



The Breast Health Global Initiative (BHGI):

BREAST CANCER SCREENING

Benjamin O. Anderson, M.D.

**Chair and Director
Breast Health Global Initiative
Fred Hutchinson Cancer Research Center**

**Professor of Surgery & Global Health Medicine
University of Washington**

Seattle, Washington




Founding Organizations

FRED HUTCHINSON
CANCER RESEARCH CENTER

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BREAST CANCER SCREENING

- Defining standards of care
- Guidelines and metrics
- Implementation research



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MEDICAL STANDARD OF CARE

- A treatment guideline that specifies appropriate treatment based on scientific evidence and collaboration between medical professionals .
- Treatment standards applied within public hospitals to ensure that all patients receive appropriate care regardless of financial means.
- The level at which an ordinary, prudent professional having the same training and experience in good standing in a same or similar community would practice under the same or similar circumstances.

BREAST CANCER EPIDEMIOLOGY

GLOBAL DISTRIBUTION OF DISEASE

	Breast cancer (deaths in thousands [95% uncertainty intervals])		
	15-49 years	≥50 years	Total
Global	94.0 (87.1-102.3)	331.2 (269.9-352.8)	425.2 (358.6-453.4)
Developing	67.8 (61.6-74.2)	145.9 (125.8-160.2)	213.7 (188.6-231.2)
Developed	26.1 (24.1-29.4)	185.3 (143.2-200.4)	211.4 (169.3-228.5)

	Cervical cancer (deaths in thousands [95% uncertainty intervals])		
	15-49 years	≥50 years	Total
Global	55.9 (39.5-78.7)	144.1 (98.9-195.7)	200.1 (139.0-276.3)
Developing	46.2 (32.7-64.3)	109.2 (73.1-146.3)	155.4 (106.2-212.1)
Developed	9.7 (6.8-13.1)	35.0 (25.6-49.3)	44.7 (32.3-62.3)

BREAST CANCER EPIDEMIOLOGY

STAGE AT DIAGNOSIS: UNITED STATES VS. INDIA

STAGE	EXTENT	5 year SURVIVAL	DISTRIBUTION	
			USA	INDIA
0	Noninvasive	100%	16%	----
I	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

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

WORLD BANK COUNTRY GROUPS

WORLD BANK CLASSIFICATION (ATLAS METHOD)

World Bank Country Groups <i>(GNI per capita)</i>	Low Income <i>(\$995 or less)</i>	Lower Middle Income <i>(\$996 - \$3,945)</i>	Upper Middle Income <i>(\$3,946 - \$12,195)</i>	High Income <i>(\$12,196 or more)</i>
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
<http://data.worldbank.org/data-catalog/health-nutrition-and-population-statistics>.



U.N. HUMAN RIGHTS LAW (1966) INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (ICESCR), ARTICLE 12(1)

“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.”



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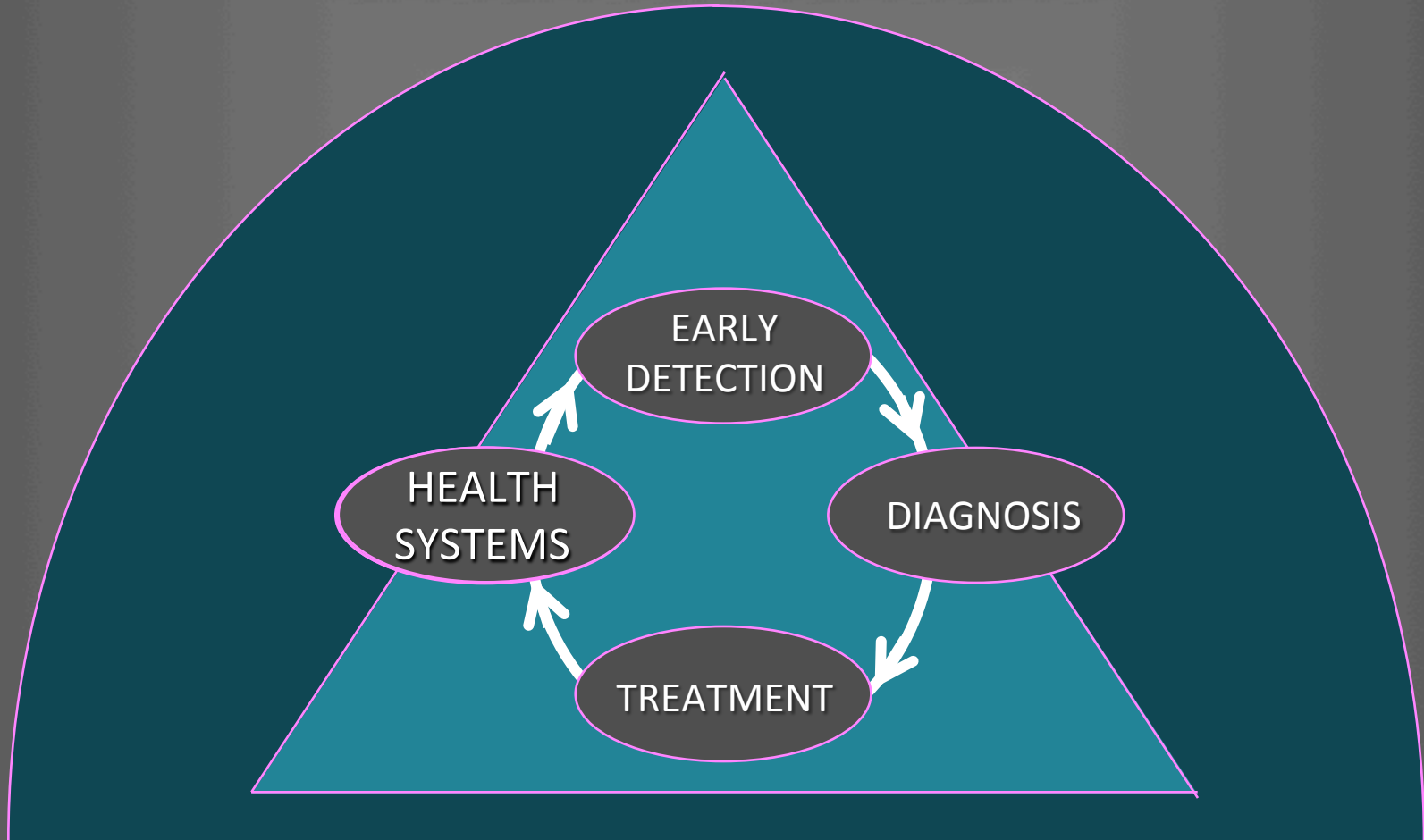
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GLOBAL SUMMIT 2005 – BETHESDA

RESOURCE STRATIFICATION





BHGI GUIDELINE DEVELOPMENT

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

Global Summit 2002: Health Care Disparities

Global Summit 2005: Resource Stratification

Global Summit 2007: Guideline Implementation

Global Summit 2010: Optimizing Delivery of Care



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

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 cancer, 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 handling 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 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 imaging access Breast prostheses 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 Psychotherapist & 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 breast	Centralized referral cancer center(s) Radiation therapy: low energy linear accelerator, electrons, brachytherapy, treatment planning system	Multidisciplinary breast programs Oncology nurse specialists Physician assistants
Maximal		Organization of national medical breast health groups		Satellite (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 outreach/education 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 linked to general health and women's health programs	Mammographic screening every 2 years in women ages 50-59 [†] 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
Basic	History Physical examination Clinical breast examination (CBE) Tissue sampling for cancer diagnosis (cytologic or histologic) prior to initiation of treatment		Pathology diagnosis obtained for every breast lesion by any available sampling procedure Pathology report containing appropriate diagnostic and prognostic predictive information to include tumor size, lymph node status, histologic type and tumor grade 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) Pain chest and skeletal radiography Liver US Blood chemistry profile* Complete blood count (CBC)*	Determination of ER status by IHC† Determination of margin status, DCIS content, presence of LV† Frozen section or touch prep SLN analyses §
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 resources	Local-Regional Treatment		Systemic Treatment (Adjuvant)		
	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 disease†
Maximal			Growth factors Dose-dense chemotherapy		

STAGE II

Level of resources	Local-Regional Treatment		Systemic Treatment (Adjuvant)		
	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Biological Therapy
Basic	Modified radical mastectomy	*	Classical CMF† AC, EC, or FAC†	Oophorectomy in premenopausal women Tamoxifen‡	
Limited	Breast conserving surgery§ Sentinel lymph node (SLN) biopsy with blue dye‡	Postmastectomy irradiation of chest wall and regional nodes for high-risk cases*			¶
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†
Maximal			Growth factors Dose-dense chemotherapy		

LOCALLY ADVANCED

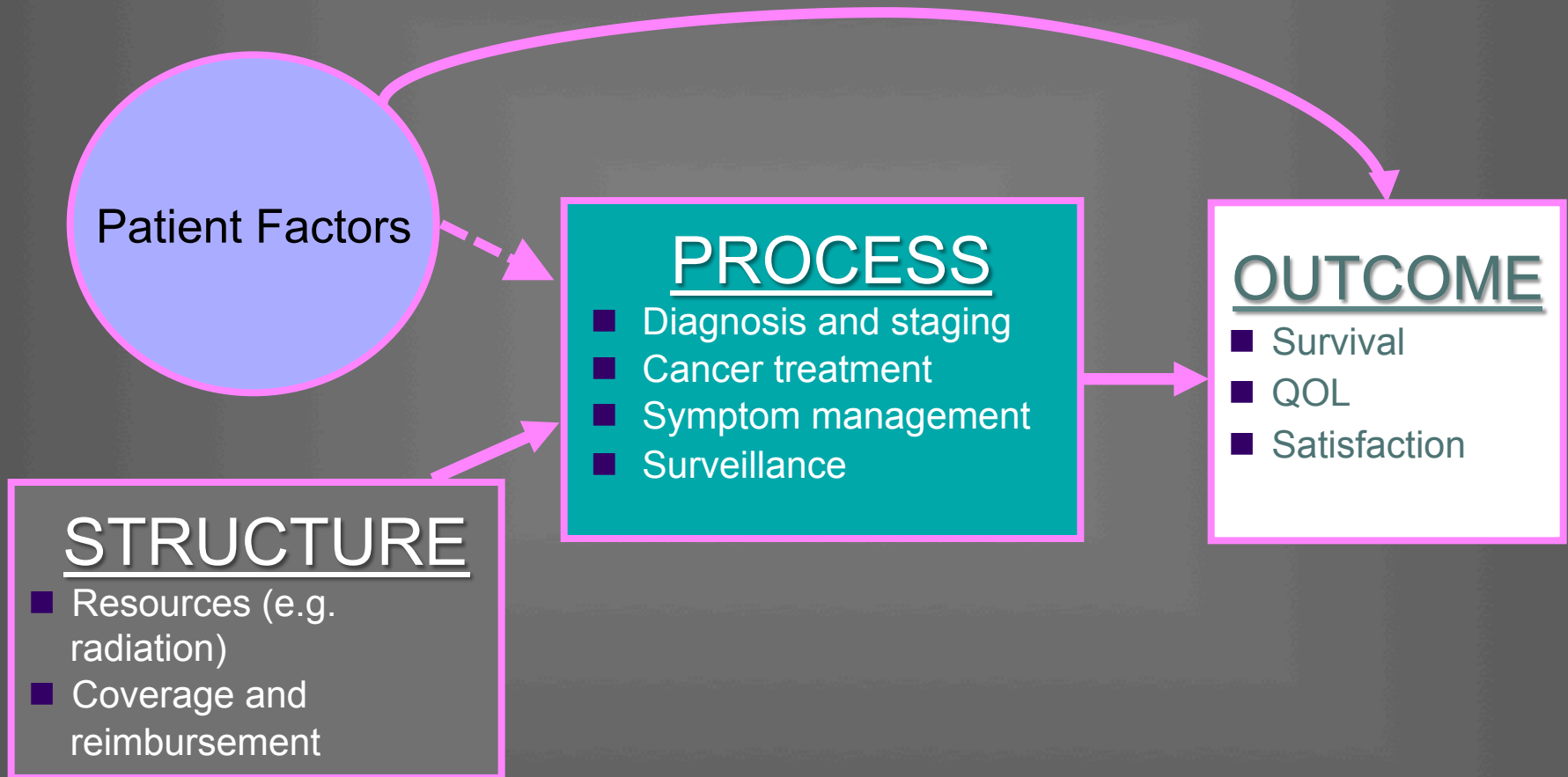
Level of resources	Local-Regional Treatment		Systemic Treatment (Adjuvant or Neoadjuvant)		
	Surgery	Radiation Therapy	Chemotherapy	Endocrine Therapy	Biological Therapy
Basic	Modified radical mastectomy		Preoperative chemotherapy with AC, EC, FAC or CMF†	Oophorectomy in premenopausal women Tamoxifen‡	
Limited		Postmastectomy irradiation of chest wall and regional nodes*			§
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 HER2-neu positive disease§
Maximal			Growth factors Dose-dense chemotherapy		

METASTATIC

Level of resources	Local-Regional Treatment		Systemic Treatment (Palliative)		
	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	Fulvestant	Growth factors



METRICS & QUALITY IMPROVEMENT





BHGI SYSTEMS METRICS

Level of resources	Early Detection	Diagnosis	Treatment	Programmatic
Basic	<p># Pts with documented H&P / # Pts evaluated</p> <p><i>Description: The ratio of the number of patients who have a recorded history and physical examination within the target group to the number of patients who were clinically evaluated within the target group for a center or program providing organized breast healthcare.</i></p>	<p># Pts with tissue dx / # Pts with suspic. mass</p> <p><i>Description: The ratio of the number of patients who receive a tissue diagnosis (benign or malignant) to the number of patients who had a "suspicious mass" (finding on CBE that the clinical examiner considers abnormal and therefore warranting further evaluation).</i></p>	<p># Pts treated for ca / # Pts with tissue dx ca</p> <p><i>Description: The ratio of the number of patients who receive cancer treatment of some fashion (surgery beyond surgical biopsy, radiation tx and/or systemic tx) to the number of patients who had a tissue diagnosis of cancer.</i></p>	<p>Median pathologic tumor size</p> <p><i>Description: The median pathologically determined size of invasive breast primary tumors within the target group for a center or program providing organized breast healthcare.</i></p>
Limited	% Pts with CBE-detected abnormalities who undergo breast imaging for work-up	% Pts with biopsy-proven cancer diagnosis who have documented TNM stage	% Pts with ca diagnosis who start treatment within 120d of tissue diagnosis	% cancer Pts who have TNM stage I or II disease at initial biopsy-proven diagnosis
Enhanced	% Pts age 50-69 who had screening mammogram within past 24 months	% Pts with biopsy-proven cancer diagnosis who have documented HER-2/neu status	% Pts treated by lumpectomy starting XRT within 120d of last surgical procedure	% cancer Pts who have TNM stage I or II disease who at 5 yrs have no evidence of disease recurrence
Maximal	Maximal category process metrics determined based upon standards of care in high-income countries	Maximal category process metrics determined based upon standards of care in high-income countries	Maximal category process metrics determined based upon standards of care in high-income countries	Maximal category process metrics determined based upon standards of care in high-income countries

Cancer: 113 (8 suppl), 2008



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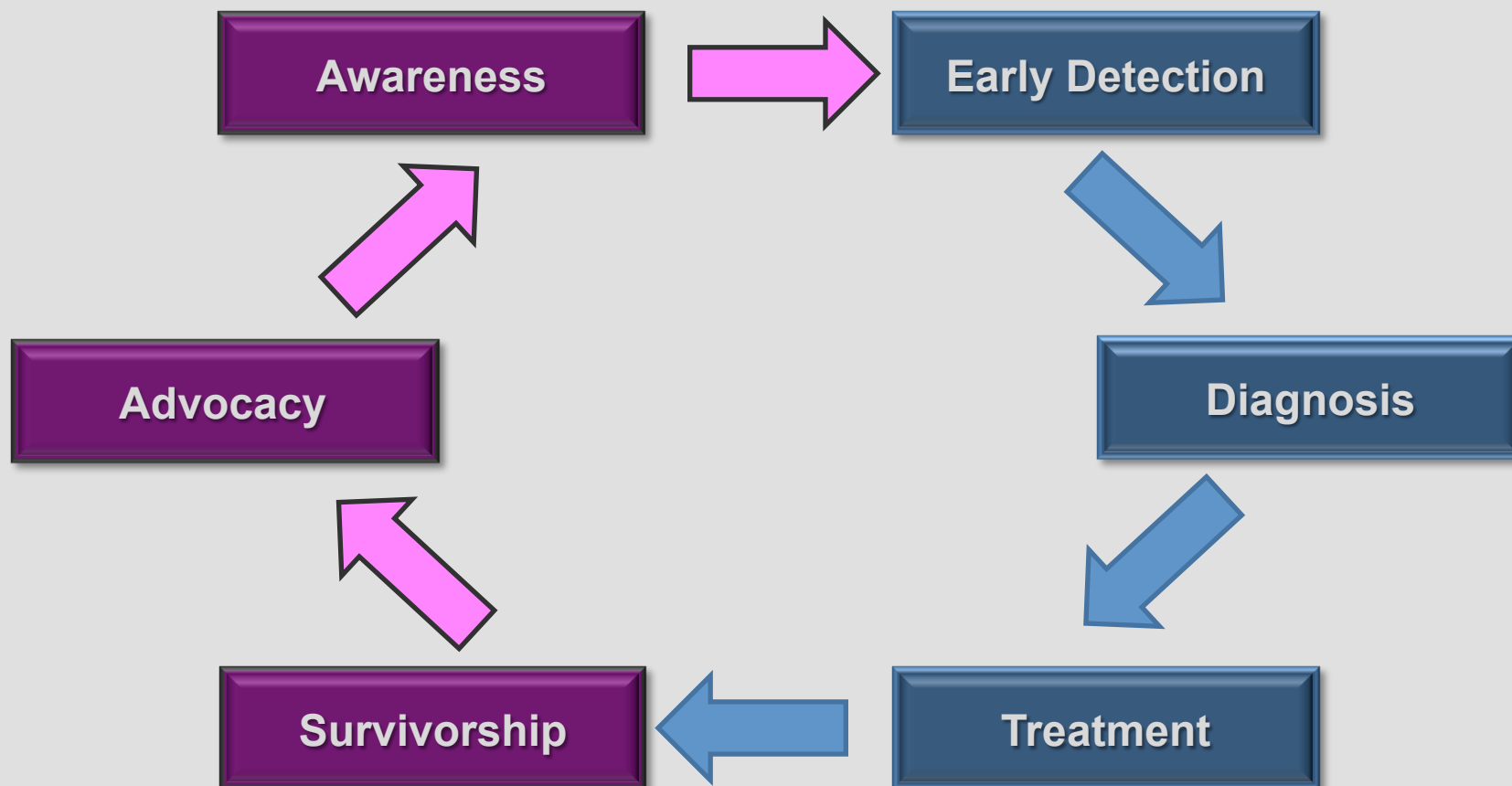
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Level of resources	Public Education and Awareness	Detection Methods	Evaluation Goal
Basic	Development of culturally sensitive, linguistically appropriate local education programs for target populations to teach value of early detection, breast cancer risk factors and breast health awareness (education + self-examination)	Clinical history and CBE	Breast health awareness regarding value of early detection in improving breast cancer outcome
Limited	Culturally and linguistically appropriate targeted outreach/education 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*	Downsizing of symptomatic disease
Enhanced	Regional awareness programs regarding breast health linked to general health and women's health programs	Mammographic screening every 2 years in women ages 50-69* Consider mammographic screening every 12-18 months in women ages 40-49*	Downsizing and/or downstaging of asymptomatic disease in women in highest yield target groups
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†	Downsizing and/or downstaging of asymptomatic disease in women in all risk groups



Public Participation

Health Care Delivery



LMC IMPLEMENTATION RESEARCH

LOW INCOME COUNTRY



Screening Attitudes in Muslim Women



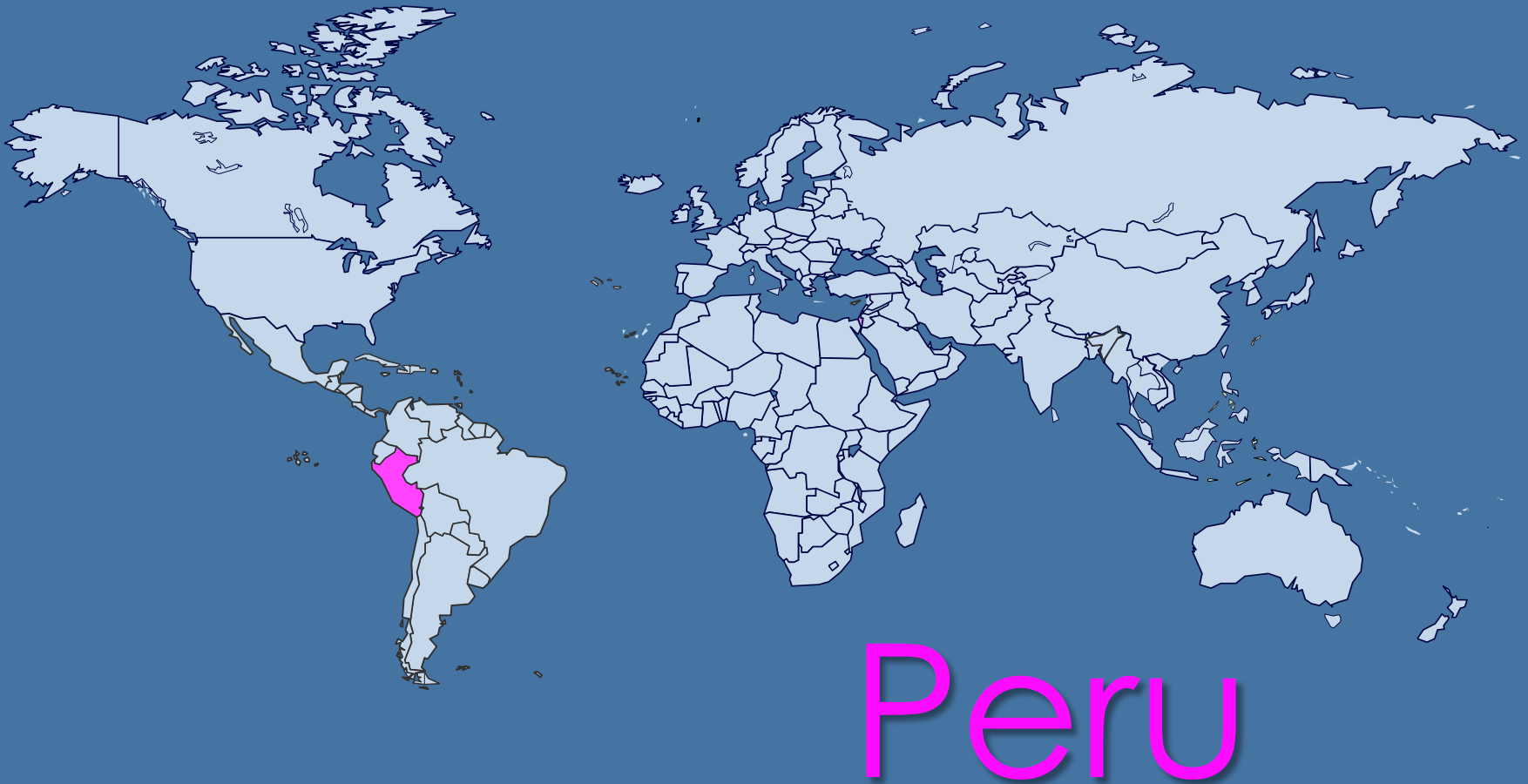
LMC IMPLEMENTATION RESEARCH

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.

LMC IMPLEMENTATION RESEARCH

LOWER-MIDDLE INCOME COUNTRY



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)



La Fora Reference Hospital



Health Centers

- Mammography
- Pathology
- Surgery
- Chemotherapy
- Radiotherapy

- FNA

- Community education
- CBE

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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



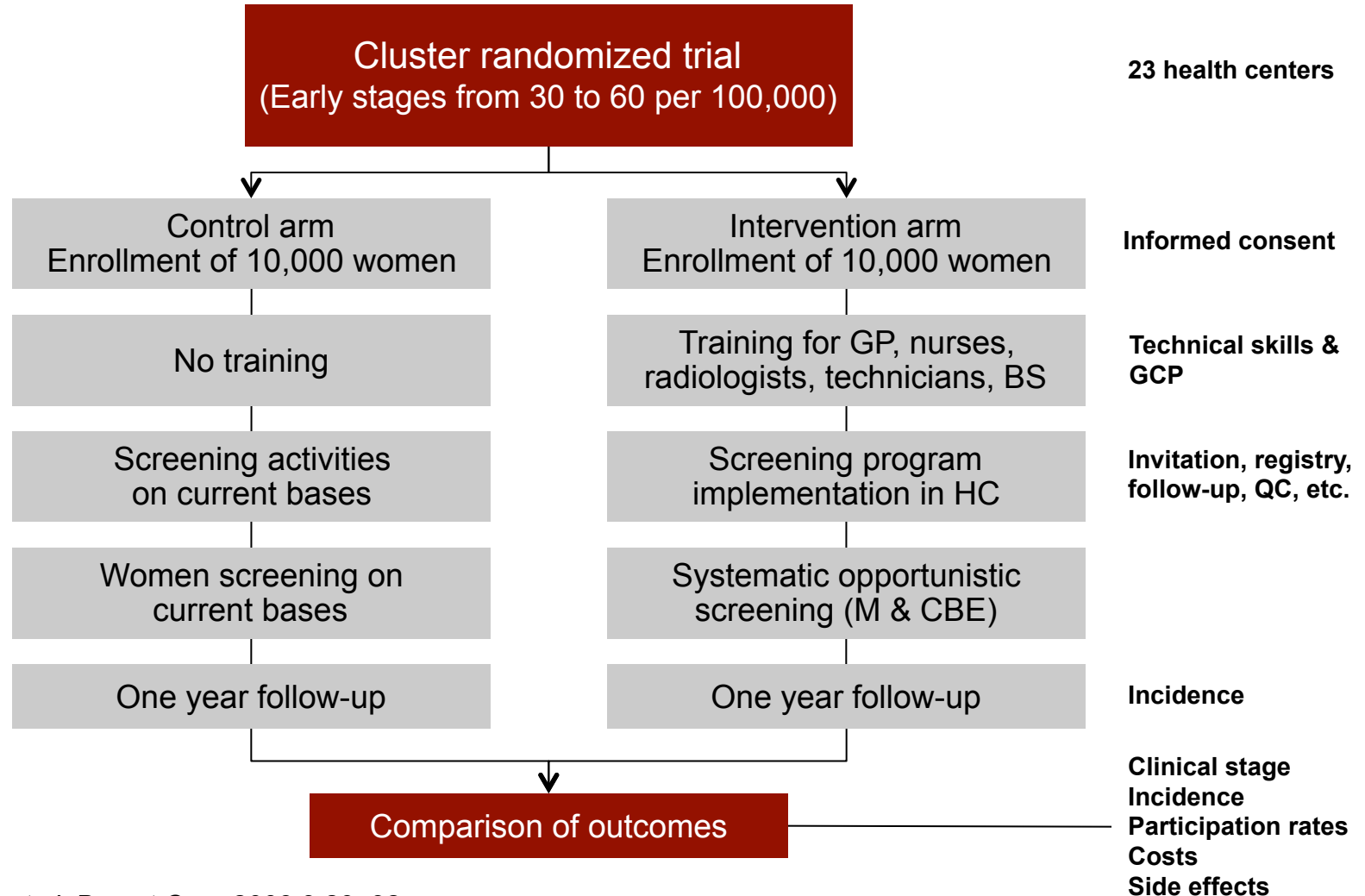
Colombia

National Early Detection Program

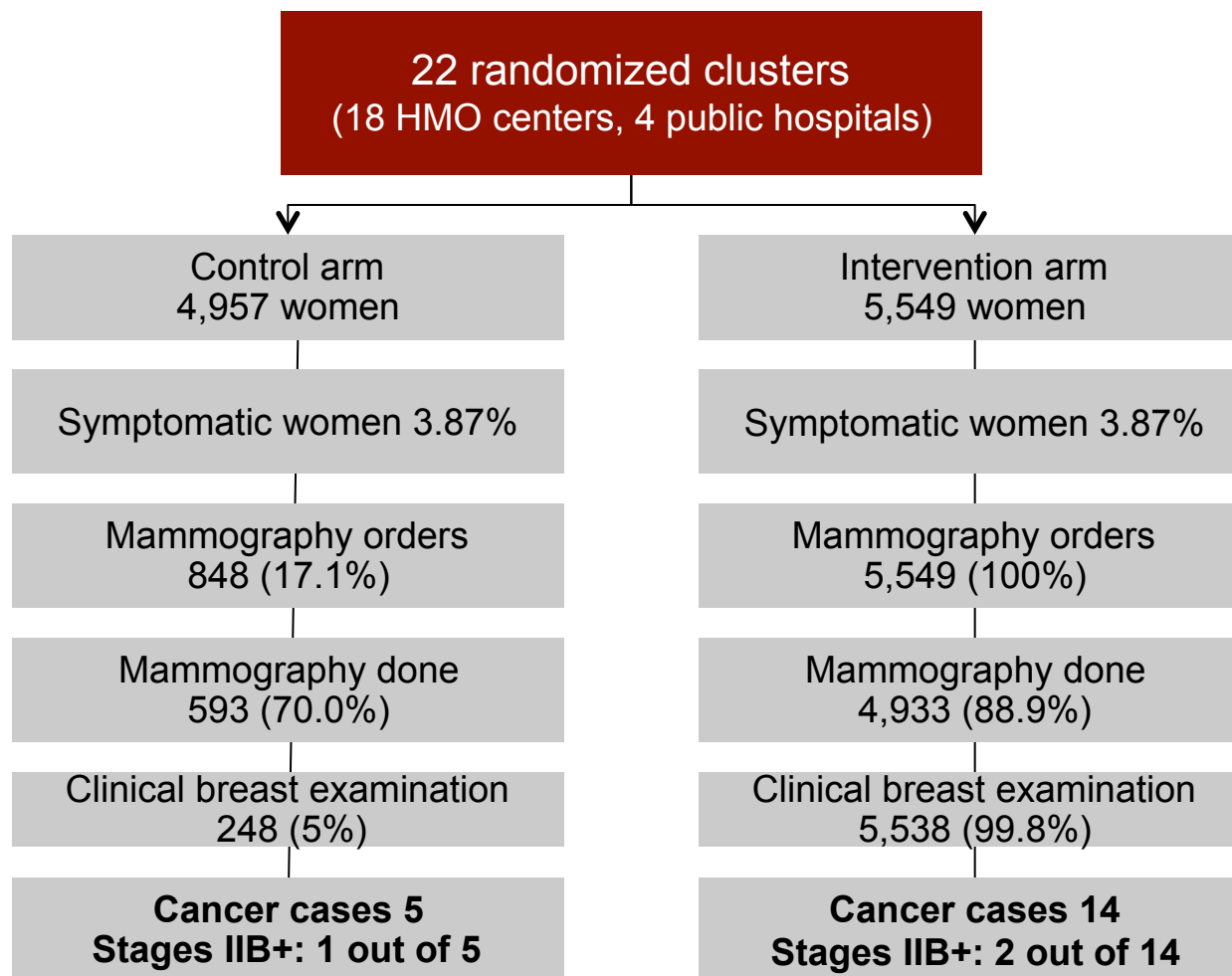
Pilot project for the introduction of breast cancer early detection programs in Colombia

Raul Murillo, MD, MPH
National Cancer Institute
Bogota - Colombia

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



Preliminary results





STANDARDS OF CARE AND QUALITY

SUMMARY

- Breast cancer is a significant issue for countries at all economic levels, not just wealthy countries.
- Resource-adapted guidelines provide a framework for cancer program implementation in low-resource settings.
- Implementation research requires practical metrics by through relevant improvements are reliably assessed.
- Sociological considerations are a necessary aspect of breast program implementation to insure public participation.



BHGI KEY PERSONNEL

BHGI Executive Committee

- Eduardo Cazap, Chair (SLACOM / UICC / ASCO)
- Elizabeth Thompson (Komen for the Cure®)
- Joe Harford (NCI Office of International Affairs)

BHGI Program Staff

- Leslie Sullivan, Managing Director
- Marisa Hartman, Administrator
- Sandra Distelhorst, Publication Editor
- Julia Chase, Program Assistant



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BHGI Research Team

- David Thomas, Senior Research Advisor
- Beti Thompson, Qualitative Research Advisor
- Gabrielle Kane, Curriculum Specialist
- Esther Jhingan, Field Coordinator, Latin America
- Ibrahim Ali, Field Coordinator, West Africa
- Wenjin Li, Field Coordinator, China



INTERNATIONAL COLLABORATORS

- Austria
 - Massoud Samiei
 - Rolando Camacho
 - Raimund Jakesz
- Belarus
 - Tanya Soldak
- Brazil
 - Luiz A Santini
 - Maira Caleffi
- China
 - Wu Fan
 - Ying Zheng
- Colombia
 - Carlos Rada
 - Raul Murillo
 - Sandra Diaz
- Egypt
 - Sherif Omar
 - Hussein M Khaled
 - Ahmed Elzawawy
 - Mohamed Shalan
- Ghana
 - Baffour Awuah
 - Joe-Nat Clegg-Lamptey
- India
 - Raj Badwe
- Italy
 - Alberto Costa
 - Riccardo Masetti
- Lebanon
 - Nagi El Saghir
- Malaysia
 - Cheng-Har Yip
- Nigeria
 - Clement Adebamowo
- Romania
 - Alexandru Eniu
- Pakistan
 - Zeba Aziz
- Turkey
 - Vahit Osmen
 - Nuran Bese
- Ukraine
 - Roman Shyyan
- U.S.A.
 - Robert Carlson
 - Jay Harness
 - Julie Gralow
 - Peggy Porter



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