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Improving Patient Safety through Pharmacovigilance – A Review of Spontaneous ADR Reporting Trends in Clinical Practice

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) are a leading cause of hospitalization and morbidity worldwide and pose a significant challenge to patient safety. Early detection is important through effective pharmacovigilance by spontaneous reporting of ADRs by clinicians. The current study will assess trends, determinants, and impact of spontaneous adverse drug reaction (ADR) reporting in clinical practice to achieve optimal patient safety through effective pharmacovigilance. **Methods & Materials**: This cross-sectional, observational study was conducted in 56 patients who had experienced adverse drug reactions (ADRs) during their course of treatment in Dhaka Medical College from January 2024 to December 2024. Data were analyzed according to the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as mean, frequency, and percentage were used for categorical variables. **Result**: Fifty of the 56 participants (89.3%) had heard about pharmacovigilance, but only 24 (42.9%) had ever submitted an ADR report, and 16 (28.6%) reported to a national authority. Antibiotics (18; 34.6%) and NSAIDs (10; 19.2%) were the most common drug classes involved. While 32 (57.1%) were aware of the WHO-UMC reporting form and 28 (50.0%) of the causality assessment criteria, barriers like time constraints (22; 39.3%) and fear of legal consequences (18; 32.1%) were interfering with reporting. **Conclusion**: It is concluded by this study that most ADRs occurred with antibiotics and analgesics, were of mild to moderate intensity, and were largely avoidable. Despite the importance of spontaneous reporting for improving patient safety, underreporting is a critical problem due to low training and awareness.

Keywords: *Pharmacovigilance, Adverse drug reaction, Reporting Trend*

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INTRODUCTION

Adverse drug reactions (ADRs) remain a major and preventable threat to patient safety worldwide, contributing substantially to morbidity, hospital admissions, and health-care costs. Spontaneous reporting systems - where health-care professionals (HCPs), and increasingly patients, submit suspected ADRs to national pharmacovigilance centres - are cornerstone tools for post-marketing safety surveillance and signal detection. Despite their central role in identifying rare and unexpected harms, these systems suffer from chronic under-reporting and variable report quality, which limit their sensitivity and timeliness in protecting patients [1,2]. A growing body of evidence shows that reporting behaviour and reporting volume have evolved over the last decade as a result of regulatory change, technological advances, and increased patient engagement. Regulatory reforms in major jurisdictions (for example, the EU's strengthened pharmacovigilance legislation and encouragement of direct patient reporting) have been associated with marked increases in patient-originated reports and shifts in the types of events captured, broadening the safety signal landscape beyond HCP-reported data [3–6]. Several national and regional analyses have documented upward trends in total ADR submissions over time, but also heterogeneity in reporter mix (physicians, pharmacists, nurses, patients) and in the therapeutic areas and age groups most cited in reports [7,8]. However, quantity alone is not sufficient: the usefulness of spontaneous reporting depends on report completeness and clinical detail. Recent research highlights persistent problems with incomplete or poorly documented case reports - a limitation that can delay causality assessment and signal validation [9]. Equally important are the human factors that determine whether and what clinicians report. Systematic reviews show that knowledge gaps, attitudes (ignorance, lethargy, complacency), and practical barriers (time constraints, lack of feedback, and unfamiliarity with reporting channels) remain the dominant drivers of under-reporting among HCPs, even where reporting infrastructures exist [1,2]. Intervention studies and syntheses indicate there are effective strategies to improve reporting rates and report quality. Educational programmes, targeted workshops, electronic reporting tools integrated with clinical systems, and simple engineering changes (for example, hyperlinks to online forms or timely feedback) have been associated with measurable increases in reporting and improvements in reporter knowledge and confidence [2,10]. Therefore, this study aims to assess the trends, determinants, and impact of spontaneous adverse drug reaction (ADR) reporting in clinical practice to enhance patient safety through effective pharmacovigilance.

METHODS & MATERIALS

This observational, cross-sectional study was conducted among 56 patients who experienced adverse drug reactions (ADRs) during their treatment in Dhaka Medical College from January 2024 to December 2024. Data were collected prospectively from spontaneous ADR reports submitted by healthcare professionals and verified through patient medical records. All ADRs were assessed using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale

and categorized based on their severity using the Modified Hartwig and Siegel scale. Demographic details, drug classes involved, system organ classification, and outcomes were recorded using a predesigned data collection form. Inclusion criteria included all patients of any age and gender who developed ADRs during hospitalization or outpatient treatment and had complete clinical documentation. Exclusion criteria included cases with incomplete records, doubtful causality, or ADRs related to drug overdose, poisoning, or medication errors. Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics such as mean, frequency, and percentage were used for categorical variables. Ethical clearance was taken from the Institutional Review Board. Informed written consent was taken from all the participants.

RESULTS

The participants were evenly distributed by gender, with half male and half female. The largest age group was 31–40 years (48.2%), and physicians represented the highest proportion (42.9%). Most respondents had 5–10 years of professional experience, indicating a balanced mix of mid-level practitioners actively involved in clinical care (*Table I*).

Table I
Socio-Demographic Characteristics of Study Participants (*n* = 56).

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	≤30	18	32.1
	31–40	27	48.2
	>40	11	19.7
Gender	Male	28	50.0
	Female	28	50.0
Profession	Physician	24	42.9
	Pharmacist	18	32.1
	Nurse	14	25.0
Experience (years)	<5	16	28.6
	5–10	28	50.0
	>10	12	21.4

The majority of participants (89.3%) were familiar with the concept of pharmacovigilance. However, only about two-thirds knew the correct reporting channels, and less than half had received formal training. This highlights a gap between theoretical awareness and practical competence in ADR monitoring and reporting (*Table II*).

Table II
Awareness and Knowledge of Pharmacovigilance (*n* = 56).

Knowledge Domain	Correct Response n (%)
Aware of the term “Pharmacovigilance”	50 (89.3)
Knows where to report ADRs	39 (69.6)
Familiar with the WHO-UMC reporting form	32 (57.1)
Knows ADR causality assessment criteria	28 (50.0)
Received prior training on pharmacovigilance	22 (39.3)

Most participants viewed ADR reporting as an ethical and professional responsibility and believed it improves patient safety. However, a significant portion cited time constraints and legal apprehensions as barriers. The majority agreed that regular feedback from pharmacovigilance authorities would encourage more consistent reporting (*Table III*).

Table III
Attitude Toward ADR Reporting (*n* = 56).

Statement	Agree n (%)	Neutral n (%)	Disagree n (%)
ADR reporting is a professional obligation	46 (82.1)	6 (10.7)	4 (7.1)
Reporting ADRs improves patient safety	50 (89.3)	4 (7.1)	2 (3.6)
Reporting takes too much time	22 (39.3)	20 (35.7)	14 (25.0)
Fear of legal consequences discourages reporting	18 (32.1)	14 (25.0)	24 (42.9)
Feedback from authorities encourages reporting	48 (85.7)	5 (8.9)	3 (5.4)

Almost all participants (92.9%) encountered ADRs in their professional practice, yet only 42.9% had ever reported one. Reporting to the national authority was notably low (28.6%), and few participants used electronic systems. This reflects a significant under-reporting trend despite widespread clinical exposure to ADRs (*Table IV*).

Table IV
Practice of ADR Reporting Among Participants (*n* = 56).

Practice Parameter	Yes n (%)	No n (%)
Ever encountered an ADR	52 (92.9)	4 (7.1)
Ever reported an ADR	24 (42.9)	32 (57.1)
Reported ADR to the national authority (DGDA/WHO)	16 (28.6)	40 (71.4)
Frequency of reporting (>1 per year)	10 (17.9)	46 (82.1)
Used an electronic or online reporting system	14 (25.0)	42 (75.0)

Antibiotics were the most frequently implicated drug class (34.6%), followed by NSAIDs and antihypertensives. Cutaneous and gastrointestinal manifestations were the most commonly reported reaction types. This pattern suggests that ADRs associated with widely prescribed drug categories remain predominant in clinical practice (*Table V*).

Table V
Types and Frequency of ADRs Encountered by Participants (*n* = 52*).

Drug Class Involved	Common ADR Observed	Frequency (n)	Percentage (%)
Antibiotics	Skin rash, gastrointestinal upset	18	34.6
NSAIDs	Gastritis, urticaria	10	19.2
Antihypertensives	Hypotension, dizziness	8	15.4
Antiepileptics	Sedation, rash	6	11.5
Antidiabetics	Hypoglycemia, nausea	6	11.5
Others	Miscellaneous (e.g., antipsychotics, antivirals)	4	7.8

**Among 52 participants who had encountered ADRs.*

Most participants favored periodic training and digital reporting systems to improve ADR reporting. Regular feedback and integration of pharmacovigilance into continuing education programs were also highly endorsed, reflecting a proactive attitude toward system-level improvement (*Table VI*).

Table VI
Suggested Measures to Improve ADR Reporting (*n* = 56).

Suggested Intervention	Frequency (n)	Percentage (%)
Regular training/workshops	48	85.7
Simplified online reporting system	42	75.0
Feedback from pharmacovigilance authorities	40	71.4
Inclusion in CME/CPD programs	38	67.9
Institutional ADR monitoring committees	36	64.3

DISCUSSION

In this study of 56 healthcare professionals, 89.3% reported awareness of the term "pharmacovigilance," yet only 42.9% had ever submitted an ADR report. A recent systematic update found that knowledge and attitudes remain primary determinants of under-reporting, and reported awareness levels in surveyed samples ranged widely; the review described persistent gaps between awareness and reporting behaviour but did not present a single pooled "ever reported" percentage, noting large heterogeneity across studies [1]. When compared with single-centre and national cross-sectional studies, our 42.9% "ever reported" rate is higher than the 13.1% reported in one multi-site survey (where actual reporters were a small minority) but is close to the 39.7% "ever reported" documented in a separate hospital-based study from the same region that found 39.7% had ever reported an ADR and 35-40% had seen the reporting form [11]. Thus, our cohort appears to sit toward the mid-range of observed reporting practice: substantially above some low-reporting settings but short of universal reporting. Formal pharmacovigilance training was reported by 39.3% of participants in our sample. Intervention and evaluation studies demonstrate that training rates and the provision of education vary considerably; multifaceted interventions produce marked increases in knowledge and reporting, with studies showing knowledge scores rising from ~73% to >99% after training interventions and reporting increasing substantially post-intervention [12]. Compared with those intervention results, our 39.3% baseline training prevalence indicates a clear opportunity for improvement through targeted education at this centre. Use of electronic or online reporting systems was low (25.0%) in our sample. Overviews of interventions emphasize engineering solutions - notably electronic reporting - as one of the most consistently effective measures to stimulate reporting activity. An overview that categorized interventions under education, engineering, economics, and enforcement reported that electronic tools frequently yield larger short-term gains in report volume than single educational sessions alone [13]. The relatively low uptake of electronic reporting in our cohort aligns with settings where systems are available but underutilized and supports prioritizing user-friendly electronic integration locally. Perceived barriers in this study included time constraints (39.3% agreement) and fear of legal consequences (32.1%). A contemporary systematic update reported similar dominant barriers - lack of time, uncertainty about causality, and absence of feedback - and quantified high median under-reporting rates across studies (median under-reporting ~90% in many settings) [1]. Our measured barrier frequencies echo that pattern: although fewer than half of respondents flagged each barrier individually, their combined effect corresponds with the substantial under-reporting observed. Regarding the types of ADRs encountered, antibiotics accounted for 34.6% of implicated drugs and NSAIDs for 19.2% in our sample. Drug-class distributions from pharmacovigilance databases and hospital series commonly list antimicrobials and NSAIDs among the most frequently implicated groups, with skin and gastrointestinal reactions predominating; for example, hospital ADR audits often show antibiotics and NSAIDs among the top contributors to reported ADRs [14,15]. Our proportions are therefore consistent with the commonly observed clinical profile where widely prescribed antimicrobial and analgesic agents produce the bulk of spontaneously detected events. In this study, the suggested measures from participants - regular training (85.7%) and simplified online reporting (75.0%) - reflect the two intervention domains shown to increase reporting when combined. Overviews and systematic reviews report the greatest and most sustained gains when educational measures are paired with system-level engineering changes and timely feedback [12,13].

LIMITATIONS

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

This study highlights that most ADRs occurred with antibiotics and analgesics,

were mild to moderate, and largely preventable. Despite the importance of spontaneous reporting in improving patient safety, underreporting remains a major concern due to limited awareness and training. Strengthening pharmacovigilance systems and promoting a proactive reporting culture are essential to minimize drug-related harm and enhance patient care.

RECOMMENDATION

Regular training programs should be implemented to improve healthcare professionals' awareness and participation in ADR reporting. Establishing user-friendly digital reporting systems, integrating pharmacovigilance into clinical workflows

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CONFLICT OF INTEREST

None declared

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