2018 GLOBAL SUMMIT: IMPROVING BREAST HEALTHCARE THROUGH RESOURCE-STRATIFIED PHASED IMPLEMENTATION

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BCI 2.5 is a global campaign to reduce disparities in breast cancer outcomes for 2.5 million women
Initiating Partners

American Cancer Society
Susan G. Komen for the Cure
Breast Health Global Initiative
Harvard Global Equity Initiative
National Cancer Institute Center for Global Health
Norwegian Cancer Society
Pan American Health Organization (PAHO)
Union for International Cancer Control (UICC)
Women’s Empowerment Cancer Advocacy Network (WE CAN)
2018 GLOBAL SUMMIT

- Resource-Stratified Guidelines
- Guideline Adoption
- Phased Implementation
2018 Global Summit

- Resource-Stratified Guidelines
- Guideline Adoption
- Phased Implementation
BHGI GUIDELINE DEVELOPMENT

- Comprehensive guidelines by selected expert panels
- Consensus opinions based on evidence review
- Publication of a) consensus and b) individual manuscripts

GUIDELINE DEVELOPMENT SUMMITS:
Global Summit 2002: Health Care Disparities
Global Summit 2005: Resource Stratification

GUIDELINE VALIDATION SUMMITS:
Global Summit 2007: Guideline Implementation
Global Summit 2010: Healthcare Delivery

Global Summit 2012: Supportive Care and QOL
GLOBAL SUMMIT 2005 – BETHESDA

RESOURCE STRATIFICATION

- **Basic level:** Core resources or fundamental services necessary for any breast health care system to function.

- **Limited level:** Second-tier resources or services that produce major improvements in outcome such as survival.

- **Enhanced level:** Third-tier resources or services that are optional but important, because they increase the number and quality of therapeutic options and patient choice.

- **Maximal level:** Highest-level resources or services used in some high resource countries that have lower priority on the basis of extreme cost and/or impracticality.
BHGI GUIDELINE TABLES

HEALTH CARE SYSTEMS

<table>
<thead>
<tr>
<th>Health Care Systems</th>
<th>Stage I</th>
<th>Stage II</th>
<th>Locally Advanced</th>
<th>Metastatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Guide</td>
<td>Basic</td>
<td>Limited</td>
<td>Consolidated</td>
<td>Breast CT</td>
</tr>
</tbody>
</table>

EARLY DETECTION

<table>
<thead>
<tr>
<th>Early Detection</th>
<th>Stage I</th>
<th>Stage II</th>
<th>Locally Advanced</th>
<th>Metastatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>Basic</td>
<td>Limited</td>
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<td>Breast CT</td>
</tr>
</tbody>
</table>

DIAGNOSIS

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Stage I</th>
<th>Stage II</th>
<th>Locally Advanced</th>
<th>Metastatic</th>
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<tr>
<td>Cancer</td>
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</tr>
</tbody>
</table>

9 Cancer: 113 (8 suppl), 2008

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BASIC LEVEL CARE (BHGI) TREATMENT (ALL STAGES)

- **Surgical services:**
  - Modified radical mastectomy
  - Breast conservation (radiation required)
- **Systemic therapy (on WHO essential drug list 2011):**
  - Tamoxifen (vs oophorectomy)
  - Cytotoxic therapy (CMF, AC, EC, FAC)
- Pain management

Anderson, Cancer 113(8 suppl):2221, 2008
Findings

1. Extent of citations over time

Internal vs. External Publications

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Findings

3. Uptake of the BHGI guidelines by region

Articles referencing BHGI guidelines by region external publications only (n= 552)

- Sub-Saharan Africa: 9.4%
- Middle East and North Africa: 13.0%
- East Asia and Pacific: 13.0%
- South Asia: 20.5%
- Europe and Central Asia: 24.3%
- Latin America and the Caribbean: 24.3%
- High income economies: 32.8%
- Non country specific: 57.8%
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2018 GLOBAL SUMMIT

- Resource-Stratified Guidelines
- Guideline Adoption
- Phased Implementation
NCCN Framework for Resource Stratification of NCCN Guidelines
(NCCN Framework™)

Invasive Breast Cancer
Enhanced Resources (Preliminary)

Version 2.2017 — June 27, 2017

NCCN.org

Continue

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The NCCN Framework™ is represented as follows:

- **Black Text**: Included recommendation
- **Gray Text**: Withheld recommendation
- **Italicized Blue Text**: Modified recommendation based on resource level
NCCN Guidelines Version 2.2017
Invasive Breast Cancer

NCCN Framework™: Enhanced Resources (Preliminary)

PREOPERATIVE SYSTEMIC THERAPY FOR INOPERABLE OR LOCALLY ADVANCED BREAST CANCER (NON-INFLAMMATORY): WORKUP

CLINICAL STAGE | WORKUP
--- | ---
Stage IIIA
T0, N2, M0
T1, N2, M0
T2, N2, M0
T3, N2, M0
Stage IIIA patients with T3, N1, M0 disease, see BINV-1
| • History and physical exam
• Diagnostic bilateral mammogram; ultrasound as necessary
• Pathology review
• Determination of tumor ER/PR status and HER2 status
• Genetic counseling if patient is high risk for hereditary breast cancer
• Breast MRI (optional), with special consideration for mammographically occult tumors
• Fertility counseling if premenopausal
• Assess for distress

Additional studies consider:
• CBC
• Comprehensive metabolic panel, including liver function tests and alkaline phosphatase
• Chest diagnostic CT with contrast
• Abdominal ± pelvic diagnostic CT with contrast or MRI with contrast
• Bone scan or sodium fluoride PET/CT (category 2B)
• FDG PET/CT (optional)

See Preoperative Systemic Therapy For Inoperable or Locally Advanced Breast Cancer (Non-Inflammatory) (BINV-16)

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 patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

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### NCCN Guidelines Version 2.2017

**Invasive Breast Cancer**

#### NCCN Framework™: Core Resources (Preliminary)

**PREOPERATIVE SYSTEMIC THERAPY FOR INOPERABLE OR LOCALLY ADVANCED BREAST CANCER (NON-INFLAMMATORY): WORKUP**

<table>
<thead>
<tr>
<th>CLINICAL STAGE</th>
<th>WORKUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage IIIA</td>
<td>• History and physical exam</td>
</tr>
<tr>
<td>T0, N2, M0</td>
<td>• Diagnostic bilateral mammogram; ultrasound as necessary</td>
</tr>
<tr>
<td>T1, N2, M0</td>
<td>• Pathology review(^a)</td>
</tr>
<tr>
<td>T2, N2, M0</td>
<td>• Determination of tumor ER/PR status and HER2 status(^b)</td>
</tr>
<tr>
<td>T3, N2, M0</td>
<td>• Genetic counseling if patient is high risk for hereditary breast cancer(^c)</td>
</tr>
<tr>
<td>Stage IIIA patient with T3, N1, M0 disease, see BINV-8</td>
<td>• Breast MRI(^d) (optional), with special consideration for mammographically occult tumors</td>
</tr>
<tr>
<td></td>
<td>• Fertility counseling if premenopausal(^e)</td>
</tr>
<tr>
<td></td>
<td>• Assess for distress(^f)</td>
</tr>
<tr>
<td>Additional studies consider:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CBC</td>
</tr>
<tr>
<td>Stage IIIB</td>
<td>• Comprehensive metabolic panel, including liver function tests and alkaline phosphatase</td>
</tr>
<tr>
<td>T4, N0, M0</td>
<td>• Chest diagnostic CT with contrast</td>
</tr>
<tr>
<td>T4, N1, M0</td>
<td>• Abdominal ± pelvic diagnostic CT with contrast or MRI with contrast</td>
</tr>
<tr>
<td>T4, N2, M0</td>
<td>• Bone scan or sodium fluoride PET/CT(^i) (category 2B)</td>
</tr>
<tr>
<td>Stage IIIC</td>
<td>• FDG PET/CT(^i) (optional)</td>
</tr>
<tr>
<td>Any T, N3, M0</td>
<td>• Chest x-ray</td>
</tr>
<tr>
<td></td>
<td>• Abdominal ultrasound</td>
</tr>
<tr>
<td></td>
<td>• Plain radiograph of symptomatic bony sites</td>
</tr>
</tbody>
</table>


\(^b\)See Principles of HER2 Testing (BINV-4).

\(^c\)See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian.

\(^d\)See Principles of Dedicated Breast MRI Testing (BINV-8).

\(^e\)See Fertility and Birth Control (BINV-7).

\(^f\)See NCCN Guidelines for Distress Management.

**Note:** This is the NCCN Framework for Resource Stratification of NCCN Guidelines. For definitions of the NCCN Framework™, see page FR.1.

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**BINV-14**

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<table>
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<tr>
<th>Clinical Stage</th>
<th>Workup</th>
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</thead>
</table>
| Stage IIIA T0, N2, M0 | - History and physical exam  
- Diagnostic bilateral mammogram; ultrasound as necessary  
- Pathology reviewa  
- Determination of tumor ER/PR status |

Stage IIIA patients with T3, N1, M0 disease, see BINV-1

Additional studies consider:  
- CBC

Stage IIIB T4, N0, M0 T4, N1, M0 T4, N2, M0  
- Chest x-ray  
- Abdominal ultrasound  
- Plain Radiograph of symptomatic bony sites

Stage IIIC Any T, N3, M0  
- Chest x-ray  
- Abdominal ultrasound  
- Plain Radiograph of symptomatic bony sites

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.

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• Currently online (75% of all cancers globally):

  - Adult Cancer Pain
  - Bladder Cancer
  - Breast Cancer
  - Cervical Cancer
  - Colon Cancer **NEW**
  - Esophageal and Esophagogastric Junction Cancers
  - Gastric Cancer
  - Head and Neck Cancers – Cancers of the Lip and Oral Cavity
  - Hepatobiliary Cancers
  - Kidney Cancer
  - Non-Small Cell Lung Cancer
  - Palliative Care
  - Pancreatic Cancer
  - Prostate Cancer
  - Rectal Cancer **NEW**
  - Uterine Neoplasms – Endometrial Carcinoma

25%
75%

Cancer Cases Covered by Framework
**NCCN Harmonized Guidelines™ for Sub-Saharan Africa**  
**Version 2.2017**  
**Invasive Breast Cancer**

**Locoregional Treatment of Clinical Stage I, IIA, or IIB Disease or T3, N1, M0**

- **≥4 positive** axillary nodes
  - Radiation therapy to whole breast with or without boost to tumor bed (category 1), infracavicular region, supraclavicular area, internal mammary nodes, and any part of the axillary bed at risk (category 1). It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

- **1–3 positive axillary nodes**
  - Radiation therapy to whole breast with or without boost to tumor bed (category 1). Strongly consider radiation therapy to infracavicular region, supraclavicular area, internal mammary nodes, and any part of the axillary bed at risk. It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

- **Negative axillary nodes**
  - Radiation therapy to whole breast with or without boost to tumor bed, and consider regional nodal radiotherapy in patients with central/medial tumors or tumors > 2 cm with other high-risk features (young age or extensive lymphovascular invasion [LVi]).
  - Consideration of accelerated partial breast irradiation (APBI) in selected low-risk patients.
  - It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

**Total mastectomy** with surgical axillary staging (category 1) ± reconstruction

**If T2 or T3 and fulfills criteria for breast-conserving therapy except for size**

- **See Locoregional Treatment** (BINV-3)

- **Consider Preoperative Systemic Therapy Guideline** (BINV-10)

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**Note:** This is the NCCN Harmonized Guidelines™ for Sub-Saharan Africa. For definitions, see page DEE-1.

**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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NCCN Harmonized Guidelines™ for the Caribbean
Version 1.2018
Invasive Breast Cancer

Locoregional Treatment of T1-3, N0-1, M0 Disease

Radiation therapy to whole breast with or without boost to tumor bed (category 1), infracavicular region, supraclavicular area, internal mammary nodes, and any part of the axillary bed at risk (category 1). It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

Radiation therapy to whole breast with or without boost to tumor bed (category 1). Strongly consider radiation therapy to infracavicular region, supraclavicular area, internal mammary nodes, and any part of the axillary bed at risk. It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

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Consideration of accelerated partial breast irradiation (APBI) in selected low-risk patients.

It is common for radiation therapy to follow chemotherapy when chemotherapy is indicated.

See Locoregional Treatment (BINV-3)

Consider Preoperative Systemic Therapy Guideline (BINV-10)

Note: This is the NCCN Harmonized Guidelines™ for the Caribbean. For definitions, see page DEF-1.

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- Phased Implementation
KEY STAKEHOLDERS

Government
Ministries/Policymakers

Policy
Protocols
Health system

Guidelines
Education and training
Technology/equipment

Clinical Healthcare
workers

Advocacy
Education
Implementation

Civil Society
Patients/Advocates
SITUATION ANALYSIS
LOW INCOME COUNTRY

Tanzania
Tanzania Situation Analysis
Tanzania Situation Analysis

Figure 2: Tanzanian health care structure

- Natl. Hospitals [2]
- Zonal Hospitals [4]
- Regional Referral Hospitals [30]
- District Hospitals [169]
- Primary Health Care Clinics

Needle biopsy available

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**PHASED IMPLEMENTATION**

**Phase 1**
- Systematic triage and diagnosis of palpable breast disease.

**Phase 2**
- Resource-adapted stage-appropriate treatment planning.

**Phase 3**
- Scaling up of targeted education interventions for public and health care staff & CBE to promote early detection of clinically detectable disease.

**Phase 4**
- Systematic upgrading of image-based diagnostic systems (technology & training) for management of non-palpable disease as a prerequisite to image-based (mammographic) screening.

**Prerequisites**
- Standardized guidelines, protocols and trained health care workforce.
LMC IMPLEMENTATION RESEARCH
LOWER-MIDDLE INCOME COUNTRY

Peru

Early Detection and Patient Triage

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Breast cancer care model

Regional Cancer Institute (Trujillo)
- Mammography
- Pathology
- Surgery
- Chemotherapy
- Radiotherapy

La Fora Reference Hospital
- FNA

Health Centers
- Community education
- CBE

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PATH
Two phases

• Phase 1:
  – Pilot demonstration of the model of care.

• Phase 2:
  – National scale-up of the model.
  – Integration of post-treatment support for patients:
    • Clinical support at the local level for women who need follow-up care and monitoring.
    • Psychosocial support in the community.
PHASED IMPLEMENTATION

Improving Breast Health Care through Resource-Stratified Phased Implementation

A BHGI Global Summit
Seattle, Washington, USA | October 15-17, 2018

Day 1: Phased Implementation for Breast Cancer Early Diagnosis
Day 2: Phased Implementation for Breast Cancer Treatment and Supportive Care
Day 3: Integration of Breast Care Strategies into Existing Health Systems
PHASED IMPLEMENTATION IN CANCER

SUMMARY

- Early detection followed by breast cancer treatment improves breast cancer outcomes and survival.
- Resource-stratified guidelines provide a framework for prioritizing sustainable health care strategies.
- Phased implementation defines sustainable approaches that integrate into existing healthcare systems to improve outcome.
BCI 2.5 UW / HUTCH TEAM

- Allison Dvaladze
- Catherine Duggan
- Marisa Hartman
- Julie Gralow
- John Scheel
- Ruth Etzioni
- Ben Anderson