

# Resource-Stratified Guidelines and Clinical Pathways



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# How Do We Optimize Resources and Quality in the Treatment of Breast Cancer?

1. **Understand the cancer demographics in the region**
  - **Incidence, Stage, Mortality**

# How Do We Optimize Resources and Quality in the Treatment of Breast Cancer?

## 2. Assess existing infrastructure, availability of equipment and human resources

- Pathology (ER, HER2 testing)
- Genomic and genetic tests
- Radiology (staging, follow-up of metastatic disease)
- Operating room and surgical services
- Radiation equipment
- Drugs and infusion services
- Supportive and palliative care

# How Do We Optimize Resources and Quality in the Treatment of Breast Cancer?

- 3. Evaluate cost-effectiveness and feasibility of interventions**
  - **WHO Essential Medicine List**
  - **Resource-Stratified Guidelines**
  - **Clinical Pathways tailored to local context**

# How Do We Optimize Resources and Quality in the Treatment of Breast Cancer?

## 4. Monitor outcomes

- Toxicity, relapse
- Use of Quality Metrics to evaluate performance

# Cancer Clinical Practice Guidelines

- **Evidence-based clinical practice guidelines provide recommendations for management of cancer with the goal of improving quality of care and optimizing outcomes**
  - **Prominent guidelines: ASCO, ESMO, NCCN**

- **Most assume availability of costly resources applied within a mature and organized health care infrastructure**
  - **Do not address how resource expenditures should be prioritized to achieve greatest benefit**
  - **Limited applicability of many existing guidelines in Low- and Middle-Income Countries (LMICs)**

# Resource-Stratified Guidelines

- **Evidence-based, economically feasible, culturally appropriate**
- **Graduated and/or region-specific strategies**
- **Take into account costs and complexity of health care delivery**
- **Aid in prioritizing resources and strategizing equitable, phased implementation of cancer services**

# Resource-Stratified Guidelines for Cancer Care and Control in Low- and Middle-Income Countries

- **World Health Organization (WHO)** called for tailoring cancer treatments to the level of available resources by country in 2002
- **Breast Health Global Initiative (BHGI)** formalized 1<sup>st</sup> stratified guidelines focusing on breast cancer shortly thereafter
- Subsequently multiple organizations have created guidelines customized for various cancer subtypes and regions, including **National Comprehensive Cancer Network (NCCN)** and **American Society of Clinical Oncology (ASCO)**



# WHO Resource-Stratification

- **Tailoring cancer treatments to level of available resources by country**
  - Stratified national health care resources into low-, medium-, and high-resource scenarios to facilitate establishment of National Cancer Control Plans to ensure most efficient use of resources
- **Examples of WHO resource-stratified recommendations:**
  - 2013 WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention
    - VIA, “screen and treat” approach
  - 2014 WHO position paper on mammography screening
    - Separates concept of early diagnosis from screening

# Breast Health Global Initiative

Founder and Past BHGI Chair and Director: B Anderson

Current BHGI Chair and Director: J Scheel



*The* Breast Health Global Initiative

- **Between 2002 and 2018, through a series of six collaborative global summits, BHGI developed a resource-stratified framework to guide all aspects of breast cancer management**

# Breast Health Global Initiative: 4-tier Stratification

Resource Level	Availability of Services
Basic	Fundamental or core services necessary for any cancer system to function (e.g. mastectomy)
Limited	Second-tier services that intend to produce major improvements in outcomes and are achievable with little financial means and modest infrastructure (e.g. tamoxifen as adjuvant therapy)
Enhanced	Third-tier services that are optional in a resource-constrained setting but are important and should produce further improvements in outcome (e.g. aromatase inhibitors)
Maximum	Services that might be used in settings where there are no resource constraints. Resources at the maximum level always depend on existence and functionality of all lower-level resources (e.g. breast MRI)

# Breast Health Global Initiative Guideline

## Example: Breast Cancer Detection

Anderson B et al, Cancer 2008

Level	Method
Basic	Clinical Breast Exam
Limited	Diagnostic ultrasound/mammogram Screening mammography of target group
Enhanced	Mammographic screening age 50-69 every 2 years
Maximal	Annual mammography 40 and older Other imaging (including MRI) for high risk groups

# ASCO Resource-stratified Guidelines: Methods and Opportunities

Al-Sukhun S et al, J Glob Oncol 4:1-8, 2018

- Intended to complement - not replace - local guidelines
- **Process**
  - **Creation of multidisciplinary Expert Panels**
    - Members represent geographic, sex, and discipline diversity
    - Most members are from (or have extensive experience in) basic- and limited-resource settings
  - **Systematic review of the evidence**, including literature search
  - **Recommendations developed by the Panel**
    - Adapted BHGI's four-tier resource-stratification levels
    - If available literature insufficient to inform an evidence-based recommendation, a formal consensus process is used
  - **Resource-Stratified guidelines published** in the open access journal, *JCO Global Oncology*

# ASCO Resource-stratified Clinical Practice Guidelines

- **Published**
  - **Cervical Cancer**
    - Primary Prevention (Arrossi S et al, JCO GO 2016)
    - Secondary Prevention (Jeronimo J et al, JCO GO 2016)
    - Treatment (Chuang L et al, JCO GO 2016)
  - **Palliative Care** (Osman H et al, JCO GO 2018)
  - **Colorectal Cancer**
    - Early detection (Lopes G et al, JCO GO 2019)
    - Treatment of early stage (Costas-Chavarri A et al, JCO GO 2019)
    - Treatment of metastatic (Chiorean G et al, JCO GO 2020)
  - **Ovarian Cancer**
    - Assessment of Adult Women With Ovarian Masses and Treatment of Epithelial Ovarian Cancer (Vanderpuye V et al, JCO GO 2021)
- **Approved in concept**
  - **Metastatic Breast Cancer**

# National Comprehensive Cancer Network (NCCN) Resource-Stratified Framework

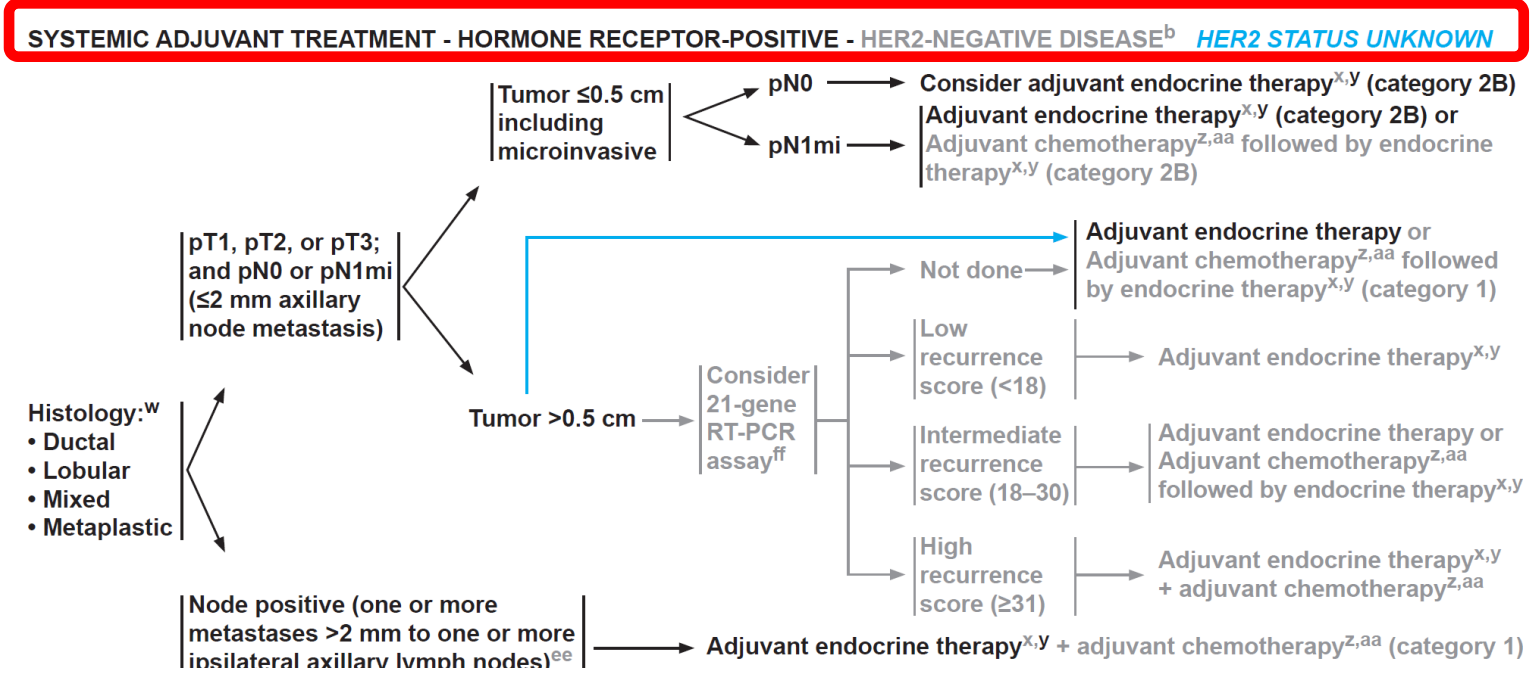


## NCCN Guidelines Version 2.2017 Invasive Breast Cancer NCCN Framework™: Basic Resources

**Black Text:** Generally available standard of care

**Gray Text:** Highly advanced/optimal care that may be costly, technically challenging, and/or have a lesser impact on outcome

**Blue Text:** Regional options that may be considered



# Resource-Stratified Guidelines

***NOT* “suboptimal care”**

**Should be seen as “aspirational”**



# Clinical Pathways

- **Clinical pathways:** a tool for enhancing quality and value
- Clinical pathways are a mechanism to reduce variation in healthcare delivery and control costs
  - Goal is high quality, value-based care
  - Efficacy, toxicity, and cost are assessed and balanced

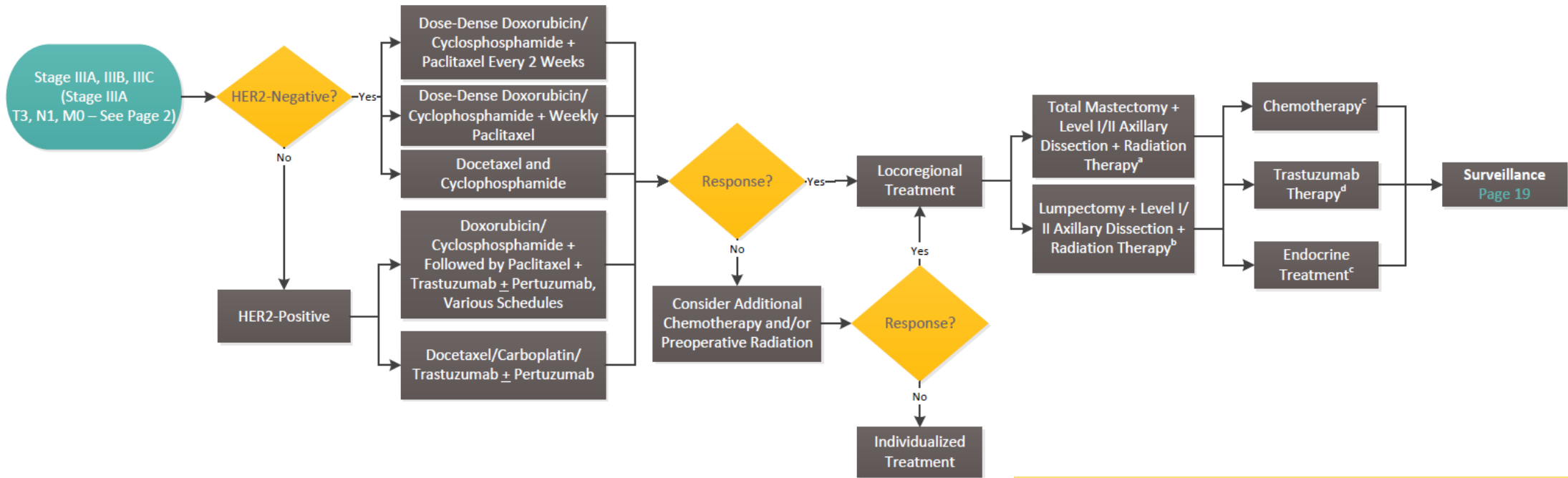
*Well-designed and effectively implemented clinical pathways can be an important tool for improving adherence to evidence-based medicine and reducing unwarranted variation in care*

# Clinical Pathway: Example

## Invasive Breast Cancer

### Preoperative Systemic Therapy for Inoperable or Locally Advanced

**NOTE:** Enrollment in a clinical trial is the preferred treatment option for eligible patients at all times



# ASCO Criteria for High Quality Clinical Pathways in Oncology

Zon RT et al, J Oncol Practice 13:207-210, 2017






- **Pathway development**
  - Expert driven, reflects stakeholder input, transparent, evidence-based, patient-focused, clinically-driven, up-to-date, comprehensive, promotes participation in clinical trials
- **Implementation and use**
  - Clear and achievable expected outcomes, integrated, cost effective technology and decision support, efficient processes for communication and adjudication
- **Analytics**
  - Efficient and public reporting of performance metrics, outcomes-driven results, promotes research and continuous quality improvement

## CHECKLIST Evaluating Oncology Clinical Pathways Programs

Clinical pathways are detailed, evidence-based treatment protocols that delineate optimal treatment options for cancer patients and may include recommended dosing, time frames, and sequencing of therapies. Payers, healthcare systems, and providers are increasingly adopting these treatment management tools, but how can your oncology practice know if a specific clinical pathway program is developed and implemented in a way that will ensure high-quality cancer care for your patients?

The questions below serve as a guide to examine a clinical pathway program your practice may currently be using or a clinical pathway that you may be considering for future use. Use the following checklist to help determine if an oncology clinical pathway program **meets, partially meets, or doesn't meet** criteria developed by the American Society of Clinical Oncology (ASCO) for a high-quality oncology pathway program, which focuses on three key areas: development, implementation/use, and analytics.<sup>1</sup>

### ONCOLOGY CLINICAL PATHWAY: DEVELOPMENT

	ASCO CRITERIA		
	Meets	Partially Meets	Doesn't Meet
 <b>Is it expert driven?</b> Did practicing oncology providers with relevant disease and/or specialty expertise play a central role in the pathway development?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 <b>Does it reflect stakeholder input?</b> Was there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 <b>Is it transparent?</b> Was there a clear, consistent process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individual or entities that contributed to the development of pathway content?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 <b>Is it evidence-based?</b> Is the clinical pathway based on the best available scientific evidence documented or disseminated in clinical practice guidelines, peer-reviewed journals, and/or other disseminated vehicles? Is a mechanism in place for considering high-quality evidence generated from validated real-world data?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
 <b>Is it patient focused?</b> Does the pathway include evidence-based options to account for differences in patient characteristics and/or preferences?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

# Conclusions

- **Resource-stratified guidelines** provide evidence-based recommendations for cancer care that can be tailored to *resource availability* and *health systems infrastructure*
- **Clinical pathways** enhance quality and value, reduce variation in healthcare delivery, and control costs
- Policymakers, clinicians, and health care administrators can employ resource-stratified guidelines and develop clinical pathways to inform *prioritization and allocation of resources* in the design and implementation of cancer control strategies
- *Effective implementation of resource-stratified guidelines and clinical pathways requires **quality metrics, monitoring, and continual re-evaluation** to guide improvements in cancer care*

# Resource-Stratified Guidelines and Clinical Pathways



**Thank You!**