Re: Efficacy of Breast Cancer Screening in the Community According to Risk Level

The study by Elmore et al. (1) was designed to evaluate, by means of a case–control design, the effectiveness of early breast cancer diagnosis among women enrolled in six U.S. health plans. Whereas breast cancer screening evaluation in service screening is important, the practice of unorganized screening programs in the United States makes this effort problematic because women are not actively invited to be screened.

We would like to have more details about the following two issues. First, as pointed out by Weiss (2), it is difficult to know the intention of the woman asking for mammography or clinical breast examination because symptoms are not usually reported or not recorded in medical records. Although Elmore et al. carefully reviewed the medical records, it would be useful to compare the frequency of screening tests before the “index period” between the matched case and control subjects. In the absence of the above-mentioned bias of selective reporting, we would expect the frequency of such tests among case subjects and control subjects to be comparable, given the negative result of the study. A lower frequency of screening tests before the index period among case subjects could suggest that unrecorded breast symptoms could have inflated the frequency of index screening tests.

Second, to assess the impact of screening, documentation about the population-based performance of the screening process is needed. In their article, Elmore et al. reported staging of breast cancers for breast cancer deaths only. Assuming that the population-based stage distribution of breast cancer cases is available from cancer registries, it could be interesting to know the changing trends of early and advanced cases over the study period. Moreover, stage distribution of breast cancer cases by screening status would be extremely helpful to validate the expected outcome of a community-based, nonorganized screening program.

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REFERENCES


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DOI: 10.1093/jnci/dji381
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RESPONSE

We thank Drs. Duffy, Smith, and Tabar, as well as Drs. Paci and Zappa, for their thoughtful comments on our study.

Duffy et al. stress that the results of our study are relevant to the efficacy of clinical breast examination in the 1980s rather than to the efficacy of high-quality mammography screening in 2005. It is true that the dominant screening modality used by the women in our study was clinical breast examination. The sensitivity of clinical breast examination is lower than that of mammography: it is estimated to be 54% based on data obtained in randomized clinical trials (1), and we suspect that the sensitivity in the community is lower still (2). For this reason, we agree that extrapolation of the results of our study to a breast cancer-screening program based primarily or exclusively on mammography may be inappropriate. Nonetheless, it should be noted that our results were similar for women screened by mammography, by clinical breast examination, or by both modalities. Also, in the one randomized clinical trial that compared the efficacy of screening mammography and clinical breast examination (3), there was no clear benefit for mammography in terms of reduced mortality from breast cancer.

Because “good quality mammography in 2005” implies that mammography has improved markedly in the last two decades, it also implies that we therefore cannot presume that our study’s estimate of screening efficacy is generalizable to the efficacy achieved in current breast cancer screening programs. We agree with Duffy et al. that it is likely that mammographic imaging and interpretation have improved over time. Nonetheless, mammography was sensitive enough to have permitted most randomized controlled trials conducted during the period of time covered by our study to have observed a reduced risk of breast cancer death in women assigned to be screened (4). We may have to wait 15 years before we are able to assess the impact of current screening mammography on breast cancer mortality.

Dr. Duffy and colleagues were also concerned with a particular bias in the evaluation of screening that has been described by Connor et al. using microsimulation (5). Connor et al. pointed out that for control subjects matched to screen-detected case subjects, the time period...
during which screening history ought to be assessed should end at the time the clinical diagnosis of their matched case subject would have occurred had screening not been done; however, Connor et al. acknowledged that this date is impossible to define in real life. We agree that this bias should be considered: If there are a substantial number of screen-detected cases among persons who die of the cancer in question and if there has been a rapid increase in the occurrence of screening during the study period, a substantial reduction in estimated screening during the study period, a substantial reduction in estimated screen-
of screening examinations. We agree that it can be challenging to differentiate screening from diagnostic examinations in a study that relies on data from medical records and that some classification bias may be present in our study. However, we reviewed all available medical record information, including notations of telephone calls from women requesting an appointment, staff comments when they checked a woman in for an examination, and handwritten comments on the mammography requisition forms that describe the reason for the examination. Drs. Paci and Zappa claim that “symptoms are not usually reported or not recorded in medical records.” However, this was not our experience for the medical charts reviewed at our study sites. Patients’ charts included thorough notes from doctors, nurses, and receptionists. In nearly all cases, we felt that we could correctly classify whether an examination was screening versus diagnostic. In addition, study staff were able to classify mammography examinations as screening versus diagnostic with high inter-rater reliability (κ = 0.85) (6). Finally, as a supplementary quality assurance mechanism, we subjected a sample of medical records to an additional review by a committee of clinicians who were masked to case–control status and that committee found no evidence of bias in classification.

We believe that women should continue to adhere to the screening recommendations that were developed largely from the results of randomized controlled trials. Nonetheless, communities and health systems must not become complacent about cancer screening programs. Once a screening test moves from the randomized clinical trial setting into the community, effort must be expended to maximize the quality and effectiveness of that screening.

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