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KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTIONS REPORTING IN NURSES OF A TERTIARY CARE HOSPITAL

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Keywords:

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ABSTRACT: Introduction: ADRs significantly contribute to death and morbidity. The underreporting of adverse drug reactions is a widespread concern worldwide. Nurses are vital to healthcare and significantly contribute to adverse drug reaction reporting inside hospitals. This study was planned to assess nurses' knowledge, attitude and practice about ADR reporting, as well as to provide suggestions for improvement. **Methods:** This research was a cross-sectional questionnaire-based study involving 60 nurses, using a questionnaire with questions on knowledge (12), attitude (5) and practice (9) about ADR reporting. Responses were analysed both item-wise and domain-wise. Knowledge (12), attitude (5), and practice (9) responses were summarized using descriptive statistics and expressed as percentages for each item. In addition to item-wise descriptive percentages, responses were grouped into three domains: knowledge (12), attitude (5), and practice (9). Domain-wise responses were summarized using descriptive statistics to describe overall trends in nurses' knowledge, attitude and practice related to ADR reporting. **Results:** A majority of the nurses (89.33%) were knew the term PV. 95% of nurses agreed that adverse drug reaction reporting is a professional obligation. 82% of nurses were aware about the existence of the ADR Monitoring Centre (AMC) located within the hospital. 72% of nurses were aware that the CDSCO is the regulatory body responsible for ADRs. 80% said that they had received training on reporting ADRs. 85% nurses noted ADRs in patients; however, only 48.33% reported to the pharmacovigilance centre. The primary cause of underreporting of ADRs was lack of time to submit reports. **Conclusions:** A notable disparity exists between adverse drug reactions noticed in patients and those reported by nurses. Participants agreed that adverse drug reactions reporting is essential and that regular awareness activities are required to enhance knowledge of adverse drug reactions, hence improving the existing state of adverse drug reactions reporting.

INTRODUCTION: According to the World Health Organization, pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [1].

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An adverse drug reaction (ADR) is defined as any noxious and unintended response to a drug that occurs at doses normally used in humans for prophylaxis, diagnosis, or treatment of disease [1].

Adverse drug reactions are linked to considerable death, morbidity, and increased treatment costs. Therefore, adequate surveillance of ADRs is essential [2, 3]. The aim of pharmacovigilance is to assurance the safe as well as judicious use of medications after their release for public usage. The primary goal of pharmacovigilance is to avert adverse effects of medication [2]. ADR monitoring facilitates the identification of novel, severe,

unfamiliar, along with most prevalent responses. It further identifies risk variables [4]. Healthcare workers, including doctors, chemists, and nurses, play a significant part in pharmacovigilance programs [5]. The underreporting of ADRs is a prevalent issue in pharmacovigilance programs [6]. It has been estimated that only a small proportion of adverse drug reactions are reported through pharmacovigilance systems worldwide, indicating substantial underreporting in spontaneous reporting programs [7]. To address underreporting of adverse drug reactions, the Pharmacovigilance Programme of India (PvPI) was launched by the Ministry of Health and Family Welfare, Government of India, in July 2010. The programme is coordinated by the Indian Pharmacopoeia Commission (IPC) and functions through a network of Adverse Drug Reaction Monitoring Centres (AMCs) located in hospitals across the country. These centres collect and report ADR data to the national database for monitoring drug safety [8]. The purpose of PvPI is to collect and evaluate ADR data and use its findings to elucidate the hazards associated with medications to Medical specialists as well as the common population [8].

The success of pharmacovigilance program relies on the engagement of healthcare specialists and the voluntary recording of ADRs [9]. Healthcare professionals are responsible for recognising and reporting ADRs and enhancing pharmacovigilance program by submitting the Adverse Drug Reaction form to the Central Medicines Quality Controlling Commission [9].

To improve the reporting rate of ADR, it is crucial to improve the knowledge, attitude, and practice about ADR reporting and pharmacovigilance amongst healthcare professionals. Before commencing any intervention, it is crucial to evaluate the initial knowledge, attitude, as well as practices regarding adverse drug reaction reporting including pharmacovigilance amongst healthcare professionals [2].

Nurses are essential to healthcare as well as play a significant role in adverse drug reaction reporting in hospitals [4]. Nurses are primarily engaged in direct patient care and spend majority of their time with patients. Nurses prepare and dispense medications and are therefore in a unique position to detect, recognise, and report adverse drug reactions [10]. Their understanding of adverse drug reactions, perspectives and attitudes towards ADR reporting, and challenges in reporting ADRs will influence the ADR reporting rate [4]. This research was conducted to evaluate the knowledge, attitudes, and practices of ADR reporting among nurses at a tertiary care teaching hospital. The objective of this study was to assess the knowledge, attitude, and practice (KAP) of nurses regarding adverse drug reaction reporting in a tertiary care hospital. The study also aimed to identify factors contributing to underreporting of ADRs and to suggest measures for improving ADR reporting practices.

MATERIAL AND METHODS:

Study Setting: Nurses at the Dr. Bhausaheb Sardesai Talegaon Rural Hospital in Talegaon Dabhade, Pune, Maharashtra, India, participated in this research. Since 2014, the institution has an ADR monitoring centre. The college's IEC granted approval for this research. The research was conducted from August 2024 to November of 2024.

Study Design: This investigation was observational, cross-sectional, and questionnaire-based. Participants were recruited using convenience sampling, and all nurses available during the study period who met the eligibility criteria and consented to participate were included. A total of 60 nurses participated in the study. No eligible participants declined participation.

Participants:

Inclusion Criteria: Registered nurses working in wards or OPD of the hospital. Nurses willing to participate and provide informed consent.

Exclusion Criteria: Nursing staff on leave during the study period. Nurses unwilling to participate.

Questionnaire: A structured questionnaire previously used in similar KAP studies on pharmacovigilance was adopted for the present study. The questionnaire consisted of 26 questions-knowledge (12 questions), attitude (5 questions), and practice (9 questions). The questionnaire was reviewed by pharmacology faculty members for content relevance and clarity and minor modifications were made to suit the local hospital setting [6].

Data Collection: The principle investigator contacted all study participants at each ward and departmental OPD personally. Nursing staff were provided with a research information sheet. The participants received one-on-one instruction on how to complete the survey. Where appropriate, they were permitted to mark more than one choice. Informed permission was obtained and appropriately signed. Nurses were asked to fill out a questionnaire and return it within 25 minutes in order to increase the response rate. Participants completed the questionnaire independently without discussion to ensure unbiased responses. Their names were kept anonymous. Participation in the study was voluntary and anonymous. The questionnaire did not collect personal identifiers such as name or employee identification number. Completed questionnaires were stored securely by the principal investigator, and access to the data was restricted to the research team.

Statistical Analysis: Using a Excel sheet in the MS Office 2021 program, KAP survey was analysed question by question, as well as its percentage was determined. Knowledge, attitude and practice responses were analysed primarily as descriptive percentages for each item; domain-wise trends were also summarized to describe overall patterns in ADR reporting awareness and practice.

RESULTS: This research had 60 participants. It took an average of 20 to 22 minutes to complete the questionnaire. The response rate among the participating nurses was 100%.

Demographic Details: Table 1 provides a summary of the nurses' demographic data.

TABLE 1: DEMOGRAPHIC DETAILS OF THE PARTICIPANTS (N=60)

Parameter	Category	n	%
Age (years)	21–25	5	8.3
	26–30	6	10
	31–35	15	25
	36–40	10	16.7
	41–45	9	15
	46–50	7	11.7
	51–55	8	13.3
Gender	Female	55	91.7
	Male	5	8.3
Qualification	ANM	9	15
	GNM	35	58.3
	BSc Nursing	13	21.7
	MSc Nursing	1	1.7
	Dai Trainer	2	3.3
Work experience (years)	0–3	8	13.3
	4–6	6	10
	7–9	9	15
	10–12	12	20
	13–15	4	6.7
	16–18	3	5
	19–21	3	5
	22–24	3	5
	25–27	9	15
	28–30	3	5

ANM: Auxiliary Nerve Midwife, GNM: General Nursery and Midwifery, BSc: Bachelor of Science, MSc: Master of Science.

Age, gender, education level, and job experience were the demographic data gathered for this study. The study included 60 nurses. Most participants were female (91.7%). The largest age group was 31–35 years (25%).

The majority of participants held a General Nursing and Midwifery (GNM) qualification (58.3%), followed by B.Sc. Nursing (21.7%). The largest proportion of nurses had 10–12 years of work experience (20%).

TABLE 2: KNOWLEDGE OF NURSES ABOUT ADR REPORTING (N=60)

Question	Options	Percentage (%)
Do you know the term pharmacovigilance?	Yes	89.33

	No	10.67
Pharmacovigilance deals with	Drug Manufacturing	12
	Drug Cost Monitoring	0
	Adverse Drug Reaction Reporting	88
The most important purpose of pharmacovigilance is	To identify safety of the drug	63
	To calculate cost of the drug	0
	To count adverse drug reactions	37
In India which regulatory body is responsible for monitoring ADR?	CDSCO	72
	ICMR	27
	State Medical Council	1
	Medical Council of India	0
Which one of the following is WHO online database for ADR reporting?	ADR advisory committee	37
	Med safe	20
	Vigiflow	43
	Med Watch	0
Is there a pharmacovigilance committee in your institute?	Yes	82
	No	8.67
	Don't know	9.33
The healthcare professionals responsible for reporting ADR in a hospital is/are	Medical practitioners	8
	Pharmacist	6
	Nurses	5
	Patients/Health worker	0
	All of the above	81
Have you ever been trained on ADR reporting?	Yes	80
	No	20
Are you aware of pharmacology staff visits for ADR monitoring?	Yes	55
	No	45
Which common ADRs have you observed? (Mark muplitple options)	Skin rash	92
	Vomiting	15
	Diarrhoea	3
	Others	3
Should ADRs due to blood transfusion and vaccination be reported?	Yes	95
	No	5
Do you think awareness programs are needed for ADR reporting?	Yes	98.33
	No	1.67

The above table details nurses' knowledge of ADR reporting as well as proportion of "Yes" or "No" answers they gave **Table 2.**

Approximately 88% of nurses understood that PV deals with ADRs, and 89.33% of nurses knew the term 'Pharmacovigilance'. 81% of nurses knew that ADR reporting can done by patients, healthcare professionals, nurses, chemists. 82% of nurses were aware that the institution had a AMC. 80% said they needed training on ADR reporting **Table 2.** About 72% of nurses were aware that the regulatory body responsible for ADR monitoring is CDSCO. 43% were aware that VIGIFLOW is a connected database for reporting ADR. In order to enhance ADR reporting, about 98.33% of nurses believed that regular awareness programs were necessary. 92% of participants have reported skin rash as the most common ADR.

TABLE 3: ATTITUDE OF NURSES TOWARDS ADR REPORTING (N=60)

Question	Options	Percentage (%)
Do you think ADR reporting is a professional obligation?	Yes	95
	No	5
Do you think ADR reporting improves patient safety?	Yes	100
	No	0
Should pharmacovigilance be taught in detail to healthcare professionals?	Yes	93.33
	No	6.67
Is the ADR reporting system in your hospital useful in practice?	Yes	98.33
	No	1.67
Reasons for underreporting of ADRs	Lack of time	49
	Lack of knowledge	25

	Difficulty in identifying ADR	16.66
	Fear of legal liability	7
	One case does not affect database	2.34

The above table details nurses' attitude towards ADR reporting as well as proportion of "Yes" or "No" answers they gave **Table 3**. 95% of nurses agreed that adverse drug reaction reporting is a professional obligation. All nurses agreed that ADR reporting will improve patient's safety. 93.33% agreed that PV should be taught in detail to healthcare professionals. The primary cause of underreporting of ADRs was lack of time to submit reports.

TABLE 4: PRACTICE OF NURSES ABOUT ADR REPORTING (N=60)

Question	Options	Percentage (%)
Have you ever seen an ADR reporting form?	Yes	88.33
	No	11.67
Are ADR forms available in IPD/OPD?	Yes	76.67
	No	3.33
	Maybe	20
Have you experienced ADRs in patients during your practice?	Yes	85
	No	15
Have you reported ADR to pharmacovigilance centre?	Yes	48.33
	No	51.67
How many ADRs do you encounter in a month?	0–5/month	100
	6–10/month	0
	>10/month	0
To which department should ADR forms be submitted?	Department of Pharmacology	85
	Department of Forensic Medicine	13.67
	Medical Superintendent	1.33
ADR should be reported when	Serious only	18.33
	Mild only	0
	All ADRs	81.67
Is it necessary to send drug sample with ADR report?	Yes	86.67
	No	13.33
How often do you advise patients about ADRs?	Usually	7
	Sometimes	21
	Never	0
	Always	72

Nurses' ADR reporting practices are shown in **Table 4**, along with the proportion of "Yes" or "No" answers. Only 48.33% of nurses reported ADRs to the pharmacovigilance centre, although 85% of nurses experienced ADRs in patients. 51.67% of nurses have not reported any adverse drug reactions, instead of reporting they had informed physician. 80% of nurses were aware that the pharmacology department get the ADR forms. While 18.33% of nurses believed that only major and life-threatening ADRs must be reported, 81.67% of nurses were alert that all ADRs must be reported.

DISCUSSION: The present study evaluated the knowledge, attitude, and practice of ADR reporting among nurses in a tertiary care hospital. The findings indicated that nurses had relatively good awareness of pharmacovigilance concepts and a positive attitude toward ADR reporting. However, the actual reporting practice was suboptimal, as only 48.33% of nurses who observed ADRs reported them to the ADR Monitoring Centre. 60 nurses from a tertiary care hospital participated in current research, which was questionnaire-based. The completed survey was analysed.

The response rate of the completed questionnaires had a 100% response rate which was more in comparison to studies conducted among nursing staff in Bhopal by Tiwari *et al.* (71%) and among nurses of two medical schools by Scandashree *et al.* (63%) [11, 12]. This might be because there were fewer research participants and the primary investigator personally met each participant at their particular ward and departmental OPD. The majority of nursing staff (91.7%) were female, in contrast to another study among nursing staff in

Deoghar by Bankar *et al.* (74%) [10]. In difference to a study done in nurses by Bankar *et al.,* which found that 87% of nurses had a B.Sc. nursing degree, the majority of nurses (58.3%) had a GNM nursing degree in present study [10]. Compared to studies conducted on health care workers by Gupta *et al.* (62.4%) and hospital nurses in Iran by Hanafi *et al.* (32.1%), 89.33%nurses knew the word PV as well as the majority (88%) understood that it deals with ADRs [3, 6].

Similar to a study done in South India among healthcare workers by Gupta *et al.* (78.2%), the majority of nurses (72%) were aware that the CDSCO is the regulatory body responsible for ADR reporting [3]. In difference to study done in nursing staff by Tiwari *et al.* (32%), 82% nurses were aware that the institution had a PV committee, as well as the study conducted by Khan *et al.* (80.9%), physicians were aware of the institute's AMC [7, 11]. Compared to the research conducted on healthcare professionals by Gupta *et al.,* only half of the nurses (55%) were aware that a staff member from the pharmacology department visited the hospital once a week to remind them to report adverse drug reactions [3]. Most nurses (95%) knew that adverse drug reactions (ADRs) from blood transfusions and vaccinations should be recorded. This was higher than the percentage of prescribers in a study by Desai *et al.* (20.6%) and comparable to the percentage of PG students in a research by Chincholkar *et al.* (89.77%) [9, 13].

Analogous to research performed on healthcare practitioners by Gupta *et al.* (80.2%) and nursing staff by Tiwari *et al.* (73%), the majority of nurses (81%) believed that medicinal doctors, chemists, patients, nurses and health workers are all can report ADRs [3, 11]. ADR reporting was seen favourably by nurses, as 95% of them believed it was a professional duty, which is consistent with research conducted among physicians by Scandashree *et al.* (93.25%) and among nursing staff by Tiwari *et al.* (90%) [11, 12]. Similar results were also found by Gupta *et al.* in a research conducted among medical staff at a South Indian teaching hospital [3]. The most frequent adverse drug reaction (ADR) they reported was skin rash (92%) which was comparable to the Chincholkar *et al.* research (79.59%) [9]. Approximately 98% of nurses thought the institute's ADR reporting system was useful, indicating that they had a favourable attitude toward ADR reporting. Underreporting of ADRs was seen in the present study. Lack of time (49%), lack of knowledge (25%), difficulty to decide ADR has occurred or not (16.66%), fear of legal liability (7%), and a single unreported case may not affect ADR database (2.34%) are the challenges and reasons for underreporting of ADRs.

The following actions must be made in order to get over these problems: 1. Display the AMC emergency phone number in conspicuous places around the hospital. 2. The ADR forms should be made readily available online and *via* mobile devices by implementing a scanner. 3. Recurring instruction on how to file an ADR.

The research conducted on healthcare workers by Gupta *et al.* (22.6%) as well as Dudhe *et al.* (60%), also found that although the majority of nurses (85%) had observed ADRs in patients, barely half of them (48.33%) reported them [3, 14]. Similar to results from research performed among nurses in Gujarat and South India, the nurses in this study exhibited a positive approach about ADR reporting. In an investigation showed in Iran by Hanafi *et al.*, the majority of nurses (91.1%) had never reported an adverse drug reactions [6]. Approximately 81% of nurses knew that the reporting of all types of ADRs is necessary. It indicates a favourable attitude towards need of reporting. This conclusion was greater in comparison to another research conducted among doctors by Dudhe *et al* (62%) and among nurses by Bahekar *et al* (53%) [14, 15]. The study's main conclusions were that healthcare workers should get thorough training in pharmacovigilance and almost all of them had the belief that ADR reporting is essential.

Limitations of the Study: The study has several limitations. First, it was conducted in a single tertiary care hospital with a relatively small sample size, limiting generalizability of the findings. Second, the study relied on self-reported responses, which may be subject to recall bias and social desirability bias. Third, inferential statistical analyses were limited, and therefore associations between demographic variables and KAP outcomes could not be fully explored.

Implications: Based on the study findings, several practical measures may improve ADR reporting within hospitals:

- Simplification of ADR reporting procedures.
- Availability of ADR forms in all wards.
- Mobile or online reporting systems.
- Periodic pharmacovigilance training programs.
- Feedback to healthcare professionals after ADR submission.
- Allocation of protected time for reporting ADRs.

CONCLUSION: This study found that nurses have relatively good knowledge and positive attitudes towards adverse drug reaction reporting. However, the actual reporting practice remained suboptimal, with a substantial gap between ADRs observed and those reported. Lack of time and insufficient awareness were identified as key barriers to reporting. Strengthening pharmacovigilance training, improving accessibility of reporting systems, and providing institutional support may help improve ADR reporting among nurses.

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Recommendation: Regular awareness programs are essential to improve knowledge of nursing staff about adverse drug reactions and pharmacovigilance.

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