# RESOURCE-STRATIFIED GUIDELINES, THE LANCET ONCOLOGY COMMISSION ON GLOBAL CANCER SURGERY, & STRATEGIC IMPLEMENTATION

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#### The Breast Health Global Initiative

www.bhgi.info

# BREAST CANCER INITIATIVE 2.5

- www.BCI25.org

Making breast health a global priority





## RESOURCE-STRATIFIED GUIDELINES

- Global Cancer Trends
- Lancet Oncology Commission
- Adapting to Existing Resources
- Analytic Tool Development
- Strategic Implementation

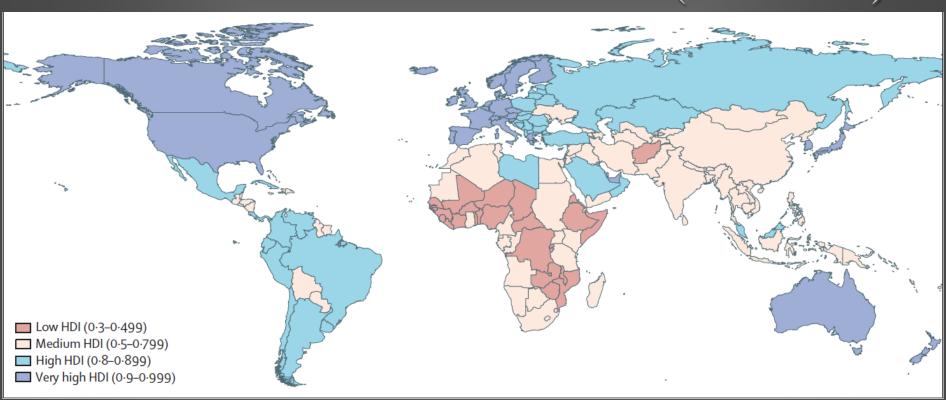


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# GLOBAL CANCER TRENDS (IARC) HUMAN DEVELOPMENT INDEX (2008-2030)



- Highest HDI: Breast, lung, colorectum, prostate cancers (over 50%)
- Medium HDI: Add esophagus, stomach, liver; Low HDI: cervical cancer



## GLOBAL CANCER TRENDS (IARC) HUMAN DEVELOPMENT INDEX (2008-2030)

	Men		Women			Scenario-based prediction for 2030*	
	Medium HDI	High HDI	Very high HDI	Medium HDI	High HDI	Very high HDI	
Stomach	-2.7%	-2.6%	-2.8%	-1.9%	-2.5%	-2.5%	2.5% annual decrease in all HDI areas per year
Cervix uteri				-1.8%	-1.2%	-2.6%	2% annual decrease in all HDI areas per year
Lung	-1.5%	-1.3%	-1.6%	-0.5%	0.5%	1.8%	1% annual decrease in high HDI and very high HDI areas (men) 1% annual increase in high HDI and very high HDI areas (women)
Liver	0.1%	0.2%	2.5%	-0.4%	0.4%	2.1%	Difficult to generalise, assume no change
Colorectum	1.5%	2.8%	0.6%	1.5%	1.8%	0.3%	1% annual increase in all HDI areas per year
Breast				2.1%	2.6%	1.6%	2% annual increase in all HDI areas per year
Prostate	3.2%	7.0%	4.4%				3% annual increase in all HDI areas per year

- 12.7 million cases in 2008 predicted to rise to 22.2 million by 2030
- Reductions in <u>infection-related cancers</u> are offset by increases in cancers associated with <u>reproductive</u>, <u>dietary and hormonal factors</u>





# CANCER CONTROL STRATEGIES PRIMARY PREVENTION

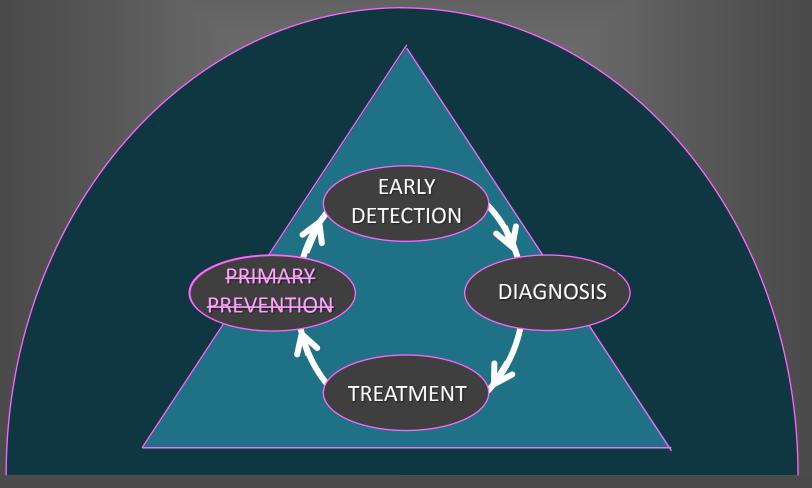
#### Population-Attributable Fraction (PAF) reflects potential prevention impact

Etiology	Carcinogenic risk factor (associated PAF)	Overall PAF (%)	Risk reduction programs	Key multisectoral partners	Estimated cost-effectiveness
Infectious etiologies	HPV (cervical cancer 90–100%)* Hepatitis B and C (HCC 77%)* <i>H. pylori</i> (gastric cancer 75%)*	18	Vaccinations	Health care workers Pharmaceutical companies Legislative bodies	Very cost-effective
Behavioral factors	Tobacco (30%)† Obesity (20%)† Diet (5%)† Alcohol (4%)†	66	Tobacco cessation Exercise programs Public education and outreach	General population (health literacy) Legislative bodies Health care workers	Very cost-effective
Environmental factors	Air pollution Aflatoxins	4	Environmental regulations	Legislative bodies Business sector	Potentially cost- effective
Clinical interventions			Insurance coverage for correctly selected individuals at elevated risk	Health care workers Pharmaceutical companies General population	Cost-effective





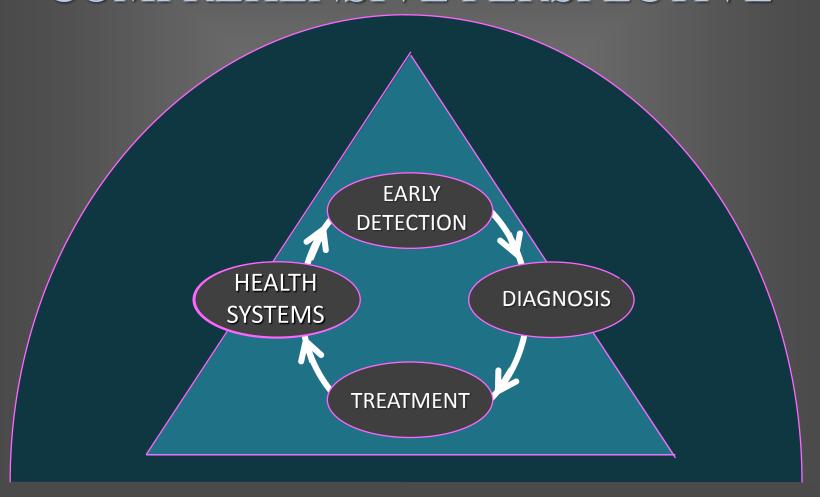
## CANCER CONTROL STRATEGIES DISEASE-BASED APPROACH







## CANCER CONTROL STRATEGIES COMPREHENSIVE PERSPECTIVE





## U.S. CANCER INCIDENCE 2015 (EST.)

Females					
Breast	231,840	29%			
Lung & bronchus	105,590	13%			
Colon & rectum	63,610	8%			
Uterine corpus	54,870	7%			
Thyroid	47,230	6%			
Non-Hodgkin lymphoma	32,000	4%			
Melanoma of the skin	31,200	4%			
Pancreas	24,120	3%			
Leukemia	23,370	3%			
Kidney & renal pelvis	23,290	3%			
All Sites	810,170	100%			

SOURCE: Seigel Ca Cancer J Clin 65:5, 2015

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## U.S. CANCER MORTALITY 2015 (EST.)

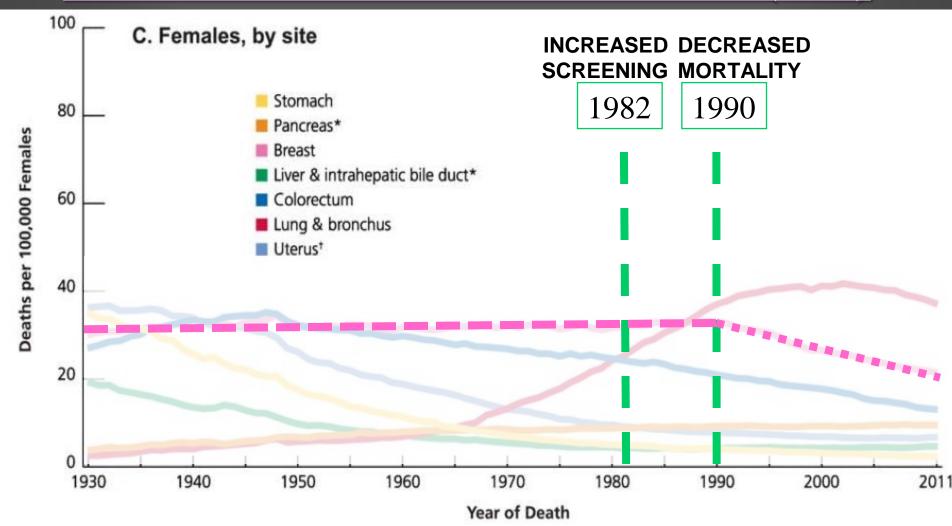
Females					
	Lung & bronchus	71,660	26%		
	Breast	40,290	15%		
X	Colon & rectum	23,600	9%		
	Pancreas	19,850	7%		
	Ovary	14,180	5%		
	Leukemia	10,240	4%		
	Uterine corpus	10,170	4%		
	Non-Hodgkin lymphoma	8,310	3%		
	Liver & intrahepatic bile duct	7,520	3%		
	Brain & other nervous system	6,380	2%		
	All Sites	277,280	100%		

SOURCE: Seigel Ca Cancer J Clin 65:5, 2015

www.bhgi.info



## U.S. CANCER MORTALITY 2015 (EST.)



SOURCE: Seigel Ca Cancer J Clin 65:5, 2015

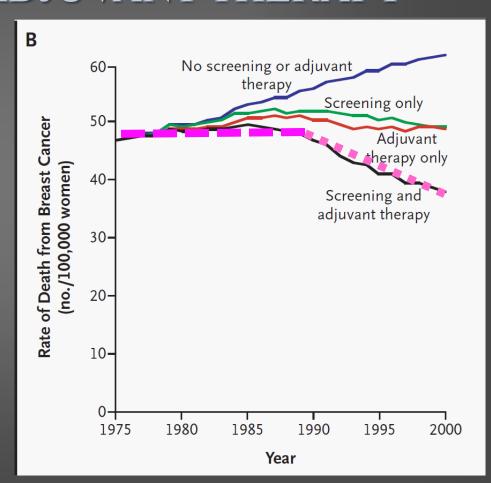
www.bhgi.info





## MORTALITY MODELING SCREENING AND ADJUVANT THERAPY

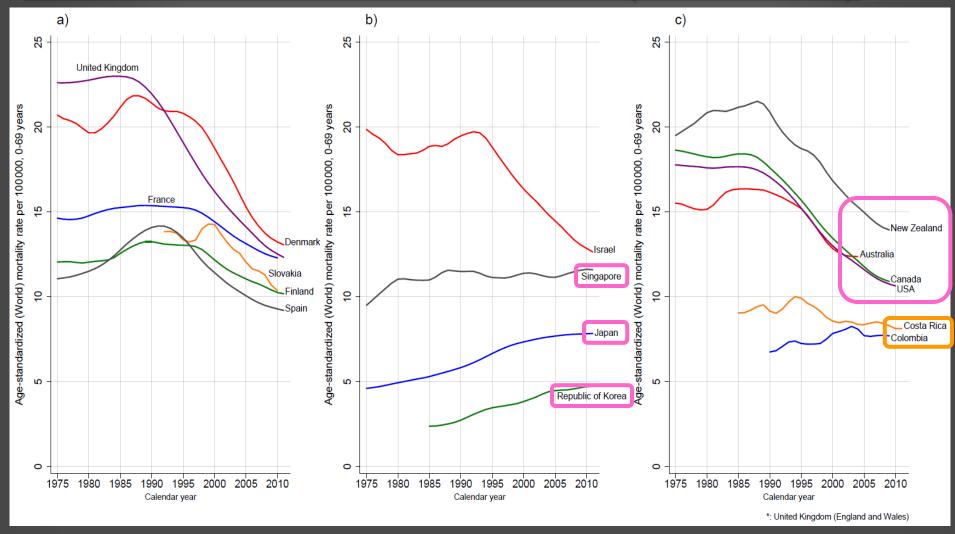
- Early detection is essential to improving outcome.
- Early detection works when followed by appropriate breast cancer treatment.
- To save lives, screening programs must be linked to timely, effective treatment.







## BREAST CANCER DEATHS (1975-2011)



SOURCE: Globocan 2012 (IARC)



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## THE LANCET Oncology

Volume 16 - Issue 11 - September 2015

www.thelancet.com/oncology

Global cancer surgery: delivering safe, affordable, and timely cancer surgery



"Surgery is essential for global cancer care...[and] must be at the heart of global and national cancer control planning."



# Reviewing the Lancet Oncology Commission

## Global Cancer Surgery

Richard Sullivan MD PhD









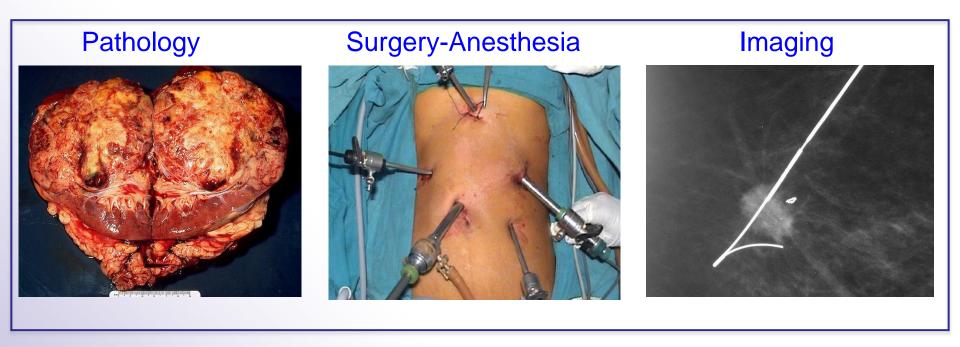








# Commission set out to understand issues and solutions to delivering affordable, safe and timely cancer surgery across all resource settings



Always careful to recognise that surgery is a SYSTEM 'Surgical Trinity' with **radiotherapy** and chemotherapy

## This Commission built on the foundations of the Lancet Global Surgery Commission

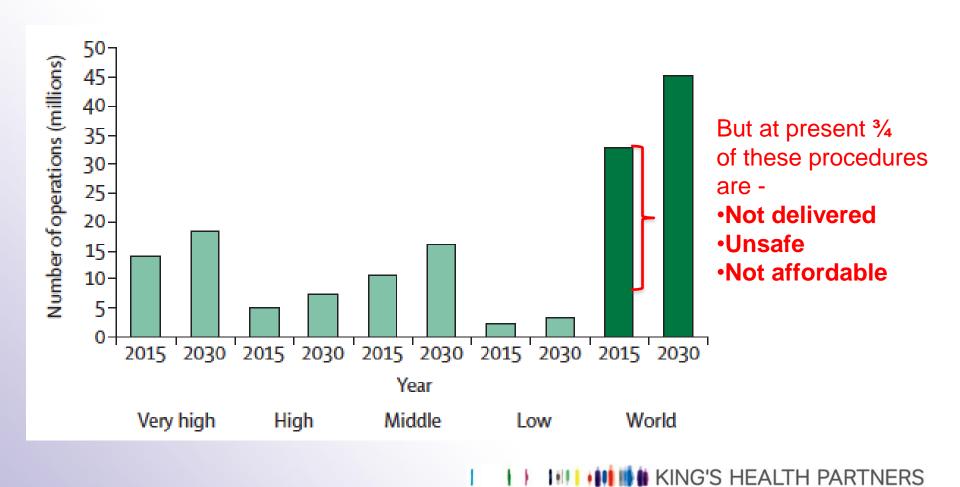


## What did we learn from Global Surgery 2030? This focused on general surgery in low resource settings

- **2/3<sup>rd</sup>** of the world's population cannot access safe surgery
- The poorest 1/3rd of the world's population receives only 6% of procedures done globally
- **33 million people** every year face catastrophic expenditures paying for surgical care
- Investing in surgery saves lives, is affordable & promotes economic growth
- Surgery is an indivisible, indispensible part of health care

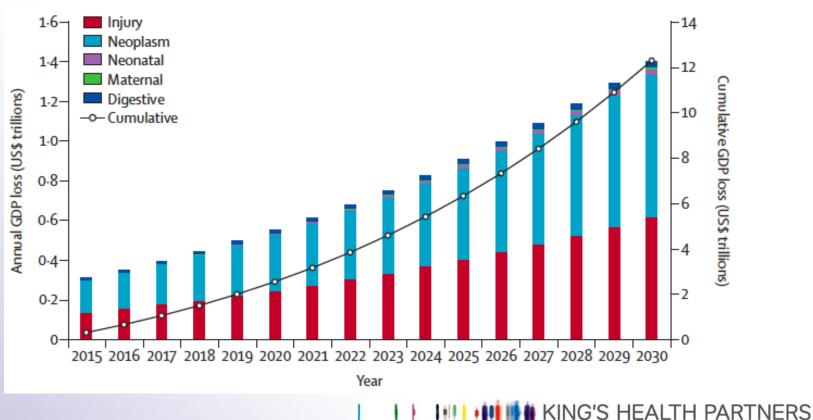


Over 80% of 15-2 million people diagnosed with cancer worldwide in 2015 will need a surgical procedure at some point in their treatment



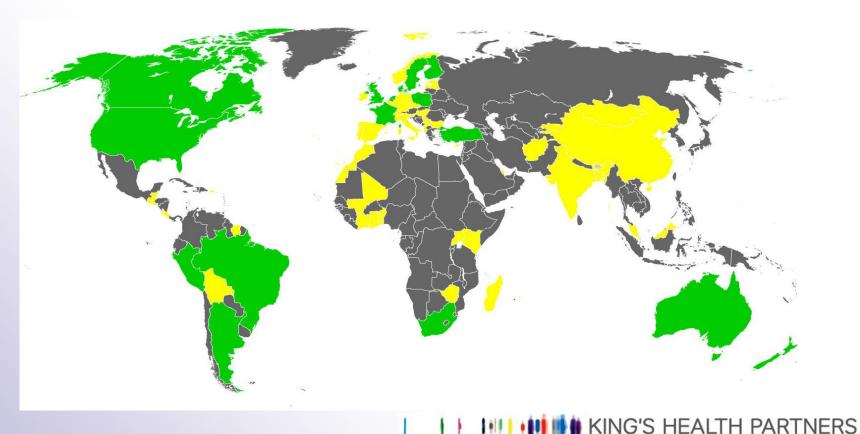
All countries are projected to lose 0.5 to 1.5% of GDP, annually, between now and 2030 if surgical systems for cancer are not strengthened

If we do nothing about strengthening cancer surgical systems, 6 trillion USD will be lost globally by 2030

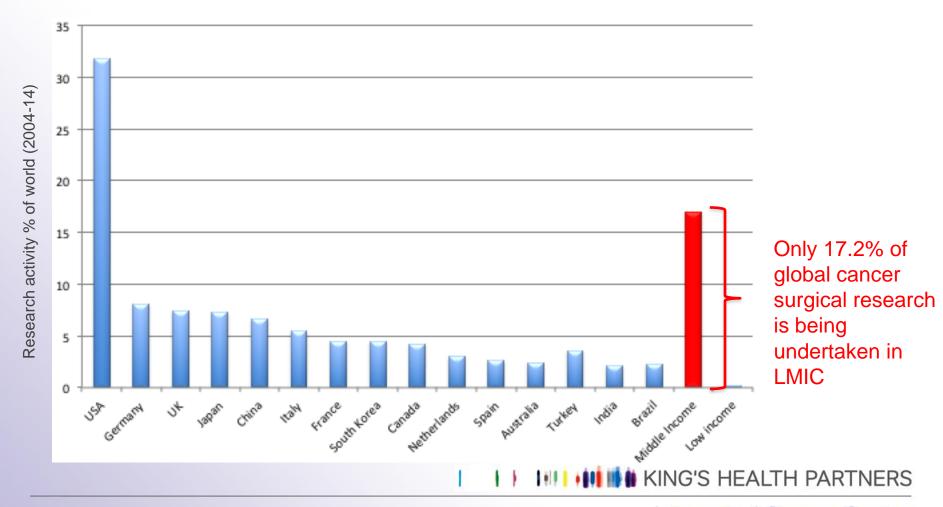


National cancer control plans must include the strengthening of surgical systems through investment in **public** sector infrastructure, education, and training

Only 9% of National Cancer Plans address surgery



Less than 5% of global cancer research is devoted to surgery despite its huge effect on patient outcomes and its importance to personalised cancer medicine



Global cancer surgery needs to be a political priority for policy makers in countries, research funders, international organisations, and global alliances



Only around 9% of national and global initiatives, statements, etc. address cancer surgery.



#### **Quality agenda for cancer surgery**

**SURCARE.** Raising quality agenda in cancer surgical research (EORTC)

**EURECCA**. European Registry of Cancer Care or EURopEan CanCer Audit (ESSO)

**Chile**. Surgical services and quality

**IAEA ImPACT.** Assessing surgical services for cancer (Kenya as demonstrator).

**India**. Surgical pathology quality program led by National Cancer Grid of India

**WHO.** Technical specifications for medical devices



#### **Better intelligence**

- What is **access** to basic cancer surgical oncology? A study of 51 countries<sup>1</sup>
- Global research into cancer surgery<sup>2</sup>
- The cost of cancer surgery: study of complex surgical costs in India<sup>3</sup>

#### **Capacity and Capability**

- African Research Group for Oncology Consortium: building capacity through research<sup>1</sup>
- Structural approaches: pancreaticoduodenectomy in India – road to centralisation<sup>2</sup>
- Challenging traditional **training** methods virtual reality simulation models for scaling up pelvic surgery for women's cancers in Zambia <sup>3</sup>
- Resource **stratification** BHGI<sup>4</sup>



#### Much more to be done

### Intelligence for policymakers

- Insufficient national data
- Insufficient focus for major organisations

### Quality agenda

- Surgical volume, minimum standard compliance
- Perioperative mortality
- Impact of technology on service delivery

### Cancer surgery & universal health coverage

- Protection against impoverishing & catastrophic expenditure
- Insurance that covers actual costs
- Managed structural and organisational changes



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## WORLD BANK COUNTRY GROUPS

## World Bank Classification (Atlas Method)

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

Health expenditure figures 2010 for calendar year 2007; GNI = gross national income <a href="http://data.worldbank.org/data-catalog/health-nutrition-and-population-statistics">http://data.worldbank.org/data-catalog/health-nutrition-and-population-statistics</a>.





## 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: <u>Core resources</u> or fundamental services necessary for any breast health care system to function.
- Limited level: <u>Second-tier resources</u> or services that produce major improvements in outcome such as survival.
- Enhanced level: <u>Third-tier resources</u> or services that are optional but important, because they increase the number and quality of therapeutic options and patient choice.
- Maximal level: <u>Highest-level resources</u> or services used in some high resource countries that have *lower priority* on the basis of extreme cost and/or impracticality.



### BHGI GUIDLINE TABLES

#### **HEALTH CARE SYSTEMS**

Level of	level of						
resources	Patient and Family Education	Human Resource Capacity Building	Patient Navigation	Cancer Care Facility	Breast Care Center		
Basic	General education regarding primary prevention of cannee, early detection and self examination.  Development of culturally adapted patient and family education services.	Primary care provider education re breast cancer detection, diagnosis and treatment Nursing education re cancer patient management and emotional support Pathology technician education re tissue handing and specimen preparation Trained community worker	Field nurse, midwife or healthcare provider triages patients to central facility for diagnosis and treatment	Health facility Operating facility Outpatient care facility Pharmacy Home hospice support External consultation pathology laboratory	Breast healthcare access integrated into existing healthcare infrastructure		
Limited	Group or one-on-one counseling involving family and peer support Education regarding nutrition and complementary therapies	Nursing education re breast cancer diagnosis, treatment and pt management.  Imaging technician education re imaging technician education re imaging technician education ror imaging technique and quality control.  Volunteer recruitment corp to support care.	On site patient navigator (staff member or nurse) facilitates patient triage through diagnosis and treatment	Clinical information systems Health system network Imaging facility Internal pathology laboratory Radiation therapy	"Breast Center" with clinician, staff and breast maging access Breast prooffleses for mastectomy pts		
Enhanced	Education regarding survivorship Lymphedema education Education regarding home care	Organization of national volunteer network Specialized nursing oncology training Home care nursing Physiotherapist & lymphedema therapist On-site cytopathologist	Patient navigation team from each discipline supports patient 'handoff' during key transitions from specialist to specialist to ensure completion of therapy	Centralized referral cancer center(s) Radiation therapy: low energy linear accelerator, electrons, brachytherapy, treatment planning system	Mutidisciplinary breast programs Oncology nurse specialists Physician assistants		
Maximal		Organization of national medical breast health groups		Satelite (non-centralized or regional) cancer centers			

#### **EARLY DETECTION**

Level of resources	Public Education and Awareness	Detection Methods
Basic	Development of culturally sensitive, linguistically appropriate local education programs for target populations to teach value of early detection, breast cancer risk factors and breast health awareness (education + self-examination)	Clinical history and CBE
Limited	Culturally and linguistically appropriate targeted outreachieducation encouraging CBE for age groups at higher risk administered at district/provincial level using healthcare providers in the field	Diagnostic breast US +/- diagnostic mammography in women with positive CBE Mammographic screening of target group*
Enhanced	Regional awareness programs regarding breast health inked to general health and women's health programs	Mammographic screening every 2 years in women ages 50-86° Consider mammographic screening every 12-18 months in women ages 40-49°
Maximal	National awareness campaigns regarding breast health using media	Consider annual mammographic screening in women ages 40 and older Other imaging technologies as appropriate for high-risk groups†

#### DIAGNOSIS

Level of resources	Clinical	Imaging and Lab Tests	Pathology
		• •	Pathology diagnosis obtained for every breast lesion by any available sampling procedure
Basic	History Physical examination Clinical breast examination (CBE) Tissue sampling for cancer diagnosis		Pathology report containing appropriate diagnostic and prognostici predictive information to include tumor size, lymph node status, histologic type and tumor grade
	(cytologic or histologic) prior to initiation of treatment		Process to establish hormone receptor status possibly including empiric assessment of response to therapy† Determination and reporting of TNM stage
Limited	US-guided FNAB of sonographically suspicious axillary nodes Sentinel lymph node (SLN) biopsy with blue dye‡	Diagnostic breast ultrasound (US) Plain chest and skeletal radiography Liver US Blood chemistry profile* Complete blood count (CBC)*	Determination of ER status by IHC† Determination of margin status, DCIS containt, presence of LVI Frozen section or touch prep SLN analysis §
Enhanced	Image guided breast sampling Preoperative needle localization under mammo and/or US guidance SLN biopsy using radiotracer‡	Diagnostic mammography Specimen radiography Bone scan, CT scan Cardiac function monitoring	Measurement of HER-2/neu overexpression or gene amplification§ Determination of PR status by IHC
Maximal		PET scan, MIBI scan, breast MRI, BRCA1/2 testing Mammographic double reading	IHC staining of sentinel nodes for cytokeratin to detect micrometastases Pathology double reading Gene profiling tests

#### STAGE I

Level of	Local-Region	nal Treatment	Systemic Treatment (Adjuvant)			
resources	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Biological Therapy	
Basic	Modified radical mastectomy			Oophorectomy in premenopausal women Tamoxifen*		
Limited	Breast conserving surgery† Sentinel lymph node (SLN) biopsy with blue dye‡		Classical CMF§ AC, EC, or FAC§			
Enhanced	SLN biopsy using radiotracer‡ Breast reconstruction surgery	Breast- conserving whole-breast irradiation as part of breast- conserving therapy†	Taxanes	Aromatase inhibitors LH-RH agonists	Trastuzumab for treating HER-2/ neu positive diseasel	
Maximal			Growth factors Dose-dense chemotherapy			

#### STAGE II

	Local-Region	nal Treatment	Systemic Treatment (Adjuvant)		
Level of resources	Surgery	Radiation Therapy	Chemotherapy Endocrine Therapy		Biological Therapy
Basic	Modified radical mastectomy	x	Classical CMF† AC, EC, or FAC†	Oophorectomy in premenopausal women Tamoxifen‡	
Limited	Breast conserving surgery§ Sentinel lymph node (SLN) biopsy with blue dyell	Postmastectomy irradiation of chest wall and regional nodes for high-risk cases"			1
Enhanced	SLN biopsy using radiotracer† Breast reconstruction surgery	Breast- conserving whole-breast irradiation as part of breast- conserving therapy§	Taxanes	Aromatase inhibitors LH-RH agonists	Trastuzumab for treating HER-2/ neu positive disease <sup>1</sup>
Maximal			Growth factors  Dose-dense chemotherapy		

#### LOCALLY ADVANCED

Level of	Local-Regional Treatment		Systemic Treatment (Adjuvant or Neoadjuvant		
resources	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Biological Therapy
Basic	Modified radical mastectomy	*	Preoperative chemotherapy with AC, EC, FAC or CMF†	Oophorectomy in premenopausal women Tamoxifen‡	
Limited		Postmastectomy irradiation of chest wall and regional nodes*			9
Enhanced	Breast- conserving surgery Breast reconstruction surgery	Breast- conserving whole-breast irradiation as part of breast- conserving therapy	Taxanes	Aromatase inhibitors LH-RH agonists	Trastuzumab for treating HER-2/ neu positive disease§
Maximal			Growth factors  Dose-dense chemotherapy		

#### METASTATIC

INIL I/ (O I/ (I IO							
Level of	Local-Region	nal Treatment	System	nic Treatment (Pal	liative)		
resources	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Supportive Therapy		
Basic	Total mastectomy for ipsilateral breast tumor recurrence after breast conserving surgery*			Oophorectomy in premenopausal women Tamoxifen†	Nonopioid and opioid analgesics and symptom management		
Limited		Palliative radiation therapy	Classical CMF‡ Anthracycline monotherapy or in combination‡				
Enhanced			Sequential single agent or combination chemotherapy Trastuzumab Lapatinib	Aromatase inhibitors	Bisphosphonates		
Maximal			Bevacizumab	Fulvestrant	Growth factors		

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### TREATMENT – LOCALLY ADVANCED

Level of	Local-Regional Treatment		Systemic Treatment (Adjuvant or Neoadjuvant)			
resources	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Biological Therapy	
Basic	Modified radical mastectomy	1000	Preoperative chemotherapy with AC, EC, FAC or CMF <sup>†</sup>	Oophorectomy in premenopausal women Tamoxifen <sup>‡</sup>		
Limited		Postmastectomy irradiation of chest wall and regional nodes*			usp	
Enhanced	Breast-conserving surgery Breast reconstruction surgery	Breast-conserving whole- breast irradiation as part of breast-conserving therapy	Taxanes	Aromatase inhibitors LH-RH agonists	Trastuzumab for treating HER-2/neu positive disease <sup>§</sup>	
Maximal	Cancer: 113	(8 suppl), 2008	Growth factors  Dose-dense chemotherapy			

### Methods

**Core Documents: 15 BHGI guidelines** 



**Search Strategy** 



**Total** 2,090

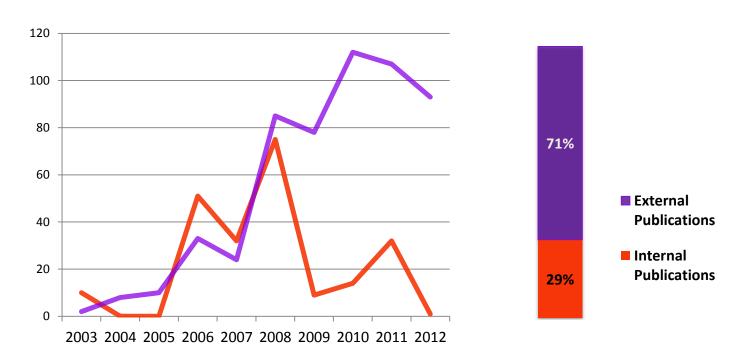
- **Inclusion and Exclusion Criteria**
- ✓ Published between 2003 -2012
- ✓ Complete documents available online
- **English Spanish Portuguese**

Full-text articles assessed for eligibility  $\rightarrow$  n= 776

### **Findings**

#### 1. Extent of citations over time

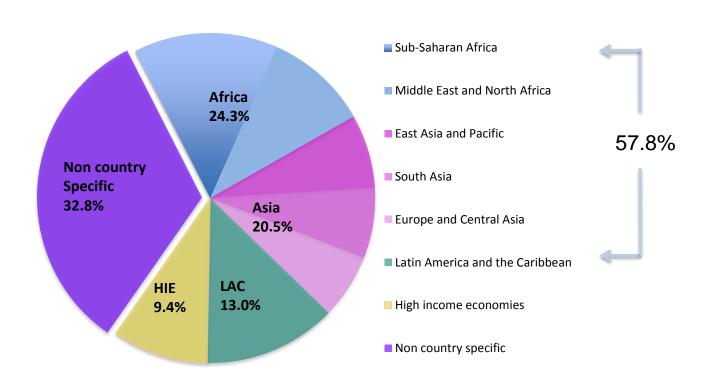
Internal vs. External Publications



### **Findings**

#### 3. Uptake of the BHGI guidelines by region

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





NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

### **Cervical Cancer**

### Resource Stratification: Maximal Level

Version 2.2015

**NCCN.org** 

Continue

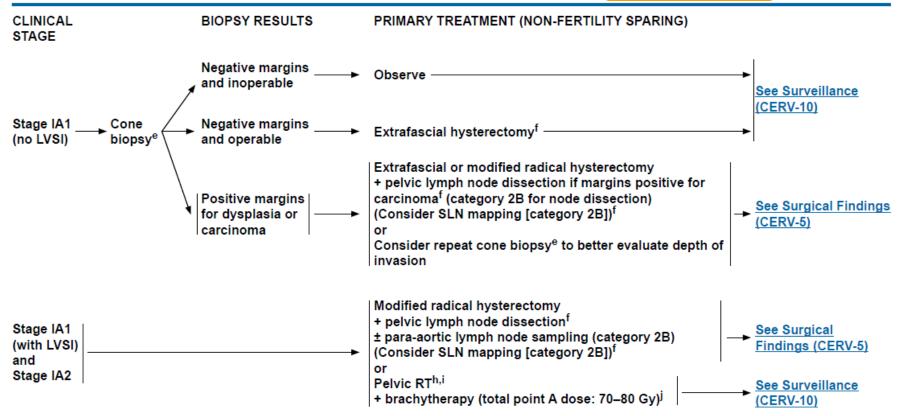


#### NCCN Guidelines Version 2.2015

**Cervical Cancer-Resource Stratification: Maximal Level** 

NCCN Guidelines Index

Cervical Cancer TOC Discussion



eCold knife conization (CKC) is the preferred method of diagnostic excision, but loop electrosurgical excision procedure (LEEP) is acceptable, provided adequate margins and proper orientation are obtained.

Note: 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.

In NCCN resource-stratified guidelines, "basic level" denotes the minimum level of cancer-specific treatment needed to achieve a measurable level of effectiveness. If higher-level resources are available, providers should use the higher level. If basic level cancer treatments or higher are unavailable, palliative and best supportive care should be provided.

See Principles of Evaluation and Surgical Staging (CERV-A).

<sup>&</sup>lt;sup>h</sup>Radiation can be an option for medically inoperable patients or those who refuse surgery.

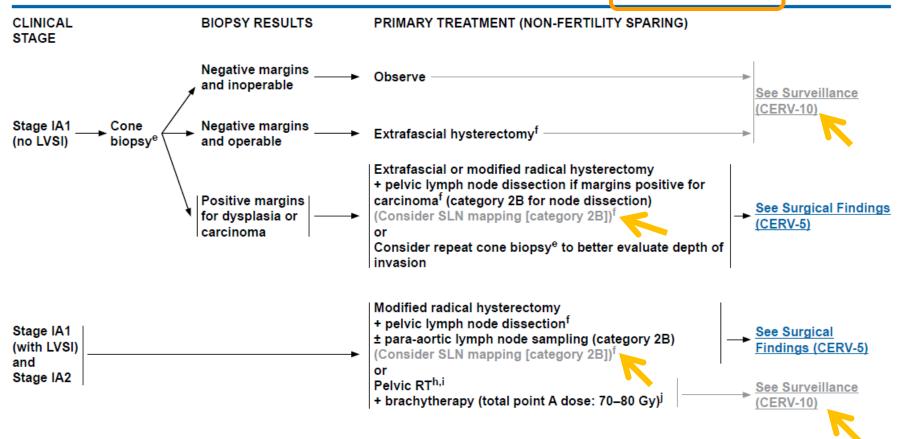
See Principles of Radiation Therapy for Cervical Cancer (CERV-B).

These doses are recommended for most patients based on summation of conventional external-beam fractionation and low-dose rate (40-70 cGy/h) brachytherapy equivalents. Modify treatment based on normal tissue tolerance. (See Discussion)

#### NCCN Guidelines Version 2.2015

NCCN Guidelines Index Cervical Cancer TOC Discussion

#### Cervical Cancer-Resource Stratification: Enhanced Level



eCold knife conization (CKC) is the preferred method of diagnostic excision, but loop electrosurgical excision procedure (LEEP) is acceptable, provided adequate margins and proper orientation are obtained.

Note: 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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See Principles of Evaluation and Surgical Staging (CERV-A).

<sup>&</sup>lt;sup>h</sup>Radiation can be an option for medically inoperable patients or those who refuse surgery.

See Principles of Radiation Therapy for Cervical Cancer (CERV-B).

These doses are recommended for most patients based on summation of conventional external-beam fractionation and low-dose rate (40-70 cGy/h) brachytherapy equivalents. Modify treatment based on normal tissue tolerance. (See Discussion)



and Stage IA2

#### NCCN Guidelines Version 2.2015

Cervical Cancer-Resource Stratification: Limited Level

NCCN Guidelines Index
Oervical Cancer TOC
Discussion

CLINICAL BIOPSY RESULTS PRIMARY TREATMENT (NON-FERTILITY SPARING) STAGE **Negative margins** and inoperable See Surveillance (CERV-10) **Negative margins** Stage IA1 Extrafascial hysterectomy<sup>f</sup> (no LVSI) and operable Extrafascial or modified radical hysterectomy + pelvic lymph node dissection if margins positive for carcinomaf (category 2B for node dissection) Positive margins See Surgical Findings (Consider SLN mapping [category 2B])f for dysplasia or carcinoma Consider repeat cone biopsye to better evaluate depth of invasion Modified radical hysterectomy + pelvic lymph node dissectionf Stage IA1 See Surgical ± para-aortic lymph node sampling (category 2B) (with LVSI) Findinas (CERV-5) (Consider SLN mapping [category 2B])

+ brachytherapy (total point A dose: 70-80 Gy)<sup>j</sup>

Pelvic RTh,i

Note: All recommendations are category 2A unless otherwise indicated.

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CERV-3

See Surveillance

<sup>&</sup>lt;sup>e</sup>Cold knife conization (CKC) is the preferred method of diagnostic excision, but loop electrosurgical excision procedure (LEEP) is acceptable, provided adequate margins and proper orientation are obtained.

See Principles of Evaluation and Surgical Staging (CERV-A).

hRadiation can be an option for medically inoperable patients or those who refuse surgery.

See Principles of Radiation Therapy for Cervical Cancer (CERV-B).

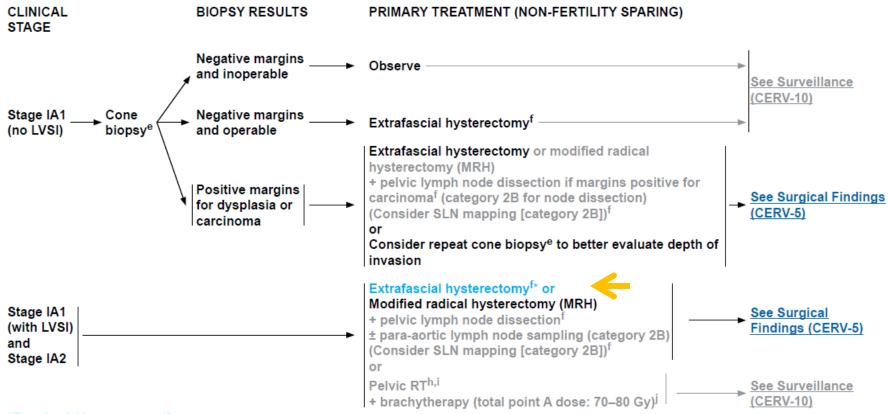
These doses are recommended for most patients based on summation of conventional external-beam fractionation and low-dose rate (40–70 cGy/h) brachytherapy equivalents. Modify treatment based on normal tissue tolerance. (See Discussion)



#### NCCN Guidelines Version 2.2015

**Cervical Cancer-Resource Stratification: Basic Level** 

NCCN Guidelines Index Cervical Cancer TOC Discussion



\*Extrafascial hysterectomy if resources not available for modified hysterectomy.

See Principles of Evaluation and Surgical Staging (CERV-A).

<sup>h</sup>Radiation can be an option for medically inoperable patients or those who refuse surgery.

See Principles of Radiation Therapy for Cervical Cancer (CERV-B).

These doses are recommended for most patients based on summation of conventional external-beam fractionation and low-dose rate (40-70 cGy/h) brachytherapy equivalents. Modify treatment based on normal tissue tolerance. (See Discussion)

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Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

In NCCN resource-stratified guidelines, "basic level" denotes the minimum level of cancer-specific treatment needed to achieve a measurable level of effectiveness. If higher-level resources are available, providers should use the higher level. If basic level cancer treatments or higher are unavailable, palliative and best supportive care should be provided.

eCold knife conization (CKC) is the preferred method of diagnostic excision, but loop electrosurgical excision procedure (LEEP) is acceptable, provided adequate margins and proper orientation are obtained.



### RESOURCE-STRATIFIED GUIDELINES

- > Global Cancer Trends
- > Lancet Oncology Commission
- Adapting to Existing Resources
- > Analytic Tool Development
- > Strategic Implementation



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# BREAST CANCER INITIATIVE 2.5

Making breast health a global priority

BCI 2.5 is a global campaign to reduce disparities in breast cancer outcomes for 2.5 million women by 2025.

### **Breast Cancer Initiative 2.5**



### **Inviting Partners**

Susan G. Komen for the Cure

American Cancer Society

**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)



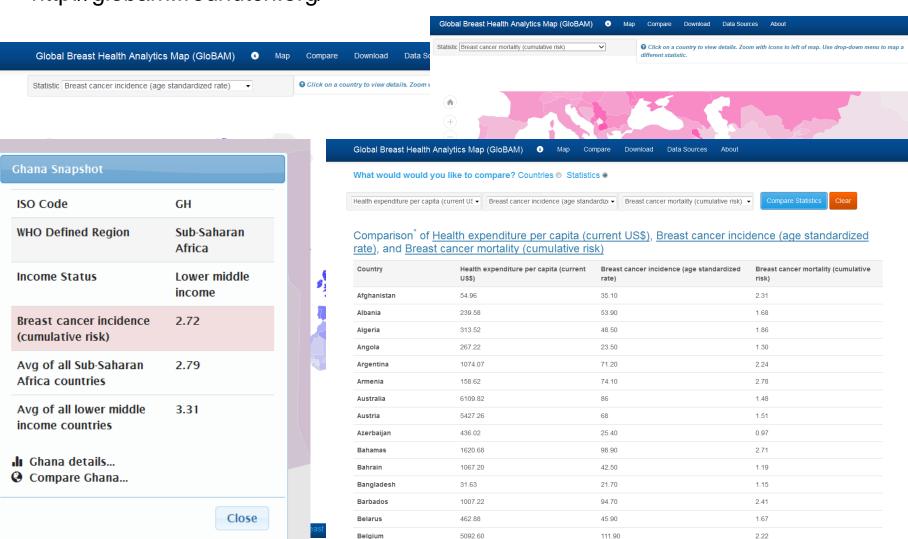


- 1. Outreach to raise awareness and build relationships;
- 2. Development of analysis and implementation tools;
- 3. Global Breast Health Analytics Map (GloBAM);
- 4. Baseline assessments / situation analysis;
- 5. Breast cancer action plans (BCAP); and
- 6. BCI2.5 Master Courses;
- 7. Technical assistance and implementation research.

### **GloBAM**



#### http://globam.fredhutch.org/



### **KNOWLEDGE SUMMARIES**





### **KNOWLEDGE SUMMARIES**



KNOWLEDGE SUMMARY

EARLY DETECTION (2 OF 3): BREAST PHYSIOLOGY AND THE CLINICAL BREAST EXAM (CBE)

**KNOWLEDGE SUMMARY** 

EARLY DETECTION (2 OF 3): BREAST PHYSIOLOGY AND THE CLINICAL BREAST EXAM (CBE)



#### POINTS FOR POLICYMAKERS PLANNING STEP 2: WHERE DO WE WANT TO BE?

#### DENTIFY OBJECTIVES AND PRIORITIES

#### Identify community and health system partnerships

- Identify partners (non-government organizations, advocates, trusted public figures, medical associations) who can help develop and disseminate breast health awareness messaging.
- Identify key decision makers who can help develop and implement a curriculum for medical training and continuing medical education.

#### Define the target population and approach

- Educational efforts should include health professional women and the general public.
- Training primary care health professionals may be a priority if previous breast health training was not provided in medical schools.
- Health professionals may require continuing medica education or "refresher" training in breast cancer prevention, risk factors, signs and symptoms and clinical breast examination (CRE)
- Women can be routinely educated during clinic visit about breast health, including any available breast cancer screening opportunities.

#### Identify gaps and barriers

- Identify prevailing myths or misconceptions regarding the signs and symptoms of breast cancer. Consider conducting focus groups with the target population to better understand prevailing beliefs.
- Identify gaps in knowledge and misconceptions among primary care providers regarding their beliefs about breast cancer. Consider conducting interviews and focus groups with primary care providers.
- Identify structural, sociocultural, personal and financial barriers to patient participation in CBE.

- Identify barriers to provider participation in breas health awareness and CBE, with a focus on nonattendees within the target population.
- Identify barriers to implementing CBE curriculum in medical training and continuing medical education

#### Set achievable objectives

- Objectives should promote a common goal for early detection; downstaging breast cancer diagnoses to improve cancer outcomes.
- Identify and classify objectives according to the healthcare sector that will manage them (e.g., health system standardzation of CBE efforts should be led by dinicians; examiner training of CBE could be led by healthcare organizations; increasing the number of qualified practitioners could be led by sponsoring institutions, academia, and the public sector).
- Develop and disseminate patient and public educatio messages that are relevant and appropriate to the target community
- Integrate health professional education and training and standardized CBE protocols with widespread dissemination and demonstration of expert clinical breast healthcare skills.
- Address gaps in referral networks to ensure diagnostic follow-up for all breast health complaints (WHO) Package of Essential Noncommunicable (PEN) disease interventions for primary care in lov/-resource settings referral mode).
- Report and document clinical findings (contribute data to cancer registry).
- Consider minimizing costs by adapting or supplementing existing programs (e.g., adding breast health education to medical school curriculum and continuing education programs).

#### Set priorities and determine feasibility o

- Implement demonstration or pilot projects with measurable outcomes to assess feasibility.
- Follow a resource-stratified pathway for program development that identifies available resources across the continuum of care.

#### **HOW DO WE GET THERE?**

Ensure dinical competency in breast health: Health systems are responsible for the clinical competency of health care staff. Health systems should partner with medical education institutions to ensure that breast health is part of the standard medical curriculum, and that the curriculum for health professionals assigned to work with women at risk for breast cancer includes training in CBE and breast courseling (see Table 1).

#### Improve patient and community knowledge of and

confidence in breast healthcare: Breast awareness efforts can improve patient knowledge of breast cancer and the importance of seeking care immediately for a breast complaint. However, if patients do not have confidence that the healthcare system can provide them with timely and affordable care, they may delay presenting for evaluation. In some low-resource settings, there is a lack of trust in the health system and a lack of confidence in the possibility of being cured of cancer, which discourages patients from presenting for evaluation of a breast complaint. NGOs have been proven as effective partners to address these issues and help navigate women to such services or provide services directly.

Strengthen referral networks: Health systems are responsible for establishing and monitoring referral networks to ensure the best care available is provided equitably to all patients in need. The high volume of women with breast health complaints requires a coordinated referral system to ensure optimal use of resources and efficient care. Referral systems should document the nature and urgency of the referral. The capacity of different health systems to care for women with breast complaints varies; scaling up expertise and establishing minimal standards of care are two possible approaches to improving care.

Implement quality assurance programs: Improving standards for CBE through training and tracking outcomes may improve the practice of CBE —an approach that has been used successfully with mammography. Increasing CBE volume and establishing trained teams or centers can improve the sensitivity and reduce the false-positive rates of CBE. Effective communications between providers can improve the care within an interdisciplinary system. Communications must be through and bidirectional to help coordinate care. For example, regional guidelines regarding the timing, type and location of imaging studies for women with breast complaints should be established to avoid duplication of studies. Similarly, breast mass biopsy findings should be communicated back to the primary care physician to coordinate appropriate follow-up and surveillance.

#### POINTS FOR POLICYMAKERS PLANNING STEP 3:

#### IMADI EMENIT AND EVALUATE

#### Establish financial support and partnerships

- Consider partnering with local, regional and national breast health stakeholders.
- Advocacy groups are key stakeholders in advancing breast health awareness and are often supported by community members and volunteer
- Partner with medical institutions to integrate training into existing programs.
- Scaling-up existing programs can optimize investments and offerts.

#### Launch, disseminate and implement

- Consider current educational programs that could be expanded or adapted to include breast health (e.g., training in clinical breast examination (CBB) should be part of the medical school core curriculum, offered as part of continuing education and available to all appropriate frontline health professionals).
- Expand the practice of CBE at the primary care
  level.
- Clarify the system for referrals and follow-up care to all health professionals and patients to avoid duplication of studies or omissions in care (e.g., suspicious lesions must be referred to a surgical team for biopsy, followed by a pathology evaluation of the biopsied specimen).
- Consider using a standardized patient care plan that provides details of a patient's diagnosis and treatment that can be shared by all members of the beauthear to trans.

#### Monitor and evaluate

- Process metrics should address program components targeted for improvement or implementation (e.g., process metrics identified in Step 2 can be routinely evaluated and updated).
- Evaluate health professional competency in CBE, breast health courseling and timely referrals (e.g., health professional self-assessment tools can be used to assess the sensitivity and specificity of CBE and inform programs planning).
- Quality control measures should be in place (e.g. data that capture false-negative findings and delays in time to definitive care can inform future program improvements).

9







#### 2. INSTITUTION: GENERAL

#### TO BE COMPLETED BY ALL RESPONDENTS.

2.1 What best describes your facility (please select only one option	by your institution, given the available res	sources?		Theathr Care Serv	ices provided
O Primary care facility - provides primary health care to patients who come to the facility concern. The services provided at the primary care facility do not have distinct special	o Partially developed: These services are not provide o Well established: All the required services or	provided in my ins	titution but does not m		n
O Provincial or Secondary-level hospital - highly differentiated by function with five to to obstetrics-gynecology, pediatrics and general surgery.	(You must p	rovide a value for	each response below)		
O Tertiary-level hospital - highly specialized staff and technical equipment. Clinical servi have teaching activities.	Breast cancer screening of asymptomatic women *must provide value	Not addressed	Partially developed	Well established	Don't know
Cancer care/breast care facility- specialized in cancer or breast cancer diagnosis and	Breast imaging for screening (i.e. mammogram, ultrasound) * must provide value	0	0	0	re
Outpatient clinic/Imaging center - detection and diagnosis of breast cancer.	Breast imaging for diagnosis *must provide value	0	0	0	0
	Pathology * must provide value	0	0	0	O re
<ul> <li>Palliative care facility - provides medical care that focuses on reducing the severity of progression of the disease itself. The goal is to prevent and relieve suffering and to im</li> </ul>	Breast surgery * must provide value	0	0	0	O
	Radiation therapy for symptom control (i.e., bone metastases)  *must provide value	0	0	0	O
2.2. What best describes the funding status of your facility?	Chemotherapy * must provide value	0	0	0	O
O Public - Government funded	Endocrine therapy (e.g., tamoxifen, aromatase inhibitors) * must provide value	0	0	0	O
O Private (for profit) - No government funding	Biological therapy (e.g. trastuzumab) *must provide value	0	0	0	O
	Multidisciplinary care  * must provide value	0	0	0	O re
O Mixed - government and private funding	Psychosocial support for cancer patients and family members (individual or group)  *must provide value	0	0	0	O
O Not-for-profit	Palliative care/pain management *must provide value	0	0	0	
O Mission/faith-based	Rehabilitation of cancer patients  * must provide value	0	0	0	O re
O Foreign aid	Follow-up of cancer patients  * must provide value	0	0	0	O re
Other (specify):	Medical record keeping * must provide value	0	0	0	O re
O Other (specify).	Cancer registry * must provide value	0	0	0	O re
	Physician training in breast health care * must provide value	0	0	0	O
2.3. Please rank in order of importance the primary source of paymemore than one answer, please rank your answers in the order of frequency	Patient education/outreach * must provide value	0	0	0	O
frequent, 2 being the second most frequent, etc.)	one, man . semig and most				

# A MODELING FRAMEWORK TO PRIORITIZE INTERVENTIONS FOR BREAST CANCER CONTROL

Ruth Etzioni

Jeanette Birnbaum

Catherine Duggan

Benjamin Anderson

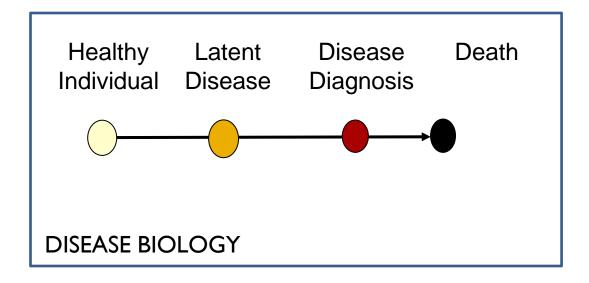




### Three Modeling Steps

#### Decouple effect of screening from effect of treatment

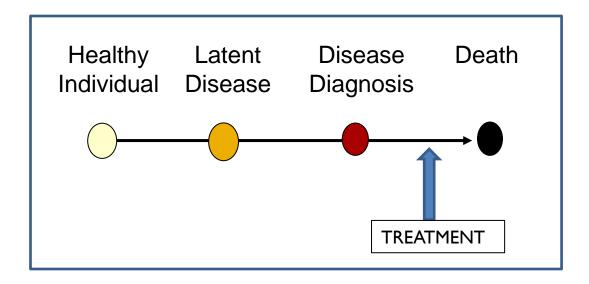
- Effect of screening
  - Reduce frequency of advanced disease
  - (Additionally) May improve survival of localized disease
- Effect of treatment
  - Improve stage-specific survival



### Three Modeling Steps

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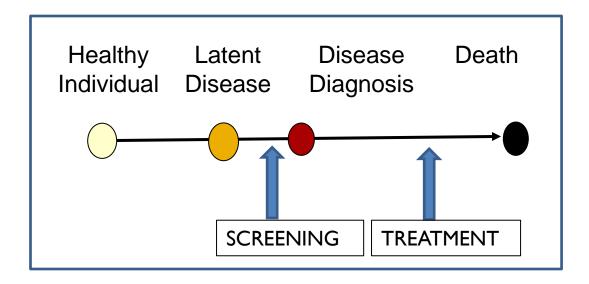
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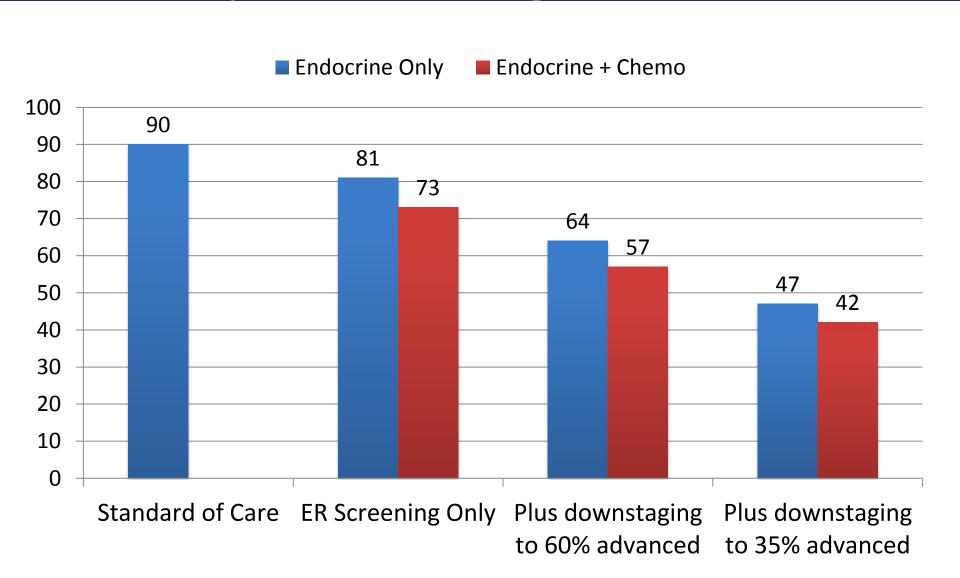
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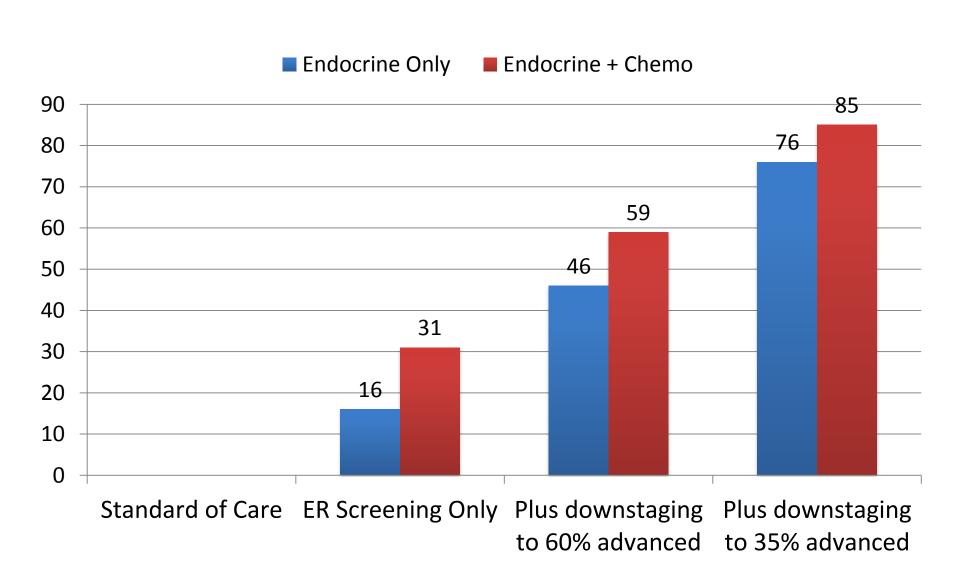
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# Tanzania: Breast Ca Mortality after 5 years per 100,000 ages 30-49



# Tanzania: Years of Life Saved after 5 years per 100,000 ages 30-49





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### LMC IMPLEMENTATION RESEARCH

### LOWER-MIDDLE INCOME COUNTRY











### **BCI2.5**



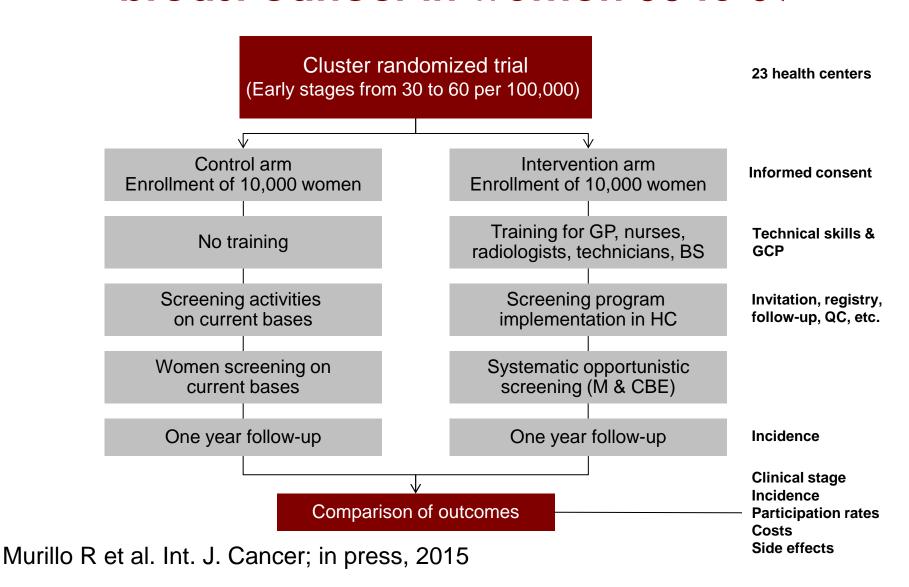
### BREAST CANCER EPIDEMIOLOGY

UPPER-MIDDLE INCOME COUNTRY



National Early Detection Program

### Study design for early detection of breast cancer in women 50 to 69



### Final Cancer Diagnosis by Stage

		Intervention		Con	Total	
Category	Stage	Year 1	Year 2	Year 1	Year 2	
	In situ	3 (14.3%)	1 (50.0%)	0	0	4
Early	I	9 (42.9%)	1 (50.0%)	1 (7.7%)	2 (40%)	13
	IIA	3 (14.3%)	0	5 (38.5%)	1 (20%)	9
	IIB	3 (14.3%)	0	5 (38.5%)	2 (40%)	10
Advanced	IIIA	1 (4.8%)	0	0	0	1
	IIIB	2 (9.5%)	0	2 (15.4%)	0	4
Total		21	2	13	5	41

Murillo R et al. Int. J. Cancer; in press, 2015

Pearson  $\chi^2 = 10.54$  Pr = 0.05

### Clinical Stage by Type of Surgery

			Type of surgery received				
Category	Stage	None	Breast Conservation Surgery (BCS)	Mastectomy			
	In situ	0	4 (16.7%)	0	4		
Early	I	0	10 (41.7%)	3 (23.1%)	13		
	IIA	0	4 (16.7%)	5 (38.5%)	9		
	IIB	1 (33.3%)	6 (25.0%)	2 (15.4%)	10		
Advanced	IIIA	0	0	1 (7.7%)	1		
	IIIB	2 (66.7%)	0	2 (15.4%)	4		
Total		3	24	13	41		

Murillo R et al. Int. J. Cancer; in press, 2015

Pearson  $\chi^2$ = 22.13 Pr = 0.02

## LMC IMPLEMENTATION RESEARCH

LOWER-MIDDLE INCOME COUNTRY



Early Detection and Patient Triage

#### **Breast cancer care model**



Regional Cancer Institute (Trujillo)



- Mammography
- Pathology
- Surgery
- Chemotherapy
- Radiotherapy



La Fora Reference Hospital



• FNA



Photos courtesy of Ben Anderson

**Health Centers** 

- Community education
- CBE



## 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.





#### PLAN DE SUPERVISIÓN HOSPITAL REGIONAL DE LORETO

JUSTIFICACIÓN OBJETIVOS METODOLOGÍA RESULTADOS INFORME

•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.





Hinchazón, calor, oscurecimiento o enrojecimiento de la mama.



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



Hoyuelos o arrugas en la piel.



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



Hundimiento del pezón o de otras partes de la mama.



Secreción repentina del pezón.



Dolor reciente y persistente en alguna parte de la mama.



Aparición de alguna masa, bolita dura, o la piel más gruesa dentro de la mama.



#### PROGRAMA DE PREVENCION Y CONTROL DE CANCER DE MAMA HISTORIA CLINICA DE SALUD MAMARIA

DATOS GENERALES			
Nombre del establecimiento	Nº Historia Clinica		
Primer Apelido S	egundo Apellido	Nombres	DNI
Dirección		Distrito	Telefono
Fecha de nacimiento Edad (años) ¿Has escuchado acerca de salud mamaria de Sc. en una sesión educativa en establecimiento de salud	s un promotor(a) de salud?	esión educativa	Fecha de consulta  Si, a través del contacto individual con el promotor
ANAMNESIS  Motivo de consulta: Por tamizaje  Sintomas	Por sintomas mam	arios 🔲	Por referencia
Relación con ciclo menetrual: Si		YM/A Kg. Talla	Duraciónmt.
Uso de anticonoeptivos: SINO	Idad menopausia:	_^	P M(A
Antecedentes personales y familiares: Historia personal de: Câncer de mama: Sl [ Historia de familiar directo de: Câncer de m Hâbitos: Tabaco: Sl NO Alo:	NO Cáncer de :	ovario: SI NO	Otro cáncer:
EXAMEN CUNICO DE MAMA:			
CARACTERISTICAS DEL TURNOS  Turnos palasisse  Turnos palasisse  Tamado Turnos 2  Considencia del turnor (blando, chara, pétres, fluctuante)  Forme del turnor (regular, irregular)  dismolr fico)  Bondos del turnor (regular, irregular)  Gonglio (assiss, supractavistale)  Secreción por pentin (salor)  Restracydos (pecole, piet)  Ecnema (pesolo, areola)  Ulterroción (pecole, piet)  Ecnema (pesolo, piet)	CM CM		33 - 31 - 32 - 33 - 33 - 34 - 35 - 35 - 35 - 35 - 35
"Piet de maranja"	Dis	tancia del pezónc	m. Distancia del pezóncm.

# MARCH 16 - 18, 2016





### BREAST CANCER EPIDEMIOLOGY

STAGE AT DIAGNOSIS: UNITED STATES VS. INDIA

STAGE	EXTENT	5 year	DISTRIBUTION	
		SURVIVAL	USA	INDIA
0	Noninvasive	100%	16%	
1	Early stage disease	100%	40%	1%
II	Early stage disease	86%	34%	23%
III	Locally advanced	57%	6%	52%
IV	Metastatic disease	20%	4%	24%

USA: 90% DCIS or early staged invasive disease at diagnosis

INDIA: 76% locally advanced or metastatic at diagnosis

www.bhgi.info

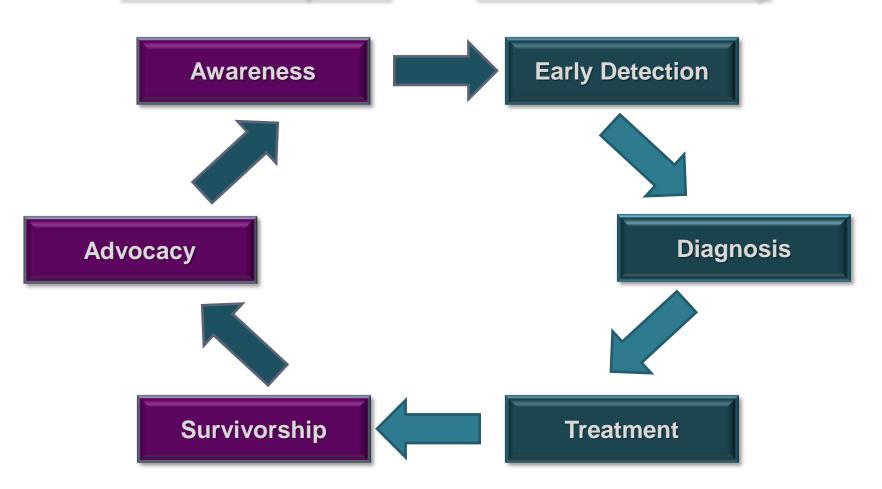
Sources: SEER Survival Monograph (NCI), 2007; Chopra, Cancer Institute Chennai, 2001 © 2016 BHGI. All rights reserved.





#### Public Participation

#### **Health Care Delivery**



## LMC IMPLEMENTATION RESEARCH

LOW INCOME COUNTRY



Screening Attitudes in Muslim Women





# LMC IMPLEMENTATION RESEARCH BREAST CANCER SCREENING IN GAZA

- Survey: 100 women living inside Gaza (WIG) and 55 Gaza women residing outside Gaza (WOG):
  - > >90% of both willing to have a diagnostic mammogram for a breast complaint,
  - > 86% of WIG and 85% of WOG believe survival increased with early detection,
  - ➤ However, only 27% of WIG and 50% WOG were willing to undergo screening mammography.





# RESOURCE-STRATIFIED GUIDELINES SUMMARY

- Cancer is increasingly affecting countries at all economic levels while health investment is failing to match the challenge.
- Cancer surgery reflects a global health need that is as underappreciated as it is underfunded.
- Resource-stratified guidelines provide a framework for prioritizing sustainable health care strategies.
- Baseline assessments are necessary to determine next steps for sequential programmatic building.
- Strategic implementation requires sustainable approaches that integrate into existing healthcare systems.



#### The Breast Health Global Initiative

www.bhgi.info

# BREAST CANCER INITIATIVE 2.5

Making breast health a global priority

www.BCI25.org