

Estimating Tamoxifen Eligibility and Net Benefit for Breast Cancer Chemoprevention Using the Gail Model and a Tamoxifen Benefit/Risk Index

Freedman AN¹, PhD, Graubard BI², PhD, Rao RS², PhD, McCaskill-Stevens W³, MD, Ballard-Barbash R¹, MD PhD, Gail MH², MD PhD. National Cancer Institute, Division of Cancer Control and Population Sciences, Division of Epidemiology and Genetics, Division of Cancer Prevention.

Background. Assessing the overall public health impact of the chemopreventive use of tamoxifen among women in the U.S. general population requires evaluating the number of women who are eligible to take the drug based on U.S. Food and Drug Administration (FDA) indications and the number for whom the adverse events of taking tamoxifen outweigh the proven benefits for breast cancer risk reduction.

Methods. Using weighted data from the 2000 National Health Interview Survey Cancer Control Module, we provide national estimates for the total number of white U.S. women without a previous diagnosis of breast cancer who would be eligible for tamoxifen chemoprevention based on FDA indications (women aged 35 years and older who had a 5-year risk of breast cancer of 1.67% using the Gail Breast Cancer Risk Assessment Model). Estimates also were calculated for the total number of white U.S. women who would benefit from tamoxifen chemoprevention based on evidence for a positive benefit/risk index. The benefit/risk index takes into account tamoxifen's adverse events, (e.g., excesses of endometrial cancer, pulmonary embolism, stroke, deep vein thrombosis, and cataracts) as well as its proven benefits for reducing breast cancer risk based on a woman's age, race, risk factors for breast cancer, and whether or not she has a uterus.

Results. For all 50,104,829 white women ages 35 to 79 in the U.S. population in 2000, 9,377,715, or 18.7% (95% = CI 17.8% to 19.7%), were eligible for tamoxifen chemoprevention based on FDA indications, but only 2,431,911, or 4.9% (95% CI = 4.3% to 5.4%), had a positive benefit/risk index. The percentage of white women benefiting varied by age, with 0% benefiting at ages 35–39, 8.1% at ages 40–49, 8.5% at ages 50–59, 2.1% at ages 60–69, and 0.1% at ages 70–79.

Conclusions. Breast cancer risk assessment models and tamoxifen benefit/risk indices can be useful in understanding the public health implications of tamoxifen use for breast cancer chemoprevention at the population level. Although a substantial percentage of U.S. women (18.7%) would be eligible for breast cancer chemoprevention with tamoxifen, based on FDA indications, a much smaller percentage (4.9%) would have an estimated net benefit based on their age and breast cancer risk factors. Few white women without a previous diagnosis of breast cancer (0.2%) currently use tamoxifen. These data have implications for educating health care professionals in evaluating the eligibility, net benefit, and appropriate use of tamoxifen for breast cancer chemoprevention for women in the U.S. population.

[JNCI 2003;95:526-32]