GUIDELINES FOR BREAST CANCER CONTROL: ISSUES & OPTIONS FOR IMPLEMENTATION IN LOW AND MIDDLE INCOME COUNTRIES

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Founding Organizations
BREAST CANCER ISSUES & OPTIONS

- Breast cancer as an NCD
- Resource-stratified framework
- Implementation projects
Breast Cancer Issues & Options

- Breast cancer as an NCD
- Resource-stratified framework
- Implementation projects
GLOBAL BREAST CANCER BURDEN
INCIDENCE AND MORTALITY: 2015-2024

- Most common cancer among women
  - 17.5 million cases in next decade
  - 9.1 million cases in less developed countries
  - By 2024, over 1 million cases per year in LMCs

- Most common cancer killer among women
  - 5 million women will die in next decade
  - 3.6 million deaths in less developed countries
  - 650,000 deaths are premature and preventable

SOURCE: Globocan 2008 (IARC)
## Global Cancer Burden:
### Female Cancer Mortality by Age

<table>
<thead>
<tr>
<th></th>
<th>Breast Cancer (deaths in thousands [95% uncertainty intervals])</th>
<th>Cervical Cancer (deaths in thousands [95% uncertainty intervals])</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15-49 years</td>
<td>≥50 years</td>
</tr>
<tr>
<td>Global</td>
<td>94.0 (87.1-102.3)</td>
<td>331.2 (269.9-352.8)</td>
</tr>
<tr>
<td>Developing</td>
<td><strong>67.8 (61.6-74.2)</strong></td>
<td>145.9 (125.8-160.2)</td>
</tr>
<tr>
<td>Developed</td>
<td><strong>26.1 (24.1-29.4)</strong></td>
<td>185.3 (143.2-200.4)</td>
</tr>
</tbody>
</table>

Draft action plan for the prevention and control of noncommunicable diseases 2013–2020

Report by the Secretariat
NCD GLOBAL ACTION PLAN
CANCER-RELATED GOALS

- Reduction in modifiable risk factors (tobacco, physical activity, obesity, saturated fat, alcohol)
- Maintain disease registries, including for cancer, if sustainable, with appropriate indicators
- Promote breast feeding (exclusive for 6 months, continue until 2 years with complementary feeding)
- Early detection is stated as “essential”, but no specific targets for diagnosis or treatment are referenced.

SOURCE: WHO Draft (11 January 2013)
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“The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”
## WORLD BANK COUNTRY GROUPS

### WORLD BANK CLASSIFICATION (ATLAS METHOD)

<table>
<thead>
<tr>
<th>World Bank Country Groups (GNI per capita)</th>
<th>Low Income ($995 or less)</th>
<th>Lower Middle Income ($996 - $3,945)</th>
<th>Upper Middle Income ($3,946 - $12,195)</th>
<th>High Income ($12,196 or more)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average female life expectancy at birth</td>
<td>57.8 yrs</td>
<td>69.3 yrs</td>
<td>74.4 yrs</td>
<td>82.4 yrs</td>
</tr>
<tr>
<td>Average GNI per capita (2009 US dollars)</td>
<td>$403</td>
<td>$1,723</td>
<td>$6,314</td>
<td>$36,953</td>
</tr>
<tr>
<td>Total national health expenditure per capita</td>
<td>$22</td>
<td>$76</td>
<td>$458</td>
<td>$4,266</td>
</tr>
<tr>
<td>Fraction of GDP spent on health care</td>
<td>5.1%</td>
<td>4.3%</td>
<td>6.4%</td>
<td>11.2%</td>
</tr>
</tbody>
</table>

Health expenditure figures 2010 for calendar year 2007; GNI = gross national income
## Breast Cancer Epidemiology

**Stage at Diagnosis: United States vs. India**

<table>
<thead>
<tr>
<th>STAGE</th>
<th>EXTENT</th>
<th>5 Year Survival</th>
<th>DISTRIBUTION USA</th>
<th>DISTRIBUTION INDIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Noninvasive</td>
<td>100%</td>
<td>16%</td>
<td>----</td>
</tr>
<tr>
<td>I</td>
<td>Early stage disease</td>
<td>100%</td>
<td>40%</td>
<td>1%</td>
</tr>
<tr>
<td>II</td>
<td>Early stage disease</td>
<td>86%</td>
<td>34%</td>
<td>23%</td>
</tr>
<tr>
<td>III</td>
<td>Locally advanced</td>
<td>57%</td>
<td>6%</td>
<td>52%</td>
</tr>
<tr>
<td>IV</td>
<td>Metastatic disease</td>
<td>20%</td>
<td>4%</td>
<td>24%</td>
</tr>
</tbody>
</table>

**Sources:** SEER Survival Monograph (NCI), 2007; Chopra, Cancer Institute Chennai, 2001

- **USA:** 90% DCIS or early staged invasive disease at diagnosis
- **INDIA:** 76% locally advanced or metastatic at diagnosis
GLOBAL SUMMIT 2005 – BETHESDA
RESOURCE STRATIFICATION

- EARLY DETECTION
- DIAGNOSIS
- TREATMENT
- HEALTH SYSTEMS
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
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>Stage</th>
<th>Level of Care</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Basic</td>
<td>Health system availability and access to care</td>
</tr>
<tr>
<td>II</td>
<td>Limited</td>
<td>Health care system needs addressing familial, geographic, and logistical issues with appropriate referral</td>
</tr>
<tr>
<td>III</td>
<td>Enhanced</td>
<td>Health care system needs addressing familial, geographic, and logistical issues with appropriate referral</td>
</tr>
<tr>
<td>IV</td>
<td>Intensive</td>
<td>Health care system needs addressing familial, geographic, and logistical issues with appropriate referral</td>
</tr>
</tbody>
</table>

#### EARLY DETECTION

<table>
<thead>
<tr>
<th>Stage</th>
<th>Level of Care</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Local</td>
<td>Disease extent known</td>
</tr>
<tr>
<td>II</td>
<td>Regional</td>
<td>Disease extent known</td>
</tr>
<tr>
<td>III</td>
<td>Distant</td>
<td>Disease extent known</td>
</tr>
</tbody>
</table>

#### DIAGNOSIS

<table>
<thead>
<tr>
<th>Stage</th>
<th>Level of Care</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
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</tr>
<tr>
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<td>Disease extent known</td>
</tr>
<tr>
<td>III</td>
<td>Distant</td>
<td>Disease extent known</td>
</tr>
</tbody>
</table>

#### STAGE I

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Local Treatments</th>
<th>Saline Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
<td>Primary surgery</td>
<td>Radiation therapy</td>
</tr>
<tr>
<td>Limited</td>
<td>Chemotherapy</td>
<td>Hormone therapy</td>
</tr>
<tr>
<td>Enhanced</td>
<td>Immunotherapy</td>
<td>Other treatments</td>
</tr>
</tbody>
</table>

#### STAGE II

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Local Treatments</th>
<th>Saline Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
<td>Primary surgery</td>
<td>Radiation therapy</td>
</tr>
<tr>
<td>Limited</td>
<td>Chemotherapy</td>
<td>Hormone therapy</td>
</tr>
<tr>
<td>Enhanced</td>
<td>Immunotherapy</td>
<td>Other treatments</td>
</tr>
</tbody>
</table>

#### LOCALLY ADVANCED

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Local Treatments</th>
<th>Saline Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
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<tr>
<td>Limited</td>
<td>Chemotherapy</td>
<td>Hormone therapy</td>
</tr>
<tr>
<td>Enhanced</td>
<td>Immunotherapy</td>
<td>Other treatments</td>
</tr>
</tbody>
</table>

#### METASTATIC

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Local Treatments</th>
<th>Saline Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic</td>
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<tr>
<td>Limited</td>
<td>Chemotherapy</td>
<td>Hormone therapy</td>
</tr>
<tr>
<td>Enhanced</td>
<td>Immunotherapy</td>
<td>Other treatments</td>
</tr>
</tbody>
</table>

Cancer: 113 (8 suppl), 2008
“T” is most fundamental element in TNM staging and is measured on clinical breast exam (CBE)

MTS is surrogate measure of early detection success in healthcare delivery system

MTS suggests early detection strategy:

- > 4 – 5cm: Awareness + CBE (no mammography)
- < 2cm: Image screening needed for down-staging
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Public Participation

- Awareness
- Advocacy
- Survivorship

Health Care Delivery

- Early Detection
- Diagnosis
- Treatment

Awareness → Early Detection
Advocacy → Diagnosis
Survivorship → Treatment
BASIC LEVEL CARE (BHGI)
EARLY DETECTION / DIAGNOSIS

- Clinical down-staging (education):
  - Breast health awareness education
  - Clinical breast examination (CBE) training

- Diagnosis (with quality control):
  - Tissue sampling (needle preferred)
  - Surgical pathology services (+/- cytology)
  - Hormone receptor assessment

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

24 Anderson, Cancer 113(8 suppl):2221, 2008
Peru

Early Detection and Patient Triage
Pilot project

- One health network within the region of La Libertad in Peru.
- Based on the use of CBE performed by midwives, followed by referral of women with suspected masses to the local hospital for evaluation by trained physicians.
Breast cancer care model

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

La Fora Reference Hospital
- FNA

Health Centers
- Community education
- CBE

Photos courtesy of Ben Anderson

Slide used with permission from PATH
Peru Site Visit 2012
Public education about breast cancer and breast health
1. Hinchazón, calor, oscurecimiento o enrojecimiento de la mama.

2. Cambio en el tamaño y/o forma de la mama.

3. Hoyuelos o arrugas en la piel.

4. Picazón, úlceras o llaga escamosa en la piel o sarpullido en el pezón.

5. Hundimiento del pezón o de otras partes de la mama.


7. Dolor reciente y persistente en alguna parte de la mama.

8. Aparición de alguna masa, bolita dura, o la piel más gruesa dentro de la mama.
Exposición del Dr. Cedano y Dr. Manrique
•Capacitación de proveedores clínicos (obstetrices y médicos) en ECM.

•El 1 y 2 de julio de 2011, un grupo de médicos y enfermeras de INEN, IREN Norte y PATH, asistió a un curso conjunto en ECM y BAAF celebrado en IREN-Norte. Donde ocho obstetrices de la Red de Salud de Pacasmayo y tres médicos del Hospital La Fora recibieron la formación en teoría científica, aplicación práctica y orientación de pacientes con respecto al ECM.
PROGRAMA DE PREVENCIÓN Y CONTROL DE CÁNCER DE MAMA
HISTORIA CLÍNICA DE SALUD MAMARIA

DATOS GENERALES
Nombre del establecimiento
-------------
Primer Apellido Segundo Apellido Nombres
-------------
Dirección Distrito
-------------
Nº Historia Clínica DNI
-------------
Fecha de nacimiento Edad (años) Establecimiento que refiere
-------------
¿Has escuchado acerca de salud mamaria de un promotor(a) de salud?
No Sí, en una sesión educativa en el establecimiento de salud Sí, en una sesión educativa en mi comunidad Sí, a través del contacto individual con el promotor
-------------
Fecha de consulta
-------------
ANAMNESIS
Motivo de consulta: Por tamizaje Por síntomas mamarios Por referencia
-------------
Síntomas
-------------
D / M / A Duración
-------------
Relación con ciclo menstrual: Sí NO Peso: ________ Kg. Talla: ________ mt.
-------------
ANTECEDENTES MAMARIOS:
Exámenes previos: Biopsia Memográfi a Ecografía Fecha: ________ Resultado:
-------------
Mastitis Otros:
-------------
Edad menarquía: ________ A Edad menopausia: ________ A
-------------
Uso de anticonceptivos: Sí NO Tipo: Oral Inyectable
-------------
Terapia de reemplazo hormonal: Sí NO Edad primer embarazo: ________ Años Lactancia Materna: Sí NO
-------------
Antecedentes personales y familiares:
Historia personal de: Cáncer de mama: Sí NO Cáncer de ovario: Sí NO Otro cáncer:
-------------
Historia de familiar directo de: Cáncer de mama: Sí NO Cáncer de ovario: Sí NO Otro cáncer:
-------------
Hábitos: Tabaco: Sí NO Alcohol: Sí NO
-------------
EXAMEN CLÍNICO DE MAMA:
CARACTERÍSTICAS DEL TUMOR
<table>
<thead>
<tr>
<th>Mama Derecha</th>
<th>Mama Izquierda</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor palpable</td>
<td>Tamaño Tumor 1 (cm) Tamaño Tumor 2 (cm)</td>
</tr>
<tr>
<td>Consistencia del tumor (bianco, duro, blando, fluctuante)</td>
<td></td>
</tr>
<tr>
<td>Forma del tumor (redonda, oval, deshídiada)</td>
<td></td>
</tr>
<tr>
<td>Síntomas del tumor (irregular, irregular)</td>
<td></td>
</tr>
<tr>
<td>Coloración (volar, superfiel roja)</td>
<td></td>
</tr>
<tr>
<td>Secreción per pezón (color)</td>
<td></td>
</tr>
<tr>
<td>Retención (pezón, piel)</td>
<td></td>
</tr>
<tr>
<td>Erosión (pezón, areola)</td>
<td></td>
</tr>
<tr>
<td>Ulceración (pezón, piel)</td>
<td></td>
</tr>
<tr>
<td>Entumecimiento o edema (pezón, piel)</td>
<td></td>
</tr>
<tr>
<td>&quot;Pest de marea&quot;</td>
<td></td>
</tr>
</tbody>
</table>
-------------
Distancia del pezón __________ cm. Distancia del pezón __________ cm.
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.
BREAST CANCER EPIDEMIOLOGY
UPPER-MIDDLE INCOME COUNTRY

Colombia
National Early Detection Program
Pilot project for the introduction of breast cancer early detection programs in Colombia

Raul Murillo, MD, MPH
National Cancer Institute
Bogota - Colombia
Study design for early detection of breast cancer in women 50 to 69

Cluster randomized trial
(Early stages from 30 to 60 per 100,000)

Control arm
Enrollment of 10,000 women
No training
Screening activities on current bases
Women screening on current bases
One year follow-up

Intervention arm
Enrollment of 10,000 women
Training for GP, nurses, radiologists, technicians, BS
Screening program implementation in HC
Systematic opportunistic screening (M & CBE)
One year follow-up

Comparison of outcomes

23 health centers
Informed consent
Technical skills & GCP
Invitation, registry, follow-up, QC, etc.
Incidence
Clinical stage
Incidence
Participation rates
Costs
Side effects

Preliminary results

22 randomized clusters
(18 HMO centers, 4 public hospitals)

Control arm
4,957 women

- Symptomatic women 3.87%
- Mammography orders 848 (17.1%)
- Mammography done 593 (70.0%)
- Clinical breast examination 248 (5%)
- Cancer cases 5
  Stages IIB+: 1 out of 5

Intervention arm
5,549 women

- Symptomatic women 3.87%
- Mammography orders 5,549 (100%)
- Mammography done 4,933 (88.9%)
- Clinical breast examination 5,538 (99.8%)
- Cancer cases 14
  Stages IIB+: 2 out of 14
## Final Cancer Diagnosis by Stage

<table>
<thead>
<tr>
<th>Stage at diagnosis</th>
<th>Intervention</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First year</td>
<td>Second year</td>
<td>First year</td>
</tr>
<tr>
<td>In situ</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>I</td>
<td>9</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>IIA</td>
<td>3</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>IIB</td>
<td>3</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>IIIA</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>IIIB</td>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>2</td>
<td>13</td>
</tr>
</tbody>
</table>
BREAST CANCER GUIDELINES

SUMMARY

- Breast cancer is the most common female malignancy in the world, the largest cancer killer among women, and disproportionately affects young women in LMCs.

- The NCD Global Action Plan currently lacks specific recommendations for diagnosis, treatment and metrics that will change breast cancer mortality in LMCs.

- PAHO can recommend an “essential package” for breast cancer care in LMCs based on resource-stratified guidelines to permit Member States to assess if and how they can best address breast cancer in their country.