

**PROPOSED REVISION OF THE GAIL BREAST CANCER (BC) RISK ASSESSMENT MODEL**

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The Gail model computes absolute 5-year BC risk by multiplying an individual's relative risk (based on four model risk factors) by the age- and ethnicity-specific hazard in the absence of any risk factors (baseline risk). The baseline risk is derived from SEER incidence rates multiplied by one minus the population-attributable risk, (1- PAR). Current Gail model PARs were based on analysis of white American (WA) BC cases from the Cancer and Steroid Hormone Study and approximately 100 African-American (AA) BC cases from the Breast Cancer Detection and Demonstration Project; these PARs estimate that Gail model risk factors account for 40% of BC in WA women and more than 50% in AA. We have previously shown (ASCO, 2002) that the Gail model yields lower risk estimates for AA compared to WA women—even among women less than 45 years [of age]—where BC incidence is higher for AA women.

We sought to improve model generalizability by evaluating its risk factor and baseline risk/PAR components in a contemporary, mixed-ethnicity data set. We studied the model in the women's Contraceptives and Reproductive Experiences (CARE) study, a population-based data set of 4,575 BC cases (1,622 AA; 2,953 WA) and 4,682 age-matched controls (1,661 AA; 3,021 WA). Chi-square analyses validated the accuracy of the model risk factors in both AA and WA participants. However, PARs calculated from this data set reveal that approximately 30% of BC in WA women can be attributed to these risk factors and less than 20% in AA women. Utilization of our revised PARs yields higher baseline risk estimates for AA women. Incorporation of these revised baseline risk estimates into Gail model absolute risk calculations should, therefore, improve model performance for AA women and increase their eligibility for chemoprevention studies.

**5-Year Baseline Risk Estimates (%) for Gail Model**

| Age   | African American |                  | White American   |                  |
|-------|------------------|------------------|------------------|------------------|
|       | Current Estimate | Revised Estimate | Current Estimate | Revised Estimate |
| 35-39 | 0.22             | 0.33             | 0.28             | 0.22             |
| 40-44 | 0.31             | 0.57             | 0.45             | 0.42             |
| 45-49 | 0.36             | 0.69             | 0.58             | 0.62             |
| 50-54 | 0.42             | 0.75             | 0.70             | 0.76             |
| 55-59 | 0.51             | 0.94             | 0.86             | 0.96             |
| 60-64 | 0.56             | 1.15             | 1.02             | 1.18             |