

ASSESSMENT OF ADVERSE DRUG REACTION REPORTING AWARENESS AMONG HEALTHCARE WORKERS IN BANNU, PAKISTAN

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Abstract

Background: Adverse drug reactions (ADRs) provide a substantial threat to patient safety globally, yet are often inadequately reported, particularly in resource-constrained environments. Comprehending healthcare professionals' awareness of adverse drug reaction reporting is essential for improving pharmacovigilance initiatives. *Objectives:* The objective of this study was to evaluate the awareness, attitudes, and practices about ADR reporting among healthcare professionals in Bannu, Khyber Pakhtunkhwa, Pakistan. *Methodology:* A descriptive, cross-sectional methodology was utilized. A total of 150 healthcare professionals, comprising physicians, nurses, pharmacists, and paramedics from both public and private healthcare institutions in Bannu, were recruited using convenience sampling. Data were collected using a standardized, self-administered questionnaire that encompassed demographic information, knowledge of adverse drug reactions (ADRs) and reporting mechanisms, as well as attitudes and practices. Responses were examined with SPSS utilizing descriptive statistics. Awareness was evaluated and classified as Good, Moderate, or Poor. *Results:* Among participants, 43.3% indicated strong awareness of ADR reporting, 36.7% showed moderate awareness, and 20.0% revealed inadequate awareness. Ninety percent concurred that ADR reporting improves patient safety, while eighty percent saw it as a component of their professional duty. Nonetheless, considerable obstacles were recognized: insufficient training (73.3%) and the unavailability of reporting forms (merely 40% had access to them). Reporting of adverse drug reactions (ADRs) was minimal: only 30% had ever reported an ADR, and merely 13.3% did so in the past year, predominantly by informal (verbal) means rather than official documentation. *Conclusions:* Despite a relatively high awareness and positive attitudes about the significance of ADR reporting, the actual reporting procedures among healthcare staff in Bannu were markedly deficient. This disparity highlights the necessity for focused measures, including training

initiatives and efficient reporting systems, to enhance ADR monitoring and strengthen patient safety in the area.

INTRODUCTION

The World Health Organization (WHO) defines adverse drug reactions (ADRs) as harmful, unanticipated effects of a medicine that manifest at levels typically administered to humans for the diagnosis, prevention, and treatment of diseases.[1] Adverse drug responses (ADRs) are typically categorized as dose-dependent and predictable (augmented), non-dose-dependent, unusual, and unpredictable (bizarre), both dose- and time-dependent (chronic), time-dependent (delayed reactions), withdrawal (cessation of usage), and unexpected therapeutic failure (failure) [2]. Undesirable drug reactions (ADRs) are significant worldwide health challenges, as every active pharmaceutical agent can induce undesirable consequences, even when used correctly [3]. Adverse drug reactions may impact patients regardless of age. While evidence is few, it is plausible that the burden is greater in developing nations due to the widespread occurrence of self-medication and counterfeit or contaminated medications [4]. Adverse drug reactions (ADRs) lead to significant morbidity, death, and substantial economic burden in hospitalized patients [5]. It represents a significant health issue for both individuals and the community, manifesting in many socioeconomic repercussions [6]. Numerous research studies ascertain the prevalence of adverse drug reactions (ADRs) within healthcare systems as a contributor to drug-related mortality and morbidity in both developed and developing nations [7]. The World Health Organization defines pharmacovigilance as the research and practices associated with the detection, [8] assessment, understanding, and prevention of adverse medication effects or other drug-related issues. The efficacy of a pharmacovigilance program relies on the proactive engagement of healthcare professionals [9]. Spontaneous reporting (SRS) of adverse drug reactions (ADRs) is a primary strategy employed worldwide to assess the benefits and risks of pharmaceuticals. This reporting is voluntary and conducted by healthcare professionals or consumers when they suspect any adverse reaction to drugs. Therefore, healthcare workers must report adverse

drug reactions to preserve patient lives [10]. This approach possesses the capability to detect unusual and unforeseen adverse drug reactions (ADRs) [11].

The European Directive on Pharmacovigilance has approved the incorporation of patient reporting due to its numerous benefits [12]. Consumer reports provide impartial viewpoints, free from the prescriber's influence; hence, they offer useful insights into the causation assessment of adverse drug reactions (ADRs). Furthermore, it clearly outlines the consequences on individuals' lives, family relationships, and professional interactions. Numerous countries, including the US, Canada, Australia, and New Zealand, have implemented direct patient ADR reporting inside pharmacovigilance systems, but many nations still lack sufficient procedures for such reporting [13]. Pakistan's pharmacovigilance system remains nascent, although the government has suggested multiple measures to improve it. The National Drug Policy of Pakistan indicated the creation of a drug monitoring and surveillance system in 2003 [14]. In 2012, the Drug Regulatory Authority of Pakistan (DRAP) Act established a pharmacovigilance division within the Division of Pharmacy Services following directives from the Supreme Court of Pakistan, [15] which led to the creation of the inaugural pharmacovigilance center in Punjab. DRAP has developed plans for pharmacovigilance efforts, and its provincial drug control unit is consistently providing medication safety alerts. [16] This outbreak resulted from a disaster at the Punjab Institute of Cardiology, where over two hundred persons perished following the administration of tainted medication (Isosorbide mononitrate 20 mg tablet, batch number J093). The provincial pharmacovigilance center in Lahore recognized reports and transmitted them to the WHO's Uppsala Monitoring Centre in Sweden [17]. The ADR Spontaneous Reporting System is a crucial method for collecting information that forms the basis of the global WHO database. This approach enables the passive collecting of data regarding adverse post-marketing hazards and incidents that were not anticipated during initial assessment. Nonetheless,

the existence of a system alone is insufficient to determine its functionality. The involvement of each stakeholder is critically important in ADR reporting. The involvement of healthcare experts is essential and enhances drug safety for the community. Notwithstanding the advantages, underreporting continues to obstruct the establishment of an effective pharmacovigilance system, thereby adversely affecting public health. Research has acknowledged the essential need for public participation in pharmacovigilance and the direct reporting of adverse drug reactions (ADRs) [18]. Adverse drug reactions (ADRs) recorded by the public corroborate those documented by healthcare experts, aiding in the emergence of new safety signals [19]. Consequently, the participation of patients or consumers in reporting adverse drug reactions (ADRs) has gained significant recognition and has been adopted in over 40 countries globally [20].

2. Research objectives.

The research objectives of the present study are as follows:

1. To assess the level of awareness regarding adverse drug reaction (ADR) reporting among healthcare workers in Bannu, Pakistan.
2. To evaluate attitudes and practices of healthcare workers towards ADR reporting.
3. To identify key barriers that hinder effective ADR reporting in healthcare facilities of Bannu.

Chapter 03 Research Methodology

3.1. Study Design and Setting

This study was a descriptive cross-sectional analysis conducted in the Bannu District of Khyber Pakhtunkhwa, Pakistan. The research concentrated on healthcare professionals, including physicians, nurses, pharmacists, and paramedics, employed in both public and private healthcare institutions. The objective was to evaluate their awareness of adverse drug reaction (ADR) reporting at a certain moment.

3.2. Participants and Data Collection

A total of 150 healthcare professionals were selected through convenience sampling. Data were gathered via a standardized, self-administered questionnaire segmented into three sections:

- Part A: Fundamental details (age, gender, occupation, years of experience, kind of establishment).
- Part B: Understanding Adverse Drug Reactions and Reporting Mechanisms.
- Part C: Perspectives and methodologies concerning ADR reporting.

The surveys were disseminated during working hours following an explanation of the study's goal and the acquisition of consent.

3.3. Data Analysis

Data has been entered and analyzed utilizing SPSS software. Descriptive statistics, including frequencies, percentages, and mean values, were employed to encapsulate the findings. Awareness scores were derived from accurate responses and classified as Good, Moderate, or Poor. Results were presented in tables, bar graphs, and pie charts.

Chapter 04 Result and Discussion

4.1. Demographic Characteristics of Participants

Table 4.1: Demographic Characteristics of Healthcare Workers (n = 150).

This table summarizes the demographic and professional characteristics of the study participants. Most respondents were aged **30–39 years** (40.0%), followed by those aged **20–29 years** (30.0%). Males comprised a larger proportion (**63.3%**) compared to females (36.7%). In terms of profession, the largest group was **doctors** (40.0%), followed by nurses (30.0%), pharmacists (16.7%), and paramedics (13.3%). Regarding work experience, **40.0%** had 5–10 years of experience, 36.7% had less than 5 years, and 23.3% had more than 10 years. Two-thirds of participants worked in **public facilities** (66.7%), while one-third worked in private facilities (33.3%).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	20–29	45	30.0
	30–39	60	40.0
	40–49	35	23.3

	50+	10	6.7
Gender	Male	95	63.3
	Female	55	36.7
Profession	Doctor	60	40.0
	Nurse	45	30.0
	Pharmacist	25	16.7
	Paramedic	20	13.3
Experience	<5 years	55	36.7
	5–10 years	60	40.0
	>10 years	35	23.3
Type of facility	Public	100	66.7
	Private	50	33.3

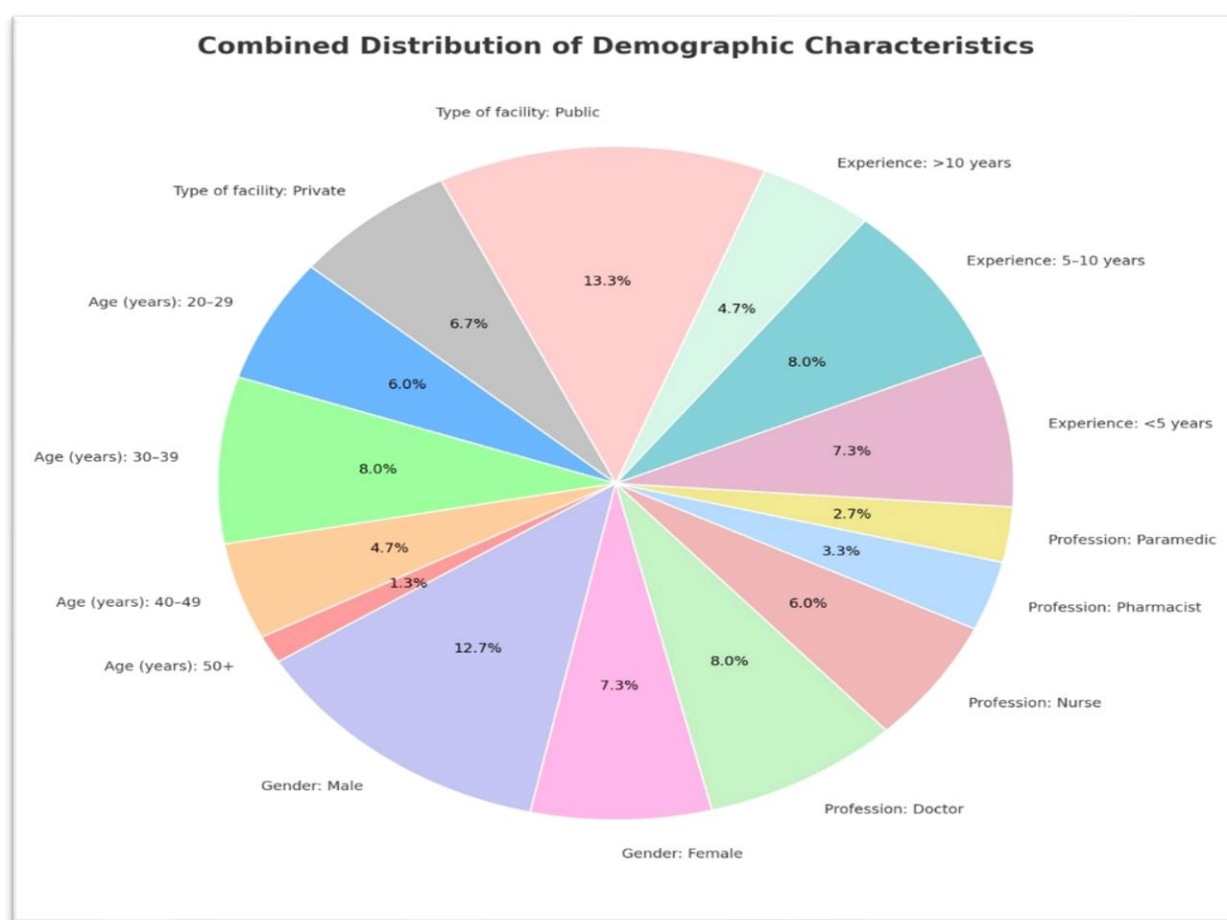


Figure 4.1

4.2. Awareness of ADR Reporting

Awareness was measured using a scoring system based on correct responses. Participants were categorized into *Good*, *Moderate*, or *Poor* awareness levels.

Table 4.2: Awareness Levels of ADR Reporting Among Healthcare Workers.

Awareness Level	Frequency (n)	Percentage (%)
Good	65	43.3
Moderate	55	36.7
Poor	30	20.0

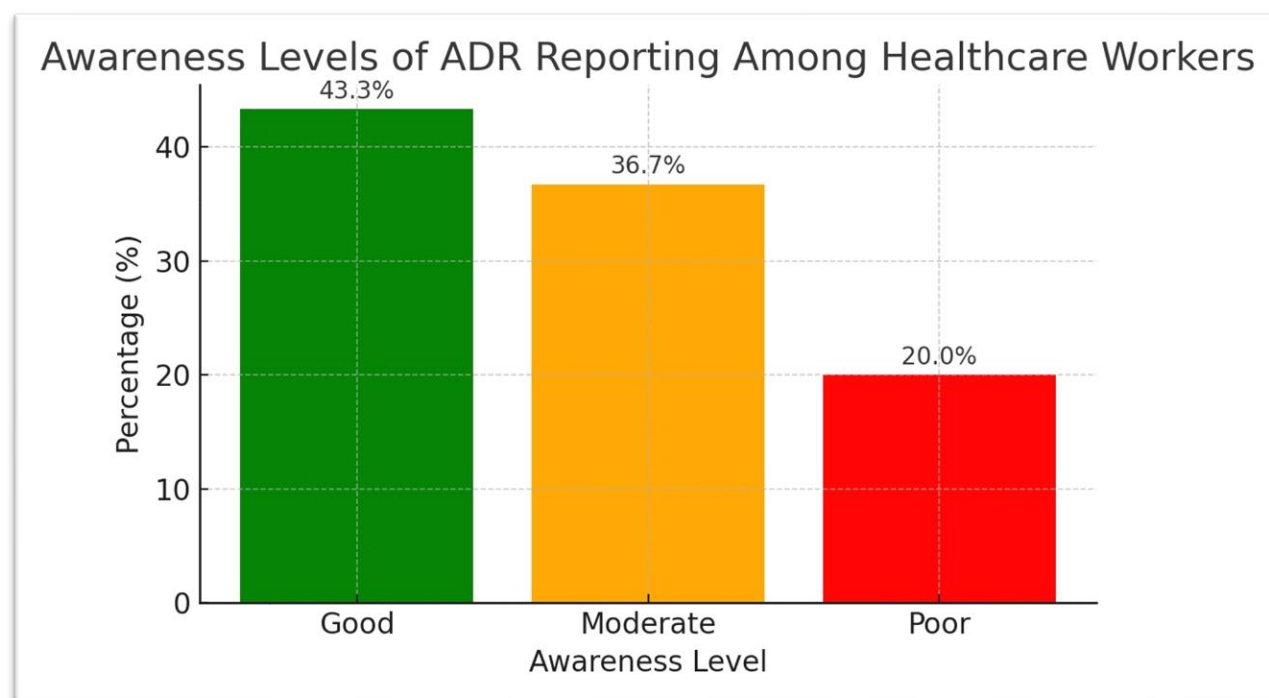


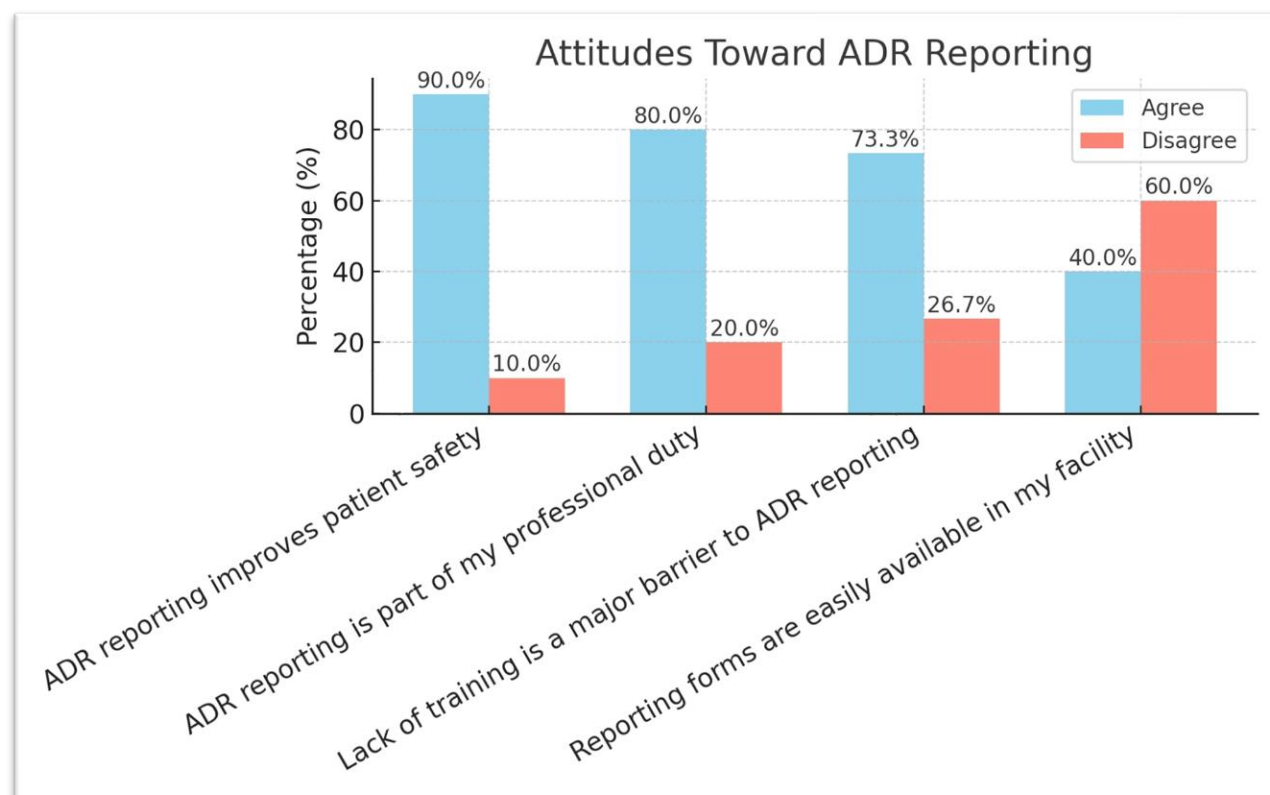
Figure 4.2

4.3. Attitudes Toward ADR Reporting

Most participants showed positive attitudes toward ADR reporting, recognizing its importance for patient safety, although barriers such as lack of training and unavailability of reporting forms were highlighted.

Table 4.3: Attitudes Toward ADR Reporting (n = 150)

Statement	Agree n (%)	Disagree n (%)
ADR reporting improves patient safety	135 (90.0)	15 (10.0)
ADR reporting is part of my professional duty	120 (80.0)	30 (20.0)
Lack of training is a major barrier to ADR reporting	110 (73.3)	40 (26.7)
Reporting forms are easily available in my facility	60 (40.0)	90 (60.0)



4.4 Practices of ADR Reporting

While attitudes were positive, actual ADR reporting practices were low among participants.

Table 4.4: Practices of ADR Reporting (n = 150)

Practice Variable	Yes n (%)	No n (%)
Ever reported an ADR	45 (30.0)	105 (70.0)
Reported in the last 12 months	20 (13.3)	130 (86.7)
Reports made through official forms	15 (10.0)	135 (90.0)
Reports made verbally to colleagues	40 (26.7)	110 (73.3)

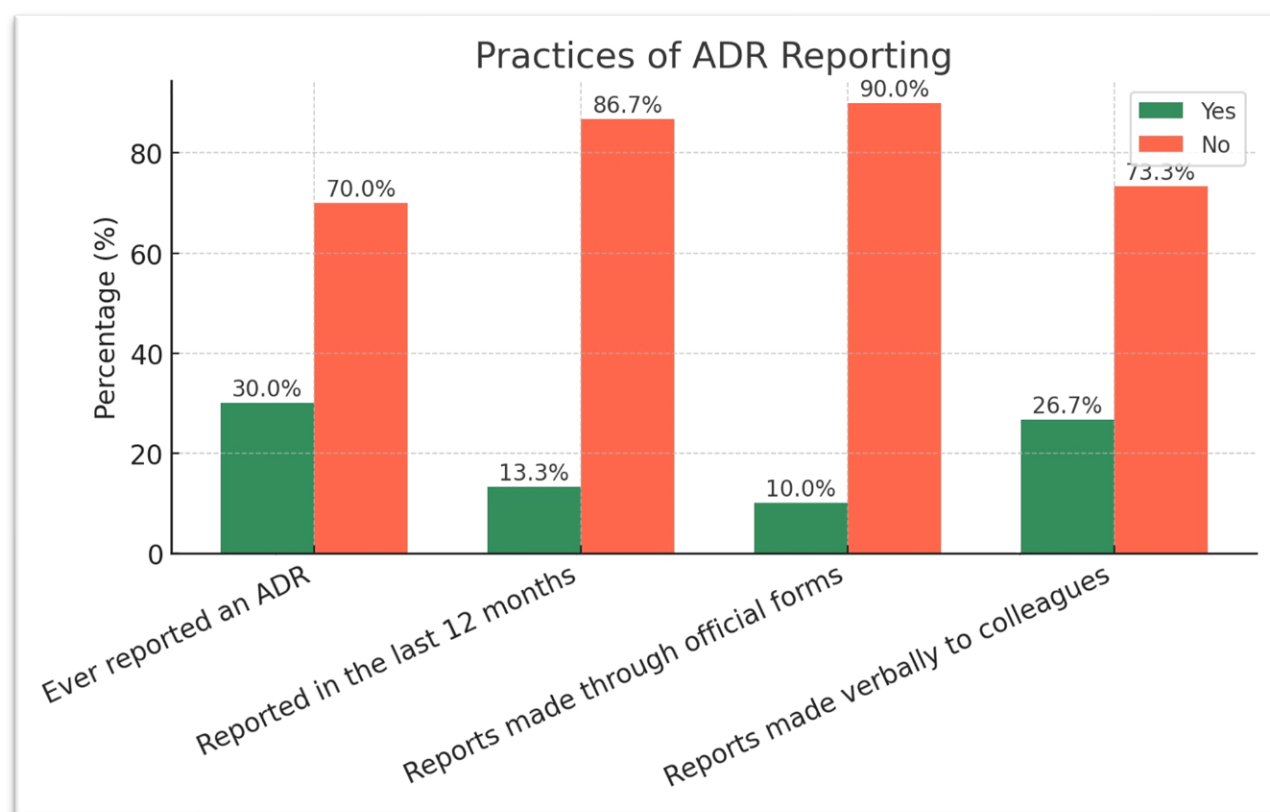


Figure 4.4

Most healthcare workers had moderate to good awareness of ADR reporting.

Positive attitudes were observed toward the importance and professional duty of ADR reporting.

Low reporting practices were noted, with major barriers being lack of training and unavailability of reporting forms.

Discussion

Adverse drug reactions (ADRs) pose a significant global threat to patient safety, and prompt reporting by healthcare workers (HCWs) is essential for identifying and mitigating medication-related harm. Nonetheless, underreporting continues to be a substantial concern in numerous nations, especially in developing areas. This study's findings, conducted among healthcare workers in Bannu District, Khyber Pakhtunkhwa, Pakistan, indicated that 43.3% of participants exhibited adequate awareness of adverse drug reaction reporting, 36.7% showed moderate awareness, and 20% displayed low awareness. Although the percentage of healthcare workers with adequate awareness is promising, the findings indicate that a significant number may still lack the requisite knowledge or willingness to engage effectively in pharmacovigilance. Our findings align with research from other regions of Pakistan and South Asia, where

awareness levels often fluctuate between 40% and 50%. Comparable results have been observed in Lahore, Karachi, and Peshawar, suggesting that issues in ADR reporting are not limited to a specific district but rather signify wider national patterns. Frequently identified obstacles encompass insufficient training, the lack of explicit reporting protocols, and minimal institutional prioritization of pharmacovigilance. In Bannu's rural and semi-urban regions, insufficient access to reporting mechanisms and limited opportunities for continuing education may exacerbate these obstacles. The observed discrepancies between public and private healthcare institutions demand careful consideration. Although the majority of participants were affiliated with public institutions, healthcare workers in private facilities may possess even fewer resources and receive less formal instruction for adverse drug reaction reporting. This indicates the necessity for district-wide initiatives that

address both sectors equitably. To enhance ADR reporting awareness in Bannu, interventions must concentrate on incorporating pharmacovigilance training into standard professional development programs, implementing streamlined reporting systems (such as mobile applications connected to the national database), and creating a feedback mechanism to ensure healthcare workers comprehend the significance of their reports. By resolving these deficiencies, local healthcare systems can enhance their role in patient safety and bolster national pharmacovigilance initiatives.

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