

Should Mammography Screening Be Promoted If Quality Assurance Is Lacking?

"Developing Cancer Control Capacity in State and Local Public Health Agencies," describes a project costing \$1.35 million aimed at researching and improving mammography and cervical cancer screening practices in older women (*Public Health Reports*, January-February 1992, pp. 15-23). It appears that, while relying on the unsubstantiated claims of others, the project researchers came to the conclusion that mammography screening is a safe and reliable procedure for the early detection of breast cancer. Unfortunately, this is not the case.

The article "Mammography Saves Lives," FDA Consumer, July-August 1991, revealed that "State surveys supported by the FDA found that the average score of images produced by mammography machines climbed from 7.8 in 1985 to 9.9 in 1990. (The range of scores is 0 to 16, with a score of 8 considered acceptable)."

The fact is that only high quality mammography (image scores 14-16) can detect a significant fraction of cancers in their early stages. Therefore, in 1990, very few facilities, if any, delivered high quality images. In many cases, women have been exposed to excessive radiation without the benefit of proper diagnostic information.

It cannot be denied that we are experiencing a breast cancer epidemic. For example, in 1979 about 90,000 women, or one in 14, developed breast cancer during their lifetimes ("Progress Against Breast Cancer," DHEW Publication No. 79-1621) as compared to 175,000, or one in 9, during their lifetime in 1991.

Obviously, mammography screening has not lived up to its expectations other than having become a lucrative business for many health providers. There is no justification for the promotion of mammography screening as long as legislation to mandate quality assurance is not enacted and strictly enforced.

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Meissner Replies

Our article, "Developing Cancer Control Capacity in State and Local Public Health Agencies," focussed on a grant program to enhance the technical capabilities of public health departments in cancer prevention and control—not on researching the effectiveness of screening mammography. However, it is true that many of the grantees chose to address breast cancer detection in their interventions. In doing so, they based their interventions on the current science.

The efficacy of mammographic screening has been established by randomized controlled trials, which show

that mortality due to breast cancer can be reduced through the use of mammography and clinical breast examination. The optimal frequency for screening is still open for debate, as are the lower age (younger than 50 years) and the upper age (older than 75 years) for which mammography is recommended. However, there is universal agreement in the scientific and medical communities that women older than 50 years will benefit from regular mammograms.

Certainly, achievement of the potential benefits of screening mammography requires proper functioning and operation of the equipment, image quality, and interpretation. Federal and State legislation, as well as the voluntary accreditation program supported by the American College of Radiology (ACR), reflects the importance of assuring mammographic quality; in fact, the FDA Consumer article cited shows that mammography quality has improved significantly in recent years. Because the ACR accreditation process is voluntary and currently backlogged, many facilities of high quality have applications pending. Women thinking of using a non-accredited facility should inquire if they are using dedicated equipment, if the technologist is certified by the American Registry of Radiological Technologists or licensed by the State, if the radiologist who reads the mammograms is specifically trained to do so, if the facility performs at least 10 mammograms each week, and if the machine is calibrated at least once a year. To help women find approved screening programs, ACR provides an updated list of its accredited facilities to the National Cancer Institute (NCI) each month. The public can call the Cancer Information Service at 1-800-4-CANCER to find out if a facility in a given area is ACR-accredited. Given the fact that about 1 of every 9 women will develop breast cancer during her lifetime, and that mammographic screening of asymptomatic women is known to be effective in reducing mortality, the NCI and many other organizations believe that promotion of mammography is essential if we are to reduce deaths from this disease.

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Taking Exception to Chronic Fatigue Syndrome Prevalence Findings by Price, et al.

We would like to address some serious methodological issues in the article, "Estimating the Prevalence of Chronic Fatigue Syndrome and Associated Symptoms in the Community," by Rumi K. Price, et al., published in the September-October issue of *Public Health Reports*. We believe that because of the deficiencies in the design

of this research, the authors' conclusions are totally illogical and invalid.

In this article, the authors conclude that Chronic Fatigue Syndrome (CFS), as defined by the Centers for Disease Control (CDC) Diagnostic Criteria, might be "quite rare" in the general population, as only 1 of 13,538 individuals studied was deemed to have CFS. The official CDC Diagnostic Criteria, however, were not utilized to diagnose cases of CFS. Instead, the researchers reviewed interview questionnaire data collected between 1981 and 1984 for a purpose unrelated to diagnosing CFS. In fact, the CDC Diagnostic Criteria were not formulated and published until 1988.

The data the authors reviewed were collected as part of the Epidemiologic Catchment Area (ECA) Program. The ECA study, however, was implemented for the clinical reappraisal of the Diagnostic Interview Schedule (DIS), a test developed to assess psychiatric morbidity. Another purpose of the ECA study was the estimation of the prevalence of psychiatric disorders.

The diagnosis of Chronic Fatigue Syndrome, according to the CDC Diagnostic Criteria, requires a comprehensive history, physical examination and laboratory workup. Price, et al., relied solely on symptom reports to diagnose CFS and did not conduct any physical examinations or laboratory studies.

Additionally, the questions utilized in the DIS to diagnose CFS only partially resemble some of the symptoms and signs cited in the CDC Diagnostic Criteria. Several important symptoms and signs cited in the CDC Diagnostic Criteria were not even included in the DIS. Utilizing the DIS to estimate the prevalence of Chronic Fatigue Syndrome is as inappropriate as relying solely on symptoms reported during the DIS interview to estimate the prevalence of peptic ulcer or coronary disease, with no physical examination or laboratory assessment.

On August 25, 1992, a letter by Ned Curran, Associate Editor of *Public Health Reports*, was released to the press. This letter announced that Price, et al. found only one case in over 13,000 that "fit the technical description on the syndrome promulgated by the Centers for Disease Control." Since the CDC Diagnostic Criteria were not utilized in the collection of the data, such a statement grossly misrepresents the findings of the study by Price, et al. Additionally, Curran set forth the notion that Chronic Fatigue Syndrome constitutes a "chimeric ailment that hyperkinetic go-getters thought they were heir to" and presented it as though it were part of the research conclusions of Price, et al.

The quality of the research, selection for publication, and manner of notifying the press of the study are far below the standards we would have expected from a journal such as *Public Health Reports*. This research was funded in part by grants from the National Institute of Mental Health and the National Institutes of Health. We would very much hope that in the future our taxpayer dollars will be put to better use.

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(Editor's Note: The letter to the press referred to was, in fact, a covering note to members of the media that accompanied copies of the actual article in question. It was designed to pique their interest and draw their attention to the article itself. To achieve that purpose, it was deliberately cast in hyperbole, although it was based on the authors' own synopsis. It was never meant to be a news release as such, standing on its own. The assumption was that news people would read the actual article and make their own interpretations—as they did. To the extent that the note is regarded as insensitive, we apologize. That was not intended.)

Price, et al., Respond

In reply to the letter from Robin, Lipkin, and Hume on "Estimating the Prevalence of Chronic Fatigue Syndrome and Associated Symptoms in the Community," we had addressed in our paper several methodological limitations they correctly identified (1). We acknowledged that the criteria of chronic fatigue syndrome (CFS) in our analysis were not identical to the Centers for Disease Control (CDC) criteria because we lacked information on physical and laboratory findings (1a); Epidemiologic Catchment Area (ECA) data collection preceded the 1988 CDC criteria (1b,1c); and the Diagnostic Interview Schedule (DIS) was not designed to study CFS (1d).

We underscored these limitations, and indeed stressed that "the findings of this study need to be verified by future studies using full CDC criteria, including clinical assessment... Such studies... would provide a more precise prevalence estimate of CFS" (1c).

Other points raised by Robin et al. need further clarification. The main purpose of the ECA was not "clinical reappraisal of the DIS" (2). The DIS questions available in the ECA data do resemble symptom descriptions in the CDC criteria (1e), though the battery of these questions was incomplete. Other authors have also successfully used DIS questions to study nonpsychiatric syndromes, including fibromyalgia (1d).

Robin et al. stated that we relied solely on patient reporting because of the absence of laboratory work-up. If the ECA study had contained laboratory information, our prevalence estimate of CFS could have been even lower, since potential CFS cases could have been suffering from physical illnesses detectable by laboratory tests. It is also worth pointing out that laboratory evaluation has little utility in the diagnostic process of chronic fatigue syndrome (3,4).

The comparison by Robin et al. of CFS to peptic ulcer and coronary artery disease actually speaks to a different point. Peptic ulcer and coronary artery disease can be objectively diagnosed by endoscopic or radiologic proce-