Is it really useful to perform clinical breast examinations (CBEs)? No one will dispute that a woman presenting to her physician with a self-detected breast lump is likely to receive such an examination before being referred for diagnostic mammography. But how useful is it for physicians to perform CBEs in a preventive or screening mode? If they actually believe the somewhat dubious assertion that “mammographic screening of women age 40 and over can reduce breast cancer deaths by at least 30 to 40 percent” (1), physicians surely must ask themselves why bother with fingers? In this issue of the Journal, Bobo et al. (2) report results of CBEs performed in the U.S. National Breast and Cervical Cancer Early Detection Program. They conclude that CBEs in community-based screening programs can detect breast cancer as effectively as those done under controlled protocols in clinical trials. What do we learn from their article? How compelling is their conclusion?

The investigators analyzed 752,081 CBE reports involving 564,708 women accrued during the period from July 1, 1995, through June 30, 1998, from screening sites located in four U.S. regions (the Midwest, the Northeast, the South, and the West) and in Indian tribal sites and territories. Approximately 10% of the CBEs were provided to women under age 40 years and 9% to women age 70 years and older. The mean age was 52.5 years. The national program was specifically designed for low-income women who were underinsured or uninsured. All screening sites submitted standardized data semiannually to the Centers for Disease Control and Prevention (Atlanta, GA), including demographic characteristics, results from CBE and mammography, and diagnostic procedures and outcomes. With such a large number of CBEs performed within a relatively brief time period, with the geographic and ethnic diversity of the participants, and with centrally collected, standardized data, an unusually important evaluation of what CBEs can do becomes possible.

In terms of breast cancer detection, CBEs performed very well in the study by Bobo et al. For first screen examinations, the detection rate was 6.9 breast cancers per 1000 CBE records (95% confidence interval = 6.6–7.2). Furthermore, the analysis reveals that, contrary to what many believe, CBEs do detect in situ cancers. The reported rates were 3.8 and 1.2 breast cancers per 1000 women, respectively, for invasive and in situ breast cancers. But this is looking at CBE in isolation from mammography. What did CBE do in the context of the mammographic results (555,983 records)? Screen examinations that yielded an abnormal CBE and a normal mammogram were associated with an overall cancer detection rate of 7.4 per 1000 records. Examinations resulting in a normal CBE and an abnormal mammogram yielded a rate of 42.0 per 1000 records, and screening examinations with both modalities recorded as abnormal yielded a rate of 170.3 per 1000 records. The authors suggest that up to 16% of breast cancers might not have been detected in the absence of CBE. Indeed, their estimates of detection rates attributable to CBE are far from trivial and are consistent with previously published screening trials.

Moreover, their estimates of CBE sensitivity and specificity are completely consistent with those published for screening studies, including the New York Health Insurance Plan Study, the Breast Cancer Detection Demonstration Project, the Canadian National Breast Screening Study, and the United Kingdom Trial of Early Detection of Breast Cancer (3–7), and with the recently published pooled estimates of Barton et al. (8). With this kind of external validation, the take-home message is that CBE sensitivity is 55%–60% and the specificity is about 95%.

However, one has to wonder whether the potential for more impressive results from CBE has yet to be realized. The authors note that “the procedural aspects of doing a CBE are not dictated” under the terms of the national program. Nevertheless, there were detailed guidelines provided to all of the screening sites stating that abnormal clinical findings include discrete palpable masses, bloody or serous nipple discharge, nipple or areolar scaliness, or skin dimpling or retraction. These are not guidelines geared to achieving early detection by CBE! Paget’s disease, dimpling (peau d’orange), and skin retraction are not subtle signs of early breast cancer. What would results in this study have shown if the guidelines had included looking for asymmetric thickening of breast tissue or slight asymmetry of breast contour? Asymmetry was not mentioned at all. It is interesting that the one screening trial that imposed standards on and monitored CBE performance and that deliberately sought subtle asymmetries reports the highest sensitivity compared with other trials. Sensitivity of CBE as a single screening modality in the Canadian National Breast Screening Study was 69% in women 40–49 years at entry and 64% in women aged 50–59 years at entry (8).

As with all large database analyses, there are always unanswered questions. Women aged 40 years and older were offered combined screening with CBE and mammography, yet mammography records were not available for 26% of the CBE records. How did this happen? How many women did not receive mammograms? The missing data may have offered additional insights. What difference would it have made to the false-negative rate for CBEs? Ten percent of the CBE records used in the analysis were from women under age 40 years, and double screening was not offered to them unless diagnostic mammography was required. This cannot explain why 26% of the records did not include mammography results. In addition, the reported

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interval cancer rate was surprisingly low—only 2% of all detected breast cancers. This may well be a reflection of the fact that the women who participated in the screening programs lacked access to medical services in the interval between scheduled screens. Or perhaps it was false reassurance after a negative screen. Finally, the fact that the subjects had to be low-income women to be eligible for screening (which also entailed entry in a large database) is not entirely a disadvantage. CBEs are more likely to be employed for breast cancer screening in low-income populations whether in the United States or in third-world countries.

We still do not know enough about what CBEs can do when performed to standards equivalent to those currently required for mammography. Bobo et al. (2) show us that CBE can do quite well under relatively uncontrolled conditions in a community setting. That is valuable and encouraging new information. But we still need to know what excellent CBE could achieve in the same setting.

On the other hand, just imagine how unimportant early detection could become if breast cancer therapy changed radically in the next decade. Just imagine how controversies relating to early detection would become irrelevant if breast cancer therapy became both relatively nontoxic and generally effective. Is it possible that relatively innocuous chemotherapy combined with the effective use of antiangiogenesis agents may change everything—and not only for women with breast cancer? Just imagine!

REFERENCES