

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



EARLY DETECTION

Breast Health Awareness and Clinical Breast Exam

Knowledge Summary



INTRODUCTION

Early diagnosis of breast cancer begins with the establishment of programs to improve early detection of symptomatic women, or women with breast lumps that patients and their providers can feel. Early recognition of symptoms and accurate diagnosis of breast cancer can result in cancers being diagnosed at earlier stages when treatment is more feasible, affordable and effective. This requires that health systems have trained frontline personnel who are able to recognize the signs and symptoms of breast abnormalities for both benign breast issues as well as cancers, perform clinical breast exam [CBE] and know the proper referral protocol when diagnostic workup is warranted. Women who can identify breast abnormalities, who have timely access to health clinical evaluation, diagnosis and treatment and who are empowered to seek this care are more likely to be diagnosed at an earlier stage [see Planning: Improving Access to Breast Cancer Care].

Diagnostic delays can occur when women do not present for evaluation, but can also occur because health care providers fail to recognize and refer women with breast cancer signs and symptoms. The challenge is to increase the early detection of breast cancer and improve cancer outcomes by optimizing available resources and providing accessible, appropriate and acceptable breast health services. When linked to effective treatment, early diagnosis can lead to better breast cancer outcomes and survival rates. All early detection programs should consider the cultural context of the target population; the resources available for program support and the sustainability of such efforts over time.

It is important to educate primary care providers and women about the signs and symptoms of breast cancer and the importance of early detection. Breast abnormalities warranting evaluation include breast masses, breast thickening, breast swelling or redness, progressive nipple inversion, bloody nipple discharge, or persistent focal breast pain. Many breast abnormalities are not a sign of cancer [benign findings, such as cysts and fibroadenomas can also cause palpable masses in the breast]; however, all breast masses need to be carefully evaluated in order to diagnose those that are cancer at a potentially curable stage.

KEY SUMMARY

Early detection programs

- Early diagnosis of breast cancer can improve survival, lower morbidity and reduces the cost of care when followed by a prompt diagnosis and effective treatment.
- An effective early diagnosis program includes:
 - Breast health awareness education.
 - Reducing barriers to accessing care.
 - Clinical breast exam [CBE] performed by primary care providers.
 - Timely diagnosis for all women found to have abnormal findings and timely treatment for all women proven by tissue diagnosis to have breast cancer.
 - If supported by evidence, a quality screening mammography program performed in a cost-effective, resource-sustainable and culturally appropriate manner.
- Ultrasound imaging is not recommended as a screening modality but is important as a diagnostic tool for evaluating breast findings, such as masses or thickenings.
- 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 [see Early Detection: Screening Mammography Programs].

Breast health awareness

- Breast health awareness includes public health and professional medical education on the risk factors and symptoms of breast cancer and the importance of seeking timely medical evaluation for breast concerns.
- Community and health care provider awareness education is an integral part of all early detection programs.
- Collaboration with cancer survivors, advocates and community groups is crucial for the design and effective dissemination of breast health awareness messages.

Clinical breast examination

- CBE performed by a trained health care provider involves a physical examination of the breasts and underarms. CBE should be offered to any woman with a breast finding that she identifies as abnormal for her.
- Incorporate CBE into standard medical school curricula and training programs.
- Employ quality assurance measures to ensure that health professionals are proficient in CBE and know how women with an abnormal CBE can access diagnostic services.
- CBE can be performed by trained nonphysician providers.
- In addition to using CBE to evaluate breast complaints, CBE may be used as part of a breast health awareness education program.

Diagnosis and coordination of care

- Establish and share standards for care (protocols) for breast health visits across institutions and departments.
- Establish structured communication networks between primary care providers and diagnostic and treatment providers to facilitate uninterrupted care and reduce delays.
- Strengthen referral networks for follow up breast cancer evaluation, diagnosis and treatment to ensure that breast cancer, once detected, receives prompt and adequate diagnosis and treatment.
- Implement quality assurance programs, including tracking outcomes, to improve standards and practices and identify areas for improvement.

Resource-stratified pathways across the continuum of care

- Develop programs based on identified needs and barriers, outcome goals and available resources.
- Pursue a defined resource-stratified pathway appropriate for available resources to ensure coordinated investment and incremental program development across the continuum of care [see Table 1].



POINTS FOR POLICYMAKERS:

OVERVIEW

Preplanning

- Identify existing early detection and referral practices and determine if a new plan is needed.
- Identify stakeholders, key decision-makers and champions.

Planning Step 1: Where are we now?

Investigate and assess

- Assess existing breast health awareness and early detection programs.
- Assess existing curriculum or training programs for clinicians on breast cancer signs and symptoms, breast health care and clinical breast exam [CBE].
- Assess referral system and existing guidelines.
- Assess community partnerships [advocacy groups, public health services, associations].
- Identify barriers to early detection [structural, sociocultural, personal, financial].

Planning Step 2: Where do we want to be?

Set objectives and priorities

- Make early detection and diagnosis of breast cancer a priority.
- Establish a referral network for follow up evaluation, diagnosis and treatment.

- Define target population for breast health awareness programs, and if appropriate, breast cancer screening programs.
- Train health professionals in CBE, referral protocol and breast health counseling.
- Ensure women with breast complaints have access to clinical evaluations, follow up evaluations, diagnostic workup and appropriate treatment.
- Make breast health awareness education and CBE a standard part of breast cancer awareness efforts.

Planning Step 3: How do we get there?

Implement and evaluate

- Pursue a resource-stratified pathway appropriate for the resources available [e.g., develop early detection programs and expand them incrementally as more resources are allocated [see Table 1]].
- Optimize primary care services and referral networks to improve awareness and reduce delays.
- Partner with key national and local stakeholders, respected public figures, survivors, advocates and media to launch a coordinated campaign.
- Implement quality assurance measures.
- Monitor quality of education and screening and evaluate impact.

WHAT WE KNOW

Breast physiology

Breast tissue changes throughout a woman's life as she experiences puberty, menstrual cycles, pregnancy and menopause. During menstruation, breast tissue is exposed to cycles of estrogen, which stimulates the growth of the milk ducts during the first part of the cycle, and progesterone, which stimulates the lobules in the second half. This process can result in breast tenderness or palpable changes in the tissue that may be reported as "lumpiness." As women age and experience menopause, there is a natural decline in estrogen and breasts become less dense or more lumpy as a result of fibrocystic changes; the majority of these lumps are benign, but some will be due to breast cancer. The risk of developing breast cancer increases as a woman ages, which is why organized screening generally does not begin before the age 40.

When a woman presents with breast concerns, a medical history and physical exam should evaluate the appearance of the breast, including new or persistent skin changes, nipple inversion and nipple discharge (including laterality, spontaneity, color, and frequency). The exam should evaluate breast pain, including duration, location and associated factors, and any palpable abnormality or breast mass, including its location, history and size during the menstrual cycle (see Table 2). If a large breast mass is identified or if axillary adenopathy is detected, careful attention should be paid to symptoms suggestive of metastatic breast cancer, such as bone, back or leg pain (bone metastases), abdominal pain, nausea, enlarged liver (liver metastases) or shortness of breath or cough (lung metastases).

Breast masses or thickenings: Relevant breast mass characteristics include duration, change in size over time, relation to menstrual cycle, presence of pain, redness, skin changes, fever or nipple discharge. A dominant mass is defined as a discrete, solid, palpable finding clearly differentiated from surrounding tissue and requires clinical evaluation. An indeterminate mass is not clearly differentiated but should be assessed for size, location and other characteristics. Breast ultrasound is extremely useful in characterizing palpable changes in the breast, especially in distinguishing simple cysts, benign masses (fibroadenomas), lumpy normal breast tissue and cancers. The follow up protocol is dictated by the clinical findings. For example, a mass that varies with menstrual cycle may be a common cyst, and a diffuse symmetrical lumpiness may be related to hormonal cycling. If a physical exam and/or ultrasound fails to reveal a dominant mass, then a follow up exam in one to two months may be advised to determine the clinical behavior over time and confirm the benign behavior of the finding.

Enlarged lymph nodes: Many women with clinically detected breast cancer will have enlarged axillary lymph nodes, although these changes are not always due to the nodal spread of cancer. The primary significance of nodal spread is that it demonstrates that a given cancer has the capacity to spread (metastasize), an important indication for systemic (drug)

therapy. Removal of lymph nodes can help control disease in the nodal bed but does not itself stop cancer from spreading. More distant lymph node spread (i.e., supraclavicular or internal mammary nodes) is an unfavorable prognostic indicator and can suggest distant metastatic spread to the lung, liver, bone or brain. Although node-positive cancers are potentially curable with multimodality treatment, cancers that have spread to distant organs are not considered curable.

Breast pain: Pain is a common breast concern but generally is not an indicator of underlying malignancy or considered a risk factor for breast cancer. No histologic findings correlate with breast pain. Breast pain can be cyclic (related to the menstrual cycle) or noncyclic. Cyclic pain is often bilateral, diffuse and radiates to the axilla, occurring during the premenstrual phase when there is increased breast swelling due to increased hormone levels. Noncyclic breast pain may be unilateral, focal or generalized. It has been associated with medications such as oral contraceptives, psychotropic drugs and some cardiovascular medications.

Generalized, diffuse breast pain should be monitored and does not, of itself, require imaging studies. Focal breast pain does require additional evaluation, even in the absence of physical exam findings. It can be associated with a tender breast cyst, acute enlargement of a cyst, infection (mastitis), trauma, pregnancy or a general tender area of nodularity. Breast pain is experienced by the majority of adult women and most cases of breast pain will resolve spontaneously.

Nipple discharge: Assessment of nipple discharge should include evaluation of color, frequency, laterality (one side only versus both sides), spontaneity, persistence, relation to the menstrual cycle, presence of other health issues, medication changes and association with an underlying palpable breast mass. The great majority of nipple discharge is associated with benign disease. The most common causes of pathologic nipple discharge are intraductal papilloma, duct ectasia, carcinoma and infection. Nipple discharge warrants workup when it is spontaneous, unilateral, bloody or watery and/or associated with a mass. Because the absence of malignant cells does not exclude cancer, cytologic examination of nipple discharge is generally not advised. Women with pathologic nipple discharges should be referred to a surgeon to consider surgical excision of the offending duct. Bilateral milky discharge (galactorrhea) is not considered abnormal and may persist for up to one year postpartum or after cessation of breastfeeding. If present in women who are not pregnant or lactating, galactorrhea should be evaluated with a pregnancy test, endocrine workup and review of recent medications.

Nipple inversion: Nipple inversion or retraction can be unilateral or bilateral, congenital or acquired, and is associated with a wide variety of diagnoses from infection to cancer. Nipple inversion associated with malignancy tends to be asymmetric and distorts the areola. Women with an acquired nipple inversion should be evaluated with diagnostic imaging and possibly biopsy.

Breast or skin thickening: Breast thickening can include breast nodularity, diffuse cystic change, fibrocystic change and breast fullness. Appropriate diagnostic workup of skin thickening includes an imaging study (either ultrasound or mammography) and close follow up if imaging studies are without focal findings. In the majority of cases, the finding will be benign, but skin thickening can be a sign of breast cancer in cases of infiltrating lobular cancer, inflammatory breast cancer or Paget's disease of the breast. Studies suggest that assessing skin thickening can be challenging and may require professional breast health education, training and experience.

Paget's disease: Paget's disease of the breast is a scaly, raw, ulcerated lesion beginning on the nipple, generally at the tip, then spreading to the base and to the areola. Paget's disease is a process in which cancer from the major central ducts extrudes at the nipple, generally (but not always) related to an underlying cancer deeper in the breast. Paget's disease is unilateral and can be associated with pain, burning and itching. Women who have a palpable mass with associated nipple erosion are more likely to have invasive cancer that is extending to and through the nipple. Nipple biopsy is important to distinguish Paget's disease from benign skin disorders such as eczema.

Breast cysts: Breast cysts are common in premenopausal women and are a common source of palpable breast masses. Before ultrasound was available, breast masses were diagnosed as a cyst if they completely resolved with the needle aspiration of fluid. Today, high-frequency ultrasound can distinguish "simple cysts" from solid masses without needle aspiration. However, follow up of breast cysts is important after aspiration, as occasional "complex cysts" (fluid cysts with associated adjacent masses) can result from the occasional breast cancer that actively secretes fluid. Cysts that actively recur after aspiration should be considered for some type of biopsy. When cyst fluid is clear or yellow it can be discarded without further analysis. Bloody or turbid fluid should be sent for laboratory analysis, but cytologic analysis of cyst fluid may not always be helpful, as the fluid often contains inflammatory cells that the cytologist cannot distinguish from cancer cells.

Clinical breast exam

Clinical breast exam is a necessary tool in any breast health program for frontline evaluation of patients with breast symptoms. Study results on the effectiveness of CBE suggest that it can detect masses not reported by women (asymptomatic cancers), but it may also miss small tumors detectable by imaging modalities [see Early Detection: Screening Mammography Programs]. Early detection screening programs can be opportunistic (i.e., initiated during routine patient visit) or organized (i.e., initiated by invitation sent to a targeted at-risk patient population).

CBE as a detection tool: CBE is a component of early detection efforts. It should be part of routine breast health care and part of any evaluation for a woman who presents with a breast concern (e.g., breast mass, skin or nipple change). A CBE should include an axillary (underarm) lymph node examination.

Adequate time should be allotted for a CBE (6–10 minutes), especially when imaging is not routinely employed. Critical components of a CBE include visual inspection of the breasts, proper positioning of the patient for breast palpation (in both the upright-seated and lying-on-the-back positions) and thoroughness (use of a vertical-strip or concentric circle search pattern with proper position and movement of the fingers). With proper training, health professionals, including nonphysicians, can achieve proficiency in performing CBE. Quality assurance protocols are required to ensure continued health professional competency in CBE.

CBE as a screening tool: CBE when used alone (without mammography) has not been adequately studied as a screening modality in an average risk population. Therefore, it is not known if screening programs using CBE alone will result in an improvement in breast cancer survival. CBE may be performed in women at age 30 as a breast health awareness education tool to help familiarize women with their own breasts. If a woman has a strong family history of breast cancer at a young age, a CBE may be performed even younger than age 30.

Allotted time: A thorough CBE requires 6–10 minutes to complete and should include both breasts and the axillary lymph nodes. At least three minutes should be spent in examining each breast, though this time frame may increase or decrease with degree of expertise, age of the patient, density of the breast tissue and patient breast health history.

Timing: Evaluation of a breast concern should occur promptly. However, for routine breast exams, the best time to evaluate the breast is when hormonal stimulation of the breast is minimized, which is during the later phase of the menstrual cycle, usually 7–9 days after the onset of menses in premenopausal women.

Technique: CBE should be performed by a health care provider trained in the technique of CBE. It should be initiated with the patient in a seated position and then again with the patient in a supine position. In the seated position, the woman should be examined with her arms relaxed, with her arms raised above her head, and with her hands pushing on her hips to exaggerate areas of retraction seen when the pectoral muscles are active. Attention should be paid to asymmetry, skin changes and nipple crusting, retraction or inversion. The exam should be repeated with the patient in the supine position with the ipsilateral arm raised above her head. It may be helpful to have the woman roll onto her contralateral hip to flatten the lateral part of the breast. The entire breast must be examined, from the clavicle to the inframammary fold and from the midsternum to the midaxillary line. Many palpation techniques have been described and no one technique is considered superior. One commonly used technique is the vertical strip pattern in which the finger pads (rather than the fingertips) are used to make small circular motions (1–2 cm circles) along a vertical path with varying levels of pressure. Another method uses a concentric circle search pattern with proper position and movement of the fingers. With either method it is important to palpate all of the breast tissue and to recognize that breast tissue can extend into the axilla.

Documentation: Any abnormality found on examination must be documented, including the size of the mass in centimeters, its location (often described as hours on a clock face) and characteristics (soft, firm, hard, tender, mobile or fixed). In general, a physical exam cannot reliably distinguish cysts from benign changes or cancer. An abnormality or suspicious finding on CBE should be referred for imaging and biopsy. It is preferable to perform imaging prior to rather than following biopsy, as changes in the breast resulting from the biopsy could interfere with accurate interpretation of the imaging study.

Lymph node exam

Lymph node exams should be performed by a medical provider trained in the technique for any woman with a breast complaint suspicious for breast cancer, as lymph node involvement can determine breast cancer stage.

Technique: The patient should be in a seated position with relaxed shoulders and arms bent. The regional nodes are examined with careful attention to the axillary, infraclavicular, supraclavicular and cervical lymph node basins. Ultrasound can be a useful adjunct in detecting enlarged lymph nodes.

Documentation: The location of each node should be documented, including size and characteristics (soft, mobile, firm, hard, tender, fixed or matted). The documentation of location must distinguish between supraclavicular fossa and cervical lymph nodes, as the diagnosis is different: lymph nodes below the supraclavicular fossa are considered locoregional metastases, whereas those above the supraclavicular region are considered distant metastases.



Diagnostic follow up

Imaging: A suspicious mass requires follow up imaging studies (ultrasound and/or mammography) and referral for biopsy. However, a normal ultrasound or mammogram is not proof of the absence of breast cancer, and an abnormal imaging finding is not proof of the presence of breast cancer.

Breast ultrasound is an important tool in the assessment of breast complaints. Ultrasound is more widely available in LMICs and can be a useful diagnostic tool that can characterize a mass as solid or cystic. However, its field of view is limited, making full breast exams difficult and time-consuming. Ultrasound is also highly operator-dependent and can be less sensitive than mammography so is not recommended as a breast cancer screening tool in asymptomatic women (see Early Detection: Screening Mammography Programs).

Diagnostic mammography should be introduced as a diagnostic tool as soon as resources are available. Magnetic resonance imaging (MRI) is only recommended as a diagnostic tool for select patients when resources are available in high resource countries. At the current time, MRI is considerably more expensive and time-consuming than other diagnostic and screening tools (see Early Detection: Diagnosis and Screening with Mammography).

Biopsy, histology and pathology: Follow up clinical and pathologic workup of a biopsy sample is required for a definitive diagnosis, which should include staging and tumor receptor status (estrogen receptor, progesterone receptor and HER2 if HER2 directed therapy is available), to inform prognosis and treatment decisions. Staging criteria are available online from the American Joint Commission on Cancer (AJCC) at <https://cancerstaging.org/Pages/default.aspx> (see Diagnosis: Clinical Assessment, Diagnostic Imaging and Staging for Breast Cancer).

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 prepared providers (sufficiently trained, with a reimbursement system for health services provided through the health system) to perform CBE and 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 (see Early Detection: Screening Mammography Programs).

WHAT WORKS

Optimizing primary care and referral services: Programs that improve access to primary care providers and expand referral networks can improve early breast cancer detection if primary care providers are educated in early detection techniques such as CBE and are able to provide access to breast diagnostic services for patients with abnormal breast findings. Improving referral networks, communication between providers and timely access to care can reduce delays in diagnosis and treatment, improve outcomes and reduce patient and health system costs.

Health professional training in CBE: Breast cancer awareness efforts targeted to health professionals, especially those serving as the point of contact for women who seek breast health care, should include training in CBE (including the signs and symptoms of breast cancer) and breast health counseling. Proficiency in CBE should be part of medical school training and continuing medical education. Nonphysician providers can also be effectively trained in CBE. Health professionals should be prepared to educate women about the risk factors, signs and symptoms of breast cancer, and to recognize abnormal changes in their breast.

Breast health awareness programs: The goal of breast health awareness is to educate women about the importance of detecting and diagnosing cancer at early stages, when treatment may be more effective. Most breast tumors are discovered by women themselves, although not usually through formal breast self-examination (BSE). Studies that have focused on formal BSE training as a screening method showed that training in BSE led to increased breast biopsies without reducing breast cancer mortality. The critical component of breast health awareness is “know your normal,” meaning a woman should know what is normal for her body and recognize any unusual or unexpected change. However, awareness and early detection is only effective in improving outcomes if it is followed by accurate diagnosis and timely, effective treatment.

Survivor and community engagement: Breast cancer awareness messages are more effective if they are culturally appropriate and developed with community input. Engaging breast cancer survivors in awareness planning and programs can provide insight into effective messages, help identify barriers to early diagnosis and encourage women with breast health concerns to seek timely care [see Planning: Improving Access to Breast Cancer Care]. The messages should emphasize that the majority of women treated for early breast cancer—when it has not spread beyond the breast and axillary (underarm) lymph nodes—will recover with timely and appropriate treatment to live healthy and productive lives. A culturally sensitive

approach to breast exams and breast health counseling can reduce a woman’s discomfort and anxiety during a breast health visit and allow her to make informed decisions about her preferred breast health care. Community support for participation in early detection programs must be matched by community support for follow up diagnosis and treatment.

Coordination of care across the continuum: Effective communications between providers can improve the care within an interdisciplinary system. Communications must be thorough 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.

Quality assurance and data collection: All early detection programs should be monitored for quality of screening techniques, false negative results, false positive results, recall rates, timeliness and quality of follow up diagnostic and treatment procedures. Data should be systematically collected, validated, reviewed, reported and used to identify deficiencies and improve program performance.

Resource-stratified pathway: Early detection is only effective when diagnostic and treatment resources are also available and accessible. 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].

Investing in higher-level resources for screening (e.g., population-wide, organized mammography screening) requires parallel investment in quality control efforts, follow up tissue sampling, pathology for suspicious findings and timely treatment for confirmed diagnoses. Without these additional services and processes, detection subjects women to a potential diagnosis without available care, and places a financial burden on the health system. Using a resource-stratified pathway can ensure that the allocation of resources for early detection align with diagnostic and treatment capacity. 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.

PLANNING STEP 1: WHERE ARE WE NOW?

Investigate and assess

Assess the burden of disease

- Information on the stage of disease at diagnosis is required to determine the focus of early detection programs. Cancer registries provide the best region-specific data. If no registry is available, hospital data can be used, with the limitation that institution-specific data suffer from patient selection bias.

Assess existing public awareness and early detection programs

- Determine which breast cancer awareness and early detection efforts are being carried out at the national, regional or local level by the health system and by advocacy and community groups.
- Assess the size of the target population for the early detection program and confirm that services are in place to meet screening, diagnostic and treatment needs.
- Identify and assess ongoing training for medical students and health professionals in clinical breast examination [CBE] and the signs and symptoms of breast cancer and other breast complaints.

Assess patient access and barriers to early detection programs

- Identify structural barriers [human resources capacity and training, geographic location, transportation, referral system, competing health priorities].
- Identify sociocultural barriers [stigma, myths and misconceptions, religion, fatalism, gender of the provider, self-efficacy and status as a decision-maker].
- Identify personal barriers [lack of awareness or low health literacy, negative health care experience, competing family and work priorities, fear of being ostracized].
- Identify financial barriers [socioeconomic, direct and indirect, childcare, lost wages].
- Determine socioeconomic status of service population and identify possible high-risk, marginalized and disenfranchised populations.
- Consider using focus groups or conducting interviews with patients, advocates, cancer survivors, health professionals and community leaders.

Assess cost and potential effectiveness of CBE

- The cost of CBE includes training personnel, service delivery and monitoring and evaluation.
- Potential effectiveness will depend on the breast cancer incidence rate and target population, health professional expertise, acceptability, availability and resources.

Assess health system capacity

- Early detection programs require the additional support of diagnostic and treatment facilities.
- Coordinate development or expansion of early detection programs with the development or expansion of diagnostic and treatment programs using coordinated resource-stratified pathways.

- Assess human resource capacity for training and conducting CBE at the primary care level.
- Assess referral system and capacity for follow up diagnosis and treatment [e.g., suspicious lesions must be referred to a surgical team for biopsy, followed by a pathology evaluation of the biopsied specimen to determine presence of disease and appropriate treatment if necessary].

PLANNING STEP 2: WHERE DO WE WANT TO BE?

Set objectives and priorities

Define target population and strategy

- Use local breast cancer incidence and demographic data to identify and define at-risk populations.
- While certain demographics [age, reproductive history, family history] help define groups at heightened risk, early detection and screening program selection criteria are primarily based on gender and age [e.g., women begin mammographic screening at a certain age [40, 45 or 50] and at defined intervals [every 1-2 years] as determined by local factors, resources and programmatic choices by local decision makers].
- Criteria for the target population may vary by type of program [opportunistic or organized], screening tool [mammography with or without CBE] and program scope [pilot program or large-scale coverage].
- Educational efforts should include health professionals, 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 medical education or “refresher” training in breast cancer prevention, risk factors, signs and symptoms and CBE.
- Women can be routinely educated during clinic visits about breast health, including any available breast cancer screening opportunities.

Identify community and health system partnerships

- Identify partners [nongovernmental 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.

Identify gaps and implementation 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 breast health awareness, CBE and patient referral.
- Identify barriers to implementing CBE curriculum in medical training and continuing medical education.

Set achievable objectives

- Objectives should promote one common goal for early detection: diagnosing cancer early so that treatment can be administered when it is most effective.
- Coordinate activities to raise awareness with improved access to timely diagnosis and treatment to increase effectiveness.
- Identify and classify objectives according to the health care sector that will manage them [e.g., health system standardization of CBE efforts should be led by clinicians; examiner training of CBE could be led by health care organizations; increasing the number of qualified practitioners could be led by sponsoring institutions, academia and the public sector].
- Develop and disseminate patient and public education 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 health care skills.
- Address gaps in referral networks to ensure diagnostic follow up for all breast health complaints [see WHO Package of Essential Noncommunicable [PEN] disease interventions for primary care in low-resource settings referral model].
- 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 of interventions

- 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.
- When deciding between optimizing existing programs and investing in new initiatives, consider local needs, regional expertise, current program effectiveness and resource availability.

Develop evaluation capacity

- Evaluate early detection programs routinely to ensure that high-quality reliable screening tests are being performed safely.
- A program self-assessment toolkit is available from the WHO at www.who.int/cancer/publications/nccp_tool2011/en/index.html

PLANNING STEP 3: HOW DO WE GET THERE?

Implement and evaluate

Establish financial support and partnerships

- Secure the necessary political and financial support for program development.
- Partner with key national and local stakeholders, respected public figures, survivors, advocates and media to launch a coordinated campaign.
- Regional, national and international advocacy groups are key strategic partners in the development and advancement of early detection programs, including fundraising and community education.
- Partner with medical institutions to integrate training into existing programs.

Coordinate, implement and disseminate

- Health care systems are central to the coordination of care and optimal use of available resources.
- Optimize and clarify referral networks for health professionals and patients to reduce delays.
- Expand the practice of CBE at the primary care level.
- Address access barriers to efficient referral for more advanced detection, diagnosis and treatment.
- 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 health care team.

Monitor and evaluate

- Process metrics should be established at the beginning of the program to measure its relevance, effectiveness and impact; impact measures include tumor size at presentation and participation rates.
- Evaluate health professional competency in CBE, breast health counseling and timely referrals.
- Monitor quality and safety of early detection programs [e.g., education, training and expertise of personnel; standardization of protocols; time from referral for diagnosis to diagnosis; time from positive diagnosis to treatment].

CONCLUSION

Breast cancer awareness is a key component of early detection efforts. It is essential that women know the most common symptoms associated with breast cancer and understand that prompt evaluation and early diagnosis improve outcomes. Women need access to health facilities that can provide an accurate diagnosis, and they must be empowered to access these services in a timely fashion. Planning and implementation of breast health awareness education and programs should include all stakeholders: women, men, community leaders, health professionals, health system administrators and policymakers. Advocacy groups can provide valuable support and influence public and political awareness.

Because the vast majority of breast complaints are not breast cancer, clinicians must be able to perform a thorough breast exam, understand the signs and symptoms of all breast complaints, not just cancer, and be able to counsel and refer women in the primary care setting. Effective breast health care at the primary care level can increase breast awareness in the community and increase participation in breast cancer screening programs.

Finally, early detection methods should match available resources [human resources, equipment, facilities] and address population needs and equitable access to care. Identifying, assessing and addressing structural, sociocultural, personal and financial barriers to accessing available breast cancer services is essential to improving early diagnosis. Implementation research on breast cancer awareness efforts, particularly studies performed in LMICs, can continue to inform and guide program development.

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

Level of resources	Basic	Limited	Enhanced	Maximal
Education and awareness	Development of culturally and linguistically appropriate local education programs targeted at primary health care providers in breast cancer risk factors, awareness, detection and referral of women with palpable disease	Community outreach and awareness programs conducted by local providers and advocates encouraging CBE for symptomatic women	Awareness programs addressing breast health and breast cancer screening for target population linked to general health and women’s health programs	National awareness campaigns regarding breast health and breast cancer screening for target population
Detection method	Clinical history and CBE	Diagnostic breast ultrasound +/- diagnostic mammography in women with positive CBE	Opportunistic mammography screening Mammographic screening every 2 years in women 50–69 years of age Consider mammographic screening every 12–18 months in women 40–49 years of age	Organized mammographic screening in women more than 40 years of age Other imaging technologies as appropriate for high-risk groups
Evaluation goal	Baseline survey and repeated survey of breast health awareness and early detection practices among primary care providers	Earlier diagnosis of palpable and symptomatic disease	Early diagnosis of asymptomatic disease in women in highest-yield target groups	Early diagnosis of asymptomatic disease in women in all risk groups

Source: the Breast Health Global Initiative (BHGI) guidelines, 2008.

Definitions: Basic resources are core resources or fundamental services absolutely necessary for any breast health care system to function; basic-level services are typically applied in a single clinical interaction. Limited resources are attainable with limited financial means and modest infrastructure. Enhanced resources are optional but important and improve options and outcomes. The maximal resource allocations are lower-priority, higher-cost options, and are generally not recommended in low- or limited-resource settings.

Table 2. Components of breast health care clinical visit

History of the present illness:

- Pain: duration, location, timing, related symptoms [tenderness, fever, nipple discharge]
- Mass: duration, change, related symptoms [pain, tenderness, fever, nipple discharge]
- Nipple discharge [pathologic if bloody, unilateral, involves single duct, watery, woman >50 yrs old] frequency, spontaneity, medications
- Nipple inversion
- Appearance: dimpling, swelling, skin retraction or thickening
- Other: recent breast trauma, pregnancy

Past medical and surgical history:

- Prior breast health diagnoses or procedures
- Lymphoma with chest irradiation
- Endocrine disorders

Medications and allergies:

- Postmenopausal hormone replacement therapy
- Neuropsychotropic medications

Social history:

- Prior exposures [e.g., radiation]

Family history:

- History of breast, ovarian, prostate cancers
- History of previous breast biopsy

Review of systems:

- Risk factors for breast cancer [e.g., estrogen exposures]
- Hormone factors at time of examination [e.g., time in menstrual cycle, pregnancy, lactation]
- Symptoms of metastatic disease [e.g., bone, back, or leg pain; abdominal pain; nausea; jaundice; dyspnea or cough]

Physical exam:

- Vital signs: fever, tachycardia
- Breast examination [documenting abnormalities including laterality and position from nipple, described as to clock-face hours as examiner faces patient]
 - Visual inspection^a [upright and supine]: contour changes, asymmetry, signs of infection, ulceration, skin changes, nipple ulceration, scarring, color [erythema]
 - Palpation: vertical strip search pattern, varying levels of pressure, use of 3 finger pads in circular motion [1–2 cm circles], at least 3 minutes per breast from clavicle to inframammary fold, mid-sternum to midaxillary line; supine then upright with ipsilateral arm on forehead, checking size, shape, consistency, mobility, texture
 - Nipple discharge^a: spontaneous, color, involved ducts
- Adenopathy: lymph node evaluation of axilla, supraclavicular, and infraclavicular fossa

^a No proven evidence to improve detection of cancer.

Source: Institute for Clinical Systems Improvement, 2012; Klein, 2005; Saslow, 2004.

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