

ORIGINAL ARTICLE

# Patient-Reported Experience Measures (PREMs) in patients with metastatic colorectal cancer undergoing treatment supported by feedback auditing: the EPIC study

A. Sartore-Bianchi<sup>1,2,3†\*</sup>, F. Toscano<sup>4‡</sup>, D. P. Bernasconi<sup>3,5‡</sup>, A. Curaba<sup>1,2</sup>, P. Colombo<sup>4</sup>, C. Mazzali<sup>4</sup>, A. Piantelli<sup>4</sup>, A. Dotti<sup>4</sup>, D. Tedesco<sup>4</sup>, K. Bencardino<sup>2</sup>, A. Amatu<sup>2</sup>, F. Tosi<sup>2</sup>, E. Bonazzina<sup>2</sup>, F. Villa<sup>2</sup>, V. Gori<sup>1,2</sup>, D. Piscazzi<sup>1,2</sup>, A. G. Agostara<sup>1,2</sup>, G. Calvanese<sup>1,2</sup>, G. Saporetti<sup>4‡§</sup> & S. Siena<sup>1,2§</sup>

<sup>1</sup>Department of Oncology and Hemato-Oncology, Università degli Studi di Milano (La Statale), Milan; <sup>2</sup>Department of Hematology, Oncology, and Molecular Medicine, Grande Ospedale Metropolitano Niguarda, Milan; <sup>3</sup>Division of Clinical Research and Innovation, Grande Ospedale Metropolitano Niguarda, Milan; <sup>4</sup>Division of Quality and Risk Management, Grande Ospedale Metropolitano Niguarda, Milan; <sup>5</sup>Bicocca Bioinformatics, Biostatistics and Bioimaging Centre – B4, Department Medicine and Surgery, Università degli Studi di Milano-Bicocca, Monza, Italy

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**Background:** Patient-reported experience measures (PREMs) offer an objective measure of the patient experience by investigating various fields of the care pathway. We analyzed PREMs in patients with metastatic colorectal cancer (mCRC) undergoing anticancer therapy integrating an auditing process to allow corrective actions.

**Materials and methods:** This is a prospective, observational, monocentric study with a four-phase sequential design: phase I validation of the PREMs questionnaires in five-level Likert item format in Italian; phase II administration of questionnaires at T0 (0-30 days since the start of oncology care), T1 (30 days-6 months), T2 (6-12 months), T3 (>12 months); phase III analysis of results during quality audits and implementation of strategies to improve care pathways; phase IV re-administration and results compared with phase II.

**Results:** PREMs were tested for validity in 47 patients (phase I of the EPIC study). In phase II, 102 patients were enrolled, 150 questionnaires were administered and 142 returned (94.6%). Sixteen questions grouped in four areas (information about care path, contacts and accessibility, patient needs, health care awareness monitoring) were analyzed. A high proportion of patients were concerned about their future/possibility of relapse at T1 (61.6%/58.3%) and T2 (62.5%/63.7%). After the implementation of a checklist for clinicians (phase III), in phase IV, 74 patients were enrolled and the proportion of patients concerned about their future/possibility of a relapse decreased at T1 (35.7%/25%) and T2 (31.3%/43.4%).

**Conclusions:** PREMs evaluation is feasible in the setting of mCRC. A checklist for clinicians tailored after an *ad hoc* audit improved results about patients' concerns about their future and possibility of relapse.

**Key words:** PREMs, metastatic colorectal cancer, healthcare pathway, feedback auditing, checklist

## INTRODUCTION

In the evaluation of health care quality, the perspective and experience of the patient play a pivotal role.<sup>1-3</sup> Traditional clinical metrics like mortality rates often fall short in capturing this perspective.<sup>4</sup> Over the past decade, Patient-Reported Measures (PRMs), which encompass data

provided directly by patients, have gained prominence.<sup>5-11</sup>

These include patient-reported outcome measures (PROMs), assessing health-related quality of life and symptoms, and patient-reported experience measures (PREMs), which gauge patients' experiences with health care.<sup>9,12,13</sup> PROMs are designed to capture the perspectives of patients on various aspects of their health, including their quality of life, physical abilities, and specific symptoms related to their condition or treatment.<sup>6,14-16</sup> On the other hand, PREMs provide objective insights into user experiences, focusing on relational and functional aspects of care (e.g. accessibility of services, waiting times for appointments, attention to pain, involvement in care decision making, information provided by health care providers, and promptness of assistance).<sup>17-22</sup> While concerns exist about

\*Correspondence to: Prof. Andrea Sartore Bianchi, University of Milan Department of Oncology and Hematology-Oncology, Milan, Italy. Tel: +39 02 6444 2291

E-mail: [andrea.sartorebianchi@ospedaleniguarda.it](mailto:andrea.sartorebianchi@ospedaleniguarda.it) (A. Sartore-Bianchi).

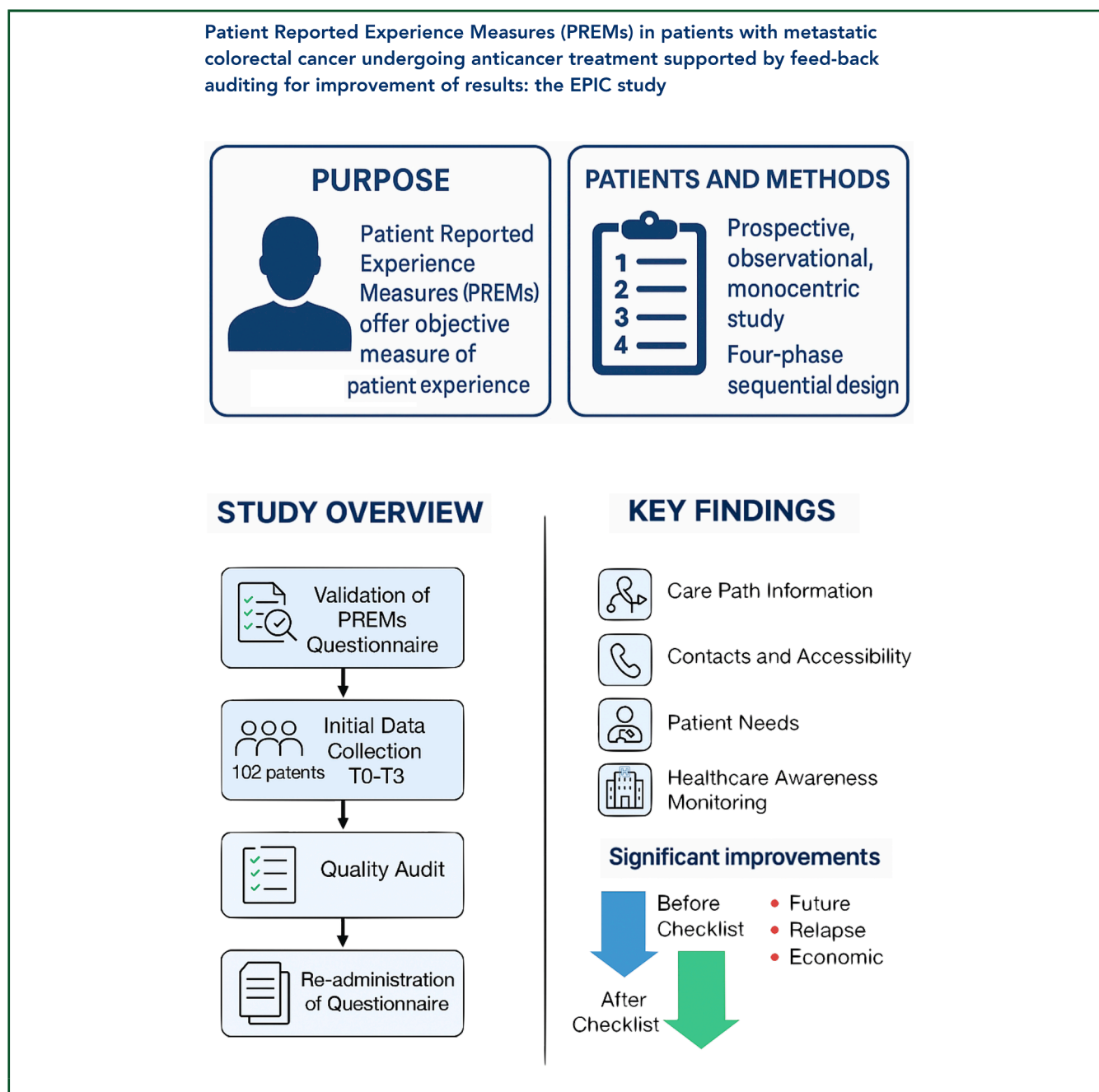
†Equally contributed as first authors.

‡Present address: ASST Rhodense, Milan, Italy.

§Equally contributed as last authors.

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**GRAPHICAL ABSTRACT**

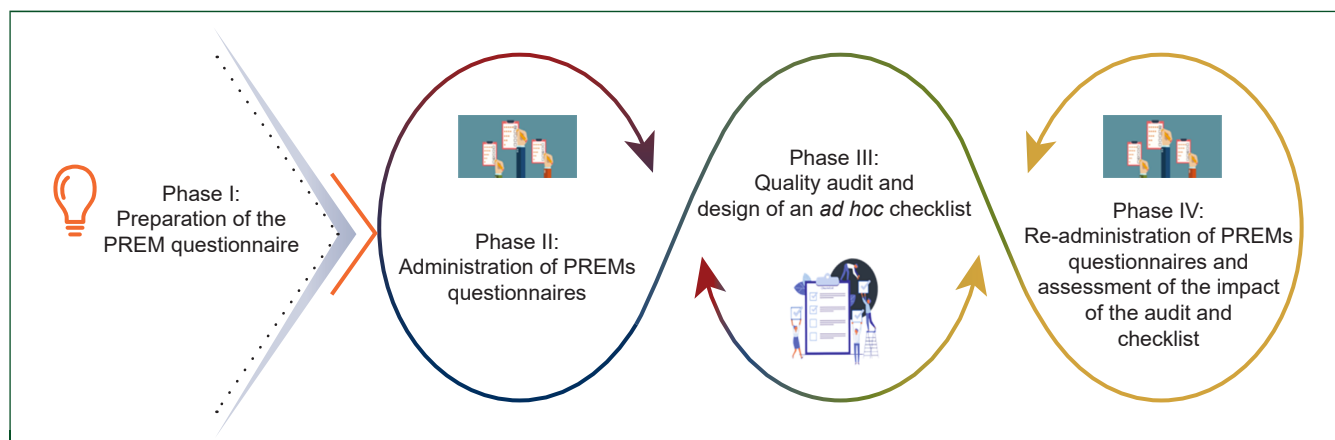


their credibility,<sup>23</sup> patient experience measures have demonstrated their value as strong indicators of health care quality.<sup>24</sup> Thus, incorporating PREMs into health care performance assessment can identify areas for improvement and foster a real-time connection between patients and their care team, ultimately enhancing patient comfort and engagement.<sup>17,25,26</sup>

Due to the multifactorial nature of the oncological journey, it is becoming increasingly important to develop personalized pathways, because each patient is unique and this is reflected both in a patient’s response to medical treatments and in the way of reacting in the disease stages.<sup>27</sup> Several studies demonstrate that the adoption of

PREMs in oncology is increasing,<sup>28</sup> facilitated by international initiatives like the Cancer Patient Experience Survey (CPES)<sup>29</sup> and the Consumer Assessment of Healthcare Providers and Systems (CAHPS).<sup>30,31</sup> In view of the complexity that characterizes the oncological field, as reported by the evidence review conducted by Saunders et al.,<sup>28</sup> it is necessary to adopt measures of evaluation of PREMs specific to the type of cancer. This shows that some PREMs questionnaires that are valid for one context may not be valid for another.

In clinical medicine, the audit process is a systematic and critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of



**Figure 1. EPIC Study design.**  
PREMs, Patient-Reported Experience Measures.

resources, and the resulting outcome and quality of life for the patient.<sup>32</sup> Audits are essential in maintaining and improving the standard of patient care. They involve a cycle of measuring performance against established standards and implementing changes to improve compliance with these standards. The integration of an audit process in the context of PREMs can be particularly vital. Indeed, it would allow health care providers to continually assess and enhance the patient experience based on direct feedback from patients. More in detail, after the collection of PREMs data and a performance analysis to identify areas where the patient experience meets the set standards and where there are gaps or shortcomings, specific changes or interventions can be designed and implemented, ranging from staff training in communication skills to changes in the scheduling system to reduce waiting times. Finally, after implementing changes, a re-audit is essential. New PREMs data can be collected to assess the impact of the changes on patient experience, evaluating whether the implemented changes have led to improvements in the areas previously identified as lacking. Along these lines, the audit process in conjunction with PREMs can be cyclical. Based on the findings of the re-audit, further changes can be made, followed by subsequent re-audits, ensuring ongoing improvement in patient experience and care quality.

This integration of an audit process with PREMs can be particularly beneficial in the treatment and management of diseases with complex care pathways, such as colorectal cancer (CRC). CRC stands as the third most frequently diagnosed cancer globally and represents the third leading cause of cancer-related death in both males and females.<sup>33</sup> Over the past four decades, the 5-year relative survival rate for CRC has increased from 50% to 65% due to significant progress in detection methods, treatments, and surgical procedures.<sup>34</sup> While metastatic CRC (mCRC) poses substantial challenges, developments in targeted therapies and enhanced surgical interventions have extended the life expectancy of patients.<sup>35–39</sup> The heightened survival rate, combined with an aging population, has led to a notable rise in cancer survivors, ~10% of whom are living with metastatic cancer.<sup>34,40,41</sup> Patients

affected by mCRC, receiving the most advanced cancer treatments, face a wide range of psychological, emotional, and practical difficulties. Therefore, it is essential to understand how the treatment impacts the patient's overall experience, with the aim of implementing improvement strategies to make the patient care journey more tolerable.

### Rationale and objectives

To date, there are no available data on the experiences of patients undergoing oncological therapy for mCRC, and the application of an audit process to improve PREMs in cancer patients has not been tested.

The primary objective of this study was to assess the quality of cancer care as perceived by patients with mCRC using a standardized PREM tool, with the goal of identifying areas of strength and potential improvement within the oncology care pathway. The secondary objective was to assess the impact of corrective strategies guided by the audit process on PREM results.

### MATERIALS AND METHODS

The EPIC trial is a single-center, observational study targeting patients aged  $\geq 18$  years with mCRC receiving oncological therapy at the Niguarda Cancer Center, Grande Ospedale Metropolitano Niguarda, Milan, Italy. The study adopts a four-phase sequential design (Figure 1). Phase I focused on questionnaire validation and assessment of face validity (Supplementary Figure S1, available at <https://doi.org/10.1016/j.esmogo.2025.100224>). In Phase II, the questionnaire was administered and the results were analyzed. Phase III consisted of quality audits aimed at identifying areas for improvement and developing corrective measures, including the design of a checklist for clinicians. Finally, in Phase IV, the questionnaire was re-administered after the planned interventions, and the results were compared with the pre-audit baseline.

The validated PREM questionnaire consists of a paper-based survey in Italian of 16 questions with a response in

**Table 1. Selected items from the PREMs questionnaire, organized into four thematic areas to guide the development of a clinician checklist for targeted corrective actions.**

<b>Area 1 - Information about care path</b>	
Q1	I received clear information about the therapy
Q2	I received clear information about the side effects
Q3	I received clear information about possible problems and complications
Q4	I received clear information about next steps of care path
Q5	I received clear advice on habits and lifestyles to lead (e.g. physical activity, nutrition, smoking)
<b>Area 2 - Contacts and accessibility</b>	
Q6	I received clear information about who to contact in case of need
<b>Area 3 - Patient needs</b>	
Q7	At my first oncology visit or during treatment, the health care staff did everything they could to control my pain
Q8	It is important at this time to be followed up nutritionally as well
Q9	The assistance of a psychologist during the course of treatment would be helpful
Q10	The oncologist helped to deal with fears and anxieties about my health condition
Q11	I do not have concerns related to the side effects of the therapy
Q12	I do not have concerns related to the future
Q13	I do not have concerns related to possible relapse
Q14	I am not afraid of death
Q15	I do not have concerns related to economic aspects
<b>Area 4 - Health care awareness monitoring</b>	
Q16	I gathered information on the internet about the possible effects of the cancer therapy I will undergo/ have undergone

PREMs, Patient-Reported Experience Measures.

**Table 2. Baseline characteristics of patients enrolled before and after the adoption of the checklist**

Variables	Pre-checklist n = 102	Post-checklist n = 74
<b>Median age (range), years</b>	63 (33-85)	61 (30-84)
<b>Sex, n (%)</b>		
Female	44 (43)	31 (41, 89)
Male	58 (57)	43 (58, 11)
<b>Social status, n (%)</b>		
Living alone	14 (14)	9 (12)
Living with caregiver	88 (86)	65 (88)
<b>Level of education, n (%)</b>		
No answer	2 (2)	0
Less than high school (HS)	41 (40)	22 (30)
HS or college	36 (35)	31 (42)
University or more	23 (23)	21 (28)
<b>Type of occupation, n (%)</b>		
No answer	1 (1)	1 (1)
Housewife	8 (8)	6 (8)
Unemployed	3 (3)	4 (5)
Temporary or atypical worker	1 (1)	1 (1)
Permanent worker	21 (21)	18 (24)
Self-employed	24 (23)	17 (23)
Retired	41 (40)	23 (31)
Other	3 (3)	4 (5)
<b>Extension of disease at presentation n (%)</b>		
De novo metastatic	56 (55)	38 (51)
Recurrent/metachronous metastatic	46 (45)	36 (49)
<b>Type of oncological treatment n (%)</b>		
Chemotherapy + anti-EGFR agent	47 (46)	36 (48)
Chemotherapy + anti-VEGF agent	34 (33)	26 (35)
Immunotherapy	3 (3)	1 (2)
Chemotherapy alone	2 (2)	2 (3)
TKI (regorafenib, trifluridine-tipiracil)	7 (7)	3 (4)
Clinical trial	9 (9)	6 (8)

EGFR, epidermal growth factor receptor; TKI, tyrosine kinase inhibitor; VEGF, vascular endothelial growth factor.

five-level Likert scale format: ‘strongly disagree, disagree, neutral, agree, strongly agree’.

For patient recruitment, the questionnaire was administered to those scheduled for same-day visit or next-day therapy, after discussing with medical staff and signing the informed consent form for participation in the study. The PREM questionnaire was given at four timepoints during oncology care, each corresponding to a specific phase: T0 (0-30 days from the start of treatment), T1 (30 days-6 months), T2 (6-12 months), and T3 (>12 months). Patients were also required to complete a personal information form, providing details such as sex, age, education level, citizenship, region of residence, occupation, and social status, including caregiver support.

**Statistical analysis**

Data from the questionnaires were inputted into the REDCap database<sup>42</sup> by authorized personnel. Descriptive analyses were performed, calculating the frequency distribution of responses to each question, comparing the results between questionnaires administered before and after the implementation of quality audits and separately for each timepoint. Due to the absence of a single primary outcome of interest and the fact that the sample size was not calculated a priori to reach a target power, the statistical analysis conducted is purely descriptive, avoiding inferential evaluations. The analysis was conducted using R version 4.3.2.

**Ethical considerations**

The study obtained approval from the Ethics Committee of Grande Ospedale Metropolitano Niguarda, Milan, Italy, (identification code NCT44201072021) and all patients signed informed consent for participating to the study.

**RESULTS**

**Preparation of the PREM questionnaire (phase I)**

Starting with the questionnaire models available in literature, a PREM questionnaire was tailored to the oncological context of mCRC. For surveys to be reliable and applicable in clinical practice, their validation is crucial.<sup>22</sup> The EPIC study questionnaire has been developed based on PREM models<sup>1,2,20,43</sup> and more specifically on the PREMs developed by the Sant’Anna School of Advanced Studies in Pisa.<sup>44</sup> In the pre-testing phase, focus groups involving staff from the Department of Oncology and the Department of Quality and Clinical Risk at Grande Ospedale Metropolitano Niguarda, along with a team of dietitians, psychologists, and PREMs experts, were conducted to identify issues in cancer patient treatment. The subsequent questionnaire was assessed by health care professionals, non-health care staff, a linguistic expert, and some patients at Grande Ospedale Metropolitano Niguarda to refine it

**Table 3.** Distribution of PREMs questionnaires according to: whether the questionnaire was administered before or after the adoption of the checklist; the time of administration of the questionnaire; the ongoing line of treatment for mCRC at the time of questionnaire administration [categorized as follows: first-line (L1), second-line (L2), third-line (3L), and more than three lines of therapy (>L3)]

	Phase II Pre-checklist				Phase IV Post-checklist			
	T0	T1	T2	T3	T0	T1	T2	T3
L1 n (%)	22 (71)	25 (67)	8 (47)	14 (39)	15 (88)	26 (90)	22 (67)	11 (42)
L2 n (%)	2 (6)	4 (11)	5 (29)	4 (11)	1 (6)	2 (7)	10 (30)	11 (42)
L3 n (%)	2 (6)	1 (3)	0 (0)	4 (11)	1 (6)	1 (3)	0	2 (8)
>L3 n (%)	5 (16)	7 (19)	4 (24)	14 (39)	0	0	1 (3)	2 (8)
NA	—	—	8	13	—	1	—	—
<b>Total</b>	<b>31</b>	<b>37</b>	<b>25</b>	<b>49</b>	<b>17</b>	<b>30</b>	<b>33</b>	<b>26</b>

mCRC, metastatic colorectal cancer; PREMs, patient-reported experience measures.

(Supplementary Figure S1, available at <https://doi.org/10.1016/j.esmogo.2025.100224>). For the ‘face-validity’, the PREM questionnaire was administered to a pool of patients along with an additional brief questionnaire, consisting of a translation in Italian of the tool proposed by Burns et al. in 2008<sup>45</sup> to investigate the completeness, clarity, and level of understanding of the items of the questionnaire. These processes led to the development of the EPIC PREM questionnaire (Supplementary Material S1, <https://doi.org/10.1016/j.esmogo.2025.100224>). For the purpose of subsequent analyses regarding the impact of the audit, we selected the sixteen most relevant questions, as judged through the focus groups, grouped in four areas (information about care path, contacts and accessibility, patient needs, and health care awareness monitoring) in order to facilitate corrective actions (Table 1).

#### Administration of PREMs questionnaires (phase II)

During the period from July 2021 to January 2023, 102 patients enrolled from the outpatient service; among them, 5 (4.9%) did not continue participation due to death.

The sociodemographic and clinical characteristics of the population are reported in Table 2. The median age was 63 years, ranging from 33 to 85 years, with a majority of male participants (57%). Additionally, Table 2 reports the type of clinical presentation (*de novo* or recurrent disease) and the ongoing therapy at the time of first data collection. The most common treatments were chemotherapy combined with anti-epidermal growth factor receptor (EGFR) or anti-vascular endothelial growth factor (VEGF) agents, reflecting the majority of enrolled patients in first-line (L1).

A total of 150 questionnaires were administered and 142 returned. The response rate was 94.6%. The distribution of questionnaires across the prespecified timepoints was as follows: 31 at T0, 37 at T1, 25 at T2, and 49 at T3 (Table 3). Regarding the treatment line ongoing at the time of questionnaire administration, this was described as L1, second-line (L2), third-line (3L), and more than three lines of therapy (>L3). At T0, the majority of questionnaires were administered to patients in the L1 (71%), gradually decreasing to 39% at T3 (Table 3).

The distribution of responses to the selected questions for the four different areas (information about care path, contacts and accessibility, patient needs, and health care

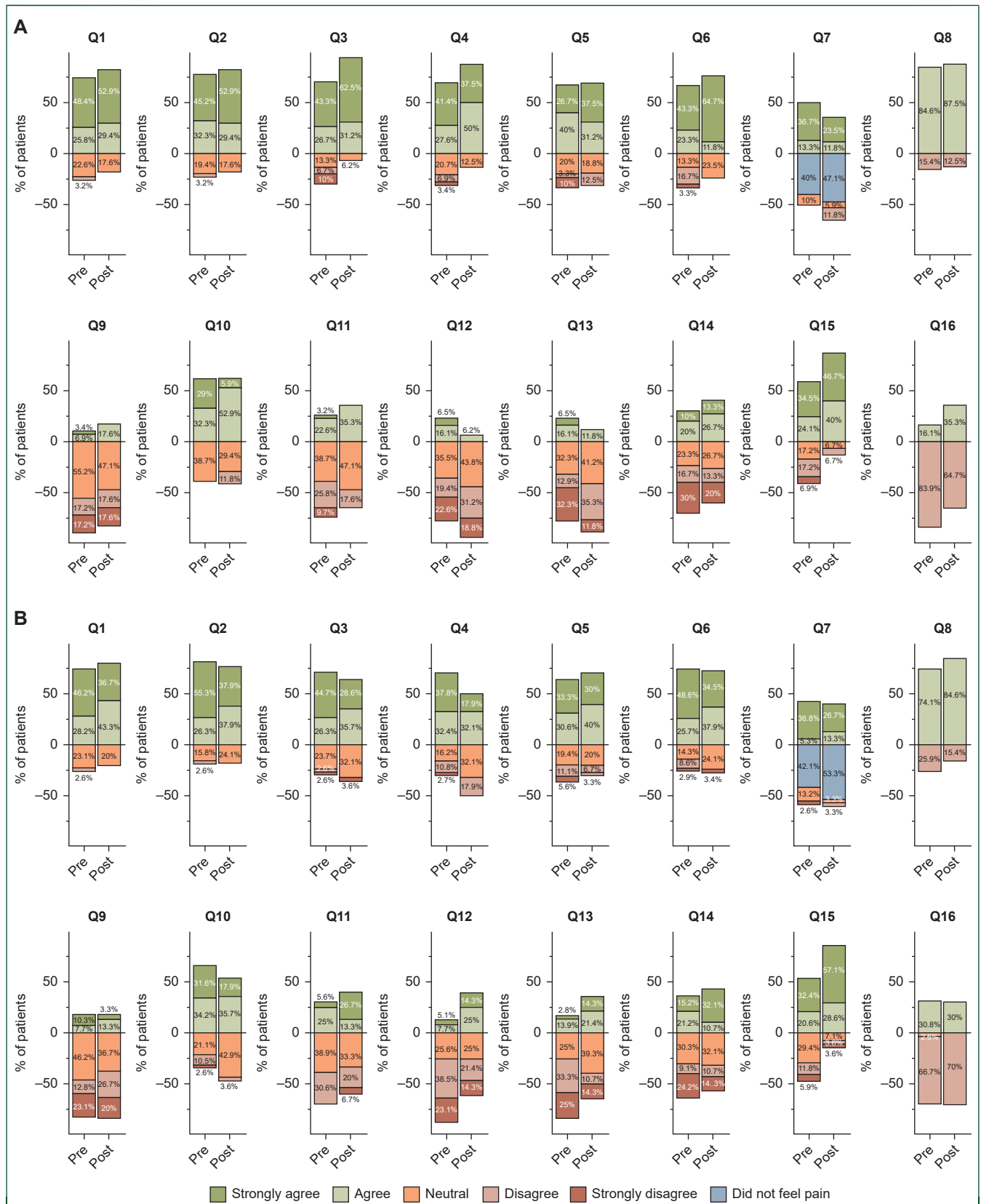
awareness monitoring) (Table 1) is reported in Figure 2A-D for each timepoint T0, T1, T2 and T3, respectively. At all timepoints, the majority of patients were satisfied (strongly agree or agree) with the information received about the care path (Q1-Q5) and with who to contact in case of need (Q6). Pain control (Q7) was judged inadequate by 40% (at T1 and T3) to 50% (at T0 and T2) of patients. At all timepoints, 60%-85% of patients considered it useful to be followed from a nutritional point of view (Q8) but a minority (10%-30%) believed that the assistance of a psychologist during the course of treatment could be helpful (Q9). Around 60% of patients believed that the oncologist helped to deal with fears and anxieties about the health condition (Q10) and this proportion was roughly constant across all timepoints. The most common concerns (Q11-Q15) were about the future (Q12) and the possibility of relapse of the disease (Q13), especially at time T1 (61.6% and 58.3%, respectively) and T2 (62.5% and 63.7%, respectively). Finally, a low proportion of patients declared they did or were willing to gather information on the internet about the possible effects of the cancer therapy (Q16) at T0 (16.1%) but this percentage increased to nearly 30%-35% at timepoints T1, T2 and T3.

#### Quality audit and design of an ad hoc checklist (phase III)

In phase III of the study, the results were discussed within the Division of Quality and Risk Management, focusing on underperforming areas and on identifying potential corrective strategies to be applied for improving the results. An audit was then performed with the staff of doctors and nurses of the Division of Oncology. This led to the development of a ‘checklist’ to be implemented in daily clinical use for health care practitioners, aiming to highlight crucial areas in patients’ perception of care that might necessitate refinement (Figure 3).

#### Re-administration of PREMs questionnaires and assessment of the impact of the audit and checklist (phase IV)

After the adoption of the checklist in the daily clinical routine of the health care staff (from July 2023 to March 2024), 74 patients were enrolled from the outpatient service, of which 21 came from phase II of the study. In this



**Figure 2.** Comparison of the responses to questions Q1-Q16 between the first (pre-checklist) and the second (post-checklist) administration of the questionnaire at time T0 (A), T1 (B), T2 (C), and T3 (D). In each panel, one stacked bar plot for each question is shown representing the percentage of each answer (Likert scale) given by patients. To ease the visual comparison between the results to each question, bars related to positive answers ('Strongly agree', 'Agree') are faced upward the zero line while bars related to neutral or negative answers are faced downwards. The full text of each question is provided in Table 1.

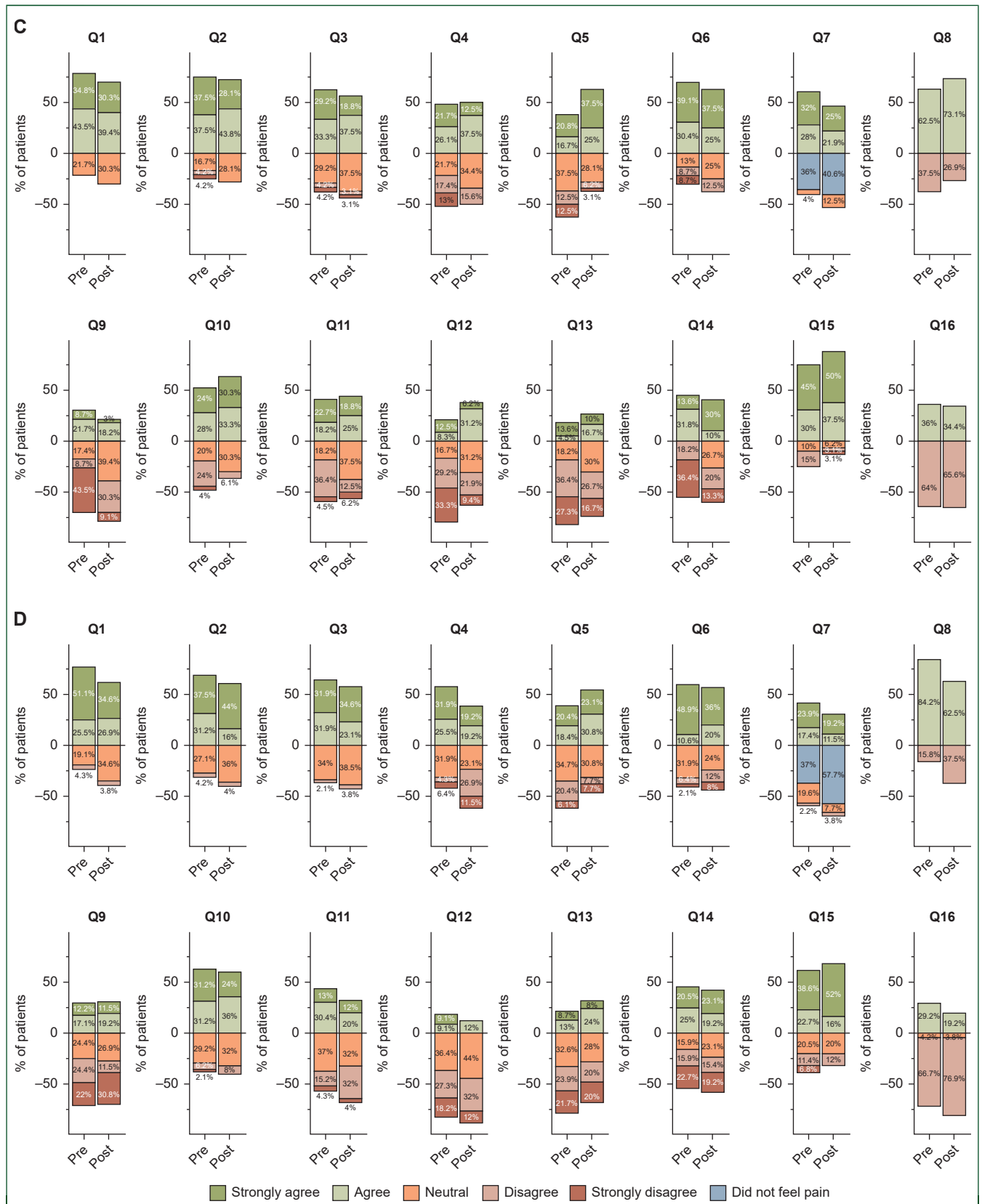


Figure 2. Continued.

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### Checklist - PREMs

**Care path**

**Information on the care path**

**Communication regarding the disease management plan:**

- The care plan has been discussed with the patient
- The implications of the therapy (advantages/disadvantages) and any side effects of the medications have been discussed
- Potential obstacles to treatment have been identified

**Initial symptom assessment**

- Pain control

**References**

**References and accessibility**

**References:**

- The patient and family have been informed:
  - Who is taking care of the patient at that moment and the health workers who will take care of him during the care path
  - Who to contact in case of need

**Needs**

**Person's needs – quality of life**

**Considerations regarding the person's needs – QoL:**

- Consider the proposal, at the end of the meeting, of a request for psychological support for patients/caregivers

**Advice: habits and lifestyle**

- Consider suggestions such as: elimination of risk factors, physical activity, diet, and specific dietary needs for which you may consider a request for the Nutritionist's intervention

**Understanding information**

**Verification of understanding information**

**Verification of understanding of the information provided to the patient and caregiver:**

- Reinforce at the next meeting following the first
- Rephrase after discussing the changes to the therapeutic plan agreed previously

**Figure 3.** Checklist developed through the audit process to improve PREMs. Items are grouped according to the main topics from the questionnaire. This checklist serves as a structured guide for health care professionals to ensure comprehensive communication and support throughout the patient's treatment journey.

phase, a total of six patients did not continue due to death (8.10%).

A total of 106 questionnaires were administered and 106 were returned; the distribution of questionnaires at the different timepoints was as follows: 17 at T0, 30 at T1, 33 at T2, and 26 at T3. The response rate was 99%.

Baseline patients' characteristics and distribution of patients according to the ongoing line of treatment for mCRC at the time of questionnaire administration were similar to those observed in phase II (Tables 2 and 3).

Within each timepoint, we compared the responses between phase II and phase IV, before and after quality audits and distribution of the checklist to the medical staff (Figure 2). At T0, the percentage of patients who expressed concerns about the side-effects of the therapy (35.5% pre-checklist versus 17.6% post-checklist), about death (46.7% versus 43.3%) and about economic aspects (24.1% versus 6.7%) decreased after the adoption of the checklist. At T1, an improvement was observed in the percentage of patients who expressed concerns about their future (61.6% versus 35.7%), about the possibility of a relapse of the disease (58.3% versus 25%) and about economic aspects (17.7% versus 7.2%). At T2, again a decrease in the percentage of patients who expressed concerns about their future (62.5% versus 31.3%) and about the possibility of a relapse of the disease (63.7% versus 43.4%) were observed as well as in the percentage of patients who are concerned about economic aspects (15% versus 6.3%). No relevant improvements were observed in any areas at T3.

**Dichotomous analysis of responses.** For the dichotomous analysis of responses, timepoint 1 (T1) was chosen as the most representative for the number of patients included ( $n = 37$ ) and because the reference timing (i.e. 30 days to 6 months) is indicative of patients in the middle of their treatment journey. In T1 there is a higher rate of negative responses, which should be interpreted also in the light of the classification employed for defining positive results, including only answers with the highest satisfaction (e.g. 'completely satisfied') and not intermediate results (e.g. 'somehow satisfied') in  $\geq 75\%$  of patients. A similar cutoff was used in a recent publication.<sup>46</sup> In essence, by setting these high cutoff thresholds, the intention was to raise the bar for what constitutes a positive response, thereby highlighting areas that may be falling short of the desired level of patient satisfaction. While this approach may result in a greater number of negative responses, it serves the purpose of identifying specific areas of concern more effectively. To assess the patients' evolving perception of their care journey over time, we conducted an 'intra-patient journey' analysis by comparing the results at T1 versus T3. This revealed a higher rate of negative responses at T3 compared with T1 in the 'care path' and 'health care awareness monitoring' domains. However, it is important to note that the results may be influenced by the difference in sample size between the two timepoints. Furthermore, an observation of the ongoing treatment line at the time of questionnaire completion reveals a significant difference

between the results at T1 and T3. Notably, a majority of the T1 questionnaire belongs to patients at early stages of treatment (78% in L1-2), while at T3, 50% of patients are in the advanced stages of the disease (L3, >L3). This emphasizes that T3 patients are predominantly in advanced disease stages, having undergone prior treatment, suggesting a potentially unfavorable prognosis and a heavier burden of disease.

**Open-ended questions.** Given the significant potential for insightful revelations that can be gleaned from open-ended questions, we decided to integrate three of them into our survey: 'What has positively struck you during this phase of your care journey?'; 'What has negatively impacted you during this phase of your care journey?'; 'Would you like to highlight someone who has positively impressed you in the way they have supported you?'. While the close-ended questions primarily address factual elements of the care experience, the open-ended comments focus on patients' personal and emotional journey through cancer treatment and its impact on their well-being.<sup>2,47</sup>

The analysis of open-ended questions from our PREM questionnaire revealed insights into response patterns across the timepoints. The first question had a high response rate of 85%, while the second had a 60% response rate, suggesting difficulty in eliciting negative feedback. The third question maintained a consistent 78% response rate throughout the study period, indicating sustained engagement.

Overall, the response rate to the open-ended questions is high, revealing a strong interest among patients in expressing their feedback about their care experience in their own words, and bringing out relevant themes that may not be captured in closed-ended questions. A preliminary analysis of free-text answers revealed significant patterns, with patients positively highlighting staff empathy, prompt assistance, and caregiver support, while expressing concerns about waiting times, appointment communication, physician rotation, and the need for additional psychological and nutritional support. A forthcoming analysis is planned in line with existing literature trends.<sup>2</sup>

## DISCUSSION

The available evidence demonstrates that the patient experience positively correlates with clinical outcomes and patient safety. This underscores the importance of incorporating PREM tools into clinical practice to optimize health care quality.<sup>26</sup> Starting with the questionnaire models available in literature, we tailored a PREM questionnaire to the oncological context of mCRC, integrating an auditing process to allow corrective actions for improvement.

As in other recent publications,<sup>1,46</sup> but differently from some previous studies,<sup>48,49</sup> we observed a very high response rate to the survey (94.7%), despite the length of the questionnaire. This indicates that the invitation to participate was well received, highlighting the importance

for patients to have the opportunity to share their opinions about their care experience. In our patient population, 84.7% of participants were living with a caregiver, underscoring the relevance of an external support. In contrast, 15.3% reported living alone, highlighting the need for tailored approaches to address the differing experiences and needs of this minority group. These findings stress the importance of considering social support systems and living arrangements when evaluating cancer care experiences, indicating potential implications for patient outcomes and well-being.<sup>50</sup>

Many patients completed the questionnaire in the hospital, often during treatment, while others did so at home. The accuracy of on-site feedback may be affected by patients' suboptimal physical or emotional distress, possibly affecting the quality-of-care feedback; moreover, time constraints of administrative and clinical procedures may hinder the completion of the questionnaire.<sup>13,19</sup> On the other hand, on-site completion ensured a higher response rate, enhancing questionnaire monitoring effectiveness. There is no definitive and universal optimal timing for completion of the questionnaire.<sup>4</sup> To maximize accessibility, we chose a paper-based survey, but considering the prevalence of digital tools and social media, providing both paper and electronic formats could engage several generations, aligning with recommendations for multiple administration modalities to ensure access for vulnerable populations.<sup>4</sup> A critical issue which emerged during the administration of questionnaires was the administrative burden related to patient selection procedures, questionnaire delivery, and retrieval. Data collection from the perspective of care providers and health care organizations requires considerable time, professional dedication, and institutional support, presenting challenges due to the associated costs and resource demands.<sup>17,51</sup> The pivotal role of physicians in the routine collection of patient-reported measures underscores the need to engage colleagues early, while leadership support and appropriate management structures further contribute to improved performance.<sup>43</sup> In our experience, engaging a wider range of medical, psychological, nursing, and administrative staff significantly increased enrollment and feedback rates, fostering team building and potentially enhancing outcome improvement strategies through collaborative result discussions.

Our study innovatively integrated quality audits to identify areas for improvement, allowing for corrective actions. In particular, in phase III of the study, health care providers have been engaged in discussions regarding potential strategies for improvement, and a checklist to be implemented in daily clinical practice was conceived. The latter was designed and divided into four areas of interest, corresponding to the four main areas identified during the analysis of the results, each of them comprising the items with the lowest performance in the PREM analysis. We found that a checklist, accessible to the medical staff of the outpatient service, appeared to be a practical, user-friendly, and readily accessible tool that can be integrated into daily workflow without significantly burdening medical

activities. It enabled a quick reference to the key patient-related topics or items to consider in order to enhance the patient care experience and could be swiftly accessed by medical and nursing staff during patients' scheduled visits to the outpatient service. The comparison of PREM results between phase II and phase IV showed changes in patients' concerns after adopting the checklist. Overall, there was a significant reduction in patients' concerns about various aspects at T0, T1, and T2, with no significant changes observed at T3. No relevant improvements were indeed observed in any areas at T3, possibly because at this timepoint (>12 months) patients were in a more advanced stage of the disease, and thus less positively impacted by corrective actions for a better communication of the treatment plan. This reveals how essential it is to pay close attention to the needs of patients early in their care journey, as these may increase with the progression of the disease, thus suggesting to clinicians and health care systems the need to intensify efforts to improve the quality of care provided with particular attention to later stages of the disease.

We acknowledge some limitations of the study. Despite the pre-post design which allowed us to evaluate the efficacy of the audit process, the study remains explorative and for this reason data were analyzed only using descriptive statistical methods. The sample size was indeed not calculated a priori based on statistical power analyses and with the aim of evaluating a prespecified hypothesis. It should be also acknowledged that the study began accrual in July 2021 when the COVID-19 pandemic was still a major health problem, potentially affecting patients' perceptions of their clinical care and introducing heterogeneity at least for those who were included in the beginning compared with patients enrolled in subsequent months.

In conclusion, the EPIC study highlights the feasibility and utility of implementing PREMs in the management of mCRC. Through a structured auditing process, we demonstrated that the integration of PREMs into clinical practice provides valuable insights into patient experiences and identifies actionable areas for improving care quality. Notably, the adoption of a tailored checklist significantly reduced patients' concerns about their future, potential disease relapse, and the economic implications of treatment, particularly in the earlier stages of their treatment journey. Despite these promising results, the study revealed persistent challenges, particularly at advanced disease stages where the effectiveness of corrective actions diminished. This underscores the need for adaptive interventions that address the evolving needs of patients throughout their care journey. Moreover, the high response rate achieved reinforces the willingness of patients to share their experiences, emphasizing the importance of their voice in shaping patient-centered care strategies. The study was exclusively focused on PREMs, thus, neither clinical outcomes nor PROMs were taken into consideration. As future perspectives, the integration of digital tools could enhance accessibility and reduce administrative burdens, enabling real-time data collection and analysis.

Additionally, incorporating artificial intelligence to analyze open-ended responses may further illuminate nuanced aspects of patient experiences. Longitudinal studies are warranted to evaluate the sustained impact of PREMs and the checklist on long-term outcomes, including patient satisfaction and quality of life.

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## DISCLOSURE

SS is an advisory board member for Amgen, Bayer, Bristol-Myers Squibb, CheckMab, Clovis, Daiichi-Sankyo, Merck, Roche-Genentech, and Seattle Genetics. ASB is an advisory board member for Amgen, Bayer, Novartis, Pierre-Fabre, and Servier. All other authors have declared no conflicts of interest.

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