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Causality Assessment of Adverse Drug Reactions Using WHO-UMC Scale

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a significant cause of morbidity and contribute to increased healthcare burden. **Objective:** To assess the causality of adverse drug reactions using the WHO-UMC causality assessment scale and to describe the demographic, clinical, and pharmacological characteristics of reported ADRs. **Methods:** This descriptive, cross-sectional study included 185 patients with suspected ADRs, conducted at Sir Gangram Hospital Lahore from Jan 2025 to July 2025. Data on patient demographics, suspected drugs, clinical presentation, severity, and outcomes were collected using a structured ADR reporting form. Each ADR was assessed and categorized according to the WHO-UMC causality scale. **Results:** The mean age of patients was 46.3 ± 15.8 years, with a male predominance (55.7%). Most ADRs occurred in hospitalized patients (65.4%) and in those receiving multiple medications (60.5%). Antibiotics were the most commonly implicated drug class (30.3%), followed by non-steroidal anti-inflammatory drugs (15.7%). Cutaneous reactions were the most frequent clinical manifestation (42.7%). The majority of ADRs were mild (42.2%) or moderate (44.9%), while 13.0% were severe. According to the WHO-UMC scale, ADRs were categorized as possible in 38.4% of cases, probable/likely in 34.1%, and certain in 10.3%. Severe reactions were more frequently observed in ADRs with certain and probable causality. **Conclusion:** ADRs are frequently encountered, particularly among hospitalized and polypharmacy patients. The WHO-UMC causality assessment scale provides a structured and effective approach for evaluating suspected ADRs and supports consistent pharmacovigilance practices aimed at enhancing patient safety.

INTRODUCTION

Adverse drug reactions (ADRs) are a major public health concern and represent a significant cause of morbidity, mortality, prolonged hospital stay, and increased healthcare costs worldwide [1]. While the World Health Organization considers a noxious and unintended response to a drug to be an Adverse Drug Reaction (ADR), it does not account for the normal doses that may be clinically necessary for the prophylaxis, diagnosis, or therapy of a given disease [2]. Even though the drug development process and regulatory requirements have improved, ADRs continue to be a common occurrence in many areas of routine clinical practice and continue to impact clinical practice, especially in hospitalized patients, the elderly and patients with polypharmacy [3]. The careful detection and assessment of an ADR is an important factor in both patient safety and rational pharmacotherapy. Even though factors such as the presence of an underlying disease, polypharmacy, drug pharmacokinetics, and individual patient factors all make it difficult to determine a causal link between a drug and an adverse event, the absence of a comprehensive ADR framework lacks standardised methodologies for addressing the issue when it arises to evaluating suspected ADRs [4]. The various methods available for assessing causality include the Naranjo algorithm, the French method, and Kramer's algorithm; however, in pharmacovigilance, the most commonly used method remains the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale [5]. WHO-UMC offers the world standardised assessment of causality and it has been recommended for use in

national and international programmes for ADR monitoring [6]. ADRs are divided into six categories, which include, (i) Based on clinical, temporal and pharmacological criteria, (ii) certain, (iii) probable/likely, (iv) possible, (v) unlikely, (vi) conditional/unclassified, (vii) unassessable/unclassifiable [7]. The WHO-UMC scale focuses on the temporal relationship between the drug being taken and the reaction, relationship to drug withdrawal (de-challenge) and to drug read ministration (re challenge), alternative cause elimination, and the clinical or other supportive evidence (if any) [8]. The WHO-UMC scale, unlike other algorithm-based approaches, incorporates more clinical discretion, which serves to help scale more accurately to the complexities of clinical practice, especially in instances where data is incomplete [9]. The improvement of ADR (adverse drug reaction) reporting and overall strengthened pharmacovigilance was due to the systematic application of the WHO-UMC scale in multiple studies [10]. The analysis of the causality distribution in reported ADRs has been useful in evaluating prescribing behaviour, assessing the need for changes in drug monitoring and regulation, determining the safety of the drugs, and identifying the need for further studies [11].

Objective

To assess the causality of adverse drug reactions using the WHO-UMC causality assessment scale and to describe the demographic, clinical, and pharmacological characteristics of reported ADRs.

METHODOLOGY

This was a descriptive, cross-sectional study conducted at Sir Gangram Hospital Lahore from Jan 2025 to July 2025 including 185 patients with suspected adverse drug reactions (ADRs). The study was designed to assess the causality of reported ADRs using the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) causality assessment scale.

Inclusion Criteria

- Patients of either gender aged 18 years and above
- Patients with suspected adverse drug reactions occurring during drug therapy
- Availability of adequate clinical information, drug history, and temporal relationship between drug exposure and reaction
- Patients willing to provide informed consent

Exclusion Criteria

- Incomplete or inadequately documented ADR reports
- Adverse events clearly attributable to underlying disease or non-drug-related causes
- Cases of intentional overdose, drug abuse, or poisoning
- Patients unwilling to participate

Data Collection

Data were collected using a structured adverse drug reaction reporting form. Information recorded included demographic characteristics, suspected drug(s), indication for use, dose, route and duration of therapy, time to onset of the reaction, clinical description of the ADR, management provided, and patient outcome. Each ADR was independently assessed for causality using the WHO-UMC causality assessment scale and classified into one of the following categories: certain, probable/likely, possible, unlikely, conditional/unclassified, or unassessable/unclassifiable. Causality assessment was performed by trained investigators to ensure uniform application of the WHO-UMC criteria.

Statistical Analysis

Data were analyzed using SPSS version 24.0. Quantitative variables such as age were expressed as mean ± standard deviation, while categorical variables including gender, type of ADR, suspected drug class, and WHO-UMC causality categories were presented as frequencies and percentages. Descriptive statistics were used to summarize ADR characteristics and causality assessment outcomes. A p-value of ≤ 0.05 was considered statistically significant where applicable.

RESULTS

The study included 185 patients with suspected adverse drug reactions, with the largest proportion belonging to the 31–45-year age group (29.2%), followed by patients aged 46–60 years (26.5%). The mean age increased progressively across age groups, ranging from 26.1 ± 3.4 years in younger adults to 68.9 ± 5.6 years in those older than 60 years. Males constituted 55.7% of the cohort, with a comparable age distribution between genders. Most ADRs were reported among hospitalized patients (65.4%), who had a higher mean age of 49.6 ± 14.8 years compared to outpatients at 41.7 ± 13.9 years. Polypharmacy was common, affecting 60.5% of patients, particularly among older and hospitalized individuals, with a mean age of 51.3 ± 14.1 years.

Table 1

Demographic and Clinical Profile of Patients with Adverse Drug Reactions (n = 185)

Variable	Category	Total n (%)	Male (n = 103)	Female (n = 82)	Mean Age ± SD (years)
Age group	18–30	38 (20.5)	21 (20.4)	17 (20.7)	26.1 ± 3.4
	31–45	54 (29.2)	31 (30.1)	23 (28.0)	38.4 ± 4.2
	46–60	49 (26.5)	28 (27.2)	21 (25.6)	53.2 ± 4.1
	>60	44 (23.8)	23 (22.3)	21 (25.6)	68.9 ± 5.6
Hospitalization	Inpatient	121(65.4)	69 (67.0)	52 (63.4)	49.6±14.8
	Outpatient	64 (34.6)	34 (33.0)	30 (36.6)	41.7±13.9
Polypharmacy	≥5 drugs	112(60.5)	67 (65.0)	45 (54.9)	51.3±14.1
	<5 drugs	73 (39.5)	36 (35.0)	37 (45.1)	38.6±12.7

Antibiotics were the most frequently implicated drug class, accounting for 30.3% of all ADRs, with a mean onset time of 4.1 ± 2.3 days, and nearly 40% administered via injectable routes. Non-steroidal anti-inflammatory drugs were the second most common cause at 15.7%, predominantly administered orally and associated with early onset reactions occurring within 2.8 ± 1.6 days. Antiepileptic drugs and antitubercular therapy contributed to 11.4% and 9.7% of ADRs respectively, with delayed onset reactions, particularly for antitubercular drugs, which showed a mean onset time of 27.4 ± 11.2 days. Cardiovascular, antidiabetic, and psychotropic drugs collectively accounted for approximately one-quarter of ADRs, reflecting the impact of chronic disease management on ADR occurrence.

Table 2

Distribution of Adverse Drug Reactions by Drug Class and Route of Administration (n = 185)

Drug Class	Total ADRs n (%)	Oral n (%)	Injectable n (%)	Top Indication	Mean Time to Onset (days ± SD)
Antibiotics	56(30.3)	34 (60.7)	22 (39.3)	Infections	4.1 ± 2.3
NSAIDs	29(15.7)	26 (89.7)	3 (10.3)	Pain / inflammation	2.8 ± 1.6
Antiepileptics	21(11.4)	21 (100.0)	0 (0.0)	Seizure disorder	18.6 ± 7.9
Antitubercular drugs	18 (9.7)	18 (100.0)	0 (0.0)	Tuberculosis	27.4 ± 11.2
Cardiovascular drugs	17 (9.2)	15 (88.2)	2 (11.8)	Hypertension	21.9 ± 9.4
Antidiabetics	15 (8.1)	13 (86.7)	2 (13.3)	Diabetes mellitus	14.3 ± 6.8
Psychotropics	14 (7.6)	14 (100.0)	0 (0.0)	Psychiatric illness	19.7 ± 8.1
Others	15 (8.1)	11 (73.3)	4 (26.7)	Mixed	11.6 ± 5.9

Skin and appendage-related reactions were the most common clinical presentation, comprising 42.7% of ADRs, followed by gastrointestinal (24.9%) and central nervous system manifestations (14.6%). Hepatobiliary and hematological reactions, although less frequent, were predominantly observed among hospitalized patients and those receiving multiple medications. In terms of severity, most ADRs were mild (42.2%) or moderate (44.9%), while severe reactions accounted for 13.0% and were overwhelmingly reported in inpatients (91.7%). Clinical outcomes were generally favorable, with 76.2% of patients achieving complete recovery, while 15.7% were still recovering at the time of assessment. Fatal outcomes were uncommon, occurring in 3.2% of cases, and were primarily associated with severe ADRs and inpatient status.

Table 3

Clinical Pattern, Severity, and Outcome of Adverse Drug Reactions (n = 185)

Parameter	Category	n (%)	Inpatients n (%)	Polypharmacy n (%)
System involved	Skin and appendages	79 (42.7)	49 (62.0)	53 (67.1)
	Gastrointestinal	46 (24.9)	31 (67.4)	28 (60.9)
	CNS	27 (14.6)	18 (66.7)	19 (70.4)
	Hepatobiliary	18 (9.7)	15 (83.3)	16 (88.9)
	Cardiovascular	9 (4.9)	6 (66.7)	7 (77.8)
	Hematological	6 (3.2)	5 (83.3)	5 (83.3)
Severity	Mild	78 (42.2)	39 (50.0)	41 (52.6)
	Moderate	83 (44.9)	60 (72.3)	55 (66.3)
	Severe	24 (13.0)	22 (91.7)	16 (66.7)
Outcome	Recovered	141(76.2)	86 (61.0)	87 (61.7)
	Recovering	29 (15.7)	22 (75.9)	17 (58.6)
	Not recovered	9 (4.9)	8 (88.9)	6 (66.7)
	Fatal	6 (3.2)	5 (83.3)	2 (33.3)

According to the WHO-UMC causality assessment, the majority of ADRs were classified as possible (38.4%) or probable/likely (34.1%), indicating a reasonable temporal relationship with suspected drugs. Certain causality was established in 10.3% of cases, all of which demonstrated a positive dechallenge and more than half showing confirmatory rechallenge. Severe ADRs were most frequently observed in the certain category (31.6%), followed by probable reactions (17.5%). Patients classified under the possible and unlikely categories showed lower proportions of severe reactions. The mean age was comparable across causality categories, ranging from 39.6 ± 11.9 years in unassessable cases to 48.9 ± 16.4 years in the unlikely group.

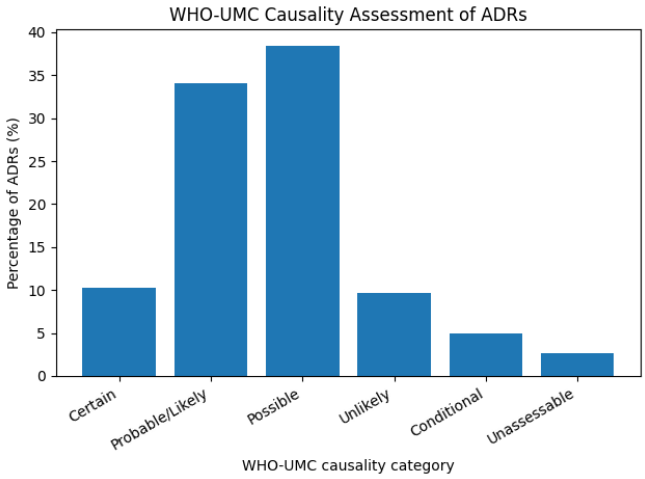
Table 4

WHO-UMC Causality Assessment With Dechallenge, Rechallenge, and Severity Correlation (n = 185)

WHO-UMC Category	n (%)	Positive Dechallenge n (%)	Rechallenge Done n (%)	Severe ADRs n (%)	Mean Age ± SD (years)
Certain	19 (10.3)	19(100.0)	12 (63.2)	6 (31.6)	44.8 ± 12.6
Probable/Likely	63(34.1)	63(100.0)	0 (0.0)	11(17.5)	46.1±14.2
Possible	71 (38.4)	29 (40.8)	0 (0.0)	5 (7.0)	45.3 ± 15.7
Unlikely	18 (9.7)	4 (22.2)	0 (0.0)	1 (5.6)	48.9 ± 16.4
Conditional	9 (4.9)	0 (0.0)	0 (0.0)	1 (11.1)	42.7 ± 13.8
Unassessable	5 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	39.6 ± 11.9

Figure 2

WHO-UMC Causality Assessment of Reported Adverse Drug Reactions



DISCUSSION

This study evaluated 185 patients with suspected adverse drug reactions (ADRs) and provides a detailed assessment of their causality using the WHO-UMC scale, highlighting key demographic, clinical, and pharmacological patterns. Among the age groups analysed, the 31-45 and 46-60 age categories each comprised 29.2% and 26.5% of the sample respectively, and the largest proportion of older adults (>60 years of age) were also represented as a sizeable proportion of the sample (23.8%), reflecting their age and the mean age of 68.9 ± 5.6 years, emphasising the susceptibility of elderly patients. In terms of sex, 55.7% were male, and most of the ADRs were reported in the inpatient cohort (65.4%), who were older than outpatients, with a mean age of 49.6 ± 14.8 years as compared to 41.7 ± 13.9 years. Among the study participants, 60.5% of patients were recorded as being on polypharmacy, with a mean age of 51.3 ± 14.1 years, emphasising its status as a major contributor to the incidence of ADRs. Such demographic trends and risk factor correlations have also been observed in the literature [12][13]. In terms of the medications implicated,

the most common CRS causing ADRs were antibiotics (30.3%), with non-steroidal anti-inflammatory drugs (NSAID) being the second at 15.7%. Antibiotics ADRs CRS were associated with a mean time to reaction (MTR) of 4.1 ± 2.3 days, with the ADR NSAID reaction at a MTR of 2.8 ± 1.6 days.

Mean onset times were 18.6 ± 7.9 days for antiepileptic (11.4%) and 27.4 ± 11.2 days for antitubercular drugs (9.7%). Cardiovascular (9.2%), antidiabetic (8.1%), and psychotropic (7.6%) drugs together accounted for almost a quarter of the ADRs, illustrating the increasing complexity of managing chronic diseases. These pattern and drug class distributions are consistent with those noted in the literature [14].

In terms of ADRs, the majority of them (42.7%) were clinically related to the skin and its appendages, closely followed by the clinical elements of the gastrointestinal system (24.9%) and the central nervous system (14.6%). While less frequent, elements of the hepatobiliary and haematological systems (9.7% and 3.2% respectively) were more prevalent among those who were hospitalised and among those on medications, or polypharmacy. Most of the ADRs were mild (42.2%) and moderate (44.9%). The more extreme ADRs accounted for 13.0% of the cases. Most of the severe ADRs (91.7%) were among those who were hospitalised, illustrating the heightened susceptibility of hospitalised individuals. Most of the patients had positive clinical outcomes; 76.2% had completed their recovery, and at the point of assessment, 15.7% were still in recovery. The outcomes that were not positive were infrequent, 3.2% of the cases, and were in line with the outcomes of studies that had been conducted previously [15][16]. The largest proportion of the ADRs in accordance with the assessment of causality and the WHO-UMC were those that were more likely to be possible (38.4%) and more likely (34.1%), while certain causality was established in 10.3% of cases. The ADRs in the unclassifiable, conditional, and non-assessable causality together accounted for 17.3% of the total. Positive dechallenge was shown for all cases that were classified as certain (63.2%) and were positive for a confirming rechallenge. Unquestionable categories had the most frequent severe ADRs (31.6%), followed by probable/likely (17.5%), while severe reactions were least likely among possible (7.0%) and unlikely (5.6%) cases. Mean age across all causality categories ranged from 39.6 ± 11.9 years in unassessable cases to 48.9 ± 16.4 years in unlikely cases. Previous studies have documented similar distributions of the WHO-UMC causality categories and their relationship to the severity of an ADR [17]. This study reaffirms the WHO-UMC scale's usability and reliability in evaluating the severity of an adverse drug reaction and reiterates the need for continued surveillance in high-risk patients to enhance patient safety and promote the judicious use of medicines.

CONCLUSION

It is concluded that adverse drug reactions are common in routine clinical practice and occur predominantly among hospitalized patients, older age groups, and individuals exposed to polypharmacy. In this study of 185 patients, antibiotics (30.3%) and non-steroidal anti-inflammatory drugs (15.7%) were the most frequently implicated drug classes, while cutaneous manifestations (42.7%) represented the most common clinical presentation. Most ADRs were mild to moderate in severity; however, severe reactions accounted for 13.0% of cases and were largely observed in inpatients. Causality assessment using the WHO-UMC scale showed that the majority of ADRs were classified as possible (38.4%) or probable/likely (34.1%), with certain causality established in 10.3% of cases and a higher proportion of severe reactions in these categories.

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