A Single Mathematical Model Predicts Physicians’ Recommendations and Postmenopausal Women’s Decisions to Participate in a Clinical Trial to Prevent Breast Cancer or Coronary Heart Disease

Clairice T. Veit, PhD

Few eligible postmenopausal women participate in clinical trial research to prevent breast cancer or coronary heart disease, making it impossible to adequately assess the efficacy of tested interventions for this vulnerable group. To elucidate the causal factors and decision model underlying participation behavior, 180 white, African American, and Hispanic postmenopausal women judged their likelihood of participation in a breast cancer or coronary heart disease prevention clinical trial in scenarios with varied cost/remuneration, perceived risk, doctor’s recommendation, and expected toxicity. In addition, 293 white, African American, and Hispanic male and female physicians judged the strength of their participation recommendation in scenarios with varied cost/remuneration, expected toxicity, patient’s age, and the source of the information about the clinical trial. An additive and constant-weight-averaging model were rejected. The same configural-weight-range model accounted for judgments in both breast cancer and coronary heart disease scenarios, with different parameter values for each group. According to this model, white and Hispanic women under 70 years of age are most likely to participate, even under somewhat adverse conditions; costs and high toxicity levels act as severe barriers to physicians’ positive recommendations and women’s participation. Perceived risk was the most important factor for women, yet only 8% and 15% reported ever having received risk information from their doctor for breast cancer and coronary heart disease, respectively. For these two diseases, respectively, 75% and 48% of women rated their risk of the disease as low and 76% and 88% reported they had never heard of a randomized clinical trial or of a prevention clinical trial being conducted. These results have implications for education, information dissemination, and prevention clinical-trial planners. Key words: prevention clinical trials; postmenopausal white and minority women; participation barriers and motivators; breast cancer; coronary heart disease; physicians’ recommendations; testing decision models. (Med Decis Making 2004;24:330–350)
testing the efficacy and side effects of proposed prevention interventions. Experiments provide the only causal basis for recommending interventions. However, eligible minorities participate in prevention clinical trials for BC and CHD in very small numbers making it difficult if not impossible for researchers to recommend interventions for these groups.

If we had a credible theory of white and minority postmenopausal women’s decisions to participate in prevention clinical trials, we would better understand what factors influenced their participation decision, how they valued and traded off these factors, how white and minority women differed in these decisions, and under which conditions they would be more likely to participate. The resulting information would guide design of clinical trials to increase participation. Judgment studies make it possible to systematically manipulate factors that are characteristic of BC and CHD prevention clinical trial situations, create many more scenarios than it would be feasible to entertain in a behavioral study, and assess the causal effects of these factors on judged participation decisions.

Researchers have suggested a number of reasons for nonparticipation in clinical trials research, but none has been studied systematically. Reasons include toxic side effects of the intervention, cost (in time, transportation, and other out-of-pocket expenses), perceived low risk of developing the disease, and the lack of a physician’s recommendation to participate in the clinical trial study. Researchers have conjectured the first 2 (among others) as reasons for physicians’ not recommending that their eligible postmenopausal patients join clinical trial research studies.

The purpose of the present research was to develop a mathematical judgment theory that explains postmenopausal women’s decisions to participate in a prevention clinical trial for BC or CHD under a variety of realistic conditions. Since the recommendation a woman gets from her primary care physician appeared to be a major variable in her decisions, this study also develops a model of physicians’ decisions to recommend that their patients participate in a BC or CHD prevention clinical trial. The 2 models will describe how women and physicians value and tradeoff factors that describe the prevention clinical trial scenarios in making their decisions. Comparison of decision models for BC and CHD helps us understand how the model for one disease may apply to another.

Because participation by postmenopausal minority women in prevention clinical trials is particularly low and because postmenopausal women of different races/ethnicities and ages might value and tradeoff participation factors differently, we stratified our study on age (younger than 70 years and 70–80 years) and race/ethnicity: (African American, Hispanic, and white). Similarly, we stratified physicians on gender, age (40 years and younger and older than 40), and race/ethnicity (African American, Hispanic, and white).

**HYPOTHESIZED PARTICIPATION AND RECOMMENDATION DECISION-MAKING MODELS**

It is likely that only a few of the many barriers or motivations suggested actually affect physicians’ recommendations or women’s decisions to participate. Therefore, in this study, we manipulated only a few factors by combining their levels to form scenarios for physicians and for women. Physicians judged the strength of their recommendations to their eligible patients in the different scenarios; women judged the chance they would participate in the prevention clinical trial. Their data were then used to test among mathematical models of recommendations by physicians and participation by postmenopausal women.

**Factors**

On the basis of data from the initial factor reduction sessions (details in the Method section), we selected 4 factors to manipulate for physicians’ and women’s studies. Physicians’ and women’s factors (and levels) are shown in Tables 1 and 2.

Some of the factor levels in Tables 1 and 2 can be viewed as motivators and some as barriers. For example, costs of $250 and severe expected toxicity levels seem like barriers to a physician’s recommendation (to join the prevention clinical trial); remunerations of $500 and a doctor’s recommendation seem like motivators for women to participate.

**Three Decision-Making Models**

We compared 3 mathematical models of judged recommendation and participation decisions: a weighted-additive model, constant-weight-averaging model, and configural-weight-range model. The mathematical formulations of these models are presented in the appendix. Given appropriate experimental designs, each model makes different predictions about how physicians value and tradeoff causal factors that affect the direction and strength of their recommendations to participate and how women value and tradeoff factors that affect their decisions to participate in a BC or CHD
clinical trial. The models are described in the next 3 sections.

Weighted-additive model. A statistician might use a weighted-additive model, for example, the multiple regression model. This model predicts that a woman associates a value with each level of the factors; attaches a weight, or measure of importance, to each factor; multiplies the weight with the value; and sums these products. (In principle, weighted-additive models [e.g., Equation A1] cannot be used to unconfound weight

Table 1  Experimental Factors and Factor Levels for Physicians

<table>
<thead>
<tr>
<th>Factor Name</th>
<th>Factor Description</th>
<th>Factor Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>The source that provides you with the information about the clinical trial</td>
<td>1) Ad in news media&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2) Personal letter from the sponsor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) Your patient</td>
</tr>
<tr>
<td>Patient’s Age</td>
<td>The age of the patient you are considering</td>
<td>1) 60 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2) 70 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) 80 years</td>
</tr>
<tr>
<td>Expected Toxicity</td>
<td>Expected side effects of the prevention intervention:</td>
<td>1) None</td>
</tr>
<tr>
<td></td>
<td>a) Possible side effects (SEs)&lt;sup&gt;b&lt;/sup&gt;: loss of appetite, depression</td>
<td>2) Mild: mild intensity of 1 SE (depression omitted); no MCs</td>
</tr>
<tr>
<td></td>
<td>b) Possible medical complications (MCs): uterine cancer (UC) and deep venous</td>
<td>3) Moderate: moderate intensity of 1 SE; &lt;1% chance of a DVT</td>
</tr>
<tr>
<td></td>
<td>thrombosis (DVT)</td>
<td>4) Severe: severe intensities of 2 to 3 SEs; &lt;1% chance of UC or DVT</td>
</tr>
<tr>
<td>Remuneration</td>
<td>Net amount you receive per enrolled patient you recommend</td>
<td>1) $250</td>
</tr>
<tr>
<td>or Cost</td>
<td></td>
<td>2) $100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) $0</td>
</tr>
<tr>
<td></td>
<td>Net cost to you per enrolled patient you recommend due to time you and your staff</td>
<td>1) $0</td>
</tr>
<tr>
<td></td>
<td>spend on related activities</td>
<td>2) $100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) $250</td>
</tr>
</tbody>
</table>

<sup>a</sup> News media include radio, TV, newspaper, magazine, and medical journal.

<sup>b</sup> In the case that the patient is randomly assigned to the treatment group.

Table 2  Experimental Factors and Factor Levels for Women

<table>
<thead>
<tr>
<th>Factor Name</th>
<th>Factor Description</th>
<th>Factor Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor’s</td>
<td>Doctor’s recommendation to participate in the trial</td>
<td>For, neutral, against</td>
</tr>
<tr>
<td>Recommendation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk</td>
<td>Perceived risk of contracting breast cancer or coronary heart disease in the next</td>
<td>High, low</td>
</tr>
<tr>
<td></td>
<td>5 years based on your doctor’s report after a thorough examination</td>
<td></td>
</tr>
<tr>
<td>Expected Toxicity</td>
<td>The toxicity you may experience as a result of the prevention intervention&lt;sup&gt;b&lt;/sup&gt;</td>
<td>None, mild, moderate, severe</td>
</tr>
<tr>
<td>Remuneration</td>
<td>The amount paid to you over the 4-year clinical trial period for your participation</td>
<td>$500, $150, $50, $0</td>
</tr>
<tr>
<td>Cost</td>
<td>Your out-of-pocket expenses over the 4-year clinical trial period</td>
<td>$0, $50, $200</td>
</tr>
</tbody>
</table>

<sup>a</sup> One example given as to why the respondent’s doctor might be neutral was that her doctor required more information about the clinical trial study and did not have time to acquire the information.

<sup>b</sup> Factor description and factor-level definitions are the same as in Table 1.
from scale-value parameters in data.17) When used as a statistical model, objective values are used as scale values (e.g., actual dollar amount). In contrast, as a judgment model, scale values are regarded as subjective values; they depend on actual values of the factor levels but are estimated from the data using the mathematical theory.

Constant-weight-averaging model. Data from a variety of judgment tasks have shown systematic deviations from the predictions of an additive model.18–22 Constant-weight-averaging models have done consistently better than additive models.

Both additive and constant-weight-averaging models imply independence among factors’ scale values in their effect on women’s and physicians’ decisions; the effect of one factor on judged decisions is predicted to be the same for all levels of other factors. For example, the effect of toxicity level on a woman’s participation should be the same whether she received a doctor’s recommendation “for” or “against” participation. However, when the number of factors describing a prevention clinical trial scenario is manipulated, additive and constant-weight-averaging models make different predictions under the assumption that, when a factor is not present in the scenario, its weight is zero. The additive model predicts that the effect of any factor is independent of the number and weight of other factors describing a scenario. In contrast, the averaging model implies that the effect of each factor is inversely related to the number and weight of the other factors describing the scenario. (The mathematical basis for this prediction is illustrated in Veit.23)

Configural-weight-range model. Both Equations A1 and A2 imply that the effect of a piece of information presented for judgment is independent of other information presented simultaneously for judgment. However, suppose that women’s judged decisions reflect interactions among factors describing a prevention clinical trial scenario. For example, suppose level of toxicity does not make much of a difference in a woman’s decision if her doctor recommends against her participation but makes a large difference if her doctor recommends that she participate. Configural-weight models have been successful in describing such interactions in a wide variety of decision dimensions.23,24–27

In configural-weight theory, the relative weight of one piece of information being judged depends in part on the relationship between the value that respondents place on that piece of information and the values that they place on the other pieces of information describing the same scenario.22,23,27–29

RESEARCH QUESTIONS

This study addressed the following research questions:

1. Do physicians make different recommendation decisions for BC and CHD prevention clinical trials? Do postmenopausal women make different participation decisions for BC and CHD clinical trials?
2. Do the factors selected to formulate the prevention clinical trial scenarios—source, patient’s age, expected toxicity, and cost/remuneration for physicians and risk, doctor’s recommendation, expected toxicity, and cost/remuneration for women—play causal roles in their respective judged decisions?
3. What models describe how physicians and women value and tradeoff among their factors in their decisions?
4. Do differences in models exist among stratified groups for physicians and women?
5. If differences exist among groups, do they require different models to account for their differences or does the same model account for all sets of data with different parameter values?

METHOD

This section describes participants, initial sessions conducted for factor selection, construction of clinical trial scenarios, and questionnaire format. We also describe the contents of the Background and Opinion Survey Questionnaire we fielded to both physicians and postmenopausal women in addition to the judgment experiment and administration procedures.

Physician Participants

Participants for factor-selection sessions were 10 physicians from the Los Angeles area, of whom 6 were family practitioners and internists, 2 were geriatricians, and 2 were oncologists. Eight physicians (including 2 physicians who were working on the project) participated in initial factor selection; 5 of these plus 2 additional physicians completed drafts of the questionnaires and provided feedback on factor definitions and item wording.

For questionnaire administration, the physician-selection design blocked on age (younger than 40 years of age and 40 or older), race/ethnicity (white, African American, and Hispanic), gender (male and female), and specialty (primary care and specialty care).
American, and Latino), and gender, producing the 12 stratified groups shown in Table 3. We solicited 714 physicians from an American Medical Association database purchased from Medical Marketing Services, Inc., with the goal of securing 30 physicians in each of the 12 groups. The 291 physicians who responded to this request plus 2 additional volunteer physicians who increased the total number to 293 are distributed across groups, as shown in Table 3. (The 2 additional physicians who completed the questionnaires—and thus pushed the total to 293—were members of the research staff.)

**Women Participants**

White, Hispanic, and African American women younger than 70 or 70 to 80 years of age were recruited from senior citizen centers, churches, and apartment complexes in the greater Los Angeles area. Requirements were that they 1) be undergoing or had completed menopause and 2) had never been diagnosed with BC or CHD. Table 4 details the stratified design for selecting participants. Two participants in each group served in initial factor-selection sessions; 30 participants in each group completed questionnaires.

*Besides the factors listed in Tables 1 and 2, these included the following for both physicians and women: perceived importance of the efficacy of the prevention intervention; total commitment (e.g., for physicians, this included time required by them and their staff; for women, this included frequency of visits, time, flexibility of hours, convenience of participating, and total length of involvement). With physicians, we also discussed patient’s desire to participate in the study, patient’s health status, and number and types of patient’s comorbid diseases. With women, we also discussed trust in clinical trial research, transportation issues, source of the information about the clinical trial (e.g., advertisement in news media; flyers at their senior citizen center, church, or doctor’s office; directly from their doctor), type of organization sponsoring the trial, family and peer support, and language and race/ethnicity of the clinical trial providers.

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**Table 3** Physicians

<table>
<thead>
<tr>
<th>Group Identifier</th>
<th>Race/Ethnicity</th>
<th>Gender</th>
<th>Age Group</th>
<th>Number in Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>WF1</td>
<td>White</td>
<td>Female</td>
<td>&lt;40</td>
<td>26</td>
</tr>
<tr>
<td>WF2</td>
<td>White</td>
<td>Female</td>
<td>≥40</td>
<td>30</td>
</tr>
<tr>
<td>WM1</td>
<td>White</td>
<td>Male</td>
<td>&lt;40</td>
<td>30</td>
</tr>
<tr>
<td>WM2</td>
<td>White</td>
<td>Male</td>
<td>≥40</td>
<td>32</td>
</tr>
<tr>
<td>HF1</td>
<td>Hispanic</td>
<td>Female</td>
<td>&lt;40</td>
<td>15</td>
</tr>
<tr>
<td>HF2</td>
<td>Hispanic</td>
<td>Female</td>
<td>≥40</td>
<td>25</td>
</tr>
<tr>
<td>HM1</td>
<td>Hispanic</td>
<td>Male</td>
<td>&lt;40</td>
<td>14</td>
</tr>
<tr>
<td>HM2</td>
<td>Hispanic</td>
<td>Male</td>
<td>≥40</td>
<td>20</td>
</tr>
<tr>
<td>AAF1</td>
<td>African American</td>
<td>Female</td>
<td>&lt;40</td>
<td>16</td>
</tr>
<tr>
<td>AAF2</td>
<td>African American</td>
<td>Female</td>
<td>≥40</td>
<td>25</td>
</tr>
<tr>
<td>AAM1</td>
<td>African American</td>
<td>Male</td>
<td>&lt;40</td>
<td>30</td>
</tr>
<tr>
<td>AAM2</td>
<td>African American</td>
<td>Male</td>
<td>≥40</td>
<td>30</td>
</tr>
</tbody>
</table>

Note: Because there was no significant effect of age, these 12 groups were reduced to 6 for analyses by combining age groups.

**Table 4** Postmenopausal Women

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Age Group</th>
<th>Number in Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>&lt;70</td>
<td>30</td>
</tr>
<tr>
<td>White</td>
<td>70 to 80</td>
<td>30</td>
</tr>
<tr>
<td>Hispanic</td>
<td>&lt;70</td>
<td>30</td>
</tr>
<tr>
<td>Hispanic</td>
<td>70 to 80</td>
<td>30</td>
</tr>
<tr>
<td>African American</td>
<td>&lt;70</td>
<td>30</td>
</tr>
<tr>
<td>African American</td>
<td>70 to 80</td>
<td>30</td>
</tr>
</tbody>
</table>

**Factor-Selection Sessions**

We began each session by discussing the clinical trial paradigm and a list of motivator and barrier factors suggested in the literature.* After discussing the factors, participants rank-ordered the factors in the importance they would give them if they were considering a 1) BC prevention intervention clinical trial study or a 2) CHD prevention intervention clinical trial study. Factors and levels we selected based on these discussion sessions are shown in Table 1 (physicians) and Table 2 (women). We selected factor levels to span reasonable ranges. For women, a 5th factor, convenience of commuting to the research site (described as being required about 3 to 6 times in a year), was fixed as “convenient.”

**Scenario Construction**

The experimental designs used to create the judgment scenarios are shown in Table 5. The 5 designs for physicians and women created 195 and 159 scenarios, respectively. For both studies, scenarios were displayed in a matrix format constructed so that columns from left to right were successively more attractive levels of one factor and rows from top to bottom were successively more attractive levels of a 2nd and 3rd factor; separate matrices represented different levels of a 4th factor. (In previous judgment research at RAND, we...
have found this format to be preferred by participants for ease in comparing among scenarios.23,30,31 Statistical tests have produced no effect of order, perhaps because people tend to compare the matrix cells in different orders.) An example of a scenario that represents 1 cell from the physician’s 4-factor design is as follows:

What would the strength of your recommendation be to one of your eligible postmenopausal patients to participate in a BC or CHD prevention clinical trial, if
- the source of your information about the prevention clinical trial came from an advertisement,
- the age of the patient you are considering is 70,
- the expected toxicity level from the prevention intervention is severe, and
- your net remuneration/cost per patient accepted into the trial is $0 (you are reimbursed for your time and your staff’s time)?

Other scenarios that included all 4 factors changed the level of 1 or more of these factors.

An example of a scenario that represents 1 cell from a single-factor design is as follows:

What would the strength of your recommendation be to one of your eligible postmenopausal patients to participate in a BC or CHD prevention clinical trial, if
- no toxicity is expected?

Physicians were instructed to respond to each scenario under the assumptions listed in Table 6. They made 2 responses to each of the 195 scenarios: one response addressed the scenario as a BC prevention clinical-trial study and the other as a CHD study. (The 5th manipulated factor, disease type [BC or CHD], doubled the size of the questionnaire; its total administration time for both disease types was be-

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Factors in Design</th>
<th>Factorial Combination</th>
<th>Number of Scenarios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians, breast cancer and coronary heart disease</td>
<td>4</td>
<td>3 (source) × 4 (toxicity) × 5 (remuneration/cost) × 3 (age)</td>
<td>180</td>
</tr>
<tr>
<td>Women, breast cancer and coronary heart disease</td>
<td>4</td>
<td>3 (doctor’s recommendation) × 2 (risk) × 4 (toxicity) × 6 (remuneration/cost)</td>
<td>144</td>
</tr>
</tbody>
</table>

Table 6  Physicians’ Assumptions for the Prevention Clinical Trial Scenario Questionnaire

- You believe in the scientific merit of the prevention clinical trial.
- You have determined that your patient meets the health status, life expectancy (10 years), risk level, and other eligibility requirements of the trial.
- The woman you are considering for either a breast cancer or coronary heart disease prevention clinical trial is at high risk for contracting the disease but has never been diagnosed as having the disease.a
- The study’s investigators will obtain your patient’s informed consent and will monitor her during the study.
- The patient will be enrolled in the study for 4 years, unless she chooses to withdraw.
- If your patient enrolls in the study, she will be randomly assigned to receive either the prevention intervention (e.g., a particular diet, nutritional supplement, vaccine, antibiotic, hormone, or some other type of medication) or a placebo that has no preventative effects. Neither she nor you will know to which group she has been assigned until the end of the 4-year study period.
- The prevention intervention does not interact adversely with any of the medications your patient is now taking.

a. This is an eligibility criterion for prevention clinical trial studies.
Women's Assumptions for the Clinical Trial Scenario Questionnaire

- You have investigated the prevention clinical trial and have determined that you are eligible to join. This means
- You meet the health status requirements.
- You meet the 10-year life expectancy requirement.
- Any medication you are now taking will not interact adversely with the prevention intervention.
- The physician associated with the clinical trial has invited you to join the study.
- If you enroll in the study, you will be randomly assigned to receive either the prevention intervention (e.g., a particular diet, nutritional supplement, vaccine, antibiotic, hormone, or some other type of medication) or a placebo that has no preventative effects. Neither you nor your physician will know to which group you have been assigned until the end of the 4-year study period.
- You may withdraw from the study at any time.
- Travel convenience associated with your participation is not a factor; it is convenient.

Women were asked to respond to each scenario under the assumptions listed in Table 7. For each scenario, women selected an integer from 1 to 9 to indicate the chance that they would participate in a BC or a CHD prevention clinical trial. (As with the physicians’ questionnaire, this 5th manipulated factor of responding to 2 diseases doubled the size of the questionnaire but not the administration time [described in the Modeling Judged Recommendation and Participation Decisions section].) Five of the categories were labeled as follows: 1 = for certain I would not, 3 = small chance I would, 5 = moderate chance I would (a “50/50” chance of participating), 7 = high chance I would, and 9 = for certain I would.

Background and Opinion Survey Questionnaires

The physicians’ survey questionnaire contained questions about their personal and professional background and experience such as age, gender, religion, income, specialty area, research experience, publications, and clinical trial participation experience; opinions about prevention clinical trial studies and conditions under which they might recommend that their postmenopausal patients participate; and their perceptions of BC and CHD risk for different patient profiles. The survey contained 80 items and took between 20 and 50 min to complete.

The women's survey questionnaire contained items such as the respondent's socioeconomic status, educational level, medical history, and insurance; ease with which she communicated with her doctor; family history of BC and CHD; estimates of her BC and CHD risks; opinions about clinical trial research and about the role of diet and exercise in preventing BC and CHD; exercise activity level; consumption of dietary fat and alcohol; and smoking habits. The survey contained a maximum of 105 items; the actual number of items for a given participant depended on her answers to some items; for example, if she took estrogen replacement therapy, she would answer more questions than a woman who did not.

Sampling and Questionnaire-Administration Procedures: Physicians

We began our physician selection by verifying names and addresses (by telephone) from the database...
we purchased from Medical Marketing Services, Inc. We selected 60 physicians randomly from each of the 12 groups, except from those groups that contained fewer than 60 names with telephone numbers (groups HF1, HM1, and AAF1). When we could not verify a name, we randomly selected a replacement name from the list, if one existed.

In 5 separate mailings over a 6-month period, we mailed a packet that contained the following items to each physician whose name and address had been verified:

- a personal letter addressed to the physician that described the research and requested her or his participation,
- a description of RAND and the University of California, Los Angeles (UCLA), Jonsson Comprehensive Cancer Center (the UCLA Jonsson Comprehensive Cancer Center assisted RAND with the physician arm of the project),
- a paragraph describing the research background of the principal investigator and the director of the UCLA Jonsson Comprehensive Cancer Center (the principal investigator, Dr Clairice T. Veit, is from RAND, and the director of the UCLA Jonsson Comprehensive Cancer Center is Dr Patricia Ganz),
- the 2 questionnaires and their instructions,
- a self-addressed, stamped return envelope, and
- an honorarium check made payable to the physician in the amount of $75 (physicians included in the main body of the study were paid $75. We also fielded an experiment that tested the hypothesis that type of honorarium payment and amount of honorarium affected return rates. The experiment was a 2 (cash, check) × 2 ($50, $100) factorial design; 200 physicians were randomly assigned to 1 of the 4 cells, resulting in 100 physicians receiving $50 honorariums and 100 physicians receiving $100 honorariums. No significant difference in return rates was found for either variable, and the interaction between the 2 variables was nonsignificant).

A note in the instructions requested that physicians call a toll-free telephone number if they had any questions about either questionnaire or preferred to take the experimental questionnaire, survey questionnaire, or both over the telephone. About one-third of the 293 physicians elected to take the experimental clinical trial scenario questionnaire by telephone.

About 1 month after questionnaires had been mailed, we began calling physicians whose questionnaires had not been returned to remind them about the study. Follow-up calls were conducted approximately bimonthly until questionnaires were returned or physicians declined to participate.

**Questionnaire-Administration Procedures: Women**

A research staff member conducted the sessions at the participating organization or in the participant’s home. All sessions began with a discussion of prevention clinical trial research and a description of the clinical trial paradigm. Before administering the Clinical Trial Scenario Questionnaire, we discussed factors and factor levels and 6 to 8 representative scenarios.

Most of the 180 participants worked one-on-one with a research staff member; a few participants worked in groups of 2 or 3. However, a staff member reviewed all questions with each participant.

Approximately half of the participants took the Clinical Trial Scenario Questionnaire first, followed by the Background and Opinion Survey, and approximately half took the survey questionnaire first. For Hispanics, sessions were conducted in either Spanish or English, depending on the preference. Sessions took from 50 min to 2 h. Women were paid $30 in cash for their participation.

**DATA ANALYSIS**

We conducted the following statistical and graphical analyses:

1. Tests for significant main and interaction effects due to disease type and stratified variables on the data for the 293 physicians and 180 women, respectively, using ANOVA. The lack of significant effects of disease type is a basis for combining BC and CHD responses for model analyses; nonsignificance of 1 or more group variables is a basis for combining data across those groups for model testing.

2. Separate graphic plots of the data for physicians and women to test the effects of varying amounts of information contained in a clinical trial description; these graphs distinguish adding from constant-weight-averaging and configural-weight-range models. In these graphs, marginal means were plotted on the y-axis, the levels of the factor under investigation on the x-axis, and separate curves for 1) the marginal means of that factor’s levels from the 4-way design and 2) the means of that factor’s levels from its single-factor design. If the slopes of the lines from the single factor designs are steeper than the slopes of the lines from the 4-factor designs, an additive model can be rejected in favor of an averaging or configural-weight-range model. In addition to the averaged data for physicians and women,
we assessed the positions of these lines in each of the stratified groups.

3. Tests of significance of main and interaction effects of the manipulated factors on data for each stratified group and on averaged data for 293 physicians and for 180 women, separately, using ANOVA. Significant interactions among manipulated factors is a basis for rejecting Equations A1 and A2 as recommendation or participation decision-making models.

4. Graphic plots of the data make it possible to examine the structures of main and interaction effects found in data. In these graphs, we plotted cell means on the y-axis, the levels of cost/remuneration on the x-axis, and a separate curve for each level of toxicity; separate panels were for each level of patient’s age (physicians) or doctor’s recommendation (women), and separate sets of panels were for each level of source of the clinical trial information (physicians) or perceived risk (women). We plotted these graphs for data averaged over the 293 physicians, data averaged over the 180 women, and the averaged data for each stratified group. Interactions in which curves fan out at higher values on the x-axis factor imply a negative $\omega$ in Equation A3; converging curves at higher factor levels on the x-axis imply a positive $\omega$.

5. Predicted and obtained graphs make it possible to assess the location, magnitude, and direction of data deviations from a model’s predictions. These analyses employ the graphs described for analysis 4 above, except that points predicted by the model being tested are added to the y-axis; thus, 2 cell means identify each “response”: One predicted by the model and an obtained data point. A computer program that uses Chandler’s STEPIT subroutine\textsuperscript{32} to find a least-squares solution yields the predicted points. The program produces the best-fit parameter values and response predictions for the model being tested, given the data. We reject a model when its predictions do not follow the systematic data structure of the responses. It is possible to reject all hypothesized models.

MODELING JUDGED RECOMMENDATION AND PARTICIPATION DECISIONS

Effects of Disease Type and Stratified Variables

For analysis purposes, the response scale for physicians was converted from a scale from $-9$ to $+9$, with 0 representing “neutral,” to a 19-point scale, with 10 representing “neutral.” An ANOVA on all the physicians’ data revealed no significant difference in responding to the 2 disease types—BC and CHD ($P < 0.05$, which is the criterion used for all statistical analyses in this report). Furthermore, there were no significant interactions between this factor and any of the blocked variables (age group, race/ethnicity, gender) or any of the manipulated variables (source, toxicity, age of patient, cost/remuneration). Thus, we averaged physicians’ BC and CHD recommendation data for model analyses.

All 180 women responded to their clinical trial scenarios precisely the same for both disease types. This outcome appeared to be because of the manipulated factor, risk. Women appeared to have a particular participation opinion based on whether their risk for developing the disease was high or low, regardless of disease type. Thus, we also tested a single-disease model for women.

An ANOVA on the physician data revealed significant effects of gender and race/ethnicity but not age group. Therefore, we averaged data across age groups within each race/ethnicity and gender group, thus reducing the number of physician groups to 6 for further data analyses. An ANOVA of data for all 180 women revealed significant effects of age group and race/ethnicity, indicating that these 6 groups should be considered separately in data and model analyses.

For model analyses in the next 4 sections, we present averaged data for all 293 physicians and 180 women since their respective averaged data are representative of each stratified group in main and interaction effects and data structure. We then discuss differences among the stratified groups separately for physicians and women.

Effects of Varying Amount of Information: Tests of the Additive Model

Recall that an averaging model predicts that a factor presented alone (as in a single-factor design) will have a greater effect on judgments than that same factor presented in scenarios with other factors (as in the 4-way design), unlike the additive model that implies that the effect of a factor is independent of the number of other factors with which it is paired in a scenario. Figure 1 presents data that test these effects.

Points on the curves in each panel of Figure 1 are the marginal means for the factor on the x-axis when this factor is presented 1) alone as the prevention clinical trial scenario (dashed lines) or 2) with 3 other factors (solid curves). In all 8 panels, the slopes of lines are clearly greater when less information is included in a scenario, refuting additive models as descriptive of either recommendations by physicians or participation decisions by women.
Interaction Effects

Tests of interaction effects provide another test of the additive model, as well as a test between the constant-weight-averaging model (Equation A2) and the configural-weight-range model (Equation A3). The configural-weight-range model can account for interactions in data, whereas both additive and constant-weight-averaging models require that the effect of one factor is independent of other factors simultaneously presented. Tests of interactions in the data are shown in Figure 2 for physicians and in Figure 3 for women.

In each panel of Figures 2 and 3, mean judgments are plotted as described in the Data Analysis section (points 4 and 5). (The 3rd level of the source factor, a personal letter from the sponsor addressed to the physician, has been omitted from the graphic data display. Those data very closely resemble the data for the physician’s patient as the information source, but the magnitude of the average responses was slightly less.) The slopes in these figures indicate the effects of cost/remuneration on judged recommendation (Figure 2) and participation (Figure 3) decisions; vertical separations between curves show effects of toxicity. The
change in values associated with each point on the curves from the left- to the right-hand panels indicates the effect of age of the patient being considered (Figure 2) or the doctor’s recommendation (Figure 3). The change in values associated with each point on the curves between associated top and bottom panels indicates the effect of the source of the information about the clinical trial (Figure 2) or perceived risk (Figure 3) on judgments.

Main effects of all factors were significant. The significant cost/remuneration × toxicity interaction is apparent in the graphs, $F(12, 5840) = 374.39$ (Figure 2) and $F(15, 4296) = 63.23$ (Figure 3). If this interaction had been absent, the curves in each panel would have been parallel: Vertical separations between any 2 curves would have been the same, independent of the dollar amount on the x-axis. Instead, the curves deviate systematically from this parallel prediction in all 6 panels. In Figure 2, when patients’ participation costs physicians money, the level of toxicity has less effect than when physicians bear no cost or receive a remuneration (vertical separations between the curves are less for $-250 than $0 on the x-axis, and separations are less for $0 than $250). Similarly, in Figure 3, effects are less when women incur out-of-pocket costs ($-200 or $-50 on the x-axis) than when costs are covered ($0 and above on the x-axis). In addition, Figure 3 shows that toxicity has reduced effects when a woman’s doctor recommends against participation than when her doctor is either neutral or positive (vertical gaps are smaller in Figures 3A and 3D than in Figures 3B and 3E or 3C and 3F); toxicity also has less effect when a woman believes her risk for developing the disease is low than when she believes it is high (vertical separations among curves are less in panels A–C than their counterparts in panels D–F).

Figure 2  Predicted and obtained data from the 4-way factorial design averaged over 293 physicians. In each panel, the dotted horizontal line represents a neutral recommendation: Physicians recommend neither for nor against participation. The dashed horizontal line represents a solid recommendation for participation; the vertical line intersects the $0 cost/$0 remuneration level on the x-axis. Interactions in the data rule out additive and constant-weight-averaging models for recommendation decisions but are in accord with the predictions of a configural-weight-range model. Filled symbols connected by solid lines are the theoretical predictions of this model; open symbols are the obtained data. Where no open symbol is visible, the predicted and obtained points coincide. The form of the interactions seen in these data is representative of each of the 6 stratified groups.
In Figure 2, the curves show a significant divergent interaction between toxicity and patient’s age, \( F(6, 3504) = 42.53 \), which can be seen from the increasing vertical separations between the top and bottom curves from the left-most to the right-most panels for a particular level of cost/remuneration on the x-axis (e.g., a cost of $250). All 2-, 3-, and 4-way interactions, except the 3-way source \( \times \) age \( \times \) toxicity interaction, were statistically significant. These significant and systematic interactions clearly rule out both additive and constant-weight-averaging models. However, such interactions are in agreement with predictions of the configural-weight-range model, as can be seen by comparing the close proximity of solid symbols connecting the lines (values predicted from the configural-weight-range model) to open symbols (obtained).

**Figure 3** Predicted and obtained data from the women’s 4-way factorial design averaged over all 180 women. In each panel, the dotted horizontal line represents a “50/50” chance that women will participate, the dashed horizontal line represents a solid decision to participate, and the vertical line intersects the $0 cost/$0 remuneration level on the x-axis. Interactions in the data rule out additive and constant-weight-averaging models for participation decisions but are in accord with the predictions of a configural-weight-range model. Filled symbols connected by solid lines are the theoretical predictions of this model; open symbols are the obtained data. Where no open symbol is visible, the predicted and obtained points coincide. The form of the interactions seen in these data is representative of each of the 6 stratified groups.

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**A Configural-Weight-Range Model for Physicians’ Recommendations and Women’s Participation Decisions**

The configural-weight-range model with a linear transformation (Equation A3) was fit to mean judged recommendations and participation decisions separately in each of the 6 physicians’ and 6 women’s groups and for the data averaged over all 293 physicians and 180 women, using a computer program that used Chandler’s STEPIT subroutine\(^2\) to find a least-squares solution.

The particular form of the configural-weight-range model for physicians called for 3 configural-weight parameters (\( \omega \) in Equation A3); it was developed on the mean data for 293 physicians, then tested separately on
the averaged data in each of the 6 groups. The configural weights weighted physicians’ extreme values ($s_{\text{MAX}}$ and $s_{\text{MIN}}$ in Equation A3) for 3 different types of clinical trial scenarios: 1) when the physician’s patient could expect to experience moderate to severe side effects from the prevention intervention and there was no cost or the physician received an honorarium for her or his participation, 2) when the level of toxicity was mild and the remuneration for the physician’s participation was $250, and 3) all other scenarios. For women, the configural-weight-range model was fit to mean data with a single configural-weight parameter as written in Equation A3.

For physicians, the model with 3 configural weights required estimation of 25 parameters to predict 195 data points: There were 15 scale values, 4 factor weights, 3 configural weights, and 1 initial impression scale value ($s_0$ in Equation A3, which represents physician’s starting value in the absence of any specific information). In addition, there were 2 constants (a and b in Equation A3) for the linear transformation function mapping psychological impressions onto the numerical response scale; the initial impression weight, $w_0$, was set to 1 without loss of generality. Thus, for the 6 sets of physicians (1170 mean data points), the model used 150 parameter values. However, the 150 parameter values predict physician recommendations for 2340 prevention clinical trial scenarios since the model with the same parameter estimates is used to predict both 195 BC and 195 CHD scenarios in 6 stratified groups. Furthermore, one can interpolate or extrapolate in the model to make predictions to additional prevention clinical trial scenarios that use a cost/remuneration value or an age level not used in this study. Because these factors are on a numerical scale (dollars, age), it is possible to estimate psychophysical functions by plotting the scale values as functions of the physical values (dollars or years of age). These psychophysical functions can be used to predict physicians’ strength of recommendation for numerous possible additional scenarios.

For each group of women, the configural-weight-range model required the estimation of 23 parameters to predict 159 data points: 15 scale values, 4 factor weights, 1 configural weight, 1 initial impression scale value ($s_0$ in Equation A3), and the 2 constants (a and b in Equation A3) for the linear transformation from psychological responses to the numerical scale women used in the study; as with physicians, the weighting parameter for the initial impression ($w_0$ in Equation A3) was set to 1. For the 6 groups, the model used 138 parameters to fit 954 means. Since the same model is for both BC and CHD, it predicts participation decisions for the 1908 study scenarios. In addition, as with physicians, it predicts to scenarios constructed from dollars and costs not used in the study because their scale values can be estimated from their psychophysical functions.

The largest data-model discrepancies are seen in Figure 3F—the overpredictions on the lowest curve (when risk is high, the woman’s doctor recommends that she participate in the clinical trial, and toxicity is severe) and the underpredictions on the top curve in Figure 3C (when risk is low, the doctor recommends that she participate, and there is no expected toxicity).
The good fit of the configural-weight-range model to physicians' and women's data can be seen in Figures 2 and 3 by the close fit of open symbols (observed data) to solid points and curves (predicted values). The least-squares solution yielded an average squared data-prediction error of 0.15 for the data shown in Figure 2.
and 0.07 for the data shown in Figure 3. For each of the 6 groups of physicians, the average squared data prediction error was as follows: for women, it was 0.14 (white), 0.17 (Hispanic), and 0.09 (African American); for men, it was 0.15 (white), 0.28 (Hispanic), and 0.17 (African American). For each of the 6 groups of women, the average squared data prediction error was as follows: for women younger than 70 years of age, it was 0.12 (white), 0.09 (Hispanic), 0.08 (African American), and for women 70 to 80 years of age, it was 0.07 (white), 0.09 (Hispanic), and 0.08 (African American).

DIFFERENCES AMONG GROUPS IN MODEL PREDICTIONS

Table 8 (physicians) and Table 9 (women) show the psychological values derived from the configural-weight-range model. The model for all groups yielded negative configural weights, indicating the tendency for both physicians and women to shift weight from higher- to lower-valued characteristics of a clinical trial scenario when making their judgments. It is this shift in psychological weight that produced the divergent interactions shown in Figures 2 and 3. Figure 4 (physicians) and Figure 5 (women) show the locations of the factor-level scale values along the psychological continuum.

In this section, we refer to Figures 2 through 5 and Tables 8 and 9 in describing the configural-weight-range model’s scale values and predicted tradeoffs in clinical trial information in physicians’ and women’s recommendations and participation decisions, respectively, and how these differed for different groups. Before beginning, recall that physicians judged the strength of their recommendations under the assumptions shown in Table 6, which include the assumption that all of the women they consider are at high risk for developing the disease; women made their judgments under the assumptions shown in Table 7.

Global Observations

The model predicts that for most scenarios, Hispanic female physicians have the strongest recommen-
Costs inhibit physicians’ recommendations more than they inhibit women’s participation decisions (compare slopes of curves in Figures 2 and 3, respectively). This factor has a wide range of scale values for physicians (Figure 4A) and the narrowest range of scale values for women (Figure 5D), indicating that women, in contrast to physicians, have a small psychological difference between their highest- and lowest-valued cost/remuneration levels, even though their actual dollar range is greater. This factor carries a high importance weight for physician groups (Table 8) but a low weight for women’s groups (Table 9), indicating that women are more likely than physicians are to trade off this variable for other clinical trial features. A tradeoff example can be seen from the squared points in Figure 3E: Women are just as likely to participate in a no-toxicity clinical trial in which they pay $200 as they are to participate in a mild-toxicity clinical trial in which they receive $150.

Physicians. When costs are involved, physicians recommend against participation. In Figure 2, at –$100, the model predicts recommendation against participation for all scenarios. Group exceptions are African American men and white and Hispanic women, who will make a very weak recommendation (just above neutral) in the best-case scenario (second to left-most point on the top curve in Figure 2F). Figure 4A shows that physician’s scale values for costs are negative and nearly equal in all groups.

In no-cost/no-remuneration scenarios, for all groups except Hispanic male physicians, recommendations across scenarios with mild to no toxicity range from about neutral to a 14 or 15; Hispanic men, however, achieve only as high as a neutral level and only for no-toxicity scenarios in which a patient provides the source of the clinical trial information. Recommendations increase in strength with increases in the size of the remuneration. For the 2 best-case scenarios (highest 2 points in Figure 2F), all groups recommend at or above the dashed line; recommendations are strongest for African American male and Hispanic female physicians.

Women. If costs are to be incurred, the group least likely to participate is African American women 70 to 80 years of age whose predictions never reach the 50/50 participation level. Other groups reach a 50/50 participation level when costs are to be incurred but only if they perceive their risk for developing the disease to be high. As shown in Figure 3 for predicted means, noticeable increases in predictions with changes from a small cost to a small remuneration scenario occur for all groups, despite the fact that these small remunerations are spread over the 4-year clinical trial period. Once women receive a $50 remuneration, additional increases produce relatively small changes in chance of participating, indicating that crucial clinical trial features for women’s participation are that their expenses be covered and a small honorarium be offered.

Toxicity Variable

Both physicians and women place a high weight on the toxicity factor (Tables 8 and 9, respectively), indicating that when toxicity levels increase, other features of the clinical trial have to compensate to maintain recommendation and participation decision levels. Figures 4B and 5B show large ranges of scale values for both physicians and women, indicating the large difference in values they associate with severe versus no toxicity for prevention clinical trials.

Physicians. If the prevention intervention carries with it severe toxicity levels, the physicians’ model predicts strong recommendations against participation. This mirrors the “no” to “very small chance” of participating predicted for women’s groups in these scenarios. Recommendations against participation become somewhat weaker for moderate levels of toxicity but do not reach the neutral level if costs are involved, except for Hispanic female physicians who provide a neutral recommendation for the scenario identified by the middle point on the “mod” curve in Figure 3F. Even when a remuneration of at least $100 is offered, if toxicity levels are moderate, only 2 groups, Hispanic female and African American male physicians, provide a positive recommendation; this recommendation is very weak and occurs only for scenarios depicting the top 2
points on the “mod” curve in Figure 2F. Mild- and no-toxicity scenarios were discussed above in the Physician section under “Cost/Remuneration Variable.”

Women and low perceived risk (Figures 3A–C). For women, toxicity levels affect participation decisions differently depending on whether they perceive themselves to be at low or high risk for getting the disease. If expected toxicity is moderate to severe and perceived risk is low, women are not going to participate. Toxicity has to be mild before predictions rise to the 50/50 level, and this occurs only for younger white women and only if they receive a remuneration. Predictions reach their highest level in the no-toxicity scenario identified by the highest point in Figure 3C: Hispanic and white women younger than 70 years are above the 50/50 level predicted for the means (close to a 6 and 7, respectively, on their predicted scales). The lowest predictions (about 4.5) for this best-case scenario are for the 3 older groups of women.

Women and high perceived risk (Figures 3D–F). Although none of the groups achieve a prediction level of 50/50 when expected toxicity is severe, when expected toxicity is moderate and the doctor is neutral, young white women achieve a prediction level of 50/50 for no-cost/no-remuneration scenarios; when the doctor recommends for participation, this group achieves the 50/50 level at a cost to them of $200; younger Hispanic women will participate at this level when they receive remunerations of at least $150. The lowest prediction (2 categories below the 50/50 level) is for African American women 70 to 80 years of age.

When expected toxicity is mild and the doctor is neutral, white women younger than 70 years reach a 50/50 chance of participating when costs are involved. This group, with Hispanic women younger than 70 years, reaches and exceeds this level when remunerations are offered. When the doctor recommends participation, African American women younger than 70 years reach a 50/50 level for a no-cost/remuneration scenario, with predictions reaching a 6.0 if remunerations are at least $150. Predictions reach the 7.0 level for white women younger than 70 years for the no-cost scenario and for Hispanic women younger than 70 years at the $150 remuneration level. Predictions stay below the 50/50 level for African American women 70 to 80 years of age, even in the best-case scenario.

When there is no expected toxicity, white and Hispanic women younger than 70 years reach the 50/50 chance of participating in scenarios identifying the top curve of Figure 3D, even when their doctor recommends against participation. When the doctor is neutral and no costs are involved (highest 4 points on the top curve in Figure 3E), these 2 groups reach prediction levels at about the dashed line, followed closely by white women in the 70- to 80-year-old age group. When the doctor recommends for participation, the model predicts participation levels at or above the dashed line for 1) white and Hispanic women younger than 70 years at a cost to them of $200, 2) African American women younger than 70 years and Hispanic and white women 70 to 80 years of age at the no-cost/no-remuneration level, and 3) African American women 70 to 80 years of age at the $50 remuneration level. The best-case scenarios identifying the top 3 points on the top curve in Figure 3F push Hispanic and white women younger than 70 years close to or at participation certainty.

Women’s Perceived Risk Variable

Perceived risk of developing the disease was the most important factor in women’s participation decisions (Table 9). Thus, for predictions to be the same for a high-risk scenario as for a low-risk scenario, other clinical trial features have to make up for the low-risk perception. For example, compare the predictions for the circled points in Figures 3C and 3F. Scale value ranges for this 2-level factor are clearly different for different groups (Figure 5A).

Women’s Doctor’s Recommendation Variable

Clearly, a doctor’s recommendation to participate in a prevention clinical trial influences the patient’s decision to participate; increases in predicted chance of participating that occur for each clinical trial scenario from the left- to the right-hand panels in Figure 3 are seen in all groups. Some tradeoffs with this variable were described in the previous sections.

Physicians’ Age and Source Variables

All 6 physician groups give stronger recommendations to 70-year-old women than to 80-year-old women; 60-year-old patients receive the highest recommendations. Only when clinical trial scenarios are characterized by no expected toxicity and a remuneration will physicians provide to their 80-year-old patients a weak to medium recommendation for participation (12–14 on the prediction scale). For a graphic
example of a tradeoff between age and toxicity, compare circled points in Figures 2A and 2C: An equally likely recommendation level is predicted for a 60-year-old patient for $0 remuneration as for an 80-year-old patient for $100 remuneration.

For all physician groups, recommendations are predicted to be stronger if the clinical trial information is received from the physician’s patient (or a letter from the sponsor) than from an advertisement, as shown in Figure 2 for predicted means. Prediction differences in these 2 sources run from about one-half of a response category for Hispanic men (note their close scale values in Figure 4D) to about 2 categories for Hispanic and African American women and white men. Scale values have a small range for all groups, and all of the groups, except white female physicians, give this variable the smallest weight (Table 8).

DISCUSSION

This study developed 2 mathematical decision-making models: 1) a model of physicians’ judged recommendations that their postmenopausal patients participate in clinical trials to prevent BC or CHD and 2) a model of postmenopausal women’s decisions to participate in such studies.

Since elderly Hispanic and African American women have especially low participation rates in prevention clinical trials, they were included along with others in this study so that results would inform us about what combination of prevention clinical trial factors has a good chance of increasing their participation rates.

Configural-Weight-Range Model

The configural-weight-range model did well in accounting for physicians’ recommendations and women’s decisions. Differences in decisions among physicians of different genders and race/ethnicities and among postmenopausal women of different ages and race/ethnicities do not appear in the mathematical formulation of their respective decision-making models but in the models’ parameters.

The models describe tradeoffs among the manipulated factor levels and allow interpolation or extrapolation to levels not used in the experiment. Model predictions to this array of scenarios will provide insights to planners of prevention clinical trials that could well result in increases in participation in those trials by postmenopausal white and minority women.

A 3rd purpose of this study was to test the generalizability of the model to other diseases. The data support the hypothesis that the configural-weight-range model explains physicians’ recommendations and postmenopausal women’s participation decisions in prevention clinical trials of both BC and CHD, suggesting the possibility that this same model may also apply to other diseases.

Configural-weight-averaging models have received support in a wide variety of judgment tasks and domains, which include mammogram screening decisions, IQ estimates, military command and control decisions, personality impressions, value estimates of used cars, ratings of attitudes and likely behaviors toward a group, morality judgments, perceived risk and attractiveness of lotteries, utility measurement and judgments under uncertainty, and numerical prediction.

Implications of This Research

Prevention and treatment clinical trials research differ in the important aspect that prevention studies involve healthy people. These healthy people cannot have (nor can they ever have had) the disease (but they are at high risk for the disease). Thus, eligible participants, perhaps especially the elderly, may shy away from taking part in any study that might damage their health, even when they are told that any side effect they encounter would be temporary. It is clear from the model of women’s decisions that increasing the participation of elderly women in these trials requires keeping toxicity levels at or below mild. For higher levels, women are very unlikely to participate, with or without a doctor’s recommendation. Furthermore, the model of physicians’ recommendations shows that they may well advise against participation in any scenario with more than minimal risks to their patients, especially their 80-year-old patients.

How important is a doctor’s recommendation? It has a significant impact on participation decisions, even though women placed a lower weight on this factor than the perceived risk and toxicity factors. It may well play the role of encouraging undecided patients to participate. The physicians’ model shows that a payment exceeding $100 per enrolled patient would encourage physicians to make positive recommendations. Combining payment with low toxicity would encourage physicians to seek out their eligible patients and educate them about their high risk for contracting the disease and about potential benefits of being a part of prevention trials.

Women placed their lowest weight on the cost/remuneration factor, indicating that they are more willing to tradeoff this factor with others. Of our women
participants, 66% reported that they preferred a free health exam to a $50 remuneration, and 44% preferred a free health exam over a $500 remuneration. This should be good news for clinical trial planners because a free health exam (a feature that benefits the study) is commonly offered to participants. However, the women's model shows that they do not want to incur costs; they even have a sharp increase in their chance of participating with a small payment. It appears that combining a free health exam with a remuneration of at least $50 and keeping toxicity levels to a mild level as a maximum might well boost elderly participation.

One possible impediment to elderly women's participation is getting the information that a prevention study is being conducted. Of our women participants, 88% reported that they had never seen or heard an advertisement of such a study from any source (doctors, posters, news media, friends). Only 24% reported that they had ever heard of a treatment study being conducted; of these, 44% were white and younger than 70 years. (Eight of the 180 women who participated in this study reported that they had participated in a randomized clinical trial—all studies were investigating a treatment intervention—of these, 7 reportedly had enrolled themselves in the trial without consulting their doctor). These findings indicate that women may not recognize a description of a randomized clinical trial if they hear or read about one, and surely they are not sufficiently familiar with the design features of these studies to assess the potential benefits of participating. In turn, it implies that more effective methods of describing and disseminating information about such trials may be crucial to reaching this at-risk elderly population.

According to the model, women's perceived risk for developing the disease is the most important factor in their decision. However, this factor cannot be manipulated as a feature of clinical trials to entice increased participation. Our data indicate that many at-risk women may misperceive their risk level for developing BC or CHD, which indicates that they would make uninformed decisions about participating in clinical trials as well as decisions about receiving diagnostic tests. In this study, 75% of women rated their risk for developing BC in their life as low to none; 48% rated their risk for developing CHD in their life as low to none (women rated their risk for developing BC and CHD, separately, by checking 1 of 4 categories: high, medium, low, or none). Furthermore, only 8% of women reported that their doctor had ever told them their risk for developing BC; only 15% reported that their doctor had ever told them their risk for developing CHD. The correlation between women's risk ratings for developing breast cancer in their lifetime and their Gail model score was only 0.43, leaving 82% of the variance in women's ratings unaccounted for by the Gail model. (We computed risk scores for white and African American women using Gail model computations for those groups; we computed risk scores for Hispanic women using Gail model calculations for African American women since computations for Hispanic women were not available.) Correlations between women's ratings of perceived risk for developing CHD (lifetime) and objective CHD risk indices were as follows: 0.40 with reported number of people in the family with heart problems, 0.34 with reported high blood pressure, 0.22 with reported high cholesterol, 0.16 with reported high blood pressure and high cholesterol, and 0.35 with reported number of health problems.

**Judgment Experiments Allow Informed Clinical Trial Construction**

This study yielded information on physicians' recommendations and women's participation decisions that would be impractical if not impossible to obtain in a behavioral study. We were able to manipulate 4 factors to create 195 different prevention clinical trial scenarios to present to physicians and to manipulate 4 factors to create 159 different prevention clinical trial scenarios to present to postmenopausal women. The experimental designs made it possible to test for causal effects of the factors on judged decisions, to distinguish between 3 commonly applied mathematical models, and to reject the 2 incorrect models.

Most clinical trial studies are designed without benefit of results obtained from causal behavioral experiments such as this one. This study illustrates how judgment studies with manipulated decision factors can be used as an adjunct or preliminary investigation to guide the design of clinical trials.

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APPENDIX

Three Hypothesized Models

The 3 models are a weighted-additive model, a constant-weight-averaging model, and a configural-weight-range model. The models are written for 4 factors: 1) a doctor’s recommendation (D) to participate in the breast cancer or coronary heart disease prevention clinical trial, 2) a woman’s perceived risk (R) of developing the disease in the next 5 years, 3) expected toxicity (T) of the prevention intervention, and 4) out-of-pocket cost or remuneration (C) incurred or received over the 4-year clinical trial period. The models are written for women’s participation decisions; a simple substitution of factor names converts the equations to models of physicians’ recommendations. (These 3 models were tested by Veit to account for decisions by elderly Latinas to have a yearly mammography.) All 3 models include a linear transformation from subjective judgments to the numerical response scale.

Weighted-Additive Model

\[
J = a[w_D s_D + w_R s_R + w_T s_T + w_C s_C] + b, \tag{A1}
\]

where \( J \) represents the woman’s judged decision to participate in the prevention clinical trial; \( w_k \) and \( s_k \) are the psychological weight and scale value of her initial impression (e.g., the participation decision in the absence of specific information); \( s_D, s_R, s_T, \) and \( s_C \) represent the scale values she places on the highest level of a doctor’s recommendation, highest level of expected toxicity, and highest level of cost/remuneration, respectively; \( w_D, w_R, w_T, \) and \( w_C \) are the weights or measures of importance she associates with these factors; and \( a \) and \( b \) are linear constants that map subjective judgment onto the numerical response scale. \( J \) that she used in the experiment to express her judged decision. (The weighting parameters [the \( w \) parameters in Equation A1] have a different meaning in psychological measurement than they do in statistics. In psychological measurement, the measurement theory is used to derive the weighting values from the data; thus, they are interpreted as measuring the importance of the factor they weight in accord with the theory. In statistics, weighting parameters are commonly interpreted as representing relative effect sizes. This interpretation can lead to incorrect conclusions about the relative importance of factors, especially when the factors are correlated.)

Constant-Weight-Averaging Model

This model can be written

\[
J = a \left[ \frac{w_D s_D + w_R s_R + w_T s_T + w_C s_C}{w_D + w_R + w_T + w_C} \right] + b, \tag{A2}
\]

The terms are defined as above for Equation A1.

Configural-Weight-Range Model

Like the constant-weight-averaging models, configural-weight-range models imply that the effect of each factor will be inversely related to the total weight of other factors in the scenario. In addition, one form of this model predicts that people place a configural weight on the range of scale values associated with factor levels describing a judgment scenario, which allows this model to account for interactions among factors in data. The mathematical form of this model is

\[
J = a \left[ \frac{w_D s_D + w_R s_R + w_T s_T + w_C s_C}{w_D + w_R + w_T + w_C} + \omega (s_{MAX} - s_{MIN}) \right] + b, \tag{A3}
\]

where \( s_{MAX} \) and \( s_{MIN} \) are the highest- and lowest-valued factor levels describing the prevention clinical trial scenario and \( \omega \) is the configural weight of this range term. The other parameters are defined as above for Equation A1.

When \( \omega \) is positive, its effect is to add weight to the factor associated with \( s_{MAX} \), that is, the scale value associated with the highest valued factor level describing the scenario being judged. When \( \omega \) is negative, its effect is to subtract weight from that factor. When \( \omega \) is zero, that is, \( s_{MAX} \) and \( s_{MIN} \) are equal, this range term goes to zero and the configural-weight-range model becomes the constant-weight-averaging model of Equation A2.
REFERENCES
