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A PHARMACOVIGILANCE STUDY EXAMINING CLINICIANS' KNOWLEDGE ATTITUDES AND PRACTICE ON REPORTING ADVERSE DRUG REACTIONS

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ABSTRACT

Background and objectives: The role of Clinicians is very essential in reporting and tracking adverse drug reactions (ADRs) to build an international database that guarantees pharmaceutical safety. However, a major problem exists when it comes to under-reporting suspected ADRs, especially in countries like India where healthcare professionals are not aware about the problem. Study was carried out at tertiary care hospital in India, the current study sought to evaluate the physicians' knowledge, attitudes, and practices (KAP) about ADR self-reporting.

Method: 120 clinicians were included in the present study from single tertiary care hospital. This study was cross-sectional, observational, and questionnaire-based; participating physicians were drawn from multiple clinical departments. This questionnaire-based research aimed to gather demographic data and details on doctors' awareness of, attitudes toward, and perceptions of reporting adverse events.

Results: The average time spent by doctors to finish answering the questionnaire was found to be fifteen minutes. From the total number of participants in the research (n = 120), 54% were postgraduate physicians and 46% were graduates. ADR reporting is essential and would help the patient, according to 92% of respondents. ADR reporting is a professional duty for physicians, according to 74% of respondents.

Conclusion: The current research concluded that most medical professionals recognized the need for reporting and had excellent knowledge and attitudes about pharmacovigilance. Nevertheless, the reporting rate was quite low. An interactive training program is required to raise healthcare workers' knowledge of reporting ADRs.

Keywords: Adverse drug reaction, Pharmacovigilance, Knowledge, Attitude, Practice.

INTRODUCTION

According to the World Health Organization (WHO), an "adverse drug reaction (ADR)" is any unpleasant, accidental, and undesirable side effect of a medication that happens at dosages used in humans for illness prevention, diagnosis, or treatment [1]. ADRs are previously known to be a global cause of illness and mortality. The Uppsala Monitoring Centre (UMC) in Sweden maintains a global database of reports on adverse drug reactions for the benefit of WHO. Pharmacovigilance is the study and practice of identifying, evaluating, comprehending, and avoiding side effects or other drug-related issues [2].

The primary source of ADRs, which are necessary for efficient Pharmacovigilance, is spontaneous reporting [3]. When determining the benefit-risk ratio of any medication, the participation of medical professionals in the reporting and monitoring adverse drug reactions (ADRs) is crucial [4,5]. Even with recent advances in Pharmacovigilance, under-reporting continues to be a significant drawback. Only 6–10% of all ADRs are reported [6].

Although India participates in the Global Program of Pharmacovigilance, it has little contributed to the database [7]. This is because doctors have not made the effort to report potential adverse drug events, or ADRs, on their own.

Therefore, physicians' involvement is crucial when it comes to ADR reporting. A study revealed that medical professionals and other healthcare providers' lack of expertise and awareness regarding Pharmacovigilance caused a substantial degree of underreporting. The current study evaluated the physicians' knowledge, attitudes, and practices (KAP) about ADR reporting in a tertiary healthcare facility in India [8,9].

MATERIAL AND METHOD

Study design:

This cross-sectional study was observational in nature and used questionnaires.

Study population:

The study was carried out after receiving written informed consent from respondent. The study was comprised of clinicians from the different departments employed at tertiary care hospital. This study involved medical professionals from medicine, dentistry, psychiatry, pulmonary medicine, and dermatology. The departments were chosen at random. A pre-designed, pre-coded, and pre-validated questionnaire was used in the study to collect data on demographics and clinicians' knowledge, attitudes, and practice regarding reporting of adverse drug reactions.

RESULTS

Table 1: Education status

Education status	Respondent
Graduate	54
Postgraduate	66

The education status of individuals surveyed reveals a considerable emphasis on higher education within the sample group. According to the data, 54% of respondents hold graduate degrees, indicating completion of undergraduate studies. Additionally, a larger proportion, accounting for 66% of the surveyed population, possesses postgraduate qualifications. This suggests a prevalent trend towards advanced education among the participants, with a notable portion having pursued further studies beyond the undergraduate level. Such findings underscore the importance of considering the educational background of the surveyed population when interpreting the results of any associated research or analysis.

Table 2: Age

Age	No of respondent
<25 Years	28
25-50 Years	47
>50 Years	45

The respondents are distributed across various age groups sheds light on the demographic makeup of the polled population. Among those who answered the questionnaire:
A relatively smaller proportion, comprising 28 respondents, falls within the age category of less than 25 years old. This suggests that a minority of the respondents are younger, likely representing a segment of the population early in their professional or academic careers.
The largest age group among the respondents is individuals aged between 25 and 50, accounting for 47 respondents. This indicates that a significant portion of the surveyed population falls within the prime working age range, where individuals may be actively engaged in professional activities, including healthcare, research, or other fields.
Lastly, 45 respondents are aged over 50 years old, indicating a notable representation of older individuals within the surveyed population. This demographic group may bring extensive professional experience and insight, potentially influencing the perspectives and responses gathered through the survey.
Overall, the distribution of respondents across different age groups highlights the diversity within the surveyed population and underscores the importance of considering age-related factors when analysing the data or drawing conclusions from the survey findings.

Table 3: KAP questionnaire responses of the study population (n=120)

Questions	No. of responses (%)		
	Yes	No	No comments
Have you ever encountered an ADR (adverse drug reaction)?	106 (88)	14 (12)	0 (0)
Do you know that patients would benefit from an ADR reporting and monitoring system?	113 (94)	0 (0)	7 (6)
Do you think that confidentiality should be upheld while reporting an ADR?	84 (70)	31 (26)	5 (4)
Do you know of any ADR reporting and monitoring centres close by?	94 (78)	10 (8)	16 (14)
Do you favour patients reporting "direct ADRs" to the appropriate authority or regulatory body rather than via their doctors?	44 (36)	52 (44)	24(20)

The table 3 presents findings from a KAP (Knowledge, Attitude, and Practice) questionnaire administered to 120 individuals to gauge their understanding, perspectives, and behaviours related to adverse drug reactions (ADRs) and reporting systems. The responses shed light on several key aspects:
Firstly, a significant majority (88%) of respondents reported having encountered an adverse drug reaction at some point, indicating a prevalent experience with medication-related side effects within the study population.

Secondly, there was widespread recognition (94%) among participants that patients stand to benefit from an ADR reporting and monitoring system, underlining a collective understanding of the importance of such mechanisms in healthcare.
Thirdly, the issue of confidentiality in ADR reporting garnered mixed opinions, with 70% of respondents advocating for upholding confidentiality. In comparison, 26% disagreed, suggesting a nuanced perspective on privacy concerns in reporting adverse events.
Furthermore, the data revealed varying levels of awareness regarding ADR reporting and monitoring centres, with 78% of participants acknowledging their presence nearby. In comparison, 8% were unaware, indicating room for improvement in disseminating information about available resources.
Lastly, opinions were divided regarding the preferred method of reporting ADRs, with 36% of respondents favouring direct reporting to regulatory bodies, 44% preferring reporting through healthcare providers, and 20% abstaining from providing comments, highlighting differing attitudes towards the most effective reporting channels.
Overall, the findings highlight the prevalence of ADR experiences and the importance of establishing effective reporting mechanisms while emphasizing the need for enhanced awareness and understanding among the general population regarding ADRs and their reporting processes.

Table 4: Clinicians responses towards the probable reasons for under-reporting of ADRs (n=120)

Probable reasons for the under-reporting of ADRs	Percentage of responses (%)
There are only safe medications on the market.	0.77
Reporting has no bearing on the course of treatment.	8.53
The doctor's hectic schedule	27.91
Insufficient motivation for regulatory bodies	19.38
Doctors should instead gather information and publish it themselves.	3.88
A suspected drug is difficult to identify, so report	8.53
The doctor is aware of ADR; thus, there's no need to report	3.1
Uncertain about who, where, or how to report	6.2
Reporting of ADRs may be a sign of medical professionals' incompetence or ignorance.	3.1
Admitting the negative consequences of medications is difficult.	5.43
Physician's lack of clinical expertise about ADRs and their reporting	13.18
ADR reporting has no bearing on anything.	0
Others	0

Table 4 outlines the perspectives of physicians regarding potential reasons contributing to the underreporting of adverse drug reactions (ADRs). Among the factors cited, the most prevalent concern appears to be the demanding schedules of doctors, with nearly 28% of respondents attributing underreporting to the hectic nature of medical practice. Additionally, a notable proportion (19.38%) identified insufficient motivation from regulatory bodies as a significant barrier to reporting. Interestingly, a sizeable portion (13.18%) highlighted physicians' lack of clinical expertise about ADRs and their reporting as a contributing factor. Other reasons mentioned include uncertainties about the reporting process, difficulty in identifying suspected drugs, and concerns about the perceived impact of reporting on the treatment course. Notably, minimal responses suggested that the belief in only safe medications on the market or the perception that ADR reporting has no bearing on anything significantly affects reporting behavior. This data underscores the multifaceted nature of

underreporting and highlights potential areas for intervention, such as improving education and support for physicians in recognizing and reporting ADRs effectively amidst their demanding professional responsibilities.

DISCUSSION

Pharmacovigilance and safety surveillance of marketed pharmaceuticals depend heavily on reporting adverse drug reactions. Numerous studies have assessed healthcare professionals' pharmacovigilance expertise. The current study focused on doctors' knowledge, attitudes, and perceptions about reporting adverse drug reactions (ADRs) in tertiary care hospitals. There were 48% women and 52% men in this study. In a related study, 35.6% of the participants were female, and 64.4% were male from Riyadh, Saudi Arabia.

Consequently, the male physician involvement rate was higher compared to the current study [10]. Research conducted at hospitals in Nagpur and Mumbai found that 64% and 57.6% of respondents were men [11,12]. Male respondents (49.3%) and female respondents (50.7%) participated in nearly equal numbers in an Andhra Pradesh study of a similar nature [13]. According to the current study, 76% of the participants were middle-aged, ranging from 25 to 50 years old [10]. Studies conducted in Mumbai and Nagpur, where the average age of the participants was 26 [11,12], also revealed similar findings. A similar poll in Saudi Arabia found that the respondents' mean age was 33.3 years [10].

According to their perceptions of the practice, 92% of doctors felt that ADR reporting was required. According to a different study report, 89.5% of doctors agreed that reporting ADRs is essential [11]. Similar findings from trials conducted in Tamil Nadu, Sikkim, and Ahmedabad showed that 97% of medical professionals agreed to report adverse drug reactions [14,16]. However, the actual situation in India is that 64.4% of ADRs were reported by doctors. Still, according to a Saudi Arabian survey, 49.3% of doctors thought that only major adverse drug reactions (ADRs) needed to be reported [17]. 74% of the doctors in this research felt that it was their duty as professionals to report adverse drug reactions. The same was confirmed by a Mumbai study, where 80.9% of respondents believed it to be required [11]. Medical professionals in Sikkim (63%) and Indore (66.2%) agreed that reporting adverse drug reactions (ADRs) was a professional duty. Although doctors were generally in favour of reporting adverse drug reactions (ADRs), there was a shortage of reporting in practice [15,18].

According to 15.19% of participants in a study conducted by a government medical college in Nagpur, ADR reporting should be legally required. Nonetheless, Mumbai research found that 89.5% of respondents felt that, as shown in the current study (88%) [11], ADR reporting should become required. ADR monitoring and reporting systems are good for patients, according to 94% of study participants. This was consistent with a study conducted in Nagpur, where 93.61% of participants thought the ADR reporting and monitoring system helped patients. A study conducted in Saudi Arabia found that 77.5% of respondents agreed that confidentiality should be preserved when reporting adverse drug reactions (ADRs). Most physicians in this survey (70%) agreed with this statement. Nonetheless, Mumbai research found that 57% of respondents agreed that confidentiality should be upheld.

According to the current study, 78% of doctors were aware that there was an ADR monitoring centre (AMC) nearby. However, research from Mumbai revealed that only 12.9% of Saudi Arabian study participants and over 50% of respondents in Mumbai were aware of a nearby ADR monitoring centre. Conversely, a Sikkim survey found that 79% of participants were ignorant of the existence of an AMC at their institution [15].

Divergent opinions existed among society around the question of "who can report ADR?" Just 36% of respondents to the current study agreed that patients should report ADRs directly. This was comparable to Saudi Arabian statistics, where many research participants (58%) disapproved of patients reporting ADRs directly. The same results were noted in Ahmedabad, where only roughly 26.2% of respondents thought that patients ought to be able to report adverse drug reactions. This further demonstrated the respondents' ignorance of the fundamentals and application of Pharmacovigilance.

Unreported adverse drug reactions (ADRs) are a frequent hindrance to the monitoring of adverse medication responses. The doctors were questioned regarding their underreporting of adverse drug reactions. They were permitted to choose from various answers on the questionnaire and were presented with several choices. Most doctors selected multiple likely explanations for their underreporting of adverse drug reactions. The greatest response, or 27.91%, stated that one of the likely causes of the underreporting of ADRs is the doctors' hectic schedules. Of all the replies, 19.38% endorsed the idea that regulatory authorities should provide incentives, and 13.18% said that doctors' inadequate clinical knowledge of ADRs is a significant likely cause of underreporting. A study conducted in Indore found that doctors working in teaching hospitals would be much less likely to report adverse events (ADRs) if they were hesitant (67.7%), lazy, or short on time (42.7%). In Ahmedabad, on the other hand, the primary cause was a lack of knowledge of the reporting system, with less attention paid to the financial and legal implications [16,18].

CONCLUSION

According to this study, most doctors have positive attitudes and good knowledge of Pharmacovigilance and ADR reporting. Clinicians generally believe reporting adverse events (ADRs) is useful and should be required. Despite this, the actual reporting rate of adverse drug reactions remains extremely low. There was a discrepancy between the reported and experienced adverse drug reactions (ADRs) by physicians, despite the majority of them believing that reporting ADRs was their professional duty. Pharmacovigilance training is required to raise medical professionals' knowledge of and reporting of ADRs. The foundation of any pharmacovigilance program is the practice of ADR self-reporting.

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