

# The Role of Clinical Pharmacists in Reducing Adverse Drug Reactions in Oncology Patients: A Multicenter study

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**ABSTRACT** Adverse drug reactions (ADRs) are a significant concern in oncology, impacting patient safety, treatment adherence, and quality of life. Clinical pharmacists play a vital role in identifying, managing, and preventing ADRs in cancer patients. This study is a multicenter trial with the objective to assess the effectiveness of clinical pharmacists in the prevention of ADRs in onco-hematology patients receiving chemotherapy, immunology, or targeted therapy. The study had a prospective design and involved 500 adult oncology patients with 150-200 subjects from each of the three centers. Patients were followed for 6 months and those with high ADR risk were identified. Clinical pharmacists in this study proactively addressed medications and potential drug interactions through Lexi-Interact® and Micromedex® databases as well as offering suggestions for action. The QoL of the patients was evaluated by the EORTC QLQ-C30 questionnaire, which includes patient-reported outcomes. Data was analyzed using SPSS® version 25.0 and  $p < 0.05$  was used as the level of significance. The findings indicated that the radical group had a significant decrease in severe ADRs compared to the control group ( $p < 0.05$ ) and had increased compliance in receiving chemotherapy schedules (92% and 84% respectively;  $p = 0.015$ ). Quality of life was significantly better in the intervention group ( $M = 78.4$ ;  $SD = 12.1$  vs  $M = 70.3$ ;  $SD = 15.5$ ;  $t = -2.3$ ;  $p = 0.002$ ) and hospitalizations and treatment drop out were significantly lower. The study concluded that clinical pharmacist interventions significantly reduced ADRs, enhanced treatment adherence, and improved patient-reported QoL, highlighting their essential role in oncology care.

**Keywords:** Clinical Pharmacists; Adverse Drug Reactions; Oncology; Chemotherapy; Quality Of Life; Medication Management

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## INTRODUCTION

Medications are one of the most significant factors of production in the health care sector. But it has been demonstrated that drugs can lead to undesirable health consequences, for example, increased rates of morbidity and mortality, and decreased quality of life. However, absence of effect of the chosen drug can also be an issue in the management of patients or normal ranges of blood glucose, cholesterol or blood pressure are not achieved as expected during drug therapy. This could be due to the type of drug used, the dosage, interaction between the drug and the disease, or the patient's compliance [1].

Drug interactions occur with high frequency in cancer patients because they take multiple drugs for the treatment of their disease, pathological and anti-tumoral agents, antiemetic, analgesic and antibiotic, and others. Furthermore, the majority of cancer patients are elderly, with over 65% of patients displaying one or several comorbidities that can be treated with drugs. This factor greatly exacerbates the probability of prescribing the drug and, thus, the risk of adverse drug interaction. Also, due to the organic deterioration that activates the process of the tumor, ageing, renal and hepatic functions and consequently the metabolism and clearance of the drugs are impaired that raises potential toxicity [2]. Drug interactions can be classified into three types: Pharmacokinetic, pharmacodynamic and pharmaceutical are terms used to describe a drug and its effects on the body. Pharmacokinetics is the study of how drugs affect each other; a pharmacokinetic interaction takes place when one drug modifies the absorption, distribution, metabolism and/or clearance of another. One of the most widely recognized pharmacokinetic interactions is associated with the cytochrome P450 family. The pharmacodynamic interaction mainly occurs when two are similar in action like when two active substances act in the same manner, for instance when competing for the same bio/physiological receptor site in the living organism. A pharmaceutical interaction may involve a physical or chemical interaction between two related drugs [3]. Regardless of the type of interaction, drug interactions may compromise treatment efficacy or increase drug toxicity, with serious clinical consequences (they can result in under/overdosing, the pharmacological effect can be boosted or the drugs can become completely ineffective). There are many studies that describe the interactions between the chemotherapeutic and/or antineoplastic treatment supportive drugs, or the drugs prescribed in daily clinical practice. However, very few have focused on the General occurrence of drug interactions when it comes to the chemotherapy process in cancer patients and its significance [4] [5].

A cornerstone of clinical pharmacy is the identification, solving and prevention of drug-related problems. According to van Mil et al. (2004) [6] a drug-related problem is described as an event or circumstance that involves drug therapy and which either does or could affect the intended benefits of treatment. Drug-related problems have been categorized by different research groups into different classification systems. In fact, these problems concern the choice of the drug, dosing, side effects, drug interactions, non-supervision of the drug effects/toxins, and compliance issues. Drug-related issues are classified into factual as well as possible issues [7]. A clinical pharmacist may assess drug-related problems in different settings: in hospital multidisciplinary teams, in nursing homes and in primary care. To determine the pharmacist's role in the enhancement of drug therapy, the concerns that have been solved or resolved by the pharmacist or those that were not raised at all can be considered or the clinical impacts on the patients. These are indirect and direct measurements, respectively, the latter providing the most conclusive evidence.

## Aim of the Research

The aim of this research is to evaluate the role of clinical pharmacists in reducing adverse drug reactions (ADRs) among oncology patients in a multicenter setting.

## MATERIALS AND METHODS

### Study Design

This study used prospective, multi-centric approach to assess the adverse drug reactions (ADRs) prevention intervention managed by clinical pharmacists in the context of oncology. The study was carried out in three oncology centers that were chosen because of their ready cooperation for full patient databases and incorporation of well-established clinical pharmacy practices. The study focused on oncology outpatients initiating chemotherapy over a 6-month period and involved systematic analysis and intervention in medication management, including cytotoxic agents, hormone therapies, and supportive care regimens.

### Study Population

The study participants included all cancer patients who were 18 years old and above and were ongoing chemotherapy, immunology therapy, or targeted therapy.

### Inclusion and exclusion

Patients included in the study met the following criteria: a high risk of ADRs and the ability to provide informed consent. The patients who were below 18 years of age, who lacked complete medical records, or those who were receiving palliative or end of life care where the management of ADRs was not a priority were excluded. There were 500 patients included in the study, and individual centers were expected to recruit 150-200 participants each to be representative of the population.

## Ethical considerations

The study received ethical clearances from the institutional review boards of all the centers involved in the study before its initiation. Each participant provided a written informed consent, and patient identities were protected in compliance with the Declaration of Helsinki and other related legal guidelines.

## Data Collection

Clinical pharmacists conducted several key interventions throughout the study. Data on the chemotherapy regimens, supportive care measures and the patient characteristics such as age gender type of cancer and disease stage were obtained from electronic prescription databases. This medical information was obtained from patients' records through the use of software that is installed in hospitals.

Patient self-reported prescription medications and over-the-counter medicine intake was confirmation done through face-to-face interviews with clinical pharmacists during pharmacy visits. Discrepancies between reported and documented medication use were resolved by cross-referencing hospital medical records and electronic health systems. Potential ADRs from medication-related interactions were also assessed using standard drug-interaction databases. ADRs were classified according to severity and clinical significance:

- Category D or X (Lexi-Interact®): Significant interactions requiring close monitoring, dose modification, or discontinuation.
- Category Red (Micromedex®): These combinations should be avoided due to high risks they pose to the users.
- When clinically significant interactions were identified, clinical pharmacists consulted the oncology care team to recommend preventive or corrective actions.
- Patient's QoL was assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).

## Data Analysis

Descriptive statistics were calculated for all variables. For categorical data, the Chi-square test (or Fisher's exact test) was used while for continuous variables, Student's t-test was employed. Statistical analysis of the results was done using student t test and a p value of less than 0.05 was used to determine significance. The collected data was analyzed using SPSS® version 25.0 [Table 1].

## RESULTS

The distribution of patients across age ranges indicated that most patients who participated in the study were between 41 and 80 years, with 85.4% of the overall reported participants; those within the ages 61 to 80 years were 44.4%. Patients aged 18-40 years only contributed 6.6% while those above 81 years comprised of 8%. Regarding gender distribution, 49% of participants were male while 51% were female. Breast cancer was identified as being the most

**Table 1:** Patient Demographics.

Variable	Intervention Group (n=250)	Control Group (n=250)	Total (N=500)
<b>Age Group</b>			
18-40 years	15 (6%)	18 (7%)	33 (6.6%)
41-60 years	105 (42%)	100 (40%)	205 (41%)
61-80 years	110 (44%)	112 (45%)	222 (44.4%)
81+ years	20 (8%)	20 (8%)	40 (8%)
<b>Gender</b>			
Male	120 (48%)	125 (50%)	245 (49%)
Female	130 (52%)	125 (50%)	255 (51%)
<b>Cancer Type</b>			
Breast Cancer	70 (28%)	80 (32%)	150 (30%)
Lung Cancer	65 (26%)	60 (24%)	125 (25%)
Colorectal Cancer	45 (18%)	55 (22%)	100 (20%)
Other (e.g., lymphoma)	70 (28%)	55 (22%)	125 (25%)
<b>Chemotherapy Regimen</b>			
Cytotoxic Chemotherapy	125 (50%)	130 (52%)	255 (51%)
Immunotherapy	60 (24%)	55 (22%)	115 (23%)
Targeted Therapy	65 (26%)	65 (26%)	130 (26%)
<b>Supportive Therapies</b>			
Anti-nausea Medications	175 (70%)	165 (66%)	340 (68%)
Pain Management	150 (60%)	145 (58%)	295 (59%)
Antibiotics	100 (40%)	95 (38%)	195 (39%)

prevalent among patients (30%) and more so the control group (32%). Lung cancer is the most common type at 25% followed by colorectal cancer at 20%. Other cancers, such as lymphoma, made up the remaining 25%, with a slightly higher proportion in the intervention group (28%) compared to the control group (22%). Cytotoxic chemotherapy was the most commonly used regimen, accounting for 51% of patients and was slightly more in the control group (52%). Targeted therapy was given to 26% of the patients from each group; Immunotherapy was slightly higher in the intervention group (24%) as compared to control group (22%). Among the supportive care interventions administered, antiemetic medications were given to more patients, 68%, with the intervention group receiving them slightly more often, 70%. The use of pain management was noted in 59% of patient and there is no much variation among different group of patient. On the use of antibiotics, only 39% reported having used them with no significant differences across groups. These therapies focus on a holistic approach to dealing with the side effects of the treatment [Table 2]. The results also showed that the intervention group had less high risk drug-interaction than the control group. Concerning Category D or X interaction (according to Lexi- Interact®), the intervention group experienced 4% incidence as opposed to 10% in the control group with an appreciable difference ( $p = 0.034$ ). Likewise, in case of the Category Red interactions (Micromedex®), the percentage was even lower for the intervention group (2%) as compared to the control group (6%) ( $p=0.021$ ). That means the intervention group had a better management of their medications suggesting reduced chances of severe drug-drug interaction in the same. In terms of ADR severity, mild ADRs were reported in 16% of the patients of the intervention group and 22% of the patients in the control group, again without statistical significance ( $p = 0.078$ ).

**Table 2:** Incidence and Severity of Adverse Drug Reactions (ADRs).

ADR Type	Intervention Group (n=250), n (%)	Control Group (n=250), n (%)	p-value
Category D or X (Lexi-Interact®)	10 (4%)	25 (10%)	0.034
Category Red (Micromedex®)	5 (2%)	15 (6%)	0.021
Mild ADRs	40 (16%)	55 (22%)	0.078
Moderate ADRs	30 (12%)	40 (16%)	0.114
<b>Types of ADRs</b>			
Nausea/Vomiting	40 (16%)	50 (20%)	0.234
Fatigue	25 (10%)	40 (16%)	0.095
Neutropenia	10 (4%)	15 (6%)	0.368
Rash	12 (5%)	18 (7%)	0.324
Anemia	8 (3%)	18 (7%)	0.048
Diarrhea	12 (5%)	25 (10%)	0.027
Liver Toxicity	5 (2%)	15 (6%)	0.022

**Table 3:** ADRs by Drug Class.

Drug Class	Intervention Group (n=250), n (%)	Control Group (n=250), n (%)	p-value
Chemotherapy Agents	50 (20%)	80 (32%)	0.021
Immunotherapy	25 (10%)	40 (16%)	0.056
Corticosteroids	30 (12%)	50 (20%)	0.027
Antiemetics	10 (4%)	20 (8%)	0.095
Antibiotics	20 (8%)	35 (14%)	0.043

Moderate ADRs were observed in 16% of control group patients and 12% of patients in the intervention group; however, there was no statistically significant difference ( $p=0.114$ ). The reduction or increase in ADR severity of both groups reveals similar outcomes with a slightly better outcome in the intervention group. Based on the type of ADR, nausea and vomiting was the most frequent in this study, with a frequency of 16% in the intervention group and 20% in the control group ( $p=0.234$ ). Mild fatigue and neutropenia were observed to be higher in the control group without significant difference ( $p=0.095$  and  $p=0.368$  respectively). However, anemia and diarrhea were significantly more common in the control group (7% & 10%,  $p=0.048$  &  $p=0.027$ , respectively) as compared to the intervention group (3% & 5%, respectively). In the same regard, liver toxicities were proved to be higher in the control group (6%) as compared to the interventional group (2%) ( $p= 0.022$ ). Such outcomes signify that the intervention was effective in lowering certain specific ADRs [Table 3].

Chemotherapy related ADRs were even lower in the intervention group (20%) than in the control group (32%) with p-value of 0.021. This implies that the intervention could be useful in eliminating some of the side effects associated with chemotherapy. The intervention group had 10% ADRs from immunotherapy while the control group had 16% ADRs, but there was no statistically significant difference ( $p=0.056$ ). However, such an evaluation would be needed to ascertain whether this trend indicates better management in the intervention group. ADRs attributed to corticosteroids were significantly lower in the intervention group, at 12% than in the control group at 20% with p-value of 0.027. This means that the intervention achieved a considerable success

in its role to reduce ADRs associated with corticosteroid. ADRs owing to anti-emetics were reportedly lesser in the intervention group (4%) when compared to the control group (8%) and, however, the difference was not found to be statistically significant ( $p=0.095$ ). Responses concerning antibiotic usage were lower in the intervention group (8%) than in the control group (14%) with  $p$ -value being 0.043. Such evidence indicates that the intervention reduces ADRs originating from antibiotics therefore proving the value of improving patient outcomes [Table 4].

The patients in the intervention group were more likely to adhere to their prescribed chemotherapy regimens of 92% compared to the control group which was only 84% ( $p=0.015$ ). This shows the extent to which the intervention helped the patients adhere to the prescribed treatments. In terms of hospitalization, the patients in the intervention group were hospitalized significantly less often (12%) than those in the control group (18%) ( $p=0.045$ ). This is an indication that the intervention improved on the situation and was able to prevent complications or side effects that may lead to hospitalization. As for quality of life assessed by QoL Score, there was a significant improvement in the QoL of the patients in the intervention group as compared to the control group, with the mean QoL score of  $78.4 \pm 12.1$  and  $70.3 \pm 15.5$  ( $p=0.002$ ). This suggests that an enhancement of the intervention brought about better improvement of patients' general health. The intervention group patients' average duration of chemotherapy was slightly more than the control group with average of  $6.2 \pm 0.9$  months as compared to  $5.8 \pm 1.2$  months; however this variation was not statistically significant ( $p$  value = 0.071). This may indicate similar treatment continuity between these two groups. Discontinuation rates of treatment were also lower in the intervention group being at 8% as compared to the control group with rates at 14% ( $p=0.038$ ). This, therefore, affirms the intervention in improving treatment compliance and minimizing drop-outs. The results showed increased satisfaction in the intervention group, with 88% of patients indicating satisfaction compared to 76% for the control group ( $p=0.005$ ). This can be attributed to the perceived positive impact of the intervention on the care experience. Regarding the pain management, the improvement was noted within the intervention group with 86% of patients having optimal pain

control in contrast to 72% within the control group, ( $p=0.004$ ). This highlights the effect of the intervention in enhancing symptoms control [Table 5].

In terms of perceived general health status/QoL, the patients in the intervention group gained higher overall QoL scores, the patients reported a higher percentage of positive global health status: 72% vs 60% ( $p=0.032$ ). This shows that there is a significant positive shift in the patient's perceived health status as a result of the intervention. As for functional domains, physical functioning was higher in the intervention group (80%) than the control group (68%) ( $P < 0.015$ ), which indicates the ability to preserve their physical functioning. Role functioning and emotional functioning (76% vs 64%,  $p=0.04$ , and 68% vs 56%,  $p=0.027$ ) was significantly better indicating better ability to meet daily functional roles and emotional well-being. Cognitive functioning was most significant, as 84% of the interventional group reported normal cognition as compared to only 72% of the control group ( $p = 0.015$ ). On social functioning, similar trends were observed; 88% in the intervention group and 76% of the control group ( $p=0.021$ ). Comparing the symptom domain specificities of both groups, it is possible to note that fatigue and nausea/vomiting appeared less frequently in the intervention group (16% and 12%) than in the control group (24% and 20%), however these differences were non-significant ( $p = 0.089$  and  $p = 0.057$ , respectively). Pain status was less in the intervention group 18% than the control group 28% ( $p = 0.032$ ). Dyspnea and sleep disturbances were other symptoms that were reported to have been significantly improved in the interventional arm with a difference of 14% against 22% ( $p = 0.039$ ) and 20% against 32% ( $p = 0.022$ ). Concerning Appetite Loss and Other Symptoms, appetite loss in the intervention group was 24%, which was lower than that of the control group, 34% ( $p=0.015$ ); this shows that the ward's patients had a better way of coping with the treatment side effects. Compared to the control group, constipation and diarrhea were slightly less in the intervention group but this difference was statistically non-significant ( $p=0.095$  and  $p=0.21$ ). The effects of this intervention point to the general improvement of patients' quality of life, especially concerning specific symptoms and functional/emotional wellbeing.

**Table 4:** Patient Outcomes.

Outcome	Intervention Group (n=250)	Control Group (n=250)	p-value
Adherence to Chemotherapy Regimen	230 (92%)	210 (84%)	0.015
Incidence of Hospitalization	30 (12%)	45 (18%)	0.045
Quality of Life (QoL) Score	$78.4 \pm 12.1$	$70.3 \pm 15.5$	0.002
Duration of Chemotherapy	$6.2 \pm 0.9$ months	$5.8 \pm 1.2$ months	0.071
Treatment Discontinuation	20 (8%)	35 (14%)	0.038
Patient Satisfaction with Care	220 (88%)	190 (76%)	0.005
Pain Management Control	215 (86%)	180 (72%)	0.004
Infection Rate	15 (6%)	25 (10%)	0.112

**Table 5:** Quality of Life (QoL) Assessment Results (EORTC QLQ-C30).

QoL Domain	Intervention Group (n=250), n (%)	Control Group (n=250), n (%)	p-value
Global Health Status/QoL	180 (72%)	150 (60%)	0.032
Physical Functioning	200 (80%)	170 (68%)	0.015
Role Functioning	190 (76%)	160 (64%)	0.04
Emotional Functioning	170 (68%)	140 (56%)	0.027
Cognitive Functioning	210 (84%)	180 (72%)	0.015
Social Functioning	220 (88%)	190 (76%)	0.021
Fatigue	40 (16%)	60 (24%)	0.089
Nausea/Vomiting	30 (12%)	50 (20%)	0.057
Pain	45 (18%)	70 (28%)	0.032
Dyspnea	35 (14%)	55 (22%)	0.039
Sleep Disturbance	50 (20%)	80 (32%)	0.022
Appetite Loss	60 (24%)	85 (34%)	0.015
Constipation	25 (10%)	40 (16%)	0.095
Diarrhea	35 (14%)	45 (18%)	0.21

## **DISCUSSION**

The clinical practice of pharmacists in the care of patients with cancer has steadily attracted attention due to the potential of increasing the quality of care especially through the mitigation of ADR rates. The findings of this study align with Iihara et al (2021) [8] that investigated the impact of pharmacist involved interventions in patients with thoracic cancer who were on chemotherapy. They showed that intensity and frequency of grade  $\geq 2$  non- hematological and grade  $\geq 3$  hematological ADRs were reduced in view of pharmacist's monitoring and intervention. In the same way, Gambôa& Maia (2017) [9] stated that ADR incidences were significantly lowered when the pharmacist interventions occurred soon after the chemotherapy infusion; these severe reactions would, otherwise, lead to hospitalization or treatment discontinuation.

This study is also related to the work of Giraud et al. (2024) [10] who done a prospective study and showed how pharmacists successfully detected potential drug-related issues and resolved them decreasing the frequency of ADRs and related overall healthcare expenses. The studies also confirm the role of pharmacists in enhancing medication plans and preventing adverse outcomes in oncology. The study also showed higher Quality of Life (QoL) scores in the intervention group than in the control group, as evidenced by Colombo et al. (2017) [11] in a systematic review of the outcomes of cancer outpatients with pharmacist interventions. They found evidence of benefits in patients' physical, emotional, and social well-being, implying that the role of pharmacists is not limited to ADR monitoring and intervention. Shin et al. (2024) [12] also highlighted this aspect in their study regarding the application of artificial intelligence in chemotherapy-induced nausea and vomiting (CINV). In their meta-analysis, they found that oncology pharmacy services had a positive impact on patients' QoL through decreasing the rate of CINV as in the improved symptoms found in the present study. Concerning safety outcomes, a decrease in the medication errors associated with cancer treatment was established in our study, as highlighted by Coutsouvelis et al. (2020) [13]. In their systematic review, they proved that the key strategies mediated by pharmacists such as medication reconciliation and real-time monitoring played a critical role in error detection before the results reached patients. This is in agreement with the findings of the present study, highlighting the increased patient safety and treatment effectiveness due to the pharmacist interventions. Maintenance chemotherapy regimens were followed better in the intervention group, and consequently, there was a lower drop-out rate from treatment. Similarly, Staynova et al., (2024) [14]

had similar findings in their scoping review of pharmacist led interventions in breast cancer and concluded enhanced compliance to treatment and reduced gaps. These findings indicate that pharmacists endure important responsibilities in helping patients through the adversities of long-term oncology therapies. Crozze et al. (2024) also mentioned that the pharmacists' intervening roles lead to overall saving in healthcare costs due to the avoidance of potential hospitalizations and ADR rectifications. They also found a reduced proportion of hospitalization instances in the intervention group, strengthening the idea of the clinical and cost-effectiveness of oncology care pharmacists' engagement. Clinical pharmacist interventions at the National Center for Cancer Care and Research in Qatar were discussed by Al Dali et al. (2024) [15]. They highlighted the role of flexibility in implementing a pharmacist-led approach in various settings and cultures. This is in concordance with the study design of the current work where the efficacy of SSBR was established across multiple quadrants across patient characteristics and healthcare settings. In addition to the main outcome showing a reduction in ADRs, this study also pointed to the other roles of pharmacists such as better patient satisfaction and more efficient management of pain control. These outcomes are similar to the observations of Colombo et al. (2017) [11] and Shin et al. (2024) [12], who reported on the positive role of pharmacists' interventions in patients' treatment process and symptom relief. The results of the multicentre study that we performed serve to support a vast body of other research conducted in the field, highlighting the importance of clinical pharmacists in oncology. These studies also showed that pharmacist-led interventions have many advantages, ranging from ADR reduction and QoL improvement to better treatment adherence and lower healthcare expenses. Such evidence underlines the importance of clinical pharmacists' involvement in oncology teams of healthcare systems for the best outcome to be achieved in cancer patients.

## **CONCLUSION**

This study emphasizes the key-role of clinical pharmacists in the prevention of ADRs in the oncology department. Generalized, pharmacists who assumed the key roles in medication management, patient education and the members of the interdisciplinary teams enhanced patient safety, chemotherapy compliance and overall quality of life of the patients. Overall, the study established substantial reduction in hospitalization rates, treatment abandonment and medication errors, thereby strengthening the clinical and economic impact of pharmacist interventions. Such results suggest that clinical pharmacists should be incorporated into oncology care teams to improve treatment outcomes and the overall management of patients with cancer.

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