OPEN ACCESS

Research Article

Restructuring of Clinical Guidelines for Colon and Rectal Adenocarcinoma in the Brazilian Unified Health System (SUS)

Abstract

In a country as large as Brazil, standardizing clinical oncology practices within the public health system (Unified Health System – SUS) remains a continuous challenge, particularly for conditions of high complexity and significant epidemiological impact, such as colorectal cancer. This study describes the transition process from the Diagnostic and Therapeutic Guidelines (DDT) to the Clinical Protocol and Therapeutic Guidelines (PCDT) for Colon and Rectal Adenocarcinoma. The analysis encompassed the existing DDT (published in 2014), national and international clinical guidelines, and protocols from Brazilian referral centers to support the definition of diagnostic, therapeutic, and monitoring criteria based on scientific evidence and adapted to the regulatory and healthcare context of SUS. The proposed recommendations were reviewed by an expert panel and subsequently submitted to public consultation, with contributions assessed and incorporated when pertinent, ensuring both clinical applicability and regulatory compliance. The main challenges identified included the heterogeneity among international guidelines and the constraints imposed by technological availability within SUS. Nevertheless, this experience highlighted the potential of a replicable methodological model for the development of PCDT in oncology, fostering greater standardization, strengthening oncology care policies, and expanding access to safe, effective, and sustainable treatments.

Keywords: colorectal neoplasms, clinical protocols, evidence-based oncology, health policy, unified health system (Brazil)

Gláucia Teles de Araujo Bueno[1]
Marta da Cunha Lobo Souto Maior[1]
Ludmila Andrade Alves Ferreira[1]
Nicole Freitas de Mello[2]

1 Department of Health Technology Management and Incorporation (DGITS), Secretariat of Science, Technology and Innovation and the Economic-Industrial Complex of Health (SECTICS), Ministry of Health, Brasília, Brazil

2 Ministry of Health, Brasília, DF, Brazil

Introduction

Colorectal cancer is one of the leading causes of morbidity and mortality in Brazil, with an estimated 45,000 new cases for the 2023–2025 period, ranking among the most incident neoplasms in the country. Addressing this condition requires the organization of clinical practices on solid normative bases to ensure quality, equity, and comprehensiveness of care provided by the public health system – the Unified Health System (SUS) [1].

In Brazil, the right to health is universal. To safeguard this right, the Brazilian Ministry of Health (MoH) publishes normative instruments designed to ensure the quality, equity, and comprehensiveness of healthcare. Evidence-based clinical guidelines are one of these instruments, intended to guide clinical decision-making according to the best available scientific evidence, while promoting high-quality care and the efficient use of public resources [1], [2]. Among the four formats of clinical guidelines published by the MoH, two are particularly relevant: the Diagnostic and Therapeutic Guidelines (Diretrizes Diagnósticas e Terapêuticas – DDT), specifically designed for oncology, and the Clinical Protocols and Therapeutic Guidelines (Protocolos Clínicos e Diretrizes Terapêuticas – PCDT) [2], [3].

Historically, DDTs have been used to guide oncology practice in SUS. This model emerged because oncology in SUS is financed through a bundled payment system, in which treatment is reimbursed as a service package. As a result, each healthcare unit retains autonomy and flexibility in defining which drugs are used for treatment. Accordingly, DDTs provide broad clinical recommendations without limiting them to technologies formally incorporated into SUS, while considering the health technology assessment process. However, this financing model has faced criticism for fostering heterogeneity in clinical practices and inequality in access to care [4].

To overcome this scenario, the MoH proposed adopting another type of clinical guideline for neoplastic diseases: the PCDT. These protocols establish diagnostic, therapeutic, and monitoring criteria, as well as define the drugs and procedures that must be mandatorily provided within SUS. In this context, the transition from DDT to PCDT aims not only to promote greater uniformity in clinical practice but also to strengthen care management and regulate access to health technologies, thereby reducing regional

disparities and enhancing safety for both healthcare managers and professionals [5], [6].

For a technology to be recommended in a PCDT, it must be approved by the National Committee for Health Technology Incorporation into SUS (Conitec), an advisory body of the MoH responsible for evaluating proposals for the inclusion, exclusion, or modification of technologies covered by SUS. In its recommendations, Conitec considers, among other parameters, scientific evidence regarding efficacy/effectiveness, safety, cost-effectiveness, and budget impact. Therefore, the transition in the format of clinical guidelines for oncology within SUS represents a landmark in Brazil's national oncology policy, as these documents now provide clearer guidance on the standard of care to be offered by cancer centers, while still allowing them the autonomy to provide additional treatments [5], [6].

This study aims to describe the process of transitioning the DDT for colon and rectal cancer into the PCDT format for colon and rectal adenocarcinoma, highlighting its challenges, outcomes, and implications for strengthening oncology care within SUS.

Methods

This study is a descriptive and reflective experience report on the transition from the Diagnostic and Therapeutic Guidelines (DDT) to the Clinical Protocol and Therapeutic Guidelines (PCDT) for colon and rectal adenocarcinoma. The development process of the PCDT followed the methodological guidelines established by the MoH for the preparation and updating of clinical protocols based on scientific evidence [5], [6]. The process began with the review of the DDT published by the MoH in 2014. To identify convergence with current clinical practices and the need for updates, thereby defining what could be considered standard practice, the following colorectal cancer guidelines were reviewed: the National Comprehensive Cancer Network (NCCN, 2024) [7], [8], the European Society for Medical Oncology (ESMO, 2023) [9], and the Brazilian Society of Clinical Oncology (SBOC, 2023) [10], [11]. Protocols from major public referral centers in Brazil, such as those of the National Cancer Institute (INCA, 2022) [12] and the São Paulo State Cancer Institute (ICESP, 2021) [13], were also analyzed. The recommendations included in these documents were examined comparatively according to the clinical condition, treatment setting, therapeutic regimen, indication criteria, and availability of the corresponding technology within SUS. This analysis was used to identify areas of convergence and divergence among the guidelines and to define recommendations considered clinically appropriate and applicable to the Brazilian healthcare context. Medications without valid registration at the Brazilian Health Regulatory Agency (Anvisa), those not previously assessed by the National Committee for Health Technology Incorporation into SUS (Conitec), or those evaluated and not recommended for incorporation into SUS were not considered in the proposed recommendations. During this analysis, the medications recommended by each guideline and their respective use criteria were identified. The information was submitted for review by a panel involved in the development of the PCDT, coordinated by the Department of Management and Incorporation of Technologies and Innovation in Health of the Secretariat of Science, Technology and Innovation and the Economic-Industrial Complex of Health (DGITS/SECTICS/MS). The development group included representatives from governmental health institutions, scientific and professional organizations, specialized healthcare institutions, and patient representation. All participants in the PCDT development process submitted conflict-of-interest declarations for prior assessment by the MoH. Participants with relevant conflicts of interest associated with specific questions were not involved in the development or drafting of those questions, although they could participate in discussions of other questions, including voting when consensus was not reached.

The recommendations were discussed in technical meetings, and the contributions of the expert panel were incorporated into the preliminary draft of the PCDT. The preliminary document was subsequently revised for clinical consistency, operational feasibility, and regulatory compliance required by the MoH.

The development process did not use the GRADE approach as an explicit framework for comparing recommendations across the different clinical guidelines. Instead, evidence assessment and formulation of recommendations followed the methodological guidance established by the MoH for PCDT development, with consideration of available evidence, regulatory requirements, health technology incorporation decisions, clinical feasibility, and applicability within SUS.

The recommendations were categorized into: preoperative chemotherapy (neoadjuvant) for colon cancer, preoperative chemotherapy (neoadjuvant) for rectal cancer, adjuvant chemotherapy, and chemotherapy for advanced colon and rectal adenocarcinoma.

Subsequently, the document followed the standard publication process, which included evaluation of the preliminary version by Conitec and submission to public consultation. Public Consultation No. 34/2024 was conducted from June 18 to July 8, 2024. A total of 33 contributions were received, predominantly from health professionals (n=15; 45.5%), followed by family members, friends, or caregivers of patients (n=6; 18.2%) and individuals interested in the topic (n=5; 15.2%). Twenty-two supporting documents were also submitted and analyzed. Contributions were quantitatively and qualitatively assessed through the reading of all submissions, identification and categorization of their central ideas, preparation of responses to the main contributions, and adjustment of the PCDT text when considered appropriate. The final version was subsequently reviewed by Conitec, which issued a favorable recommendation for publication.

Results

The transition process of the guidelines culminated in the consolidation of diagnostic, therapeutic, and monitoring criteria for patients with colon and rectal adenocarcinoma within SUS, providing greater uniformity to clinical practices. Updated therapeutic regimens were established, aligned with the best available scientific evidence while respecting regulatory constraints and the formal decisions of the MoH regarding the availability of health technologies in the public system. This process enabled the comparison of international recommendations with the national context, ensuring technical consistency and alignment with Brazilian epidemiological needs, while simultaneously reinforcing the principles of equity, comprehensiveness, and universality that underpin SUS.

Main differences between the 2014 DDT and the PCDT

Among the main differences between the previous DDT and the new PCDT, the following stand out:

- the transition from broader clinical recommendations to standardized diagnostic, therapeutic, and monitoring criteria linked to the health technologies incorporated into SUS;
- the non-recommendation of drugs not yet assessed by Conitec or those evaluated and not recommended for incorporation, thus providing greater transparency and legal certainty to clinical practice;
- the establishment of objective parameters for clinical follow-up and monitoring, facilitating the evaluation of health outcomes;
- greater integration between clinical recommendations, health technology incorporation decisions, and the organization of care within SUS.

Public consultation

Public consultation provided an additional stage of external review of the proposed PCDT. Public Consultation No. 34/2024 received 33 contributions, predominantly from health professionals (n=15; 45.5%), followed by family members, friends or caregivers of patients (n=6; 18.2%) and individuals interested in the topic (n=5; 15.2%). Twenty-two supporting documents were also submitted and analyzed. Contributions were reviewed and categorized according to their central ideas, and the PCDT text was adjusted when the suggestions were considered pertinent.

The consultation resulted in specific changes to the document. For example, a contribution concerning the histological classification of mucinous and adenosquamous tumors resulted in an adjustment of the corresponding text. Suggestions regarding short-course neoadjuvant radiotherapy were also accepted and incorporated into the PCDT. Other contributions resulted in partial adjustments, including greater clarification of therapeutic recommendations.

Conversely, suggestions concerning technologies that had not been prioritized for assessment were not incorporated when they fell outside the scope or lacked the necessary assessment within the development process. For example, suggestions regarding robotic surgery and PET-CT were not incorporated because these technologies had not been prioritized by the specialists during the PCDT development meetings. The responses also emphasized that new technology assessments may be requested subsequently according to the applicable legal framework.

Among the main advances compared with the DDT, the following stand out:

- the standardization of treatment lines according to the health technologies currently incorporated into SUS, thereby reducing heterogeneity in clinical practice and mitigating regional disparities;
- the non-recommendation of drugs not yet assessed by Conitec or those evaluated and not recommended, thus providing greater transparency and legal certainty to clinical practice;
- the establishment of objective parameters for clinical follow-up and monitoring, facilitating the evaluation of health outcomes.

The process of changing the guideline format was not merely a technical revision, but rather a reflection of the strengthening of oncology governance, harmonizing clinical practices and contributing to greater safety for both patients and health system managers (Table 1, Figure 1).

Discussion

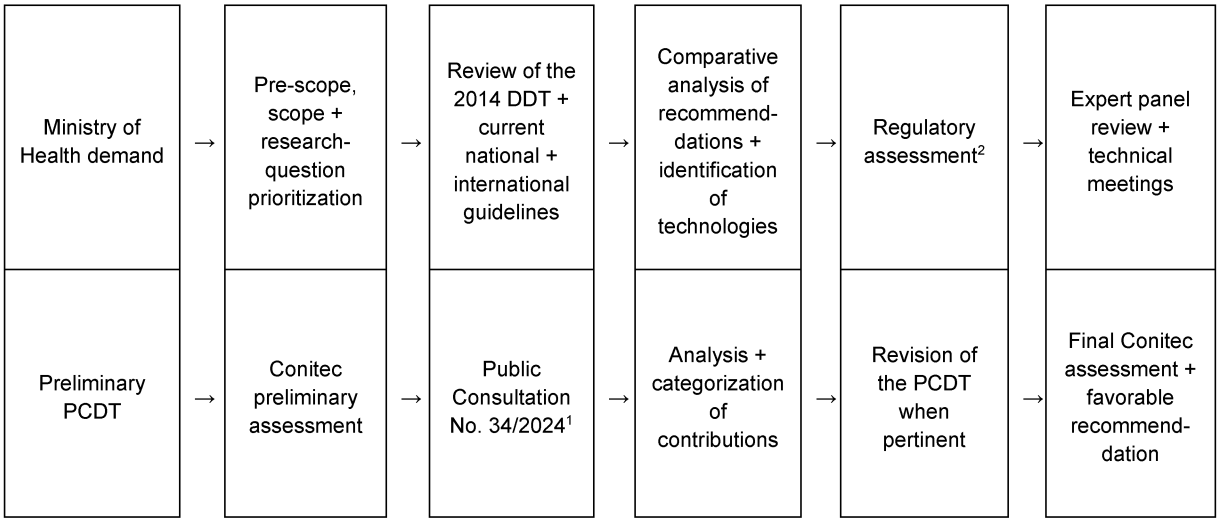
The transition of the document from the DDT to the PCDT format, in the context of colon and rectal adenocarcinoma, represented a highly complex methodological process that went beyond the mere update of clinical recommendations. This change of format required the incorporation not only of the best available scientific evidence but also of normative, regulatory, and operational feasibility criteria to ensure applicability, legitimacy, and sustainability within SUS.

One of the main challenges was the heterogeneity among the clinical guidelines analyzed, both national and international. The divergences in therapeutic regimens, treatment lines, and indication criteria reflected not only different interpretations of the literature but, more importantly, the contexts in which these documents were developed, tied to health systems with financing models, technology access, and incorporation policies very different from those in Brazil. Furthermore, guidelines developed by scientific societies, such as ESMO, SBOC, and NCCN, are essentially technical-scientific in nature, without responsibility for financing decisions or for the incorporation of technologies into their respective health systems. This condition increases the gap between their

Table 1: Main differences between the DDT and the PCDT for colon and rectal adenocarcinoma

Aspect	DDT	PCDT
Guideline format	Diagnostic and Therapeutic Guidelines (DDT), historically used for oncology within SUS	Clinical Protocol and Therapeutic Guidelines (PCDT)
Scope of recommendations	Broader clinical recommendations, allowing greater flexibility in the selection of treatments by healthcare units	Diagnostic, therapeutic, and monitoring criteria linked to technologies incorporated into SUS
Health technologies	Recommendations were not restricted to technologies formally incorporated into SUS	Recommendations are aligned with technologies incorporated into SUS and with formal Conitec decisions
Treatment organization	Greater flexibility in the definition of therapeutic regimens by healthcare units	Greater standardization of treatment lines and therapeutic regimens
Technologies not incorporated into SUS	Could be discussed within the broader clinical guidance framework	Not recommended when not assessed by Conitec or when incorporation received an unfavorable recommendation
Monitoring	Less explicitly structured within the guideline format	Objective clinical follow-up and monitoring parameters
Governance	Greater separation between clinical guidance and financing/technology incorporation decisions	Greater integration between clinical guidance, technology incorporation, and oncology care governance

Source: Authors' own elaboration.



[1] 33 contributions + 22 supporting documents

[2] Anvisa registration + Conitec assessment/incorporation decisions

Source: Authors' own elaboration

Figure 1: Development pathway of the PCDT for colon and rectal adenocarcinoma

ideal recommendations and the practical reality of implementation in a public health system such as SUS, which operates under budgetary restrictions and unequal distribution of services across a continental territory [2], [14]. Nevertheless, the comparative analysis of these guidelines was an important element, as it enabled the identification of minimal consensus, revealed gaps in the literature, and highlighted opportunities to adapt international practices to the Brazilian reality. At this stage, the strategic role of the expert panel was crucial: their clinical experience and knowledge of SUS were decisive in reinterpreting the evidence in light of practical feasibility, technological availability, and equity of access. The expertise of this group functioned as a bridge between global science and the Brazilian healthcare reality, making feasible recommendations possible without compromising technical-scientific rigor [14], [15].

The development of the PCDT therefore enabled the establishment of clear, updated, and technically robust diagnostic and therapeutic criteria, aligned with the principles of SUS, particularly regarding equity and comprehensiveness of care. By considering only drugs registered with Anvisa, previously assessed by Conitec, and recommended for incorporation, the process ensured the legal and regulatory compliance of the proposals, while guaranteeing that decisions were guided by consistent technical-scientific criteria [5], [6].

The public consultation also contributed to the refinement of the final document by providing an additional mechanism for external review. The analysis of the 33 contributions and 22 supporting documents resulted in adjustments to the PCDT when considered pertinent, while contributions that fell outside the scope or lacked sufficient methodological or regulatory basis were not incorporated with corresponding justification. This process illustrates how public participation can contribute to the transparency and refinement of clinical guidelines without replacing the methodological and regulatory requirements underlying their development.

More than a technical product, the experience of transitioning from DDT to PCDT illustrates the importance of adopting a structured and transparent approach to the prioritization of health technologies, especially in areas of high complexity and significant epidemiological and financial impact, such as oncology. Such an approach is fundamental to expanding access to best evidence-based practices without compromising the sustainability of the public health system [2], [15].

Finally, this process also highlights a critical point: the periodic updating of PCDTs is indispensable to keeping pace with the speed at which new evidence and technologies emerge in the field of oncology. Without agile and systematic review mechanisms, there is a risk of recommendations becoming obsolete, thereby undermining both the quality of care and the rational allocation of resources. In this context, future update cycles should remain integrated with mechanisms for monitoring new evidence, changes in health technology incorporation decisions, and emerging needs within SUS. Such mechanisms may strengthen the governance of clinical guidelines by ensuring that recommendations remain clinically relevant, regulatorily consistent, and operationally feasible over time. In this sense, the transition analyzed represents not only a regulatory milestone but also an institutional learning process on how to balance science, management, and policy in the formulation of clinical protocols for SUS [2], [4], [15].

Conclusions

The development of the PCDT for colon and rectal adenocarcinoma represents an important advancement in the organization of oncology care within SUS. By aligning clinical recommendations with current regulatory and health technology incorporation decisions, the document promotes the standardization of care, enhances equity, and ensures the use of safe and cost-effective therapies. Moreover, the methodological model adopted in this process—grounded in the critical analysis of national and international guidelines, regulatory review, and validation by experts and society—may serve as a reference for the development and updating of other oncology protocols. In this way, the experience reported here contributes not only to improving care for patients with colorectal cancer but also to strengthening Brazil's national oncology care policy and national health technology management policy, fostering greater equity, rationality, and effectiveness in healthcare delivery.

Notes

Competing interests

The authors declare that they have no competing interests.

Use of AI

No artificial intelligence tools were used in the preparation, writing, editing, or revision of this manuscript.

References

1. Instituto Nacional de Câncer (INCA). Estimate 2023: cancer incidence in Brazil. Rio de Janeiro: INCA; 2022. 160 p.
2. Mega TP, Lopes ACDF, Santos VCC, Petramale CA. Clinical guidelines in Brazilian Public Health System: history, challenges and prospects. Rev Gest Saude. 2015;6(4):3275-85.
3. Brasil Ministério da Saúde. Manual de atividades da Coordenação-Geral de Gestão de Protocolos Clínicos e Diretrizes Terapêuticas. 2nd ed. Brasília: Ministério da Saúde; 2023. 116 p.
4. Gadelha MIP. Cancer care in the thirty years of the Brazilian Unified Health System. Rev Bras Cancerol. 2018;64(2):231-9.
5. Brasil. Ministério da Saúde; Secretaria de Ciência, Tecnologia, Inovação e do Complexo Econômico-Industrial da Saúde. Diretrizes metodológicas: elaboração de diretrizes clínicas. 3rd ed. Brasília: Ministério da Saúde; 2022.
6. Brasil. Ministério da Saúde; Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde. Protocolo Clínico e Diretrizes Terapêuticas: adenocarcinoma de cólon e reto: relatório de recomendação. Brasília: Ministério da Saúde; 2024.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer, Version 1.2024. Plymouth Meeting (PA): NCCN; 2024.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer, Version 1.2024. Plymouth Meeting (PA): NCCN; 2024.
9. Cervantes A, Adam R, Roselló S, Arnold D, Normanno N, Taïeb J, Seligmann J, De Baere T, Osterlund P, Yoshino T, Martinelli E; ESMO Guidelines Committee. Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol. 2023;34(1):10–32. DOI: 10.1016/j.annonc.2022.10.003
10. Sociedade Brasileira de Oncologia Clínica. Diretrizes de tratamentos oncológicos: cólon: doença avançada. São Paulo: SBOC; 2023.
11. Sociedade Brasileira de Oncologia Clínica. Diretrizes de tratamentos oncológicos: cólon: doença localizada. São Paulo: SBOC; 2023.
12. Instituto Nacional de Câncer (INCA); Superintendência Estadual do Ministério da Saúde no Rio de Janeiro. Protocolo unificado para o tratamento das neoplasias malignas não hematológicas. Rio de Janeiro: INCA; 2022.

13. Instituto do Câncer do Estado de São Paulo (ICESP). Manual de condutas em oncologia. 3rd ed. São Paulo: ICESP; 2021.

14. Silva RM, Petramale CA, Elias FTS. The different clinical guideline standards in Brazil – high cost treatment diseases versus poverty-related diseases. PLoS One. 2018;13(10). DOI: 10.1371/journal.pone.0204723

15. Colpani V, Kowalski SC, Stein AT, Buehler AM, Zanetti D, Côrtes G, et al. Clinical practice guidelines in Brazil – developing a national programme. Health Res Policy Syst. 2020;18(1):69. DOI: 10.1186/s12961-020-00582-0

Corresponding author:
Gláucia Teles de Araujo Bueno
Department of Health Technology Management and Incorporation (DGITS), Secretariat of Science, Technology and Innovation and the Economic-Industrial Complex of Health (SECTICS), Ministry of Health, Brasília, Brazil
glaucia.araujo@saude.gov.br

Please cite as
Teles de Araujo Bueno G, da Cunha Lobo Souto Maior M, Andrade Alves Ferreira L, Freitas de Mello N. Restructuring of Clinical Guidelines for Colon and Rectal Adenocarcinoma in the Brazilian Unified Health System (SUS). GMS Health Innov Technol. 2026;19:Doc03. DOI: 10.3205/hta000143, URN: urn:nbn:de:0183-hta0001438

This article is freely available from
https://doi.org/10.3205/hta000143

Published: *2026-11-20*

Copyright
©2026 Teles de Araujo Bueno et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution 4.0 License. See license information at http://creativecommons.org/licenses/by/4.0/.