

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



About this Knowledge Summary (KS):

This summary focuses on the clinical aspects of the early detection of breast cancer. The topics addressed include signs and symptoms of breast abnormalities, the importance of performing an accurate clinical breast exam (CBE) as part of breast awareness and early diagnosis, the need for appropriate and timely follow-up, diagnostic imaging, and pathology workup for a suspicious finding. Details about breast health awareness and imaging programs are covered in the two companion modules *Early Detection: Breast Health Awareness and Early Detection Strategies* and *Early Detection: Diagnosis and Screening with Mammography*.

KEY SUMMARY

Breast health awareness

- Ensure breast health awareness programs educate women about the signs and symptoms of breast cancer and encourage women to promptly communicate any breast concerns to a healthcare provider.
- Collaboration with cancer survivors, advocates, providers and community groups is crucial for the effective creation and dissemination of breast health awareness messages.

Medical training and clinical breast examination (CBE)

- Incorporate breast health education and CBE training into medical school curriculum.
- Provide continuing medical education training on CBE as well as on multidisciplinary breast cancer treatment for health professionals.
- CBE can be performed by trained non-physician providers in low-resource settings.
- CBE screening is a lower cost, less resource intensive screening approach than is mammographic screening and is appropriate for previously unscreened populations.
- Ensure breast health education addresses reducing discomfort and anxiety and counseling to ensure women are able make informed decisions regarding their breast healthcare.

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 pathway

- Follow a defined resource-stratified pathway in line with available resources and capacities to allow for coordinated incremental program improvement across the continuum of care (see Table 1).



INTRODUCTION AND THE CHALLENGE

Breast cancer is on the rise globally, but women in low-resource settings are bearing a disproportionate share of the burden. Women in low and middle income countries (LMICs) are often diagnosed with breast cancer at an advanced stage, when treatment needs are more intensive and costly and outcomes are poor. Diagnosis of breast cancer at earlier stages can result in improved outcomes when followed with timely and appropriate treatment. Women who can identify breast abnormalities, who have access to health facilities where clinical evaluation and diagnosis are available, and who are empowered to seek this care are more likely to be diagnosed at an earlier stage. Diagnostic delays can occur when women do not present for evaluation, but also can occur because healthcare providers fail to recognize and refer women with breast cancer signs and symptoms. The challenge is to provide education and training about the signs and symptoms of breast cancer so it can be diagnosed and an early stage when treatment may be curative.

POINTS FOR POLICYMAKERS: OVERVIEW

Preplanning

- Identify existing early detection efforts; is a new plan needed?
- Identify stakeholders, key decision-makers and champions.

Planning Step 1: Where are we now? (investigate and assess)

- Assess existing curriculum or training programs for clinicians on breast cancer signs and symptoms, breast health care and the clinical breast exam (CBE).
- Assess partnerships with medical institutions and continuing education programs.
- Identify barriers to improving early detection.

Planning Step 2: Where do we want to be? (set objectives and priorities)

- Early breast cancer diagnosis must be a priority.
- Empower women through educational programs and public awareness efforts to understand breast cancer symptoms and seek medical evaluation for breast concerns.
- Train health professionals in CBE and breast health counseling.
- Ensure women have access to early diagnosis clinical evaluations, follow-up evaluations and treatment.
- Establish a referral network for follow-up evaluation, diagnosis and treatment.

Planning Step 3: How do we get there? (implement and evaluate)

- Partner with and engage appropriate stakeholders and resources.
- Follow a resource-stratified pathway to link early detection efforts to effective and accessible diagnosis and treatment resources.
- Implement quality assurance measures.
- Monitor and evaluate.

WHAT WE KNOW

To improve global breast cancer outcomes, healthcare systems need strategies to recognize and promptly diagnose breast cancers at earlier stages. To do so, health professionals should be able to recognize the signs and symptoms of breast abnormalities for both benign breast issues as well as cancers, perform effective CBE and properly assess what tests are needed to determine if cancer is present. Early recognition of symptoms and accurate diagnosis of breast cancer can result in breast cancers being diagnosed at earlier stages of progression, at which point treatment is more likely to be feasible, affordable and effective.

Breast health should be a part of routine clinical evaluations. Primary care providers trained in breast physiology and the evaluation of breast concerns can refer women for further evaluation, as needed. Evaluation of breast concerns should include a detailed medical history and physical exam, including a CBE, to determine the degree of suspicion for breast cancer (see Table 2) and to plan for next steps in a diagnostic work-up. If resources are available, breast evaluations should include a breast cancer risk assessment, counseling on identified risks, referral (when appropriate) for genetic testing and a discussion of possible preventive health strategies (see *Prevention: Breast Cancer Risk Factors and Prevention*). In LMICs, these additional breast health services should be included as resources become available.

It is important to educate women and primary care providers 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.

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 40 (see *Early Detection: Breast Health Awareness and Early Detection Strategies*).

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 1). 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 thickening: 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 identified 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 and 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 (LNs): Many women with clinically detected breast cancer will have enlarged axillary LNs, although these changes are not always due to the nodal spread of cancer. The primary significance of nodal spread is its demonstration that a given cancer has the capacity to spread (metastasize) and is 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. There are no histologic findings that 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 without focal findings 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 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 work-up when it is spontaneous, unilateral, bloody or watery and/or associated with a mass. 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 post-partum or after cessation of breastfeeding. If present in women who are not pregnant or lactating, galactorrhea should be evaluated with a pregnancy test, endocrine work-up and review of recent medications. Because the absence of malignant cells does not exclude cancer, cytologic examination of nipple discharge is generally not advised.

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 work-up 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 of the nipple and then 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.

CBE

Allotted time: A thorough CBE requires 6-10 minutes to complete, and should include both breasts and the axillary lymph nodes. At least 3 minutes should be spent in examining each breast, though this 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 seven to nine days after the onset of menses in premenopausal women.

Technique: CBE should be performed by a healthcare 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 while her arms are relaxed, then when her arms are raised above her head, and then when her hands are pushed 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, from the mid-sternum to the mid-axillary line. Many palpation techniques have been described and no one technique is considered superior. One commonly used technique is the vertical strip pattern that uses the finger pads (rather than the fingertips), with small circular motions (1-2 cm circles) along a vertical path with varying levels of pressure. 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, and include the size of the mass in centimeters, its location (often described by 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 a biopsy could interfere with accurate interpretation of the imaging study.

Lymph node exam

Lymph node (LN) exams should be performed by a medical provider trained in the technique, on 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 LN 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 loco-regional 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 highly operator-dependent and can be less sensitive than mammography; it is not recommended as a breast cancer screening tool. (see *Early Detection: Diagnosis and Screening with Mammography*).

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. 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 work-up of a biopsy sample is required for a definitive diagnosis, which should include staging and hormone receptor status, to inform prognosis and treatment decisions. Staging criteria are available online from the American Joint Commission on Cancer (AJCC) <https://cancerstaging.org/Pages/default.aspx>. (see *Diagnosis: Clinical Assessment, Diagnostic Imaging and Staging for Breast Cancer*).

Special concerns: 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, since 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, although cytologic analysis of cyst fluid may not be helpful, since the fluid often contains inflammatory cells that the cytologist cannot distinguish from cancer cells.

POINTS FOR POLICYMAKERS

PLANNING STEP 1: WHERE ARE WE NOW?

INVESTIGATE AND ASSESS

Assess existing public awareness and training efforts

- Determine what breast cancer awareness efforts are ongoing at a national, regional or local level by the health system as well as by advocacy and community groups.
- 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 the size of the target population for the early detection program and confirm services are in place to meet the screening, diagnostic and treatment needs, with particular emphasis on equity of access.

Assess barriers to early detection and diagnosis

- Identify structural barriers to early detection programs (e.g., lack of health professional expertise and/or training in the core components of a breast exam, including expertise in CBE and breast health counseling, location of services or lack of an adequate referral network).
- Identify sociocultural, personal and financial barriers to participation in early detection and screening programs (e.g., lack of awareness, fear, gender issues, stigma, cost).
- 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 screening includes the cost of training personnel, the delivery of services and monitoring and evaluation.
- Potential effectiveness will depend on the breast cancer incidence rate, the percentage of women presenting with late stage disease (opportunity to improve) and the current capacity and competence of health professionals in clinical breast health evaluation.

Assess health system capacity

- 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.



WHAT WORKS

Breast health awareness and access to care

An effective breast cancer care program is founded on a woman's access to skilled, efficient, timely care that does not have prohibitive social or financial costs. Effective breast health education programs lead to increased awareness of the signs and symptoms of breast cancer and should result in women both recognizing the need to report symptoms and feeling more comfortable reporting symptoms to a healthcare provider. Cancer survivors, advocates, providers, and civil society organizations can be valuable partners in developing appropriate and effective breast health awareness messages.

Reducing structural, sociocultural, personal and financial barriers to access and providing coordination of care is essential to providing effective diagnosis, treatment and supportive care. Coordination of services, strong referral networks, patient navigators, and other structural initiatives such as human capacity development and training can improve patient access to timely diagnosis and treatment. Individual and community stigma and fear of breast cancer can hamper communication between a woman and her provider and unnecessarily delay care (see *Planning: Improving Access to Breast Cancer Care*).

CBE training

Proficiency in CBE should be part of medical school training and continuing medical education. Non-physician providers can also be effectively trained in CBE, which can be taught using silicone training models or supervised patient exams after obtaining consent from a patient. CBE is a skill that requires both training and practice for proficiency. Adequate time must be allotted during a clinical visit for a thorough patient history, physical exam and clinical breast exam. Studies suggest that continuing medical education of primary care physicians can improve CBE skills, can have a sustained impact on higher-quality CBE, is best done in person rather than through online-study, and can improve the ability to accurately diagnose breast masses.

CBE Screening Programs

CBE screening programs are generally linked to breast health awareness education and possibly cervical cancer screening, making the age of initial CBE screening younger than what is recommended for mammographic screening. Although mammographic screening programs are not initiated until ages 40, 45 or 50, CBE screening can be provided to women in their 30s. CBE screening programs should collect and contribute data on breast cancer tumor stage, breast cancer incidence rates and other pre-identified program metrics. Screening programs of any type must provide women with access to diagnostic work-up of abnormalities identified during screening (see *Early Detection: Breast Health Awareness and Early Detection Strategies*).



POINTS FOR POLICYMAKERS

PLANNING STEP 2:

WHERE DO WE WANT TO BE?

IDENTIFY OBJECTIVES AND PRIORITIES

Identify community and health system partnerships

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

Define the target population and approach

- Educational efforts should include health 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 clinical breast examination (CBE).
- Women can be routinely educated during clinic visits about breast health, including any available breast cancer screening opportunities.

Identify gaps and barriers

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

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

Set achievable objectives

- Objectives should promote a common goal for early detection: downstaging breast cancer diagnoses to improve cancer outcomes.
- Identify and classify objectives according to the healthcare sector that will manage them (e.g., health system standardization of CBE efforts should be led by clinicians; examiner training of CBE could be led by healthcare organizations; increasing the number of qualified practitioners could be led by sponsoring institutions, academia, and the public sector).
- Develop and disseminate patient and public 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 healthcare skills.
- Address gaps in referral networks to ensure diagnostic follow-up for all breast health complaints (WHO Package of Essential Noncommunicable (PEN) disease interventions for primary care in 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.

HOW DO WE GET THERE?

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

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

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

Implement quality assurance programs: Improving standards for CBE through training and tracking outcomes may improve the practice of CBE – an approach that has been used successfully with mammography. Increasing CBE volume and establishing trained teams or centers can improve the sensitivity and reduce the false-positive rates of CBE. Effective communications between providers can improve the care within an interdisciplinary system. Communications must be 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.

POINTS FOR POLICYMAKERS

PLANNING STEP 3: HOW DO WE GET THERE?

IMPLEMENT AND EVALUATE

Establish financial support and partnerships

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

Launch, disseminate and implement

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

Monitor and evaluate

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

CONCLUSIONS

The goal of early diagnosis programs is the downstaging of clinically detectable or symptomatic disease. This requires that women recognize evolving or persistent changes in their breasts and seek evaluation for breast symptoms early. Women are more likely to seek early evaluation for suspicious breast cancers if they understand that breast cancer can be more effectively treated when diagnosed at an early disease stage. Clinicians need to be alert for signs and symptoms of breast cancer, be able to accurately perform a CBE and be able to diagnose and facilitate care for women whose clinical findings suggest cancer.

Medical training must include breast healthcare, including core components of a breast health clinical visit and accurate performance of CBE. Health systems can improve breast healthcare through standardization of physical exam skills protocols for breast health clinical visits at local and centralized facilities.

Health systems should provide protocols for referrals that avoid excessively centralized early detection breast cancer care, as this can create a barrier to care due to access limitations in low-resource settings.

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.

Table 1. Resources Stratified Pathway: Early Detection Methods and Goals

Level of Resources	Detection Method	Evaluation Goal
Basic	Breast health awareness (education +/- self-exam) CBE (clinical education)	Baseline assessment and repeated survey
Limited	Targeted outreach/education encouraging CBE for at-risk groups Diagnostic ultrasound +/- diagnostic mammography	Downstaging of symptomatic disease
Enhanced	Diagnostic mammography Opportunistic mammographic screening	Opportunistic screening of asymptomatic patients
Maximal	Organized mammographic screening Other imaging technologies as appropriate: high-risk groups, unique imaging challenges	Population-based screening of asymptomatic patients

Adapted from the Breast Health Global Initiative (BHGI) guidelines, 2008

Table 2. Core Components of Breast Health Clinical Visit**Core Components of Breast Health Clinical Visit****History of the Present Illness:**

1. Pain: duration, location, timing, related symptoms (pain, tenderness, fever, nipple discharge)
2. Mass: duration, change, related symptoms (pain, tenderness, fever, nipple discharge)
3. Nipple discharge: pathologic if bloody, unilateral, involves single duct, watery, if woman >50yo; medication; frequency, spontaneity
4. Nipple inversion
5. Appearance: dimpling, swelling, skin retraction or thickening
6. Other: recent breast trauma, pregnancy

Past Medical & Surgical History:

1. Prior breast health diagnoses or procedures
2. Lymphoma with chest irradiation
3. Endocrine disorders

Medications & Allergies:

1. Postmenopausal hormone replacement therapy
2. Neuropsychotropic medications

Social History:

1. Prior exposures (e.g., radiation)

Family History:

1. History of breast, ovarian, prostate cancers
2. History of previous breast biopsy

Review of systems:

1. Risk factors for breast cancer (e.g., estrogen exposures)
2. Hormone factors at time of examination (e.g., time in menstrual cycle, pregnancy, lactation)
3. Symptoms of metastatic disease: bone, back, or leg pain; abdominal pain; nausea; jaundice; dyspnea or cough

Physical Exam:

1. Vital signs: fever, tachycardia
2. Breast examination: (abnormalities documented with laterality, position from nipple, according to clock face hours as examiner faces patient)
 - a. Visual inspection (upright and supine): contour changes, asymmetry, signs of infection, ulceration, skin changes, nipple ulceration, scarring, color (erythema)
 - b. Palpation: vertical-strip search pattern, varying levels of pressure, use of 3 finger pads in circular motion (1-2cm circles), at least 3min per breast from clavicle to inframammary fold, midsternum to midaxillary line. Supine then upright with ipsilateral arm on forehead. Size, shape, consistency, mobility, texture.
 - c. Nipple discharge: spontaneous, color, involved ducts
3. Adenopathy: lymph node evaluation of axilla, supraclavicular, and infraclavicular fossa
 - a. No proven evidence to improve detection of cancer

Ref: (Institute for Clinical Systems Improvement 2012, Klein 2005, Saslow 2004)



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