetected before approval [13]. This may be due to prescribers' apathy and ignorance, among other factors [14].

To improve the dismal state of ADR reporting in India, it is crucial to comprehend these causes.

The purpose of hospital-based ADR monitoring and reporting programmes is to identify and measure the hazards related to drug usage. This knowledge may help identify and reduce avoidable ADRs while overall boosting prescribers' ability to deal with ADRs more effectively. It is uncommon for patients or consumers to take part in

national pharmacovigilance programs[15]. To improve the dismal state of ADR reporting in India, it is crucial to comprehend these causes.

The purpose of hospital-based ADR monitoring and reporting programmes is to identify and measure the hazards related to drug usage. While generally boosting knowledge, this information may be helpful in recognising and eliminating avoidable adverse drug reactions (ADRs). Only in a few nations are patients involved in these programmes. Patients will have the ability to contact the Medicines and Healthcare products Regulatory Agency (MHRA) to report suspected adverse drug reactions (ADRs) without the assistance of a healthcare provider, according to Health Minister Lord Warner. Consumers have submitted the user-friendly yellow form[16]. Patient participation in such activities has been minimal in India due to the prevalence and ongoing development of patient literacy-related difficulties. Getting patients to report adverse drug reactions (ADRs) in a way that works for them is difficult because it is well known that people do so more quickly than medical professionals[17]. he study came to the conclusion that patient self-monitoring would be a promising addition to the current doctor-based reporting system and a potential early warning system for identifying adverse drug reactions (ADRs) to new medications. There aren't many initiatives to involve consumers more fully in the process, and there isn't a thorough framework in place for them to report negative experiences. Although the specifics of how patients would report suspected ADRs are not yet known, trial programmes may be implemented to find the most effective way.

Customer reports should be verified by a medical expert (MHRA, 2005).

By informing the appropriate authorities of his ADR via a passive monitoring system, the consumer can play a significant role. Consumers should report issues as soon as possible so that the agency can act quickly. Despite having strong incentives, consumers are rarely managed actively in the process, and there is no comprehensive structure in place for them to report negative events. Customer reports should be verified by a medical expert[18].

By informing the appropriate authorities of his ADR via a passive monitoring system, the consumer can play a significant role. Consumers should report issues as soon as possible so that the agency can act quickly. Despite the fact that consumers have strong incentives, there are little attempts to manage them more actively throughout the process and The fact that reporting systems used in many nations vary raises a potential issue, and there has been a need for them to be uniform[19].

So, the population as a whole will profit from the creation of a better infrastructure for consumer reporting.

The study of consumers' (patients') roles in adverse drug reaction monitoring is one of the goals and objectives.

Goal:

- To Analyze the Difference between the information collected via patient and health care Professionals.
- To create and put into place a unique, user-friendly adverse drug reaction reporting form for customers.
- To investigate patient education status in relation to their awareness of ADR.
- To establish the interval between the occurrence of an ADR and its reporting
- To examine the data gathered from the parents of the kids.

Inclusion criteria:

- All IPD patients from the paediatric and medical departments.

Age: 5 years to 65 years.

- Consent to treatment provided in writing from the patient and any parents or other family members.

Exclusion criteria:

Refusal of the patient to provide informed consent.

- People who are suffering from

Methodology/Study Design: This study was conducted to examine how consumers (patients) can become aware of, report, and gain knowledge about adverse drug reactions (ADRs). This study +also compared the data that was gathered from patients and healthcare providers. This study followed patients from the departments of medicine and paediatrics at the Dr. Ulhas Patil Hospital for a period of six months. The research team has direct access to the patients in this investigation. The data was gathered in CRFs, which include ADR reporting forms, and then statistical analysis was performed on the results to determine causality analysis (using the WHO Scale and Naranjo's Scale), preventability (Schumock and Thronton, 1992), severity, and seriousness.

The study lasted six months, and the sample size was 300 patients.

- **Sampling Strategy:** A straightforward random sampling technique was used to choose the patients.
- **Test Arm:** Information gathered from Customer /Patients.

Information gathered from healthcare professionals serves as the control arm.

Consumers: Patients, patients' relatives, and other members of the public who have reported ADRs.

Six (6) months were spent on the study.

- 300 Patients Make Up the Sample
- **Sampling Strategy:** A straightforward random sampling technique was used to choose the patients.
- **Test Arm:** Information gathered from Customer /Patients.

Information gathered from healthcare professionals serves as the control arm.

Consumers: Patients, patients' families, and other members of the public who report ADRs

Healthcare Professionals: Nurses, doctors (hospital doctors), RMOs, and pharmacists have submitted ADR reports.

Consumers (Patients) received an easy-to-use questionnaire that evaluated their understanding of the disease and its unintended effects.

- The ADR form for the actual adverse event was given to the medical staff.

The utility of the information provided by healthcare professionals was evaluated based on data from consumers and healthcare professionals.

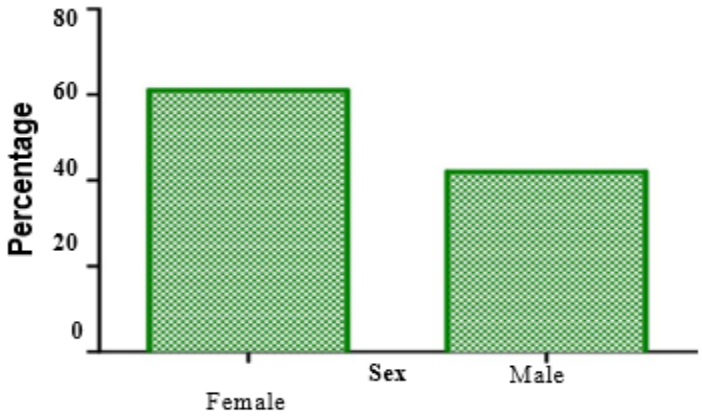
ATC Group: The Anatomical Therapeutic Chemical (ATC) classification scheme. The information given by consumers and healthcare providers was converted into the generic name on ATC.

Descriptive analysis of reported adverse drug reactions (ADRs) categorised as serious: We looked at the distribution of reported ADRs categorised as serious, broken down by system organ class and ATC group. The classification of ADR reports based on seriousness criteria is done in accordance with internationally accepted standards (Volume 9A). ADRs considered as significant if the study has caused mortality, congenital defects in the foetus, foetal death and spontaneous abortion; involved in the protracted inpatient hospitalisation, involving persistent or substantial disability/incapacity or were life threatening.

Study of consumer reports' traits in comparison to those of medical experts the national pharmacovigilance data base of the Zonal Pharmacovigilance Centre and the collected ADRs from consumers were examined in order to identify any discrepancies between the information given by consumers and healthcare providers. Consumer ADR Reporting Form: The ADR reporting form was created using user-friendly techniques for the consumer. the translation of the form into the regional tongue.

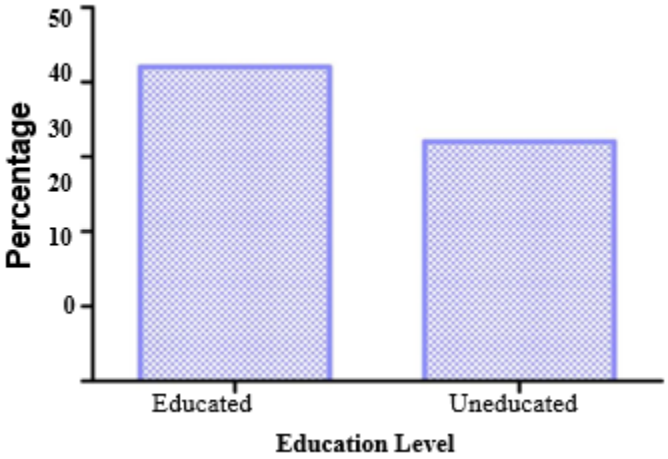
Results

Graph 1.1: When disease related awareness was checked with the help of Z test for difference between 2 proportion then we found value of Z as 1.925, which was less than 2 hence we accept our null hypothesis i.e. there is no significant difference between in disease related information between males and females.



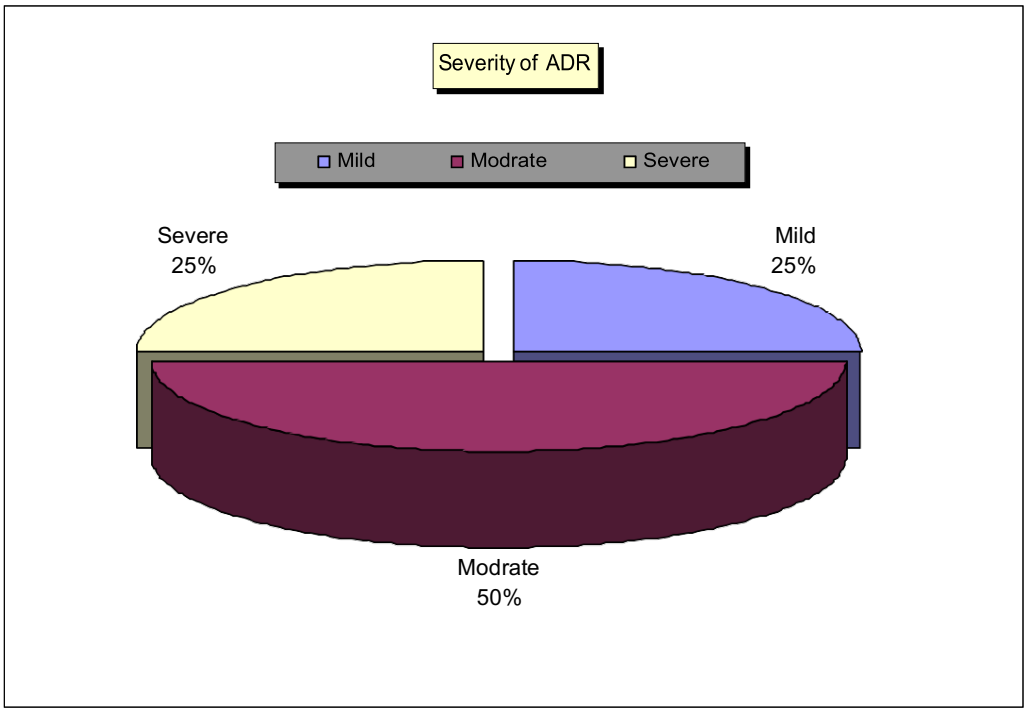
Graph 1: Percentage of Male Vs Female Consumer Aware About TheirDisease

Graph 2: When disease related awareness in educated and uneducated class was checked with the help of Z test for difference between 2 proportion then we found value of Z as 1.31, which was less than 2 hence we accept our null hypothesis i.e. there is no significant difference between in disease related information between educated and uneducated.



Graph 2: Uneducated and Educated Patients with Their DiseaseInformation

Graph 3: Severity of Adverse Drug Reactions Reported by theConsumer 50 % of the reaction reported by the consumer found to be moderate typewhile 25% was mild and 25% severe type



Graph 3: Severity of ADR

Table 1: Number Of Patients who are Aware about The Medication They Were Taking

Patients	37*/300	12.33%

All the patients know about their medication

Thirty-Seven (37) out of the 300 patient (12.33 %) know what medication theyare receiving.

Table 2: Number of patients who were aware of adverse effectsabout their medication

Patients	32*/300	17.33%

*Educated

The information about the adverse event was asked, only the 22 out of 300(1.10 %) was reported the information about the AE.

Table 3: Number of patients who reported their AE

Patients	13/300	4.33%

Thirteen (13) out of the 300 patients were communicated their adverse event to theirphysician

Table 4: Number of patients who were aware about the reason of theirADR

Six out of 300 patients were aware about the reason of the ADR
Patient who knew probable reason $\frac{6}{300}$ 2%

This patient thought that his ADR was due to wrong dose administration of givenmedications.

Table 5: Causality Analysis For The Consumer Reported ADRs byNaranjos and WHO Scale

ADR	Causality	Drug	Number of patients Reported ADE
Bleeding	Probable	Warfarin	6
Rash	Probable	Vancomycin	9
Abdominal Pain	Possible	Isoniazide	3
Seizure	Possible	Phenytoin	4

Table 6: Distribution of ADRs by reporters and Criteria on Seriousness

Reporters	Consumers	Health Care Professionals			Total
Seriousness		Physicians (Hospital Doctors)	Nurses	RMO*	
Serious	5	5	15	7	27
Non–Serious	17	2	9	10	21
Total	22	7	24	17	48

*Residence Medical Officers

When we compared the consumer reports to the health care professionals, the consumer's reports less serious adverse event, we received three serious adverse events from consumers. The reporting patterns are totally contrast in the health care professionals. Heath care professionals reports more serious adverse event than the non-serious adverse event.

Table N7: Distribution of ADRs reported by consumers by ATC level

ATC	Consumer Report
A (Alimentary tract and Metabolism)	3
B (Blood and Blood Frame Organs)	6
C (Cardiovascular System)	-
D (Dermatological)	9
G (Genito Urinary System and Sex hormones)	-
H (Systemic Hormonal Preparations)	-
J (Antiinfectives for systemic Use)	-
L (Antineoplastic and Immonumodulating Agent)	-
M (Musculo-skeletal System)	-
N (Nervous System)	4
P (Antiparasitic products, Insecticides and repellents)	-
R (Respiratory System)	-
S (Sensory Organs)	-
V (Various)	-

The consumer reports categorized into Anatomical Therapeutic Classification (ATC).From the observation it was easier for the consumer to report dermatological adverse event.

Table 8: Comparison between the Consumer Report and HealthCare Professionals Reports

S. N>	Consumer	Health Care Professionals
Causality		
Certain / Definite	1	5
Probable	15	24
Possible	7	15
Unlikely	1	2
Unclassified	Nil	1
Unclassifiable	Nil	1
CTCAE* Classification version 3.0		
Grade I (Mild AE)	3	27
Grade II (Moderate AE)	2	18
Grade III (Severe AE)	Nil	3
Grade IV (Life Threatening AE)	Nil	Nil
Grade V (Death Related AE)	Nil	Nil
Preventability		
Definitely Preventable	3	29
Probably Preventable	2	19

*CTCAE=Common Terminology Criteria for Adverse Drug Events

Discussion

The direct reporting of adverse drug reactions by patients is becoming a increasingly important topic for discussion in the world of pharmacovigilance. Very few studies have analyzed the role of consumers in the in the drug safety on literature survey itwas found that most studies conducted in India were regarding the ADR incidence, classifications & analysis, but the reason for poor or under reporting of ADR in different strata of our society was sidetracked by all studies. Our study made an effort to identify some of these ADR reporting-related problems. We discovered that only 0.59% of patients actively reported their ADRs, and those reports were only made to the treating physician; none of the patients had any knowledge of the other ADR reporting methods.

When compared to other research, our study's ADR incidence—which was only 2.27 percent—was quite low, at roughly 6 to 10%. (Arulmani R *et al*., 2008) According to our study, patients were over 40% aware of their ailment, 3.42% were aware of their medications, and just 2.27% were aware of adverse drug reactions. We also conducted a gender-based analysis of disease and medication awareness, revealing that women (61.29%) were more knowledgeable than men (42.36%). Even the fundamental elements of their health problems, such as the illness they had and the medications they were taking, were unknown to these individuals.

Our investigation proved that 59.04% of patients had no idea of their condition, their medicine, or any side effects. Few patients—nearly 2.85%—reported being sensitive to some medications, but the majority of them were unable to identify the specific drug to which they were hypersensitive. This means that patients should first be made aware of the fundamentals, such as the sickness they are now experiencing, the medications they are

taking, and any potential adverse drug reactions they may be afraid of.

The best people to handle this would be the serving healthcare experts. Few patients—nearly 2.85%—reported being sensitive to some medications, but the majority of them were unable to identify the specific drug to which they were hypersensitive. This means that patients should first be made aware of fundamental issues including the sickness they are now experiencing, the medications they are taking, and any potential adverse drug reaction After learning more, patients may well apply this knowledge and at the very least inform their medical physicians about their ADR. It is important to promote knowledge of alternative ADR reporting methods, such as those that use the Internet, telephones, or reporting to medical professionals like pharmacists and nurses.

A user-friendly ADR reporting form for patients, investigators, and participating healthcare practitioners has been developed as part of our study Regarding the many areas of ADR Reports relating to medications dispensed, this form contained sufficient information. Even for lay or uninformed patients, this method has been shown to be quite practical for reporting an ADR. In order to update ADR information with relevant medications, such forms should be made available with every national programme (ART Centers, National TB Program, National Malaria Program, etc.).

Advertising about them in all mass media outlets might help stimulate active ADR reporting and various reporting methods Consumers can only report one ADR that is considered serious, which means patients can only report non-serious ADRs. In the current study, health care professionals reported more serious ADRs than non-serious ADRs. Professionals report a greater percentage of serious ADRs. Our investigation shows same outcome as that of Somers *et al*., 2003. e WHO and Naranjo's algorithm's techniques for determining causality were both applied to ADRs reported by consumers where only one ADR fit into a clear category. As we spoke with the patient, they responded about how often the rash occurred after taking paracetamol. highlighting the consumers' contribution to the "Definite" class of ADRs

Only one of the 83 probable ADRs was labelled as "doubtful" using a generally utilised causality assessment method in the study's subsequent review of the patient reports.

The fact that there are more female consumer reporters than male indicates that women are better conscious of their rights as consumers. There are several cases where customers are unable to disclose as warfarin toxicity or laboratory results as increased INR. Only symptoms-related information can be reported by the patient; however, the implications must be determined by healthcare specialists in order to appropriately assess ADR. Although our study was unable to detect the creation of new information by consumers, our conclusions show that patient reporting does enhance expert reports of adverse drug reactions by identifying potential new responses. Patient reports are clearly desired from a political and strategic standpoint. The reporting of side effects has been characterised by Edwards as worry reporting (Edwards *et al*. 2000). Apart from medical professionals, drug users also worry about these things. Yet, there is now ample evidence from numerous nations where patient reporting is established that patients have discovered potential novel adverse drug reactions (ADRs). Poor patient report quality has not been noted as a problem in any of the nation’s using patient reporting systems. A well-organized reporting system might carefully examine patients' experiences with particular drug classes.

We draw the conclusion that patient reporting should be implemented in India right away, along with thorough process and result review.

Conclusion

Reporting in collaboration with the prescribing doctor and/or pharmacist and patients seems to be the optimal form of reporting, assuming that these professionals do report. Adverse medication responses affect patients as well as the prescribing doctor and the delivering pharmacist.

Limitations

The study was carried out in a tertiary medical facility that mostly treats patients from low socioeconomic statuses or with rural ties. Such a study would be advantageous if it were carried out at private hospitals because it would inform us of other study-related elements. DE-challenge and Re-challenge were two components of ADR analysis that weren't used. If this study had been done, there would have been many more study-related components in the picture. Multi-centric.

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