

Guide on how to

Develop resource- appropriate colorectal cancer management guidelines

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Purpose of the guide

The purpose of this guide is to outline the steps and procedures for designing resource-appropriate colorectal cancer management guidelines in the context of the City Cancer Challenge Foundation (C/Can) project as it is implemented at the city level. This guide is intended to respond to the urgent need to reduce inequities in access to colorectal cancer diagnosis (clinical evaluation, pathology, imaging, staging), multimodality treatment (surgery, radiotherapy, systemic therapy), genetic counselling and palliative care services in selected C/Can cities.

To create resource-appropriate colorectal cancer management guidelines, the guidelines development team requires an accurate understanding of currently available resources (infrastructure, human resources, equipment, and renewable supplies) for colorectal healthcare to avoid creating a guideline that is scientifically sound but financially unsustainable. The situation assessment required to provide this baseline information is beyond the scope of this guide but is assumed to be available to the guideline's development team.

Colorectal polyps and early colorectal cancer early detection is necessary for improving colorectal cancer outcomes at the population level (see Annex 1). However, this document focuses on providing a guide on how to obtain an accurate and prompt colorectal cancer diagnosis, appropriate staging and required oncological services. These are imperative considering that the great majority of the patients with colorectal cancer are diagnosed with locoregionally advanced (Stage III) or metastatic disease (Stage IV). Multi-modality therapy is required for the majority of these patients in order to improve overall outcome.

The guide has been prepared through a collaboration between C/Can and Higinia Cardenes MD PhD [Professor of Radiation Oncology, Weill Cornell Medicine, NY] and Eloy Espin-Basany [Professor of Surgery, Universitat Autònoma de Barcelona, Spain], with the aim of supporting the different groups that are established by the cities as they prioritise the development of colorectal cancer management guidelines. These groups are recommended to interpret, analyse, and tailor the recommendations made in this guide considering the local context and the need to build a multisectoral consultative process within their cities.

Structure and suggested contents of the guideline document to be produced by the guideline development team

1. Introduction

1.1. COLORECTAL CANCER IMPACT

- Current and projected colorectal cancer burden (incidence, mortality, prevalence, Disability-adjusted life years (DALYs) in the world, region and country;
- Economic impact of colorectal cancer in the country and city as measured by lost productivity and social disruption related to colorectal cancer morbidity and deaths;
- Potential for improved colorectal cancer outcomes based on early detection strategies in the country and city to reduce the fraction of patients presenting with advanced stage disease requiring more extensive and costly treatments;
- Potential for improved colorectal cancer outcomes as measured by lower recurrence and higher survival rates based on the implementation of proven therapeutic strategies;
- Potential for improved functional results after colorectal cancer treatment with the spread of information and knowledge regarding this patient-centred objective.

1.2. COLORECTAL CANCER DIAGNOSIS AND TREATMENT OVERVIEW

- Synergistic role of early detection, diagnosis and multimodality treatment to improve colorectal cancer outcomes in the general population;
- Reinforce the need of accurate and timely surveillance of the high-risk population such as Lynch Syndrome, Familial Adenomatous Polyposis and Attenuated Familial Adenomatous Polyposis;
- Access requirements for early identification of symptoms related to colorectal cancer, and appropriate diagnostic work-up at the city level;
- Diagnostic services to establish colorectal cancer diagnosis and clinical staging (clinical evaluation, imaging, endoscopy, pathology) and Genetic counselling;
- Multimodality treatment for invasive colorectal cancer [surgery, radiotherapy, chemotherapy];
- Requirement for supportive care to help patients get through multimodality treatment without abandonment [social workers, support groups];
- Value of supportive care after treatment in survivorship to help patients reintegrate in their community;
- Importance of palliative care for patients with untreatable metastatic disease and end-of-life care.

1.3. PHASED IMPLEMENTATION STRATEGIC PLANNING PERSPECTIVE

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- Baseline assessment provides summary of existing diagnostic and treatment services and resources in city;
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- Resource-stratified framework outlines the core service gaps needing to be filled or circumvented in city;
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- Resource-appropriate guidelines should be both functional (biologically predictable to improve cancer outcomes) and sustainable (realistic and affordable) in order to meet the needs of the community;
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- Phased implementation strategy defines a stepwise pathway for optimizing sustainable resource-utilisation while improving service delivery for colorectal cancer diagnosis, treatment, palliation and survivorship.
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2. Aims of the guideline document

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- Explain the purpose of the document and the potential interested audiences;
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- Consider the clinical demand for colorectal cancer diagnosis and treatment services based on epidemiological data and projected needs based on quality benchmarks within a determined timeframe (up to 10 years);
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- Discuss the available material resources (infrastructure, equipment and consumable materials) for colorectal cancer detection, diagnosis, treatment and supportive services;
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- Reflect on the current and future training requirements to have an optimally functional work force to meet the current and projected patient demand for colorectal cancer diagnosis and treatment;
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- Propose standardised guidelines for describing feasible interventions to bridge the early diagnosis and treatment gaps in terms of facilities, equipment and trained staff considering concepts like the rational use of existing resources (Fecal Occult Blood testing (FOBT), endoscopy).
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3. Objectives of the city-specific colorectal cancer management guidelines

- This document should guide the users in terms of the rationale and necessity for creating colorectal cancer guidelines adapted to their city's context and available resources;
- The guidelines should state the overall goal of the project to contribute to, and demonstrate its linkage with, a national or broader cancer control programme;
- The guidelines should align with the identified problems and needs, contributing to the expected impact;
- The guidelines document should describe the specific objectives and their links to expected outcomes;
- The specific objectives of the guidelines should address changes and effects expected with implementation;
- The guidelines document should expand on:
 - the increase of coverage in terms of equipment and personnel workload;
 - the projected improvements in the accessibility to colorectal cancer diagnosis and treatment services and in the quality and safety of treatments; and,
 - anticipated technology requirements and the corresponding staff training and education that will be required to deliver these projected outcomes.
- The guidelines should serve as the basis for a city-wide phased implementation strategy potentially such as a four-step "APIM" (Assess, Plan, Implement, Monitor) approach to maximise the benefits of resource-stratification by permitting situation-specific adaptation.

4. Guidelines development

4.1. GUIDELINES DEVELOPMENT TEAM MEMBERSHIP

- Guidelines development is a comprehensive process requiring the active involvement, input and ratification of all specialties and services involved in guidelines implementation. Those core specialties include (at least) all of the following:
 - Surgery;
 - Radiation oncology;
 - Medical oncology;
 - Radiology (diagnostic imaging and nuclear medicine);
 - Pathology.

 - Guidelines implementation is most successful when ancillary and supportive services are directly involved in the guideline development process and have the opportunity to provide input. Key supportive services include:
 - Genetic Counselling;
 - Nursing;
 - Supportive/palliative care;
 - Physical therapy;
 - Patient navigation services.

 - Guidelines implementation is most likely to be sustained over time when their practical and financial implications are evaluated and vetted by those groups that will be required to continue and sustain their application over time. These administrative entities include:
 - Hospital and clinic administration;
 - Health insurers;
 - Health services oversight (ministry of health or equivalent);
 - National Societies of Surgical, Medical and Radiation Oncology when available.
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4.2. GUIDELINES DEVELOPMENT PROCESS

- A series of guidelines development meetings should be planned to permit writing, review, editing and ratification of the guidelines document:
 - Creation [or designation] of a committee of experts in colorectal cancer including representatives of all the disciplines involved in early detection programmes (screening and early diagnosis), diagnosis and treatment of colorectal cancer patients;
 - Clearly define datelines to avoid unnecessary delays;
 - Initial guidelines drafting;
 - Internal review to consider issues of practicality of implementation;
 - Guidelines revision based on internal review;
 - External expert (s) review to evaluate predicted efficacy;
 - Guidelines revision based on external review;
 - Administrative review to consider resource requirements and fiscal implications of implementation;
 - Guidelines finalisation.

 - Principles of guidelines development include the following:
 - Guidelines are most practical to apply when they follow an algorithmic approach mirroring the anticipated patient pathway (see Annex 1);
 - Guidelines effectiveness depends on standardisation of care; when patients receive some but not all the essential interventions, improvement in cancer outcomes cannot be expected to occur;
 - Guidelines have limited utility when they are aspirational but unachievable or unaffordable.

 - Given the complexity and rapidly evolving improvements in the diagnosis and management of colorectal cancer, the guideline development team should strongly consider the use of existing resource-stratified guidelines such as the NCCN Framework for Resource Stratification of NCCN Guidelines™ (<https://www.nccn.org/framework/default.aspx>) as a starting point for guidelines development:
 - The guidelines development team begins with a map of existing resources and services to determine how patients currently flow (or fail to flow) through the existing system and infrastructure;
 - The existing map of patient services permits gap analysis to identify where necessary services are missing or inadequately functional to meet service needs;
 - Resource-appropriate guidelines are useful for prioritizing improvements to be implemented to provide an orderly progression based on existing needs that target the best predicted outcomes balanced against intervention costs.
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- In **Colorectal Cancer diagnosis**, certain questions commonly arise that need to be addressed in the guidelines to establish a prioritisation scheme for implementation, such as:
- Education of Primary Care Physicians in identifying common clinical symptoms related to colorectal cancer;
 - Implementation of early detection programs for the general population;
 - Implementation of Surveillance Programs in the High-Risk Population, such as Lynch Syndrome, Familial Adenomatous Polyposis and Attenuated Familial Adenomatous Polyposis;
 - Timeliness of diagnostic services, FOBT and colonoscopy, access to avoid excessive delays;
 - Diagnostic imaging studies to assess the local extent for the disease: Transrectal Endoscopic Ultrasound, MRI Pelvis (with/without contrast);
 - Work up Staging:
 - Tumour Marker: CEA;
 - Imaging to detect regional (nodal) and/or metastatic disease: CT scan Chest – Abdomen and Pelvis with contrast; PET-CT scan.
 - Tissue sampling methods:
 - Core Biopsy: preferred for the primary site;
 - Fine Needle Aspiration biopsy (FNA): Lymph nodes and lesions at distant sites, concerning metastatic site.
 - Pathology Report:
 - Standard histopathological information;
 - Molecular / Genetic information (if available)
 - › KRAS, NRAS, and BRAF Mutation Testing;
 - › Microsatellite Instability (MSI) or Mismatch Repair (MMR) Testing -
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- In **Colorectal Cancer treatment**, certain questions commonly arise that need to be addressed in the guidelines to establish a prioritisation scheme for implementation, such as:
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1. Discussion in the Multidisciplinary Tumour Board of ALL cases prior to initiation of therapy is imperative in order to determine the most appropriate sequence of therapy

 2. Define intent of treatment: Non-metastatic vs Metastatic disease
 - 1- Non-Metastatic:
 - a. Preoperative or Postoperative approach;
 - b. In rectal cancer, consideration of Total Neoadjuvant Therapy (TNT) followed by Total Mesorectal Excision (TME) or Non-operative Management (NOM) – Watch and Wait approach.
 - 2- Metastatic:
 - a. Induction Systemic Therapy;
 - b. Synchronous vs Metachronous management of Primary and Metastatic Disease.

 3. Surgical Management
 - a. Endoscopic resection;
 - b. Local excision;
 - c. Total or Partial Mesorectal Excision - TME or PME - depending on tumor location (distal two thirds or upper third);
 - d. Pelvic Exenteration;
 - e. Resection of Oligometastatic sites (i.e. liver – lung).

 4. Systemic Therapy:
 - a. Chemotherapy Protocols;
 - b. Access to Targeted Therapy;
 - c. Access to Immunotherapy;

 5. Radiation Therapy:
 - a. Access to Radiation Oncology Facilities;
 - b. Treatment modalities;
 - c. Familiarity with Short and Long courses of RT;
 - d. Protocols of Chemo-Radiotherapy
 - I. Induction;
 - II. Consolidation.
 - e. Timing from RT or Chemo-RT to Surgery.
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In **Colorectal Cancer supportive and palliative care**, certain questions commonly arise that need to be addressed in the guidelines to establish a prioritisation scheme for implementation, such as:

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- a. Supportive care services during cancer treatment (especially those that help avoid treatment abandonment);

 - b. Supportive care following treatment in survivorship to assist patients in returning to their community;

 - c. Colostomy education;

 - d. End-of-life palliative care for those patients in whom treatment has not been successful in eradicating the disease.
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In **Colorectal Cancer Surveillance** certain questions commonly arise that need to be addressed in the guidelines to establish a prioritisation scheme for implementation, such as:

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- a. Which tests;

 - b. Frequency.
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Under each package of interventions, a distinction between core and desirable elements to be included should be made to account for planning with scarce resources while complying with minimal requirements, without leaving out optimal scenarios.

5. Conclusions: implementation, monitoring and future guidelines revisions

- Phased implementation is an evolutionary process requiring ongoing adaptation as the systems improve;
- As implementation takes place, ongoing monitoring is required to assess the degree to which the system is improving so that next steps in each critical phase in colorectal cancer diagnosis and treatment can be recognised and re-prioritised;
- Guidelines revisions should be considered episodically (one to two years), based on actual outcomes.

6. Contributors

A detailed list of all members of the city team that contributed to the drafting of the document, including the participants in the peer review meetings conducted in the city, and all the external experts that reviewed and edited the final draft.

7. References and bibliography

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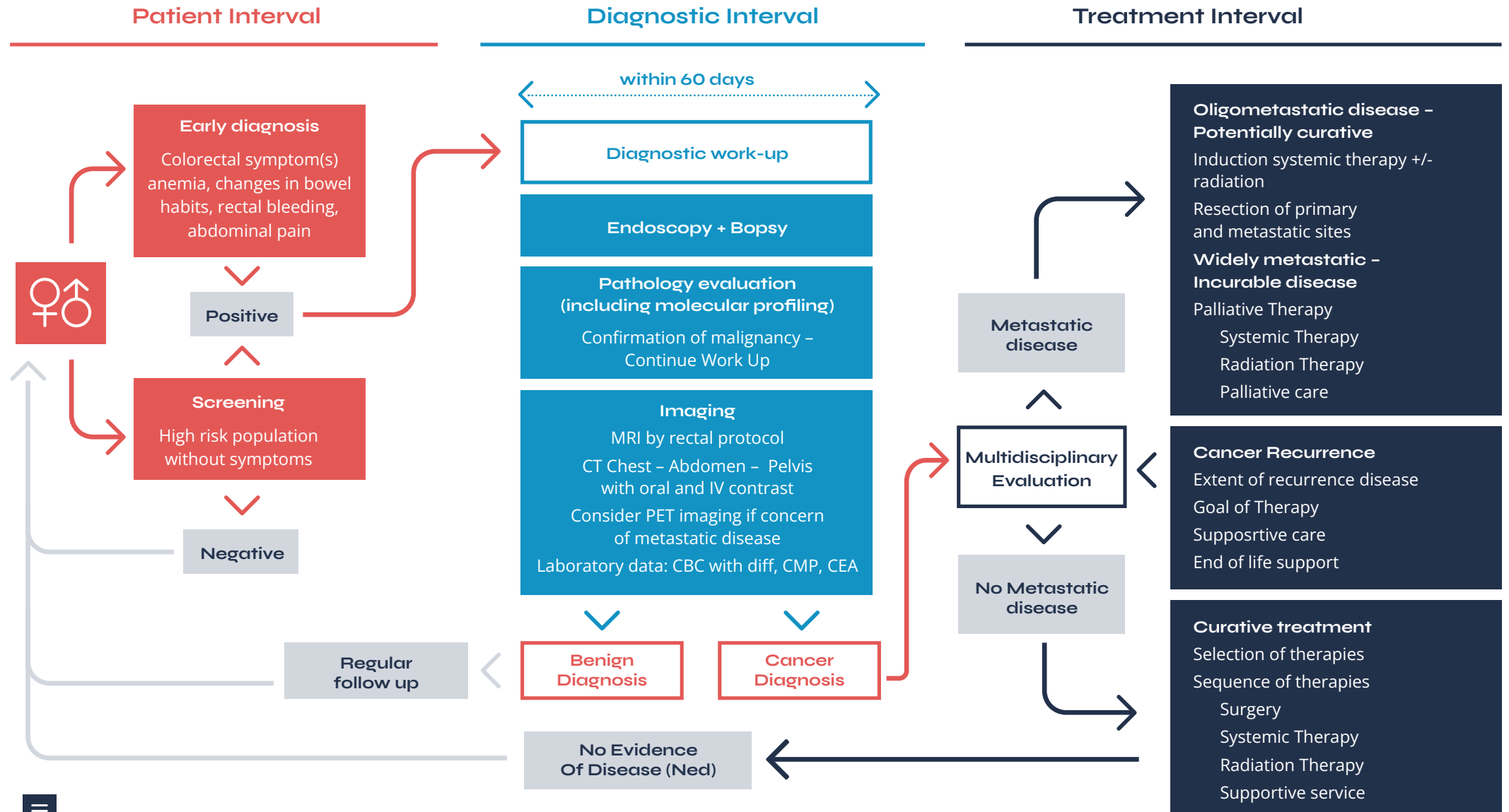
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Annex 1. Universal colorectal cancer patient pathway





<https://citycancerchallenge.org/>

