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Drug Utilisation Evaluation, Drug-Related Problems, and Adverse Drug Reactions in Colorectal Cancer Patients: A Cross-Sectional Study

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Abstract

Colorectal cancer (CRC) care involves complex regimens and polypharmacy, creating substantial risks for drug-related problems (DRPs) and adverse drug reactions (ADRs). We conducted a cross-sectional retrospective review of consecutive adults with CRC who received systemic anticancer therapy at a tertiary center from 01 December 2024 to 31 July 2025 (N=240; adjuvant n=108; metastatic n=132; median age 59 years; 61% male). Drug utilisation was evaluated against NCCN guidance; relative dose intensity (RDI) and on-time delivery were calculated, supportive care appropriateness (antiemetics, primary G-CSF) was assessed, DRPs were coded using PCNE v9.1, and ADRs were graded by CTCAE v5.0 with Naranjo, Hartwig, and Schumock–Thornton assessments. Guideline-concordant regimen choice was high (adjuvant 92%; metastatic 82%). Median RDI was 90% (IQR 82–97) in adjuvant therapy and 86% (78–95) in metastatic therapy; proportions achieving RDI ≥85% were 68% and 60%, respectively. On-time cycle delivery occurred in 74% (adjuvant) and 69% (metastatic). Antiemetic prophylaxis was appropriate in 91% and 88%; primary G-CSF use when indicated was 80% and 77%. DRPs averaged ~2 per patient, led by monitoring/documentation/duplication issues (29%), effectiveness problems (28%; dose calculation/organ-function adjustment), and clinically relevant drug–drug interactions (24%). Any-grade ADRs occurred in 77.9% and grade ≥3 in 22.1%; notable events included nausea/vomiting grade ≥2 (32.1%), mucositis ≥2 (15.8%), neuropathy ≥2 (27.9%), diarrhea ≥3 (9.2%), hand–foot syndrome ≥2 (14.2%), neutropenia ≥3 (17.9%), thrombocytopenia ≥3 (7.1%), and anemia ≥3 (7.9%). Preventable ADRs comprised 29.9%. These findings support targeted pharmacist-led interventions to strengthen monitoring, optimize dosing, mitigate interactions, and sustain RDI to improve safety and effectiveness in CRC treatment.

Keywords: Colorectal cancer, drug related problems, adverse drug reactions, relative dose intensity.

Introduction

Colorectal cancer (CRC) is a major global health burden, ranking as the third most commonly diagnosed cancer and second leading cause of cancer death worldwide (1). In India, CRC is especially significant: it is the fourth most incident cancer in both sexes, with an estimated 64,863 new cases and 38,367 deaths reported in 2022. This high incidence and mortality in India contrasts with declining trends in Western countries (2). Urban regions of India have seen particularly rapid increases in CRC incidence, reflecting a growing public health challenge.

CRC treatment typically involves complex, multi-agent chemotherapy regimens (for example, fluorouracil-based combinations), which improve outcomes but also carry high

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10.5530/ctbp.2026.2s.15

toxicity risks (1). Most CRC patients have co-occurring chronic conditions and require multiple medications. Consequently, cancer therapy in CRC has a risk of drug-related problems (DRPs) (3). A DRP – defined as any event involving drug therapy that may interfere with desired health outcomes – can lead to increased morbidity, prolonged hospitalization, and higher costs (4). Adverse drug reactions (ADRs) and drug–drug interactions (DDIs) are among the most frequent DRPs in oncology (1).

ADRs, defined as noxious and unintended responses to medications, are particularly concerning in CRC patients, where chemotherapy-induced toxicities such as neutropenia, diarrhea, and neuropathy can lead to treatment delays, dose reductions, or hospitalizations (5). Promoting safe and rational drug use in CRC thus requires systematic evaluation of prescribing patterns. Drug utilisation evaluation (DUE) is one such approach: it is a systematic review of medication use aimed at ensuring rational therapy at the patient level (6). In practice, DUE compares actual drug regimens against evidence-based protocols (for example, NCCN or ESMO guidelines) to identify inappropriate use or errors. Despite its importance, DUE of chemotherapy and detailed assessment of DRPs have been limited in Indian CRC settings. Our study aimed to evaluate drug utilisation patterns and identify drug-related problems (including adverse drug reactions) in colorectal cancer patients.

Materials and Methods

Study design and setting

We conducted a cross-sectional based on a retrospective review of consecutive adults with colorectal cancer (CRC) who received systemic anticancer therapy at a tertiary cancer center between 01 December 2024 and 31 July 2025. A census sampling approach was used; all eligible patients within the window were included (N = 240).

Study Participants

a) **Inclusion Criteria**: (i) Age ≥ 18 years; (ii) histologically confirmed CRC; (iii) receipt of systemic therapy (intravenous and/or oral) in adjuvant or metastatic settings during the study window.

b) **Exclusion Criteria**: (i) Fewer than one completed chemotherapy cycle; (ii) missing core data that precluded drug utilisation evaluation (DUE), drug-related problem (DRP) classification, or adverse drug reaction (ADR) grading.

Data Collection

At baseline, we captured only variables necessary to interpret utilisation and safety: age, sex, ECOG performance status, body mass index, and major comorbidities (diabetes, hypertension, chronic kidney disease). A focused laboratory panel (hemoglobin, absolute neutrophil count, platelet count, serum creatinine for Cockcroft–Gault creatinine clearance, albumin, and transaminases) was accepted if obtained within 14 days before to 7 days after the index treatment date. Tumour details included treatment setting (adjuvant or metastatic), primary tumour sidedness and major metastatic sites for stage IV disease. Prior colorectal surgery/ostomy and limited concomitant medicines with interaction or bleeding relevance (proton-pump inhibitors, anticoagulants/antiplatelets) were recorded; polypharmacy was flagged at ≥5 non-oncology drugs.

Treatment exposure fields were confined to items required to reproduce utilisation metrics: regimen name, key administration/dispensing dates, and planned vs delivered doses sufficient to calculate relative dose intensity (RDI) and on-time delivery (±3 days). Supportive care was captured as appropriateness of antiemetic prophylaxis by emetogenic risk and indication/use of primary G-CSF by febrile-neutropenia risk. Drug-related problems were identified within routine pharmacist review and coded using PCNE v9.1 (problem, cause, intervention, outcome). Adverse drug reactions were ascertained from clinician documentation and lab triggers, graded by CTCAE v5.0, severity (Hartwig & Siegel

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

Scale), and preventability (Schumock–Thornton scale) applied; the highest grade per patient was used for summaries.

Schumock-Thornton Preventability Assessment Scale (S-T PAS)

Developed by Schumock and Thornton in 1992, the Schumock-Thornton Preventability Assessment Scale (S-T PAS) is an instrument designed to determine whether adverse drug reactions (ADRs) could have been prevented. This tool evaluates six distinct criteria: the appropriateness of medication selection, accuracy of dosing and treatment duration, potential for drug-drug interactions, consideration of patient allergies or sensitivities, adequacy of therapeutic monitoring, and occurrence of administration errors. Each criterion is rated individually, and the cumulative score indicates the degree of preventability—higher scores reflect ADRs that were more likely avoidable through clinical intervention.

Drug Utilisation Evaluation (DUE)

National Comprehensive Cancer Network (NCCN) guidance served as the comparator standard for: (i) regimen selection by setting/line (e.g., oxaliplatin-based doublets in adjuvant stage III; biologic selection in metastatic disease guided by RAS status and primary tumour sidedness); (ii) antiemetic prophylaxis according to the regimen's emetogenic risk category; and (iii) primary G-CSF use when the febrile-neutropenia (FN) risk was ≥20% or 10–20% with patient-level risk factors.

Relative dose intensity (RDI). For each patient we computed RDI using the Hryniuk convention:

$$\text{RDI (\%)} = \frac{Delivered\ Dose\ Intensity}{Planned\ Dose\ Intensity} \times 100$$

$$\text{Delivered dose intensity (mg/m}^2\text{/week)} = \frac{Total\ delivered\ dose\ (mg/m2)}{Actual\ Treatment\ Duration\ (in\ weeks)}$$

RDI was summarised as median (IQR), and the proportion achieving RDI ≥ 85% was reported. On-time cycle delivery was defined as administration within ±3 days of the planned interval. Figure 1 displays guideline concordance and RDI ≥ 85% (bars) with antiemetic and G-CSF appropriateness (line overlays).

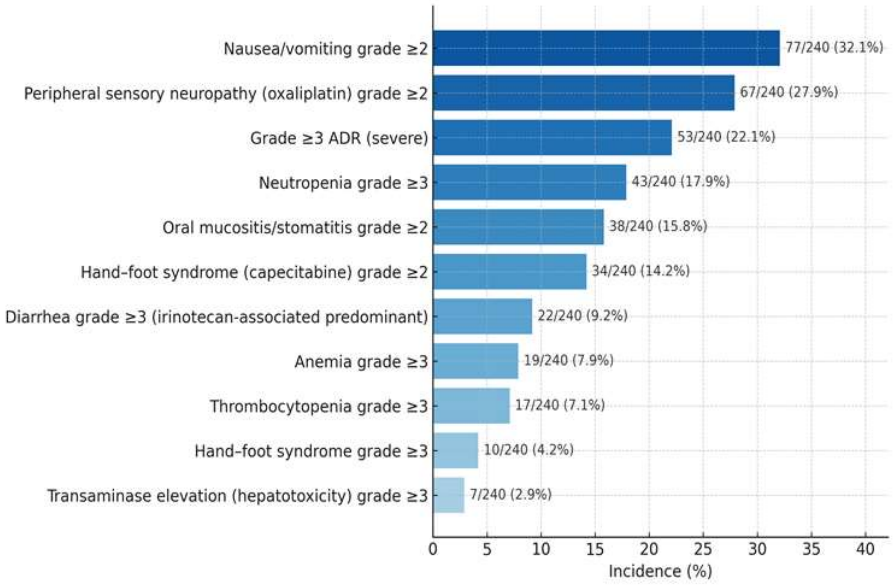

Fig. 1: Incidence of chemotherapy related Grade ≥2 ADR in the cohort

A Cross-Sectional Study

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

Drug-related problems (DRPs)

DRPs were identified through pharmacist review of each cycle's orders, concomitant medicines, laboratory trends, and supportive-care prescriptions. Problems were coded using PCNE Classification v9.1 across domains (problem, cause, intervention, outcome). Clinically significant drug–drug interactions (DDIs) were verified in an authoritative compendium (Micromedex®); high-risk categories were flagged. Intervention acceptance was defined as the prescriber implementing the pharmacist's recommendation before the next scheduled dose/cycle; resolution required documentation that the precipitating problem was addressed (e.g., dose corrected, prophylaxis added, DDI mitigated).

Adverse drug reactions (ADRs)

ADR detection combined clinician documentation, laboratory signal detection (e.g., neutropenia thresholds), and review of emergency/unscheduled care. All events were graded by CTCAE v5.0; where multiple grades occurred for the same toxicity, the highest grade per patient during the window was analysed for summary tables. Causality was assessed with the Naranjo algorithm (definite/probable/possible/doubtful); severity with Hartwig & Siegel (mild/moderate/severe); and preventability with the Schumock–Thornton criteria. Agent-specific summaries were pre-specified for oxaliplatin neuropathy, irinotecan-associated diarrhoea, capecitabine hand–foot syndrome (HFS), and class-specific toxicities (bevacizumab-related hypertension/proteinuria/thromboembolism; anti-EGFR-related acneiform rash, hypomagnesaemia, infusion reactions). ADR incidence was reported as n/N (%) using the whole cohort denominator unless specified as "within-exposure."

Data Analysis

We summarized continuous variables as median (interquartile range [IQR]) and categorical variables as counts and percentages. For drug utilisation evaluation (DUE), we reported patient-level proportions for guideline-concordant regimen selection, achievement of relative dose intensity (RDI) ≥ 85%, on-time cycle delivery (±3 days), and appropriateness of antiemetic prophylaxis and primary granulocyte colony-stimulating factor (G-CSF) use. Drug-related problems (DRPs) were summarized as total count, rate per patient, distribution by PCNE v9.1 categories, and intervention acceptance/resolution rates. Adverse drug reactions (ADRs) were presented as incidence and highest CTCAE v5.0 grade per patient, with distributions by Naranjo causality, Hartwig severity, and Schumock–Thornton preventability.

Results and Discussion

The median age of 59 is below Western medians but consistent with Indian series (median ~50) (7), potentially reflecting demographic differences or the rising burden of CRC in younger adults. The 61% male predominance mirrors global patterns of higher CRC risk in men (8). Most patients (77%) had ECOG 0–1, supporting fitness for intensive therapy. The median BMI was 24.6 kg/m² (IQR 22.1–28.4), near the upper limit of normal; overweight/obesity is an established CRC risk factor (relative risk ~1.2–1.8 for BMI ≥25) (7), suggesting a substantial metabolic risk burden. Comorbid hypertension (36%) and diabetes (22%) were common, compared with ~22% and ~11% in prior CRC cohorts (9). CKD (stage ≥3) was present in 8%, comparable to ~10% in CRC surgical series (10). Notably, pre-surgical hypertension and hyperglycemia predict poorer post-resection prognosis (9). Overall, our cohort's comorbidity profile indicates a high burden of systemic illness that may adversely influence outcomes (Table 1).

Sixty-five percent had undergone major colorectal resection, consistent with surgery as the cornerstone of CRC care. An ostomy was present in 18%, within literature estimates that ~18–35% of CRC survivors require a temporary or permanent ostomy (11), likely reflecting distal/rectal tumors and some emergency resections. Among metastatic cases, 36% had ≥2 involved sites;

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

Table 1: Baseline characteristics and treatment setting (n=240)			
Characteristic	Overall	Adjuvant (n=108)	Metastatic (n=132)
Age, years, median (IQR)	59 (49–67)	58 (48–65)	60 (50–68)
Male sex, n (%)	146 (61)	62 (57)	84 (64)
ECOG 0–1, n (%)	186 (77)	93 (86)	93 (70)
BMI, kg/m², median (IQR)	24.6 (22.1–28.4)	24.2 (22.0–27.6)	24.9 (22.3–29.0)
Diabetes mellitus, n (%)	52 (22)	22 (20)	30 (23)
Hypertension, n (%)	87 (36)	38 (35)	49 (37)
CKD stage ≥3, n (%)	19 (8)	8 (7)	11 (8)
Hemoglobin, g/dL, median (IQR)	11.8 (10.6–12.9)	12.1 (11.0–13.0)	11.5 (10.4–12.7)
Albumin, g/dL, median (IQR)	3.6 (3.2–4.0)	3.8 (3.4–4.1)	3.5 (3.1–3.9)
Creatinine clearance <60 mL/min, n (%)	48 (20)	15 (14)	33 (25)
Prior major colorectal surgery, n (%)	157 (65)	103 (95)	54 (41)
Ostomy present, n (%)	43 (18)	26 (24)	17 (13)
Stage III / high-risk II (adjuvant), n (%)	—	92 (85) / 16 (15)	—
Stage IV (metastatic), n (%)	—	—	132 (100)
Left-sided primary, n/available (%)	—	—	78/132 (59)
≥2 metastatic sites, n (%)	—	—	48 (36)
Concomitant PPI, n (%)	60 (25)	24 (22)	36 (27)
Anticoagulation/antiplatelet use, n (%)	34 (14)	12 (11)	22 (17)
BMI = body mass index; CKD = chronic kidney disease; ECOG = Eastern Cooperative Oncology Group; IQR = interquartile range PPI = proton-pump inhibitor			

the most frequent were liver (54%), lung (28%), and peritoneum (22%), mirroring registry-based patterns in which the liver predominates (12). One-quarter used proton-pump inhibitors and 14% used anticoagulant/antiplatelet therapy; PPIs have not been shown to increase CRC risk in epidemiologic studies (13).

Care was largely guideline-concordant: 92% in the adjuvant setting and 82% in metastatic disease, comparable to multi-institutional reports (>90%) and a Canadian registry showing 87–94% adjuvant chemotherapy uses in stage III colon cancer (14,15). Median relative dose intensity (RDI) was 90% (IQR 82–97) for adjuvant therapy and 86% (IQR 78–95) for metastatic treatment, aligning with recommendations to maintain ≥80–85% in adjuvant CRC and roughly >90% in first-line metastatic settings to avoid compromising outcomes (16,17). Overall, 68% (adjuvant) and 60% (metastatic) achieved ≥85% RDI. Although our medians are high, these proportions indicate room to minimize avoidable dose reductions or delays (Table 2). Other series have reported lower component RDIs (~74–76% in adjuvant FOLFOX/CAPOX), and achieving >80% individual-agent dose intensity has been associated with improved survival (16). Calendar adherence was also robust: 74% (adjuvant) and 69% (metastatic) of cycles were delivered on schedule (±3 days), supporting maintenance of planned dose intensity.

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

Table 2: Drug utilisation evaluation (DUE) metrics

Metric	Adjuvant	Metastatic
Guideline-concordant regimen choice	92%	82% overall
Median RDI (IQR)	90% (82–97)	86% (78–95)
RDI ≥85%, % of patients	68%	60%
On-time cycle delivery (±3 days)	74%	69%
Appropriate antiemetic prophylaxis (moderate/high risk IV)	91%	88%
Primary G-CSF appropriate when indicated	80%	77%

DUE = drug utilisation evaluation; RDI = relative dose intensity; IQR = interquartile range; G-CSF = granulocyte colony-stimulating factor

Antiemetic prophylaxis was appropriate in 91% (adjuvant) and 88% (metastatic) of patients receiving moderate-to-high emetic risk regimens, consistent with guidance recommending at least a 5-HT3 receptor antagonist plus dexamethasone for oxaliplatin- or irinotecan-based combinations (19). These rates far exceed historical adherence, where MASCC-recommended prophylaxis was reported in only ~3% of similar CRC cases (19). Primary G-CSF was used per guidelines in ~80% of indicated adjuvant cases and 77% of metastatic cases, in line with NCCN/ASCO criteria (high-risk >20% FN risk; intermediate 10–20% with risk factors), yet still reflecting underuse comparable to prior analyses (20).

Chemotherapy-related drug-related problems (DRPs) averaged ~2 per patient, underscoring the complexity and narrow therapeutic index of oncology regimens. The most frequent category (29%) comprised monitoring/documentation/duplication issues—for example, missing lab checks, incomplete reconciliation, or redundant therapy—similar to audits that found limited dose verification and gaps in supportive-care planning (Table 3) (21,22). Effectiveness problems (28%), primarily underdosing or calculation errors, were also prominent. Common contributors included underestimated BSA or non-evidence-based BSA capping at 2 m^2 (58 instances); ASCO discourages unwarranted dose reductions in patients with obesity because they may compromise outcomes (23). We also observed 47 omissions of organ-impairment dose adjustments, consistent with reports of frequent non-compliance with labeling in moderate-to-severe renal dysfunction (24). Potential DDI-related risks accounted for 24% of DRPs, notably capecitabine–warfarin, capecitabine–phenytoin, and irinotecan with strong CYP3A4 inhibitors; these interactions are well documented, including bleeding with warfarin potentiation, phenytoin toxicity, and elevated toxicity risks with targeted agents and QT-prolonging combinations (22,25,26).

Adverse drug reactions (ADRs) were common: 77.9% of patients experienced at least one ADR of any grade, and 22.1% experienced a severe (grade ≥3) event. These rates are consistent with prior CRC cohorts and meta-analyses: one study reported 85.6% with any toxicity but 13.0% grade III–IV (27), while a meta-analysis reported ~45.7% with clinician-reported grade ≥2 toxicity, implying overall rates near 75–80% when milder events are included (28). Gastrointestinal/mucosal toxicities were frequent: moderate-to-severe nausea/vomiting occurred in 32.1% and oral mucositis/stomatitis in 15.8%. CRC regimens such as 5-FU, capecitabine, irinotecan, and oxaliplatin are classified as moderately emetogenic (baseline risk ~30–90% without prophylaxis), and clinically meaningful mucositis is well described in solid-tumor chemotherapy (Table 4) (29,30).

Horizontal bars show the proportion of patients with each event at the indicated CTCAE grade thresholds. Numeric labels denote counts and percentages (n/N, %). Agent-specific events are indicated in

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

Table 3: Drug-related problems (DRPs) coded by PCNE v9.1	
PCNE domain	n (%) of all DRPs
Treatment effectiveness (dose too low / incorrect calculation)	142 (28.2)
• BSA underestimation without indication	58 (11.5)
• Organ-function adjustment omitted (renal/hepatic)	47 (9.3)
• Unwarranted dose-intensity reduction (no criteria met)	37 (7.3)
Adverse-event risk: clinically relevant DDI	121 (24.0)
• Capecitabine–warfarin (↑INR/bleeding risk)	32 (6.3)
• Irinotecan + strong CYP3A4 inhibitor/inducer	26 (5.2)
• Capecitabine–phenytoin (↑phenytoin levels/toxicity)	18 (3.6)
• QT-prolonging combination (e.g., ondansetron + fluoroquinolone)	22 (4.4)
• Bevacizumab + therapeutic anticoagulation (↑bleeding risk)	23 (4.6)
Treatment safety: missing indicated prophylaxis	95 (18.8)
• Antiemetic under-prophylaxis for moderate emetogenic regimens	54 (10.7)
• Primary G-CSF not started despite FN risk threshold	29 (5.8)
• No loperamide plan for irinotecan	12 (2.4)
Monitoring / documentation / duplication	146 (29.0)
• Pre-cycle ANC delayed/missing	41 (8.1)
• Magnesium not monitored with anti-EGFR therapy	36 (7.1)
• Duplicate therapy (same-class antiemetics)	21 (4.2)
• Cycle delay without documented clinical justification	24 (4.8)
• Capecitabine adherence concern (missed doses)	24 (4.8)

Table 4: Adverse drug reactions (ADRs) by regimen/agent with CTCAE v5.0 grading	
ADR outcome	n/N (%)
Any-grade ADR (grade 1–5)	187/240 (77.9)
Grade ≥3 ADR (severe)	53/240 (22.1)
Nausea/vomiting grade ≥2	77/240 (32.1)
Oral mucositis/stomatitis grade ≥2	38/240 (15.8)
Diarrhea grade ≥3 (irinotecan-associated predominant)	22/240 (9.2)
Hand–foot syndrome (capecitabine) grade ≥2	34/240 (14.2)
Hand–foot syndrome grade ≥3	10/240 (4.2)
Peripheral sensory neuropathy (oxaliplatin) grade ≥2	67/240 (27.9)
Neutropenia grade ≥3	43/240 (17.9)
Thrombocytopenia grade ≥3	17/240 (7.1)
Anemia grade ≥3	19/240 (7.9)
Transaminase elevation (hepatotoxicity) grade ≥3	7/240 (2.9)
Severity (Hartwig): moderate / severe	94 (49.7) / 23 (12.3)
Preventability (Schumock–Thornton): preventable	56/187 (29.9)

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

parentheses (irinotecan—diarrhea; capecitabine—hand–foot syndrome; oxaliplatin—peripheral sensory neuropathy). Abbreviation: CTCAE, Common Terminology Criteria for Adverse Events

Agent-specific "signature" toxicities occurred at expected frequencies. Oxaliplatin-related peripheral sensory neuropathy reached grade ≥2 in 27.9%, consistent with high any-grade rates (>85%) but lower grade 3 rates (~10–18%) in trials (31). Irinotecan-associated diarrhea was observed at 9.2% grade ≥3, within real-world metastatic CRC ranges. Capecitabine-related hand–foot syndrome occurred in 14.2% at grade ≥2 (4.2% grade ≥3), in keeping with reports of common any-grade HFS (22–77%) but lower high-grade events (32,33). Hematologic toxicities were notable for grade ≥3 neutropenia in 17.9%, similar to pooled estimates in treated CRC populations, with comparatively lower rates of severe thrombocytopenia (7.1%) and anemia (7.9%)—a profile typical of 5-FU/oxaliplatin-based therapy (34).

By severity and preventability, roughly half of ADRs were "moderate" by Hartwig's scale and ~12% were "severe," comparable to chemotherapy series reporting predominantly moderate events with smaller severe fractions (35,36). Approximately 29.9% were "preventable" by Schumock–Thornton criteria, echoing other oncology studies that attribute a substantial minority of ADRs to preventable causes such as missed premedication, DDIs, or gaps in supportive care (35).

Clinical implications

The high DRP rate (2 per patient) and preventable ADRs (29.9%) highlight opportunities for clinical pharmacist intervention in CRC care. Focus should target monitoring gaps (29% of DRPs), dose optimization (28%), and DDIs (24%). Improving antiemetic prophylaxis, G-CSF use, and adherence to RDI ≥85% could enhance outcomes. Structured medication reviews and protocol-driven supportive care may reduce preventable toxicities while maintaining treatment efficacy in this complex patient population with significant comorbidities.

Limitations

This study has several limitations. The eight-month timeframe may not capture seasonal variations in treatment patterns. It is a single-center study may lack generalizability to diverse practice settings. We relied on routine clinical records, so some events may have been missed. Because of the observational design, associations cannot be interpreted as cause–effect. Some adverse drug reactions might have been under-identified through chart review alone.

Conclusion

This study identifies substantial drug-related challenges in CRC care, with 2 DRPs per patient and 29.9% of ADRs preventable. Major issues included monitoring gaps (29%), dose optimization (28%), and DDIs (24%). Despite reasonable guideline concordance, opportunities exist to improve RDI ≥85% achievement and supportive care. Clinical pharmacist interventions through structured medication reviews could reduce preventable toxicities while maintaining efficacy. Future research should evaluate prospective pharmacist-led interventions across diverse settings, assess cost-effectiveness of optimized medication management, and examine long-term survival outcomes associated with DRP resolution in CRC patients with comorbidities, particularly in resource-constrained healthcare systems where polypharmacy risks are amplified.

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Conflicts of Interest

The authors declare no conflicts of interest.

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.15

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