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Meeting Report

Recommendations of the Consensus Development Panel on Breast Cancer Screening

The NCI[1] has received the final conclusions and recommendations of a 16-member panel that examined the issues and state of the art of breast cancer screening. The Panel,[2] which met September 14 to 16, 1977, at Bethesda, Md., consisted of clinicians, scientists, and lay people and was chaired by Dr. Samuel Thier, professor and chairman of the Department of Internal Medicine at Yale University.

The Panel concluded that scientific evidence of the benefit of X-ray mammography was provided in a study conducted in the 1960's by the Health Insurance Plan of Greater New York. It agreed that benefit, as measured by mortality, was established for women age 50 and over and that this benefit was provided through combined use of physical examination and mammography. The individual contribution of each method and the benefit to women under 50 are not known.

The Panel emphasized the difference between the use of mammography as a screening tool and as a diagnostic technique. The value of mammography in diagnosis for evaluating symptoms or clinical signs of breast cancer, such as the presence of a lump, swelling, discharge, dimpling, thickening, or other abnormality in the breast, was not questioned.

Panel members acknowledged that mammography has improved markedly in recent years in the detection of smaller and presumably earlier cancers and that radiation dosage from the procedure has been reduced greatly. Nonetheless, they accepted the presumed risk of exposure to radiation from mammography as outlined in a report submitted in March 1977 by Dr. Arthur C. Upton, who was then head of an *ad hoc* working group studying the risk of radiation exposure. According to the report, current evidence strongly suggests a direct linear relationship between the amount of radiation exposure and the risk of developing cancer. The report placed the presumed increased risk from exposure to the breast at less than 1%/rad. This implies that a mammogram involving current low-dose techniques would increase a woman's presumed lifetime risk of breast cancer from an average natural level of about 7% to a level of less than 7.07% following mammography.

The NCI has accepted these findings and, on the basis of the Panel's recommendations, has instructed directors of the 27 BCDDP to restrict the routine use of mammography in annual screening to women 50 years of age and older. Women in the age range of 40 through 49 will be offered mammography in screening only if they have a prior history of breast cancer or if their mother or sister(s) have had breast cancer. For women in the age range of 35 through 39, mammography will be restricted to those with a history of breast cancer. Except for this age group, these guidelines are identical with those followed by the demonstration projects since May 1977.

Since 1973, these projects, cosponsored by the NCI and the American Cancer Society, have enrolled 280,000 women in the age range of 35 through 74 in a voluntary screening program. Medical history, physical examination, X-ray mammography, thermography, and the teaching of breast self-examination demonstrate methods for the early detection of breast cancer.

The consensus group concluded that, although there is no known harmful effect from thermography, no scientific data support its value as a routine breast cancer screening technique under present conditions of general use. It suggested strongly that research be carried out to improve thermographic techniques and to determine its role in screening. The group recommended that thermography be discontinued as part of the routine BCDDP screening process except in those centers where proficiency is available to justify further clinical investigation under appropriate research design.

The NCI will consult with project directors to determine which centers might provide valuable information by continuing the use of thermography. Until these determinations are made, all centers will continue to offer thermography as part of the routine screening process.

Panel members concluded that the BCDDP may have an ethical obligation to continue to offer mammography to women under 50 enrolled in the program, if these women are aware through informed consent that the benefit has not been proved, that there is presumed risk, and that the panel does not recommend its routine use for this age group.

The NCI has made no final determination in this matter. A new informed consent form that will reflect these concerns is being developed. Until it is completed, the BCDDP have been instructed to continue screening with mammography only those women designated by the panel or those whose personal physicians submitted written requests for mammography. As the panel recommended, the new informed consent form also will include the radiation dosage received. This information will be supplied at each project and will be updated when it is appropriate to do so.

Data on the breast cancer detection rates of the BCDDP were provided in a report from the Working Group to Review the NCI–American Cancer Society BCDDP, chaired by Dr. Oliver Beahrs of the Mayo Clinic. The Pathology Review Committee of the Beahrs group reviewed 506 cases of minimal cancers (less than 1 cm in size, or papillary or

[1] The abbreviations used are: NCI, National Cancer Institute; BCDDP, Breast Cancer Detection Demonstration Projects.

[2] The panel consisted of Kenneth Casebeer, Esq., Dr. Archie Cochrane, Willie Dell, Dr. Milton Elkin, Sister Margaret Farley, Dr. Emil Frei, III, Patricia R. Hall, Dr. Raffaele Lattes, Dr. Virgil Loeb, Dr. Brian MacMahon, Dr. George Mishtowt, Dr. Francis Moore, Dr. Edward Radford, Dr. Leo Rigler, Dr. Samuel Thier, and Dr. Jane Wright.

intraductal cellular proliferations). Of these, they concluded that 66 cases previously interpreted as cancerous should be reclassified as benign. (This figure later was revised to 64 cases.) They designated an additional 22 cases as "borderline," because agreement could not be reached on whether the lesions were benign or malignant. The Panel recommended that in these instances the women involved should be notified that their cases had been reinterpreted.

To pursue these developments, the NCI began an immediate review of the cases in question and found that the Pathology Review Committee may not have received consistently all the pathology slides used by the hospital pathologist in making the diagnosis. For example, when the entire tumor was removed during biopsy, tissue samples obtained following subsequent surgery contained no malignant tissue. In a number of cases, a two-stage procedure (biopsy during one operation and surgery as a later, separate procedure) was performed. In many such cases, the original pathologist considered the case to be borderline and consulted several other pathologists before treatment decisions were made. Often, the woman was informed of the difficulty in making a pathological assessment, and she was involved in the decision to proceed with surgery. Therefore, in most instances the original pathologist recognized difficulty in assessing the lesion; interpretation may have depended critically on the particular slide or slides examined; differences of opinion about these lesions may not be uncommon; and a final assessment may be fraught with considerable uncertainty.

The project directors were asked: to review the materials sent to Dr. Beahrs' BCDDP Working Group; to obtain additional slides not available to the Review Committee; to discuss the diagnosis, treatment, and other pertinent information (such as medical history) with the project pathologist, hospital pathologist, and personal physician; and to submit to the Beahrs group all information that might clarify the findings of the Pathology Review Committee. The group was asked to examine this additional information and recently submitted a final report on its findings.

It is expected that the number of cases in which reclassification as benign or borderline persists will be lower than that first reported by the Beahrs group. A procedure for notifying the women whose cases may deserve to remain reclassified after further review is being developed by the NCI, the project directors, and the collaborating physicians.

The Consensus Development Panel recommended that those women in whom cancer was detected should become the subjects of follow-up studies that could provide valuable scientific information. Panelists could not reach a consensus as to whether those women in whom no cancers were found also should be subjects of follow-up studies after conclusion of the screening program.

The NCI recognizes that follow-up studies on women with cancer, particularly of the "minimal"type, can provide valuable insight into the progression of breast cancer. The NCI will develop procedures to follow women whose cancers were diagnosed through BCDDP screening. Follow-up of women found to be normal in the screening is under study.

The Panel cited a need for quality control of the screening procedures, including physical examination, and of the pathological review. It recommended that the two-stage procedure of concurrent pathological review by consulting pathologists of "minimal" lesions be performed routinely prior to treatment. The NCI will work out details with BCDDP project directors to implement this recommendation.

Before making its recommendations, the panel heard presentations on the benefits and risks of routine breast cancer screening of symptom-free women from 4 groups of scientists who have studied the issue and from other professionals and concerned members of the public.

Additional material on the background and issues on which these recommendations were made will be published along with a summary of the report from Dr. Beahr's group in an upcoming issue of the *Journal of the National Cancer Institute.*

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