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The Call for Change in Breast Cancer Screening Guidelines

One of the more remarkable aspects of the efforts to promote breast cancer screening has been the influence of rigorously conducted research. From an epidemiologic standpoint, the sequence of events could not have been better orchestrated.

In the 1950s and early 1960s, mammography emerged as a procedure that could lead to the detection of breast cancer at an earlier stage of the disease than could be detected in general clinical practice. This raised the question of whether mammography could be an effective screening tool when applied in the population at large. The screening efficacy of mammography, unlike that of the Papanicolaou smear for cervical cancer, was tested in a randomized controlled trial. The intervention consisted of both mammography and clinical breast examination; the latter was included because of the unknown sensitivity and specificity of mammography as a screening tool. The HIP trial (initiated in 1963 at the Health Insurance Plan of Greater New York with contract support from the National Cancer Institute) enrolled women aged 40 through 64 years for annual screening; the control group continued to receive usual care.[1]

Thirty years of randomized controlled trials, diverse in content and design, have been conducted in various parts of the world.[2] Their diversity is important. Trials differed in whether they applied single- or two-view mammography. In Sweden, four trials have used mammography alone in different age groups and with varied periods between screens. In Edinburgh, alternate-year mammograms and annual clinical breast examinations were offered to women aged 45 through 64 years at entry into the trial. In Canada, two trials are under way. In one, annual mammograms and clinical breast examinations are aimed at women aged 40 through 49 years; in the other, the test is to determine the value of adding annual mammograms to annual clinical breast examinations for women aged 50 through 59 years at entry.

Case–control and quasi-experimental studies have added to the information about the value of mammography. During the 1970s, the Breast Cancer Detection Demonstration Project in the United States demonstrated that mammography screening had increased the capability to detect breast cancer early among young and older women; additional improvements in mammography have occurred since then. Now that results from numerous randomized controlled trials are available, data from studies based on other designs have been relegated to an ancillary position in assessing the contribution of screening to the reduction of breast cancer mortality.

At the same time, many studies testing the effectiveness of different methods of engaging women in mammography screening are under way, frequently within the context of guidelines from the National Cancer Institute (NCI), American Cancer Society, and other organizations. These guidelines specify mammography screening every year or two for women aged 40 through 49 years and every year for women aged 50 years and older, and clinical breast examinations every year for all women aged 40 and older. The goal for breast cancer screening in the National Health Promotion and Disease Prevention Objectives calls for increases in acceptance of screening at ages 50 and older.[3(p72)] Among the detailed recommendations, however, is mammography screening for minority and low-income women in their 40s.[3(p115)] The results of the randomized controlled trials suggest that the guidelines should be changed.

One might best summarize the current situation by using the data from randomized controlled trials presented at the International Workshop on Screening for Breast Cancer in February 1993.[4] The task force charged with drawing conclusions that might affect screening guidelines found as follows:

1. The benefits of mammography screening for women aged 40 through 49 years are uncertain; the evidence from trials is "consistent in showing no benefit 5–7 years after entry (to screening), an uncertain, and, if present, marginal benefit at 10 to 12 years." In short, the value of mass mammography screening at these ages is judged to be questionable on the basis of currently available information.

2. The evidence is unequivocal that mammography screening leads to reductions in breast cancer mortality of about 30% at ages 50 through 69 years. The benefit is clear in all of the randomized controlled trials despite the variety in procedures (e.g., screening intervals from 12 to 33 months, single-view or two-view mammography, screening with or without clinical breast examination).

3. Evidence is lacking as to whether screening is efficacious at age 70 years and older. (Others have made the point that screening is advisable, unless health status is poor, because of the high risk for breast cancer at these ages and the compelling argument that there is no reason to expect an upper age limit in benefit.)[5]

Critics of the above conclusions—especially those with regard to women

Editor's Note. See related editorial by Zapka (p 12) and articles by Skinner et al. (p 43), King et al. (p 104), and Etzi et al. (p 107) in this issue.

aged 40 through 49 years—have emphasized that these trials, except for the Canadian study, were not designed to assess the efficacy of screening at particular ages and do not have the statistical power to detect meaningful benefits by age.[6] Other criticisms have been aimed at the trials' conduct, which affects results for women aged 40 through 49 years. In the case of the Canadian study, issues cited were poor quality of mammography in the early years, possible aberrations in the sampling procedure, and, as it turned out, a sample size inadequate to test for the effects projected. Problems with the Swedish two-county trial included the use of single-view mammography and a 2-year interval of screening at ages 40 through 49. More generally, statistical power was reduced in most, if not all, of the trials owing to the use of mammography by some women in the control groups.

There are counterarguments. For example, crossover by the controls does not come close to the far greater exposure to screening mammography in the intervention group, and the Canadian trials demonstrated that mammography had made substantial contributions in the detection of breast cancer. In the end, however, we have to make a choice about the evidence with regard to screening for women aged 40 through 49: we must either conclude that the results of the trials are too uncertain to support mass mammography screening as a public health measure or reject the studies, individually or collectively, as inadequate. In either case, we are left without scientific support for a public health policy that advocates routine screening with mammography at these ages (i.e., a policy that actively encourages all asymptomatic women to seek screening).

The NCI statement that was released in early December 1993, "Updating the Guidelines for Breast Cancer Screening," calls attention to the controversy about routine screening mammography for women aged 40 through 49 and the lack of convincing evidence on any reduction of breast cancer mortality related to screening in this age group. The statement also indicates that "routine screening every 1 to 2 years with mammography and clinical breast examination can reduce breast cancer mortality by about one-third for women ages 50 and over." Although the American Cancer Society and various professional groups have not changed their guidelines, the implications of the NCI proposal seem clear. New guidelines would emphasize mammography screening at 1- to 2-year intervals for women aged 50 years and older; for asymptomatic women aged 40 through 49 years, the guidelines would emphasize that patients and health care professionals should together discuss the uncertainty of the benefits, along with the risk factors, of mammography screening.

This issue of the Journal contains two papers reporting results of tests of alternative interventions to increase participation in mammography screening. In one study, attention was directed at women aged 50 through 74 years enrolled in an independent practice organization (IPO) type of health maintenance organization.[7] A reminder letter led to major improvements in use of mammography screening, and telephone calls were distinctly more effective than written communications in converting residual nonparticipants. In the other study, the subjects were women aged 40 through 65 years who had visited one of two family practice groups within the previous 2 years.[8] Physicians' letters tailored to the woman's situation (e.g., a letter to an older woman mentioned the relevance of her age as a risk factor) increased screening more effectively than a standardized letter. A third paper examines the accuracy of self-reports of mammography use by economically disadvantaged women aged 50 through 75; the conclusion is favorable for self-reports.[9]

A great deal more needs to be said about these papers, and this discussion will be found in this issue's editorial by Dr Jane Zapka.[10] The point being made here is that a change in guidelines will reduce if not resolve ambiguities regarding ages to be covered in demonstration programs and emphasized in research to promote mammography screening. There will be voices raised against a change that focuses routine mammography screening on women aged 50 and older, just as there are challenges (albeit less frequent) to screening at any age. But in making decisions on mammography screening for millions of women, we need to continue to rely on evidence from research, and the uncertainty of the available evidence for women aged 40 through 49 calls for a change in guidelines that excludes these women from programs for mass, routine screening with mammography. □

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