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A Retrospective Audit on Evaluation of Acute Adverse Drug Reactions at Hameed Latif Hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a major cause of patient morbidity and can lead to prolonged hospitalization, increased healthcare costs, and in some cases, life-threatening complications. **Objective:** To evaluate the incidence, patterns, severity, and documentation quality of acute adverse drug reactions reported at Hameed Latif Hospital, and to assess adherence to WHO and institutional reporting standards. **Methods:** This retrospective audit was conducted at Hameed Latif Hospital from Jan 2023 to Dec 2024. A total of 219 ADR forms were reviewed, all of which reported reactions occurring within 24–72 hours of drug administration. Data were extracted on patient demographics, suspected drugs, type and severity of reactions, management strategies, outcomes, and quality of documentation. **Results:** The incidence rate of acute ADRs was 1.90% among 11,510 hospital admissions. Females accounted for 64% of cases, and the highest frequency was observed in patients aged over 50 years. Comorbidities such as diabetes (35%) and hypertension (36%) were common among affected individuals. Antibiotics, analgesics, and iron infusions were the most frequently implicated drug classes. Most ADRs were of mild to moderate severity, but 19% required hospitalization and 3% needed ICU care. Drug discontinuation was the most common management strategy (81%), and 91% of patients achieved complete recovery. However, only 62% of forms included a formal causality assessment, and 28% were submitted beyond the recommended reporting timeframe. **Conclusion:** It is concluded that acute ADRs are prevalent and clinically significant, particularly among patients with comorbid conditions and those exposed to high-risk drug classes. While most cases were managed successfully, deficiencies in documentation, delayed reporting, and inconsistent use of assessment tools highlight the need for improved pharmacovigilance practices.

INTRODUCTION

Adverse drug reactions (ADRs) impose a significant threat and are a cause of increased morbidity and mortality in healthcare settings. ADRs occur after a short time of administering a drug, resulting in serious consequences, including organ failure, various other life-threatening conditions, and are largely preventable [1]. Effective reduction of patient risks and an increase in the overall outcomes can be achieved by identifying issues in early stages, reporting and documenting accordingly, and treating them respectively. The Adverse drug reactions (ADRs) have been described as any unintended, undesirable responses to a drug in a dosage normal to prophylaxis, diagnosis, or treatment of a disease in human beings [2]. Of these, the acute itself, acute ADRs, which arise very soon after drug administration, are especially dangerous because of their sudden and unpredictable occurrence and the possibility of leading the patient to severe clinical intensification. ADRs emerge as a source of patient safety as well as due to the additional emergency visits, longer hospital stays, subsequent tests, and even irreversible complications or death in hospital environments. ADRs constitute a big burden on the world [3]. The World Health Organization mentions that ADRs rank among the leading causes of morbidity and mortality in the top 10 of high-income countries, and the same flow continues in the low- and middle-income countries, where pharmacovigilance system development is not adequate [4]. However, these numbers indicate the underreporting of ADRs even despite these barriers, which include the ignorance of health care professionals, a low level of training on how to report ADRs, fear of legal penalties, and the lack of appropriate feedback. The absence of systematic hospital-based mechanisms to capture, analyze, and intervene on ADR data is easily cited as one of the foremost impediments towards prevention of ADRs [5]. ADR reporting in most institutions is either poor or passive, as there is compliance with set standards like the guidelines given by WHO or by national pharmacovigilance programs, which is highly variable [6].

Such monitoring and reporting of ADR thus need a strong culture to present quality improvement in healthcare systems. Evaluating acute ADRs not only helps in identifying frequently implicated drugs but also assists in recognizing patterns based on age groups, gender, underlying comorbidities, and routes of administration [7]. Such data can guide clinicians in making safer prescribing decisions and help pharmacologists in updating institutional formularies [8]. Moreover, assessing the severity of ADRs is critical in prioritizing interventions. The use of standardized severity scales, such as those from the Merck Manual, and causality assessment tools, such as the Naranjo Algorithm, allows for consistent classification and enhances the reliability of the evaluation process [9]. Severity assessments also help in resource allocation, such as deciding which ADRs warrant ICU admission or immediate discontinuation of therapy. Understanding the outcome of ADR management, whether recovery is complete, partial, or results in further complications, can serve as a quality indicator for hospital care [10].

Objectives

To evaluate the incidence, patterns, severity, and documentation quality of acute adverse drug reactions reported at Hameed Latif Hospital, and to assess adherence to WHO and institutional reporting standards.

METHODOLOGY

This retrospective audit was conducted at Hameed Latif Hospital, a tertiary care facility, to evaluate the occurrence, characteristics, and documentation quality of acute adverse drug reactions (ADRs) over a defined study period from Jan 2023 to Dec 2024. The study included all ADR forms submitted to the hospital's pharmacology department during the specified timeframe and aimed to assess the frequency, severity, patterns, and management of acute ADRs, as well as the extent of adherence to institutional reporting standards.

Inclusion and Exclusion Criteria

ADR reports were eligible for inclusion if they documented adverse reactions that occurred within 24 to 72 hours following the administration of a medication, by the standard definition of acute ADRs. Reports were excluded if they were incomplete (i.e., missing more than 50% of essential data fields) or if the reported reactions were related to chronic, long-term drug use or side effects outside the acute window.

Data Collection Procedure

All ADR forms received during the audit period were collected from the pharmacy department. Each report was reviewed in detail, and data were extracted using a structured tool designed to capture relevant clinical, pharmacological, and administrative variables. The extracted data included patient demographics (age, gender, and admission status), drug-related information (name and class of the suspected drug, dosage, and route of administration), and reaction characteristics (type of reaction, time of onset post-administration, and severity). Management strategies were also noted, including whether the drug was discontinued, any symptomatic treatment or antidotes used, and whether the reaction required hospitalization or intensive care. Patient outcomes were categorized as complete recovery, partial recovery, no improvement, or mortality. In addition, each ADR form was evaluated for documentation quality, including the completeness and timeliness of reporting, in alignment with WHO and institutional guidelines.

Severity and Causality Assessment

The severity of each ADR was classified using the Merck Manual's guidelines. Mild reactions were defined as those that did not require any change in therapy and did not prolong hospitalization. Moderate reactions required some modification of therapy, such as dose adjustment, additional symptomatic treatment, or prolonged stay. Severe reactions were defined as life-threatening events requiring urgent discontinuation of the suspected drug, intensive therapeutic intervention, or admission to a higher level of care such as an intensive care unit. Causality was assessed using the Naranjo Adverse Drug Reaction Probability Scale.

Data Analysis

The collected data were entered and analyzed using SPSS version 26. Descriptive statistics such as frequencies, percentages, means, and standard deviations were used to summarize categorical and continuous variables. The incidence rate of ADRs was calculated by dividing the number of reported ADRs by the total number of hospital admissions during the study period. Associations between categorical variables, such as gender or comorbidities, and the severity of ADRs, were assessed using chi-square tests, with a p-value <0.05 considered statistically significant.

RESULTS

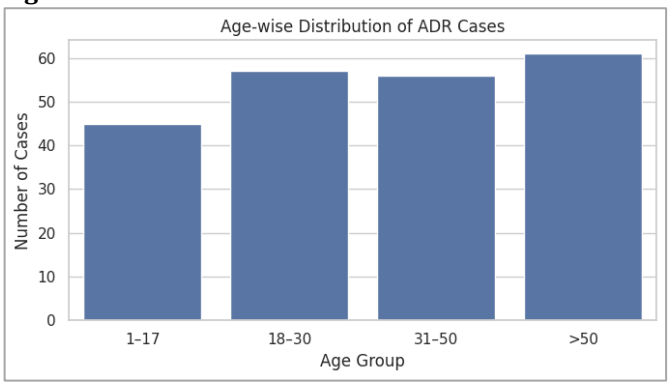
A total of 219 acute adverse drug reaction (ADR) cases were identified during the audit period, out of 11,510 hospital admissions, yielding an overall incidence rate of 1.90%. The demographic distribution of patients with acute adverse drug reactions (ADRs) shows a higher proportion of females (64%) compared to males (36%). Age-wise, the largest group of patients was aged >50 years (28%), followed by patients aged 18–30 years and 31–50 years, each comprising 26% of the total. The least represented age group was 1–17 years, accounting for 20%. In terms of comorbidities, the majority of patients had hypertension (36%) and diabetes mellitus (35%).

Table 1

Demographics of Patients with Acute ADRs (n = 219)

Variable	Number (n)	Percentage (%)
Gender		
Male	79	36%
Female	140	64%
Age Group (years)		
1–17	45	20%
18–30	57	26%
31–50	56	26%
>50	61	28%
Comorbidity		
Diabetes Mellitus	76	35%
Hypertension	78	36%
Renal Impairment	11	5%
Hepatic Dysfunction	13	6%

Figure 1



Adverse drug reactions were most frequently reported in patients over 50 years of age, followed closely by the 18–30 and 31–50 age groups, while the 1–17 age group had the fewest reported cases.

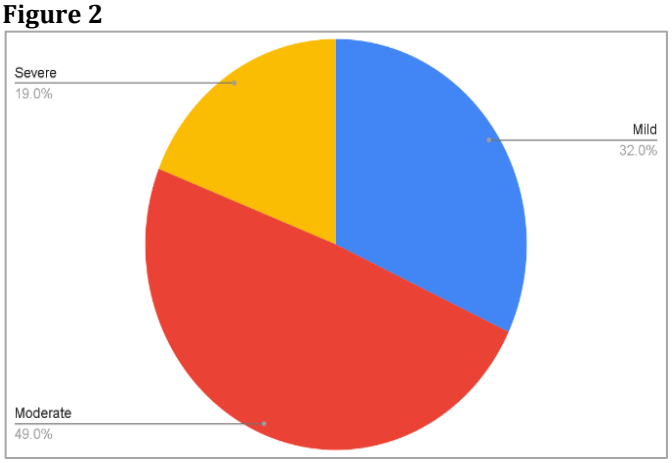
The incidence rate of acute adverse drug reactions (ADRs) in this hospital was 1.90%, based on a total of 11,510 hospital admissions and 219 reported ADR cases. This indicates that nearly 2% of patients admitted to the hospital experienced an acute ADR during their stay.

Table 2

ADR Incidence Rate

ADR Incidence Rate	Value
Total hospital admissions	11,510
Total ADR cases	219
Incidence Rate	1.90%

Figure 2



The severity of adverse drug reaction (ADR) cases in this study was classified according to the Merck Manual's guidelines. Reactions were categorized as mild, moderate, or severe based on clinical presentation and the level of intervention required. Mild reactions were those that did not necessitate any antidote or change in therapy and did not result in prolonged hospitalization. Moderate reactions required a change in treatment, such as dosage adjustment or the addition of new medications, and were sometimes associated with extended hospital stays or the need for specific therapeutic interventions. Severe reactions were defined as potentially life-threatening events requiring immediate discontinuation of the suspected drug and intensive medical management, including possible ICU admission.

The majority of patients with acute adverse drug reactions (ADRs) were managed by discontinuation of the suspected drug, accounting for 81% of cases. Symptomatic treatment was provided to 74% of patients, while 19% required dose adjustment and 19% were hospitalized. ICU admission was necessary for only 3% of patients, indicating that most cases were manageable without the need for intensive care.

Table 3

Management Strategies for ADRs (n = 219)

Management Strategy	Number of Cases	Percentage (%)
Discontinuation of Suspected Drug	195	81%
Dose Adjustment	41	19%
Symptomatic Treatment	162	74%
Hospitalization	42	19%
ICU Admission	7	3%

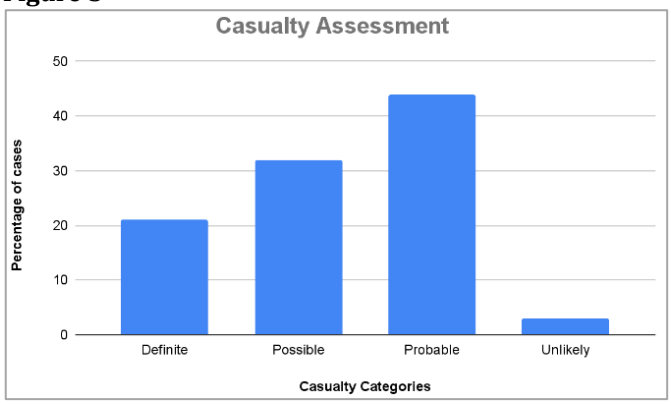
The majority of patients with acute adverse drug reactions (ADRs) experienced complete recovery, accounting for 91% of cases. Partial recovery was observed in 8% of patients, while only 1% showed no improvement.

Table 4

Patient Outcomes Post-ADR Management (n = 219)

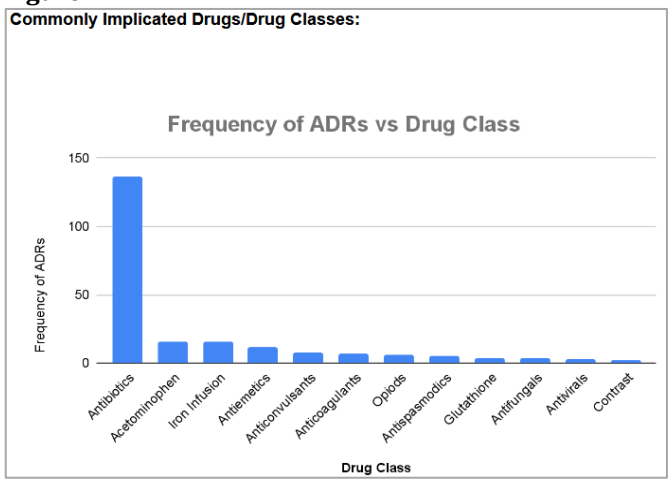
Outcome	Number of Cases	Percentage (%)
Complete Recovery	199	91%
Partial Recovery	18	8%
No Improvement	2	1%
Mortality	0	0%

Figure 3



The majority of adverse drug reactions in this study were assessed as probable at approximately 45 percent, followed by possible at 32 percent, definite at 21 percent, and a small proportion classified as unlikely, accounting for less than 5 percent.

Figure 4



Antibiotics were the most commonly implicated drug class in adverse drug reactions, followed by acetaminophen, iron infusions, antiemetics, and anticonvulsants, while other classes such as anticoagulants, opioids, and contrast agents contributed minimally.

Compliance with Standards

Compliance with institutional and international pharmacovigilance standards was assessed by evaluating the completeness and timeliness of adverse drug reaction (ADR) reporting forms submitted during the audit period. All the ADRs were supposed to be reported in the standard reporting format suggested by the pharmacology department of the hospital, according to the World Health Organization (WHO) guideline on spontaneous ADR reporting. Among the 219 ADR forms reviewed, 184 forms (84%) could be assessed as being complete with the necessary fields, including patient demographic data, specifications of the drug, description of the reaction, management plans, and the outcome of the patient. Nonetheless, 35 forms were found as incomplete; some bits were either missing or unclear in at least one of the essential fields, namely, the recording of the day when onset occurred and the process used to assess causality. On the part of timeliness, 158 ADR reports (72.00%) were reported within 24 hours after the reaction was identified, and 61 reports (28.00%) took longer than the recommended time [11]. The time of delayed reporting was found to be more common in those patients where the initial clinical manifestation of ADR was non-specific and those where the reporting roles and responsibilities are not well defined among staff. Fewer than half (69 percent) of the ADR forms states a formal, numerical grading of severity based on the restatement of the reporting clinician or pharmacist, and fewer than half (62 percent) carry some kind of structured causality evaluation (e.g. Naranjo Scale).

Reporting adherence to WHO guidelines

Reporting of adverse drug reactions (ADRs) was evaluated by the criteria outlined by the World Health Organization (WHO). These criteria underline early detection, well-documented cases, organized causality evaluation, and active participation of prescribers and pharmacists in the pharmacovigilance process. Out of 219 ADR reports considered, 84 percent of the reports fulfilled the minimum reporting requirements of WHO, which entails reporting the name of the patient involved, the suspected drug, the nature of the adverse effect, and the source of the report. Yet, just 62 percent of the reports recorded a formal causality evaluation with a validated instrument, i.e., the Naranjo scale, which is recommended by both WHO and FDA. Moreover, a well-structured severity grade was present in only 69 percent of the forms, which is vital in measuring clinical significance and calculating the need to report to the regulator. Time reporting was also adherent to the FDA expectations in parts, as they expect reporting within 24 hours in case of moderate to severe reactions [12].

Areas of Improvement

The audit revealed several critical areas in need of improvement to enhance the quality, reliability, and utility of adverse drug reaction (ADR) reporting within the hospital. First, although a majority of ADR forms were completed, a substantial number lacked essential details such as the time of onset, specific drug dosage, or complete causality and severity assessments. This inconsistency in documentation undermines the accuracy of pharmacovigilance data and limits the ability to conduct meaningful trend analysis or establish causal relationships. Second, there was notable variation in the timeliness of ADR reporting. While over two-thirds of reports were submitted within the recommended 24-hour window, nearly one-third were delayed, which could negatively impact patient outcomes, especially in the context of severe or rapidly progressing reactions. Delayed reporting also affects the hospital's ability to implement timely risk mitigation strategies.

DISCUSSION

This audit evaluated the frequency, characteristics, and documentation quality of acute adverse drug reactions (ADRs) at a tertiary care hospital, providing important insights into current pharmacovigilance practices. With an incidence rate of 1.90% among 11,510 admissions, the findings are consistent with previously reported rates in similar hospital-based studies, which estimate ADRs to account for 1–3% of inpatient events. This strengthens the existing burden of drug-related adverse events during routine medical practice and the necessity of organized monitoring programs. The demographic characteristics of ADRs showed a prevalent number of females (64 percent), with the expectation that females might be more prone to ADRs because of the physiological variation in response to drugs as a result of poor pharmacokinetics and metabolism, hormonal influences, and immune reaction [13]. The chronic illnesses have been reported to be capable of modifying the metabolism and excretion of drugs, and thus, they are likely to make ADRs prone, considering polypharmacy and drug-illness interaction. Less frequent but clinically important, renal and hepatic impairment causally relate to drug clearance and accumulation and increase the risk of a toxic effect even with a normal dose [14]. The most common drugs in this category were antibiotics, and then acetaminophen, iron infusions, and antiemetics. The trend is in line with reported cases of pharmacovigilance around the world, which pegs antibiotics as the top cause of hypersensitivity reactions, ranging from mild rashes and severe anaphylaxis. Their prevalence in the reported cases of ADRs can also be attributed to their heavier use and frequent prescriptions, especially in the acute care sector. The severity analysis indicated that the ADRs, either mild or moderate, prevailed, but a significant percentage of them resulted in hospitalization (19%) or required ICU status (3%); this fact highlights the clinical importance of these incidences [15]. Serious ADRs were quite rare, but their risks are high, and they require immediate response, which is why it is necessary to mitigate their consequences by recognizing them early enough and grading them consistently. The consistency of the classification was achieved through the application of the Merck Manual criteria but the lack of recording the severity of the situation in 31 percent of cases indicates the lack of

conformance with the institutional procedures. The assessment of the causality was measured by the Naranjo scale in 62 percent of the cases, which is a moderate adherence to the best practices. It is a vital tool in recognizing real ADRs and choosing a better decision among other clinical events.

RECOMMENDATIONS

Based on the findings of this audit, it is recommended that the hospital strengthen its pharmacovigilance practices through a multifaceted approach. Regular training sessions should be conducted to improve awareness and competence in ADR identification, severity grading, and causality assessment using standardized tools like the Naranjo Scale. Transitioning to a digital ADR reporting system is essential to ensure timely submission, reduce data loss, and improve completeness of documentation. Clinical staff should be encouraged to complete all critical fields on ADR forms, especially those related to drug details, time of onset, and clinical outcome. Establishing a multidisciplinary ADR review committee can enhance oversight, facilitate root cause analysis, and support evidence-based corrective actions. Real-time feedback mechanisms and a mandatory 24-hour reporting window, especially for moderate to severe ADRs, should be implemented to improve responsiveness.

CONCLUSION

It is concluded that acute adverse drug reactions (ADRs) continue to pose a significant clinical challenge, with an incidence rate of 1.90% among hospital admissions at the study site. The majority of ADRs were associated with commonly prescribed medications, particularly antibiotics, and were more frequently observed in patients with underlying comorbidities such as diabetes and hypertension. Although most reactions were mild to moderate and resulted in full recovery, a considerable number required hospitalization or additional medical intervention, reflecting the potential severity of these events.

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