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Assessment of severity and preventability of adverse drug reactions to chemotherapy in eastern Nepal

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Abstract

Introduction: Chemotherapy is associated with a high risk of adverse drug reactions (ADRs), which can affect treatment outcomes and patient quality of life. Limited data are available from Nepal on the severity and preventability of chemotherapy-induced ADRs. This study aimed to assess the types, severity, and preventability of ADRs in cancer patients receiving chemotherapy in a tertiary care hospital.

Method: A hospital-based cross-sectional study was conducted among cancer patients receiving chemotherapy in the day care unit of the Oncology Department, Birat Medical College Teaching Hospital, over 6 months period from May 19 to Nov 20, 2024. The ADRs identification, severity, and preventability were assessed. Data were analysed in SPSS-26 using descriptive statistics, Chi-square/Fisher's exact test, and logistic regression to identify predictors of preventable ADRs.

Result: All 195 patients experienced some form of ADRs. Moderate ADRs were 98(50.3%), mild 57(29.2%) and severe 40(20.5%). Preventable ADRs were 52(26.7%), probably preventable 69(35.4%) and non-preventable 74(37.9%). Association between chemotherapy regimen and ADR was not significant (p=0.073). We did not identify independent predictors of preventable ADRs.

Conclusion: Moderate ADRs were most common among cancer patients on chemotherapy. The female gender had significant associations with severity. None of the independent variables (gender, age, type of cancer, comorbidity) was significantly associated with ADR preventability. About two-thirds of ADRs were preventable, highlighting a critical need to enhance pharmacovigilance and monitoring systems.

How to cite

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Introduction

Cancer is an alarming disease today. Numerous treatment options, including immunotherapy, surgery, radiation therapy, and chemotherapy, exist. Chemotherapy is a commonly utilized therapy and has adverse drug responses (ADRs), including some severe cases.[1]

The ADRs are unpleasant and unexpected reactions to a medication, according to the World Health Organization (WHO). One of the leading causes of death worldwide is ADRs.[2,3] Researches show a high frequency of chemotherapy-related ADRs (often 30–90%) with nausea/vomiting, hair loss, myelosuppression (neutropenia, anaemia), mucositis, and injection-site or infusion responses.[4]

Combination chemotherapy has more exaggerated ADRs than a single agent.[5,6] The ADRs are underappreciated due to underreporting and require careful estimation.[7,8] These days, the preventability evaluation tool's modified version is frequently employed. It determines if ADR can be avoided, which is divided into three sections: definitely preventable, probably preventable, and non-preventable.[9,10] The ADRs are divided into seven severity categories in a study.[11] Severity is more rationally categorized as mild, moderate, severe, and deadly.[12]

This study investigates ADRs linked to chemotherapy, emphasizing severity assessment among cancer patients. It addresses a gap in research on the preventability and severity of ADRs in Nepal, contributing to pharmacovigilance and creating a related database. Findings aim to improve oncology practices, including integration with DOTS clinics for ADR monitoring.

Method

A cross-sectional observational study was conducted in the day care unit of the Oncology Department, Birat Medical College Teaching Hospital, over a period of 6 months from 19 May to 20 Nov 2024. Ethical approval was obtained from the institutional review committee (IRC Ref: IRC-PA-393/2024). Patients above 18 years of age who were diagnosed with cancer and receiving chemotherapy were included. Those who had undergone radiotherapy or surgery in addition to chemotherapy and developed ADRs were also eligible.

Patients with end-stage cancer, those receiving only radiotherapy or surgery, and pregnant women were excluded. Repeated visits of the same patient were not considered for data collection. Convenient sampling was used. Based on a reference proportion of 54.9% ADR causality, a confidence interval of 95%, and a margin of error 7%, the sample size was estimated to be 195 patients.[13] Each cancer case developing ADRs under chemotherapy served as a sample unit.

Data were collected through a standard questionnaire and review of patient records. Socio-demographic details, type of cancer, comorbid conditions, anti-cancer drugs, and observed ADRs were documented. Adverse drug reaction severity was assessed using the Hartwig and Siegel Scale, categorizing reactions into mild (levels 1–2), moderate (levels 3–4), and severe (levels 5–7). Preventability was assessed using the Modified Schumock and Thornton Preventability Assessment Scale, classifying ADRs as definitely preventable, probably preventable, or non-preventable. Written informed consent was obtained prior to enrolment, and interviews were conducted in the local language.

Data were coded and analysed using SPSS version 26. Normality of data dispersion (distribution) was checked. Descriptive statistics were applied to summarize socio-demographic and clinical variables. Frequencies and percentages were calculated for ADR types, severity, and preventability. Associations between independent variables (age, sex, occupation, cancer type, comorbidities) and dependent variables (ADRs, severity, and preventability) were examined using chi-square or Fisher's exact test where appropriate. Logistic regression was performed to identify independent predictors of preventable ADRs. A p-value ≤0.05 was considered statistically significant.

Result

A total of 195 cancer patients who developed chemotherapy-induced ADRs were included in the study. Females constituted a higher proportion 115(59.0%) compared to males 80(41.0%). The mean age of participants was 54.98±14.16 years, with the majority belonging to the 50–59 years (60, 30.8%) and 60–69 years (46, 23.6%) age groups.

The most common type of cancer was lung cancer 36(18.5%), followed by breast cancer 32(16.4%), ovarian cancer 21(10.8%), and colon cancer 21(10.8%). Other malignancies, such as gallbladder cancer, acute lymphoblastic leukaemia, nasopharyngeal cancer, and lymphomas, were also represented in smaller proportions. One-third of patients 65(33.3%) had no comorbidities, whereas hypertension 36(18.5%) and diabetes 33(16.9%) were the most prevalent associated conditions, Table 1.

A wide range of chemotherapeutic regimens was prescribed, with oxaliplatin + 5-fluorouracil + leucovorin 29(14.9%) being the most frequently used combination, followed by cyclophosphamide + doxorubicin 24(12.3%) and cisplatin + gemcitabine 23(11.8%). Paclitaxel 16(8.2%), cyclophosphamide 13(6.7%), and doxorubicin 12(6.2%) were the most common single-agent regimens, while other miscellaneous regimens accounted for 20%. The pattern of ADRs observed varied considerably. Vomiting 19(9.7%), stomach pain 17(8.7%), anorexia and alopecia 16(8.2%), diarrhoea 15(7.7%), neuropathy 14(7.2%), and fatigue 14(7.2%) were the most frequently reported. Less common ADRs included constipation, headache, shortness of breath, and infections, Table 2.

Adverse drug reactions (ADRs) were frequently seen across several chemotherapy regimens; alopecia was most frequently related to doxorubicin 3(25%) and paclitaxel 3(18.8%). Neuropathy arose most often 4(22.2%) with oxaliplatin and doxorubicin. Anorexia was most strongly correlated with carboplatin and paclitaxel 4(30.8%); vomiting was most often connected to cyclophosphamide combined with doxorubicin 4(16.7%). Headaches 2(15.4%) and vomiting 2(15.4%) were among the other frequently seen ADRs in this group. Cisplatin administered with gemcitabine 5(21.7%) most often caused diarrhoea, again followed by neuropathy with doxorubicin and oxaliplatin 4(22.2%). Other therapies showed varied ADRs; nausea 4(10.3%), vomiting 5(12.8%), and fatigue 7(17.9%) were among most often reported. For changes in treatment schedules, statistical significance (p=0.073) was, however, not attained.

Regarding severity, most undesired ADRs were moderate 98(50.3%), then mild 57(29.2%), and severe 40(20.5%). Common ADRs include anorexia, vomiting, diarrhoea, and alopecia. Severity had no strong link with ADR occurrence. About preventability, 74(37.9%) of ADRs were non-preventable; and 69(35.4%) were probably preventable, and 52(26.7%) were clearly preventable. A significant association was found between gender and ADR severity (p=0.004), with female patients experiencing a higher proportion of moderate ADRs. While a trend was observed where older patients were more likely to experience severe ADRs, the association with age was not statistically significant (p=0.054), Table 4.

Logistic regression was performed to assess independent predictors of preventable ADRs. The overall model was not statistically significant, $\chi^2(5)=7.386$, p=0.193, with Cox & Snell $R^2=0.037$ and Nagelkerke $R^2=0.051$, explaining about 3.7–5.1% of the variance in preventability. The Hosmer-Lemeshow goodness-of-fit test indicated adequate model fit ($\chi^2=9.305$, p=0.317). None of the independent variables (gender, age, type of cancer, comorbidity) was significantly associated with ADR preventability at $p<0.05$. However, comorbidity showed a borderline effect (OR=0.535, 95% CI: 0.278–1.028, p=0.061), suggesting that patients with comorbidities may have lower odds of experiencing preventable ADRs compared to those without comorbidities. Lack of significant predictors reflects the multifactorial nature of ADR preventability, which depends on a complex interplay of patient-specific, prescriber, and systemic healthcare factors not fully captured in this model.

Table 1. Clinicodemographic of cancer patients assessed for adverse drug reactions due to chemotherapy, n=195

Variables	n	%
Gender		
Male	80	41.0
Female	115	59.0
Age group (y), mean 54.98±14.16		
18-30	10	5.1
30-39	13	6.7
40-49	35	17.9
50-59	60	30.8
60-69	46	23.6
70-79	26	13.3
≥80	5	2.6
Type of cancer		
Lungs	36	18.5
Breast	32	16.4
Ovary	21	10.8
Nasopharyngeal	14	7.2
Pancreatic	3	1.5
Urinary bladder	7	3.6
Colon	21	10.8
Rectum	7	3.6
Stomach	11	5.6
Gallbladder	15	7.7
Marginal lymphoma	6	3.1
NHL	9	4.6
ALL	15	7.7
Comorbidities		
None	65	33.3
Diabetes	33	16.9
Hypertension	36	18.5
Thyroid disorder	10	5.1
Other	23	11.8
Both HTN & DM	23	11.8
HTN & thyroid disorder	5	2.6

Table 2. Distribution of chemotherapeutic agents and its ADRs, n=195

Variables	n	%
Chemotherapeutic agents		
Paclitaxel	16	8.2
Cyclophosphamide	13	6.7
Doxorubicin	12	6.2
Cisplatin	8	4.1
Oxaliplatin + 5-Fluoro + Leucovorin	29	14.9
Oxaliplatin + Doxorubicin	18	9.2
Cisplatin + Gemcitabine	23	11.8
Cyclophosphamide + Doxorubicin	24	12.3
Carboplatin + Paclitaxel	13	6.7
Other (Vincristine, bleomycin, dacarbazine, Trastuzumab)	39	20.0
ADR observed		
Nausea	10	5.1
Vomiting	19	9.7
Diarrhoea	15	7.7
Constipation	9	4.6
Stomach pain	17	8.7
Anorexia	16	8.2
Taste changes	12	6.2
Fever	12	6.2
Fatigue	14	7.2
Headache	9	4.6
Shortness of breath	13	6.7
Neuropathy	14	7.2
Alopecia	16	8.2
IDA + Headache	4	2.1
Infection	2	1.0
Other	13	6.7

Table 3. Frequency distribution of severity and preventability of ADRs due to chemotherapy, n=195

Variables		n	%
Severity of ADRs	Mild	57	29.2
	Moderate	98	50.3
	Severe	40	20.5
Preventability of ADRs	Definitely preventable	52	26.7
	Probably preventable	69	35.4
	Non-preventable	74	37.9

Hartwig and Siegel Scale, Schumock and Thornton Preventability Assessment Scale

Table 4. Association between socio-demographic with severity and preventability of ADRs due to chemotherapy, n=195

Variable	Severity of ADRs, n(%)				Preventability of ADRs, n(%)			
	Mild	Moderate	Severe	p-value	Definitely	Probably	Non preventive	p-value
Gender								
Male	31(38.8)	29(36.3)	20(25)	0.004	22(27.5)	27(33.8)	31(38.8)	0.923
Female	26(22.6)	69(60.0)	20(17.4)		30(26.1)	42(36.5)	43(37.4)	
Age groups in years								
18-30	7(70.0)	2(20.0)	1(10.0)	0.054	2(20.0)	3(30.0)	5(50.0)	0.093
30-39	5(38.5)	8(61.5)	0		3(23.1)	3(23.1)	7(53.8)	
40-49	11(31.4)	17(48.6)	7(20.0)		9(25.7)	12(34.3)	14(40.0)	
50-59	15(25.0)	35(58.3)	10(16.7)		17(28.3)	22(36.7)	21(35.0)	
60-69	10(21.7)	22(47.8)	14(30.4)		9(19.6)	21(45.6)	16(34.8)	
70-79	6(23.1)	12(46.2)	8(30.8)		7(26.9)	8(30.8)	11(42.3)	
≥80	3(60.0)	2(40.0)	0		5(100)	0	0	
Comorbidities								
None	21(32.3)	31(47.7)	13(20.0)	0.436	19(29.2)	27(41.5)	19(29.2)	0.277
DM	11(33.3)	15(45.5)	7(21.2)		8(24.2)	15(45.5)	10(30.3)	
HTN	10(27.8)	21(58.3)	5(13.9)		10(27.8)	13(36.1)	13(36.1)	
TD	0	8(80.0)	2(20.0)		1(10)	3(30.0)	6(60.0)	
Other	10(43.5)	8(34.8)	5(21.7)		5(21.7)	6(26.1)	12(52.2)	
HTN & DM	4(17.4)	13(56.5)	6(26.1)		7(30.4)	3(13.0)	13(56.5)	
HTN & TD	1(20.0)	2(40.0)	2(40.0)		2(40.0)	2(40.0)	1(20.0)	

DM- diabetes mellitus, HTN-Hypertension, TD- Thyroid disorder

Table 5. Association between severity and preventability of ADR due to chemotherapy, n=195

ADRs	Mild n(%)	Moderate n(%)	Severe n(%)	Total n(%)	Non.Preventable n(%)	Preventable n(%)	Total n(%)
ADRs							
Nausea	3(5.3)	7(7.1)	0	10(5.1)	2(2.7)	8(6.6)	10(5.1)
Vomiting	6(10.5)	7(7.1)	6(15)	19(9.7)	2(2.7)	17(14)	19(9.7)
diarrhoea	5(8.8)	7(7.1)	3(7.5)	15(7.7)	5(6.8)	10(8.3)	15(7.7)
Constipation	2(3.5)	4(4.1)	3(7.5)	9(4.6)	0	9(7.4)	9(4.6)
Stomach pain	3(5.3)	9(9.2)	5(12.5)	17(8.7)	2(2.7)	15(12.4)	17(8.7)
Anorexia	4(7)	7(7.1)	5(12.5)	16(8.2)	1(1.4)	15(12.4)	16(8.2)
Taste changes	4(7)	4(4.1)	4(10)	12(6.2)	11(14.9)	1(0.8)	12(6.2)
Fever	4(7)	7(7.1)	1(2.5)	12(6.2)	1(1.4)	11(9.1)	12(6.2)
Fatigue	4(7)	7(7.1)	3(7.5)	14(7.2)	8(10.8)	6(5)	14(7.2)
Headache	5(8.8)	4(4.1)	0	9(4.6)	1(1.4)	8(6.6)	9(4.6)
Shortness of Breath	6(10.5)	5(5.1)	2(5)	13(6.7)	4(5.4)	9(7.4)	13(6.7)
Neuropathy	3(5.3)	10(10.2)	1(2.5)	14(7.2)	10(13.5)	4(3.3)	14(7.2)
Alopecia	3(5.3)	11(11.2)	2(5)	16(8.2)	15(20.3)	1(0.8)	16(8.2)
IDA+headache	1(1.8)	2(2)	1(2.5)	4(2.1)	0	4(3.3)	4(2.1)
Infection	1(1.8)	0	1(2.5)	2(1)	0	2(1.7)	2(1)
Other	3(5.3)	7(7.1)	3(7.5)	13(6.7)	12(16.2)	1(0.8)	13(6.7)
Total	**57(100)**	**98(100)**	**40(100)**	**195(100)**	**74(100)**	**121(100)**	**195(100)**
p-value		**0.754**				**0.005**	

Discussion

This study on the severity and preventability of ADRs associated with chemotherapy in cancer patients attending a tertiary hospital in Nepal, revealed that moderate ADRs were the most frequent, followed by mild and severe reactions. This pattern aligns with studies from India and Ethiopia, which reported that the majority of chemotherapy-related ADRs were moderate in severity.[14,15]

Moderate ADRs often include gastrointestinal disturbances, fatigue, and haematological toxicities, which, though not immediately life-threatening, significantly impair patient quality of life and may affect adherence to therapy.[16]

Gender differences were observed in ADR severity, with female patients more frequently experiencing moderate ADRs. This observation corresponds with earlier reports that women are more vulnerable to ADRs, potentially due to lower body weight, hormonal influences, and differences in drug metabolism compared to men.[17,18] However, other studies have not consistently confirmed this association, indicating that sex differences may vary by drug class, genetic profile, and cancer type.[19]

Age also influenced ADR patterns. Patients aged ≥60 years showed a greater proportion of severe ADRs, although the association was not statistically significant. Elderly patients are more susceptible to drug toxicity because of

age-related pharmacokinetic changes, polypharmacy, and comorbidities.[20]

The current study's findings regarding ADRs associated with chemotherapy regimens resonate with previously published data. Alopecia was notably frequent with doxorubicin (25%) and paclitaxel (18.8%), aligning with established reports where anthracyclines and taxanes induce alopecia in approximately 20-30% of treated patients.[1,13] Neuropathy, predominantly linked to oxaliplatin and doxorubicin, emerged in 22.2% of cases here, whereas in some studies reporting up to 90% incidence with oxaliplatin, falls within a representative clinical range considering patient and dosage variability.[21,22] Gastrointestinal ADRs such as anorexia and vomiting showed a strong association with carboplatin, paclitaxel, cyclophosphamide, and doxorubicin, supporting literature that highlights their emetogenic potential and necessitates vigilant antiemetic management.[13,23]

Diarrhoea occurred most often with cisplatin plus gemcitabine, consistent with documented toxicities that adversely affect patient quality of life and treatment adherence.[21,22] The observed headaches and fatigue also reflect commonly reported nonspecific chemotherapy side effects.[1] Notably, despite these ADRs, changes in treatment schedules lacked statistical significance (p=0.073), suggesting effective symptomatic management that prevents frequent treatment interruptions, a trend similarly noted in supportive oncology care studies.[21,13] Collectively, these findings emphasize the importance of tailored monitoring and proactive supportive care in chemotherapy to balance toxicity control and therapeutic efficacy.

In this study, the majority of chemotherapy-induced ADRs were moderate in severity (50.3%), followed by mild (29.2%) and severe (20.5%) reactions. This distribution is comparable to other reports, where moderate ADRs formed the largest category, but with considerable proportions of mild and severe reactions.[13] Common ADRs, including anorexia, vomiting, diarrhoea, and alopecia, predominantly caused moderate-to-severe responses, similar to findings of substantial clinical impact of gastrointestinal and dermatologic toxicities among cancer patients receiving chemotherapy.[21]

Preventability assessment revealed that a substantial proportion of ADRs were either definitely or probably preventable. Similar findings were reported in an Indian study, where nearly 40% of ADRs were judged preventable using validated scales.[24] Preventable ADRs are often linked to factors such as inappropriate dosing, inadequate monitoring, or lack of prophylactic use of supportive agents (e.g., antiemetics, growth factors).[25] In our setting, limited resources and weak pharmacovigilance practices may have contributed to preventable ADRs.

Overall, these findings underscore the complexity of ADR severity and preventability, reinforcing the need for individualized assessment and preventive strategies based on patient age, sex, and treatment regimen to optimize chemotherapy safety and tolerability.

Study reports no statistically significant independent predictors of preventable ADRs. The lack of significant predictors likely reflects the multifactorial nature of ADR preventability, which depends on a complex interplay of patient-specific, prescriber, and systemic healthcare factors.[26]

These findings have important implications for Nepal's pharmacovigilance system. Currently, under-reporting of ADRs is a major challenge in Nepal, particularly in oncology.[13,27] Establishing a systematic ADR monitoring framework within cancer centres is critical. Integration of ADR reporting into hospital electronic medical records, regular training of oncology staff, and active surveillance of chemotherapy patients could significantly reduce preventable ADRs. Furthermore, the creation of a national oncology ADR database would support policy-making and improve clinical decision-making. Strengthening pharmacovigilance at the institutional and national levels will also align Nepal with global initiatives on patient safety.

This study has some limitations. First, it was conducted in a single tertiary hospital, which may limit generalizability to other healthcare

settings. Second, the cross-sectional design captures ADRs during treatment but does not account for late-onset toxicities. Third, ADR assessments relied on clinical judgment using standard scales, which, though validated, retain some subjectivity. Finally, pharmacogenomic testing, which could explain inter-individual variability in ADR risk, was not available. Future multicentre longitudinal studies incorporating larger sample sizes and genetic testing could provide more robust predictors of ADR severity and preventability.

Conclusion

This study found that moderate adverse drug reactions (ADRs) were the most common among cancer patients receiving chemotherapy. A significant association was identified between gender and ADR severity, more in females. However, no statistically significant association was found between patient age and ADR severity. A substantial majority of ADRs (two-thirds) were deemed definitely or probably preventable. However, none of the independent variables (gender, age, type of cancer, comorbidity) was significantly associated with ADR preventability. This highlights a critical gap in current management practices and a need to strengthen pharmacovigilance, enhance monitoring protocols, and implement proactive supportive care.

Author contribution

Concept and design: RS; Literature search: RS, SS, LS; Data acquisition and compilation: RS, LS, AS; Statistical analysis and manuscript preparation: RS, AS; Agreement to be accountable for all aspects of the work: ALL

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Conflict of interest

None

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Supplementary material

Data and supplementary material that support the findings of this study are available from the corresponding author upon reasonable request.

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Tools/Questionnaire

- **Demography data:**
  1. Participate code no: 2. Age: 3. Sex: Male Female 4. Comorbid disease: ……

- **Circle one of the following correct answers /fill in the blanks of following Question (Day care Unit) Type of Cancer**
  a) Breast b) Gall bladder c) Stomach d) Small intestine e) Duodenum f) Rectum g) Lymphoma
  g) Pancreas h) Blood i) Lung j) Prostate k) others ……

- **Type of chemotherapy regimen**

Chemotherapy Regimen	√/×
i. Docetaxel+Cyclophosphamide	
ii. Paclitaxel+Carboplatin	
iii. Gemcitabine + Carboplatin	
iv. Eribulin Mesylate	

v. Epirubicin+Cyclophosphamide	
vii. Paclitaxel (paclitec)	
Viii. Paclitaxel+Tranztuzumab	
IX. Gemcitabine + Docetaxel	
X. Others ……	

- **Adverse effects observed by anticancer drugs (√/×)**

Body Pain, Nausea, Headache, Joint Pains, Vomiting, Fatigue, Insomnia, Tremors, Anorexia, taste changes, Blurred Vision, Chest pain, ototoxicity, Fever, Shortness of Breath, gastritis, Hearing Problems, Constipation, Loss of Hair, Diarrhoea, Leucoplakia, Peripheral Neuropathy, Missed Menstrual Periods, Stomach Pain, other…….

- Severity assessment of ADRs **(Hartwig's scale)**

Circle the severity level of the ADR Example of ADR a/c to different level

Level 1	An ADR occurred but required no change in treatment with the suspected drug	e.g-
Level 2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS)	e.g-
Level 3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR An Antidote or other treatment was required. No increase in LOS	
Level 4	Any Level 3 ADR which increase length of stay by at least I day. OR The ADR was the reason for the admission	
Level 5	Any Level 4 ADR which requires intensive medical care	
Level 6	The adverse reaction caused permanent harm to the patient	
Level 7	The adverse reaction either directly or indirectly led to the death of the patient	

ADR= adverse drug reaction

Mild-level 1, level 2, Moderate- level 3, level 4, severe- level 5, level 6 & level 7

- **Preventability criteria a/c to Schumock and Thomton scale**

	Yes	No	Unknown
1. Was there a history of allergy or have Previous reaction to the drug?			
2. Was the drug involved inappropriate for the patient clinical condition?			
3. Was the dose, route or frequency of administration inappropriate for the patient's age, weight or disease state?			
4. Was a toxic serum drug concentration (or laboratory tests not performed?			
5. Was there a known treatment for adverse drug reactions?			
6. Was required therapeutic drug monitoring or other necessary laboratory tests not performed			
7. Was a drug interaction involved in the ADR?			
8. Was poor compliance involved in the ADR?			
9. Were preventative measures not prescribed or administered to the patient?			
10. If all above criteria not fulfilled.			

- **Schumock and Thornton scale**

The Schumock and Thornton criteria was established for assessing the preventability of ADRs. It has three sections namely definitely preventable, probably preventable and non-preventable. Section A comprises of five questions while section B has four questions. All the answers are categorized as “Yes” or “No”. ADRs were “definitely preventable” if answer was “yes” to one or more questions in section A. If answers were all negative then we proceeded to section B. ADRs were “probably preventable” if answer was “yes” to one or more questions in section B. If answers were all negative then we proceeded to section C. In Section C the ADRs were non-preventable.