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Clinical Implementation of a Breast Cancer Risk Assessment Program in a Multiethnic Patient Population: Which Risk Model to Use?

To the Editor:

The integration of risk assessment into clinical breast screening holds promise in increasing health care efficiency and decreasing morbidity and mortality associated with breast cancer diagnosis. While the National Cancer Comprehensive Network recommends risk counseling and increased screening for women with a 5-year risk of $\geq 1.7\%$ based on the Gail model or other risk model (1,2), the US Preventive Services Task Force recommends that women who are at increased risk for breast cancer and at low risk for adverse medication effects be offered risk-reducing medications, such as tamoxifen or raloxifene, by their clinicians (3). However, neither recommendation clearly specifies which risk model to use; rather, they mention a number of different risk models. Thus, clinicians seeking to integrate breast cancer risk assessment into their practice are faced with uncertainty on how to assess risk in their patients.

Concerns have been expressed regarding the limited clinical applicability of the Gail model (4,5). In addition, the Gail model does not consider some established risk factors, including breast density, obesity, and hormone use. We sought to determine the potential impact of adding two other models, the Breast Cancer Surveillance Consortium (BCSC) and the Tyrer-Cuzick models, on assessing screening mammography patients' breast cancer risk in the University of California, Irvine (UCI) Athena Breast Health Network Risk Assessment Program (6).

After obtaining approval by the UCI Institutional Review Board, 3,426 research participants were recruited from the risk assessment program between March 2011 and January 2014. For this pilot study, a sample of 325 research participants were consecutively

selected starting with the most recent enrollment date, based on age and race/ethnicity, resulting in $\sim 25\%$ between 40–49, 50–59, 60–69, and 70–79 in each of the three most populous race/ethnicity categories in our patient population: non-Hispanic White, Hispanic, and Asian. Patients who met exclusionary criteria for the Gail, BCSC, or Tyrer-Cuzick models were excluded, resulting in 307 participants in our analytic pilot study cohort. All data except breast density data were obtained from the Athena Breast Health Questionnaire, which also served as an electronic intake form for the patients. Breast density data, categorized as BIRADS 1–4, were extracted from radiologist-dictated mammogram reports accessed through patients' electronic medical records. The data were used to calculate each patient's breast cancer risk scores using three risk assessment tools: (a) the Breast Cancer Risk Assessment Tool (www.cancer.gov/bcrisktool), based on the modified Gail model (7); (b) the BCSC Risk Calculator (tools.bcsc-scc.org/BC5yearRisk) (8); and (c) the IBIS Breast Cancer Risk Evaluation Calculator (www.ems-trials.org/riskevaluator), which calculates Tyrer-Cuzick scores (9). The distinct and overlapping risk factors considered in each of these models are depicted in Figure 1.

As expected, the average risk scores for White women (1.66–1.86%) were higher than for Hispanic (0.90–1.19%) and Asian (1.01–1.34%) women according to all models tested, and Pearson correlation coefficients between risk models ranged from 0.54 to 0.80 (data not shown). Women were categorized as “increased risk” according to a given risk model if their 5-year risk score was $\geq 1.7\%$. Using this criterion, the percentages of women at “increased risk” were higher in White women (42.6–43.6%) than in Hispanic (6.5–15.0%) and Asian (11.1–23.2%) women ($p < 0.0001$ using chi-squared test for both comparisons and for all three models; Fig. 2A). Risk stratification was also performed according to combinations of the three models used. Increasing the strin-

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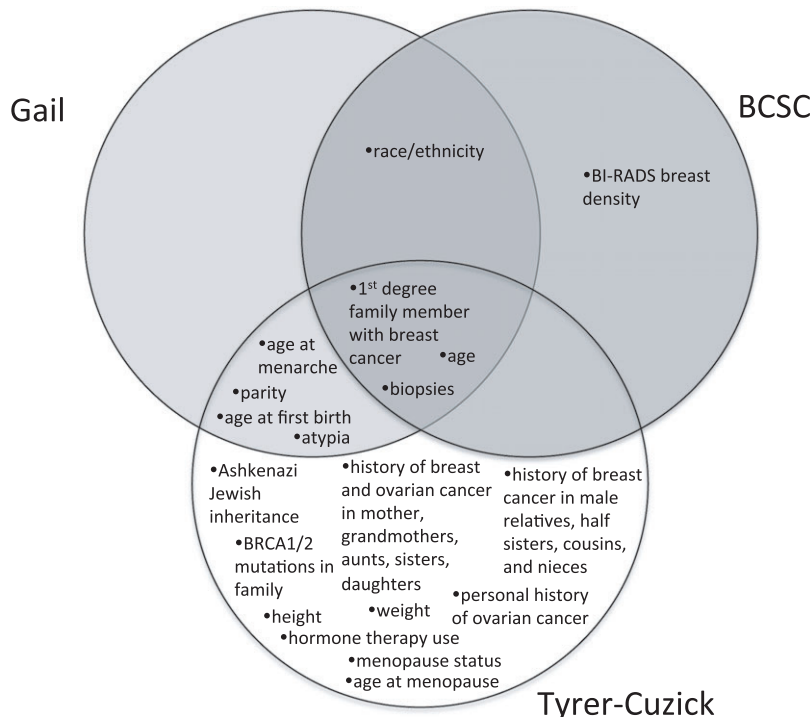


Figure 1. Factors considered in the Gail, Breast Cancer Surveillance Consortium (BCSC), and Tyrer-Cuzick models.

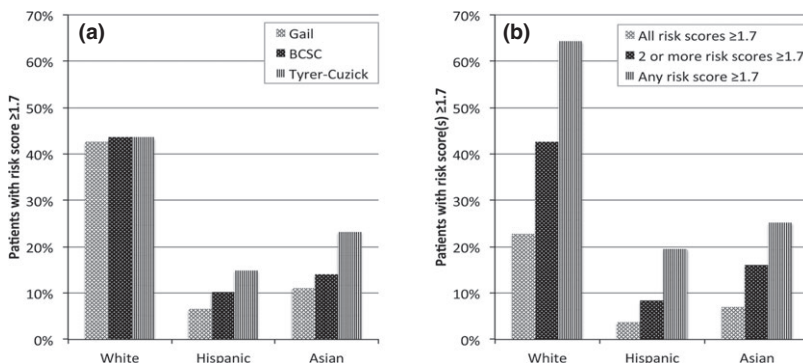


Figure 2. (a) Percent of patients with risk scores $\geq 1.7\%$ according to each of the three risk models tested. (b) Percent of patients with risk scores $\geq 1.7\%$ according to either all, ≥ 2 , or any of the three models tested.

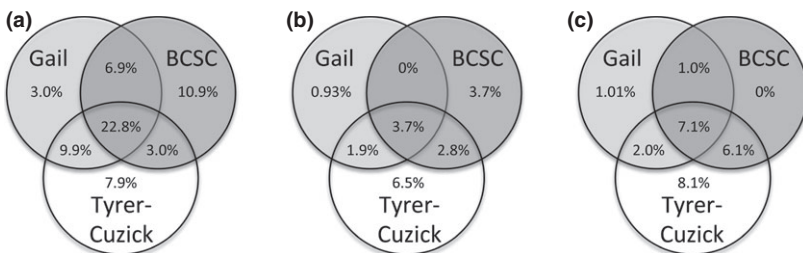


Figure 3. Percent of patients with risk scores $\geq 1.7\%$ according to different/overlapping risk models by race/ethnicity. (a) White; (b) Hispanic; (c) Asian.

gency of criteria such that at least two risk scores had to be $\geq 1.7\%$ decreased these percentages, and further increasing the stringency to all three scores further decreased these percentages. Conversely, decreasing the stringency to having *any* risk score $\geq 1.7\%$ dramatically increased the percentages (Fig. 2B).

The percent of patients with risk scores $\geq 1.7\%$ according to distinct and overlapping risk models by race/ethnicity is depicted in Figure 3. While the Gail model identified 42.6% of White screening mammography patients as “increased risk,” it missed an additional 21.8% who had a score $\geq 1.7\%$ according to one of

the other two models tested. Taken another way, only 66.1% of White women with any risk score $\geq 1.7\%$ were identifiable by the Gail model. Moreover, only 33.1% of Hispanic and 44.0% of Asian women with any risk score $\geq 1.7\%$ were identifiable by the Gail model, whereas 67.7% of White, 76.2% of Hispanic, and 92.0% of Asian women with any risk score $\geq 1.7\%$ were identifiable by the Tyrer-Cuzick model.

Our results clearly indicate that basing breast cancer risk status on only one model could result in the misclassification of a significant proportion of women compared with if their risk were assessed using a different model, in a race/ethnicity-dependent manner. Using two or more models would provide a wide spectrum of frequencies of women categorized as “increased risk,” depending on how stringent the criteria were (e.g., $\geq 1.7\%$ according to *any* of the three models versus *all* three models). Thus, depending on the volume of patients undergoing risk assessment and the resources of staff and services providing risk counseling and other downstream services, a breast health program may opt to use a combination of risk models suitable for their patient population based on race/ethnicity or on a personalized basis. However, a larger study with follow-up data on breast cancer incidence is needed to further examine the potential impact of using multiple breast cancer risk assessment models in a breast health program.

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