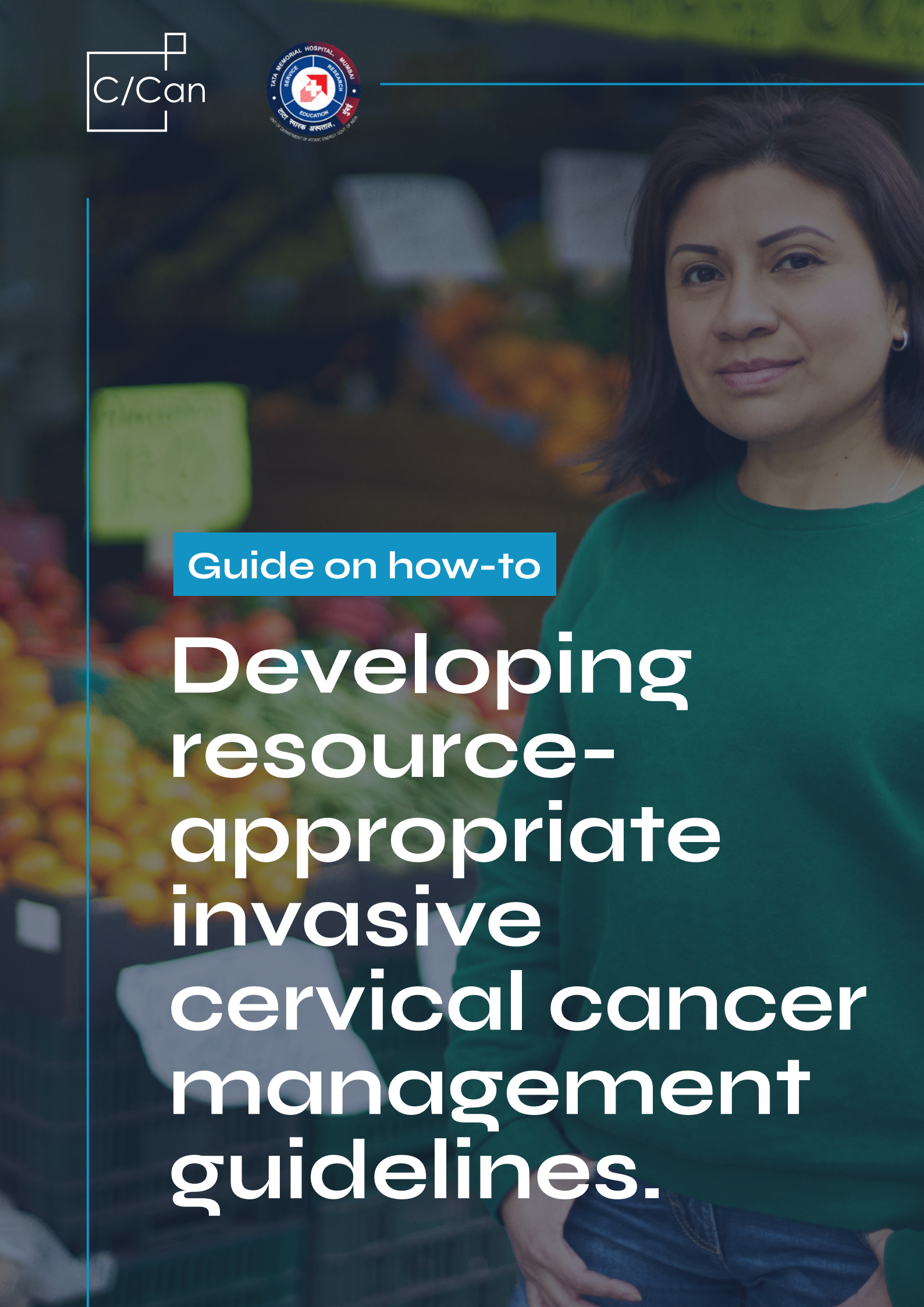


Guide on how-to

Developing resource-appropriate invasive cervical cancer management guidelines.

Table of contents

Purpose of the guide.

The purpose of this guide is to outline the steps and procedures for designing resource-appropriate invasive cervical 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 cervical cancer diagnosis (clinical evaluation, imaging, tissue sampling), multimodality treatment (surgery, radiotherapy, systemic therapy) and palliative care services in selected C/Can cities. The development of multidisciplinary teams and cancer networks will improve communication and care pathways, as well as successful implementation of guidelines.

Cervical cancer is potentially preventable. There are well-established primary prevention (HPV vaccine) and secondary prevention strategies (cytology/HPV testing/VIA/colposcopy) available for prevention and early detection of cervical cancer at population level. The burden of cervical cancer is very high in cities and countries where national screening programmes are non-functional. Therefore, most of these cancers are diagnosed at advanced stages, causing further resource constraints. Cervical cancer is also curable. In addition to the prevention and early detection actions, increasing access to quality and timely cervical cancer treatment is essential to reducing mortality.

To create resource-appropriate invasive cervical cancer management guidelines, the guideline development team requires an accurate understanding of currently available resources (infrastructure, human resources, equipment, and renewable supplies) for cervical cancer healthcare, so as to avoid creating guidelines that are 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 development team.

This document focuses on guidelines for establishing effective cervical cancer diagnosis and treatment services, which is a necessary prerequisite for cancer downstaging efforts to be effective, even when the majority of cervical cancers cases are diagnosed as locally advanced or metastatic disease.

The guide has been prepared through a collaboration between C/Can and Professor Dr Shylasree TS, MD, FRCOG, Professor and consultant gynaecological oncologist at the Tata Memorial Hospital, Mumbai, India, with the aim of supporting the different groups established by cities as they prioritise the development of cervical cancer management guidelines. These groups should interpret, analyse, and tailor the recommendations made in this guide, taking into account 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.

CERVICAL CANCER IMPACT

- Current and projected cervical cancer burden (incidence, mortality, prevalence, DALYs lost) in the world, region and country.
- Economic impact of cervical cancer in the country and city as measured by lost productivity and social disruption related to cervical cancer morbidity and deaths.
- Potential for improved cervical cancer outcomes based on prevention and early detection strategies in the country and city to reduce the overall incidence and the number of patients presenting with advanced stage disease, requiring more extensive and costly treatments.
- Potential for improved cervical cancer outcomes as measured by lower recurrence and higher survival rates based on the implementation of proven therapeutic strategies.

CERVICAL CANCER DIAGNOSIS AND TREATMENT OVERVIEW

- Synergistic role of early detection, diagnosis and multimodality treatment to improve cervical cancer outcomes.
- Access requirements for diagnostic work-up of clinically detected cervical abnormalities at the city level.
- Diagnostic services to establish cervical cancer diagnosis and clinical staging (clinical evaluation, imaging, tissue sampling, pathology).
- Multimodality cervical cancer treatment for non-metastatic Cervical cancer [surgery, radiotherapy, chemotherapy, and targeted therapies (when available)].
- Requirement for supportive care to help patients get through multimodality treatment without abandonment.
- Value of supportive care after treatment in survivorship to help patients reintegrate in their community.
- Importance of palliative care for patients with metastatic disease and in end-of-life care.

PHASED IMPLEMENTATION STRATEGIC PLANNING PERSPECTIVE

- Baseline assessment provides summary of existing diagnostic and treatment services and resources in city.
- Resource-stratified framework outlines the core service gaps needing to be filled or circumvented in city.
- 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.
- Phased implementation strategy defines a stepwise pathway for optimizing sustainable resource-utilisation while improving service delivery for Cervical cancer diagnosis, treatment and palliation.

2. Aims of the guideline document.

CERVICAL CANCER IMPACT

- Explain the purpose of the document and the potential interested audiences.
- Consider the clinical demand for Cervical cancer diagnosis and treatment services based on epidemiological data and projected needs based on quality benchmarks within a determined timeframe (up to 10 years).
- Discuss the available material resources (infrastructure, equipment and consumable materials) for Cervical cancer detection, diagnosis, treatment and supportive services.
- Reflect on the current and future training requirements to have an optimally functional work force to meet the current and projected patient demand for Cervical cancer diagnosis and treatment.
- 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 rational use of existing city resources and technology transfer and deployment in a stepwise approach.

3. Objectives of the city-specific cervical cancer management guideline.

- This document should guide the users as regards the rationale and necessity for creating Cervical cancer guidelines adapted to their city's context and 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 cervical cancer diagnosis and treatment services and in the quality and safety of treatments.
  - 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.

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 (Gynaecology).
  - 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:
  - Nursing.
  - Supportive/palliative care.
  - Physical therapy.
  - Patient navigation services.
- Guideline 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).

GUIDELINE DEVELOPMENT PROCESS

- A series of guideline development meetings should be planned to permit writing, review, editing and ratification of the guideline document:
  - Initial guideline drafting.
  - Internal review to consider issues of practicality of implementation.
  - Guideline revision based on internal review.
  - Administrative review to consider resource requirements and fiscal implications of implementation.
  - External expert review to evaluate predicted efficacy.
  - Guideline revision based on external review.
  - Guideline finalisation.
- Principles of guideline 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 should consider already existing scientific evidence based recommendations included in recognized guidelines such as the European Society of Gynaecology Oncology guidelines (ESGO)[1] and the International Federation of Obstetrics and Gynecology (FIGO) guidelines for staging and management.[2]
  - Guidelines have limited utility when they are aspirational but unachievable or unaffordable.
  - Given the complexity and extensive knowledge about cervical cancer diagnosis and treatment, the guideline development team should strongly consider the use of existing resource-stratified guidelines such as the American Society of Clinical Oncology (ASCO) Resource-Stratified Clinical Practice Guideline for management and care of women with Invasive cervical cancer[3] as a starting point for guidelines development.
  - 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.

- 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.

- In **cervical cancer diagnosis**, certain questions commonly arise that need to be addressed in the guideline to establish a prioritisation scheme for implementation, such as:
  - Timeliness of service access to avoid excessive delays.
  - Diagnostic imaging studies of the cervical lesion and adjacent spread to uterus, parametrium or lymph nodes (colposcopy, ultrasound, CT, MRI, etc.).
  - Staging studies to detect metastatic disease (ultrasound, CT, MRI, nuclear medicine studies).
  - Tissue sampling methods (cone biopsy, LEEP (loop electrosurgical excision procedure), cervical punch biopsy).

- In **cervical cancer treatment**, certain questions commonly arise that need to be addressed in the guideline to establish a prioritisation scheme for implementation, such as:
  - Cervical lesion surgical management and considering fertility sparing approaches in surgical management (cone biopsy or trachelectomy or modified radical hysterectomy or radical hysterectomy).
  - Pelvic lymph node surgical management with or without para-aortic lymphonodes assessment.
  - Radiation therapy management (timeliness of access to indicated radiotherapy).
  - Systemic therapy options (chemotherapy protocols, access to targeted therapies in appropriately selected patients).

- In **cervical cancer supportive and palliative care**, certain questions commonly arise that need to be addressed in the guideline to establish a prioritisation scheme for implementation, such as:
  - Supportive care services during cancer treatment (especially those that help avoid treatment abandonment).
  - Supportive care following treatment in survivorship to assist patients in returning to their community.
  - End-of-life palliative care for those patients in whom treatment has not been successful in eradicating the disease.
- 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 guideline 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 cervical cancer diagnosis and treatment can be recognised and re-prioritised.
- Guideline revisions should be considered episodically (one to two years), based on actual outcomes.

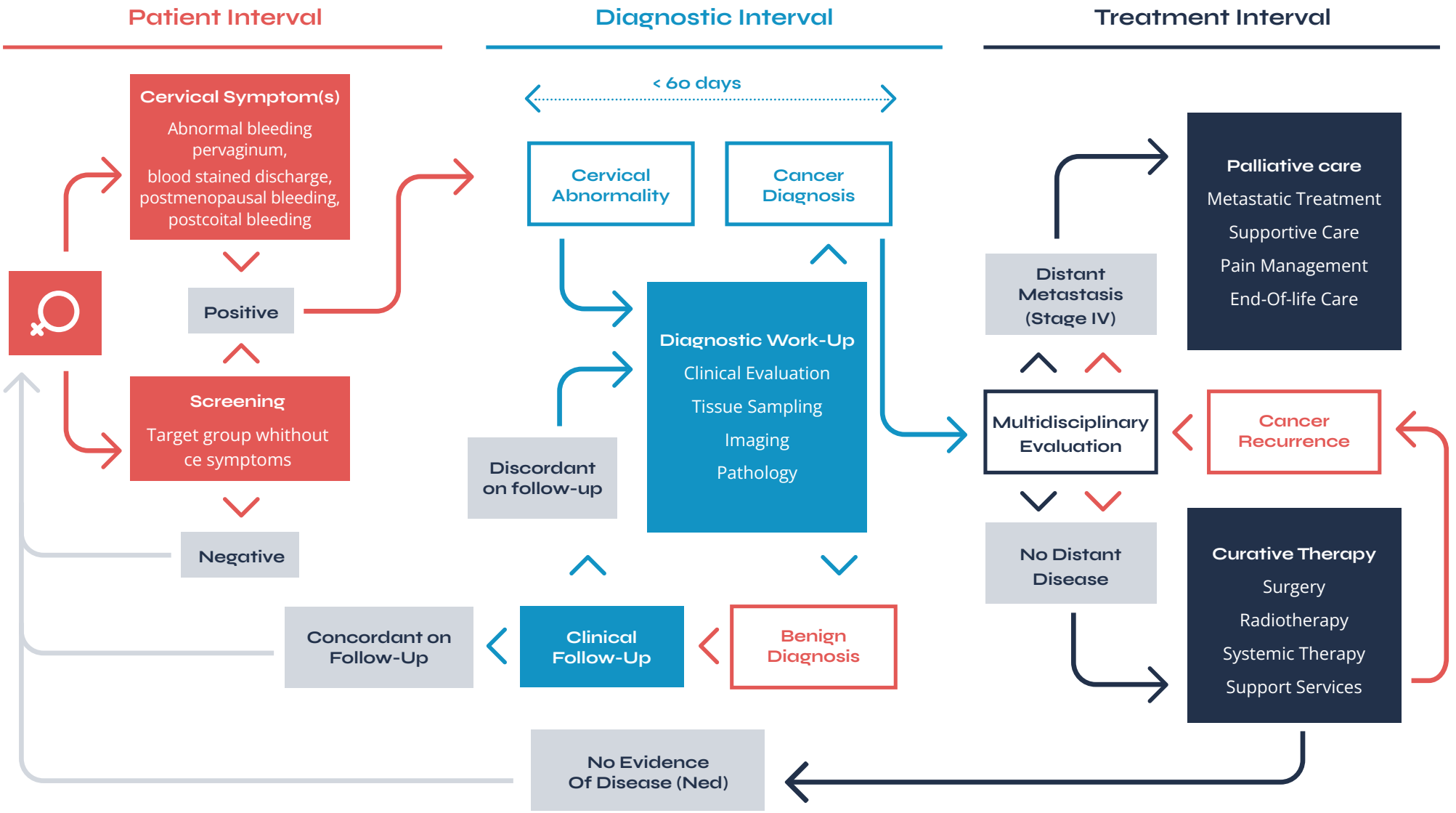
6. Contributors.

- Include 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.

- List of all publications referenced in the Cervical Cancer Management Guidelines, including the reference guidelines considered by the guidelines development team.

Annex 1. Universal Breast Cancer Patient Pathway.



Source: Breast Health Global Initiative (BHGI). 2019. This illustration is an adaptation of the orginial BHGI graph. The algorithm is adapted with permission.

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https://citycancerchallenge.org/