

CONSENSUS CONFERENCE 2000: ADJUVANT THERAPY FOR BREAST CANCER

National Institutes of Health Consensus Development Conference Statement
November 1-3, 2000.

The National Institutes of Health convenes consensus development conferences on various topics. Pertinent to practice in breast cancer, its most recent conference held November 1-3, 2000, addressed adjuvant therapy for breast cancer. The conclusions of the conference statement are reported below. The full NIH Consensus Statement on Adjuvant Therapy for Breast Cancer is available by calling 1-888-NIH-CONSENSUS (1-888-644-2667) or by accessing the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

During the past 10 years, substantial progress has been made in the treatment of breast cancer. For the first time, breast cancer mortality rates are decreasing in the United States. Refinements of adjuvant treatment have contributed to this advance.

Generally accepted prognostic and predictive factors include age, tumor size, lymph node status, histological tumor type, grade, mitotic rate, and hormonal receptor status. Novel technologies, such as tissue and expression microarrays and proteomics, hold exciting potential. Progress, however, will depend on proper design and analysis of clinical and pathological investigations.

Decisions regarding adjuvant hormonal therapy should be based on the presence of hormone receptor protein in tumor tissues. Adjuvant hormonal therapy should be offered to women whose tumors express hormone receptor protein. At present, 5 years of tamoxifen is standard adjuvant hormone therapy; ovarian ablation represents an alternative option for selected premenopausal women. Adjuvant hormonal therapy should not be recommended to women whose tumors do not express hormone receptor protein.

Because adjuvant polychemotherapy improves survival, it should be recommended to the majority of women with localized

breast cancer regardless of nodal, menopausal, or hormone receptor status. The inclusion of anthracyclines in adjuvant chemotherapy regimens produces a small but statistically significant improvement in survival over nonanthracycline-containing regimens.

Available data are currently inconclusive regarding the use of taxanes in adjuvant treatment of node-positive breast cancer. The use of adjuvant dose-intensive chemotherapy regimens in high-risk breast cancer and of taxanes in node-negative breast cancer should be restricted to randomized trials. Ongoing studies evaluating these treatment strategies should be supported to determine if they have a role in adjuvant treatment.

Studies to date have included few patients older than 70 years. There is a critical need for trials to evaluate the role of adjuvant chemotherapy in these women.

There is evidence that women with a high risk of locoregional tumor recurrence after mastectomy benefit from postoperative radiotherapy. This high-risk group includes women with four or more positive lymph nodes or an advanced primary cancer. Currently, the role of post-mastectomy radiotherapy for patients with one to three positive lymph nodes remains uncertain and should be tested in a randomized, controlled trial.

Individual patients differ in the importance they place on the risks and benefits of adjuvant treatments. Quality of life needs to be evaluated in selected randomized clinical trials to examine the impact of the major acute and long-term side effects of adjuvant treatments, particularly premature menopause, weight gain, mild memory loss, and fatigue. Methods to support shared decision making between patients and their physicians have been successful in trials; they need to be tailored for diverse populations and should be tested for broader dissemination.

NIH Consensus Statements are prepared by a nonadvocate, non-federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a two-day public session, (2) questions and statements from conference attendees during open discussion periods that are part of the public session, and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the federal government.