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Debbie Saslow, PhD; Judy Hannan, RN, MPH; Janet Osuch, MD, MS;
 Marianne H. Alciati, PhD; Cornelia Baines, MD; Mary Barton, MD; Janet Kay Bobo, PhD;
 Cathy Coleman, RN, OCN; Mary Dolan, MD, MPH; Ginny Gaumer, RN, MS;
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 Helen Meissner, PhD, ScM, MPH; Candace Moorman, MPH; Henry Penypacker, PhD;
 Peggy Pierce, RN, MSN, MPH; Eva Sciandra; Robert Smith, PhD; Ralph Coates, PhD

ABSTRACT Clinical breast examination (CBE) seeks to detect breast abnormalities or evaluate patient reports of symptoms to find palpable breast cancers at an earlier stage of progression. Treatment options for earlier-stage cancers are generally more numerous, include less toxic alternatives, and are usually more effective than treatments for later-stage cancers. For average-risk women aged 40 and younger, earlier detection of palpable tumors identified by CBE can lead to earlier therapy. After age 40, when mammography is recommended, CBE is regarded as an adjunct to mammography. Recent debate, however, has questioned the contributions of CBE to the detection of breast cancer in asymptomatic women and particularly to improved survival and reduced mortality rates. Clinicians remain widely divided about the level of evidence supporting CBE and their confidence in the examination. Yet, CBE is practiced extensively in the United States and continues to be recommended by many leading health organizations. It is in this context that this report provides a brief review of evidence for CBE's role in the earlier detection of breast cancer, highlights current practice issues, and presents recommendations that, when implemented, could contribute to greater standardization of the practice and reporting of CBE. These recommendations may also lead to improved evidence of the nature and extent of CBE's contribution to the earlier detection of breast cancer. (*CA Cancer J Clin* 2004;54:327-344.) © American Cancer Society, Inc., 2004.

INTRODUCTION

The Clinical Breast Examination's (CBE's) Contributions to the Earlier Detection of Breast Cancer

No clinical trial has compared CBE alone with a no-screening condition, and evidence demonstrating that mammography alone reduces breast cancer mortality makes it highly unlikely that a trial of CBE alone will ever be conducted.¹

As discussed in the accompanying literature review,² CBE detects some cancers not found by mammography, although the magnitude of its contribution to the early detection of breast cancers among asymptomatic women is relatively small.³⁻⁶ In addition, CBE may be important for women who do not receive regular mammograms, either because mammography is not recommended (ie, women aged 40 and younger) or because some women do not receive screening mam-

Dr. Saslow is Director, Breast and Gynecological Cancers, American Cancer Society, Atlanta, GA.

Ms. Hannan is Chief, Education and Training Section, Program Services Branch, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, GA.

Dr. Osuch is Professor of Surgery and Epidemiology, Michigan State University, East Lansing, MI.

Dr. Alciati is President, Management Solutions for Health, Inc., Reston, VA.

Dr. Baines is Professor Emerita, Department of Health Sciences, Faculty of Medicine, University of Toronto, Toronto, Canada.

Dr. Barton is Assistant Professor, Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, Boston, MA.

Dr. Bobo is Health Research Leader and Senior Epidemiologist, Battelle Centers for Public Health Research and Evaluation, Seattle, WA.

Ms. Coleman is Consultant, Breast Center Development, Tiburon, CA.

Dr. Dolan is Division Chief, Women's Primary Healthcare, University of North Carolina School of Medicine, Chapel Hill, NC.

Ms. Gaumer is Nurse Consultant for Quality Assurance, Georgia Department of Human Resources, Savannah, GA.

Dr. Kopans is Director, Breast Imaging Division, Massachusetts General Hospital, Boston, MA.

Dr. Kutner is Chair, Breast Cancer Task Force of Northern California Kaiser Permanente, and Surgeon, Santa Teresa Medical Center, San Jose, CA.

Dr. Lane is Associate Dean, Continuing Medical Education, and Distinguished Service Professor, Vice Chair and Residency Program Director, Department of Preventive Medicine, Stony Brook University School of Medicine, Stony Brook, NY.

Dr. Lawson is Senior Medical Advisor, Program Services Branch, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, GA.

Dr. Meissner is Chief, Applied Cancer Screening Research Branch, National Cancer Institute, Rockville, MD.

Ms. Moorman is Chief, Professional Education Unit, Cancer Detection Section, California Department of Health Services, Sacramento, CA.

Dr. Pennypacker is Professor of Psychology, University of Florida, and President, Mammatech Corporation, Gainesville, FL.

Ms. Pierce is Assistant Professor, University of Tennessee College of Nursing, Knoxville, TN.

Ms. Sciandra is Director of Breast Health, American Cancer Society, Eastern Division, Loudonville, NY.

Dr. Smith is Director, Cancer Screening, American Cancer Society, Atlanta, GA.

Dr. Coates is Associate Director for Science, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, GA.

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mography consistent with recommended guidelines.⁷⁻⁹ Furthermore, CBE's contribution to women's health may extend beyond its ability to identify previously undetected palpable masses. Specifically, CBE presents an opportunity for health care providers to educate women about breast cancer, its symptoms, risk factors, and advances in its early detection, as well as normal breast composition and variability.⁷ It also lets clinicians discuss the benefits and limits of breast self-examination (BSE) and demonstrate BSE for women who elect to do it.

Recommendations by Major Organizations

Organizations that provide clinical guidelines and practice policies for the early detection of breast cancer vary in their recommendations for CBE. Variation is by age at initiation, breast cancer risk status, frequency of CBE performance, and the strength of language used to recommend CBE. Some organizations continue to recommend CBE, while others make no recommendation regarding CBE for breast cancer screening among asymptomatic women (Table 1). For example, the revised 2003 guidelines of the American Cancer Society recommend CBE as part of a periodic health examination, preferably at least every 3 years for women in their 20s and 30s and annually among asymptomatic women aged 40 years or older.⁷ The Susan G. Komen Breast Cancer Foundation also recommends CBE at least every 3 years among women aged 20 to 39 and annually beginning at age 40.¹⁰ Annual CBE beginning at age 40 also is recommended by the American College of Obstetricians and Gynecologists¹¹ and the American College of Radiology.¹² The American Medical Association¹³ recommends CBE every 1 to 2 years for

women aged 40 to 49 years and annually beginning at 50 years of age.

Several international groups also recommend CBE. The Canadian Task Force on Preventive Health Care recommends CBE every 1 to 2 years among women aged 50 to 69.¹⁴ The Scottish Intercollegiate Guidelines Network and the Royal New Zealand College of General Practitioners¹⁵ recommend CBE among specific age and breast cancer risk groups. Some of these organizations also emphasize the role of CBE in patient education and assisting women to become familiar with their own breasts.

Other US and international organizations make no specific recommendation either for or against CBE. The US Preventive Services Task Force, for example, following a review of published literature on breast cancer screening,^{16,17} concluded that the evidence is insufficient to recommend for or against routine CBE alone to screen for breast cancer. The American College of Preventive Medicine,¹⁸ the American College of Physicians,¹⁹ and American Association of Family Practitioners²⁰ do not address CBE in their breast cancer screening statements.

Use of CBE in the United States

In practice, CBE is a common component of current breast cancer screening and is performed extensively across the United States. Screening trends assessed by the National Health Interview Survey found that, by 1992, 90% of women aged 40 or older had ever received a CBE (per the self-reported data), and 50% of women aged 40 or older had received a CBE in the previous year.²¹ More recent data (also from self-reports) from the Behavioral Risk Factor Surveillance System, a state survey system of health risk behaviors, suggest similar levels. Behavioral Risk Factor Surveillance System data from 2000 revealed that an overall median across states of 91% of women aged 40 years and older had a CBE at least once.²² Additionally, the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is mandated under law to provide both mammography and CBE screening

TABLE 1 Recommendations by Major Health Organizations for the Performance of CBE Among Asymptomatic Women

| Organization | Recommendations | | | Role in Breast Awareness and Patient/Provider Interaction |
|---|---|---|---|---|
| | Age (years) | | | |
| | 20-39 | 40-49 | 50 and older | |
| United States | | | | |
| Government-convened panel | | | | |
| United States Preventive Services Task Force | No recommendation | No recommendation | No recommendation | Not discussed |
| Professional associations | | | | |
| American College of Obstetricians and Gynecologists | No recommendation | Annually | Annually | Not discussed |
| American College of Physicians | No recommendation | No recommendation | No recommendation | Not discussed |
| American College of Radiology | No recommendation | Annually | Annually | Not discussed |
| American Medical Association | No recommendation | Every 1-2 years | Annually | All medical care decisions should involve patient/provider deliberation |
| American College of Preventive Medicine | No recommendation | No recommendation | No recommendation | Not discussed |
| American Association of Family Practitioners | No recommendation | No recommendation | No recommendation | Not discussed |
| Voluntary health organizations | | | | |
| American Cancer Society | As part of a periodic health examination Preferably at least every 3 years | As part of a periodic health examination Preferably annually | As part of a periodic health examination Preferably annually | Opportunity for women and providers to discuss breast changes |
| Susan G. Komen Breast Cancer Foundation | At least every 3 years | Annually | Annually | Opportunity for women and providers to discuss breast changes |
| International | | | | |
| Government agency | | | | |
| Canadian Task Force on Preventive Health Care | No recommendation | No recommendation | Every 1 to 2 years, women aged 50 to 69 years | Not discussed |
| Scottish Intercollegiate Guidelines Network | Annually among high risk women | Annually among high risk women | Continue more frequent screening | Not discussed |
| Professional association | | | | |
| Royal New Zealand College of General Practitioners | No recommendation | No recommendation | In conjunction with biennial mammography (aged 50 to 74 years) | Not discussed |

for the early detection of breast cancer. Now in its 12th year, the NBCCEDP has provided screening services to uninsured women in all 50 states, the District of Columbia, 6 US territories, and 15 American Indian/Alaska Native organizations, including more than four million breast and cervical screening examinations, and has diagnosed more than 14,000 breast cancers.²³ Taken together, these results show that large numbers of US women have received at least one CBE and that many women receive CBE on a periodic basis.

Studies of physicians vary in the proportions reporting routine performance of CBE. For example, one study of family physicians and internists in Long Island community hospitals

showed that only 56% regularly performed CBE on women aged 50 to 75 years,²⁴ but in a study of preventive services delivery among family practice physicians in Ohio, 85% of women aged 50 to 69 years were observed to receive a CBE during well visits.²⁵ Several studies found that the proportion of physicians reporting routine performance of CBE varied as a function of specialty.^{26,27}

Barriers to High-quality Performance

Although CBE generally continues to be recommended by many groups as a component of comprehensive breast cancer screening and is performed by large numbers of US physicians, the

way in which it is performed varies considerably.^{2,28} In the NBCCEDP, reporting is standardized, but the method of performing CBE is not.³ The technique has also not been standardized in most screening trials.^{1,2} While the sensitivity and specificity of CBE were generally comparable across the NBCCEDP and screening trials, these levels of performance are lower than what could be achieved with standardization of technique and training to that standard.

Studies that used well-described, standardized methods for performing CBE provide some evidence of higher levels of sensitivity in clinical examination.^{1,9} Training studies using objective, structured clinical examination have observed improvements in performance of CBE techniques and in patient interaction skills.²⁹ Studies using silicone breast models show that both training in CBE technique and experience in detecting breast lumps can increase sensitivity for detecting lumps in the models,^{28,30,31} although specificity in many studies declines at higher levels of sensitivity.² A study demonstrated that training with silicone breast models increased detection of known benign lumps in women,³² providing evidence that detection skills learned using silicone models can be effectively applied to patients.

Despite the potential of training to enhance performance, studies of medical students and residents reveal low performance scores on objective examinations of CBE components, as well as low sensitivity and specificity using silicone breast models.^{29,33} Medical students' perceptions of their own need for additional training and the small number of CBEs they have actually performed illustrate the limits of current medical school training in the performance of CBE.^{2,29,31,32} Similarly, physicians report lack of confidence in their CBE skills^{34–36} and indicate high levels of interest in improving them.³⁶

Developing Recommendations for CBE Performance and Reporting

CBE presents an interesting challenge for clinical practice and public health. It is widely practiced, yet concern remains about its effectiveness in reducing breast cancer mortality. CBE appears to find some cancers missed by mammography—

although a small proportion—and may be useful in women for whom mammography is not recommended or who do not receive screening mammography consistent with recommended guidelines. CBE is practiced with little standardization despite reasonable evidence that performance can be improved by training and experience. Furthermore, the lack of standardized performance and reporting has limited the availability of data to address questions about CBE's role in breast cancer detection.

In this context, the American Cancer Society, in collaboration with the Centers for Disease Control and Prevention, initiated a planning process to develop recommendations for optimizing the performance and reporting of CBE. Providing standards that are based on existing literature and expert opinion should lay the foundation for enhancing test sensitivity and specificity to the extent possible and provide a valuable tool to assist providers in improving test performance and communicating about test findings within and across specialties. Such assistance is particularly important in the case of breast cancer, where failure to diagnose is the primary cause for malpractice claims in the United States and the second-leading reason for subsequent payments to claimants.³⁷ Furthermore, enhancing the standardization of CBE performance, combined with more uniform interpretation and reporting, will provide a basis for gathering much-needed data about the nature of CBE's contribution to earlier detection of breast cancer. Such data are essential to resolving inconsistent practice guidelines across organizations and the resulting confusion for women and their health care providers.

The process of developing recommendations for CBE performance and reporting began with a thorough review of the literature.² This review covered numerous areas, including trials and case series reports; standards (or lack thereof) for performing CBE and reporting results; factors influencing specificity and sensitivity; proficiency of providers in performing CBE; the effect of provider training, experience, and specialty on proficiency; and barriers to performing CBE.

Additionally, to ensure that the full range of clinical and public health issues related to CBE

performance and reporting were addressed, interviews were conducted with experts in the early detection of breast cancer. These experts identified issues that needed to be addressed to understand the contribution of CBE to the detection of breast cancer and what would be required to realize substantial improvements in performance and reporting. The issues identified included the level of evidence supporting CBE as a screening examination, test characteristics, current practices, interpretation and reporting of results, examiner training, and CBE's relationship to other screening tests for breast cancer.

Based on the research literature and expert guidance, a committee was formed of national and international experts well versed in CBE and its performance and reporting. This committee was charged with developing recommendations for physicians and health organizations that would enhance CBE performance and reporting.

Members of the committee conferred in working groups and as a full committee through a series of conference calls and a face-to-face meeting held in Atlanta on October 10 and 11, 2002. The committee also worked in concert with a related American Cancer Society advisory group, the Breast Physical Examination Working Group (one of five working groups within the Breast Cancer Early Detection Guideline Review).⁷ Early drafts of the committee's report were disseminated to a broad range of professional and public health organizations for review and comment. After comments were compiled and assessed, modifications were made to the report.

The intent of this effort was to provide a framework for standardization, recognizing that additional detail would be needed in some areas (eg, development of a lexicon for interpreting and reporting that would be compatible with the Breast Imaging Reporting and Data System, development of a sample reporting form) and that implementation of some recommendations would require additional efforts involving collaboration among organizations and supplemental funding. Identification of processes and funding for implementation were beyond the scope of the committee's work. The committee envisioned that the report would provide a tool for immediate action in

some areas and a stimulus for follow-up action in others.

This report provides detailed descriptions of each recommendation, its components, the committee's rationale for the recommendation, and responsibilities for implementation. The balance between support from research and from practical evidence varies across recommendations. In general, evidence about CBE, including its contributions to early detection of breast cancer and subsequent reduction in mortality as discussed above, as well as factors that influence its performance, is limited. As a result, several aspects of these recommendations rely on clinical expertise and practical experience. Not surprisingly, the committee's final recommendation is a call for research into particular questions that will provide a firmer foundation for decisions about the practice of CBE as a component of women's health care.

RECOMMENDATIONS

Recommendations are presented in two areas, the clinical breast examination itself and overcoming barriers to performance. Some recommendations can be implemented immediately within clinical settings, and clinicians are encouraged to lead this effort (Table 2). Others will require partnerships between the clinical community and health care organizations to establish systems, increase awareness, and gather necessary information to achieve outcomes.

BREAST EXAMINATION

The premise underlying CBE is that visually inspecting and palpating of the breast and surrounding tissue can detect breast abnormalities. CBE was considered by the committee to include a continuum of integrally related components, from the examination itself, to interpretation and reporting of findings, to patient follow up. The recommendations for performance in this report represent general standards that can be immediately disseminated and adopted based on current evidence. Although these recommendations reflect an im-

TABLE 2 Summary of CBE Recommendations and Lead Responsibility for Implementation

| | Lead Responsibility | |
|---|--------------------------------------|-----------------------------------|
| | Health care Clinicians organizations | Research sponsoring organizations |
| CBE | | |
| <i>The examination</i> | | |
| Adopt standards for CBE that include a stepwise progression of elements consisting of clinical history, visual inspection, and palpation. | ✓ | |
| Encourage widespread dissemination of standards for CBE. | | ✓ |
| <i>Interpretation and reporting</i> | | |
| Reporting should consist of a summary of relevant portions of a patient's history and a description of whether the CBE is interpreted as normal/negative or abnormal. If abnormal, include a description of the visual and palpable finding, including changes in the appearance of skin or nipples, the presence of nipple discharge, the presence of breast masses or palpable asymmetries, and the presence of palpable lymph nodes. | ✓ | ✓ |
| Develop a consistent, standardized lexicon and format for documenting the interpretation and reporting of specific CBE findings. | | ✓ |
| <i>Follow up</i> | | |
| Adopt a standardized approach to follow up that provides continuous care to the patient until an appropriate resolution of findings is reached. This approach should make use of all appropriate follow-up options, ensure appropriate timing of subsequent actions, involve communication and coordination with other providers, and include proper documentation and tracking. | ✓ | |
| Overcoming barriers to the implementation of CBE | | |
| <i>Examiner training</i> | | |
| Develop and promote training systems to improve and maintain the proficiency of those who perform CBE, and encourage the integration of such systems into basic and continuing education programs for health care professionals. | | ✓ |
| <i>Public education</i> | | |
| Promote and encourage public education about CBE so that women know what to expect in the performance of CBE and follow-up care, understand the benefits, limitations, and potential harms associated with CBE, and become familiar with their own breast characteristics as well as health practices that might increase the likelihood of identifying breast abnormalities. | | ✓ |
| <i>Research and quality improvement</i> | | |
| Support and encourage research in key aspects of CBE, particularly questions related to characteristics of abnormalities found by CBE, the timing of the examination, training of examiners (clinicians), reporting systems, and CBE's contributions to early detection of breast cancer, and the reduction of morbidity and mortality from this disease. | | ✓ |
| | | ✓ |

portant first step, the committee recognizes the need for more detailed practice algorithms and for reporting forms that have been tested. Efforts to develop these follow-up tools are currently planned.

Neither CBE nor mammography is a substitute for the other as an independent examination for detecting breast abnormalities. When a suspicious mass is found on CBE, it must be evaluated and explained even if mammography examination does not show an abnormality.

1. The Examination:
 - a. Adopt standards for CBE that include a stepwise progression of elements con-

sisting of clinical history, visual inspection, and palpation.

Lead responsibility for implementation: clinicians.

- b. Encourage widespread dissemination of standards for CBE.

Lead responsibility for implementation: health care organizations.

Studies have assessed the influence of test characteristics (such as search pattern, palpation, pressures, duration), patient characteristics (such as tissue density, and nodularity), and tumor characteristics (such as size, depth, mobility) on the CBE's sensitivity and specificity.²

CBE techniques have been described and illustrated in several recent reviews;^{1,2,38} figures from one of these reviews are used to illustrate the recommendations presented here (Figures 1-3).¹ These studies provide some basis for recommendations concerning the specific way CBE is performed. Not all aspects of visual inspection and palpation have been studied in controlled settings, however, and thus the following recommendations rely in part on the clinical expertise of the committee and the premise that visual inspection and palpation of every area of the breast and surrounding tissue will lead to identification of more breast masses.

Clinicians are encouraged to adopt and implement the following standards for performance of the CBE examination. Efforts to encourage widespread dissemination of these standards must be implemented as a partnership between clinicians and health care organizations.

Clinical History

A clinical history that identifies the patient's personal and family health history is useful in assessing risk of breast cancer. Some women will not report symptoms until asked, and a clinical history provides an important opportunity to seek out this information. This health history can direct attention to potentially relevant symptoms and provides important context for interpreting findings. The clinical guidelines and policy statements of many organizations concerning the performance of screening CBE emphasize the importance of a woman's individual risk for breast cancer.¹⁵ Furthermore, information on clinical history can help guide follow up. The clinical history also provides an opportunity for the provider to explain the benefits and limitations of the examination, its elements, the time involved, and the related events that occur after the examination (interpretation, reporting, and follow up).

The clinical history should:

- **Identify screening practices for breast health**, when they were performed, and results. These practices include breast self-examination (BSE), prior CBE, and prior screening and diagnostic mammograms.

- **Ask about any breast changes** and how they were identified. This includes changes in appearance of skin or nipples, presence of lumps, pain (focal versus general and constant versus cyclic), itching, or staining of garments or bed sheets that would indicate spontaneous nipple discharge.
- **Assess risk** by asking about age and personal history, including benign breast disease, biopsy, cancer, cosmetic or other breast surgery, history of hormonal therapy, and/or oral contraceptive use, obstetric history, family history, and health promotion habits (eg, exercise, nutrition).

Visual Inspection

Once the clinical history has been completed, the patient's breasts should be visually inspected. To minimize awkwardness and potential misunderstandings, providers should inform women in advance that a visual inspection will be performed and describe what is being assessed during this part of the examination. The patient should sit with her hands pushing tightly on her hips. This position contracts the pectoralis major muscles and enhances identification of asymmetries. Although adding multiple positions (eg, hands over head and hands at sides) may further assist identification of asymmetries, it does not add substantively to the single position recommended and may reduce time devoted to palpation. When conducting the visual inspection, the provider must view the breasts from all sides and should:

- Assess symmetry in breast shape or contour (subtle changes or differences),^{2,38,39} and
- Assess skin changes, particularly any skin erythema, retraction or dimpling, and nipple changes.^{2,38,39} Physical signs associated with advanced breast cancer have been summarized using the acronym BREAST, signifying Breast mass, Retraction, Edema, Axillary mass, Scaly nipple, and Tender breast.³⁸

If the clinician is seeing the patient on a regular basis, visual inspection allows the monitoring of changes in appearance over time when observations are compared with previously documented examination. Visual inspection takes only a short amount of time, with the

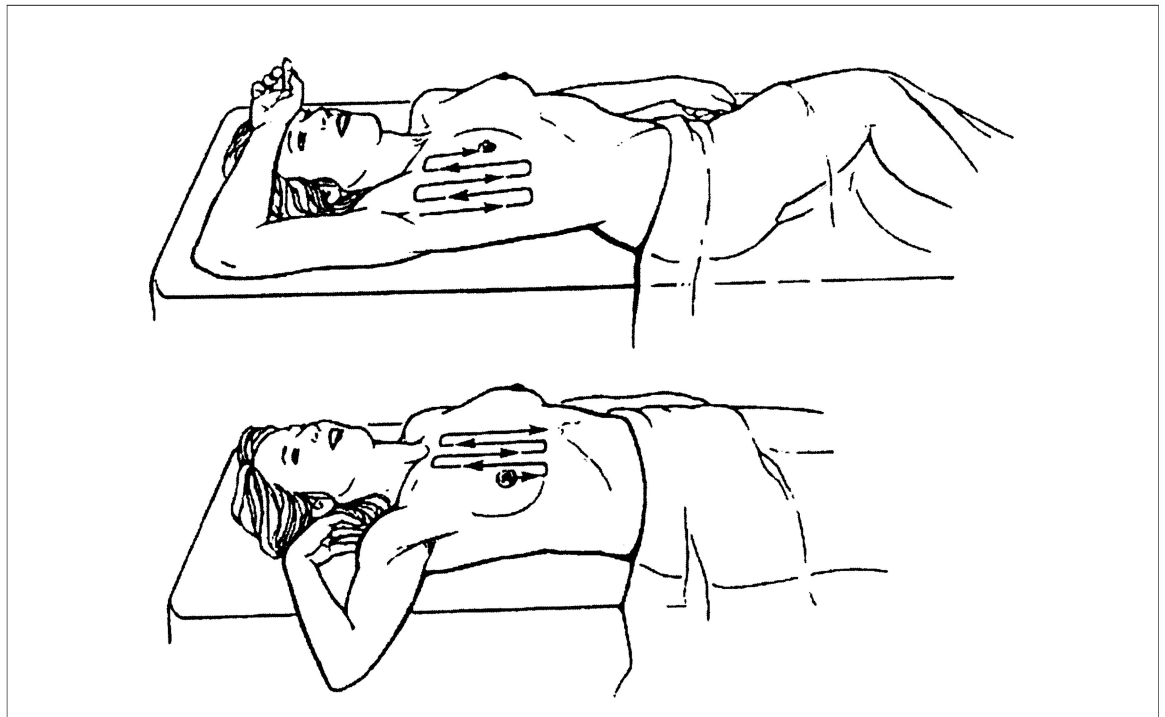


FIGURE 1 Position of Patient and Direction of Palpation for the CBE.

The top figure shows the lateral portion of the breast, and the bottom picture shows the medial portion of the breast. Arrows indicate the vertical strip pattern of examination. (Reprinted with permission from Barton MB, Harris R, Fletcher SW.¹)

remainder of the examination spent predominately on palpation.

Palpation

Following the visual inspection, the examiner palpates each breast and nearby lymph nodes. To minimize awkwardness and the potential for misunderstanding, providers should inform women in advance that palpation will be performed and describe what is being assessed during this part of the examination. Palpation provides an opportunity for discussion of the normal variability of breast characteristics and the importance of women becoming familiar with the characteristics of their own breasts. Thoroughness is essential; palpation must examine all breast tissue as well as nearby lymph nodes. Appropriate palpation includes five key characteristics:

- **Position:** Patients should be sitting for palpation of the axillary, supraclavicular, and infraclavicular lymph nodes. Patients should be lying down for breast palpation, with their ipsilateral hand overhead to flat-

ten the breast tissue on the chest wall, thereby reducing the thickness of the breast tissue being palpated (Figure 1). If this maneuver does not result in a relatively even distribution of breast tissue, the breast should be further centralized by placing a small pillow under the shoulder/lower back on the side of the breast being examined. The tissue being examined needs to be as thin as possible over the chest wall. The examiner must be able to see the full palpation area.

- **Perimeter:** All breast tissue falls within a pentagon shape (as opposed to the traditional perception of the breast as a conical structure). The examiner should use the following landmarks to cover all of this area: down the midaxillary line, across the inframammary ridge at the fifth/sixth rib, up the lateral edge of the sternum, across the clavicle, and back to the midaxilla.
- **Pattern of search:** The full extent of breast tissue should be searched using a “vertical strip” pattern (Figure 1).^{2,40} (A systematic analysis demonstrated the supe-

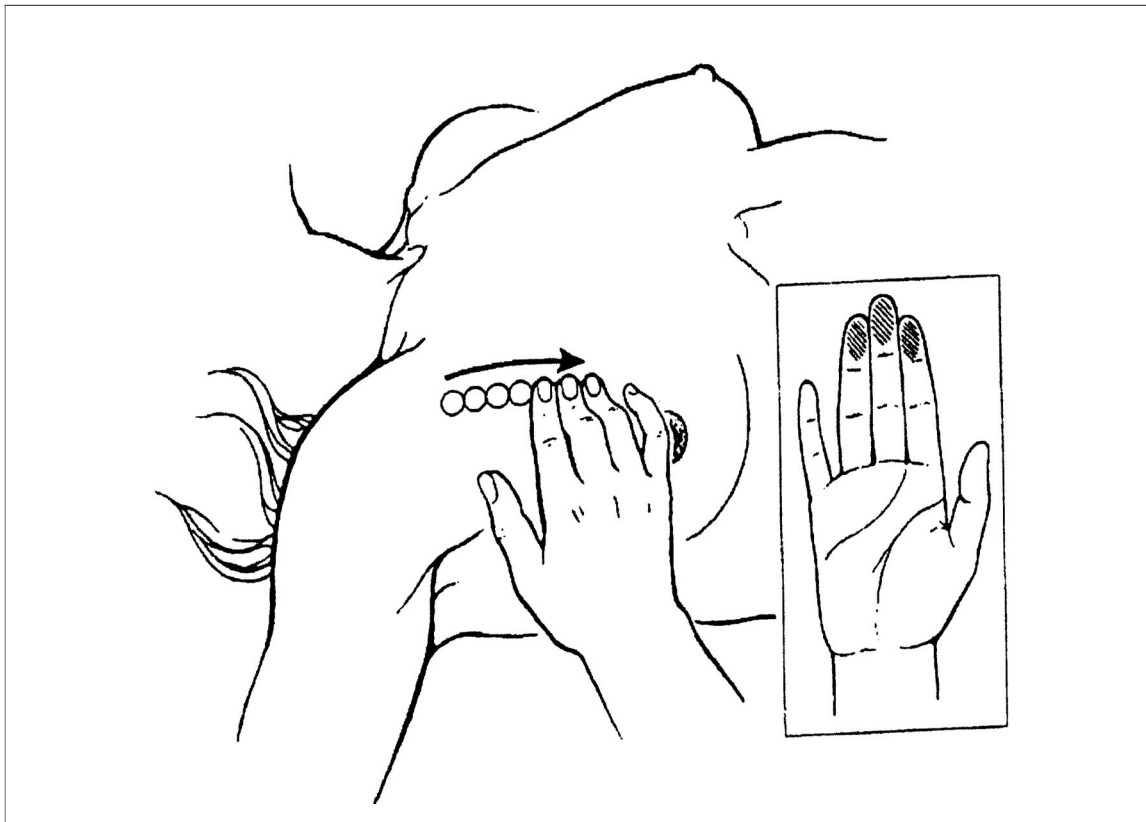


FIGURE 2 Palpation Technique.

Pads of the index, third, and fourth fingers (*inset*) make small circular motions, as if tracking the outer edge of a dime. (Reprinted with permission from Barton MB, Harris R, Fletcher SW.¹)

riority of the vertical strip search pattern over concentric circle and radial spoke patterns in thoroughness of coverage, as performed by women trained in BSE to examine themselves.⁴⁰) The search should be initiated at the axilla. If a mastectomy has been performed, the chest wall, skin, and incision should be included.

- **Palpation:** The examiner should use the finger pads of the middle three fingers to palpate one breast at a time (Figure 2). Palpate with overlapping dime-sized circular motions.^{2,30} Tissue at and beneath the nipple should be palpated, not squeezed. Squeezing often results in discharge as well as discomfort. Only spontaneous discharge warrants further evaluation.⁴¹ Breast tissue in the upper outer quadrant and under the areola and nipple should be thoroughly searched, as these are the two most common sites for cancer to arise.⁴²

- **Pressure:** As each area of tissue is examined, three levels of pressure should be applied in sequence: light, medium, and deep, corresponding to subcutaneous, mid-level, and down to the chest wall (Figure 3). Adapt the palpation to the size, shape, and consistency of tissue, and accommodate pressure to other factors such as breast size and the presence of breast implants. Providers sometimes lack confidence performing CBE in women with breast implants; implants correctly placed are located behind the tissue of the breast. Therefore, the steps for CBE are exactly the same as in women without implants.

The duration of the examination is intentionally not specified, for several reasons. First, while thoroughness is related to time spent performing CBE, performance time can decrease with increased proficiency. Additionally, a variety of patient factors, such as breast size, tenderness,

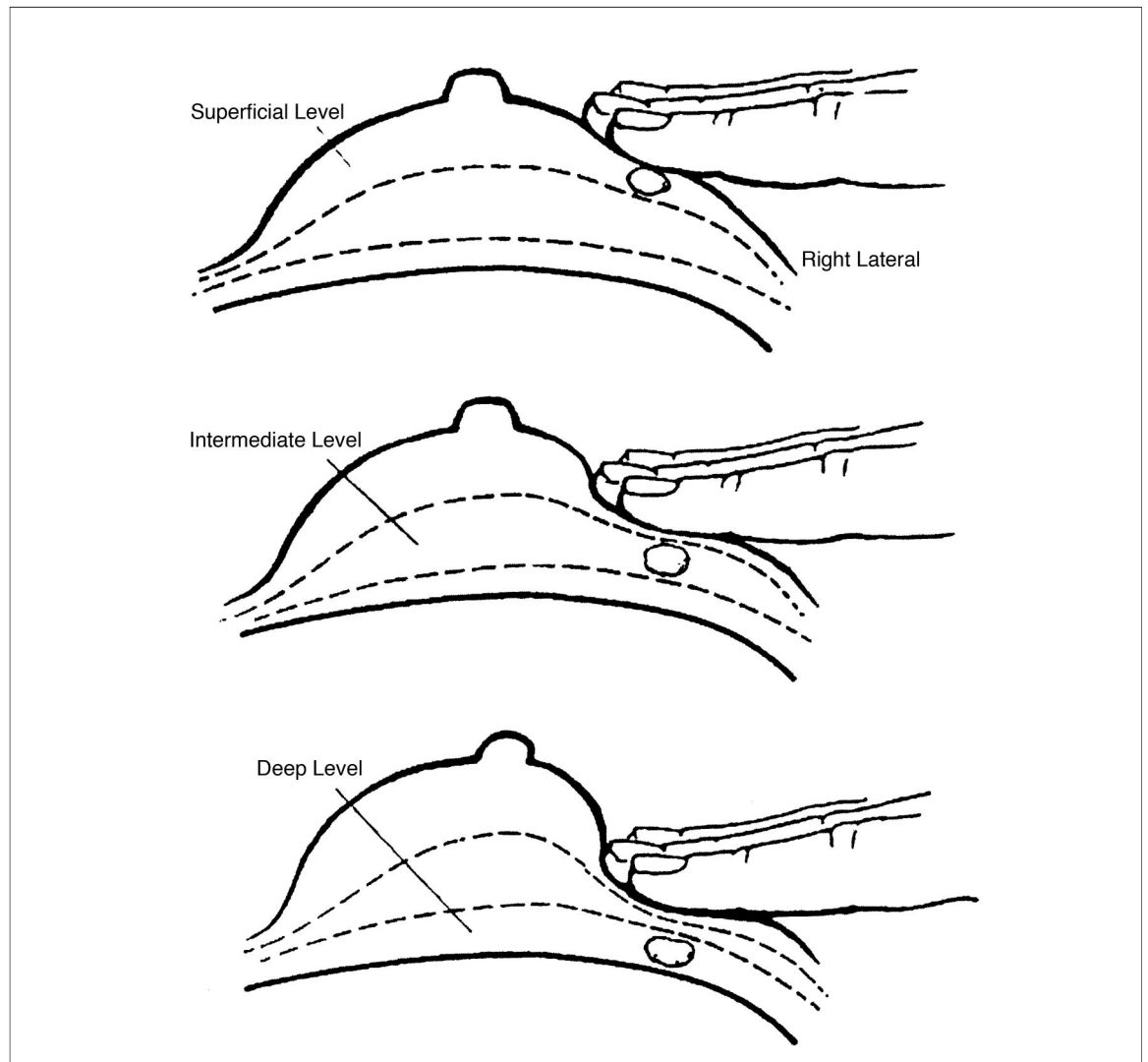


FIGURE 3 Levels of Pressure for Palpation of Breast Tissue Shown in a Cross-sectional View of the Right Breast. The examiner should make three circles with the finger pads, increasing the level of pressure (subcutaneous, mid-level, and down to the chest wall) with each circle. (Reprinted with permission from Barton MB, Harris R, Fletcher SW.¹)

lumpiness, body weight, and risk factors, can influence the time required to perform a proficient CBE. The committee determined that specifying a uniform time frame would be misleading more often than not and would inappropriately shift the focus of performance away from proficiency and thoroughness.

2. Interpretation and Reporting:

- a. Reporting should consist of a summary of the relevant portions of a patient's history and a description of whether the CBE is interpreted as normal/negative or abnormal. If abnormal, include a description of the

visual and palpable findings, including changes in the appearance of skin or nipples, the presence of nipple discharge, the presence of breast masses or palpable asymmetries, and the presence of palpable lymph nodes.

Lead responsibility for implementation: clinicians and health care organizations.

- b. Develop a consistent, standardized lexicon of terms and format for documenting the interpretation and reporting of specific CBE findings.

Lead responsibility for implementation: health care organizations.

The primary function of CBE is to identify abnormalities that warrant further evaluation; CBE alone is not capable of accurately distinguishing benign from malignant status. Interpreting the visual and tactile observations of CBE is complex. A variety of patient characteristics can influence interpretation, including age, parity, tissue density and nodularity, menopausal status, phase of the ovarian cycle, and health history.² For example, bloody nipple discharge during the last trimester of pregnancy or the first 3 months of lactation may be considered a normal physiologic change, but it would be interpreted quite differently in a woman who was not pregnant or lactating. Similarly, skin erythema or lymphedema would not necessarily be cause for further evaluation in a woman having recently undergone radiation therapy of the breast but would certainly require follow up in a woman without such a history. A more common and difficult challenge involves breast lumpiness or nodularity, which varies considerably among women and over time for the same woman. For example, increased nodularity might be normal during the luteal phase of the menstrual cycle, but at other times it might be cause for further examination.

As with the performance of CBE, no standard system exists for interpreting or reporting CBE findings. No standardized terminology exists for describing findings such as degree of nodularity; thickening versus a mass; dimpling of skin; or the size, mobility, shape, or consistency of an abnormality. Thus, even if CBE was performed uniformly to its highest potential sensitivity and specificity, differences in interpretation and how findings are reported limit its potential benefits in guiding further evaluation and permitting earlier treatment of breast cancer. Efforts to improve the interpretation of mammography reporting and subsequent associated management recommendations have resulted in improvements in accuracy and consistency in those areas, but several studies demonstrate the importance of continued system refinement and training.⁴³⁻⁴⁵ Standardization of interpretation and reporting might yield similar positive effects for CBE. Although development of a detailed lexicon for CBE was beyond the scope of this initiative, the committee

recommends further development of a system that complements the Breast Imaging Reporting and Data System and its lexicon developed by the American College of Radiology. The framework provided below under Reporting represents an initial step in this process and provides immediate guidance for practice.

Another important byproduct of standardizing interpretation and reporting is the potential to provide data for more accurate estimates of sensitivity and specificity in clinical practice settings. Estimates of false-positive and false-negative results based on reporting and medical records data could be used to provide feedback to health care professionals to improve their proficiency.

Information about the number of cancers first identified by CBE, particularly as a function of age and other population characteristics, could help clarify the role of CBE as a component of early detection and the use of this examination in relationship to other screening modalities.

Interpretation

Interpretation involves three elements: identification of visual and palpable characteristics of the breasts and lymph nodes; accurate assignment of specific, common, descriptive terminology to each characteristic; and determination of appropriate follow-up actions for identified findings. The interpretation and reporting elements described below provide a general framework for identifying all relevant features of a proficient CBE, describing visual and physical findings, and reporting these findings and follow-up recommendations. This framework is general, representing an important initial step in the process of developing a standardized lexicon and patient follow up, as well as a reporting format for CBE. Describing and interpreting findings can be challenging, as when women have highly nodular breasts, for example. The role of CBE, however, is to identify and appropriately describe visual and palpable findings; determination of benign or malignant status can be established only through further evaluation. Clinicians are encouraged to adopt and begin implementing this framework for CBE interpretation and reporting. Development and implementation of a detailed system, as

well as analysis of reporting data, must be undertaken as a partnership between clinicians and health care organizations.

In the most general form, the results of CBE can be interpreted in two ways:

- **Normal/Negative:** No abnormalities on visual inspection or palpation.
- **Abnormal:** Asymmetrical finding on either visual inspection or palpation that warrants further evaluation and possible referral. Findings will reflect a continuum of possible outcomes, from probably benign to highly suspicious of cancer. Determination of benign or malignant status, however, can be established only through further evaluation.

Reporting

Reporting should include a description of all findings in specific and precise language, regardless of interpretation. In the case of a negative interpretation, description of findings provides a baseline for interpreting future results from visual inspection and palpation. In the case of an abnormal interpretation, a description provides an important guide for follow-up examination.

Reporting should follow the same sequence as the examination itself. The following outline directs providers' attention to those aspects of the exam that represent unique patient characteristics or abnormalities. To the extent possible, electronic reporting should be encouraged to provide compatibility with existing medical records systems and more efficient analysis of reporting trends. Additional research assessing reporting consistency, feasibility, and systems-related issues should be performed.

Normal/Negative CBE: Normal Breast Characteristics

- Clinical history – describe:
 - Breast screening practices.
 - Breast changes.
 - Risk factors for breast cancer.
 - Hormonal factors at time of examination (eg, time in menstrual cycle, pregnancy, breast feeding, hormonal contraceptives, hormone therapy).

- Visual inspection – describe:
 - Scarring.
 - Symmetry of breast shape and appearance of skin and nipple-areolar complex.
- Palpation of lymph node – describe results with respect to:
 - Infra- and supraclavicular nodes.
 - Axillary nodes.
- Breast palpation – describe results with respect to:
 - Nodularity.
 - Normal nodularity should not be described as a fibrocystic condition.
 - Normal cyclic breast tenderness should not be described as a pathologic condition.
 - Symmetry.
 - Tenderness (focal versus generalized and constant versus intermittent).
- Recommended follow up.

Abnormal CBE: Abnormal Breast Characteristics

- Clinical history – describe:
 - Breast screening practices.
 - Breast changes.
 - Risk factors for breast cancer.
 - Hormonal factors at time of examination (eg, time in menstrual cycle, pregnancy, breast feeding, hormonal contraceptives, hormone therapy).
- Visual inspection – describe:
 - Contour (skin retraction, dimpling).
 - Color (erythema).
 - Texture (skin thickening or lymphedema).
 - Skin retraction or dimpling.
 - Nipple scaling or retraction.
 - Nipple inversion (age of onset during adulthood).
 - Location of abnormal findings or mass according to a clock face as the examiner faces the patient, clearly indicating whether the abnormality is in the right or left breast.
 - Size/extent of abnormal finding or mass.
- Palpation – for each palpable abnormality (including breast tissue and infraclavicular,

supraclavicular, and axillary lymph nodes), describe:

- Three-dimensional dominant mass or two-dimensional thickening.
 - Location in three dimensions (subcutaneous, midlevel, next to chest wall, and according to a clock face as the examiner faces the patient).
 - Size.
 - Shape (round, oblong, irregular, lobular [having one to four rounded or curved extensions from a central mass]).
 - Mobility (mobile, fixed to skin or chest wall).
 - Consistency (soft, similar to surrounding breast tissue, hard).
 - External texture (smooth, irregular [having bumps distributed over the external surface of the mass]).
- Nipple discharge.
 - Spontaneous.
 - Color.
 - Number of involved ducts.
 - Right or left breast, or both.

- Recommended follow up.

3. Follow Up:

Adopt a standardized approach to follow up that provides continuous care to the patient until an appropriate resolution of findings is reached. This approach should make use of all appropriate follow-up options, ensure appropriate timing of subsequent actions, involve communication and coordination with other providers, and include proper documentation and tracking.

Lead responsibility for implementation: health care organizations.

The final but equally important component of the CBE is follow up; different types of findings will require different follow-up actions, but appropriate follow up is essential. The committee recommends the following basic approach for follow up, supplemented by more detailed follow-up algorithms appropriate to the provider's profession and unique health care system.

Follow Up for Normal/Negative CBE

In the case of a normal/negative CBE, a repeat CBE at the next screening interval or preventive health examination is the appropriate follow up. Descriptive findings from the normal/negative CBE should serve as the baseline for the next interval CBE.

Follow Up for Abnormal CBE

In the case of an abnormal CBE:

- The provider should not discount an abnormal CBE because of a negative mammogram or other imaging examination.
- Providers must follow up all conflicting or abnormal findings to satisfactory resolution using the actions outlined below.
- All referrals must ensure that a copy of the CBE report is provided to specialists performing follow-up imaging to assist in examination and interpretation.

One or more of the following follow-up options are available:

- Repeat CBE.
- Medical management of probably benign condition.
- Referral to a breast specialist.
- Imaging (ultrasound, mammography, magnetic resonance imaging).
- Aspiration.
- Biopsy (percutaneous or excisional).

Timing

The timing of follow-up actions must be appropriate to the findings and should be designed to minimize patient burden and psychological stress. For women aged 40 and older, a repeat CBE in the case of negative findings will likely occur as part of the woman's regular preventive health care. Among women aged 40 and younger with a negative CBE, this interval may be longer. In the case of abnormal findings, follow up should take place at a shorter interval, at least within 6 months and usually within a shorter time frame.

Coordination

If follow up is necessary, examiners may need to work with other care providers, including radiologists, oncologists, surgeons, and other breast health specialists. Clear communication about follow up and effective coordination of any follow-up actions are essential.

Tracking to Ensure That Follow Up Has Occurred

Appropriate tracking must be in place to ensure that follow up has occurred. This involves making adequate documentation, reminders to resolve outstanding issues or patient questions, having a system for patient callback and reminders, and taking actions to obtain patient feedback.

OVERCOMING BARRIERS TO THE PERFORMANCE OF CBE

The recommendations forwarded by the committee to address barriers to proficient CBE focus on examiner training, public education, and research and quality improvement.

4. Examiner Training:

Develop and promote training systems to improve and maintain the proficiency of those who perform CBE, and encourage the integration of such systems into basic and continuing education programs health care professionals.

Lead responsibility for implementation: health care organizations.

CBE training should build on existing training programs designed to improve CBE proficiency and include the components described below. In addition, training programs should be made more available, and these programs integrated into medical and nursing school curricula, programs for residents and fellows, and continuing medical and nursing education. Expanding the availability of training will require collaborative efforts among clinicians, health organizations, and the community.

Training Components

Didactic Presentation

Training should include a didactic presentation that:

- Provides basic information on the anatomy and physiology of the breast.
- Provides the rationale for performing CBE through background information on breast health and disease.
- Identifies and describes elements of standard CBE—clinical history, visual inspection, palpation, interpretation and reporting, and follow-up of abnormal results to resolution.

Visual Presentation

Training also should include a visual, real-time CBE performance—either a video or demonstration—so that trainees can see correct CBE techniques.

Practice and Feedback

Finally, and no doubt most important, trainees should have an opportunity to practice CBE skills and to obtain feedback from experienced examiners. This skills-building element should involve the use of high-quality silicone models and, if possible, instructors posing as patients. Live models provide a more realistic clinical experience, allow training in components of CBE beyond palpation, provide palpation experience with breast tissue, and can provide valuable feedback about provider-patient interactions. If instructors are not available to pose as patients during the initial training, training programs should develop a plan for ensuring that trainees are given skills practice on live models with feedback in the near future. Training also must include measuring and demonstrating adequate levels of sensitivity and specificity of lump detection.

Training Characteristics

Training Should Be Flexible to Accommodate Diverse Settings and Trainee Needs

Training programs should be tailored to suit a variety of settings, including basic medical education, residency, fellowship, nursing edu-

cation, and continuing medical education. Training in all three components—the examination, interpretation and reporting, and follow up—may not be possible to complete in one session or a brief series of sessions. It may be more effective in some cases to divide training into phases so that examiners can improve their skills in each component through successive sessions.

Participation in Training Should Be Incentive Based

Training and retraining programs need to provide incentives for health care professionals to participate, such as continuing education units, information and skills for clinicians, and certification that might reduce the clinician's risk of successful malpractice claims.

Training Should Offer General Guidance on Follow Up That Focuses on Resolution of Findings

The level of detail in instruction about appropriate follow up may vary across the trainee's profession and the setting. The fundamental training principle is that providers must follow the patient to resolution or refer her to another health care professional, depending on the complexity of the problem. Within established standards of care, algorithms that are appropriate to the examiner's health care system/institution can direct specific actions.

Sponsoring Institutions Should Develop Strategies to Increase the Number of Qualified Trainers

As the demand for CBE training grows, we must ensure that a sufficient supply of qualified trainers is available. Furthermore, because CBE is a tactile skill and didactic instruction alone is insufficient, institutions will need to help potential instructors become skilled at behavioral and skill-based teaching techniques, including providing constructive and motivating feedback.

Training of Trainers Should Have Four Core Elements

The four core elements of training should be:

- Teaching all components of CBE.
 - Encouraging consistent performance of a standardized exam as necessary for providing a quality CBE.
 - Providing the necessary information for interpreting CBE findings.
 - Teaching new skills and improving existing skills.
5. Public Education

Promote and encourage public education about CBE so that women:

- a. Know what to expect in the performance of CBE and follow-up care.
- b. Understand the benefits, limitations, and potential harms associated with CBE.
- c. Become familiar with their own breast characteristics as well as health practices that might increase the likelihood of identifying breast abnormalities.

Lead responsibility for implementation: health care organizations.

Many women are not aware that many health organizations recommend CBE in addition to regular mammograms, and most do not know what to expect in a CBE. Being informed and educated will help women become active partners with their provider in their own health care decisions. Professional organizations play a valuable role in influencing their members to follow current guidelines as a component of comprehensive breast cancer screening. Public education messages about CBE should be part of a wider effort to promote informed health care decision-making among women. Messages should be simple, clear, and tailored to different groups of women, if possible. CBE is an opportunity for dialogue between women and their providers and should parallel education about the importance of women understanding their own normal breast characteristics.

Public education efforts should convey the following messages:

- Why CBE can be important.
 - It contributes to the detection of palpable breast cancers and other breast abnormalities.
 - It offers a test for detecting palpable breast cancers at an earlier stage of progression; it adds to, but does not replace, mammography.
 - However, its contribution to the detection of breast cancer among asymptomatic women is relatively small. Not all organizations recommend CBE.
 - What should be expected in a proficient CBE.
 - Components include careful visual inspection and palpation of the breast and lymph nodes.
 - It provides a trained examination and an opportunity for patient/provider interaction about breast health.
 - What should happen if an abnormality is identified.
 - Follow up should be conducted to an appropriate resolution.
 - Follow up is required for an abnormal CBE regardless of the results from the mammogram.
 - What a woman can do to improve the quality of her CBE.
 - Provide a complete history.
 - Adhere to a schedule of appointments.
 - When screening CBE should be performed.
 - Premenopausal women.
 - These women should be screened as part of a periodic health examination according to screening guidelines.
 - If possible, screening should be a week or two after a woman's period to avoid breast tenderness and shortly before her mammogram.
 - Postmenopausal women.
 - These women should be screened as part of a periodic health examination according to screening guidelines.
 - If possible, screening should be shortly before a woman's mammogram.
 - Pregnant and breastfeeding women.
 - These women should be screened as part of a periodic health examination according to screening guidelines.
 - These women might expect increased breast tenderness and nodularity.
6. Research and Quality Improvement
- Support and encourage research in key aspects of CBE, particularly questions related to characteristics of abnormalities found by CBE, the timing of the exam, training of examiners (clinicians), reporting systems, and CBE's contributions to early detection of breast cancer and the reduction of morbidity and mortality from the disease.
- Lead responsibility for implementation: health care organizations and research sponsoring organizations.*
- The evidence regarding many aspects of CBE is insufficient. Standardized performance, reporting, and follow up, combined with reporting and surveillance systems, could provide the foundation for assessing the relative contributions of CBE to the earlier detection of breast cancer. Such information may enable more accurate estimates of sensitivity and specificity of CBE in clinical practice settings. Information about the number of cancers first identified by CBE, particularly as a function of age and other population characteristics, could help clarify the role of this examination as a component of early detection and the most effective use of CBE relative to other screening modalities. Such data might also be used to assess the costs and benefits of CBE as an early detection test. This type of information is essential to resolving the confusion engendered by having disparate practice guidelines across organizations. Furthermore, such data could provide the basis for further enhancements in training providers to be proficient in CBE.
- Research Needs:
- CBE characteristics.
 - Sensitivity and specificity.
 - In clinical practice.
 - Among women at different ages (premenopausal, perimenopausal, postmenopausal).
 - Method of initial detection of abnormalities.

- CBE, mammography, BSE.
- By woman, partner, provider.
- Characteristics of masses identified.
 - Size, shape, consistency, mobility, external texture.
- Timing.
 - Effect of examination performance at different times of the menstrual cycle on sensitivity and specificity.
 - Effect of dissociating CBE from other screening modalities for breast cancer.
- CBE training.
 - Components of optimal training.
 - Optimal frequency.
 - Systems for integrating CBE training with other medical/health care training.
 - Characteristics of effective trainers.
 - Measurement of training effectiveness.
- CBE reporting systems.
 - Acceptability of using a uniform or standardized lexicon for reporting.
 - Feasibility of expanding medical records or registry databases to include information about detection of breast abnormalities by CBE.
- Contribution to the earlier detection of breast cancer and reductions in breast cancer mortality.

CONCLUSION

CBE can contribute to the ability of health care professionals and women to detect some breast cancers and should lead to appropriate follow-up care. The committee recognizes

that these recommendations are a first step in an incremental process of change and that many organizations and groups should be involved in defining and conducting such a process. Rather than develop a set of detailed algorithms and recommended procedures, the members chose to articulate a smaller group of general recommendations that embody several key themes and principles. In addition to appearing in this publication, these recommendations and accompanying text have been distributed to a wide range of stakeholders and interested parties to serve as a catalyst for further discussion and action. These recommendations provide a strong foundation for informing clinical practice, professional training, public education, and research efforts.

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