

**BREAST
CANCER
INITIATIVE 2.5**
Making breast health a global priority

EARLY DETECTION

Screening Mammography Programs

Knowledge Summary



Screening Mammography Programs

INTRODUCTION

Early detection is an important component of a comprehensive breast cancer care strategy. It includes early diagnosis of symptomatic women and may include screening programs offered to asymptomatic women. The goal of early detection is to increase the chances of successful treatment by detecting the disease at an early stage, when the available treatments are more effective. Mammography can play an important role in breast cancer control programs when the incidence of breast cancer in the target population is high and resources for providing an accurate diagnosis and effective treatment are universally available and accessible in a timely manner. Screening programs require health system coordination of patient care so that follow up diagnostic and treatment services are available for women with positive screening tests.

In high-income countries (HICs), mammography screening programs have been shown to reduce breast cancer mortality rates by 38% (18–53%). In these settings, the rate of breast cancer in the target population is high (92 per 100,000 in North America) and observed mortality reductions among women exposed to screening principally apply to women ages 50–74. In settings where women under age 50 are invited to mammography screening, similar mortality reductions have been observed, but due to the lower prevalence of disease, absolute benefits are lower. In low- and middle-income countries (LMICs) breast cancer incidence rates are much lower (27 per 100,000). In addition, unless there is universal access to diagnostic and treatment services, even the downstaging of tumors through screening programs of asymptomatic women are not likely to reduce breast cancer mortality. To date, there are no data available from LMICs demonstrating the efficacy of mammography screening programs. Health care systems in basic and limited resource settings should focus efforts on increasing health system capacity for breast cancer diagnosis and treatment, as well as education and awareness of health professionals and the general population so that symptomatic women (those with a breast lump or other breast symptoms) seek care for the diagnosis of breast cancers at an early, treatable stage [see *Early Detection: Breast Physiology and the Clinical Breast Exam*].

Screening programs must consider local capacity, barriers to participation and available resources. They require guidelines for screening and investments in mammography equipment and its quality assurance, including maintenance, training of personnel, feedback on performance (e.g., auditing of mammography reports for continued quality improvement), management of program outreach and access to diagnostic and treatment services. Sustainable resources are needed to ensure a program's success. Screening mammography programs have not been widely implemented and thus not proven effective in basic or limited resource settings.

WHO considers an effective, organized screening program to be one in which the participation rate (number of invitees actually screened) of the target population is over 70%. However, high participation rates may not be achieved in the first few years of a program, and programs should set short-term and long-term goals. Short-term measures of program effectiveness include low false positive, false negative and recall rates. Long-term measures of program effectiveness include a reduction in the percentage of women presenting with late-stage disease. A program's long-term success is determined by a reduction in breast cancer mortality ascertained through population-based registry data. Using data from the randomized clinical trials of mammographic screening, mortality only starts to fall by the third year, when the earliest effect of the first screen is expressed and will continue to decline for several years.

KEY SUMMARY

Screening

- As defined by WHO, screening refers to the use of tests across a healthy population in order to identify individuals who have disease, but do not yet have symptoms.
- Population-based screening programs should be undertaken only when they have been shown to reduce disease-specific mortality, when capacities exist for confirming diagnoses and for treatment and follow up of those with abnormal results, when prevalence of the disease is high enough to justify the effort and costs of screening and when resources (personnel, equipment, etc.) are sufficient to cover nearly all of the target group.
- Guidelines for screening eligibility criteria should include when (age) to start and stop screening and screening interval, and they should be based on local breast cancer incidence rates, demographics and resources available to support program implementation and follow up.
- Effective screening programs require available resources for both the screening modality chosen and diagnostic and treatment modalities for abnormalities detected in screening.
- Pilot programs can help assess feasibility, efficacy, applicability and cost effectiveness of programs before introduction of a national or regional population-based program.

Mammography

- Mammography uses X-rays to image the breast and identify malignant changes and can be used both as a diagnostic tool to examine symptomatic women and as a screening test in asymptomatic women.
- The goal of screening mammography is to detect breast cancer early, prior to feeling a breast lump. The success of screening mammography depends on the quality performance of the technology as well as having an organized screening program that achieves high screening coverage of women in the at-risk age group, followed by prompt diagnosis and treatment for women with abnormal results.

- Prerequisites to mammography screening include patient tracking and follow up, quality control efforts to ensure low false positive and false negative rates, and services for confirming diagnoses and providing treatment. Resources are also needed for ensuring quality performance of the imagers and for maintaining equipment.
- Mammography screening is not recommended in basic or limited resource settings with health systems lacking adequate capacity. If appropriate, screening mammography programs can be implemented once the effective use of diagnostic mammography and effective management (treatment) of palpable and nonpalpable disease is established.
- Mammography can be introduced in a stepwise fashion, first as a tool for confirming diagnosis of suspicious cases, then as a tool for screening of at-risk women in a target population once the necessary prerequisites are in place and quality performance has been demonstrated.

- The effectiveness of screening mammography programs depends on the breast cancer incidence rate in the target community, the participation rate, the follow up treatment rate and the community and health system resource levels.

Population participation

- To achieve high participation rates, barriers to participation and follow up should be addressed in the planning phase, including: structural [health system] barriers, societal barriers and patient barriers, including stigma associated with screening, early detection and a breast cancer diagnosis.
- Strategies to overcome participation barriers include outreach programs to increase awareness of breast cancer and breast cancer screening, education of health professionals at all levels, direct invitations to participate in screening, active follow up of screen-positive women, subsidized transportation to screenings and follow up care, patient navigation, breast cancer support groups and appropriate effective and affordable treatment.

POINTS FOR POLICYMAKERS:

OVERVIEW

Preplanning

- Identify data sources to help estimate the disease burden and current capacity to detect, diagnose and treat palpable breast masses.
- Identify or establish a population-based registry for long-term monitoring of breast cancer mortality.
- Identify what new resources or reallocation of resources might be needed and available for a screening program.
- Identify who will lead the effort as well as stakeholders to be engaged.

Planning Step 1: Where are we now?

Investigate and assess

- Assess disease burden and identify at-risk populations.
- Assess current capacity to detect, diagnose and treat palpable and nonpalpable disease.
- Assess costs and potential cost effectiveness of screening approaches.
- Assess knowledge, attitudes and awareness of women and of health providers regarding breast cancer and mammography screening.

Planning Step 2: Where do we want to be?

Set objectives and priorities

- Identify target screening population, including age to start and stop screening.
- Identify gaps and strategies to overcome these gaps [e.g., referral processes for follow up, diagnosis, treatment and palliative care].
- Revise or adapt program plans based on current evidence of best practices, situational analysis of target communities and resources available to support program implementation.
- Determine objectives, such as improving availability, technical expertise, patient access and participation.
- Develop evidence-based and culturally-tailored education strategies for women, including information about the benefits and harms of breast cancer screening.

Planning Step 3: How do we get there?

Implement and evaluate

- Develop a resource-stratified approach for screening programs. For example, mammography can be introduced incrementally, first as a diagnostic tool for use in evaluating symptomatic women who have an abnormality on clinical breast exam. Once effective diagnosis and treatment systems are in place, then mammography units could be used in pilot screening projects before being used in larger population-based screening programs.
- Engage advocacy groups and other partners in raising awareness to increase participation rates and provide supportive services, including emotional and logistical needs [e.g., patient navigation].
- Support and strengthen a coordinated patient pathway and referral system to improve patient flow from detection through diagnosis and treatment.

WHAT WE KNOW

Opportunistic versus organized screening: Opportunistic programs provide screening to women who have accessed the health care system for some other purpose and request or are offered screening, whereas organized programs provide outreach to all women in the targeted subgroup at heightened risk in the population. Opportunistic screening can be carried out during any health care visit if the health system has trained providers who can refer patients for further tests if appropriate. In opportunistic screening, additional diagnostic services and care are coordinated by the woman and her health care team. Both opportunistic and organized screening programs require quality control measures, including the collection of data on false positive, false negative and recall rates.

Screening mammography: Mammography distinguishes various tissue components in the breast—such as adipose tissue, fibroglandular tissue and calcification of tissue—using density and differential absorption of x-rays. Screening mammography has been shown to decrease breast cancer mortality in high-resource settings when used annually or biennially in women aged 40–74. Organized population-based screening mammography programs can reduce breast cancer mortality by 18–53%. Population-based screening mammography has also increased the detection of ductal carcinoma in situ (DCIS), a non-invasive lesion that may become cancer. The identification and treatment of DCIS leads to overtreatment, as DCIS will not always develop into an invasive cancer.

Organized screening requires a purposeful investment in health system infrastructure and in human and material resources, including data systems, to support organized screening efforts. The ability to track participants is key to ensuring that patients with abnormalities obtain appropriate follow up care to identify delays that adversely affect the quality and impact of the screening program. Utilization of opportunistic screening depends on individual factors: knowledge and behavior of the patient and provider; the cost of screening, diagnosis and treatment to the patient and the pattern of patient encounters with health services.

Technical aspects of mammography

Digital versus film: Digital mammography is more costly to implement than film mammography, but has technical advantages over film mammography, including lower average radiation dose, greater contrast resolution with greater specificity and improved visualization of skin and peripheral breast tissue. Using computer-aided detection (CAD) methodology, digital images can be reviewed immediately. Digital images can also be stored more easily and sent electronically to permit remote and/or synchronous viewing. CAD has a higher initial cost and higher recall rate due to increased detection of calcifications, but is an acceptable alternative to film screen techniques. Film mammography has a lower initial cost, but requires a reliable supply of x-ray film, developing capabilities, clean water and storage facilities. Over the long-term film screen is costly and processing can be hazardous.

Number of views: Two standard views of each breast, the mediolateral oblique (MLO) and cranial-caudal (CC) provide better visualization of the full breast. They can also assist in distinguishing overlapping structures from a true abnormality. In circumstances when only one view will be performed, the MLO view is preferred because it images a significantly greater volume of breast tissue than the CC view.

Double readings: Double reading by experienced imagers (or the combination of one experienced and one inexperienced reader) can improve quality reporting by decreasing the number of unnecessary recalls and increasing the possibility of detecting smaller cancers. However, there are additional costs, such increased use of radiologist's time, increased cost per exam and potential delay in time to final interpretation.

Sensitivity and specificity: Sensitivity estimates for mammography range from 68% to over 90%. Specificity estimates generally exceed 90%, with positive predictive values ranging from 2–22%. Sensitivity decreases in women with dense breast tissue. Factors associated with breast density include younger age (premenopausal), phase of the menstrual cycle (luteal phase) and use of hormonal replacement therapy. Some histologic features of a breast cancer are associated with higher or lower mammographic detectability: lobular or mucinous tumors are less likely to be detected than DCIS. False negative findings generally decrease with improvements in mammographic technology and quality control measures.

False positive and false negative findings: Mammography is not perfect—there are both false positive and false negative findings. False positive findings are perceived abnormalities on screening mammography that do not result in a cancer diagnosis within 365 days. False negative findings include mammograms interpreted as negative, but result in a breast cancer diagnosis in 365 days. Up to 15% of breast cancers cannot be detected on mammography screening.

Benefits versus harms: A primary criticism of screening mammography is that a significant subset of women will have false positive results, potentially leading to a range of adverse consequences, including the physical harms of unnecessary medical procedures, psychological harms and financial harms to the woman and/or the health system. Higher recall rates are associated with higher false positive findings and result in higher overall costs in the short- and long-term. Regardless of the additional interventions necessary to evaluate an abnormal mammographic finding that will ultimately be shown to be benign, the majority of women appear willing to accept screening and its follow up tests.

Radiation exposure: The absolute level of radiation exposure and corresponding radiation risk from mammography is very low and depends on factors such as the type of mammography used (film or digital), number of views and the x-ray machine. Although a safe lower limit (or threshold) for radiation exposure has not been determined, the amount of radiation exposure with mammography screening has not been demonstrated to cause breast cancer.

Age range and frequency of mammography screening: The age range and frequency of screening (e.g., annual, every two years) should be based on local demographics (e.g., age-related breast cancer incidence), resource availability and appropriate individual patient counseling, and will vary by national program and resources available. There is no global consensus on the most effective age to begin screening; however, existing programs start at ages 40, 45 and 50. Studies continue to inform recommendations for screening intervals for different age groups. Generally, premenopausal women are screened annually due to potentially faster tumor growth rates and some evidence showing an increased risk of being diagnosed with an advanced breast cancer if screened at biennial vs. annual intervals. The screening interval for mammography should be no more than every two years for women aged ≥ 50 years old.

Quality assurance: Quality control is important to guarantee high-quality mammographic images and robust management of the technical aspects of mammography. Screening programs should be monitored for participation rates, quality of screening techniques (false positives, false negatives and recall rates), tumor stage, percentage of women who have a positive screening test who undergo diagnostic testing, time from positive screening test to diagnosis, percentage of women with a cancer diagnosis who initiate treatment and time from diagnosis to treatment.

Cost-effectiveness: Mammographic screening every two years for women aged 50–69 years of age is a recommended intervention of the Global Action Plan for the Prevention and Control of NCDs 2013–2020 on the basis of its proven cost effectiveness in high-resource settings. The potential cost effectiveness of early detection programs in LMICs will depend

on disease incidence, available resources, strength of the health care system and regional prices. The rate of false positive findings increases the cost of a screening program and reduces the cost effectiveness of screening programs.

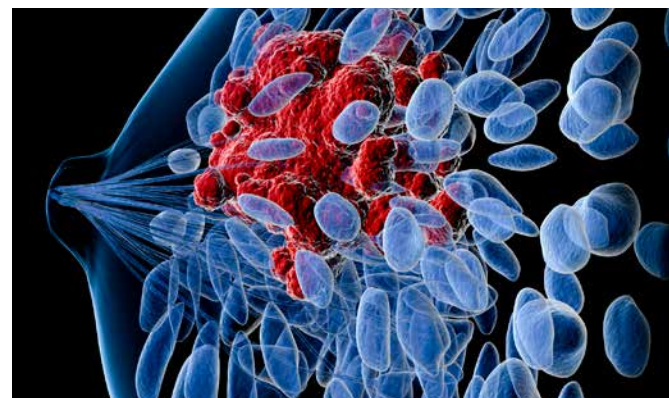
Additional screening modalities

Clinical breast examination: Clinical breast examination (CBE) has not been studied independently in randomized controlled trials. Thus, it is not possible to assess the efficacy of CBE as a screening modality when it is used alone versus usual care (no screening activity).

Breast self examination: Two large studies reported that the population-based teaching of breast self-examination (BSE) resulted in an increase in biopsies but no decrease in breast cancer mortality. Therefore, the formal teaching of BSE is not recommended as a breast cancer screening test.

Breast Ultrasound: Breast ultrasound is not recommended as a stand-alone tool for breast cancer screening, but may be appropriate as an adjunct to mammography screening, particularly for young women with dense breast tissue (see *Diagnosis: Clinical Assessment, Diagnostic Imaging and Staging*).

Magnetic Resonance Imaging: Magnetic Resonance Imaging (MRI) is expensive, more time consuming than mammography and requires additional expertise. There is insufficient evidence to support the use of screening MRI for women at an average risk of developing breast cancer. Screening MRI may be recommended, as an adjunct to mammography, in high-risk women ($\geq 20\%$ lifetime risk of developing breast cancer) such as *BRCA1/2* mutation carriers or women treated with mantle irradiation for Hodgkin's lymphoma at a young age.



WHAT WORKS

Screening program participation: Strategies used to encourage participation in screening programs should consider factors within the target population that encourage or discourage participation, which may vary by region. Strategies can be directed toward individual women (e.g., a letter of invitation with education material or text messaging), communities (e.g., announce establishment of a program and encourage community participation), health care provider programs (e.g., medical assistant phone calls or audits of referrals) or specific groups (e.g., translated guides of educational materials). Studies suggest that personalized methods of contact have a more robust affect on improving screening participation rates than print interventions. One-on-one or small group education can increase involvement, particularly when tailored to specific community needs. Primary health centers can use patient records (files, card index systems, or computerized listings) to identify patients to invite them to participate; social services and community health workers can also help identify participants in the target population. In resource-appropriate settings, data can be used to identify women overdue for mammograms, connect them with providers and monitor them for completion of screening.

Motivational factors that increase screening behavior include understanding the benefits of screening, perceiving a personal risk and believing one can survive breast cancer. Interventions to increase participation in screening mammography should involve cultural experts familiar in the local language, breast cancer beliefs and barriers/facilitators to screening. Strategies are also needed to address health system barriers that inhibit optimal screening coverage, such as location of services, hours of operation, scheduling procedures, quality of care by providers, etc. Addressing structural barriers, such as providing free transportation, can increase the number of women screened.

Referral system: Both opportunistic and organized screening methods require a referral system that ensures women receive timely follow up diagnosis and treatment. Women may not pursue follow up evaluations after initial positive screening mammography due to misinformation, cost or fear of diagnostic tests or treatment, including the fear of breast removal or disfigurement. Providing breast counseling as part of screening programs may help improve adherence to treatment. Health system barriers to timely referral may also delay diagnosis or treatment and should be addressed, including clear referral protocols that indicate the urgency of the referral.

Screening guidelines: Establish guidelines addressing the age group, timing, type and location of mammography for the target screening population and/or women with breast complaints. This also includes establishing the quality assurance methods for mammography. Systems also need to be in place to track women with positive screening tests to ensure that they follow up for diagnostic testing and treatment. National

and regional guidelines for breast cancer screening should be evidence-based, regularly reviewed as more evidence becomes available and include relevant stakeholders (e.g., breast cancer experts, breast cancer advocates and survivors, health professionals and community leaders).

Workforce capacity: Early detection programs need to anticipate the impact of screening programs on existing health services. An influx of asymptomatic women who present for diagnostic evaluation of breast abnormalities may result in a sharp increase in health professionals' workloads. Diagnostic and treatment facilities should be prepared for this. Pilot projects can help measure this so that diagnostic and treatment programs can increase capacity in anticipation of the increased resources needed as screening programs expand.

Cultural context: Focus group discussions with women, community health care workers, survivor and advocacy groups, traditional healers and local leaders can help identify potential barriers to successful screening programs. In addition to financial and structural barriers, cultural attitudes toward breast cancer screening tests and modesty, a lack of encouragement by family members and physicians and fear of the screening test itself have been identified as major inhibitors to women's participation in breast cancer screening (see *Planning: Improving Access to Breast Cancer Care*).

Performance indicators and data: Early detection programs should include an evaluation component. Indicators can include participation rate (an indicator of potential effectiveness of a program), treatment rate, cancer prevalence rate at initial screening and cancer prevalence after screening, stage or tumor size, distribution of screened cancers and breast cancer mortality rates (a long-term outcome measure that can take up to 7 years to see maximal effect). Other data to collect include technical repeats, recall rates and the benign/malignant biopsy ratio for subsequent biopsies. Measurement of the positive predictive value can provide information about referral levels for biopsies.

Resource-stratified pathway: Mammography screening is the final stage in establishing a breast cancer early detection program and should not be introduced until a health system can effectively detect, diagnose and treat palpable and non-palpable breast masses. Program implementation can start at a basic level of resource allocation with breast health awareness and training of health care providers in the performance of CBE. As more resources are allocated, programs can continue along a resource-stratified pathway and include targeted outreach and diagnostic ultrasound and mammography, opportunistic mammography screening and population-based mammography screening, which should be the final step (see Table 1). Using a defined pathway across the continuum of care can ensure that the allocation of resources for early detection align with diagnostic and treatment capacity.



POINTS FOR POLICYMAKERS:

PLANNING STEP 1: WHERE ARE WE NOW?

Investigate and assess

Assess the breast cancer burden and screening needs

- Identify the breast cancer burden and disease stage at presentation to help inform health system planning and placement of services.
- Assess the breast cancer incidence rate in the targeted at-risk population.

Assess current capacity to detect, diagnose and treat palpable and nonpalpable breast tumors

- Assess the availability and quality of early detection methods.
- Assess current capacity for diagnosis and treatment of palpable and non-palpable breast tumors.
- Project increases in the need for diagnostic evaluation and treatment of breast cancers resulting from breast awareness

- and early detection programs, and assess resources needed.
- Assess available imaging equipment, supplies and trained personnel [technicians and radiologists].
- Review referral system and protocols.
- Assess data from existing diagnostic mammography services on cancer detection rate, tumor stage, false positive rates, false negative rates, and recall rates.
- Review quality control protocols and update as needed.

Assess cost and effectiveness

- Consider pilot projects that build on existing resources before implementing larger regional or national screening mammography programs.
- National screening mammography programs require large initial investments and are not expected to see a measurable benefit in terms of decreasing breast cancer-specific mortality for many years.

Assess patient safety

- Safety issues related to screening mammography include patient discomfort and radiation exposure. False positive tests may result in psychological harms and unnecessary diagnostic tests and treatment.

PLANNING STEP 2: WHERE DO WE WANT TO BE?

Set objectives and priorities

Identify target population and strategy

- Identify local breast cancer incidence rates to help identify the at-risk patient population. The target population should be further defined by the screening program goals, available screening modalities and available resources for treatment and follow up care.

Identify gaps and barriers

- Identify health system barriers, including equipment availability, safety, quality performance, workforce availability and expertise and patient access to care.
- Identify gaps in referral processes, follow up, diagnosis, treatment and supportive care.
- Infrastructure changes may be needed to introduce an organized screening program or transition one from opportunistic screening to organized centralized screening.
- Design programs to minimize patient barriers and consider social, cultural and political norms.

Set achievable objectives

- Determine objectives such as improving availability, technical expertise, patient access and participation, as well as the safe use of imaging modalities for breast cancer diagnosis and screening.
- Include a component for monitoring effectiveness in achieving stated goals.
- Set priorities and determine feasibility of interventions.
- Consider using pilot projects to assess feasibility of new screening programs.
- Follow a resource-stratified pathway for program development that identifies available resources across the continuum of care.

PLANNING STEP 3: HOW DO WE GET THERE?

Implement and evaluate

Establish financial support and partnerships

- Advocacy groups are key stakeholders in advancing breast health awareness and are often supported by community members and volunteers.
- Medical professional associations and nongovernmental organizations (NGOs), may be able to assist in the establishment of screening programs, particularly for pilot projects.
- Invested stakeholder and advocacy groups can assist with the design and evaluation of programs to ensure they are accessible and culturally appropriate.

Implement and disseminate

- Actively invite women to participate in screening mammography.
- Support and strengthen a coordinated patient pathway and referral system to improve patient flow from detection through diagnosis and treatment.
- Consider training patient navigators to help women move through the system and improve the completion of care.
- Review the patient pathway to identify unacceptable delays and barriers (patients, survivors and practitioners can provide valuable insight into access barriers, utilization and loss to follow up).
- Standardize documentation, use BIRADS [or equivalent] to communicate results to women and referring providers and for tracking screening results and patient outcomes.
- Implement quality assurance regulations for screening mammography at all facilities performing or interpreting imaging studies.

Monitor and evaluate

- Document and monitor performance indicators and follow up tracking of patients to assess the effectiveness of screening programs.
- Routinely follow quality assurance methods, including calibrating equipment and conduct safety checks to ensure the quality of services.
- Monitor the safe operation and maintenance of equipment [conduct training as needed].
- Review metrics and data to inform future programs and ensure standardization of screening services.

CONCLUSION

Screening is an important component of comprehensive breast cancer care. It permits the early detection of occult breast cancer in asymptomatic women, and the earlier diagnosis of symptomatic women. Mammographic imaging is currently the most effective screening tool when resources are available and health systems are properly prepared and equipped. Once the necessary prerequisites have been met, establishment of mammography-based screening programs should include thorough preplanning, assessment, development and implementation that is integrated into the existing health system and considers the needs of all components of breast cancer control: early detection, diagnosis, treatment, palliation and policy [see Checklist].

Checklist for an organized population-based mammography screening program:

- ☑ Evidence-based information about benefits and harms of mammography screening to women
- ☑ Organizational and financial resources that ensure the sustainability of the program, including the availability of the necessary equipment, infrastructure and workforce
- ☑ Screening linked to adequate diagnosis, treatment, rehabilitation and palliative care services available
- ☑ Referral and communication system that ensures prompt access and compliance to evidence-based diagnosis, treatment and rehabilitation of detected cases, as well as palliative care for advanced cases
- ☑ Call and recall system that ensures that over 70% of the target population is screened regularly
- ☑ Monitoring and evaluating the screening programmed, including adequate information systems and quality improvement strategies
- ☑ Quality assurance program

Table 1. Resource-stratified pathway for breast cancer early detection and screening programs

Level of resources	Basic	Limited	Enhanced	Maximal
Public education and awareness	Development of culturally sensitive, linguistically appropriate local education programs for target populations to teach the value of early detection, breast cancer risk factors and breast health awareness [education + self-examination]	Culturally and linguistically appropriate targeted outreach and education, encouraging CBE for age groups at higher risk administered at district/provincial level using health care providers in the field	Regional awareness programs regarding breast health linked to general health and women's health programs	National awareness campaigns regarding breast health, using media
Detection method	Clinical history and CBE	Diagnostic breast ultrasound +/- diagnostic mammography in women with positive CBE Mammographic screening of target group	Mammographic screening every 2 years in women ages 50-69	Consider annual mammographic screening in women ages 40 and older Other imaging technologies as appropriate for high-risk groups
Evaluation goal	Breast health awareness regarding the value of early detection in improving breast cancer outcomes	Early diagnosis of symptomatic disease	Early diagnosis of asymptomatic disease in women in the highest yield target groups	Early diagnosis of asymptomatic disease in women in all risk groups

Source: the Breast Health Global Initiative [BHGI] guidelines, 2008

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