PHARMACOVIGILANCE IN PRACTICE : ASSESSMENT OF REPORTED SERIOUS ADVERSE DRUG EVENTS IN NINEVEH HEALTH INSTITUTIONS

Abdulnaser J. A. Almustafa [1], Mustafa B. Al-Khyat [1,2], Hasan S. Aldewachi[2*]

[1] *Department of Pharmacy, Nineveh Health Directorate, Mosul, Iraq*

[2] *Department of Pharmaceutics and Industrial Pharmacy, College of Pharmacy, Nineveh University, Mosul, Iraq*

**Corresponding author*: hasan.saad@uoninevah.edu.iq

ABSTRACT

Introduction: Serious adverse drug reactions (SADRs) cause significant morbidity and mortality. This study describes SADRs reported to the Nineveh pharmacovigilance system and evaluates patient demographics, implicated drugs, affected organ classes, and clinical outcomes. **Methods:** This cross-sectional study analyzed spontaneous serious individual case safety reports (ICSRs) in the Nineveh VigiFlow® database during 2025. Data were coded using MedDRA and ATC classifications, with causality assessed via the WHO-UMC system. **Results:** Of 1,300 ICSRs, 419 (32.2%) met WHO seriousness criteria, encompassing 897 SADRs. Most reports involved females (70.2%) and adults aged 18–64 (62.3%). Skin/subcutaneous (15.5%) and respiratory/thoracic (13.8%) disorders were the most affected organ classes, with dyspnea (11.0%) being the most frequent presentation. Antineoplastics (45.7%) and systemic anti-infectives (23.9%, predominantly ceftriaxone) were the most implicated drug classes. Most reactions were life-threatening (31.5%) or required hospitalization (27.5%). While 64.7% of patients recovered, three fatalities (0.7%) occurred following parenteral cephalosporin administration. Causality was deemed probable in 49.6% and possible in 40.4% of cases. **Conclusion:** Antineoplastics and systemic antibiotics (especially ceftriaxone) are primarily linked to reported SADRs in Nineveh, frequently presenting as skin and respiratory hypersensitivity reactions. These findings emphasize the need for enhanced pharmacovigilance training, rational antimicrobial prescribing, and targeted medication-error prevention.

Keywords: Pharmacovigilance, adverse drug reactions, reporting systems, causality assessment, Nineveh

INTRODUCTION

Pharmacovigilance, as defined by the World Health Organization (WHO), "involves the science and activities related to the detection, assessment, understanding, and prevention of adverse reactions and other drug-related problems".(wang et al., 2025).

Pharmacovigilance combines reporting systems, registries, and databases that allow safety signals to be identified early, which matters most for patients exposed to a drug in routine care. (Baldo et al., 2018). A central step in pharmacovigilance is the spontaneous reporting of ADRs that occur during treatment. Its effectiveness depends on continuous participation by all healthcare professionals and on patient education so that patients can also recognize and report problems (Chamberlain et al., 2022).

Adverse drug reactions (ADRs) are a source of concern in healthcare as they negatively affect patients. The World Health Organization (WHO) defines an ADR as "a response to a drug which is noxious and unintended, occurring at doses normally used in humans for the prophylaxis, diagnosis, or therapy of a disease, or for the modification of physiological function" (Pirmohamed et al., 2004).

Edwards and Aronson further defined an ADR as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product" (Cosgrave et al., 2025).

Seriousness is a regulatory classification and should not be confused with severity. A reaction is serious (an SADR) if it results in death, is life-threatening, causes disability or persistent incapacity, produces a congenital anomaly, requires hospitalization or prolongs it, or is another medically important event requiring intervention to prevent permanent impairment. (Santoro et al., 2017) Severity, in contrast, describes the intensity of a reaction (for example, mild, moderate, or severe). A severe reaction is not necessarily serious, and a serious reaction is not necessarily severe. In this paper, the terms serious adverse drug reaction (SADR), serious adverse drug event (SADE), and serious adverse event are used interchangeably. SADRs are reported in individual case safety reports (ICSRs), and each SADR case in this study relates to one patient.

Global evidence indicates that healthcare professionals' engagement in ADR and SADR reporting remains suboptimal, leading to underreporting and limited data quality, which weakens the utility of PV systems. Studies show that multifaceted interventions—including educational programs, multidisciplinary team involvement, and streamlined reporting tools—improve healthcare staff participation and the volume and quality of adverse event reports (Khalid et al., 2025; Varallo et al., 2017).

Furthermore, evidence from general hospital settings indicates that the systematic reporting of serious adverse drug events (SADEs) plays a key role in improving patient safety, facilitating effective risk communication, and reinforcing institutional responsibility for medication-related outcomes (Montané et al., 2024)

In Iraq, pharmacovigilance has developed steadily since the Iraqi Pharmacovigilance Center (IPVC) became a full member of the WHO Programme for International Drug Monitoring in 2010. The IPVC coordinates a nationwide network of Regional Pharmacovigilance Divisions within the Directorates of Health, which receive reports from affiliated institutions, mainly hospitals(Ministry of Health, 2024).

Despite these advances, regional data from Iraq remain limited. Existing studies have identified gaps in pharmacovigilance knowledge, attitudes, and practices, as well as inconsistent reporting of serious events (Saleem et al., 2025). Standardized causality methods, such as the WHO-UMC criteria and the Naranjo algorithm, are also underused, which reduces the consistency of causality assessment and the quality of safety signal detection (Théophile et al., 2013)

This study describes SADRs reported to the Nineveh pharmacovigilance system in 2025. It examines reporting sources, patient demographics, implicated drugs and therapeutic classes, affected system organ classes, seriousness criteria, clinical outcomes, and WHO-UMC causality. The contribution is descriptive: it documents what a regional spontaneous reporting system captures, which is a practical first step toward understanding local safety patterns. It does not estimate incidence.

METHODS

This cross-sectional study used spontaneous ICSRs entered in the VigiFlow® database (13) from 1 January to 31 December 2025. Pharmacovigilance officers in hospitals, specialized centres, and primary health care centres collected the SADRs. They entered them into the Iraqi electronic reporting system via VigiFlow–Iraq, which is provided by the Uppsala Monitoring Centre, a WHO collaborating centre for international drug monitoring. Reports were then forwarded to the Nineveh Regional Pharmacovigilance Center for processing.

Inclusion and exclusion criteria. All ICSRs submitted to the Nineveh Regional Pharmacovigilance Center in 2025 were screened (n = 1,300). Reports were included if they met at least one WHO seriousness criterion, giving 419 SADR cases (32.2%). Non-serious reports (n = 881) were excluded and are not described here. Each SADR case corresponds to one patient. The 419 cases contained 897 SADRs, because each reaction term reported in a case was counted separately; the figure of 897 therefore counts reactions, not patients.

Active ingredients were standardized according to the WHO Drug Dictionary and classified using the Anatomical Therapeutic Chemical (ATC) system (Ndai et al., 2024)

Seriousness was assessed with the WHO seriousness criteria: death, disabling or incapacitating, life-threatening, congenital anomaly or birth defect, hospitalization or prolongation of hospitalization, and other medically important condition (Jalloh et al., 2026). We assessed causality using the WHO-UMC system and classified it as certain, probable/likely, possible, unlikely, conditional/unclassified, or unassessable (Karamat et al., 2025; Manjhi et al., 2024).

Statistical analysis

Data were exported from VigiFlow and analyzed descriptively in Microsoft Excel Professional Plus 2021. Two counting units are used. (i) SADR cases (n = 419 ICSRs, one patient each) are used for patient demographics, reporter, reporting organization, seriousness, and outcome. (ii) SADRs (n = 897 reaction terms in the 419 cases) are used for system organ classes, preferred terms, ATC attribution, and WHO-UMC causality. Suspected and concomitant medicine entries (n = 580: 455 suspected, 125 concomitant) are reported separately and are not used as denominators for the drug-class percentages.

Ethical approval

The study followed the standards of the Iraqi Ministry of Health. It was approved by the Research Committee of the National Center for Training and Human Development within the Ministry of Health (approval number 2025224, 1 October 2025).

RESULTS

Characteristics of SADR Cases

During January–December 2025, a total of 1,300 ICSRs were submitted to the Nineveh Regional Pharmacovigilance Center through VigiFlow. Of these, 419 (32.2%) met WHO seriousness criteria and were analyzed as SADR cases. These 419 cases, one patient each, contained 897 SADRs, a mean of 2.1 per case.

The mean patient age was 28 years. Adults aged 18–64 years accounted for 261 reports (62.3%), followed by patients aged 65 years or older (17.9%). Children aged 2–11 years accounted for 11.0% of reports, adolescents aged 12–17 years 4.5%, infants aged 28 days to 23 months 3.1%, and neonates 1.2%. Females made up the majority of reported cases (70.2%; n = 294), and males 29.8% (n = 125).

Pharmacists submitted most reports (268 reports, 64.0%), followed by physicians (119, 28.4%), other health professionals (21, 5.0%), and consumers or other non-health professionals (2, 0.5%). The reporter was not recorded in 9 reports (2.2%). The Oncology Hospital contributed the highest proportion of reports (84, 20.1%), followed by Ibn Al-Atheer Hospital (70, 16.7%), Research Center Hospital (59, 14.1%), and Al-Khansaa Hospital (55, 13.4%).

Hospital (70, 16.7%), Research Center Hospital (59, 14.1%), and Al-Khansaa Hospital (55, 13.1%). The remaining 36.0% of reports came from other health institutions (Table 1).

Table 1: Distribution of SADR cases by age group, sex, reporter and reporting organization (n = 419).

Category	**ICSR NO**	**Percentage**
Age group		
Adult (18-64)	261	62.29
Elderly ≥65y	75	17.90
Child (2y-11y)	46	10.98
Adolescent(12y-17y)	19	4.53
Infant (28d-23m)	13	3.10
neonate (0-27d)	5	1.19
Gender		
Female	294	70.2
Male	125	29.8
Reporter		
Pharmacist	268	63.96
Physician	119	28.40
Other health professional	21	5.01
N/A	9	2.15
Consumer or other non-health professional	2	0.48
Organization	**ICSR NO**	**Percentage**
Oncology Hospital	84	20.05
Ibn Al-Atheer Hospital	70	16.71
Research Center Hospital	59	14.08
Al-Khansaa Hospital	55	13.13
Ibn Sina Hospital	39	9.31
Mosul General Hospital	26	6.21
Ninava Regional Center	23	5.49
Al-Salam Hospital	18	4.30
Al-Shifaa Hospital	9	2.15
Al-Jumhouri Hospital	7	1.67
Al-Hadbaa Specialized Hospital for Blood Diseases and Bone Marrow Transplantation	7	1.67
Specialized Center for Ophthalmology and Eye Surgery	6	1.43
Right Sector	6	1.43
Tel Kaif Sector	4	0.95
Al-Hamdaniya Hospital	4	0.95
Al-Wafaa Specialized Center	2	0.48

Distribution of SADRs by System Organ Class

A total of 897 SADRs were classified by MedDRA System Organ Class (SOC). The most frequently affected SOCs were skin and subcutaneous tissue disorders (139 SADRs, 15.5%), respiratory, thoracic and mediastinal disorders (124, 13.8%), nervous system disorders (102, 11.4%), gastrointestinal disorders (91, 10.1%), and general disorders and administration site conditions (82, 9.1%). The most common preferred term was dyspnea (99 SADRs, 11.0%), followed by pruritus (36, 4.0%), hypotension (27, 3.0%), rash (28, 3.1%), erythema (26, 2.9%), tachycardia (20, 2.2%), vomiting (18, 2.0%), and diarrhea (17, 1.9%) (Table 2).

Table 2: SADRs by system organ class and preferred term (n = 897 SADRs)

System Organ Class (SOC)	SADRs by Preferred Term (PT)	No. of SADRs (%)
Skin and subcutaneous tissue disorders	Pruritus (36), Rash (28), Erythema (26), Hyperhidrosis (8), Palmar-plantar erythrodysesthesia syndrome (6), Urticaria (4), Rash erythematous (4), Dermatitis allergic (3), Alopecia (3), Other SADRs (21)	139 (15.50)
Respiratory, thoracic and mediastinal disorders	Dyspnea (99), Epistaxis (5), Cough (4), Cyanosis (4), Oropharyngeal pain (3), Other SADRs (9)	124 (13.82)
Nervous system disorders	Dizziness (16), Headache (16), Hypoesthesia (14), Seizure (11), Loss of consciousness (6), Paresthesia (6), Dysgeusia (4), Tremor (4), Depressed level of consciousness (3), Somnolence (3), Other SADRs (19)	102 (11.37)
Gastrointestinal disorders	Vomiting (18), Diarrhea (17), Abdominal pain (10), Nausea (8), Abdominal pain upper (6), Haematemesis (5), Constipation (3), Faeces discoloured (3), Other SADRs (21)	91 (10.14)
General disorders and administration site conditions	Pyrexia (11), Swelling face (11), Fatigue (9), Asthenia (7), Chills (7), Peripheral swelling (5), Infusion related reaction (4), Swelling (3), Other SADRs (25)	82 (9.14)
Injury, poisoning and procedural complications	Off label use (12), Labelled drug-drug interaction issue (6), Accidental exposure to product (5), Accidental overdose (4), Product prescribing issue (4), Accidental exposure to product by child (3), Contusion (3), Intentional product misuse to child (3), Labelled drug-food interaction medication error (3), Other SADRs (27)	70 (7.80)
Vascular disorders	Hypotension (27), Flushing (8), Hypertension (6), Pallor (4), Orthostatic hypotension (3), Other SADRs (6)	54 (6.02)
Cardiac disorders	Tachycardia (20), Palpitations (15), Bradycardia (3), Other SADRs (3)	41 (4.57)

System Organ Class (SOC)	SADRs by Preferred Term (PT)	No. of SADRs (%)
Immune system disorders	Angioedema (6), Drug reaction with eosinophilia and systemic symptoms (6), Anaphylactic reaction (4), Drug hypersensitivity (4), Hypersensitivity (4), Other SADRs (8)	32 (3.57)
Investigations	Blood pressure increased (9), Heart rate increased (7), Other SADRs (15)	31 (3.46)
Eye disorders	Ocular hyperaemia (4), Vision blurred (4), Other SADRs (17)	25 (2.79)
Blood and lymphatic system disorders	Thrombocytopenia (9), Anaemia (3), Neutropenia (3), Other SADRs (7)	22 (2.45)
Musculoskeletal and connective tissue disorders	Muscle spasms (3), Other SADRs (14)	17 (1.90)
Psychiatric disorders	Confusional state (2), Other SADRs (12)	14 (1.56)
Metabolism and nutrition disorders	Decreased appetite (4), Other SADRs (8)	12 (1.34)
Renal and urinary disorders	Dysuria (2), Other SADRs (7)	9 (1.00)
Ear and labyrinth disorders	Tinnitus (3), Other SADRs (4)	7 (0.78)
Product issues	Product ineffective (3), Drug ineffective (2), Manufacturing materials issue (1), Product communication issue (1)	7 (0.78)
Reproductive system and breast disorders	Uterine pain (2), penile ulceration (1), Amenorrhea (1), vaginal hemorrhage (1)	5 (0.56)
Infections and infestations	Oral candidiasis (2), Sepsis (1)	3 (0.33)
Neoplasms benign, malignant and unspecified	Essential thrombocythemia (3)	3 (0.33)
Hepatobiliary disorders	Hepatitis (1), jaundice (1)	2 (0.22)
Pregnancy, puerperium and perinatal conditions	Neonatal disorder (1), Infantile apnea (1)	2 (0.22)
Congenital, familial and genetic disorders	Drug-drug pharmacokinetic interaction (1)	1 (0.11)
Endocrine disorders	cushingoid (1)	1 (0.11)
Surgical and medical procedures	Therapy interrupted (1)	1 (0.11)

* “Other SADRs” includes preferred terms reported fewer than three times within each SOC.

Suspected Drugs and Therapeutic Classes

The 580 medicine entries identified in the 419 SADR cases comprised 455 suspected medicines (78.4%) and 125 concomitant medicines (21.6%). Most cases (387, 92.4%) listed one suspected medicine, and 32 (7.6%) listed more than one. Table 3 distributes the 897 SADRs by the ATC class of the suspected medicine in the same report. Because one suspected medicine can cause several SADRs, the percentages are expressed against the 897 SADRs (100%) and not against the 455 suspected medicines. Antineoplastic and immunomodulating agents (ATC group L) accounted for 410 SADRs (45.7%), followed by anti-infectives for systemic use (ATC group J; 214, 23.9%), cardiovascular drugs (48, 5.4%), nervous system drugs (44, 4.9%), musculoskeletal drugs (44, 4.9%), and alimentary tract and metabolism drugs (37, 4.1%). Within group L, docetaxel (25), oxaliplatin (24), carboplatin (24), bevacizumab (19), rituximab (15), and paclitaxel (14) were the most frequent. Among anti-infectives, ceftriaxone was the leading agent (71 SADRs), followed by ciprofloxacin (30), amoxicillin (22), levofloxacin (20), cefepime (13), and vancomycin (12).

Table 3: Distribution of SADRs by ATC anatomical therapeutic class of the suspected medicine (n = 897 SADRs, 100%)

ATC Code	Anatomical Therapeutic Class	SADRs by suspected drug	SADRs, N (%)
L	Antineoplastic & Immunomodulating agents	Docetaxel (25), Oxaliplatin (24), Carboplatin (24), Bevacizumab (19), Paclitaxel (14), Rituximab (15), Fluorouracil (13), Gemcitabine (11), Trastuzumab (10), Irinotecan (10), Doxorubicin (9), Cyclophosphamide (7), Pembrolizumab (7), Capecitabine (6), Ifosfamide (6), Tacrolimus (4), Etoposide (5), Mesna (2), Axitinib (2), others (210)	410(45.71)
J	Anti-infectives for systemic use	Ceftriaxone (71), Ciprofloxacin (30), Amoxicillin (22), Levofloxacin (20), Cefepime (13), Vancomycin (12), Meropenem (11), gentamicin (10), Azithromycin (10), Metronidazole (9), Cefotaxime (6),	214(23.86)
C	Cardiovascular system	Metoprolol (6), Irbesartan/HCTZ (4), Warfarin (4), Digoxin (3), alteplase (2) Lercanidipine	48(5.35)

ATC Code	Anatomical Therapeutic Class	SADRs by suspected drug	SADRs, N (%)
		(1), Atorvastatin (1), others (27)	
N	Nervous system	Valproate (11), Phenytoin (9), Olanzapine, Nefopam (5), Piracetam (3), Escitalopram (2), others (14)	44(4.91)
M	Musculo-skeletal system	Ibuprofen (7), Etoricoxib (4), Piracetam (3), Tizanidine (3), Aceclofenac (2), Naproxen (1) others (24)	44(4.91)
A	Alimentary tract & metabolism	Ondansetron (16), semaglutide (9), Metoclopramide (5) Omeprazole, Aripiprazole (3) Sitagliptin/Metformin (4),	37(4.12)
B	Blood & blood forming organs	Acetylsalicylic acid (11), Iron products (10), Enoxaparin (2), Albumin (5),	28(3.12)
H	Systemic hormonal preparations	Dexamethasone (6), somatropin (2), others (10)	18(2.3)
G	Genito-urinary system & sex hormones	Progesterone (8), Cabergoline (2), Oral contraceptives (7)	17(1.90)
R	Respiratory system	Salbutamol (4), Hydrocortisone (4), others (14)	22(2.45)
V	Various (supplements, Herbal products)	Weight loss/gain supplement, Skin/hair/nail supplements, Omega-3,	15 (1.67)

Seriousness Criteria

Multiple seriousness criteria could apply to a single case. Of the 419 SADR cases, life-threatening events were the most frequent criterion (31.5%), followed by hospitalization or prolonged hospitalization (27.5%), disabling or incapacitating events (21.5%), and other medically important conditions (18.6%). Three cases resulted in death, and one involved a congenital anomaly (Figure 1).

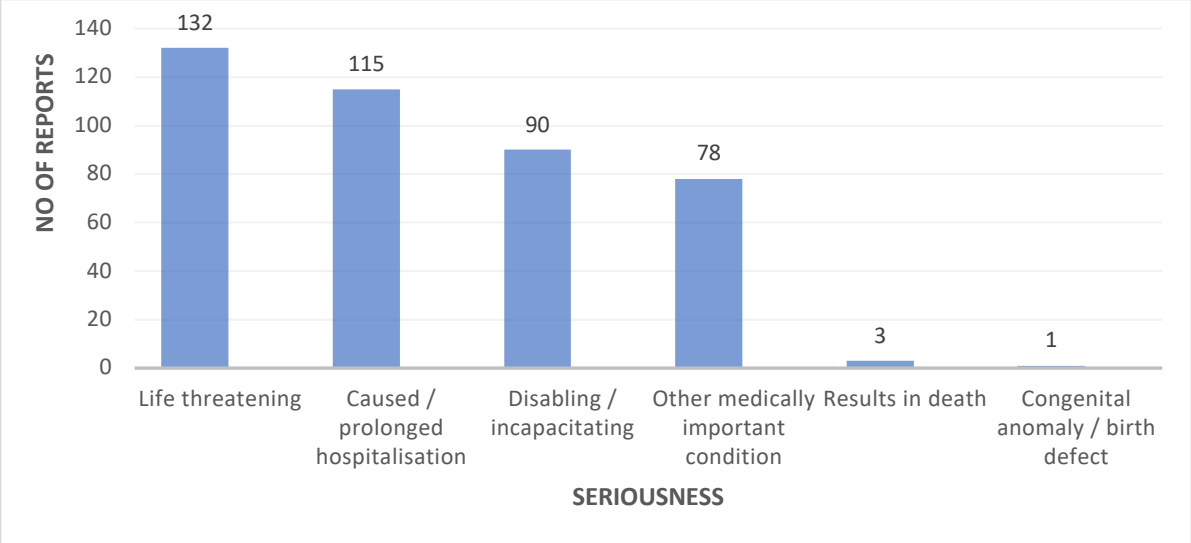


Figure 1: Seriousness criteria of the 419 SADR cases. A case may meet more than one criterion.

Outcomes

Outcomes were recorded at the time of reporting, as documented in each ICSR. Of the 419 SADR cases, 271 (64.7%) recovered or were completely resolved, 68 (16.2%) had ongoing or unresolved reactions, 44 (10.5%) were recovering at the time of reporting, 23 (5.5%) recovered with sequelae, 10 (2.4%) had unknown outcomes, and three (0.7%) were fatal (Figure 2).

The three fatal cases were drawn from the VigiFlow case records for 2025. All three were reported by health professionals in Ninawa, and all involved parenteral cephalosporins. Case 1 was a 40-year-old woman who developed an anaphylaxis-like reaction (hypotension, shortness of breath, and sialorrhea) within one minute of intravenous cefepime and died. She had received ceftriaxone after surgery before the switch to cefepime. Case 2 was a 46-year-old man with a chest infection who received reconstituted cefotaxime by direct intravenous injection without a prior hypersensitivity test. He developed shortness of breath within five minutes and died before reaching the hospital. Case 3 was a 49-year-old man who received two cefepime vials intramuscularly and a third vial intravenously. The report records a wrong route of administration and a product administration error, but the clinical course leading to death is not described. In all three cases,

the suspected drug was judged causally associated with death, with a WHO-UMC causality category of probable/likely.

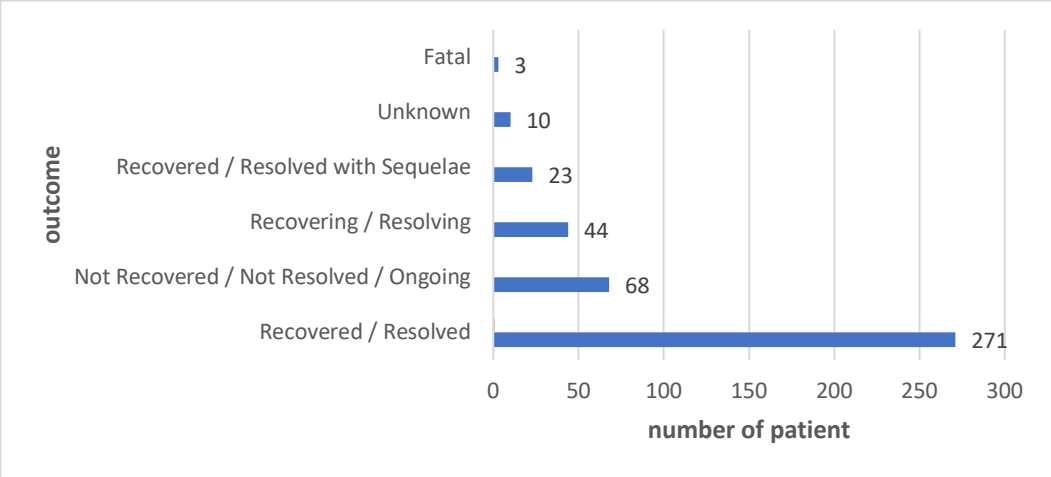


Figure 2: Outcomes of the 419 SADR cases

Causality Assessment

Using the WHO-UMC system, 49.6% of SADRs were classified as probable/likely and 40.4% as possible. Unlikely reactions accounted for 7.0% (63 SADRs). Certain, conditional/unclassified, and unassessable categories accounted for 2.3%, 0.4%, and 0.2% of SADRs, respectively (Figure 3). Because these percentages refer to the 897 SADRs, they do not match the proportion of cases.

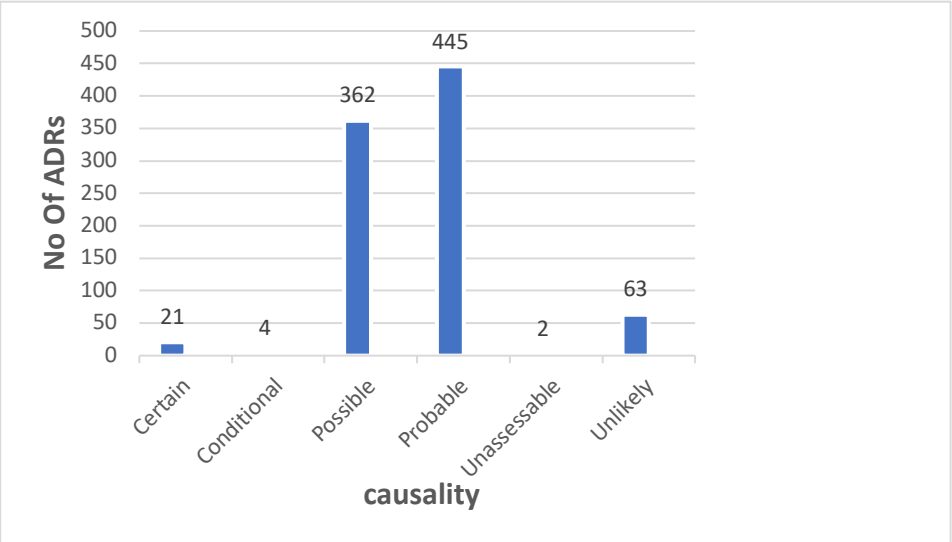


Figure 3: WHO-UMC causality of the 897 SADRs

DISCUSSION

To our knowledge, this is among the first descriptive analyses of SADRs from the Nineveh regional pharmacovigilance system using VigiFlow data. About one-third of submitted ICSRs (32.2%) met seriousness criteria. Because this is a spontaneous reporting dataset, that proportion reflects the reports that reached the system, not the true share of serious reactions among all treated patients.

Adults were the largest affected group (62.3%; Table 1), which is expected given their greater exposure to pharmacotherapy and health services. The 17.9% of reports involving elderly patients are clinically important, since age-related physiological change, multimorbidity and polypharmacy are established risk factors for SADRs.(18) Female patients made up 70.2% of reports. This pattern has been described in many pharmacovigilance studies and may reflect sex-related differences in pharmacokinetics and pharmacodynamics, healthcare use, and reporting behavior. (19, 20) Docetaxel, which is widely used in breast cancer treatment, may partly explain the female predominance, although we did not analyze drug by sex. An earlier Iraqi study of docetaxel reactions reported similar gender patterns (Hameed et al., 2020).

Pharmacists submitted nearly two-thirds of the reports, which suggests an active role in pharmacovigilance in Nineveh. This may reflect better awareness, clear reporting duties, and involvement in regional programs(Hussain et al., 2021; Rasel et al., 2023). Participation by physicians, other health professionals, and patients remains limited, and broader participation is needed to improve report completeness, detect rare events, and strengthen signal detection.

The Oncology Hospital contributed the largest share of reports (20.1%). This is consistent with the risk profile of oncology patients, who often receive medicines with narrow therapeutic indices, complex multidrug regimens and prolonged treatment, and who are closely monitored. Anticancer therapies are commonly associated with SADRs that require hospitalization or intensive intervention (Strumia et al., 2022; Yan et al., 2024). In Iraq, antineoplastic agents have been linked to a large share of deaths in a national drug-safety database, with about 40% of reported deaths attributed to them (Sami et al., 2024a).

Skin and respiratory disorders were the most frequently reported SOCs. Pruritus, rash, erythema, urticaria, dyspnea, and other hypersensitivity features suggest that allergic and infusion-related reactions may contribute substantially to SADRs in this setting. However, spontaneous reports cannot confirm mechanisms. Similar patterns, in which skin and respiratory symptoms often appear early in drug hypersensitivity reactions, have been described elsewhere (Reid et al., 2025; Seghers et al., 2023). Severe cutaneous reactions such as Stevens–Johnson syndrome and toxic epidermal necrolysis were not among the frequently reported terms, but their occurrence in other settings shows the potential severity of immune-mediated drug toxicity (Sami et al., 2024b; Wu et al., 2025)

Antineoplastic and immunomodulating agents were the most frequently implicated therapeutic class. This is plausible given the narrow therapeutic indices and the cytotoxic and immunomodulatory mechanisms of these drugs. Cytotoxic agents such as docetaxel, carboplatin, oxaliplatin, paclitaxel, fluorouracil, and doxorubicin are known to cause myelosuppression, gastrointestinal toxicity, hypersensitivity reactions, and organ-specific toxicity (Sharma et al., 2018). Immune checkpoint inhibitors such as pembrolizumab can cause immune-mediated events affecting several organ systems, including blood, lymphatic, and thyroid disorders (Postow et al., 2018).

Anti-infective agents were the second most frequently implicated therapeutic category. Ceftriaxone, a third-generation cephalosporin, was the most frequently implicated anti-infective. Its high count likely reflects its wide hospital use as a first-line agent, and possibly outpatient use and infusion-related administration problems. These explanations are hypotheses, since the present data contain no exposure (denominator) information to test them. Cephalosporins are β-lactam antibiotics and a recognized cause of immediate and delayed hypersensitivity. Current understanding is that the β-lactam ring binds covalently to host proteins, and that immunogenicity depends on the R1 side chain (Butranova et al., 2024). Ciprofloxacin, cefepime, and vancomycin are also recognized causes of hypersensitivity, infusion reactions, and gastrointestinal disturbance. The frequent dyspnea, hypotension, tachycardia, and flushing observed are consistent with acute allergic, anaphylactic, or infusion-associated mechanisms described in the literature. (Antolín-Amérigo et al., 2024).

Most SADRs were classified as probable/likely or possible under WHO-UMC rules. This suggests a reasonable temporal and pharmacological link in many cases, but it also reflects the limits of spontaneous reports, which often lack full clinical detail and confirmatory tests. The low number of certain cases is therefore expected in routine practice.

Serious reactions and hospitalization-related events were the most common outcomes. These findings show the clinical burden of SADRs and the value of early recognition and intervention. Although deaths were rare (three cases), each death may represent a potentially preventable event and merits a detailed review of the signal and its risk factors (Puliyel & Naik, 2018).

The reports of medication errors and product-use problems are noteworthy. These included off-label use, drug–drug and drug–food interactions, accidental exposure and dosing or administration problems, which together form the category “Injury, poisoning and procedural complications” (70 SADRs, 7.8%). These findings point to opportunities to improve medication-safety systems and clinical governance. The WHO recognizes medication errors as a significant source of preventable harm (Alghamdi et al., 2019). Integrating pharmacovigilance with medication-safety activities can help detect preventable errors and support corrective action.

The three deaths deserve particular attention. All involved parenteral cephalosporin administration, and each case recorded a preventable administration factor: direct intravenous injection (Case 1), direct intravenous injection without a hypersensitivity test (Case 2), and the wrong route of administration (Case 3). Cephalosporin hypersensitivity can cause fatal anaphylaxis, but these reports also suggest that rapid intravenous administration and route errors may have contributed to the events. This supports strengthening training on injection technique, confirming the route before administration, and checking whether local allergy or test-dose procedures are applied before parenteral cephalosporins. Case 3 involved the wrong route of administration, a medication error, although the suspected drug was judged probably causal. Its inclusion among SADRs shows that the reporting system captures medication errors as well as adverse reactions, which affects how the findings should be interpreted.

These findings show that spontaneous reporting can detect SADRs across healthcare settings, including rare, unexpected, and clinically significant safety issues that may not appear in pre-marketing trials (Jiao et al., 2024).

Limitations

This study has several limitations. First, spontaneous reporting captures only a fraction of SADRs, and underreporting varies by reporter, institution, and drug, so these data cannot provide the incidence or prevalence of SADRs. Second, the analysis has no exposure denominator, so risk per treated patient cannot be estimated, and drugs cannot be compared on safety. Third, reporting bias is likely: the Oncology Hospital and pharmacists contributed large shares, and drugs that are more closely monitored or more often reported may appear more frequently. Fourth, documentation was incomplete for some reports: the outcome was unknown in 10, and the reporter was missing in nine, and other fields may also be incomplete, which can affect coding and causality assessment. Fifth, causality was judged from the information in each report, without independent review of medical records or confirmatory tests. Sixth, MedDRA coding requires judgment, and the “other SADRs” categories group many terms together. Seventh, the study covers one region and one year and cannot be generalized to Iraq as a whole. Finally, the analysis is descriptive, with no inferential statistics or comparison group, so associations between particular drugs and the observed patterns should be interpreted cautiously.

CONCLUSION

Serious ADRs remain an important patient-safety concern in Nineveh health institutions. In this descriptive analysis, antineoplastic agents and anti-infectives accounted for most reports, and hypersensitivity-type skin and respiratory reactions were the most common clinical presentation. These findings support stronger pharmacovigilance training, better reporting practices, and medication-safety measures to reduce preventable harm. Confirming these patterns will require systematic follow-up, denominator data, and multicenter studies.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data are available upon request from the corresponding author with justification.

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