

# Performance and Reporting of Clinical Breast Examination: A Review of the Literature

Sharon McDonald; Debbie Saslow, PhD; Marianne H. Alciati, 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, when treatment is more effective and treatment options are greater than for later stage disease. Evidence suggests that, for some women, CBE can be an important complement to mammography in the earlier detection of breast cancer; CBE identifies some cancers missed by mammography and provides an important screening tool among women for whom mammography is not recommended or women who do not receive high-quality screening mammography according to recommended guidelines. But CBE performance and reporting approaches are inconsistent. Health care providers indicate that they are not confident in their CBE skills and would welcome training. Studies demonstrate that training can enhance CBE performance, measured in terms of execution of CBE components and accuracy. This literature review provides evidence to the extent that it is available, to support the specific recommendations of Saslow, et al.<sup>1</sup> for optimizing CBE performance and reporting and to guide further research on CBE performance characteristics, reporting systems, barriers to high-quality CBE performance, and training. (*CA Cancer J Clin* 2004;54:345-361.) © American Cancer Society, Inc., 2004.

**Ms. McDonald** is Consultant, Management Solutions for Health, Inc., Raleigh, NC.

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

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

This article is available online at <http://CAonline.AmCancerSoc.org>

## INTRODUCTION

This literature review provides supplemental evidence for the American Cancer Society and the Centers for Disease Control and Prevention collaboration to develop recommendations for optimizing clinical breast examination (CBE) performance and reporting. The literature used to develop this review was identified through a PubMed search from January 1990 through September 2003 using the search terms “physical examination AND palpation AND breast” and was limited to articles in English. Literature identified in the reference lists of several key articles, as well as referrals from experts in the field, also were included. This review explores the contribution of CBE as a screening method for the early detection of breast cancer; however, it does not specifically address CBE’s effectiveness in reducing mortality from breast cancer. The latter issue was addressed by the American Cancer Society as part of a separate review of its breast cancer early detection guidelines.<sup>2</sup>

## CBE’S CONTRIBUTIONS TO THE EARLY DETECTION OF BREAST CANCER

CBE seeks to detect palpable breast cancers at an earlier stage of progression, when treatment is more effective and treatment options are greater than for later stage disease.<sup>2</sup> Mammography’s ability to identify cancers before they become palpable, evidence demonstrating screening mammography’s contributions to reductions in breast cancer mortality, and the lack of randomized trials demonstrating CBE’s independent contributions to reduced mortality have raised questions about the value of CBE as a screening tool for breast cancer.<sup>2</sup> Historically, a significant number of breast cancers were detected by CBE alone.<sup>3,4</sup> But today among women who receive regular screening with high-quality mammography, it is less clear how important CBE is in the early detection of breast cancer. CBE may

contribute to the earlier detection of breast cancer in women under the age of 40, for whom mammography is not recommended, in women who are not adherent with recommended guidelines for various reasons, and among women who participate in regular screening. However, apart from the general observation that smaller tumors have better prognosis than larger tumors,<sup>5</sup> the impact of CBE on extending survival or reducing breast cancer mortality is not known. Given this level of uncertainty, most screening guidelines either recommend CBE as a complement to mammography,<sup>2,6-9</sup> or do not recommend for or against its use.<sup>10</sup>

#### **Detection of Cancers Not Found by Mammography**

Several studies have evaluated the proportion of cancers identified by CBE that were not detected by mammography. The highest levels were in older studies and/or where mammography sensitivity was lower than that attained by current technology.<sup>3,11-13</sup> Of the most recent studies, three showed 4.6% to 5.7% of cancers were identified by CBE alone<sup>14-16</sup> and a fourth showed 10.7% of cancers identified by CBE alone.<sup>17</sup>

In a study of women aged 50 and over who were diagnosed with breast cancer between 1988 and 1991 in Wisconsin, before the time that mammography was recommended for women in their forties, 10.7% of cancers were reported by women as initially detected by CBE.<sup>17</sup> In a second study, 5.7% of breast cancers diagnosed between 1988 and 1994 were found by CBE alone as reported in medical records.<sup>16</sup> However, it has been postulated that these reported detection rates may overestimate the true detection rate of CBE alone, primarily because many women present to their physician for physical examination after identifying a breast abnormality themselves.<sup>2</sup> A third study assessed outcomes for over 300,000 women aged 50 to 69 screened by CBE and mammography in four Canadian-organized breast cancer screening programs between 1996 and 1998.<sup>14</sup> In addition to mode of detection, Bancej and colleagues measured referral rates,

positive predictive value, and pathological features of tumors. CBE alone detected 4.6% (first screen) to 5.9% (subsequent screen) of cancers, increasing the rate of detection of small invasive cancers by 2% to 6% over mammography alone. The authors calculated that without CBE, 30 invasive cancers would be missed for every 100,000 screening examinations and 3 to 10 small ( $\leq 10$  mm) invasive cancers would be missed for every 100,000 screens.<sup>14</sup> In comparison, they determined that without mammography, 250 to 310 invasive cancer would be missed for every 100,000 screening examinations, and 136 to 142 of these would be  $\leq 10$  mm.

An assessment of CBE performed in community settings from 1995 to 1998 as part of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which provides annual mammography and CBE to uninsured and underinsured women aged 40 and over, found that 5.1% of malignancies were detected by CBE in patients having a negative, benign, or probably benign mammography finding.<sup>15</sup> This is comparable to the findings of Bancej, et al.<sup>14</sup>

One population-based analysis, relying on women's recall of the method of breast cancer detection, found that the proportion of breast cancers detected by CBE (9.3%) was lower than either the proportion of cancers that were self-detected (71.2%) or the proportion identified by mammography (19.6%) among women aged 20 to 44 years.<sup>18</sup> This study suggests that even in young women, CBE appears unlikely to make a large, independent contribution to breast cancer early detection. Nevertheless, over 200,000 women are diagnosed with invasive breast cancer in the United States each year.<sup>19</sup> If approximately 5% of these are detected by CBE alone, then approximately 10,000 otherwise undetected cancers may be identified each year through the use of CBE. CBE might play a particularly important role in identifying cancers during periodic health visits among the significant proportion of women who are not adherent to mammography screening guidelines, but see their primary care provider on a regular basis.

### Sensitivity and Specificity

The sensitivity and specificity of CBE have been estimated based on data from large screening studies, a nationwide community-based program, and a managed care organization. Barton and colleagues<sup>20</sup> examined screening data from the Health Insurance Plan of New York Study (1963–1966), the United Kingdom Trial (1979–1988), the Breast Cancer Detection Demonstration Project (1973–1981), the West London Study (1973–1977), National Breast Screening Study (NBSS) 1 (1980–1988), and NBSS2 (1980–1988). NBSS2 was the only randomized, controlled screening trial in which the control group used CBE as a sole screening modality among women aged 50 to 59 years.<sup>13</sup> These authors defined sensitivity as the number of cancers detected by CBE (true positives) divided by the sum of cancers detected by either CBE or mammography plus interval cancers diagnosed within 12 months after screening (true positives + false negatives).<sup>20</sup> The number of interval cancers often is considered to be an index of the effectiveness of a screening program, although these cancers include some that likely become detectable only after screening, as well as those that are missed at screening due to breast density, technical shortcomings, or failure to perceive a visible abnormality.<sup>21</sup> Specificity was defined as the number of women with normal CBE results who did not develop breast cancer within 12 months after screening (true negatives) divided by the total number of women without cancer within 12 months after screening (true negatives + false positives).<sup>20</sup>

Pooling data for the six studies examined by Barton and colleagues resulted in an overall estimate of 54.1% for CBE sensitivity and 94.0% for CBE specificity.<sup>20</sup> These estimates are comparable to the recently published values for CBE sensitivity (58.8%) and specificity (93.4%) observed in the NBCCEDP.<sup>15</sup> This study suggests that CBE in such community-based programs can detect breast cancer at least as effectively as CBE performed in screening trials and demonstration programs. However, it should be noted that the sensitivity values in the screening trials are inflated by the fact that they reflect mammography done with older technology and at wider

screening intervals, thus allowing tumors to grow larger in the interscreening interval. Further, the values do not distinguish between prevalent (first) and incident (subsequent) screens. Even in the more modern example of the NBCCEDP, the majority of the data were based on women with only one screening record. In contrast, a study of one managed care organization<sup>16</sup> found lower overall sensitivity levels, with a large range depending on patient and tumor characteristics including patient age (range, 26% to 48%), tumor size (range, 17% to 58%), ethnicity (range, 35% to 88%), body weight (range, 23% to 48%), menopausal status (range, 31% to 33%), and hormone use (range, 33% to 52%).

While emphasis often is placed on achieving high sensitivity, achieving high CBE specificity is important in minimizing the risk of false positive results and the consequent unnecessary medical procedures and stress for patients. Although mammography has received extensive scrutiny and criticism for the number of false positive results it generates, CBE was estimated in a 10-year retrospective study of screening through an HMO's health centers to result in somewhat lower rates of false positive results (CBE, 3.7%; mammography, 6.5%).<sup>22</sup> These results for CBE and mammography may not necessarily apply to other populations or more current mammography technology; nevertheless, the data underscore the relative rates of specificity across screening methods.

### Survival

Data clearly indicate that the survival time of women with invasive breast cancer is inversely associated with tumor size, independent of the method of detection (Table 1).<sup>5</sup> Studies also have demonstrated an inverse relationship between tumor size and detection by CBE;<sup>23,24</sup> smaller tumors are more difficult to detect and CBE can only find cancers that have grown to a palpable size. However, physicians can detect lumps as small as 3.0 mm by CBE,<sup>25</sup> well within the size range for which a survival advantage has been demonstrated. Further, studies have shown that training can increase CBE sensitivity to detect lumps in silicone breast models<sup>26,27</sup> and that training using silicone breast models can increase

TABLE 1 Breast Carcinoma by Tumor Size\*

Tumor size (mm)	Surviving Patients (%)†		
	van Nuys (≈ 1980–1990)	Tabar, et al. (1977–1985)	Tubiana, et al. (1954–1972)
10–14	86	87	—
15–19	72	80	—
20–29	67	55	—
30–49	46	44	—
10–25	75	—	73
26–35	53	—	58
36–45	—	—	44
46–55	—	—	34
56–65	—	—	22
66–75	—	—	17
76–85	—	—	19
86–95	—	—	8

\*Adapted from Michaelson, et al.<sup>5</sup>

†van Nuys data, 15-year survival rates; Tabar, et al. data, 13.3-year survival rates; Tubiana, et al. data, distant metastatic disease at 25 years (assumed equivalent to survival). References and methods related to the van Nuys data, Tabar, et al. data, and Tubiana, et al. data are found in Michaelson, et al.<sup>5</sup>

detection of small known benign lumps in natural breast tissue.<sup>28</sup> Thus, it is reasonable to suggest that increased proficiency in CBE that leads to detection of smaller tumors may contribute to enhanced survival from breast cancer.

#### THE EXAMINATION

The examination techniques for CBE have been described and illustrated in diagnostic textbooks,<sup>29</sup> as well as several relatively recent reviews.<sup>20,30–33</sup> Although these descriptions vary in some details of how to perform a CBE and few address how to report CBE results, all include visual inspection of the breasts and palpation of the breasts and lymph nodes as central components of the examination.

#### Visual Inspection

Visual inspection seeks to identify physical signs of breast cancer. Early signs of breast cancer include subtle changes, such as either flattening of breast contour or areas of fullness or thickening evident in one breast but not in the other. In a diagnostic CBE, the examiner looks for all signs of advanced disease by comparing the breasts for major asymmetry and differences in skin color, texture, temperature, and venous patterns. Particular attention is given to any rashes, discoloration,

visible lumps, swelling, or nipple discharge. 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.<sup>30</sup> Many descriptions of visual inspection suggest that women change the position of their arms to accentuate asymmetries in breast shape and contour and in thickening of breast tissue, particularly for identifying subtle changes associated with early breast malignancy.<sup>30,31</sup>

Beyond descriptive reports, however, few studies have evaluated the independent contributions of visual inspection to the early detection of breast cancers. Some older studies indicate that visual inspection alone identifies only a small percentage of breast cancers, even in symptomatic women. In a 1982 Canadian case series, only 4% (11 of 286) of breast cancers were identified by visual inspection alone—1% by retraction (skin or nipple) and 3% by nipple abnormality.<sup>34</sup> In a 1990 Australian study, 13% (22 of 169) of breast cancers (with no palpable lump) were identified through observable symptoms that included inverted nipple, swollen arm, alteration in breast shape, ulcer, breast swelling, skin retraction, Paget's disease, and nipple discharge.<sup>35</sup> These are both small studies, and what accounts for these differences and their significance is unclear.

No studies have assessed the influence of position on CBE accuracy, as measured by sensitivity and specificity. And no studies have evaluated the relative contributions of different arm positions to the identification of breast cancers during visual inspection, described variously as arms relaxed at sides, arms raised over head, and hands pressed at hips. Barton and colleagues, noting the lack of data on visual inspection and arm positioning, as well as the time constraints of clinical practice, recommend a practical approach emphasizing palpation while still visually inspecting the breast and increasing attention to visual inspection in the event of an abnormality.<sup>20</sup>

### Palpation

At its simplest, palpation involves using the fingers to physically examine all areas of breast tissue and the lymph nodes to identify lumps that might be cancer. During palpation, lumps that are discrete and differ from surrounding tissue are identified. These lumps might move within the tissue, feel fixed within the tissue, or even be visible. Subtle findings are more difficult to interpret. Such findings may include areas that do not move or compress as anticipated or that are asymmetric relative to the other breast, such as asymmetric thickening of breast tissue or slight asymmetry of breast contour.<sup>36</sup> Descriptive studies consistently indicate that palpation of lymph nodes should extend above and below the clavicles and axillary nodes (lateral, central, subscapular, pectoral), and that lymph node palpation should be performed while the woman is in a sitting position.<sup>30,31</sup> No studies have examined the relationship between lymph node palpation characteristics and sensitivity or specificity in finding lumps.

In terms of breast palpation, the most widely published and studied technique is the MammaCare method, developed by Penny-packer and colleagues.<sup>33,37</sup> This method describes positioning of the breast such that the breast tissue is flattened over the chest wall, facilitated by a supine position with arm over head, and palpating the full area that extends vertically from the midaxilla to the rib just

beneath the breast, and continuing horizontally along the underside of the breast to the midsternum, up the midsternum to the clavicle, across the clavicle to the shoulder, and back to the midaxilla.<sup>38</sup> The finger pads of the middle three fingers move in dime-size circular motion, applying three levels of pressure at each point along a vertical strip search pattern.

Published techniques other than the MammaCare method differ in how many and in what way CBE components are performed. For example, one article on CBE presented as a topic in primary care medicine suggests that palpation can be done by using two or three fingers in circular motions with varying pressure, rolling tissue between two fingers, sliding the fingers over the surface of the breast, or using some combination of these.<sup>31</sup> This same article states that CBE is a rapid procedure that can be carried out in 2 or 3 minutes, even though the comprehensive examination procedure presented seems to contradict that claim. Another article describing CBE emphasizes that palpation of the breast should be very gentle, because the tactile sense is greater with gentle palpation, but offers no supporting data.<sup>39</sup> Several articles either advise using the flat of the fingers for palpation<sup>32,39</sup> or do not indicate what part of the finger to use.<sup>31</sup> In this context, it is not surprising that standardization of CBE performance, particularly palpation, has eluded clinical practice.

The contribution of various palpation components to CBE effectiveness, including the extent of area examined, position of the breast tissue, type of finger motion, part of the finger, number of fingers, pressure, search pattern, and duration of search have been the focus of several investigations. Most of these studies have used silicone breast models to simulate the human breast; many have used the standardized research and evaluation set manufactured by the MammaCare Corporation, enhancing the degree of comparison that can be made across studies.<sup>38,40</sup> This research and evaluation set includes six silicone breast models containing 18 standardized lumps that vary in size (0.3, 0.5, or 1.0 cm), hardness (20, 40, or 60 durometers, with 60 being the hardest), and depth of placement (medium or deep). (Note that the

MammaCare training sets include lumps at three depths—surface, medium, and deep). One lump of each size and firmness is located at each of the two depths. One model in each set contains no lumps; each of the other five models contains between one and five lumps. The breast models can be made in three grades of softness and three grades of nodularity. Generally, in studies with these models, sensitivity is defined as the percentage of correctly identified lumps and specificity is defined as the proportion of models in which no false positive findings occur. Findings in a study by Hall and colleagues<sup>28</sup> provide evidence that detection skills learned on silicone breast models can be effectively applied to patients.

A study by Fletcher and colleagues<sup>41</sup> found that CBE technique variables accounted for 27% to 29% of the variance in sensitivity of lump detection and 14% to 33% of the variance in specificity. In several training-related studies, examiners who correctly used more components of the MammaCare method after training showed improved lump detection.<sup>26,42–44</sup> One analysis of four studies using silicone breast models found consistently across each study that examiners who had test sensitivities above the group median used a significantly larger number of correct components than examiners having test sensitivities below the group median.<sup>20</sup> All of these studies defined correct palpation technique as including use of circular motion, finger pads, three fingers, variable pressure, and vertical search pattern. Examiners in these studies included women patients, medical students, medical residents, and practicing physicians.

Although evidence supports the combined contributions of palpation components, limited information exists regarding the individual contributions of palpation components to sensitivity and specificity. Duration is perhaps the component most consistently shown to have a positive relationship to exam sensitivity and specificity. Multiple regression analysis in one study of lump detection in silicone breast models found a highly significant correlation between duration and lump detection ( $r = 0.59$ ,  $P \leq .01$ ). It was estimated that a one-minute increase in mean search duration per model

would result in 1.8 more lumps being detected overall (higher sensitivity), but likely also would result in more false positives (lower specificity).<sup>25</sup> The observed mean search duration per silicone model was 1.9 minutes (range, 0.7 to 3.7 minutes) in this study. In other studies, increased search duration on breast models was correlated with higher sensitivity and lower specificity for physicians ( $r = 0.55$ ,  $r = -0.59$ , respectively),<sup>41</sup> trained nurses (sensitivity,  $r = 0.30$ ; false positives,  $r = 0.36$ ),<sup>45</sup> and untrained women ( $r = 0.46$ ,  $r = -0.33$ , respectively).<sup>41</sup>

Thus, duration of breast palpation appears to reflect a balance between enhancing sensitivity and reducing specificity. No studies have provided evidence supporting an optimal palpation timeframe. Coleman and colleagues<sup>30,46</sup> recommend about 1 second per circular motion at each of three depths for each point along a vertical strip search pattern. Pennypacker and Pilgrim<sup>33</sup> recommend eight or nine vertical strips to fully cover a teaching breast model, assumed to reflect an average size breast. Based on these parameters, a search pattern of eight strips and eight areas of palpation per strip would require 3.20 minutes ( $8 \times 8 \times 3$  seconds / 60 seconds/min) to complete, and a search pattern of nine strips and nine areas of palpation per strip would require 4.05 minutes ( $9 \times 9 \times 3$  seconds / 60 seconds/min) to complete. This calculation suggests that the time required to examine both breasts of an average patient would range from about 6 to 8 minutes.

Studies of the independent contributions of each of the other components of palpation (extent of area examined, position of the breast tissue, type of finger motion, part of the finger, number of fingers, pressure, and search pattern) have provided some support for completeness of search, position, variable pressure, and search pattern in enhancing test sensitivity. Chalabian and Dunnington,<sup>47</sup> studying graduating primary care physicians' execution of CBE components in standardized patient encounters and lump detection in breast models, found small but significant correlations between sensitivity and supine position/arm overhead ( $r = 0.31$ ) and systematic palpation ( $r = 0.39$ ); no corre-

lations were found with specificity. Fletcher and colleagues<sup>25</sup> found that physicians who used a consistent search pattern, did a complete search, and used variable pressure had slightly higher detection rates ( $P \leq .20$ ) in a set of six silicone breast models, compared with physicians who did not execute these palpation components. Unexpectedly, this same study found that physicians who used fewer than three fingers ( $P \leq .05$ ), used a noncircular motion ( $P \leq .20$ ), and used their fingertips ( $P \leq .20$ ) appeared to have slightly higher detection rates.<sup>25</sup> Interestingly, however, about twice as many physicians in this study used these latter palpation components compared with the number using three fingers, circular motion, and finger pads,<sup>34</sup> potentially confounding statistical findings.

As discussed above, both the Chalabian and Dunnington<sup>47</sup> and Fletcher, et al.<sup>25</sup> studies found support for the contribution of a consistent search pattern to enhanced sensitivity. However, neither study described the specific pattern of a systematic search. Only one study has compared different search patterns, including vertical strips, radial spokes that converge at the nipple, and concentric circles, in relationship to completeness of search. Saunders and colleagues<sup>37</sup> measured breast self-examination thoroughness by using a numbered grid projected on the woman's chest and an observer to mark each square of the grid palpated on an identical score sheet. In this study, the vertical strips pattern significantly increased search proficiency compared with the radial spokes pattern (67.9% versus 44.7%, respectively) or the concentric circles pattern (64.4% versus 38.9%, respectively). Further, each of the four studies included in the Barton, et al.<sup>20</sup> analysis that showed a correlation between use of correct palpation technique and increased sensitivity used the vertical strip pattern. The NBSS1 and NBSS2 screening trials also used the vertical strip search pattern.<sup>12,13</sup>

#### Interpreting and Reporting Results for CBE

At present, no standardized system exists for interpreting and reporting the results of CBE. Only a few of the articles identified that de-

scribe techniques for carrying out CBE address how to interpret and report findings. One author states, "any deviation from expected findings requires further assessment."<sup>31</sup> Other studies suggest that CBE findings should be recorded on a simple breast diagram included in the patient's notes.<sup>32,39</sup> The information recorded should include "general comments regarding breast size, consistency, scars... details of any lumps, including size, shape, consistency, mobility, tenderness, and fixation to skin or muscle... and the exact position should be described in terms of the clock face and distance from the nipple."<sup>32</sup>

#### TUMOR, PATIENT, AND EXAMINER CHARACTERISTICS THAT INFLUENCE CBE ACCURACY

In addition to performance characteristics associated with visual inspection and palpation, studies indicate that tumor, patient, and examiner characteristics all influence CBE sensitivity and specificity.

#### Tumor Characteristics

The size, firmness, and location of breast tumors affect the ease or difficulty of detection. The easiest tumors to detect are those that are large, firm, and near the surface. The most difficult tumors to detect are those that are small, soft, and deep within the breast tissue. Data from studies using MammaCare breast models support associations of lump size, firmness, and location with sensitivity and specificity of detection.<sup>25,40,42-45</sup> For example, in one study, physicians detected more 1.0-cm lumps than 0.3-cm lumps (87% versus 14%, respectively) and more hard lumps than medium or soft lumps (56% versus 36% and 40%, respectively). No differences were observed for detection of lumps at medium and deep depths (44%).<sup>25</sup> Overall, the 1.0-cm hard lump was easiest to detect (94%) and the 0.3-cm soft lump was the most difficult to detect (4%); none of the 80 physicians in the study detected the 0.3-cm, soft, deeply placed lump. A more recent study, also using the MammaCare evaluation set of silicone breast models, reported

that the sensitivity of detection decreased from 78% to 38% for 1.0-cm versus 0.3-cm lumps, from 61% to 52% for hard versus soft lumps, and from 63% to 53% for medium depth versus deep lumps.<sup>40</sup>

Patient data confirm the importance of tumor size in CBE accuracy. A study of breast cancer patients reported a CBE sensitivity of 94% for tumors larger than 2 cm, but a significantly smaller CBE sensitivity of 80% for tumors smaller than 2 cm.<sup>24</sup> CBE sensitivity assessed among women in a managed care organization's breast cancer screening program found 17% sensitivity for tumors  $\leq 0.5$  cm and 58% for tumors  $\geq 2.1$  cm.<sup>16</sup> In a retrospective study carried out to examine why breast cancers were missed in patients during screening, no tumor less than 0.5 cm was clinically palpated; 19%, 48%, and 82% of tumors were palpated for increasing tumor sizes of 0.6 to 1.0 cm, 1.1 to 1.5 cm, and 1.6 to 2.0 cm, respectively. Invasive cancers were more easily palpated than in situ cancers—for example, 86% versus 45% for cancers ranging in size from 1.6 to 2.0 cm.<sup>24</sup> Overall, only 58% of breast cancers in this study were palpated. It is important to note that little is known about the possible relationship between tumor pathology and tumor density; it may not be possible to palpate some malignancies, regardless of their size.

#### Patient Characteristics

Two characteristics of woman's breast tissue, density and nodularity, have received the greatest attention in terms of their relationship to CBE accuracy. Breast density has been linked to menopausal status, with more fatty, less firm breast tissue frequently associated with postmenopausal breasts, and less fatty, more firm breast tissue associated with premenopausal breasts. Lump detection might be expected to be more difficult in premenopausal women, and many studies on CBE, especially those using MammaCare models designed to simulate premenopausal and postmenopausal breast tissue, make this observation. Women also have varying degrees of background nodularity, or "lumpiness," in their breast tissue. As

with breast density, nodularity is related to age and is more common in younger women. A smooth breast with no lumpiness is very uncommon; also, a breast with multiple hard lumps is very uncommon. Most women fall between these extremes, with some diffuse lumpiness over the whole breast. This type of lumpiness and risk of breast cancer are not correlated.<sup>31</sup> In women whose breasts have a high degree of background lumpiness, screening with CBE is thought to result in more false positives and consequently lower specificity.<sup>23</sup>

In a study that used MammaCare silicone breast models to investigate the effect of differences in breast density and nodularity on lump detection by physicians, one set of breast models with the least firmness and least nodularity was used to simulate the breast tissue of postmenopausal women, whereas another set of models with the greatest firmness and most nodularity was used to simulate the breast tissue of premenopausal women.<sup>40</sup> Overall, detection sensitivity was significantly lower for models simulating premenopausal tissue (51%) than for models simulating postmenopausal tissue (64%). Generally, sensitivity increased with lump size and firmness in both simulated premenopausal and postmenopausal tissues; sensitivity decreased with depth in simulated premenopausal tissue, but not in the softer postmenopausal tissue. Detection specificity was significantly higher for simulated premenopausal tissue (82%) compared with simulated postmenopausal tissue (73%).

While menopausal status establishes a marked distinction between greater and lesser nodularity, there still is considerable variation in both breast density and composition in pre- and postmenopausal women. To illustrate, in a study of 1,353 women aged 25 to 79 years, parenchymal breast density progressively decreased with age overall. Nevertheless, 38% of women aged 25 to 39 years had predominantly fatty breast tissue ( $< 50\%$  parenchymal tissue), and 14% of women aged 50 to 79 years had very dense breast tissue ( $\geq 90\%$  dense parenchymal tissue).<sup>48</sup> Also, no significant changes in density of parenchymal breast tissue were observed at either menopause or at age 50, often used as a proxy for menopause. It is important to note here that the parenchymal density of



the breast, which can be assessed only by mammography, does not correlate with the actual firmness and degree of compressibility of the breast tissue, which are characteristics relevant for CBE.<sup>48</sup>

CBE sensitivity also is influenced by menopausal status. Consistent with the observed pattern in simulated pre- and postmenopausal breast models (ie, models that include masses and are used for teaching technique), examinations of 201 women with solid palpable breast masses observed that CBE sensitivity was lower in premenopausal women (70%), intermediate in perimenopausal women (87%), and greatest in postmenopausal women (93%). Statistical significance was achieved only when premenopausal and perimenopausal groups were combined and compared with postmenopausal women.<sup>23</sup> While these data appear to be inconsistent with findings from NBSS1,<sup>12</sup> NBSS2,<sup>13</sup> and NBCCEDP<sup>15</sup>—which used age as a proxy for menopausal status and found that CBE had a higher sensitivity among premenopausal (aged 40 to 49 years) compared with postmenopausal (ages 50–59 years) women—these studies were designed to address very different questions, and criteria for patient inclusion differed considerably across studies. The van Dahm study was a retrospective analysis of the correlation between screening examination results (CBE, mammography, ultrasound, thermography) and histological findings, and included only those women with a palpable mass on CBE in whom biopsy was performed within 1 month of additional imaging tests. The NBSS1 and NBSS2 studies were randomized, controlled screening trials. The NBSS1 study provided only a single CBE, thus the CBE sensitivity presented was for participants screened by CBE without mammography. An initial screening examination will have higher sensitivity because it will detect prevalent cancers. The NBCCEDP is a community-based screening program providing both CBE and mammography. The use of age as a proxy for menopausal status also may confound assessment of the independent effects of menopause on CBE accu-

racy. Oestreicher and colleagues<sup>16</sup> observed an inverted U shape association between age and CBE sensitivity (aged 40 to 49, 26% sensitivity; aged 50 to 59, 48% sensitivity; aged 60 to 69, 36% sensitivity; aged 70 to 79, 33% sensitivity; aged 80+, 18% sensitivity). However, these findings are based on cancers that were missed by mammography as well as CBE, and thus are influenced by the accuracy of mammography for each of the age groups.

Goodson and Moore<sup>49</sup> recently assessed delay in diagnosis as a function of “durty” of breast tissue, referring to compression during palpation, and nodularity. Delay based on palpation alone (failure to detect a mass or identify a mass as benign, not requiring follow-up) was least common in breasts of less durty and less nodularity and greatest in breasts of less durty and more nodularity. Delay also was less common in breasts of more durty and more nodularity compared with breasts of more durty and less nodularity, suggesting that nodularity may be a greater influencing factor in lump detection and interpretation than durty.

Other patient characteristics associated with differences in CBE sensitivity include body weight, hormone use, and race. Oestreicher and colleagues<sup>16</sup> found that CBE sensitivity decreased with increased body weight (48% sensitivity for the lowest weight quartile and 23% for the highest weight quartile). Additionally, this study found that CBE was more sensitive in Asian women compared with white women (88% versus 33%, respectively). The picture for hormone use is less clear. Oestreicher and colleagues<sup>16</sup> observed higher CBE sensitivities among current versus noncurrent users of estrogen and progesterone combination therapy (52% current versus 33% noncurrent users). But a retrospective review of medical records of postmenopausal women with breast cancer found that those who had ever taken hormone replacement therapy (HRT) were less likely to have had their cancer identified by palpation compared with mammography; non-HRT users in this study were more likely to have had their cancer identified by palpation.<sup>50</sup> It is not clear how these findings may have been affected by differences in

the screening behaviors of women who use HRT and women who do not.

#### Examiner Characteristics

It is difficult to compare the performances of examiners across studies, because of study differences in methods (CBE performed on women versus breast models) and guidelines for evaluating CBE proficiency. Some comparisons, however, can be made among studies that used silicone breast models to determine proficiency. Also, some studies provide data that allow examiner proficiency to be compared within studies.

Fletcher and colleagues<sup>25</sup> reported that the mean number of lumps detected in silicone breast models varied by physician specialty as follows: general medicine, 50%; family medicine, 46%; general surgery, 42%; and obstetrics/gynecology, 40%. Detection varied across physicians in this study from 17% to 83% of lumps. In other studies, primary care physicians in an office setting detected only 24% of the lumps in breast models before training,<sup>51</sup> compared with 62% detection by attending physicians and 55% by house staff who had outpatient practices and were associated with a medical school.<sup>42</sup> Specificity was approximately 75% for the attending physicians and the house staff.<sup>42</sup> Campbell and colleagues<sup>44</sup> reported that, before training, physicians and nurses achieved similar sensitivities (57% versus 55%, respectively) in lump detection in breast models, whereas physicians had higher specificity than nurses (52% versus 46%, respectively).

Based on patient screening data from the NBSS2, CBE sensitivity at screen 1 and screen 2 was 85.2% and 75.0%, respectively, for trained physician examiners compared with 82.5% and 71.1%, respectively, for trained nurse examiners; these differences were not statistically significant.<sup>52</sup> CBE specificity at both screens was lower for physician examiners (80.6% at screen 1 and 90.8% at screen 2) than for nurse examiners (89.9% at screen 1 and 94.6% at screen 2). One study using patients—which examined agreement in CBE results between surgeons and nurses, among surgeons, and among nurses—re-

ported significantly better performance for surgeons in detecting abnormalities, especially breast masses.<sup>53</sup> However, there was a higher degree of variability among surgeons than among nurses. In this study, the nurses were trained in CBE by the surgeons, and CBE techniques were not standardized among surgeons.

Although only one study specifically addressed the role of examiner experience in detecting lumps, experience appears to play some role in the sensitivity and specificity achieved by the examiner. In this study, CBE sensitivity for physicians with prior tactile experience (ie, having felt at least five cancerous lumps or having practiced lump detection on simulated models) was 60%, compared with 51% for those without such experience.<sup>41</sup>

---

#### LACK OF PERFORMANCE CONSISTENCY AND STANDARDIZATION

The important elements of CBE technique, including various palpation components as described above, are inconsistently applied in clinical practice. Even in CBE trials, examination techniques were generally not described or monitored against a standard.<sup>54</sup> Examiners and study surgeons in the NBSS trials received a specific protocol for CBE and performance was monitored.<sup>21,52</sup> In the NBCCEDP, the procedure for conducting a CBE was not dictated, although detailed guidelines were provided that defined benign findings, such as fibrocystic changes and diffuse lumpiness, and highlighted abnormal findings typical of more advanced disease, including a discrete palpable mass, bloody or serous nipple discharge, nipple or areolar scaliness, and skin dimpling or retraction.<sup>15</sup>

Health care professionals themselves indicate that they “don’t know how” to perform CBE.<sup>38</sup> Several studies assessing clinical performance among physicians-in-training confirm physicians’ own assertions. A number of these studies used an objective structured clinical examination (OSCE), which assesses clinical skills in standardized patient encounters against a checklist. Chalabian and Dunnington<sup>47</sup> assessed CBE skills among graduating primary

care physicians in terms of correct performance of a number of different CBE maneuvers. In this study, only about half of physicians examined the patient in a supine position/arm overhead (52%) or conducted a systematic palpation (55%). Only about one-third examined the supraclavicular region (37%), and only one quarter examined the axillae (25%) or performed a visual inspection of the breasts (25%). Examination of standard silicone breast models by these same graduating physicians resulted in a mean sensitivity of 40.2% and a mean specificity of 77.5%.<sup>47</sup> These levels are in reasonable agreement with similar data among third-year medical students (sensitivity, 43.5%; specificity, 75.4%) from another recent study,<sup>55</sup> but lower than the estimate from the NBCCEDP (sensitivity, 58.8%; specificity, 93.4%).<sup>15</sup>

In one study of medical students and residents, lump detection sensitivity was higher and specificity was lower for first-year medical students (61.5% and 68.4%, respectively) and second-year medical students (53.9% and 62.0%, respectively) compared with third-year medical students.<sup>55</sup> An earlier study by Chalabian and colleagues<sup>56</sup> reported significantly lower mean OSCE performance scores for first-postgraduate year and second-postgraduate year surgery residents combined (score, 36.4) compared with third-year medical students. This study found that 27% of first and second-postgraduate year residents failed to perform axillary examination, 46% failed to examine the supraclavicular region, and 36% failed to perform a visual inspection. When first postgraduate year residents were assessed at the beginning of their second year of training, following an orientation program that included a CBE checklist, their performance scores increased across all items. Another assessment of CBE proficiency by OSCE demonstrated a similar pattern, reporting higher mean performance scores and lower failure rates for third-year medical students (72% and 44%, respectively) compared with first-postgraduate year surgical residents (60% and 65%, respectively), but not second-postgraduate year surgical residents (71% and 43%, respectively).<sup>57</sup> Thus, in addition to highlighting failures to perform CBE components among medical students and residents, taken together, these studies also suggest that

CBE performance may diminish over the course of the clinical years of medical training. Chalabian and colleagues suggest that lack of practice and exposure to CBE skills among residents and lack of an ongoing curriculum and feedback may contribute to diminished skills.<sup>56</sup>

#### TRAINING ON CBE PROFICIENCY

Findings in training studies indicate that many health care professionals believe they need and are receptive to receiving more training in CBE.<sup>26,51,58-62</sup> In a study of medical students, 83% of fourth-year students reported needing additional training in CBE.<sup>63</sup> Although the majority of students (68%) had performed more than six CBEs during medical school, 11 students (15%) reported performing three or fewer CBEs; 2 of the 11 students had never performed a CBE. In one survey, 39% of physicians indicated that a clinical skills course on breast examination would be very useful;<sup>64</sup> in another, 76% of physicians indicated either high or very high levels of interest in improving their breast palpation skills.<sup>65</sup> In one intervention, the self-perceived need of nurse practitioners for improvement in CBE significantly decreased after a 4-day training session on the MammaCare method of CBE.<sup>58</sup> Similarly, a physician education intervention that consisted of a 1- to 2-hour, in-office training program using silicone breast models, a standardized patient, and/or a self-study workbook found significantly lower self-reported needs relating to CBE skills among physicians receiving the intervention.<sup>59</sup> Research findings detailed below and in Tables 2 and 3 indicate that training in CBE may be an effective means for addressing physicians' concerns about how to perform a CBE.<sup>38</sup>

A number of studies have explored whether training in CBE techniques influences the sensitivity and specificity of lump detection in breast models. Most of these studies used the MammaCare method; several others used some variation of MammaCare or did not describe the training method. CBE proficiency was assessed by checklists of CBE components<sup>56,61,66-68</sup> or, when silicone breast models were used, the per-

TABLE 2 Clinical Breast Examination (CBE) Training Studies Using the MammaCare Method

Author/Year	Examiners	Training	Sensitivity	Specificity	CBE Components
Trapp, et al., 1999 <sup>45</sup>	34 nurses	3.5 days (approx. 20 hrs) of MammaCare-based CBE training	Mean, 76% of 18 lumps detected; range, 44% to 100%	Median, 1 false-positive; range, 0–85 false positives	Duration of exam was associated with lumps detected ( $r = 0.30$ ) and false positives ( $r = 0.36$ )
Costanza, et al., 1999 <sup>61</sup>	156 community-based primary care physicians	50-min CBE module that included: 10-min lecture, 10-min video, MammaCare technique, 30-min group session, standardized patients	Not applicable (used checklists)	Not applicable	Pretest versus posttest: composite skills score, 24.8 versus 34.7; breast palpation score, 5.5 versus 9.3; duration of exam, 66.7 versus 120.6 sec
McDermott, et al., 1996 <sup>40</sup>	82 housestaff and attending physicians	30-min video, MammaCare technique; practice on silicone models; perform CBE on patient-instructor	Pretest versus posttest: Housestaff, 55% versus 68%; attending physicians, 62% versus 66%; pretest data for control group not given	Pretest versus posttest: housestaff, 75% versus 70%; attending physicians, 76% versus 79%; pretest data for control group not given	Posttest, intervention versus control group: used circular motion, 73% versus 38%; used vertical strip pattern, 63% versus 23%
Benincasa, et al., 1996 <sup>26</sup>	50 primary care physicians	Office-based program; 30-min session, individualized instruction in MammaCare method; 30-min didactic session on screening; educational package on screening plus a free silicone breast model	Pretest versus posttest: lumps detected using a 5-lump model, 0.66 versus 3.2; at pretest, 58% of physicians detected no lumps	Pretest versus posttest: false positives using a 5-lump model, 2.9 versus 1.16	Pretest versus posttest: 3 fingers, 36% versus 92%; finger pads, 30% versus 90%; small circular motion, 24% versus 94%, vertical strip pattern, 0% versus 80%; 3 pressures, 2% versus 58%; median duration, 98 versus 170 sec
Smith, et al., 1996 <sup>51</sup>	985 primary care physicians	Office-based program, MammaCare models; 15-min hands-on evaluation (1 model); 30-min training session (3 models); 15-min didactic teaching	Pretest versus posttest (1 model): 24% versus 83%	Data not given	Data not given
Campbell, et al., 1994 <sup>27</sup>	54 first-year medical students, 70 second-year medical students	First-year students: 1-hr standardized instruction by either family medicine faculty or well women teachers using MammaCare models; students in well women group spent 1 extra hour examining the women's breasts Second-year students: non-standardized teaching from faculty during clinical rotations	First year versus second year: 71% versus 55% First year (well women group*) versus first year (faculty group): 76% versus 67%	First year versus second year: 48% versus 71% First year (well women group) versus first year (faculty group): 46% versus 49%	First year versus second year: approx. 75% versus 50% used varying pressures and a horizontal or vertical search pattern and showed thoroughness First-year students taught by well women used more CBE components correctly (data not given)
Pilgrim, et al., 1993 <sup>43</sup>	156 second-year medical students	Control group: lecture on breast cancer screening and CBE, video demonstration of CBE Experimental group: lecture on breast cancer screening and CBE, video demonstration of CBE, practice on MammaCare breast models (also one model provided for home practice), small group training session 5 mos later	Experimental versus control: 4.7 versus 4.4 lumps detected	Experimental versus control: 78% versus 82% had 0 false positives	Experimental versus control: 5.3 versus 2.1 suggested palpation techniques used; duration (model), 182 versus 147 sec; duration (patient), 183 versus 121 sec

(cont)

TABLE 2 Clinical Breast Examination (CBE) Training Studies Using the MammaCare Method (Cont)

Author/Year	Examiners	Training	Sensitivity	Specificity	CBE Components
Campbell, et al., 1991 <sup>44</sup>	64 internal medicine residents, 32 nurses	Control group: no special training Experimental group: 1 hour instruction, MammaCare models, practice, patient examination	Experimental group, pretest versus posttest: residents, 57% versus 65%; nurses, 55% versus 58%	Experimental group, pretest versus posttest: residents, 52% versus 33%; nurses, 64% versus 58%	Posttest: statistically significant differences between experimental and control groups in all CBE components except thoroughness and use of three fingers Duration, pretest versus posttest: Experimental group, 2.5 versus 2.3 min/model; control group, 2.4 versus 1.6 min/model

\*With or without practice on well women.

centage of lumps detected (sensitivity) and the percentage of models with no false positives detected (specificity).<sup>27,28,42-45,51</sup> Training with silicone breast models has been shown to increase detection of known benign lumps in breast tissue.<sup>29</sup> One breast self-examination study weighted examination components—based on judged importance of components by experts in CBE and breast self-examination—and developed a scoring system yielding a composite measure of proficiency.<sup>68</sup> Although study data (not included in this review) indicated that this scoring system showed potential as a tool to measure relative performance across BSE studies, no validated weighted scoring system or other standardized scoring system has been developed for assessing CBE proficiency.

#### Studies Using the MammaCare Method

Eight CBE training studies that used the MammaCare method were identified. Selected elements of these studies are presented in Table 2. Training protocols, which differed considerably except for use of the MammaCare method, included 3.5 days of CBE training in the Nurses Providing Annual Cancer Screening training program;<sup>45</sup> 1-hour, office-based training programs for primary care physicians;<sup>26,51</sup> various teaching interventions and training programs in medical school settings;<sup>27,42-44</sup> and a 50-minute module on CBE as part of a 5-hour course that also focused on improving physicians' skills in mammography counseling.<sup>61</sup>

Overall, examiner training in the MammaCare method resulted in greater proficiency in carrying out CBE, as measured by execution of CBE components, and in higher sensitivity (but lower specificity), as measured by lump detection in silicone breast models. Lower specificity (more false positives) in CBE, as discussed previously, may result in unnecessary biopsies, medical visits, and referrals as well as unnecessary stress for patients.

The 34 nurses who completed the Nurses Providing Annual Cancer Screening training program found 76% of the lumps in breast models; however, the average duration of examination was approximately 9.8 minutes per model.<sup>45</sup> In an office-based training program that used only one model (5 lumps), the mean number of lumps detected increased from 0.66 before training to 3.2 lumps after training; before training, 58% of the primary care physicians detected no lumps.<sup>26</sup> In this study, only one-third of the primary care physicians used any aspect of the MammaCare method before training; after training, each MammaCare component was used by at least four out of five physicians. Campbell and colleagues<sup>27</sup> reported that medical students who received standardized MammaCare teaching from either trained family medicine faculty or trained well-woman teachers had more consistent examination techniques and higher sensitivity (but lower specificity) than students who received unstandardized teaching during clinical rotations. The students taught by well women

TABLE 3 CBE Training Studies Using Methods Other Than the MammaCare Method

Author/Year	Examiners	Training	Results
Chalabian, et al., 1996 <sup>56</sup>	Intervention group: incoming house officers Traditional group: house officers in first or second year postgraduate year	Intervention group received CBE and patient-physician interaction checklists and were oriented to the CBE and checklists as part of the intern orientation Traditional group rotated on traditional breast/tumor and other general surgical services, no other intervention	Percent of intervention group versus traditional group performing CBE skills correctly: Axillary exam, 67% versus 14%; skin inspection, 100% versus 28%; systematic palpation, 11%* versus 48%; supraclavicular exam, 78% versus 18%; explained physical exam, 100% versus 74%
Costanza, et al., 1995 <sup>66</sup>	38 primary care physicians; 15 physicians participated twice, approximately 18 months apart	A 1-hr long, 1-on-1 skills course in examining and counseling women at risk for breast cancer, with a patient instructor; 36 points of a 77-point checklist related to CBE; physicians examined the patient instructor, who then rated the physician using the checklist and provided feedback to the physician	Mean performance scores for 15 physicians who participated twice, first score versus second score: Amenities (e.g., wash hands, explain procedure, proper patient draping), 58.5% versus 71.5%; lymph node palpation, 57.6% versus 93.2%; observation, 47.8% versus 62.6%; palpation (sitting), 59.0% versus 53.3%; palpation (supine), 55.6% versus 76.6%
Warner, et al., 1993 <sup>67</sup>	14 primary care physicians	30–45 min, office-based training program, with a nonphysician trainer and a simulated patient; elements included a pretraining CBE, feedback/instruction on CBE technique, practice on simulated patient, and a posttraining CBE	Percent of physicians demonstrating breast palpation skills, pretraining versus posttraining: Palpation of axillary tail, 29% versus 93%; palpation of nipple, 21% versus 100%; palpation of 4 quadrants, 93% versus 100%; use of small finger movement, 64% versus 71%; consistent firm pressure, 29% versus 78%; consistent pattern, 100% versus 100%; use of fingerpads, 100% versus 100%
Hall, et al., 1980 <sup>28</sup>	20 volunteer women, no previous CBE training	20–30 min training session (14 trials, 30 min maximum) with silicone models (precursors for the standard MammaCare models); 2 training groups (A and B, 10/group), which received different training sequences; before and after training, examined 6 women who had a total of 13 benign breast lumps (most between 1.0 and 2.0 cm, several < 1.0 cm)	Pretraining versus posttraining: Approx. percent of lumps detected in women by A and B (combined), 25% versus 50%; approx. duration of exam by A and B (combined), 50 sec versus 90 sec; approx. number of false positives, 3 versus 13 (Group A), 10 versus 23 (Group B); significant correlation between lump detection and duration of exam at pretest ( $r = 0.46$ ) and at second posttest ( $r = 0.49$ )

\*Tendency to perform exam with patient in sitting position or not to have the patient's arm above her head.

appeared to perform slightly better than those taught by faculty, but differences were not significant. In another study, the post-training sensitivity of lump detection in breast models for internal medicine residents was significantly higher than for graduate nurses (65% versus 58%, respectively), and posttraining specificity was significantly lower than for nurses (33% versus 58%, respectively); before training, both groups showed similar sensitivity (57% versus 55%, respectively), but residents had higher spec-

ificity than nurses (52% versus 46%, respectively).<sup>44</sup>

#### Studies Using CBE Methods Other Than MammaCare

Four CBE training studies that used CBE methods other than the MammaCare method were identified. Components of examination techniques were similar, but not identical, to those used in the MammaCare method. None of these studies used the standard

MammaCare silicone breast models. Selected elements of these studies are presented in Table 3. Training protocols included a medical school orientation to CBE with CBE and patient-physician interaction checklists;<sup>56</sup> a one-on-one skills course for community primary care physicians using a patient instructor;<sup>66</sup> a 45-minute, office-based training program for primary care physicians;<sup>67</sup> and a 20 to 30 minute training session for female volunteers, using silicone breast models that were precursors to the standard MammaCare models.<sup>28</sup>

Overall, training resulted in greater CBE proficiency as measured by execution of CBE components. Chalabian and colleagues<sup>56</sup> reported that the overall CBE skills of incoming surgical residents improved when they were given CBE checklists and CBE orientation as part of their intern orientation program. The exception was breast palpation skills; 89% of residents tended to perform the examination with the patient either in the sitting position or without her arm above her head. Patient interaction skills also improved; 94% of standardized patients were satisfied with their interaction with residents who received checklists/orientation, whereas only 34% of patients were satisfied with residents who did not receive checklists/orientation. Fifteen of the primary care physicians who participated in the one-on-one skills course twice, approximately 18 months apart, improved CBE component scores by 13% to 36%; only the score for palpation with the patient in a sitting position did not improve.<sup>66</sup> Interestingly, 3 of 14 physicians in the office-based training program did not remember having formal CBE training in medical school or during their residency.<sup>67</sup> The study by Hall and colleagues<sup>28</sup> is significant in that a relatively short (20 to 30 minutes) training session with silicone breast models, which contained steel spheres ranging from 0.08 cm to 0.36 cm in diameter, significantly increased the ability of trainees to detect relatively small known benign breast lumps in natural breast tissue. The training session included as many as 14 prac-

tice trials and verbal feedback from the trainer.

#### CONCLUSION

The literature reviewed here indicates that CBE identifies some breast cancers not detected on mammography.<sup>2,12,14-17,20</sup> Historically, CBE has been recommended as one part of breast cancer screening in women also undergoing mammography for this very reason, ie, mammography does not have perfect sensitivity. Further, in women under age 40 or 50 who were not recommended to receive regular mammograms, CBE was recommended as a method for detecting palpable breast cancer earlier. Although it has never been specifically emphasized, CBE also could provide an opportunity to identify palpable masses in women who either had no access to mammography, or who were averse to having mammograms.

Evidence clearly suggests that a considerable variety of methods are used to perform CBE and report results, despite evidence and growing consensus for the core components of a proficient CBE.<sup>20,25,33,38,41-44</sup> Health care professionals recognize the need for additional training in CBE performance<sup>26,51,58-62,67</sup> and many studies provide evidence that training can improve execution of CBE components and accuracy.<sup>27,28,43,44,47,51,56,61,66,67</sup> Clearly, a need exists for the development, dissemination, and use of a standardized performance method and form of reporting that optimizes CBE proficiency and enhances risk management.<sup>69</sup>

In tandem with such efforts, additional research must be conducted to address remaining questions, particularly in three areas. First, more information is needed about the relationship between specific CBE components and CBE accuracy, particularly as this relates to breast tissue characteristics (nodularity, density, compressibility), exam duration, and trade-offs between test sensitivity and specificity. Second, reporting systems have not been studied and model systems need to be developed and validated. These could provide an important foundation for further research, ensuring compatibility of information across settings and studies. Third, additional evi-

dence is needed about the specific components of training programs that increase proficiency and the timing and benefits of retraining.

Finally, in addition to standardized performance and reporting for CBE and research to address remaining questions, it must be noted that greater efforts are needed to improve adherence to timely mammography screening and to ensure that women receive the highest quality of existing mammography technology. Such improvements would ultimately reduce reliance on techniques that can detect cancers at an earlier stage of progression, but at best can detect only those breast cancers large enough to be palpated.

#### ACKNOWLEDGMENTS

The authors express their appreciation for the thoughtful review and comments provided by Ralph Coates, PhD, Janet Rose Osuch, MD, MS, Robert Smith, PhD, and other members of the committee to establish practical recommendations for optimizing performance and reporting of clinical breast examination.<sup>1</sup> Support for this project was provided by the American Cancer Society and the Centers for Disease Control and Prevention. Management Solutions for Health, Inc., developed this review under contract to the American Cancer Society.

#### REFERENCES

- Saslow D, Hannan J, Osuch J, et al. Clinical breast examination: practical recommendations for optimizing performance and reporting. *CA Cancer J Clin* 2004;54:327-344.
- Smith RA, Saslow D, Sawyer KA, et al. American Cancer Society guidelines for breast cancer screening: update 2003. *CA Cancer J Clin* 2003;53:141-169.
- Shapiro S. Periodic screening for breast cancer: the HIP randomized controlled trial. *J Natl Cancer Inst Monogr* 1997;22:27-30.
- Smart CR, Byrne C, Smith RA, et al. Twenty-year follow-up of the breast cancers diagnosed during the Breast Cancer Detection Demonstration Project. *CA Cancer J Clin* 1997;47:134-149.
- Michaelson JS, Silverstein M, Wyatt J, et al. Predicting survival of patients with breast carcinoma using tumor size. *Cancer* 2002;95:713-723.
- Feig SA, D'Orsi SJ, Hendrick RE, et al. American College of Radiology guidelines for breast cancer screening. *Am J Roentgenol* 1998;171:29-33.
- American College of Obstetricians and Gynecologists. Breast cancer screening. *ACOG Practice Bulletin* 2003;42:12.
- Canadian Task Force on Preventive Health. 1998 Rewording: Screening for breast cancer. Available at: [www.ctfphc.org](http://www.ctfphc.org). Accessed September 9, 2004.
- National Guidelines Clearinghouse Guidelines Synthesis. Screening for breast cancer. Available at: [www.guideline.gov/compare/comparison.aspx?file=BRSCREEN8.inc#table2](http://www.guideline.gov/compare/comparison.aspx?file=BRSCREEN8.inc#table2) recommendations. Accessed September 23, 2004.
- US Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. *Ann Intern Med* 2002;137:344-346.
- Chamberlain JCR, Nathan BE, Price JL, Burn I. Error-rates in screening for breast cancer by clinical examination and mammography. *Clin Oncol* 1979;5:135-146.
- Miller AB, Baines CJ, To T, Wall C. Canadian National Breast Screening Study: 1. Breast cancer detection and death rates among women aged 40 to 49 years. *Can Med Assoc J* 1992;147:1459-1476.
- Miller AB, Baines CJ, To T, Wall C. Canadian National Breast Screening Study: 2. Breast cancer detection and death rates among women aged 50 to 59 years. *Can Med Assoc J* 1992;147:1477-1488.
- Bancej C, Decker K, Chiarelli A, et al. Contribution of clinical breast examination to mammography screening in the early detection of breast cancer. *J Med Screen* 2003;10:16-21.
- Bobo JK, Lee NC, Thames SF. Findings from 752,081 clinical breast examinations reported to a national screening program from 1995 through 1998. *J Natl Cancer Inst* 2000;92:971-976.
- Oestreicher N, White E, Lehman CD, et al. Predictors of sensitivity of clinical breast examination (CBE). *Breast Cancer Res Treatment* 2002;76:73-81.
- Newcomer LM, Newcomb PA, Trentham-Dietz A, et al. Detection method and breast carcinoma histology. *Cancer* 2002;95:470-477.
- Coates RJ, Uhler RJ, Brogan DJ, et al. Patterns and predictors of the breast cancer detection methods in women under 45 years of age (United States). *Cancer Causes Control* 2001;12:431-442.
- Weir HK, Thun MJ, Hankey BF, et al. Annual Report to the Nation on the Status of Cancer, 1975-2000, featuring the uses of surveillance data for cancer prevention and control. *J Natl Cancer Inst* 2003;95:1276-1299.
- Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: Should it be done? How? *JAMA* 1999;282:1270-1280.
- Baines CJ. Physical examination of the breasts in screening for breast cancer. *J Gerontol* 1992;47:63-67.
- Elmore JG, Barton MB, Mocerri VM, et al. Ten-year risk of false positive screening mammography and clinical breast examinations. *N Engl J Med* 1998;338:1089-1096.
- van Dam PA, van Goethem MLA, Kerschot E, et al. Palpable solid breast masses: retrospective single- and multimodality evaluation of 201 lesions. *Radiology* 1988;166:435-439.
- Reintgen D, Berman C, Cox C, et al. The anatomy of missed breast cancers. *Surg Oncol* 1993;2:65-75.
- Fletcher SW, O'Malley MS, Bunce LA. Physicians' abilities to detect lumps in silicone breast models. *JAMA* 1985;253:2224-2228.
- Benincasa TA, King ES, Rimer BK, et al. Results of an office-based training program in clinical breast examination for primary care physicians. *J Cancer Ed* 1996;11:25-31.
- Campbell HS, McBean M, Mandin H, Bryant H. Teaching medical students how to perform a clinical breast examination. *Acad Med* 1994;69:993-995.
- Hall DC, Adams CK, Stein GH, et al. Improved detection of human breast lesions following experimental training. *Cancer* 1980;46:408-414.
- Bates B. A Guide to Physical Examination and History Taking. Philadelphia, PA: JB Lippincott Co.; 1998.
- Coleman EA, Heard JK. Clinical breast examination: an illustrated educational review and update. *Clin Excell Nurse Pract* 2001;5:197-204.
- Goodson WI. Clinical breast examination. *West J Med* 1996;164:355-358.
- Henderson MA, Cawson JM, Bilous M. Breast cancer: getting the diagnosis right. *Med J Austral* 1995;163:494-499.
- Pennypacker HS, Pilgrim CA. Achieving competence in clinical breast examination. *Nurse Pract Forum* 1993;4:85-90.
- Mahoney L, Csima A. Efficiency of palpation in clinical detection of breast cancer. *Can Med Assoc J* 1982;127:729-730.
- Day PJ, O'Rourke MGE. The diagnosis of breast cancer: a clinical and mammographic comparison. *Med J Aust* 1990;152:635-639.
- Baines CJ. Screening for breast cancer: how useful are clinical breast examinations. *J Natl Cancer Inst* 2000;92:958-959.



37. Saunders KJ, Pilgrim CA, Pennypacker HS. Increased proficiency of search in breast self-examination. *Cancer* 1986;58:2531-2537.
38. Pennypacker HS, Naylor L, Sander AA, Goldstein MK. Why can't we do better breast examinations? *Nurse Pract Forum* 1999;10:122-128.
39. Isaacs JH. Physician breast examination and breast self-examination. *Clin Obstet Gynecol* 1989;32:761-767.
40. McDermott MM, Dolan NC, Huang J, et al. Lump detection is enhanced in silicone breast models simulating postmenopausal breast tissue. *J Gen Int Med* 1996;11:112-114.
41. Fletcher SW, O'Malley MS, Pilgrim CA, Gonzalez JJ. How do women compare with internal medicine residents in breast lump detection? *J Gen Int Med* 1989;4:277-283.
42. McDermott MM, Dolan NC, Rademacher A. Effect of breast-tissue characteristics on the outcome of clinical breast examination training. *Acad Med* 1996;71:505-507.
43. Pilgrim C, Lannon C, Harris RP, et al. Improving clinical breast examination training in a medical school. *J Gen Int Med* 1993;8:685-688.
44. Campbell SH, Fletcher SW, Lin S. Improving physicians' and nurses' clinical breast examination: a randomized controlled trial. *Am J Prev Med* 1991;7:1-8.
45. Trapp MA, Kottke TE, Vierkant RA, et al. The ability of trained nurses to detect lumps in a test set of silicone breast models. *Cancer* 1999;86:1750-1756.
46. Coleman EA, Pennypacker H. Evaluating breast self-examination performance. *J Nurs Qual Assur* 1991;5:65-69.
47. Chalabian J, Dunnington G. Do our current assessments assure competency in clinical breast evaluation skills? *Am J Surg* 1998;175:497-502.
48. Stomper PC, D'Souza DJ, DiNitto PA, Arredondo MA. Analysis of parenchymal density on mammograms in 1353 women 25-79 years old. *Am J Roentgenol* 1996;167:1261-1265.
49. Goodson WH 3rd, Moore DH. Overall clinical breast examination as a factor in delayed diagnosis of breast cancer. *Arch Surg* 2002;137:1152-1156.
50. Cheek J, Lacy J, Toth-Fejel S, et al. The impact of hormone replacement therapy on the detection and stage of breast cancer. *Arch Surg* 2002;137:1015-1019.
51. Smith RL, Hanchak NA, Bloom H, et al. The effectiveness of postgraduate education on the clinical breast examination skills of primary care physicians. *Am J Man Care* 1996;2:989-995.
52. Baines CJ, Miller AB, Bassett AA. Physical examination: its role as a single screening modality in the Canadian National Breast Screening Study. *Cancer* 1989;63:1816-1822.
53. Thomas DC, Spitzer WO, MacFarlane JK. Inter-observer error among surgeons and nurses in presymptomatic detection of breast disease. *J Chronic Dis* 1981;34:617-626.
54. Baines CJ, Miller AB. Mammography versus clinical examination of the breasts. *J Natl Cancer Inst Monographs* 1997;22:125-129.
55. Lee KC, Dunlop D, Dolan NC. Do clinical breast examination skills improve during medical school? *Acad Med* 1998;73:1013-1019.
56. Chalabian J, Garman K, Wallace P, Dunnington G. Clinical breast evaluation skills of house officers and students. *Am Surg* 1996;62:840-845.
57. Sloan DA, Donnelly MB, Schwartz RW, et al. Assessing medical students' and surgery residents' clinical competence in problem solving in surgical oncology. *Ann Surg Oncol* 1994;1:204-212.
58. Lannotti RJ, Finney LJ, Sander AA, De Leon JM. Effect of clinical breast examination training on practitioner's perceived competence. *Cancer Detect Prev* 2002;26:146-148.
59. Lane DS, Messina CR, Grimson R. An educational approach to improving physician breast cancer screening practices and counseling skills. *Patient Educ Couns* 2001;43:287-299.
60. Desnick L, Taplin S, Taylor V, Coole D, Urban N. Clinical breast examination in primary care: perceptions and predictors among three specialties. *J Womens Health* 1999;8:389-397.
61. Costanza ME, Luckmann R, Quirk ME, et al. The effectiveness of using standardized patients to improve community physician skills in mammography counseling and clinical breast exam. *Prev Med* 1999;29:241-248.
62. Freund KM, Burns RB, Antab L. Improving residents' performances of clinical breast examination. *J Cancer Ed* 1998;13:20-25.
63. Kann PE, Lane DS. Breast cancer screening knowledge and skills of students upon entering and exiting a medical school. *Acad Med* 1998;73:904-906.
64. Costanza ME, Hoople NE, Gaw VP, Stoddard AM. Cancer prevention practices and continuing education needs of primary care physicians. *Am J Prev Med* 1993;9:107-112.
65. Warner SL, Worden JK, Solomon LJ, Wadland WC. Physician interest in breast cancer screening: a survey of Vermont family physicians. *J Fam Pract* 1989;29:281-285.
66. Costanza ME, Greene HL, McManus D, et al. Can practicing physicians improve their counseling and physical examination skills in breast cancer screening? A feasibility study. *J Cancer Ed* 1995;10:14-21.
67. Warner SL, Solomon LJ, Foster RS Jr, et al. Continuing education in the physician's office: a pilot study for breast exams. *Fam Pract Res J* 1993;13:179-183.
68. Coleman EA, Pennypacker H. Measuring breast self-examination proficiency. *Cancer Nurs* 1991;14:211-217.
69. Physician Insurers Association of America. Breast cancer study - 2002. Rockville, MD: Physician Insurers Association of America, 2002.