

# NCCN Framework for Resource Stratification: A Framework for Providing and Improving Global Quality Oncology Care

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## Abstract

More than 14 million new cancer cases and 8.2 million cancer deaths are estimated to occur worldwide on an annual basis. Of these, 57% of new cancer cases and 65% of cancer deaths occur in low- and middle-income countries. Disparities in available resources for health care are enormous and staggering. The WHO estimates that the United States and Canada have 10% of the global burden of disease, 37% of the world's health workers, and more than 50% of the world's financial resources for health; by contrast, the African region has 24% of the global burden of disease, 3% of health workers, and less than 1% of the world's financial resources for health. This disparity is even more extreme with cancer. NCCN has developed a framework for stratifying the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) to help health care systems in providing optimal care for patients with cancer with varying available resources. This framework is modified from a method developed by the Breast Health Global Initiative. The NCCN Framework for Resource Stratification (NCCN Framework) identifies 4 resource environments: basic resources, core resources, enhanced resources, and NCCN Guidelines, and presents the recommendations in a graphic format that always maintains the context of the NCCN Guidelines. This article describes the rationale for resource-stratified guidelines and the methodology for developing the NCCN Framework, using a portion of the NCCN Cervical Cancer Guideline as an example.

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## Background

More than 14 million new cancer cases and 8.2 million cancer deaths are estimated to occur worldwide on an annual basis.<sup>1</sup> Of these, 57% of new cancer cases and 65% of cancer deaths occur in low- and middle-income countries (LMICs). The disparities in available resources for health care are enormous and staggering. The WHO estimates that the United States and Canada have 10% of the global burden of disease, 37% of the world's health workers, and more than 50% of the world's financial resources for health; by contrast, the African region (AFRO) has 24% of the global burden of disease, 3% of health workers, and less than 1% of the world's financial resources for health.<sup>2</sup>

This health resource disparity is even more extreme with cancer. In 2012, 5.3 million people died of cancer

in LMICs, which notably exceeds the number of deaths attributed to the combination of HIV/AIDS (1.3 million), tuberculosis (1.3 million), and malaria (855,000).<sup>3</sup> Despite cancer's high incidence and mortality in LMICs, a disproportionately low fraction of development assistance for health (DAH) is allocated to cancer care. Of the \$14.5 billion in DAH in 2007 for which project-level information was available, \$6.6 billion (45.5%) was directed to HIV/AIDS (\$5.1 billion), malaria (\$0.8 billion), and tuberculosis (\$0.7 billion).<sup>4</sup> In comparison, only about 1.5% (\$549 million) of the \$35.6 billion in DAH in 2012 was allocated to the combination of all major noncommunicable diseases (NCDs), including heart disease, lung disease, diabetes, and cancer.<sup>5</sup> Of this small amount directed to NCDs, only an estimated 5% was allocated specifically for cancer.<sup>6</sup> Management

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of infectious diseases should remain a high global health priority, but the cancer burden is greatest in the regions and environments where health care is most resource-limited and disorganized. The result is that optimal cancer care is neither available nor possible in large segments of the world.

International health organizations increasingly acknowledge that evidence-based tools are desperately needed to delineate essential packages of potentially cost-effective measures for countries to consider and adapt if they are to make successful cancer control investments.<sup>7</sup> A number of clinical practice guidelines in oncology are available to assist practitioners and patients in making decisions regarding options of cancer care. However, most of these practice guidelines assume the availability of costly diagnostic and treatment resources applied within a mature and organized health care infrastructure. They make no recommendations about how resource expenditures should be prioritized to achieve the greatest clinical benefit and outcome. Most of the currently available clinical practice guidelines, such as those developed by NCCN, the European Society of Medical Oncology, or ASCO, are developed for the maximal level of resources. This makes the applicability of existing practice guidelines of limited utility in LMICs.

The WHO has articulated the concept of tailoring cancer treatments to the level of available resources by country.<sup>8</sup> The WHO, however, has not provided a framework for how LMICs should prioritize cancer treatment interventions based on formal resource assessment. The Breast Health Global Initiative (BHGI) was organized in 2002 to improve the outcomes of women with breast cancer in countries with limited resources. The BHGI pioneered the development of clinical practice guidelines that acknowledge and respect that different levels of resources are available regionally through a process of evidence-based resource stratification for breast cancer early detection, diagnosis, and treatment.<sup>9</sup> The BHGI methodology acknowledges varying levels of health care resources and develops a framework for providing diagnosis and treatment recommendations across 4 resource levels: basic, limited, enhanced, and maximal (Table 1).<sup>10</sup> In the BHGI framework, regions with low resource levels focus on providing therapy at the basic or limited level. The BHGI framework for resource-stratified oncology care has

**Table 1. Definitions of Resource Stratification Levels Used by the Breast Health Global Initiative<sup>9,18</sup>**

Resource Level	Description
Basic	Core resources or fundamental services absolutely necessary for any breast health care system to function
Limited	Resources or services that produce major improvements in outcome, such as increased survival, but which are attainable with limited financial means and modest infrastructure
Enhanced	Resources or services that are optional but important; may produce minor improvements in outcome but increase the number and quality of therapeutic options and patient choice
Maximal	Resources or services that may be used in some high-resource countries, but nonetheless should be considered lower priority than those in the basic, limited, or enhanced categories on the basis of cost or impracticality for limited-resource settings

been recognized by multiple international organizations, including the Institute of Medicine and the Council on Foreign Relations, as an innovative, intuitive, and effective way to optimally use limited health care resources and to provide a framework for the improvement in extent and effectiveness of cancer care as additional resources become available and health care infrastructures develop.<sup>11–18</sup> The BHGI framework is increasingly cited in the literature as a practical framework for defining realistic cancer care pathways by authors from both high-income countries and LMICs.<sup>19</sup>

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are a comprehensive set of evidence-based, consensus-driven guidelines for delivering multidisciplinary cancer care across the continuum, from risk assessment through prevention, screening, diagnosis, treatment, and survivorship, to end-of-life care. The NCCN Guidelines were intentionally developed for use at the resource level available in the United States. However, the required resource level and infrastructure to apply the NCCN Guidelines recommendations makes adher-

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ence impractical in resource-limited regions of the world. To address this limited utility and to provide a framework for delivering and improving cancer care in low- and middle-resource settings, NCCN initiated a program to develop a framework for resource-stratifying the family of NCCN Guidelines.

The NCCN Framework for Resource Stratification of the NCCN Guidelines (NCCN Framework) outlines a rational approach for building cancer management systems to provide the highest achievable level of cancer care by applying available and affordable services in a logical sequence. Each resource level builds on the one before it, providing a framework for improving cancer care with incremental changes to the availability and allocation of resources. In highly selected circumstances, treatment options are added for consideration in lower resource settings that are not typically used in US-based NCCN Member Institutions. Treatment recommendations applicable to each level of the NCCN Framework can be viewed within the context of the NCCN Guidelines. The methodology used by NCCN in developing the NCCN Framework is similar to that arising from the efforts of the BHGI. This report describes the rationale and methods used by NCCN to develop the resource-stratified framework from the NCCN Guidelines.

## Methods

The NCCN Guidelines are developed by disease-oriented, multidisciplinary expert panels that review the available scientific evidence and update the guideline recommendations on a continuous basis. Updating the NCCN Guidelines involves an intentional, systematic literature search to identify relevant scientific data, a formal review and input process from experts within the NCCN Member Institutions, and a formal mechanism for input into the process from external stakeholders. The NCCN Guideline panels review this information, evaluate it for scientific rigor, and update the recommendations in the NCCN Guidelines as appropriate. The guidelines recommendations are based on scientific evidence whenever evidence is available, and where evidence is insufficient, recommendations are based on expert consensus. Each of the recommendations is associated with a level of evidence and extent of expert panel consensus supporting the recommenda-

tion. A manuscript accompanying the algorithmic guidelines provides the rationale for the specific recommendations.

The NCCN Guidelines are available free of cost on the NCCN Web site. These guidelines are widely used by practitioners, pharmacists, nurses, patients, payers, and students. Translated versions of many of the guidelines are available in many different major languages. The guidelines are used for the assessment of quality care in the United States, but are also used extensively in other countries. Currently, 47% of the 754,000 verified users of the NCCN Web site are from 198 countries outside the United States and approximately 36% of the guidelines downloads are from outside the United States.

The widespread use of the NCCN Guidelines outside the United States in LMICs combined with the desire to provide a set of situationally appropriate, useful recommendations in cancer care led NCCN to create a formal, standardized resource stratification process for its guidelines library. In this effort, NCCN uses a standard methodology adapted from that used by the BHGI. The process begins with the selection of an appropriate guideline for stratification. A subgroup of multidisciplinary experts is chosen from the guideline panel to implement the stratification process. Each panelist is educated regarding the principles and practice of NCCN Framework resource stratification. A table listing every diagnostic test and treatment recommendation from the NCCN Guideline is generated, and the panel members are asked to assign a priority to each recommendation based on resource availability formally defined by NCCN (Table 2). These assignments are used to draft an initial resource-stratified framework to be reviewed by the full guidelines panel for appropriateness, comment, and revision suggestions. Once the panel agrees on the resource-stratified framework for each guideline, a preliminary version of the NCCN Framework is developed. The preliminary version is then circulated to external expert reviewers with experience with the disease at various resource levels. The additional comments from these reviewers are evaluated, and further revisions are made as needed before the resource-stratified NCCN Framework is finalized on the NCCN Web site.

NCCN considers “basic resources” the minimum essential resources that must be available before a health care system can begin to treat a specific

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disease circumstance. Because basic resources are so fundamental to successful treatment, their absence essentially defines conditions in which successful treatment cannot be anticipated. Thus, if basic resources are not available, referral to another treatment center with at least basic resources should be considered, or the therapeutic focus should shift from curative treatment goals to palliative care. “Core resources” include interventions that substantially improve outcome over those achieved with basic resources alone but that are not cost-prohibitive. In most cases, treatment facilities must have at least core resources to be a referral cancer center with adequate capacity to provide effective cancer diagnosis and treatment.

“Enhanced resources” add interventions that provide smaller incremental benefit and/or are cost-prohibitive at the basic or core resource framework.

**Table 2. Definitions of NCCN Framework for Resource Stratification of NCCN Guidelines**

Resources Available	Description
Basic resources	Essential services needed to provide basic minimal standard of care
Core resources	Includes services provided in the Framework for Basic Resources plus additional services that provide major improvements in disease outcomes (eg, survival) that are not cost-prohibitive
Enhanced resources	Services provided in the Framework for Core Resources and additional services that provide lesser improvements in disease outcomes and/or services that provide major improvements in disease outcomes, but are cost-prohibitive in lower resource settings
NCCN Guidelines	The NCCN Guidelines are evidence-based, consensus-driven recommendations based on services available at centers of excellence in the United States; they include services from the Framework for Enhanced Resources and additional services that provide minor improvements in disease outcomes, interventions that are cost-prohibitive in lower resource settings, and/or services that do not provide improvement in disease outcomes but are desirable services

Although enhanced resources may not be mandated and can be considered optional when resources are particularly limited, they provide valuable goals for an evolving center of excellence, especially when the additions decrease treatment morbidity or increase treatment acceptance by the patient population. The NCCN Guidelines represent the care recommended with “maximal resources,” and include all clinically appropriate choices and options, including interventions that are cost prohibitive with enhanced resources and may be aimed primarily at improving quality of life. From these data, graphic frameworks for basic, core, and enhanced resources are generated.

The graphic resource-stratified frameworks always maintain the context of the NCCN Guidelines. This is done by displaying any recommendations that exists on the NCCN Guidelines but not on a lower resource level in a light gray font. Recommendations included at the given resource level are displayed in black (Table 3). In situations where a treatment or approach would be contemplated in a lower resource setting but is not believed appropriate in the NCCN Guidelines, the recommendation is presented in blue. This allows the users of the basic, core, and enhanced resource-stratified versions of the NCCN Framework to immediately understand the context of the recommendations relative to care provided in the NCCN Guidelines, and to understand which therapies are optimally applied in each given resource setting (Figure 1).

## Results

The first resource-stratified framework developed by NCCN was for the treatment of cervical cancer. The NCCN Guidelines for Cervical Cancer use the In-

**Table 3. Recommendations Provided in The NCCN Framework for Resource Stratification<sup>a</sup>**

Text Style	Meaning
Black text	Included recommendation
Gray text	Withheld recommendation
<i>Italicized blue text</i>	<i>Modified recommendation based on resource level</i>

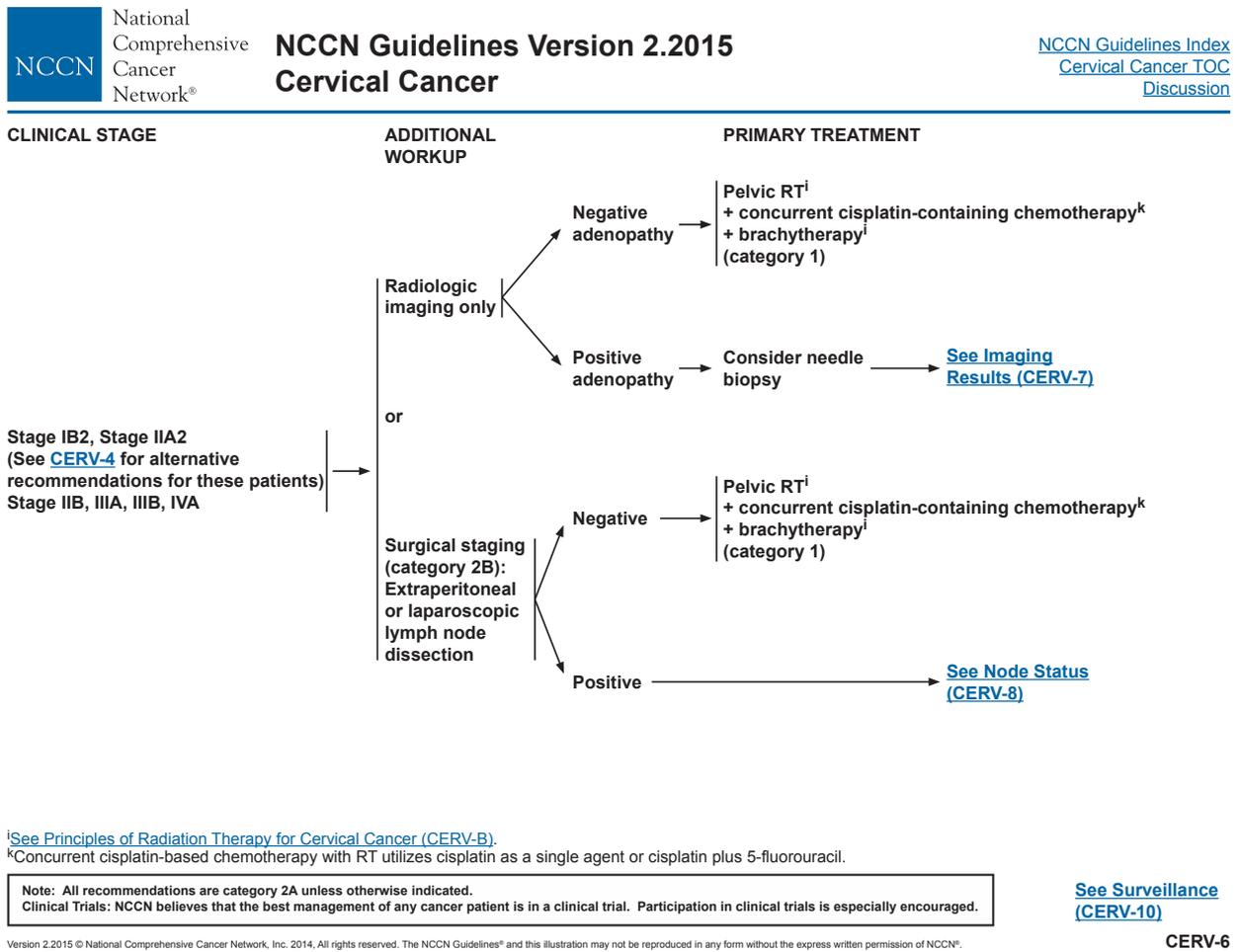
<sup>a</sup>Recommendations provided in The NCCN Framework for Resource Stratification are identified as being an included recommendation, a recommendation in the NCCN Guidelines but withheld in a given resource framework, or a recommendation included in a Resource Framework but not included in the parent NCCN Guideline.

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ternational Federation of Gynecology and Obstetrics (FIGO) staging system, in which cervical cancer is staged largely by clinical evaluation.<sup>20,21</sup> Although surgical staging is more accurate than clinical staging, surgical staging often cannot be performed in low-resource regions where the cervical cancer incidence and mortality are highest.<sup>21–25</sup> For illustrative purposes, the NCCN Guidelines for the evaluation and primary treatment of locally advanced cervical cancer (stages IIB, IIIA, IIIB, and IVA) are shown in Figure 1. In the NCCN Guidelines for high-resource environments, lymph node disease is a key determinant of treatment recommendations. In high-resource settings, radiologic imaging or surgical staging can be used in addition to clinical examination to assess lymph node status. Recommended primary treatment for locally advanced disease includes ra-

diation therapy (RT), with treatment fields based on lymph node involvement; concurrent cisplatin-containing chemotherapy; and brachytherapy.

Figure 2 shows the NCCN Framework for care in the basic resource setting. The gray text represents treatments in the NCCN Guidelines that are not recommended in the Framework for Basic Resources. Black text represents recommendations or information included in the Framework for Basic Resources and in the NCCN Guidelines. Blue text represents recommendations that are included in the Framework for Basic Resources but that are not found in the NCCN Guideline. In the Framework for Basic Resources, primary treatment decisions are based solely on clinical staging in the absence of specialized surgery or advanced imaging. Additionally, alternative treatment approaches have been



**Figure 1.** NCCN Clinical Practice Guidelines in Oncology for Cervical Cancer. High-resource level or parent guideline outlines treatment recommendations for services available at centers of excellence in the United States. (See Table 3 for legend.)

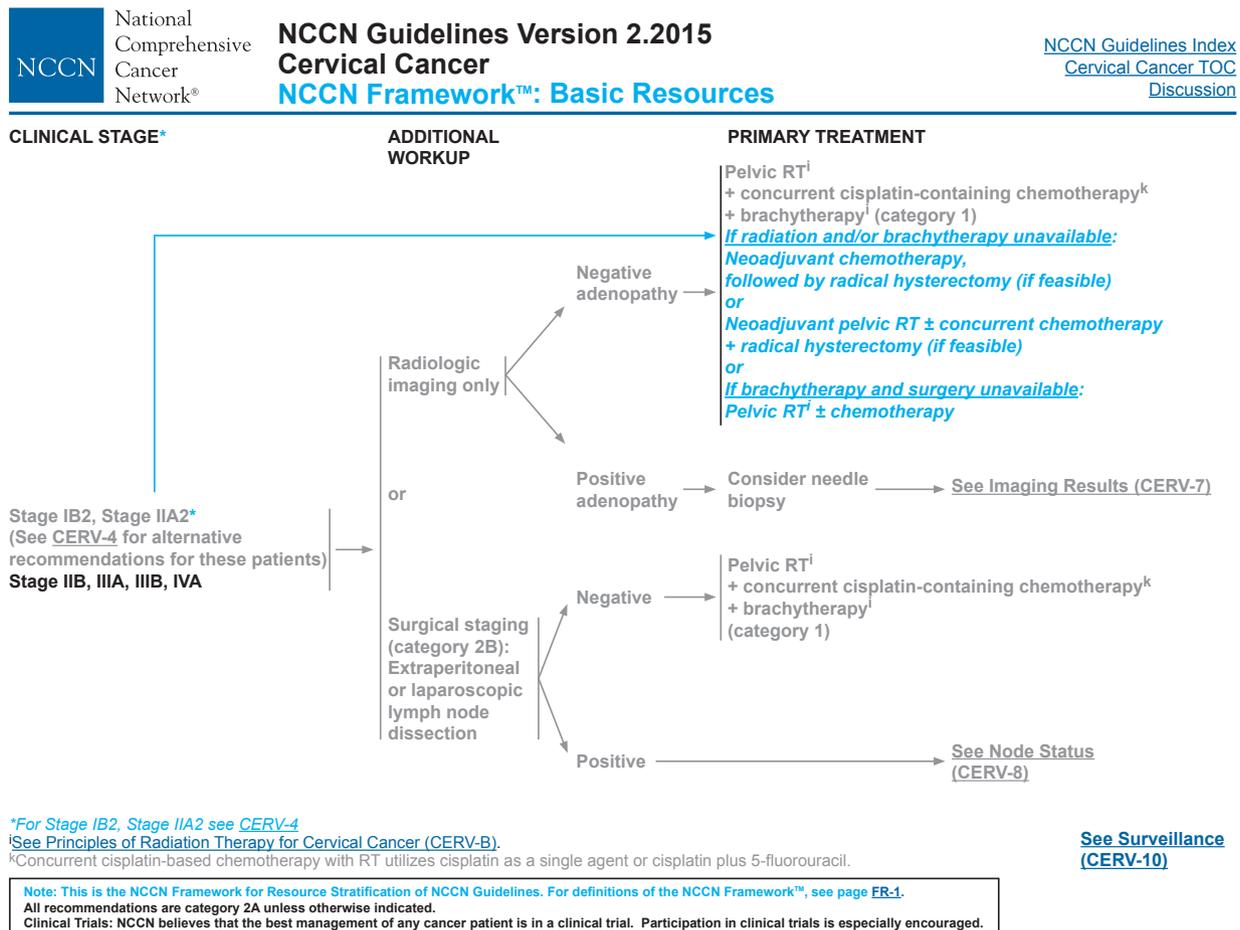
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proposed for situations in which RT, brachytherapy, and/or surgery are unavailable. Examples noted in blue text include neoadjuvant chemotherapy or neoadjuvant chemoradiation performed in combination with primary surgery when feasible. This strategy allows cytoreduction with chemotherapy followed by potentially curative surgery in settings where RT is not typically available. These alternative treatment modalities represent elemental steps that have been shown to provide a measurable survival benefit through tumor shrinkage, which allows for surgical resection in some patients.<sup>26–28</sup>

Figures 3 and 4 represent the corresponding NCCN Framework for Core Resources and Enhanced Resources for locally advanced cervical cancer, respectively. In the Framework for Core Resources (Figure 3), primary treatment determinations con-

tinue to be made based on clinical staging alone. If feasible, recommended treatment includes pelvic RT with concurrent cisplatin-containing chemotherapy and brachytherapy. However, if brachytherapy is not feasible, alternative treatment modalities with curative potential can be determined from clinical trial data. Treatment paradigms that incorporate neoadjuvant chemotherapy or chemoradiation offer a measurable level of success.<sup>26–28</sup>

In the NCCN Framework for Enhanced Resources (Figure 4), specialized surgical techniques required for precise staging may be unavailable. However, treatment decisions can be facilitated by incorporating radiologic imaging with clinical staging. In this setting, primary treatment recommendations concur with the NCCN Guidelines and are guided by the presence or absence of radiologically detected adenopathy.



**Figure 2.** NCCN Framework for Resource Stratification of NCCN Guidelines showing basic resources for workup and primary treatment of stage IIB, IIIA, IIIB, and IVA disease. Essential services needed to provide basic minimal standard of care are shown. (See Table 3 for legend.)

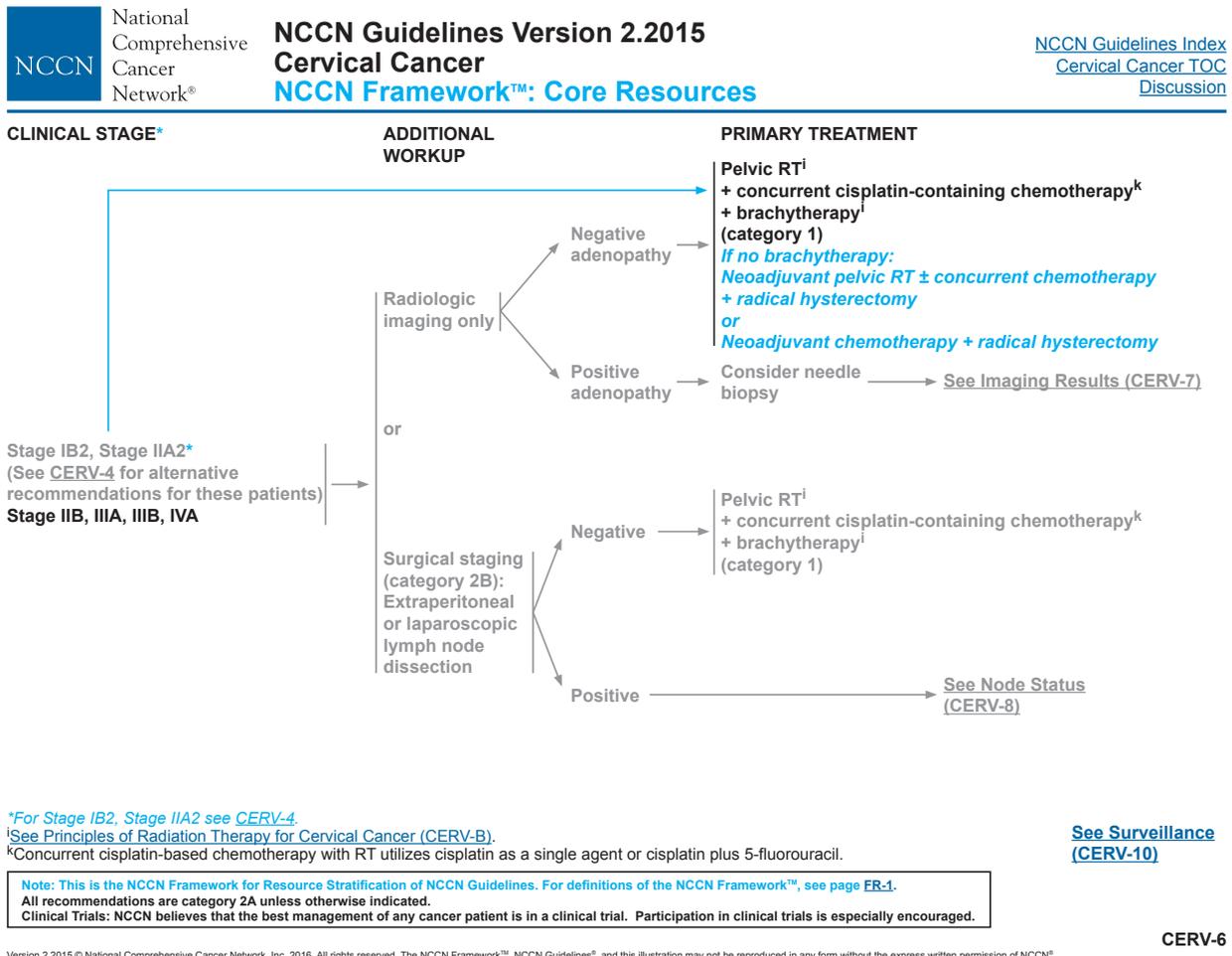
**Discussion**

Clinical practice guidelines are widely used to assist health care decision-making in high-resource settings; the same opportunity exists for resource-constrained health care environments. The optimal application of limited resources requires that the magnitude of benefit and the required resources for cancer care be considered explicitly. Resource-stratified frameworks are intended to aid the optimal use of the resources that are available, not to limit their use. The expectation is that health care systems will deliver the best care possible with available resources and will strive to advance through the levels, with the goal of incrementally approximating and achieving the maximal level of care and resources as described in the NCCN Guidelines.

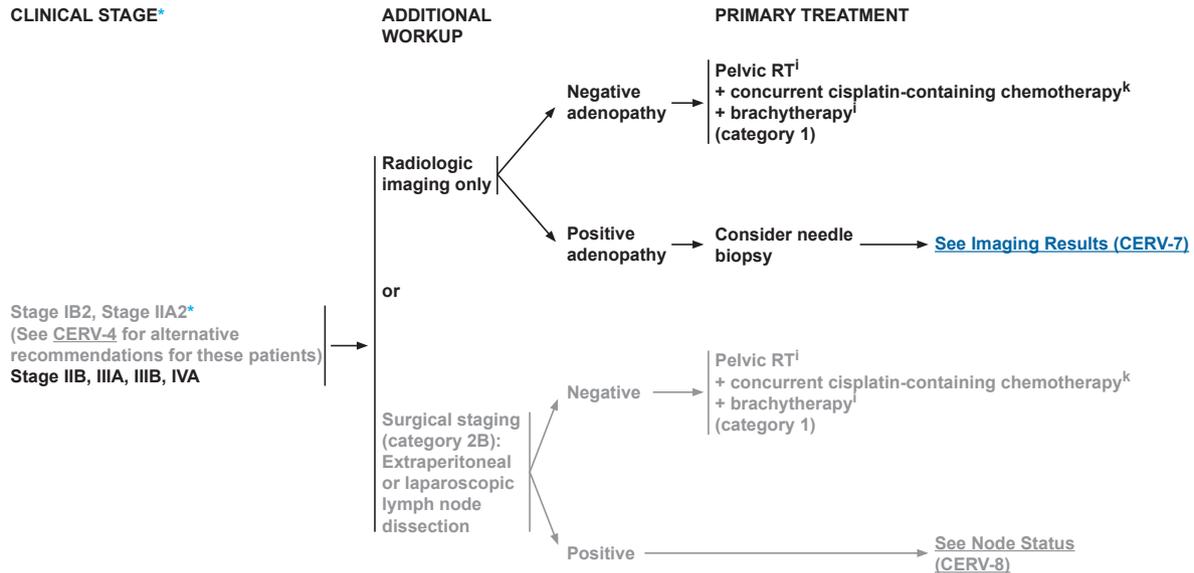
Optimal allocation of scarce resources is also a priority, so that in lower-resource settings they can be used only when their use results in demonstrable improvement in outcomes. The inability to offer maximal care within a limited-resource setting should not deprive patients of the very best care that can be provided based on the resources that are available.

Resource stratification can be used at either the regional or the health care setting level. More resource-intensive frameworks might be used in centralized tertiary care centers, whereas Enhanced, Core, or Basic Frameworks might inform resource allocation in regional hospitals or local clinic settings.

Many cancer care delivery systems in LMICs are inadequate and ineffective because of resource constraints and suboptimal organization. Government agencies and ministries, nongovernment organizations,



**Figure 3.** NCCN Framework for Resource Stratification of NCCN Guidelines showing core resources for workup and primary treatment of stage IIB, IIIA, IIIB, and IVA disease. This framework includes services from the framework for basic resources and additional services that provide major improvements in disease outcomes, such as survival, that are not cost-prohibitive. (See Table 3 for legend.)



\*For Stage IB2, Stage IIA2 see CERV-4.

<sup>i</sup>See Principles of Radiation Therapy for Cervical Cancer (CERV-B).

<sup>k</sup>Concurrent cisplatin-based chemotherapy with RT utilizes cisplatin as a single agent or cisplatin plus 5-fluorouracil.

[See Surveillance \(CERV-10\)](#)

Note: This is the NCCN Framework for Resource Stratification of NCCN Guidelines. For definitions of the NCCN Framework™, see page FR-1. All recommendations are category 2A unless otherwise indicated. Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

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**Figure 4.** NCCN Framework for Resource Stratification of NCCN Guidelines showing enhanced resources for workup and primary treatment of stage IIB, IIIA, IIIB, and IVA disease. Services from the Framework for Core Resources and additional services that provide lesser improvements in disease outcomes and/or services that provide major improvements in disease outcomes but are cost-prohibitive in lower-resource settings are included. (See Table 3 for legend.)

health care systems, hospitals, clinics, and individual practitioners can use resource-stratified approaches to optimize treatment and improve patient outcomes. The NCCN Framework for Resource Stratification provide an evidence-based approach for improving the quality, effectiveness, and efficiency of health care delivery by outlining optimal strategies for use of existing resources. At the same time, futile and resource-wasting approaches are explicitly identified when essential, basic-level services are unavailable, under-resourced, or dysfunctional. Rather than restricting treatment to a limited number of individuals through the overuse of expensive strategies of marginal benefit, resource stratification frameworks can be used to develop optimized strategies for equitable health care delivery in service of the entire community.

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