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AWARENESS AND ATTITUDES TOWARDS ADVERSE DRUG REACTION REPORTING AMONG PATIENTS IN RURAL MADHYA PRADESH: A CROSS-SECTIONAL STUDY OF DISTRICT HOSPITALS.

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Abstract:

Background: Pharmacovigilance is an essential component of pharmacological sciences, encompassing the investigation, assessment, detection, and mitigation of adverse drug reactions with the aim of safeguarding pharmaceutical safety. Even while drugs have many advantages, patients who use many medications may experience unforeseen bad effects. Enhancing patient safety and optimizing the benefit-risk profile of medications across their whole lifespan depend on effective pharmacovigilance. Key players in national and international ADR monitoring include the Pharmacovigilance Programme of India (PvPI) and the Uppsala Monitoring Centre. **Aim:** To assess patients' awareness of and attitudes regarding reporting adverse drug reactions. **Methods:** A cross-sectional study was conducted among patients visiting for treatment at district hospital. Adult patients' knowledge, awareness, and reporting habits of ADRs were evaluated. **Results:** A response rate of 77.5% was recorded. Most were between the ages of 18 and 40. Just 8% knew what pharmacovigilance was and 38.7% knew what ADRs were. Notifying healthcare practitioners and halting medication were the main priorities for reporting ADRs. Common obstacles to reporting ADRs include ignorance and the belief that they are not significant. **Conclusions:** Despite their encounters with ADRs, the study reveals a gap in patients' knowledge and comprehension of ADR reporting.

Keywords:

Pharmacovigilance, Adverse Drug Reactions, ADR reporting, Patient safety.

INTRODUCTION:

Pharmacovigilance (PV) focuses on monitoring and ensuring the safety of medicinal products. PV involves four key activities, which are detection of adverse effects and other drug-related issues, assessment of the gathered safety data, understanding the mechanisms and implications of drug-related problems, and prevention of potential adverse reactions and complications.[1] Pharmaceutical products, may produce unwanted side effects when administered at therapeutic dosages, even as they deliver their intended benefits. These unintended consequences are commonly referred to as adverse effects. Unless its causality is determined, an adverse event (AE) may not always represent an adverse drug reaction (ADR). Patients who take multiple medications concurrently are more likely to experience ADRs. These reactions may be due to changes in the drug's pharmacokinetics and pharmacodynamics, drug-drug interactions, drug hypersensitivity, or genetic factors like age, sex, gender.

The ultimate goal is to enhance patient safety and optimize the benefit-risk profile of pharmaceutical interventions throughout their lifecycle, from development to post-marketing surveillance. Since ADRs are the reason for hospital admission, it is imperative that all the healthcare professionals monitor medications and their corresponding ADRs. The Uppsala Monitoring Centre (UCC), Sweden, is in charge of international drug monitoring and operates with technical assistance and advice from WHO.[2] The UCC has developed many tools that seamlessly support reporting of suspected ADRs. Drug manufacturers, healthcare providers, and even patients can frequently use different tools available through the Pharmacovigilance Programme of India (PvPI) to report AE and ADRs. PvPI currently operates with 311 AMCs in India.

Healthcare professionals can report the suspected ADRs using the Red English imprint form (Version 1.3). The consumer reporting form in blue is meant for voluntary reporting by consumers/patients (Version 1.0), which is developed in ten vernacular languages for consumer convenience.[3] By calling the toll-free number, 1800-180-3024, ADRs can also be directly reported to NCC-PvPI.

The PvPI makes every effort to gather data on AEs from all around the nation and occasionally provides stakeholders with safety information on medical products through its numerous resource materials.

METHODS

Study setting

Situated in the eastern region of Madhya Pradesh, district accommodates 1.47% of the state's total population. The District Health System (DHS) of consists of 229 functional subhealth centres (SHC), 32 rural primary health care centres (PHC), one urban PHC, seven community health centres (CHC), one district hospital (DH) in Shahdol and one civil hospital (CH) at Beohari. (3) A study was conducted at various OPD attendees of the district hospital.

Study design

This was a questionnaire-based cross-sectional study that was conducted for a duration of one month (July–August 2019) among the patients attending the District Hospital, after getting ethical approval.

Study population

All the adult patients who were attending the district hospital for medical care were enrolled in this study only after obtaining informed consent.

Sample size determination

As no similar study was conducted in this geographical area till now, all the adult patients aged over 18 attending the district hospital OPD during the months of July and August 2019 were included in the study after obtaining informed consent.

Data collection instrument

The semi-structured questionnaire for patients consisted of socio-demographic information, knowledge, awareness, and understanding of pharmacovigilance and ADR reporting, as well as ADR reporting practice. Two academic researchers with extensive knowledge in ADRs and pharmacovigilance evaluated the questionnaires for content validity. This is done in order to make sure that there are no unclear questions or statements and to determine how thorough the item-statements in the questionnaires are in relation to the study objectives. Minor changes were made to the questionnaires based on feedback from the pretest and validity assessments. The patient's questionnaire and the informed consent form were translated into the local Hindi language for ease of patients understanding.

Data collection procedure

While patients waited for their turn at various OPDs to receive treatment for their health-related issues from the healthcare professionals, they were enrolled for participation. Before recoding the response to the questionnaire from each participant, the informed consent form in the approved protocol was read and explained to them. This form contained information about the risks and benefits of participation, the expected duration of involvement, the study's objectives and procedure, and other pertinent details. Participants were informed that participation in the study is completely voluntary and that their answers would remain anonymous. All the responses were recorded by the single investigator to eliminate intra-rater errors, if any.

Data analysis

The SPSS version 20.0 was used for database management and analysis. The data was summarized using descriptive statistics, such as percentage and frequency. In the knowledge domain, "adequate" general knowledge of ADRs and reporting was defined as a total correct score > 80% (i.e., > 10 out of the 13 maximum attainable scores), while "inadequate" knowledge was defined as a total score ≤ 80%. A "positive" attitude toward ADR reporting was indicated in the attitude domain by a total ranked score > 80% (i.e., > 36 out of 45

maximum points), whereas a "negative" attitude was indicated by a total ranked score ≤ 80%. In the knowledge and attitude categories, the cut-off for the overall percent score was derived from Bloom's cut-off point criteria and other relevant research.[4] Using Pearson Chi-square test, associations between patients' sociodemographic traits and knowledge of ADRs, pharmacovigilance awareness, and reporting of ADR experiences were examined. $P < 0.05$ was considered as the statistical significance threshold.

RESULTS:

Socio-demographic characteristics of patients (Table 1)

Out of the 400 eligible patients who were asked to participate in the study, 310 of them (77.5%) granted consent and were enrolled in the study. There were 188 (60.6%) females and 122 (39.4%) males in total. Of those surveyed, 232 (74.8%) belonged to the 18–40 age group, while 78 (25.0%) were older than 40. Of the patients, the majority 185 (59.6%) were self-employed. Thirty-two patients (10.3%) had never attended school, whereas 188 patients (60.6%) had attended high school and 90 patients (29.0%) had completed graduation or university education.

Patients' knowledge and awareness of pharmacovigilance and reporting adverse drug reactions (Table 2)

Twenty-five patients (8%) had heard of the term "pharmacovigilance," primarily from their prior educational experiences and also from the healthcare professionals they knew. A total of 120 patients, or 38.7%, had an accurate understanding of what an ADR is. Of the patients who report ADRs, seventeen (5.5%) were already aware of the ADR reporting forms. The majority of them—09, or 52.9 percent—learned about them from online sources. None of them stated that they had found an ADR form drop box at the OPD premises.

ADR reporting practice among patients (Table 3)

ADRs had occurred in one way or another for 276 patients (89%) out of the total. Patients who reported ADRs prioritized notifying a healthcare provider (178; 38.1%) and stopping the medication (103; 22%) among the actions they took. ADRs experienced before were reported by 82 patients (26.4%). Some explanations put forth for why experienced ADRs were not reported were a lack of awareness of the significance of ADR reporting (116; 37.4%) and the non-seriousness of the ADRs (98; 31.6%).

Association between patients' socio-demographic characteristics and pharmacovigilance awareness, as well as ADR knowledge and reporting of previously experienced ADRs. (Table 4)

Patients who had 'graduated and above degrees' were those with better pharmacovigilance awareness (68%), ADR knowledge (80.6%), and ADR reporting practice (80.8%).

Compared to those with lower educational qualifications ($p < 0.05$), patients who were within the age range of 18–40 years (68.9%) constituted those who largely reported the experiencing ADRs compared to those above 40 years (31.1%).

DISCUSSION

According to our research, fewer than 10% of the patients had heard of pharmacovigilance, and only approximately 5.5% were aware of the "ADR REPORTING FORMS" that were used to report ADRs. Our findings correlate with similar studies from Durrieu G et al and Dutta A et al.[5,6] However, over one-third of the patients showed a thorough comprehension of what constitutes an ADR. In our study, men showed a higher level of understanding of ADRs than women (62% vs. 37%).

Prior research has likewise revealed a low degree of pharmacovigilance activity awareness.[7,8] The majority of patients who were aware of pharmacovigilance learned about it via prior educational experiences and from a close healthcare provider, which is noteworthy. Our research has not identified news or social media sites as possible sources. The healthcare facilities' remote location could be one of the causes of this. Nonetheless, it should be highlighted that about 67% of the patients reported having previously encountered ADRs. The reason for why experienced ADRs is not reported in our study were ignorance of the significance of ADR reporting and the insignificant nature of the ADRs. Compared to patients over aged 40, those between the ages of 18 and 40 reported suffering ADRs substantially more frequently (68.9% vs. 31.1%). This could indicate that more work needs to be put into educating the public about the value of promptly reporting experienced ADRs to healthcare providers or using ADR forms to report experienced ADRs to the National Pharmacovigilance Centre. ADRs occurred in about 89% of the patients at some point. The most common actions taken by patients who experienced an ADR were stopping the drug(s) and notifying a medical practitioner. It is noteworthy that 92% of patients reported ADRs to a healthcare provider directly, whereas 0.32% of patients—or 1 out of 310—reported ADRs by filling out an ADR reporting form. None of them reported ADR by any of the online means. This may highlight the need to investigate a variety of strategies, such as social media platforms, to ensure public awareness and information sharing about the early identification and reporting of adverse drug reactions.

The following limitations must be taken into account despite the valuable information this study has to offer. First, there may be selection bias due to the study's cross-sectional nature, which only included a snapshot of participants from one district hospital, particularly among the patients. The study's self-reported design may also have some inherent drawbacks, such as individuals who may report information more or less accurately, and recall bias may not always be completely ruled out. Nevertheless, it has been reported that self-report measures, particularly when used in conjunction with non-threatening or judgmental asking techniques, are a trustworthy means of getting respondents to provide fairly accurate information since they may feel more comfortable being honest.[9,10]

However, to ensure a comprehensive conclusion, future research might need to consider the highlighted gaps.

CONCLUSIONS

A gap in the formal ADR reporting system was identified in the study. It was evident that many of them do not realize the necessity of reporting ADRs. Study reported low awareness of pharmacovigilance and availability of ADR reporting forms. To enhance ADR reporting practices, there is a need for increased public awareness about pharmacovigilance and the reporting process.

STUDY LIMITATIONS:

The study acknowledges limitations, including potential selection bias, self-reporting issues, and recall bias. Despite these limitations, self-reported measures, especially when designed to be non-threatening, are considered reliable for gathering accurate information.

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COMPETING INTERESTS

No conflicting interests have been disclosed by the authors.

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TABLES:

Table 1: Socio-demographic characteristics of patients.

Variables		N (%)
Age (year)	18-40	232 (74.8)
	41 and above	78 (25.0)
Gender	Male	122 (39.4)
	Female	188 (60.6)
Marital status	Unmarried	55 (38.5)
	Married	84 (58.7)
	Widowed/Divorced	4 (2.8)
Occupation	Public servant	49 (15.8)
	Self-employed	185 (59.6)
	No active employment	76 (24.5)
Educational qualification	No formal education	32 (10.3)
	High school degree	188 (60.6)
	Graduation and or above	90 (29.0)

Table 2: Patients' knowledge and awareness of pharmacovigilance and ADR reporting.

Variable		N (%)
Ever heard of pharmacovigilance (n = 310)	Yes	25(8)
	No	285(91.9)
If yes, the source of awareness (n = 25)	Social media platform	5(20)
	Newspaper	1(4)
	Previous educational experience	11(44)
	A close healthcare professional	8(32)
What is your understanding of an ADR ? (n = 310)	Any effect from a medication one is taken	135(43.5)
	Unexpected reaction after taking a medication	120(38.7)
	Expected reaction	55(17.7
	Do not know	8(2.6)
A serious ADR means: (n = 479)**	A reaction that may lead to hospitalisation	147(30.6)
	A reaction that is life-threatening	115(24)

	A reaction that requires another drug treatment	209(43.6)
	A reaction that resolves on its own	0(0)
	Do not know	8(1.7)
Ever heard of availability of ADR reporting form for reporting ADRs (n = 310)	Yes	17(5.5)
	No	293(94.5)
If yes, source of awareness code (n = 17)	Friends	4(23.5)
	A known healthcare professional	4(23.5)
	Presence of ADR drop box at OPD	0(0)
	Online sources	9(52.9)

**=multiple response

Table 3: Adverse drug reaction reporting practice among patients.

Variable	Frequency	N (%)
Have you ever experienced ADR? (n = 310)	Yes	276(89)
	No	34(10.9)
Action taken in the case of ADR/AE (n =467)**	Informed a healthcare professional	178(38.1)
	Stopped the drug(s)	103(22)
	Did nothing because the reaction was tolerable	64(13.7)
	Did nothing because the reaction resolved on its own	36(7.7)
	Used another drug to treat symptoms of reaction	39(8.4)
	Switched to herbal/traditional medicines	24(5.1)
	Switched to another drug	23(4.9)
Sources of obtaining information about ADRs (n = 625)**	Drug leaflet	89(14.2)
	Physician	205(32.8)
	Nurse	172(27.5)
	Pharmacist	105(16.8)
	Internet	54(8.6)
Suggested reasons why patients do not report experienced ADRs (n = 310)	Do not know the importance of reporting ADRs	116(37.4)
	ADR may not be very serious	98(31.6)
	Do not know how to report such reactions	54(17.4)
	Not sure if ADR is related to medication(s) used	23(7.4)

	AE/ADR resolved on its own	19(6.1)
Preferred methods of adverse drug reaction reporting (n = 310)	Reporting directly to healthcare professional	287 (92.6)
	Filling a reporting form	01(0.32)
	Online application designed for ADR reporting	0(0)
	Phone call or text message	0(0)

**=multiple respons

Association between patients' socio-demographic characteristics and PV awareness, ADR knowledge and reporting of previously experienced ADRs.

Variables		Knowledge of ADR definition		PV Awareness		Reporting of experienced ADRs	
		Adequate	Inadequate	yes	no	Yes	no
Age (year)	18–40	81(62.3)	151(83.9)	20(80)	212(74.4)	144 (68.9)	88(87.1)
	41 and above	49(37.7)	29(16)	5(20)	73(25.6)	65 (31.1)	13(12.9)
		Chi-square = 18.6701. p < .05.		chi-square = 0.3847. The result is not significant at p < .05.		chi-square = 12.0166. p < .05.	
Gender	Male	101(67.3)	21(42)	24(96)	98(57.3)	103 (61.3)	19(59.4)
	Female	29(22.3)	159(88.3)	1(4)	187(65.6)	170 (62.3)	18(48.6)
		Chi-square = 137.8749. The p-value is < .00001.		chi-square = 36.5585. p < .00001.		chi-square = 2.5335. The result is not significant at p < .05.	
Marital status	Unmarried	51(63.8)	4(2.5)	17(68)	38(32.2)	36 (17.5)	19(51.4)
	Married	78(60.5)	6(60)	7(28)	77(65.3)	67 (65)	17(47.2)
	Widowed/ Divorced	1(0.8)	3(33.3)	1(4)	3(2.5)	1 (1.5)	3(15)
		Chi-square = 21.6307. p < .05.		chi-square = 11.9037. p < .05.		chi-square = 8.1562. p < .05.	
Occupation	Public servant	39(30)	10(76.9)	19(76)	30(10.5)	42 (97.7)	7(70)

	Self-employed	78(60)	107(91.5)	5(20)	180(63.2)	131 (75.7)	54(88.5)
	No active employment	13(10)	63(37.1)	1(4)	75(26.3)	5 (3.7)	71(56.8)
		Chi-square = 47.7825. p < 0.00001.		chi-square = 74.1759. p < 0.00001.		chi-square = 109.9598. p is < 0.00001.	
Educationa l status	No formal education	7(7)	25(28.4)	0(0)	32(12.3)	7 (58.3)	25(26)
	High school degree	18(18)	170(87.2)	8(32)	156(59.8)	19 (73.1)	169(87.1)
	Graduation and or above	75(75)	15(8.1)	17(68)	73(28)	80 (80.8)	10(5.6)
		Chi-square = 153.2868. p < 0.00001.		chi-square = 111.7975. p < 0.00001.		chi-square =22.3347. The p = .000014.	