Reasons for Participation in Risk Assessments for the Study on Tamoxifen and Raloxifene—Study Design

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The objective of this research project is to study what meanings individualized risk estimates—e.g., the Gail model (1)—take on in an individual's life and to evaluate if and how the risk estimates are used as decision aids.

The population for this study is women who were screened for the chemoprevention clinical trial Study of Tamoxifen and Raloxifene (STAR). The eligibility criterion for STAR is a 1.67 percent elevated risk of getting breast cancer in the next 5 years, as determined by the modified Gail model. Women who are screened for the trial receive an estimate of their absolute risk of developing breast cancer and, if eligible, a risk-benefit analysis of adverse events involved in taking the studied drugs.

It has been noted that people routinely misinterpret numerical information about the probability of an event (2). Societal institutions, culture, and the way risk information is presented influence risk perception (3). This study analyzes what kinds of meanings are ascribed to individualized risk estimates by those women who went through the risk assessment for the STAR trial. A mixed methodology is used that combines qualitative, in-depth, narrative interviews; a questionnaire assessment; and an analysis of the risk assessment forms. The questionnaire addresses the reasons women complete the risk assessment forms and their attitudes towards clinical trials. With a subset of the sample, in-depth, narrative interviews (4) are conducted on what the risk estimates mean to them and how that relates to their decision concerning STAR participation. The interviews will be recorded, transcribed, and entered into ATLAS.TI, a computer software program designed to analyze qualitative data. Analysis will follow the rules of grounded theory (5). In addition, expert interviews will be conducted with study recruiters and other staff. At the completion of STAR recruitment, T-test and chi-square tests will be performed on variables collected during the recruitment process for STAR through the risk assessment forms to analyze differences between participants and study decliners.

These three types of data will be used for triangulation and will thus enable a multidimensional view on uses and meanings of individualized risk estimates for women at increased risk of developing breast cancer—as well as on STAR participation.

(1) Gail, M. H. (2001). "The Estimation and Use of Absolute Risk for Weighing the Risks and Benefits of Selective Estrogen Receptor Modulators for Preventing Breast Cancer." Annals New York Academy of Science: 286-291.
(2) Rothman, A. J. and M. T. Kiviniemi (1999). "Treating people with information: an analysis and review of approaches to communicating health risk information." J Natl Cancer Inst Monogr(25): 44-51.
(3) Douglas, M., A. B. Wildavsky (1983). "Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers." University of California Press
(4) Honer, A. (1993). "Lebensweltliche Ethnographie: eine explorativ-interpretativer Forschungsansatz am Beispiel von Heimwerker-Wissen." Deutscher Universitaets-Verlag
(5) Glaser, B.G., A. L. Strauss (1967). "Discovery of Grounded Theory: Strategies for Qualitative Research." DeGruyter