Preventability of Antibiotic-Associated Adverse Drug Reactions Reported to a Regional Pharmacovigilance Center: A Cross-Sectional Descriptive Study

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Research Article

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Abstract

Background

Antibiotic-associated adverse drug reactions (ADRs) are a major contributor to medication-related harm and healthcare burden. Data on their preventability in Vietnam remain limited.

Objectives

To characterize the severity, implicated drug classes, and preventability of antibiotic-related ADRs reported to the Ho Chi Minh City DI & ADR Center in 2023.

Methods

A cross-sectional descriptive study was conducted using retrospective data of all ADR reports involving antibiotics from January–December 2023. Causality was assessed using the WHO-UMC criteria, severity according to clinical outcomes, and preventability using the WHO P-method.

Results

Among 3,307 ADR reports, 1,437 (43.5%) involved antibiotics; 1,403 (97.6%) had a confirmed causal relationship. Most ADRs were non-serious (66.9%). Skin and subcutaneous tissue disorders (68.1%) and rash (42.4%) were the most common manifestations. Other beta-lactams (52.1%) and fluoroquinolones (13.4%) were the leading causative drug classes, with ceftriaxone most frequently reported. Fifty-seven cases (4.1%) were preventable, most commonly due to inappropriate route of administration (31.6%), history of hypersensitivity (26.3%), or failure to adjust for patient characteristics (24.6%).

Conclusion

Antibiotic-related ADRs accounted for a substantial proportion of regional ADR reports, predominantly involving broad-spectrum beta-lactams. The proportion of preventable ADRs was lower than reported in previous studies, likely reflecting underreporting in spontaneous reporting systems. Strengthening antibiotic stewardship, electronic prescribing alerts, and healthcare worker training may reduce preventable ADRs and support safer antibiotic use.

1. Introduction

ADRs represent a major global public health and medication safety concern, exerting a substantial impact on patient outcomes and healthcare systems. Globally, ADRs are estimated to rank among the

4th to 6th leading causes of death, [1], comparable to chronic conditions such as cardiovascular diseases and cancer. A study in the United Kingdom reported that ADRs account for approximately 6.5% of hospital admissions, prolong hospitalization, and contribute to death in about 0.15% of all admitted patients [2].

Antibiotics are among the most widely prescribed drug classes and are a frequent cause of ADRs [3–5]. A systematic analysis reported that antibiotics accounted for roughly 16% of all ADR cases, representing the highest proportion among therapeutic classes [6]. Antibiotic-associated ADRs range from mild to severe manifestations. While many cases involve mild gastrointestinal disturbances or cutaneous rashes, severe reactions—such as anaphylactic shock—can be life-threatening. In the United States, an estimated 145,490 emergency department visits annually are attributed to antibiotic-related adverse effects, with allergic reactions representing 74.3% of these cases [7].

To mitigate the burden of ADRs, pharmacovigilance systems have been established globally. Since the 1960s, the World Health Organization (WHO) has coordinated the international program for ADR monitoring [8]. To date, only one study by Tran et al. (2023) has analyzed the national database to assess the preventability of antibiotic-related ADRs, reporting that approximately 8.4% of cases were preventable, mainly associated with beta-lactam antibiotics [9]. Apart from this study, most ADR research in Vietnam has been conducted at single hospitals and has primarily focused on reporting practices and severity assessment, without examining the preventability of ADRs [10–12]. This highlights a significant research gap in Vietnam regarding the assessment of preventable ADRs, particularly those caused by antibiotics.

The Ho Chi Minh City DI & ADR Center is one of two regional pharmacovigilance centers in Vietnam, responsible for receiving, documenting, and assessing ADR reports from the southern region, including major referral hospitals. This region is highly populated, with high antibiotic prescribing rates and distinct disease patterns and prescribing habits compared to northern Vietnam. Consequently, data from the Ho Chi Minh City DI & ADR Center provide an important regional perspective and complement the nationwide pharmacovigilance database. To date, no published studies have specifically analyzed the Center’s database, particularly regarding the severity and preventability of antibiotic-related ADRs. Therefore, this study was conducted to characterize the severity and evaluate the preventability of all antibiotic-associated ADR reports recorded at the Ho Chi Minh City DI & ADR Center in 2023.

2. Methods

2.1 Study subjects

All antibiotic-associated ADR reports recorded in the database of the Ho Chi Minh City Regional DI & ADR Center from January 1 to December 31, 2023.

Inclusion criteria and exclusion criteria

Inclusion criteria and exclusion criteria are presented in Table 1.

Table 1
Inclusion criteria and exclusion criteria

Inclusion criteria	Exclusion criteria
ADR reports from the Ho Chi Minh City Regional DI & ADR Center in which an antibiotic was identified as the suspected drug causing the ADR	- Reports in which the “suspected drug” was not an antibiotic. - Reports related to drug quality issues. - Reports of reactions occurring after drug hypersensitivity (skin) testing.

2.2. Methods

Study design

A cross-sectional descriptive study was conducted using retrospective data from ADR reports submitted to the Ho Chi Minh City Regional DI & ADR Center in 2023.

Sample size

All ADR reports that met the inclusion criteria and did not meet the exclusion criteria were included in the study.

Study variables

General characteristics of ADR reports: level of healthcare facility reporting the ADR and type of reporter. Patient characteristics: age, sex, and history of drug allergy.

Information on suspected drugs: causality assessment between drug and ADR, classification by indication for drug use, route of administration, therapeutic drug classes involved, list of suspected drugs, severity classification of ADRs, and clinical outcomes after management.

Information on preventable antibiotic-related ADRs: classification of ADRs by affected organ system, clinical manifestations, assessment of preventability using the WHO preventability criteria, and classification of preventable ADRs according to their underlying causes.

2.3. Data Processing and Analysis

Causality Assessment

The WHO-UMC causality assessment system was applied, which is widely used in pharmacovigilance practice for the evaluation of individual case safety reports. This method considers clinical–pharmacological aspects of the case and the quality of the information provided. Based on defined criteria, causality is categorized into six levels: certain, probable/likely, possible, unlikely, unclassified,

and unclassifiable [13]. Reports categorized as certain, probable/likely, or possible were considered to have a causal relationship between the suspected drug and ADR. For reports containing multiple drug–ADR pairs with different causality categories, the highest category was assigned.

Severity Assessment

ADR severity was classified according to clinical outcomes. An ADR was considered serious (serious adverse event – SAE) if it resulted in one of the following: death, life-threatening event, persistent or significant disability/incapacity, hospitalization or prolongation of hospitalization, or congenital anomaly/birth defect. All other ADRs were classified as non-serious [14].

Preventability Assessment

Reports with an established causal relationship were further evaluated for preventability using the WHO P-method. Results were classified into three categories: preventable, non-preventable, and not assessable. An ADR was deemed preventable when at least one critical criterion was identified. ADRs with no identified criteria were considered non-preventable. Cases with insufficient or missing data were classified as not assessable. Each report could contain more than one ADR [15]. Drug references for assessment were prioritized as follows: Vietnam National Drug Formulary, official package inserts (US/UK/France), Micromedex, and relevant clinical treatment guidelines.

Statistical Analysis

Data were processed using Microsoft Excel 2010. Continuous variables with normal distribution were presented as mean ± standard deviation; those with non-normal distribution were presented as median (interquartile range). Categorical variables were presented as frequencies and percentages.

3. Results

A total of 3,307 ADR reports from healthcare facilities were submitted to the Ho Chi Minh City Regional DI & ADR Center between January 1 and December 31, 2023. After excluding reports related to drug quality issues and reports in which the suspected drug was not an antibiotic, 1,437 antibiotic-associated ADR reports were identified, accounting for 43.5% of all reports in 2023. Following causality assessment using the WHO-UMC scale, 1,403 antibiotic-associated ADR reports (97.6% of included reports) were classified as having a causal relationship between the drug and the ADR. These reports were subsequently assessed for preventability using the WHO P-Method. In total, 57 antibiotic-associated ADRs (4.1%) were determined to be preventable.

General characteristics of the included ADR reports are summarized in Table 2.

Table 2
General characteristics of antibiotic-associated ADR reports (n = 1,437)

Characteristics		Frequency (Percentage) n = 1,437
Level of healthcare facility	Provincial/City hospitals	904 (62.9)
	District hospitals	186 (12.9)
	Central hospitals	175 (12.2)
	University hospitals	152 (10.6)
	Private hospitals	20 (1.4)
Type of reporter	Doctors	531 (37.0)
	Pharmacists	297 (20.7)
	Other healthcare staff	550 (38.3)
	Missing information	59 (4.1)
Gender	Male	554 (38.6)
	Female	875 (60.9)
	Unknown	8 (0.6)
Age group	< 18 years	341 (23.7)
	18–64	845 (58.8)
	≥ 65	248 (17.3)
History of allergy	Antibiotic allergy	70 (4.9)
	Allergy to other drugs	65 (4.5)
	Non-drug allergies	52 (3.6)
	Missing information	1264 (88.0)

According to Table 2, the majority of antibiotic-associated ADR reports were submitted by provincial/city hospitals (62.9%), followed by district hospitals (12.9%), central hospitals (12.2%), university hospitals (10.6%), and private facilities (1.4%). Regarding the type of reporter, most ADR reports were submitted by doctors (37.0%) and pharmacists (20.7%). Female patients accounted for a higher proportion of ADRs than males, with a male-to-female ratio of 1:1.58. The highest frequency of ADR reports was observed in patients aged 18–64 years (58.8%). Among patients with allergy history, antibiotic allergy was the most commonly reported (4.9%).

Causality Assessment Between Drug and ADR

The causality relationship between drugs and ADRs was assessed using the World Health Organization–Uppsala Monitoring Centre (WHO–UMC) causality assessment system. As each report could include one or more suspected drugs and each drug could be associated with one or more ADRs, the total number of drug–ADR pairs was assessed. The distribution of causality assessment outcomes for antibiotic–ADR pairs is presented in Table 3.

Table 3
Causality assessment results for antibiotic–ADR pairs

Causality category	Drug-ADR pairs (n, %) n = 1,583	Reports (n, %) n = 1,437
Certain	149 (9.4)	144 (10.0)
Probable/Likely	821 (51.9)	732 (50.9)
Possible	578 (36.5)	527 (36.7)
Unlikely	10 (0.6)	10 (0.7)
Unclassified	21 (1.3)	21 (1.5)
Unclassifiable	4 (0.3)	3 (0.2)

Among the 1,583 antibiotic–ADR pairs, 1,548 pairs (97.8%) were classified as “certain,” “probable,” or “possible.” These pairs corresponded to 1,403 patients (97.6% of all reports included in the study). The remaining 34 pairs (2.4%) were categorized as “unlikely,” “unclassified,” or “unclassifiable,” for which a definitive causal relationship between drug and ADR could not be established.

Drug-Related Information

[Table 4 should appear here]

Table 4
Classification of antibiotic-related ADR reports by indication (ICD-10)

Indication (ICD-10)	All antibiotic-related ADR reports (n = 1,403)	Preventable ADRs (n = 57)
	n, %	n, %
Respiratory diseases (J00–J99)	334 (23.8)	21 (36.8)
Factors influencing health status and contact with health services (Z00–Z99)	294 (21.0)	9 (15.8)
Infectious and parasitic diseases (A00–B99)	275 (19.1)	13 (22.9)
Genitourinary system diseases (N00–N99)	90 (6.3)	0 (0.0)
Digestive system diseases (K00–K93)	66 (4.6)	3 (5.3)
Skin and subcutaneous tissue diseases (L00–L99)	45 (3.1)	1 (1.8)
Nervous system diseases (G00–G99)	26 (1.8)	0 (0.0)
Symptoms, signs, and abnormal clinical and laboratory findings not elsewhere classified (R00–R99)	23 (1.6)	1 (1.7)
Congenital malformations, deformations and chromosomal abnormalities (Q00–Q99)	17 (1.2)	0 (0.0)
Musculoskeletal and connective tissue diseases (M00–M99)	16 (1.1)	0 (0.0)
Pregnancy, childbirth and puerperium (O00–O99)	15 (1.1)	0 (0.0)
Endocrine, nutritional and metabolic diseases (E00–E90)	10 (0.7)	0 (0.0)
Circulatory system diseases (I00–I99)	7 (0.5)	0 (0.0)
Certain conditions originating in the perinatal period (P00–P96)	7 (0.5)	0 (0.0)
Ear and mastoid process diseases (H60–H95)	4 (0.3)	0 (0.0)
Neoplasms (C00–D48)	3 (0.2)	0 (0.0)
Diseases of the blood, blood-forming organs, and immune mechanism disorders (D50–D89)	3 (0.2)	0 (0.0)
Eye and adnexa diseases (H00–H59)	3 (0.2)	1 (1.8)
Injury, poisoning and certain other consequences of external causes (S00–T98)	1 (0.1)	0 (0.0)
External causes of morbidity and mortality (V01–Y98)	1 (0.1)	0 (0.)

Indication (ICD-10)	All antibiotic-related ADR reports (n = 1,403)	Preventable ADRs (n = 57)
	n, %	n, %
Unknown (N#A)	219 (15.6)	9 (15.8)

According to Table 4, among 1,403 antibiotic-related ADR reports, respiratory diseases accounted for the largest proportion (23.8%), followed by factors influencing health status and contact with health services (21.0%) and infectious and parasitic diseases (19.1%). Other indications each accounted for < 7%. Notably, 15.6% of reports lacked information on the indication. Among preventable ADRs (p-ADR) cases, the highest proportions were observed in respiratory diseases (36.8%) and infectious diseases (22.9%), while many categories reported no p-ADR.

Table 5
Most frequently reported antibiotic groups causing ADR (ATC classification)

Antibiotic group (ATC)	All antibiotic-related ADR reports (n = 1,548)	Preventable ADRs (n = 57)
	n, %	n, %
Other beta-lactams (cephalosporins, monobactams, carbapenems) (J01D)	806 (52.1)	28 (49.1)
Quinolon (J01M)	207 (13.4)	19 (33.3)
Antituberculosis agents (J04A)	181 (11.6)	4 (7.0)
Other antibiotics (glycopeptides, polymyxins, nitrofurans, etc.) (J01X)	163 (10.5)	2 (3.5)
Beta-lactam (penicillin) (J01C)	128 (8.3)	4 (7.0)
Aminoglycosides (J01G)	26 (1.7)	0 (0.0)
Macrolides, lincosamides và streptogramins (J01F)	23 (1.5)	0 (0.0)
Sulfonamides và trimethoprim (J01E)	10 (0.6)	0 (0.0)
Tetracyclin (J01A)	3 (0.2)	0 (0.0)
Combination antibiotics (J01R)	1 (0.1)	0 (0.0)

According to Table 5, Other beta-lactams accounted for the highest proportion of ADR reports (52.1%), followed by quinolones (13.4%), antituberculosis agents (11.6%), and other antibiotics (10.5%). Remaining groups each accounted for < 10%. For p-ADRs, quinolones (33.3%) and other beta-lactams (49.1%) were most frequently implicated.

Table 6
Most frequently reported antibiotics causing ADR

No.	All antibiotic-related ADRs (n = 1,548)	n (%)	No.	Preventable ADRs (n = 57)	n (%)
1	ceftriaxon	239 (15.4)	1	levofloxacin	16 (28.07)
2	cefazolin	182 (11.8)	2	ceftriaxon	16 (28.07)
3	cefotaxim	132 (8.5)	3	cefazolin	7 (12.28)
4	vancomycin	120 (7.8)	4	ciprofloxacin	2 (3.51)
5	ciprofloxacin	112 (7.2)	5	amoxicilin/acid clavulanic	2 (3.51)
6	levofloxacin	81 (5.2)	6	vancomycin	2 (3.51)
7	ceftazidim	68 (4.4)	7	piperacilin/tazobactam	1 (1.75)
8	rifampicin/isoniazid/ pyrazinamid	45 (2.9)	8	cefixim	1 (1.75)
9	piperacillin/ tazobactam	41 (2.6)	9	cycloserin	1 (1.75)
10	ethambutol	38 (2.5)	10	cefotaxim	1 (1.75)

As shown in Table 6, ceftriaxone was the most frequently reported antibiotic (15.4%), followed by cefazolin (11.8%), cefotaxime (8.5%), and vancomycin (7.8%). All other antibiotics accounted for < 8%. Among p-ADR cases, levofloxacin and ceftriaxone were most commonly implicated (28.07% each), followed by cefazolin (12.28%).

Table 7
Severity and outcomes of antibiotic-related ADRs

	All antibiotic-related ADRs (n = 1,403)	Preventable ADRs (n = 57)
	n (%)	n (%)
Severity of ADR		
Death	2 (0.1)	0 (0.0)
Life-threatening	126 (9.0)	4 (7.0)
Hospitalization/Prolonged Hospital Stay	311 (22.2)	14 (24.6)
Persistent/Significant Disability	0 (0.0)	0 90.0)
Congenital Anomaly/Birth Defect	0 (0.0)	0 (0.0)
Non-serious	938 (66.9)	38 (66.7)
Missing Information	26 (1.9)	1 (1.7)
ADR Outcome		
Death related to ADR	1 (0.1)	0 (0.0)
Death unrelated to drug	1 (0.1)	0 (0.0)
Not recover	15 (1.1)	1 (1.8)
Recovering	421 (30.0)	15 (26.3)
Recovered with sequelae	7 (0.5)	0 (0.0)
Recovered without sequelae	901 (64.2)	39 (68.4)
Missing information	57 (4.1)	2 (3.5)

According to Table 7, Most antibiotic-related ADRs were classified as non-serious (66.9%), whereas 22.2% required hospitalization or prolonged hospitalization, and 9.0% were life-threatening. Only 0.1% were death. Regarding outcomes, 64.2% of patients recovered without sequelae, 30.0% were recovering at the time of reporting, and a small proportion had not yet recovered (1.1%). Among p-ADRs, 66.7% were non-serious, while 24.6% required hospitalization. Most patients (68.4%) recovered without sequelae

[Table 8 should appear here]

Table 8
ADRs related to antibiotics classified by System Organ Class

No.	System Organ Class *	Antibiotic-related ADRs n = 1,403	No.	System Organ Class *	p-ADR n = 57
1	Skin and subcutaneous tissue disorders (0100)	956 (68.1)	1	Skin and subcutaneous tissue disorders (0100)	39 (68.4)
2	Gastrointestinal disorders (0600)	152 (10.8)	2	Gastrointestinal disorders (0600)	8 (14.0)
3	Respiratory system disorders (1100)	125 (8.9)	3	Respiratory system disorders (1100)	8 (14.0)
4	Administration site conditions (1820)	124 (8.8)	4	Administration site conditions (1820)	4 (7.0)
5	General disorders (1810)	117 (8.3)	5	Central and peripheral nervous system disorders (0410)	4 (7.0)
6	Cardiovascular disorders (1010)	51 (3.6)	6	Cardiovascular disorders (1010)	3 (5.4)
7	Immune system disorders (1830)	49 (3.5)	7	Hepatobiliary disorders (0700)	2 (3.5)
8	Central and peripheral nervous system disorders (0410)	47 (3.3)	8	General disorders (1810)	2 (3.5)
9	Hepatobiliary disorders (0700)	35 (2.5)	9	Immune system disorders (1830)	1 (1.8)
10	Urinary system disorders (1300)	13 (0.9)	10	Red blood cell disorders (1210)	1 (1.8)

**ADRs were classified by System Organ Class.*

According to Table 8, among 1,403 antibiotic-related ADRs, skin and subcutaneous tissue disorders accounted for the highest proportion (68.1%), followed by gastrointestinal disorders (10.8%) and respiratory system disorders (8.9%). Others accounted for less than 9.0%. For the p-ADR group (n = 57), skin and subcutaneous tissue disorders predominated (68.4%), followed by gastrointestinal disorders (14.0%) and respiratory system disorders (14.0%), with others below 5.0%.

Table 9
Most frequently reported clinical manifestations of antibiotic-related ADRs

Clinical manifestation	All antibiotic-related ADRs (n = 1,403)	Preventable ADRs (n = 57)
	n (%)	n (%)
Rash	595 (42.4)	18 (31.6)
Pruritus	383 (27.3)	19 (33.3)
Urticaria	221 (15.8)	10 (17.5)
Dyspnea	113 (8.1)	5 (8.8)
Vomiting	97 (6.9)	3 (5.3)
Fatigue	95 (6.8)	5 (8.8)
Peripheral edema	77 (5.5)	6 (10.5)
Nausea	70 (5.0)	2 (3.5)
Dizziness	40 (2.9)	0 (0.0)
Anaphylactic shock/reaction	31 (2.2)	0 (0.0)

According to Table 9, among 1,403 antibiotic-related ADR reports, rash was the most common manifestation (42.4%), followed by pruritus (27.3%) and urticaria (15.8%). Other manifestations accounted for less than 10.0%. For the p-ADR group (n = 57), pruritus accounted for the highest proportion (33.3%), followed by rash (31.6%) and urticaria (17.5%). Other manifestations were below 11.0%.

Table 10
Preventability assessment of antibiotic-related ADRs

Classification	n, (%) n = 1,403
Preventable	57 (4.1)
Unpreventable	1334 (95.1)
Not assessable	12 (0.9)

According to Table 10, 4.1% of antibiotic-related ADR reports were classified as preventable. “Unpreventable” cases accounted for the majority (95.1%), and 0.9% were not assessable.

Table 11
Classification of p-ADR reports by cause

Cause	n (%) n = 57
Inappropriate route of administration	18 (31.6)
History of hypersensitivity to the drug or another drug in the same class	15 (26.3)
Inappropriate for patient characteristics	14 (24.6)
Inappropriate for patient's current clinical condition/disease	5 (8.8)
Inappropriate dose	2 (3.5)
Self-medication with prescription drug	3 (5.3)

According to Table 11, the most common cause of p-ADR was inappropriate route of administration (31.6%), followed by history of hypersensitivity (26.3%) and inappropriate drug use for patient characteristics (24.6%). Other causes included mismatch with clinical condition (8.8%), self-medication with prescription drug (5.3%), and inappropriate dose (3.5%).

4. Discussion

This study analyzed 1,437 antibiotic-related adverse drug reaction (ADR) reports submitted to the Ho Chi Minh City DI & ADR Center in 2023, of which 97.6% demonstrated a causal drug–ADR relationship. The findings indicated that 4.1% of ADRs were preventable. Most ADRs were non-serious (66.9%), with the most frequently implicated antibiotic class being other beta-lactams (52.1%), and rash being the most common manifestation (42.4%).

Doctors were the predominant reporters, and female patients accounted for a higher proportion of cases than males (60.9%). ADRs were most frequently reported in individuals aged 18–64 years. These findings are consistent with those reported by Tran Ngan Ha et al. (2023), who observed a female predominance (56.1%) and a similar age distribution (58.2%) [9]. Antibiotic-related ADRs constituted 43.5% of all ADR reports received by the Ho Chi Minh City DI & ADR Center. Among these, other beta-lactams (including cephalosporins, monobactams, and carbapenems) and fluoroquinolones were the leading antibiotic classes, accounting for 52.1% and 13.4% of ADRs, respectively. These results align with Tran Ngan Ha et al. (2023), who reported similar rankings (59.8% and 17.3%) [9]. The high proportion of broad-spectrum beta-lactams in ADR reports reflects local prescribing practices in Vietnam, where cephalosporins, carbapenems, and other broad-spectrum antibiotics are frequently prescribed—particularly in inpatient settings for severe or suspected resistant infections. Vu Quoc Dat et al. also highlighted that "Watch" antibiotics (third-generation cephalosporins, carbapenems, and fluoroquinolones) remain widely used, contributing to selective pressure and the emergence of resistant bacterial strains [16]. Several studies have further reported a rapid rise in Gram-negative resistance,

including carbapenem resistance [17], [18], [19]. Therefore, implementing robust antibiotic stewardship programs is critical to reducing both ADR occurrence and the accelerating threat of antimicrobial resistance.

Of the 1,403 ADR reports with confirmed drug–ADR causality, 57 cases (4.1%) were classified as preventable. This proportion was lower than that reported by Tran Ngan Ha et al. (2023) (8.4%) [9], and markedly lower than the 58.4% reported by Sadia Iftikhar et al. (2019) [20]. This discrepancy may stem from differences in sample size and methodology. The present study applied the WHO-recommended P-method, whereas Tran Ngan Ha et al. used the standardized Olivier scale [9], and Iftikhar et al. employed the Schumock and Thornton criteria [20]. The relatively low proportion of preventable ADRs observed may not reflect the true population-level incidence, as the study relied on a spontaneous reporting system. Such systems depend heavily on the initiative of healthcare professionals, who may underreport ADRs—especially mild or moderate ones—when time-constrained, unaware, or when the event appears clinically trivial [21], [22]. Reporting typically prioritizes severe or unusual ADRs, while mild events or those resembling underlying disease symptoms are less likely to be captured [23]. The completeness of ADR reports also impacts the ability to assess preventability; missing data frequently hinders accurate classification. Among preventable ADRs, inappropriate route of administration was the most common contributing factor (31.6%). This error is entirely avoidable through healthcare staff training, reminders to follow preparation and infusion protocols, and the integration of electronic medical record (EMR) alerts. Enhanced monitoring of infusion practices and standardized hospital guidelines may substantially reduce administration-related p-ADRs. A history of hypersensitivity to the same or related drugs accounted for 26.3%, emphasizing the need for thorough allergy history taking and EMR-based alerts to assist prescribers and pharmacists. Patient-related factors (24.6%)—such as failure to adjust dose or drug selection based on renal/hepatic function, age, or nutritional status—also contributed to p-ADR risk. Mitigation strategies should include EMR-based prescribing alerts, pre-prescription allergy screening protocols, and real-time antibiotic utilization surveillance. Strengthening interprofessional collaboration and implementing regular training programs for healthcare workers are essential for timely identification and prevention of antibiotic-related ADRs.

5. Conclusion

This study demonstrated that antibiotic-related ADRs accounted for a considerable proportion of regional pharmacovigilance reports, with the majority being non-serious yet clinically relevant. The proportion of preventable ADRs was low (4.1%) and predominantly attributable to modifiable factors. Implementation of antibiotic stewardship programs, electronic prescribing alerts, and structured healthcare staff training is essential to mitigate preventable ADRs and improve patient safety.

Abbreviations

ADR – Adverse drug reaction

p-ADR – Preventable adverse drug reaction

DI – Drug information

WHO – World Health Organization

UMC – Uppsala Monitoring Centre

EMR – Electronic medical record

Declarations

Ethics approval and consent to participate

The ethics of this study was approved by the Institutional Review Board of Hong Bang International University under decision No. 160/PCT-HĐĐĐ-SĐH. The research was conducted in accordance with the Declaration of Helsinki. All data were used exclusively for research purposes and were anonymized and kept confidential at the DI & ADR Center. The requirement for individual informed consent was waived due to the retrospective nature of the study and the anonymity of the data.

Clinical trial number

Not applicable

Consent for publication

Not applicable

Availability of data

The datasets generated by or analyzed during the current study are available from the corresponding author, Thi Thu Thuy Nguyen (thuyntt1@hiu.vn), upon reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors’ contribution

QBN and TTTN conceptualized the manuscript. QBN wrote the original draft. QBN, TKUN, THN, and TTTN supervised the process. QBN and TTTN reviewed and edited the manuscript. All authors read and approved the final manuscript.

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