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Real-World Patterns of Immune-Related Toxicity in Gastrointestinal Cancer Patients Treated with Immunotherapy: A service evaluation

Authors: Laura Collantes Espinosa[1],✉ Wladzia Czuber-Dochan[2], Ann Muls[3]

Corresponding Author: laucollantes@gmail.com

Affiliation: [1,3]The Royal Marsden NHS Foundation Trust, London, UK., [2]Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King's College

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Affiliation: [1,3]The Royal Marsden NHS Foundation Trust, London, UK., [2,]Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King's College

ABSTRACT

Introduction: Immune checkpoint inhibitors (ICIs) have transformed cancer treatment and are now the standard therapy for several gastrointestinal (GI) malignancies. Although they can improve survival, ICIs are associated with immune-related adverse events (irAEs) that may affect multiple organ systems, potentially impacting treatment continuity and quality of life. Gastrointestinal toxicities, including diarrhoea and colitis, are among the most frequently reported adverse effects. As the use of ICIs expands, understanding the incidence and management of irAEs in routine clinical practice is essential. This service evaluation aimed to quantify ICI use in GI cancers at a tertiary cancer centre, determine the proportion of patients who developed irAEs, and describe referral and management patterns.

Methodology: A retrospective observational evaluation was conducted at a London-based hospital. Electronic health records were reviewed to identify patients with GI cancers treated with ICIs between October 2023 and October 2025. A subsequent subgroup analysis was performed for patients who developed irAEs. Data collected included irAE presentation, affected organ system, CTCAE grade, referral source, specialist involvement, and management, including hospital admission, treatment, follow-up, and ICI rechallenge. Findings were summarised using descriptive statistics.

Results: Fifty patients were included (mean age 62.2 years; 60% male). Tumour types included liver (50%), upper GI adenocarcinoma (44%), oesophageal squamous cell carcinoma (4%), and rectal cancer (2%). Most patients received first-line ICIs (92%) with palliative intent (90%). Overall, 20 patients out of 50 (40%) developed irAEs, most of which were grade 1–2 (90%). The most affected systems were the gastrointestinal tract (31.8%), skin (18.2%), joints (18.2%), and liver (13.6%), with diarrhoea and rash being the most frequent presentations. Most cases were identified during routine clinic review (59%), and 23.8% required hospital admission. Management included corticosteroids or supportive care, with multidisciplinary referral required in 35% of cases. Treatment discontinuation occurred in 22.7% of confirmed irAE events.

Conclusions: irAEs were common but largely manageable. These findings emphasise the need for structured monitoring and coordinated multidisciplinary care to support safe ICI delivery in routine practice.

Keywords: *Immune checkpoint inhibitors (ICIs); Immune-related adverse events (irAEs); Gastrointestinal cancers; Oncology nursing; Toxicity management.*

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INTRODUCTION

The development of immune checkpoint inhibitors (ICIs) represents a significant advancement in cancer therapy. ICIs work by harnessing the immune system to target malignant cells[1]. GI cancers include malignancies of the oesophagus, stomach, small intestine, colon, rectum, pancreas, and liver[2]. Collectively, they account for approximately 26% of the global cancer incidence and 35% of cancer-related deaths worldwide[3,4,5].

Multiple clinical trials have demonstrated that ICIs can offer durable responses and improved survival in selected GI cancer populations. Positive outcomes have been observed in upper GI and hepatobiliary (HPB) cancers, as well as in microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) colorectal cancer[6,7,8,9,10,11]. ICIs have become part of standard treatment protocols across several malignancies, including GI cancers[12].

Alongside their therapeutic benefits, ICIs have introduced a unique spectrum of toxicities known as immune-related adverse events (irAEs). These can affect multiple organ systems[13,14]. Gastrointestinal irAEs, such as diarrhoea and colitis, are among the most frequent and can range from mild to life-threatening[15]. One study[16] reported that 66% of patients receiving ICIs developed at least one irAE of any grade, 52% experienced grade ≥2 events, and 14% had grade ≥3 toxicities. The most common toxicities were endocrine (22.3 %), dermatological (19.8 %), gastrointestinal (17.9 %), pulmonary (14.2 %), and hepatic (9.1 %).

Different treatment regimens, such as single agent versus dual ICIs or combinations with chemotherapy, are associated with different irAE profiles. irAEs can affect patients' quality of life (QoL), treatment adherence, and clinical outcomes[16]. In addition, chronic or persistent irAEs are increasingly recognised as a long-term consequence of therapy and could have significant implications for survivorship and health-related QoL[17]. Management of irAEs often requires immunosuppressive treatment such as corticosteroids or biologics, treatment interruption, or permanent discontinuation of ICIs[18].

Although clinical trials have reported the incidence of irAEs, these data often come from highly selected patient populations with strict inclusion criteria and may not fully represent real-world clinical practice. Therefore, real-world evaluations can provide critical insights into the frequency, severity, and management of irAEs among patients with GI cancers treated with ICIs in routine care.

An increasing number of patients with GI cancers are being treated with ICIs as part of standard care at this tertiary cancer centre. However, local data on the incidence and management of irAEs in this population are not yet available. Evaluating this is important to determine the scale of toxicity within the service, identify areas for improved monitoring and patient support, and inform clinical decision-making and resource allocation.

This service evaluation therefore aimed to quantify the number of patients with GI cancers treated with ICIs, determine how many develop irAEs and describe subsequent management strategies. The findings will help improve patient care and inform future quality improvement initiatives and research.

The primary objective was to determine the proportion of patients who developed confirmed irAEs of any grade. The secondary objectives included characterising irAE presentation, affected organ systems, Common Terminology Criteria for Adverse Events (CTCAE) grade, referral pathways, and management strategies.

METHODOLOGY

This retrospective observational service evaluation was conducted at a tertiary cancer centre in London. Electronic health records were reviewed to identify patients with GI cancers treated with ICIs between October 2023 and October 2025. A total of 50 patients with GI malignancies receiving ICIs were identified and included in the service evaluation, with subgroup analysis performed for patients who developed immune-related adverse events (irAEs).

Eligible patients were identified from a GI oncology cohort at The Royal Marsden Hospital. Inclusion criteria comprised patients with GI malignancies treated with ICIs during the study period. Patients with non-GI tumour types were excluded.

Data were extracted from electronic patient records (EPIC) and institutional data service databases (RM Insight). Confirmed irAEs were identified through review of documented clinical assessments, investigations, management decisions, and multidisciplinary correspondence. irAE attribution was assessed retrospectively by review of the medical records by LCE. Where alternative causes were documented or judged more likely, these events were not classified as confirmed irAEs.

Adverse events were graded retrospectively using the Common Terminology Criteria for Adverse Events (CTCAE), based on documented clinical information in the medical records. The CTCAE classifies adverse events according to severity, from grade 1 (mild) to grade 5 (death related to an adverse event)[19].

Variables collected included demographic characteristics, tumour type, line and intent of treatment, irAE presentation, affected organ system, CTCAE grade, referral source (e.g. routine clinic, acute oncology service, emergency department), specialist involvement, and subsequent management. Management variables included hospital admission, treatment (e.g. corticosteroids or supportive care), follow-up, and ICI rechallenge, where applicable.

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Where patients experienced more than one confirmed irAE, each event was recorded separately. Patient-level denominators were used for cohort characteristics and the proportion of patients developing irAEs. Event-level denominators were used to describe the affected organ systems and treatment modifications. Missing data were recorded where identified.

Data were recorded in a secure, password-protected Excel database stored on the institutional network (T drive) accessible only to the person collecting the data. Patient identifiers were limited to hospital numbers for data linkage.

Descriptive statistics were used to summarise the data. No formal sample size calculation was performed, and all eligible patients within the study period were included.

This project was conducted as a service evaluation with reference number SE1567; therefore, formal research ethics committee approval was not required. Institutional governance processes were followed, including the submission of a project outline for review and approval prior to data collection and submission of results upon completion.

As this was a retrospective service evaluation using routinely collected clinical data, individual patient consent was not required under the institutional governance approval. Data were handled in accordance with the local information governance procedures.

RESULTS

Fifty patients were included in this service evaluation (mean age, 62.2 years; 60% male). Tumour types included hepatobiliary (n = 25, 50%) with 16 patients with a diagnosis of biliary tract cancer (BTC) and 9 patients with hepatocellular carcinoma (HCC), upper GI adenocarcinoma (n = 22, 44%), oesophageal squamous cell carcinoma (n = 2, 4%), and rectal cancer (n = 1, 2%).

Most patients received first-line ICIs (n = 46, 92%) with palliative intent (n = 45, 90%), indicating that the tumours were either metastatic or unresectable. In these cases, treatments are aimed at improving survival and QoL, as well as delaying tumour progression[20]. Most patients received up to 12 cycles of ICIs (n= 37, 74%), nine patients (18%) received between 12-24 cycles and three patients (6%) received more than 24 cycles; one patient received an unknown number of cycles. Most of these treatments are given in 3 weekly cycles meaning that 12 cycles equate to 9 months of treatment **(Table 1)**.

Table 1. *Patient Characteristics, irAEs and Management*

Category	Variable	N (%)	
Patient characteristics		Total patients	50
		Mean age (years)	62.2
		Male	30 (60%)
		Female	20 (40%)
Tumour type		Liver cancers (HCC, BTC)	25 (50%)
		Upper GI adenocarcinoma (oesophagus, GOJ, stomach)	22 (44%)
		Oesophageal squamous cell carcinoma	2 (4%)
		Rectal cancer	1 (2%)
Line of treatment		First line (new diagnosis)	41 (82%)
		First line (relapse/ progression)	5 (10%)
		Second line	2 (4%)

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	Not known	2 (4%)
Treatment intent	Palliative	45 (90%)
	Curative	2 (4%)
	Other	1 (2%)
	Not known	2 (4%)
Regimen	Durvalumab + Gemcitabine + Cisplatin (CISP 25, D1,D8)	16 (32%)
	Nivolumab (360,3W)	11 (22%)
	Nivolumab + Ipilimumab (240/1)	1 (2%)
	Pembrolizumab + Trastuzumab + CAPOX	9 (18%)
	Atezolizumab + Bevacizumab	8 (16%)
	Tremelimumab (300MG) AND Durvalumab (1500MG, 4W)	1 (2%)
	Nivolumab + Regorafenib (NIVO D1,D15)	1 (2%)
	CAPOX + Pembrolizumab	1 (2%)
	Nivolumab (360,3W)/CARBOX	1 (2%)
	Nivolumab (360,3W)/CAPOX	1 (2%)
Number of cycles received	1-5	22 (44%)
	6-12	15 (30%)
	12-24	9 (18%)
	>24	3 (6%)
	Not known	1 (2%)

Key: irAE: Immune related adverse event, HCC: Hepatocellular carcinoma, BTC: Biliary Tract Cancer, GI: Gastrointestinal, GOJ: Gastro-oesophageal junction, CAPOX: Capecitabine+ oxaliplatin, CARBOX: Carboplatin+ capecitabine

Overall, 20 of the 50 patients (40%) developed confirmed irAEs. Among these 20 patients, the maximum recorded CTCAE grade was grade 1 in 13 (65%), grade 2 in five (25%), and grade 3 in two (10 %) patients. No grade 4 or 5 irAEs were recorded. Because some patients experienced more than one confirmed irAE, a total of 22 irAE events were recorded. The most affected systems were the gastrointestinal (n = 7), skin (n = 4), joints (n = 4), and liver (n = 3), with diarrhoea and rash being the most frequent presenting symptoms.

Complete time-to-onset data were available for 19 confirmed irAE events. The mean time from ICI initiation to irAE onset

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was 145.8 days, with a range of 20 to 502 days.

Most suspected immune-related toxicity presentations were identified during routine clinic reviews (n = 13, 59%), while the remainder were identified through hotline or other referral pathways (n = 9, 41%), emphasising the importance of structured symptom assessment and proactive monitoring.

Hospital admission data were available for 21 patients assessed for suspected immune-related toxicity; five (23.8%) required hospital admission, whereas the remainder were managed through ambulatory pathways.

Management commonly included corticosteroids (topical, oral, or intravenous, depending on severity) or supportive interventions. Specialist multidisciplinary referral was required in seven patients (35%).

Treatment remained unchanged in 8 of 22 irAE events (36.4%), was temporarily interrupted or delayed in 9 (41%), and was permanently discontinued in 5 (22.7%). In one case, treatment was temporarily interrupted because of suspected myocarditis, but it was resumed after this diagnosis was excluded. **Tables 2 and 3** provide further details.

Table 2. *Patient-level summary of immune-related adverse events (irAEs)*

Category	Variable	N (%)
Full cohort	Patients treated with ICIs	50 (100%)
irAE status	Patients with confirmed irAEs	20 (40%)
2 (4%)		
Maximum CTCAE grade (patients with confirmed irAEs)	Grade 1	13 (65%)
	Grade 2	5 (25%)
	Grade 3	2 (10%)
Specialist referral	Required	7 (35%)

Key: irAEs: Immune-related adverse events CTCAE: Common Terminology Criteria for Adverse Events ICI: Immune checkpoint Inhibitors

Table 3. *Event-level summary of confirmed immune-related adverse events (irAEs)*

Category	Variable	N (%)
Confirmed irAEs	Total confirmed irAEs	22
Affected organ	Gastrointestinal	7 (31.8%)
	Skin	4 (18.2%)
	Joints	4 (18.2%)
	Liver	3 (13.6%)
	Others (thyroid, bladder, lung, adrenal)	4 (18.2%)

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Referral source	Routine clinic	13 (59%)
	Hotline / other routes	9 (41%)
Hospital admission (n = 21)	Yes	5 (23.8%)
	No	16 (76.2%)
Treatment modification (confirmed irAE events, n = 22)	None	8 (36.4%)
	Temporary interruption / delay	9 (41%)
	Treatment stopped	5 (22.7%)
Time from ICI initiation to onset of confirmed irAE with available data (n = 19)	Mean number of days	145.76
	Minimum	20
	Maximum	502

Key: irAEs: Immune-related adverse events CTCAE: Common Terminology Criteria for Adverse Events ICI: Immune checkpoint Inhibitors

DISCUSSION

The findings of this evaluation reflect the increasing integration of ICIs into routine GI oncology practice. In this real-world cohort, 20 of 50 patients developed confirmed irAEs, resulting in a patient-level irAE proportion of 40%. Most patients who developed irAEs experienced grade 1–2 toxicity, while two patients experienced grade 3 events. Gastrointestinal, skin, joint, and liver toxicities were the most frequently observed. These findings are consistent with the recognised multisystem nature of ICI toxicity and highlight the need for robust monitoring pathways in routine GI oncology services.

A key challenge identified was the recognition of irAEs, which frequently present with nonspecific or mild symptoms. This creates a risk of delayed identification in routine clinics, where such symptoms may be easily attributed to other causes, including disease progression and treatment-related fatigue[21,22]. This is particularly relevant in GI oncology, where diarrhoea, abdominal symptoms, fatigue, deranged liver function, and general deterioration may have multiple potential causes. These results reinforce the importance of structured symptom assessment and clear documentation of new or worsening symptoms in patients treated with ICIs.

Most confirmed irAE events in this evaluation were identified during routine clinic reviews, while the remainder were detected through hotline or other referral pathways. This finding emphasises the importance of systematic toxicity screening during scheduled consultations, alongside accessible routes for patients to report symptoms between appointments. Nurses must maintain a high level of vigilance for irAEs when patients report symptoms during any clinical encounter. Early recognition is critical, as prompt intervention could prevent progression to more severe toxicity or discontinuation of treatment.

Patient-reported symptoms should be assessed consistently and escalated appropriately across all nursing practice levels. For nurses working at foundational levels, assessment is generally protocol-driven and focuses on early recognition, documentation, and escalation. In this role, nurses act as key gatekeepers, ensuring that early signs of irAEs are not overlooked during routine reviews or patient contact[23]. At advanced practice level, Clinical Nurse Specialists (CNSs) and Advanced Nurse Practitioners (ANPs) contribute to more complex assessments, investigations, treatment modification discussions, advanced symptom management, and coordination with specialist teams. This expanded scope is important, but it also introduces additional workload and service capacity pressures[24,25,26,27,28].

The findings of this evaluation demonstrate the need for timely multidisciplinary involvement, consistent with the current literature[13]. Seven patients with confirmed irAEs

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required specialist referral, and five patients with toxicity required hospital admission. Therefore, although most irAEs were grade 1–2, the service impact should not be underestimated. These findings support the need for clear referral pathways between oncology and other specialties, depending on the affected organ.

Patient education is central to the early detection of toxicity. Patients need clear information about potential irAEs, when to seek advice, and why symptoms should be reported promptly, even if they are mild. This is particularly important because immune-related toxicity can develop weeks or months after treatment initiation and may occur after treatment is interrupted or discontinued. Without adequate education, early symptoms may not be reported, contributing to delays in assessment and management[13,29,30,31].

Several practical strategies have emerged from this evaluation. Structured toxicity assessment during routine consultations, nurse-led telephone triage, hotline support, clear escalation pathways, and formalised multidisciplinary referral processes may support earlier recognition and more consistent management of irAEs. These approaches are especially relevant given that treatment was temporarily interrupted or delayed in nine of the 22 confirmed irAE events and permanently discontinued in five events. However, the effectiveness of these strategies depends on adequate staffing, training, documentation systems, and organisational support[32].

The finding that permanent treatment discontinuation occurred in five of 22 confirmed irAE events (22.7% of events) suggests that many irAEs were managed without permanent cessation of immunotherapy. However, this should be interpreted with caution. Treatment interruption, hospital admission, and specialist referral were required in a clinically significant proportion of cases. Therefore, the results support the conclusion that many irAEs were manageable with appropriate intervention but not that irAEs were low-risk or low-impact.

The implications for oncology nursing practice are significant. As ICIs become increasingly established in GI oncology, nursing roles are evolving to include structured toxicity assessment, patient education, early escalation, triage, and coordination of care. This evaluation supports the need for ongoing immunotherapy education, competency development, and service-level pathways to enable nurses to consistently recognise and escalate suspected irAEs. These systems are particularly important in real-world practice, where patients may have complex disease, multiple treatment-related symptoms, and comorbidities that make attribution challenging.

This service evaluation has several limitations. It was retrospective and conducted at a single tertiary cancer centre, with a relatively small sample size. Therefore, the findings may not be generalisable to other centres or patient populations. IrAE identification and grading depended on the quality and completeness of documentation in the electronic health record, meaning that mild or self-managed symptoms may have been underreported. The attribution of symptoms to ICIs was based on a retrospective clinical record review, and competing causes such as disease progression, infection, chemotherapy toxicity, comorbidities, or other medications may have affected the classification. Some data were incomplete, including time-to-onset and hospital admission data for all the events. The evaluation also did not include a comparator group; therefore, it could not determine whether toxicity patterns differed from those of patients receiving non-ICI treatments.

Despite these limitations, this evaluation provides useful real-world insights into the frequency, presentation, referral pathways, and management of irAEs among patients with GI cancers receiving ICIs. The findings support structured toxicity assessment, patient education, nurse-led triage, clear escalation pathways, and multidisciplinary collaboration as key components of safe immunotherapy care in routine GI oncology.

CONCLUSION

irAEs were common but largely manageable, indicating that while toxicity remains a frequent consequence of ICI therapy, it does not necessarily preclude treatment continuation. These findings emphasise the importance of structured monitoring and coordinated multidisciplinary care to support the safe and effective delivery of ICIs in routine clinical practice.

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