Clear-cut evidence that screening through clinical breast examination (CBE) alone can reduce breast cancer mortality has been elusive. Even if such evidence exists, it may never be discoverable in the current environment.

Many clinicians in the United States perform CBE on patients (1), and in 2005, 65% of US women reported having had a screening CBE in the previous 2 years (2). Another recent study found that CBE was routinely performed along with screening mammography at eight (18%) of 45 mammography facilities surveyed in the United States (3). The most frequent justification for performing CBE in developed countries, where high-quality mammography is widely available, is that CBE can detect lesions missed by mammography. Yet, there is a price to pay for this benefit. Although the addition of CBE to mammography screening can increase the overall sensitivity of the examination (4), the cost of any improvement in sensitivity is a decrease in specificity. In this issue of the Journal, Chiarelli et al. (5) have quantified this cost in the Ontario Breast Screening Program in terms of the number of false-positive examinations for each additional cancer detected.

The breast cancer screening program employed by the provincial program in Ontario permitted standardized information gathering on breast cancer screening, follow-up, and cancers diagnosed at nine regional cancer centers and 59 affiliated centers across the province. The data reported by Chiarelli et al. on 290230 women indicate that there is a steep price for the potential gains of adding CBE to mammography. The authors reported that for a theoretical population of 100000 women between the ages of 50 and 69 years, the addition of CBE would lead to the detection of breast cancer in only four women whose cancer would be missed by mammography. However, adding CBE would also lead to false-positive results for an additional 219 women, who would be referred for workup only to discover that they do not have cancer. The remaining 9777 women would neither benefit nor be harmed. For comparison purposes, the same figures for mammography screening in the Ontario program are 709 women per 10000 would have a positive finding and would be referred for workup, among whom 59 cancers would be discovered. Even for the four additional women whose cancer was diagnosed because of CBE, we cannot know if they obtain a mortality benefit because of the early detection (6).

Although the use of CBE to screen for breast cancer may be decreasing in the United States (7), CBE is still of high interest to nations that lack advanced screening technologies and abundant health-care resources. Trials of breast cancer screening with CBE are currently under way in India and Egypt (8,9), and another trial has been attempted in the Philippines (10). In addition, data available from the 2003 National Health Interview Survey indicate that up to 35% of breast cancers were detected through CBE or self-detection (11).

If CBE is going to be done, it needs to be done well. Although many clinicians might consider the sensitivity of 47.4% for initial CBE screens done at the regional cancer centers reported by Chiarelli et al. to be low for a medical test, this value is actually higher than that found for CBE in US community-based samples, for which a maximum sensitivity of around 35% has been reported (12). The nurses in the study by Chiarelli et al. received special training and quality improvement support, and they examined a minimum of 500 women each year. Most importantly, they spent 8–10 minutes per woman on each examination. The duration of CBE has been consistently associated with its sensitivity in studies that used silicone breast models (4). In addition, whereas the nurses in the study were described as using a circular or “clock” pattern for CBE, the search pattern of the breast examination in actual practice has not been found to be uniform when studied; in fact, one group even found that 40% of physicians used no clear search pattern at all (13). Just as we would not mow our lawns in a random or circular pattern for fear of missing areas of grass, for CBE, we recommend an organized up-and-down search method, which has been found to achieve better coverage than other approaches (14).

Several unique elements are crucial to the production of the kind of data presented by Chiarelli et al. Their results were obtained through standardized methods of training in CBE, of performing CBE, of documenting test results, and of tracking outcomes. The closest example of this type of CBE data in the United States comes from the Breast and Cervical Cancer Detection Program (BCDDP), which has published data on 750000 CBEs (15). However, as might be expected in the decentralized US health-care system, even though there is a single payer for the BCDDP (ie, the Centers for Disease Control), this program has not been able to maintain a focus on standardized CBE training or performance, and, on a programmatic level, it has been unable to track all of the women who received normal examinations. Thus, the BCDDP cannot provide reliable estimates of sensitivity (15,16).

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To illustrate how having standards for CBE training, performance, and tracking might improve both the practice of CBE and our ability to study it, we can learn from the field of mammography. The Mammography Quality and Standards Act (17) elaborated helpful standards for training and experience for breast imaging practitioners, and the Breast Imaging Reporting and Data System manual (18) provided a classification system that standardized the clinical language of mammographic findings. These steps have enabled some very productive research on mammography performance, much of it under the auspices of the Breast Cancer Screening Consortium (19).

Although the creation of standards for CBE has been recommended by a joint working group from the American Cancer Society and the Centers for Disease Control (20), no such standards have yet emerged. In a noteworthy example, the Breast Health Education program at Oregon Health Sciences University offers training to primary care providers in a single standardized technique for CBE (21); this training qualifies physicians for a discount on malpractice insurance premiums (E. Steiner, MD, personal communication, 2009). This is a key incentive, given that failure to detect breast cancer has been the number one reason for medical malpractice claims in the United States for many years (22). Strengthening the case for CBE training and experience is evidence from Chiarelli et al. (5) that the screening centers with the highest volumes also had the highest sensitivity and the lowest false-positive rates.

How can we use these new data to improve shared decision making with patients? It is well documented that patients and clinicians struggle with numeracy and the ability to understand information regarding risk (23). Both groups benefit when patients are well informed and play a substantial role in deciding how to manage their health care (24). To make informed decisions, however, women must understand the risks, benefits, and side effects associated with each screening test and associated diagnoses. For some women, numbers on risks and harms may be hard to understand (25), and fear of breast cancer may hamper communication with their clinician (26). Moreover, the challenges of understanding both cancer risk and numeric information are shared equally by patients and their providers (25,27).

The way risk information is presented, including the choice of words and the framing of the discussion, can affect how the information is interpreted. When discussing risks, we need to express logically equivalent information in a variety of forms. For example, positive framing emphasizes desirable outcomes (eg, adding CBE to a screening program for 10,000 women can lead to detecting breast cancer in four more women whose cancer would otherwise be missed by mammography), whereas negative framing emphasizes risks (eg, 55 women will have false-positive examinations for every additional cancer detected by CBE; these women may experience anxiety, radiation exposure from additional testing, and perhaps unnecessary biopsies). In addition, cultural norms are important to consider in such discussions. In some countries, women will tolerate a high level of false-positive examinations (28,29).

Low-tech primary care interventions that can decrease the burden of cancer in women are extremely appealing. At the same time, ineffective practices, or those with even marginal net benefit, would be a disservice to our patients. More answers are needed on the role of CBE in breast cancer screening before definitive recommendations for or against its use can be made (31). While we wait for those answers, the data presented by Chiarelli et al. suggest that CBE must be done well if it is to be done at all, with the acknowledgment that overall referrals and false-positive results will increase.

References


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