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Research Article

Cancer Prevention Research

NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 Results: Decision Making in Breast Cancer Risk Reduction

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Abstract

Selective estrogen receptor modulators (SERMs) reduce breast cancer risk. Adoption of SERMs as prevention medication remains low. This is the first study to quantify social, cultural, and psychologic factors driving decision making regarding SERM use in women counseled on breast cancer prevention options. A survey study was conducted with women counseled by a health care provider (HCP) about SERMs. A statistical comparison of responses was performed between those who decided to use and those who decided not to use SERMs. Independent factors associated with the decision were determined using logistic regression. Of 1,023 participants, 726 made a decision: 324 (44.6%) decided to take a SERM and 402 (55.4%) decided not to. The most important factor for deciding on SERM use was the HCP recommendation. Other characteristics associated with the decision included attitudes and perceptions regarding medication intake, breast cancer worry, trust in HCP, family members with blood clots, and others' experiences with SERMs. The odds of SERM intake when HCP recommended were higher for participants with a positive attitude toward taking medications than for those with a negative attitude ($P_{\text{interaction}} = 0.01$). This study highlights the importance of social and cultural aspects for SERM decision making, most importantly personal beliefs and experiences. HCPs' recommendations play a statistically significant role in decision making and are more likely to be followed if in line with patients' attitudes. Results indicate the need for developing interventions for HCPs that not only focus on the presentation of medical information but, equally as important, on addressing patients' beliefs and experiences. *Cancer Prev Res; 10(11); 625–34.* ©*2017 AACR.*

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Introduction

The primary prevention of breast and other cancers presents an ongoing challenge for prevention research and for clinical practice (1–4). Advancing the prevention of breast cancer is particularly pressing, as this disease is the leading cancer in females worldwide (5, 6). On the basis of recent SEER data (6), 12.4% of U.S. women will be diagnosed with breast cancer during their lifetime. Thus far, two medications have been approved by the FDA for breast cancer risk reduction: tamoxifen and raloxifene (2). Both are selective estrogen receptor modulators (SERMs) that have been shown to reduce breast cancer risk by up to 50% in prevention clinical trials (7–9). The American Society for Clinical Oncology recommends the counseling of women at high-risk on the risks and benefits of these medications for the prevention of breast cancer (10). There exists a range of decision aids to guide women's decision making about SERM use (11, 12), which have been shown to increase knowledge about risks and benefits of SERMs, but they have not led to an increase in SERM use. There is emerging evidence suggesting that decision making is guided by beliefs and understandings prior to counseling and by expectations women have regarding the perceived impact of their choice on emotional well-being (13–15). The National Surgical Adjuvant Breast and Bowel Project (NSABP) DMP-1 study (16) was designed to improve our understanding of the psychologic, social, and cultural factors influencing women's decision making regarding

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breast cancer chemoprevention. We surveyed participants at two time points, who were counseled as part of their regular medical care, on the risks and benefits of SERM use: (i) immediately after the counseling (T1), and (ii) after they made a decision regarding SERM use (T2). We assumed that women's views and beliefs regarding trust in the health care provider (HCP), and perceptions on the pharmaceutical industry and on medication intake, influence women's decision making regarding SERM use for breast cancer risk reduction. In addition, we hypothesized that women's experiences regarding the implicated medications and the implicated diseases influence their decision making and that such factors are more important than risk perception and women's objective risk in decision making.

Materials and Methods

The primary aim of the DMP-1 study was to determine the influence of social, cultural, and psychologic factors on the decision of women at risk for breast cancer to take or not take chemoprevention agents. Secondary aims included the description of the influence of such factors on women's decision by menopausal status. The results of these primary and secondary analyses are presented in this report.

Both quantitative and qualitative research approaches were utilized in DMP-1, including a video recording of the counseling session and an interview substudy at two sites in the United States (17). Participants provided written consent, which was approved by local Institutional Review Boards, and in accordance with assurances filed with and approved by the Department of Health and Human Services (ClinicalTrials.gov identifier: NCT01399359).

Study sample

English-speaking women who discussed SERM use for breast cancer risk reduction with an HCP, and who consented to participate, were eligible. Those with previous invasive breast cancer of any type, a previous history of DCIS or LCIS if treated with mastectomy, radiotherapy, or endocrine therapy, were ineligible. Women with any history of or current use of tamoxifen, raloxifene, or other SERM therapy for any reason were also excluded.

Eligibility was determined by the HCP based on if s/he discussed SERM use for breast cancer risk reduction with a patient. For eligibility, it did not matter who initiated the conversation on preventive SERM use, patient or HCP. The patient was then invited to participate. A sample size of 1,000 women was determined sufficient to ensure that enough SERM users and nonusers would exist for a comparison between the two groups.

Survey design and administration

After the counseling session (T1), participants received a questionnaire (Q1; Supplementary Material, Questionnaire 1) aimed at assessing the content of the counseling with the HCP, including which risks and benefits were discussed. In addition, perceptions about SERMs, participants' experiences with breast cancer, blood clotting, cataracts, endometrial cancer, and osteoporosis, and sociodemographic factors, were evaluated. Participants were asked to complete Q1 within 6 weeks of the consultation so that they could still recall the session. If a participant indicated on Q1 that she had made a decision regarding SERM use, she received a second questionnaire (Q2) within 2 weeks (Supplementary Material, Questionnaire 2). It was permissible to provide Q2 to participants to complete on the day of their clinical visit. Participants who had not made a decision at the T1 time point were contacted by phone after 3 months from the counseling to ask whether they had made a decision. Those who had were then sent Q2 by mail. All others received Q2 after either 6 months from the counseling or 3 months after the follow-up phone call. In addition, participants were given contact information to call once they had made a decision, for Q2 to be sent out. Q2 assessed those factors that we assumed influenced SERM decision making. Treatment decision making in risk contexts should involve careful weighing of risks and benefits. On the basis of our previous studies (11, 12, 18), we assumed that decision making may need some time, which is why we allowed 6 months for the distribution of Q2.

Both questionnaires were developed on the basis of existing instruments and on results and experiences from previous studies by the research team (11, 12, 18) and were pilot-tested at the University of Michigan (Ann Arbor, MI).

Staff at the study sites used reminders by means of postcards and telephone calls to contact participants as means to collect delinquent questionnaires.

Statistical analysis

Participants' decision on the use of a SERM to prevent breast cancer was identified on the basis of their responses to Q2. The distribution of participants' sociodemographic characteristics, social factors, and the description of the counseling session were compared between those who decided to take and those who decided not to take a SERM by means of the likelihood ratio tests. We focused on social, psychologic, and cultural characteristics, such as a woman's beliefs regarding medication, trust in HCP, and perceptions of the pharmaceutical industry, as well as medical factors, such as risks and benefits the participants remembered having discussed in the counseling session and the woman's objective breast cancer risk score. Unadjusted ORs and corresponding 95% confidence intervals (CI) were estimated on the basis of univariate logistic regression.

Three scale scores of domain-related questions were created, including trust in the HCP scale (10 questions), trust in pharmaceutical companies scale (2 questions), and attitudes about taking medication scale (9 questions). The scale scores were composed by summing responses to individual questions, with negatively stated items being reversed. If any of the item responses were missing, the scale score was prorated as long as more than 50% of the items were answered.

Multivariate logistic regression was used to determine a key set of independent variables that were associated with the decision of whether or not to use a SERM and to determine their relative importance. A stepwise model building procedure was implemented. Items with a univariate P value of ≤ 0.2 were considered for the forward selection step, which were entered into the model in the order of their P values, starting with the most statistically significant. A significance level of 0.1 was used to keep the covariates in the model. After the completion of the forward selection step, backward elimination was performed, starting with the least statistically significant covariate. A significance level of 0.05 was used at this final step. After the final main effects model was identified, the presence of interactions was investigated. The assessment described above was repeated for subsets of women by menopausal status.

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Results

Study sample

NSABP DMP-1 opened for accrual August 1, 2011. Accrual was terminated on February 22, 2013, with the exception of the two participating video sites, where it continued until 30 evaluable video recordings were completed. A total of 1,023 women were accrued to the study from 44 health institutions, including 94 study sites across the United States. The recruiting health institutions were comprised of 12 university hospitals or cancer centers, 23 community clinics from the community clinical oncology program (19, 20), and 9 general medical centers or hospitals. With the exception of one cancer center that participated in the video subcomponent of DMP-1 and recruited 106 participants, distribution of participants assigned to the study were similar across institutions, ranging between 1 and 75. Participant characteristics of the study population are presented in Table 1. Sixty-one percent of the participants were ≥50 years, 10% identified as black or other, and 5% identified as Hispanic or Latina. The majority of participants were considered to be postmenopausal (64%).

Of the 1,023 participants, 8 were ineligible, 97 did not submit Q1, and 19 completed Q1 outside the 6-week window from the counseling session and therefore were excluded.

Q1 was available from 899 participants. Among these, 795 submitted Q2. Reasons for nonsubmission of Q1 and Q2 were not related to participant's physical or emotional state. Characteristics of participants with available data were comparable with those of the women who did not submit one or both questionnaires (Table 1), with the exception of some differences in race distribution.

Of the 795 participants who submitted both questionnaires, 324 (40.7%) decided to take a SERM, 402 (50.6%) decided not to take a SERM, and 66 (8.3%) were undecided. Three participants did not indicate their decision on Q2. The median time between the counseling session and making a decision regarding chemoprevention was 6 days (IQR = 0–99). There were 479 women who made a decision at the time of completion of Q1, 147 of whom submitted Q2 on the day of the counseling session. Ten participants made a decision and submitted Q2 at least a year after the session, and the last patient completed Q2 19 months after the session.

The comparison of participants' characteristics between those who decided to take and those who decided not to take a SERM is presented in Tables 2–5. Overall, sociodemographic variables, such as age and educational level, did not differ between SERM users and nonusers (Table 2). The recommendation from the HCP to take tamoxifen or raloxifene was received by 292 (90.1%) users and 180 (44.8%) nonusers (Table 3).

Most survey participants [296 (91.4%) SERM users and 351 (87.3%) SERM nonusers] remembered discussing two or more risks of SERMs at the consultation (Table 3). There were 248 (76.5%) SERM users and 288 (71.6%) SERM nonusers who indicated that the HCP had discussed two or more benefits of SERMS with them. Results of a mammogram, or a breast MRI, and/or biopsy results were also discussed at the counseling sessions of 236 (72.8%) SERM users and 240 (59.7%) nonusers. Most SERM users [272 (84.0%)] indicated having had at least one breast biopsy, 208 of whom also reported atypical hyperplasia. At the same time, 296 (73.6%) of nonusers indicated having had at least one breast biopsy, 190 of whom also reported atypical hyperplasia (Table 4). The majority of SERM users [195 (60.2%)] expressed a highest level of worriedness about getting breast cancer in the next 5 years. Meanwhile, only 155 (38.6%) of nonusers expressed the same level of worriedness (Table 5). Overall, few participants [106 (14.6%)] stated considering a

Table 1. NSABP DMP-1 participant characteristics

		Submitted questionnaire(s)[a]					
Characteristics	Full cohort (N = 1,023) No. (%)	Submitted Q1 and Q2 (n = 795) No. (%)	Submitted only Q1 (n = 104) No. (%)	$P^{b,c}$	Total (n = 899) No. (%)	Ineligible or did not submit Q1 (n = 124) No. (%)	$P^{b,d}$
Age, y							
≤49	403 (39.4)	305 (38.4)	43 (41.3)	0.81	348 (38.7)	55 (44.4)	0.38
50–59	384 (37.5)	307 (38.6)	37 (35.6)		344 (38.3)	40 (32.3)	
≥60	236 (23.1)	183 (23.0)	24 (23.1)		207 (23.0)	29 (23.4)	
Race as reported by the site							
White	903 (88.3)	711 (89.4)	88 (84.6)	0.12	799 (88.9)	104 (83.9)	0.01
Black/African American	73 (7.1)	47 (5.9)	10 (9.6)		57 (6.3)	16 (12.9)	
Other	31 (3.0)	24 (3.0)	6 (5.8)		30 (3.3)	1 (0.8)	
Unknown	16 (1.6)	13 (1.6)	0 (0.0)		13 (1.4)	3 (2.4)	
Ethnicity as reported by the site							
Hispanic or Latina	51 (5.0)	38 (4.8)	7 (6.7)	0.37	45 (5.0)	6 (4.8)	0.98
Not Hispanic or Latina	951 (93.0)	746 (93.8)	94 (90.4)		840 (93.4)	111 (89.5)	
Unknown	21 (2.1)	11 (1.4)	3 (2.9)		14 (1.6)	7 (5.6)	
Menopausal status							
Premenopausal	367 (35.9)	282 (35.5)	33 (31.7)	0.45	315 (35.0)	52 (41.9)	0.13
Postmenopausal	656 (64.1)	513 (64.5)	71 (68.3)		584 (65.0)	72 (58.1)	
Quartiles of 5-y Gail risk score[e]							
≤2.26		195 (24.5)	31 (29.8)	0.57	226 (25.1)		
>2.26, ≤3.14		201 (25.3)	26 (25.0)		227 (25.3)		
>3.14, ≤4.62		202 (25.4)	21 (20.2)		223 (24.8)		
>4.62		197 (24.8)	26 (25.0)		223 (24.8)		

[a]Among eligible participants.
[b]Pearson χ^2 test, unknowns were excluded for calculation of P values.
[c]Comparing participants who submitted only Q1 to those who submitted Q1 and Q2.
[d]Comparing eligible participants who submitted Q1 to all other participants.
[e]The information required to calculate Gail score was collected on Q1.

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Table 2. NSABP DMP-1: Comparison of demographic characteristics of those who decided to take a SERM and those who decided not to take a SERM to reduce the risk of developing breast cancer

		Decision about a SERM ($n = 726$)			
		To take ($n = 324$)	Not to take ($n = 402$)		
Characteristics	Categories	No. (%)	No. (%)	OR[a](95% CI)	P[b]
Age, y	≤49	114 (35.2)	165 (41.0)	—	0.27
	50–59	128 (39.5)	146 (36.3)	1.27 (0.91–1.78)	
	≥60	82 (25.3)	91 (22.6)	1.30 (0.89–1.91)	
Race, self-identified	White	294 (90.7)	357 (88.8)	—	0.72
	Black	16 (4.9)	23 (5.7)	0.84 (0.44–1.63)	
	Other	13 (4.0)	20 (5.0)	0.79 (0.39–1.61)	
	Unknown	1 (0.3)	2 (0.5)		
Ethnicity, self-identified	Hispanic or Latina	16 (4.9)	19 (4.7)	—	0.89
	Not Hispanic or Latina	306 (94.4)	382 (95.0)	0.95 (0.48–1.88)	
	Unknown	2 (0.6)	1 (0.2)		
Menopausal status	Premenopausal	106 (32.7)	148 (36.8)	—	0.25
	Postmenopausal	218 (67.3)	254 (63.2)	1.20 (0.88–1.63)	
Marital status	Currently not single	246 (75.9)	299 (74.4)	—	0.66
	Currently single	77 (23.8)	101 (25.1)	0.93 (0.66–1.30)	
	Unknown	1 (0.3)	2 (0.5)		
Education	Less than high school	9 (2.8)	4 (1.0)	—	0.26
	High school graduate	61 (18.8)	67 (16.7)	0.40 (0.12–1.38)	
	Some college	87 (26.9)	115 (28.6)	0.34 (0.10–1.13)	
	College graduate or more	167 (51.5)	216 (53.7)	0.34 (0.10–1.14)	
Income	<$30,000	38 (11.7)	46 (11.4)	—	0.62
	≥$30,000, <$60,000	61 (18.8)	71 (17.7)	1.04 (0.60–1.80)	
	≥$60,000, <$90,000	60 (18.5)	61 (15.2)	1.19 (0.68–2.08)	
	≥$90,000	134 (41.4)	180 (44.8)	0.90 (0.56–1.46)	
	Unknown	31 (9.6)	44 (10.9)		

[a]OR, the relative odds for SERM uptake, "—" identifies the baseline level of the covariate.
[b]P value is based on the likelihood ratio test, unknowns were excluded for calculation of P values.

prophylactic mastectomy as an option to reduce their risk of breast cancer.

Of the 726 participants who made a decision regarding SERM use, 472 (65%) were postmenopausal. Postmenopausal women were more likely to agree on SERM use compared with premenopausal women; however, this difference was not statistically significant (univariate OR = 1.20; 95% CI, 0.88–1.63, $P = 0.25$). The comparisons of the characteristics between SERM users and SERM nonusers by menopausal status are presented in Supplementary Tables S1–S8. In general, the distributions of the participants' characteristics and their relation to the decisions on SERM use were similar for the premenopausal and postmenopausal subgroups, as well as both groups combined. Among 218 postmenopausal women who decided to take a SERM, 118 decided to take tamoxifen, 93 decided to take raloxifene, and 7 did not report their decision regarding a SERM of their choice.

Multivariate analysis

Primary analysis. Characteristics that were considered for multivariate modeling (univariate $P \leq 0.2$) are presented in bold typeface in Tables 2–5. Because there was only one participant in the positive-decision group who received a recommendation from the HCP not to take a SERM, this category was combined with the "No recommendation" category. Of 27 characteristics univariately identified as important factors in a participant's decision, 11 were identified as having independent associations (Table 6). The majority of the 11 independent factors were related to participants' personal experience with breast cancer and their attitude(s) toward medication. The odds of a participant deciding to take a SERM for breast cancer prevention when the HCP recommended it were 14.00 (95% CI, 8.39–23.37, $P < 0.001$) compared with a participant not receiving such a recommendation. Similarly, the odds of a participant who thought of SERM users as brave, smart, or taking good care of themselves were 7.57 (95% CI, 3.41–16.78, $P < 0.001$) compared with those who did not think of SERM users in such terms. Other factors that proved to be important included attitudes about taking medication, worry about breast cancer, trust in the HCP, having a family member with blood clotting problems, and not knowing someone who took the medication or who had had good and/or bad experiences with SERMs. Finally, those who discussed the results of a diagnostic test, such as a biopsy, a mammogram, or an MRI, and those who had atypical hyperplasia, were more likely to decide to take a SERM. The number of risks and benefits of SERM use discussed in the consultation did not reach statistical significance in the multivariate setting. A presence of interaction between the HCP recommendation and attitudes about taking medication scale was detected ($P = 0.01$). The odds to take a SERM when the HCP recommended it were higher for participants with a positive attitude toward taking medications than for those with a negative attitude toward taking medications.

Secondary analyses. The sets of characteristics by menopausal status, independently associated with a participant's decision, are presented in Table 6. Several of the covariates were identified in all three multivariate models, such as recommendation from the HCP, a participant's perception about a SERM user, not knowing someone who took the medication, and discussion of diagnostic test results during the consultation session. Some other characteristics had stronger associations with the decision for one subgroup, but not for the

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Table 3. NSABP DMP-1: Comparison of characteristics related to the counseling session of those who decided to take a SERM and those who decided not to take a SERM to reduce the risk of developing breast cancer[a]

		Decision about a SERM ($n = 726$)			
Characteristics	**Categories**	**To take ($n = 324$) No. (%)**	**Not to take ($n = 402$) No. (%)**	**OR[b](95% CI)**	**P[c]**
Recommendation from HCP[d]	No recommendation	28 (8.6)	171 (42.5)	—	**<0.001**
	Not to take a SERM	1 (0.3)	45 (11.2)		
	To take a SERM	292 (90.1)	180 (44.8)	12.08 (7.86–18.57)	
	Unknown	3 (0.9)	6 (1.5)		
The type of HCP you spoke with the most at today's appointment	Regular doctor/Regular nurse	141 (43.5)	154 (38.3)	—	**0.01**
	Another doctor/another nurse	158 (48.8)	192 (47.8)	0.90 (0.66–1.23)	
	Other	22 (6.8)	53 (13.2)	0.45 (0.26–0.78)	
	Unknown	3 (0.9)	3 (0.7)		
Talked at today's appointment about:	Mammogram and/or breast MRI and/or biopsy results	236 (72.8)	240 (59.7)	1.81 (1.32–2.48)	**<0.001**
	Breast cancer prevention	289 (89.2)	337 (83.8)	1.59 (1.03–2.47)	**0.04**
	BC family history and/or my BC risk and/or genetic testing	300 (92.6)	378 (94.0)	0.79 (0.44–1.43)	0.44
What did the HCP use most when discussing risk and benefits?	Did not talk about risk/benefits	3 (0.9)	9 (2.2)	—	0.24
	Mostly used words	124 (38.3)	166 (41.3)	2.24 (0.59–8.45)	
	Mostly used numbers	167 (51.5)	193 (48.0)	2.60 (0.69–9.75)	
	Unknown	30 (9.3)	34 (8.5)		
Did you discuss risks of SERMs at today's appointment?	No or yes, less than two risks	28 (8.6)	51 (12.7)	—	**0.08**
	Yes, two or more risks	296 (91.4)	351 (87.3)	1.54 (0.94–2.50)	
Did you discuss benefits of SERMs at today's appointment?	No or yes, less than two benefits	76 (23.5)	114 (28.4)	—	**0.13**
	Yes, two or more benefits	248 (76.5)	288 (71.6)	1.29 (0.92–1.81)	

Abbreviation: BC, breast cancer.

[a]Headings in bold typeface indicate items considered for multivariate modeling.

[b]OR, the relative odds for SERM uptake, "—" identifies the baseline level of the covariate.

[c]P value is based on the likelihood ratio test, unknowns were excluded for calculation of P values.

[d]For modeling purposes, the "no recommendation" category was combined with the "recommended not to take" category.

other. Previous thoughts about taking a SERM and having a family member with a history of endometrial cancer were two additional factors not identified in the pulled analysis but that proved to be important for premenopausal participants' decision.

For postmenopausal participants who had a discussion of the diagnostic test results during the consultation, the odds to take a SERM were qualitatively different ($P_{\text{interaction}} = 0.01$) between those who had positive perceptions about SERM users (OR = 2.19; 95% CI, 1.25–3.83) as compared with those who had negative perceptions about SERM users (OR = 0.17; 95% CI, 0.03–0.96). Two more statistically significant interactions were identified for the postmenopausal model: (i) between the HCP recommendation and attitudes toward taking medication scale ($P = 0.02$), and (ii) the HCP recommendation and not knowing someone who took the medication ($P = 0.03$). The magnitude of the positive effect of the HCP recommendation to take a SERM was different based on the level of worry about taking a drug that no one the participant knows has taken, as well as her perception of taking medications in general.

The effect and statistical significance of the items identified in one of the three final models, but not included in the other models, were checked by introducing those factors into the final model one at a time (Table 6, italics). None became statistically significant or significantly modified the effects of other covariates already included in the final multivariate models.

Discussion

A recent meta-analysis (21) identified the following factors associated with taking a SERM: having an abnormal biopsy, a physician recommendation, higher objective risk, fewer side effects or trial concerns, and older age. Our study reiterates the importance of the HCP recommendation. In addition, our study shows the influence of cultural and social factors that are unrelated to the clinical encounter on SERM decision making.

Most DMP-1 participants had received information regarding risks and benefits of SERM use as indicated by current guidelines. This information was not an independent factor in participants' decision making. The HCP's recommendation was the most important predictor for the decision to take a SERM for breast cancer risk reduction. This recommendation, however, was more likely to be followed by women who had a positive attitude toward medication intake.

In addition, DMP-1 participants who perceived women who took a SERM for breast cancer risk reduction as brave or smart were more likely to engage in preventive medication use. This highlights the importance of cultural beliefs and perceptions in engaging in different types of preventative health behaviors for breast cancer risk reduction. Personal experiences and peers were also implicated in the decision-making process. In addition, women who came in for the HCP visit to discuss diagnostic results were more likely to take a SERM. These findings are echoed in the analysis of the DMP-1 qualitative data (17), which showed that the HCP recommendation, particularly the framing of the information by the HCP, influenced and was important for individual decision making, but it did not determine the decision to take a SERM.

Guidelines for breast cancer risk reduction therapy stress the need to counsel women on a range of prevention strategies and to discuss the risks and benefits of SERMs (10). However, there is

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Table 4. NSABP DMP-1: Comparison of characteristics related to participants' personal experience with breast cancer and the medical conditions related to taking SERMs of those who decided to take a SERM and those who decided not to take a SERM to reduce the risk of developing breast cancer[a]

		Decision about a SERM ($n = 726$)			
Characteristics	**Categories**	**To take ($n = 324$) No. (%)**	**Not to take ($n = 402$) No. (%)**	**OR[b](95% CI)**	**P^c**
No. of breast biopsies	None or unknown	52 (16.0)	106 (26.4)	—	**<0.001**
	One	140 (43.2)	177 (44.0)	1.61 (1.08–2.40)	
	≥2	132 (40.7)	119 (29.6)	2.26 (1.49–3.42)	
No. of first-degree relatives with BC	None or unknown	167 (51.5)	162 (40.3)	—	**0.01**
	One	117 (36.1)	182 (45.3)	0.62 (0.45–0.86)	
	≥2	40 (12.3)	58 (14.4)	0.67 (0.42–1.06)	
AH	No breast biopsies	52 (16.0)	106 (26.4)	—	**<0.001**
	No breast biopsies with AH, or AH unknown	64 (19.8)	106 (26.4)	1.23 (0.78–1.94)	
	At least one biopsy with AH	208 (64.2)	190 (47.3)	2.23 (1.52–3.28)	
Quartiles of 5-yr Gail risk score	≤2.26	60 (18.5)	111 (27.6)	—	**0.007**
	>2.26, ≤3.14	77 (23.8)	107 (26.6)	1.33 (0.87–2.05)	
	>3.14, ≤4.62	91 (28.1)	92 (22.9)	1.83 (1.19–2.81)	
	>4.62	96 (29.6)	92 (22.9)	1.93 (1.26–2.95)	
Know someone in your age group with BC?	No	87 (26.9)	101 (25.1)	—	0.54
	Yes	232 (71.6)	299 (74.4)	0.90 (0.64–1.26)	
	Unknown	5 (1.5)	2 (0.5)		
Ever had blood clotting problems?	No	300 (92.6)	367 (91.3)	—	**0.02**
	Yes	8 (2.5)	24 (6.0)	0.41 (0.18–0.92)	
	Unknown	16 (4.9)	11 (2.7)		
Anyone in the family ever had blood clotting problems?	No	212 (65.4)	239 (59.5)	—	**0.02**
	Yes	94 (29.0)	152 (37.8)	0.70 (0.51–0.96)	
	Unknown	18 (5.6)	11 (2.7)		
Know someone in your age group who has ever had blood clotting problems?	No	257 (79.3)	312 (77.6)	—	0.54
	Yes	64 (19.8)	87 (21.6)	0.89 (0.62–1.28)	
	Unknown	3 (0.9)	3 (0.7)		
Ever had cataracts?	No	261 (80.6)	331 (82.3)	—	0.66
	Yes	51 (15.7)	59 (14.7)	1.10 (0.73–1.65)	
	Unknown	12 (3.7)	12 (3.0)		
Anyone in the family ever had cataracts?	No	140 (43.2)	156 (38.8)	—	0.22
	Yes	169 (52.2)	228 (56.7)	0.83 (0.61–1.12)	
	Unknown	15 (4.6)	18 (4.5)		
Know someone in your age group who has ever had cataracts?	No	245 (75.6)	308 (76.6)	—	0.82
	Yes	77 (23.8)	93 (23.1)	1.04 (0.74–1.47)	
	Unknown	2 (0.6)	1 (0.2)		
Ever had endometrial cancer?	No	299 (92.3)	384 (95.5)	—	0.48
	Yes	5 (1.5)	4 (1.0)	1.61 (0.43–6.03)	
	Unknown	20 (6.2)	14 (3.5)		
Anyone in the family ever had endometrial cancer?	No	274 (84.6)	336 (83.6)	—	0.21
	Yes	26 (8.0)	44 (10.9)	0.73 (0.44–1.21)	
	Unknown	24 (7.4)	22 (5.5)		
Know someone in your age group who has ever had endometrial cancer?	No	298 (92.0)	351 (87.3)	—	**0.05**
	Yes	25 (7.7)	48 (11.9)	0.61 (0.37–1.02)	
	Unknown	1 (0.3)	3 (0.7)		

Abbreviations: AH, atypical hyperplasia; BC, breast cancer.

[a]Headings in bold typeface indicate items considered for multivariate modeling.

[b]OR, the relative odds for SERM uptake, "—" identifies the baseline level of the covariate.

[c]*P* value is based on the likelihood ratio test, unknowns were excluded for calculation of *P* values.

increasing evidence that decision making in breast cancer risk reduction is much more complex (18, 22). Such findings are strengthened by the DMP-1 study, which shows that discussions on risks and benefits are not driving women's decision making. The risks and benefits discussed in the counselling are gauged against personal experiences and those of close family and friends (17, 23). DMP-1 results suggest that HCPs need to seriously engage with their patients' experiences and attitudes. HCPs engaging in counseling on SERM use should clearly assess their patients' attitudes toward medications and prevention behaviors and relate to those when discussing the risks and benefits of chemoprevention options to make the information relevant to the patients. Further research is needed to investigate how to effectively relate experiential information with medical information on the risks and benefits of medication intake, particularly in situations in which a woman's attitudes differ from the HCPs' perspective.

The DMP-1 study included a high number of women who indicated that they chose to take a SERM for breast cancer risk reduction. It should be noted that this does not suggest actual SERM use or adherence. We did not assess how many of the participants actually started taking a SERM. Studies that compared self-report of hormonal therapy use after a breast cancer with microelectronic monitoring showed a statistically

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Table 5. NSABP DMP-1: Comparison of characteristics related to participants' perceptions related to breast cancer and SERMs of those who decided to take a SERM and those who decided not to take a SERM to reduce the risk of developing breast cancer[a]

		Decision about a SERM ($n = 726$)			
		To take ($n = 324$)	Not to take ($n = 402$)		
Characteristics	**Categories**	**No. (%)**	**No. (%)**	**OR[b](95% CI)**	***P*[c]**
Ever before thought about taking a SERM?	No	173 (53.4)	267 (66.4)	—	<**0.001**
	Yes	150 (46.3)	134 (33.3)	1.73 (1.28–2.34)	
	Unknown	1 (0.3)	1 (0.2)		
Ever before heard about taking a SERM to prevent BC?	No	95 (29.3)	142 (35.3)	—	**0.09**
	Yes	225 (69.4)	256 (63.7)	1.31 (0.96–1.80)	
	Unknown	4 (1.2)	4 (1.0)		
Influenced by someone's BC diagnosis?	No	171 (52.8)	300 (74.6)	—	<**0.001**
	Yes	153 (47.2)	99 (24.6)	2.71 (1.98–3.71)	
	Unknown	0 (0.0)	3 (0.7)		
Perception on risk of developing BC in the next 5 years	Less than average	12 (3.7)	20 (5.0)	—	<**0.001**
	Average	97 (29.9)	188 (46.8)	0.86 (0.40–1.83)	
	More than average	213 (65.7)	191 (47.5)	1.86 (0.89–3.90)	
	Unknown	2 (0.6)	3 (0.7)		
Worried about BC in the next 5 years?	Not worried	52 (16.0)	126 (31.3)	—	<**0.001**
	Worried somehow	76 (23.5)	119 (29.6)	1.55 (1.00–2.39)	
	Worried a lot	195 (60.2)	155 (38.6)	3.05 (2.07–4.48)	
	Unknown	1 (0.3)	2 (0.5)		
Would you change your diet to reduce BC risk?	No	72 (22.2)	105 (26.1)	—	0.21
	Yes	252 (77.8)	295 (73.4)	1.25 (0.88–1.76)	
	Unknown	0 (0.0)	2 (0.5)		
Would you increase exercising to reduce BC risk?	No	51 (15.7)	79 (19.7)	—	**0.16**
	Yes	273 (84.3)	321 (79.9)	1.32 (0.89–1.94)	
	Unknown	0 (0.0)	2 (0.5)		
Would you have a mastectomy to reduce BC risk?	No	274 (84.6)	336 (83.6)	—	0.91
	Yes	47 (14.5)	59 (14.7)	0.98 (0.65–1.48)	
	Unknown	3 (0.9)	7 (1.7)		
Know someone with bad experience who took tamoxifen and/or raloxifene?	No	278 (85.8)	304 (75.6)	—	<**0.001**
	Yes	46 (14.2)	98 (24.4)	0.51 (0.35–0.76)	
Know someone with good experience who took tamoxifen and/or raloxifene?	No	196 (60.5)	311 (77.4)	—	<**0.001**
	Yes	128 (39.5)	91 (22.6)	2.23 (1.62–3.08)	
Nervous about taking a drug that no one you know has taken?	Knows someone who took drug	149 (46.0)	163 (40.5)	—	<**0.001**
	Not nervous	98 (30.2)	79 (19.7)	1.36 (0.94–1.97)	
	Nervous somewhat	46 (14.2)	41 (10.2)	1.23 (0.76–1.98)	
	Nervous a lot	31 (9.6)	119 (29.6)	0.28 (0.18–0.45)	
Ratings of traits of the average woman who takes a drug to prevent BC	Brave or smart or healthy or takes good care of her health	313 (96.6)	295 (73.4)	10.32 (5.44–19.59)	<**0.001**
	Scared or sickly or hypochondriac or anxious/a worrier or over medicated	143 (44.1)	228 (56.7)	0.60 (0.45–0.81)	<**0.001**
Scales[d,e]		**Mean (SD)**	**Mean (SD)**		
	Trust in the HCP	44.9 (5.2)	42.6 (6.2)	1.07 (1.04–1.10)	<**0.001**
	Trust in pharmaceutical companies	6.9 (1.7)	6.2 (1.7)	1.30 (1.18–1.42)	<**0.001**
	Attitudes about taking medication	32.3 (5.8)	28.6 (6.6)	1.10 (1.07–1.13)	<**0.001**

Abbreviation: BC, breast cancer.

[a]Headings in bold typeface indicate items considered for multivariate modeling.

[b]OR, the relative odds for SERM uptake, "—" identifies the baseline level of the covariate.

[c]*P* value is based on the likelihood ratio test, unknowns were excluded for calculation of *P* values.

[d]The "Trust in HCP" scale ranges from 10 to 50, and "Trust in pharmaceutical companies" ranges from 2 to 10, such that the higher score means a higher level of trust. The "Attitudes about taking medication" scale ranges from 9 to 45, such that the higher score means a more positive attitude.

[e]OR is per unit change.

significant difference between both measurements (24, 25). However, adherence studies in other disease fields suggest that there is a correlation between self-report and objective measurements (26).

The counseling that women received was part of their regular care and was not standardized; rather, each HCP followed his/her usual practice of how they treated and counseled women considered at risk for breast cancer. To account for these differences, we asked the participants about the counseling session. Participants were asked about all known risks and benefits of SERM use and if it was discussed in the counseling session. They were also asked how an HCP described this information (words or numbers). Most participants remembered discussing at least two risks and two benefits of SERM use. However, particular traits of an HCP or other factors of the counseling sessions that we did not account for in the surveys may have influenced the counseling, such as the exact wording and framing of the information by the HCP (17).

In a recent review, Padamsee and colleagues (22) highlighted the limited knowledge we have on breast cancer risk reduction decision making from the perspective of women who are at increased risk of developing the disease but have no known

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Table 6. NSABP DMP-1: Final multivariate models of participants' characteristics associated with the decision about taking SERMs for breast cancer risk reduction

	Overall		Premenopausal		Postmenopausal	
Characteristics	**OR[a](95% CI)**	***P*[b]**	**OR[a](95% CI)**	***P*[b]**	**OR[a](95% CI)**	***P*[b]**
Recommendation from HCP						
No recommendation/not to take a SERM	—	<0.001	—	<0.001	—	<0.001
To take a SERM	14.00 (8.39–23.37)		17.73 (6.27–50.14)		13.32 (7.43–23.90)	
Nervous about taking a drug that no one she knows has taken						
Knows someone who took drug	—	<0.001	—	0.002	—	<0.001
Not nervous	1.43 (0.83–2.48)		0.80 (0.28–2.30)		1.78 (0.93–3.40)	
Nervous somehow	1.81 (0.91–3.60)		0.88 (0.23–3.40)		2.62 (1.18–5.80)	
Nervous a lot	0.31 (0.17–0.56)		0.16 (0.06–0.43)		0.37 (0.18–0.79)	
Attitudes about taking medication scale[c]	1.05 (1.02–1.09)	0.004	*1.06 (0.996–1.13)*	*0.07*	1.05 (1.00–1.09)	0.03
Worried about BC in the next 5 years						
Not worried	—	<0.001	—	*0.10*	—	<0.001
Worried somehow	1.56 (0.85–2.86)		*2.52 (0.78–8.16)*		1.40 (0.70–2.82)	
Worried a lot	3.61 (2.04–6.38)		*3.14 (1.09–9.02)*		4.15 (2.14–8.05)	
Trust in the HCP scale	1.06 (1.02–1.10)	0.003	*1.05 (0.99–1.13)*	*0.11*	1.05 (1.00–1.10)	0.053
Knows someone with good experience who took SERMs						
No	—	0.002	—	*0.97*	—	0.008
Yes	2.06 (1.30–3.26)		*1.02 (0.43–2.41)*		2.11 (1.21–3.68)	
Knows someone with bad experience who took SERMs						
No	—	<0.001	—	*0.07*	—	<0.001
Yes	0.38 (0.22–0.64)		*0.39 (0.14–1.08)*		0.27 (0.14–0.52)	
Anyone in the family ever had blood clotting problems?						
No	—	0.02	—	0.005	—	*0.14*
Yes	0.59 (0.38–0.92)		0.27 (0.11–0.69)		*0.67 (0.40–1.13)*	
"Good" traits[d,e]						
No	—	<0.001	—	<0.001	—	
Yes	7.57 (3.41–16.78)		62.19 (7.4–520.84)			
Talked about testing results						
No	—	0.01	—	0.03	—	
Yes	1.80 (1.13–2.86)		2.40 (1.07–5.41)			
AH						
No breast biopsies	—	0.01	—	*0.31*	—	*0.20*
No breast biopsies with AH or status of AH unknown	0.66 (0.35–1.27)		*1.30 (0.39–4.33)*		*0.61 (0.29–1.30)*	
At least one biopsy with AH	1.48 (0.85–2.57)		*2.07 (0.75–5.75)*		*1.09 (0.56–2.11)*	
Anyone in the family ever had endometrial cancer?						
No	—	*0.53*	—	0.025	—	*0.58*
Yes	*0.79 (0.39–1.63)*		0.18 (0.04–0.87)		*1.25 (0.56–2.79)*	
Had you ever thought about taking SERM before?						
No	—	*0.57*	—	0.02	—	*0.93*
Yes	*1.14 (0.73–1.77)*		2.49 (1.15–5.40)		*1.03 (0.59–1.77)*	
"Good" traits[d,e]/Talked about testing results						
No No					—	0.006
No Yes	—		—		0.17 (0.03–0.96)	
Yes No					—	
Yes Yes					2.19 (1.25–3.83)	

Abbreviations: AH, Atypical hyperplasia; BC, breast cancer.

[a]OR, the relative odds for SERM uptake, "—" identifies the baseline level of the covariate.

[b]*P* value is based on the likelihood ratio test, unknowns were excluded for calculation of *P* values.

[c]*Italics* indicate that these covariates were not in the final model, however, their effect and significance were tested by adding them into the model one at a time.

[d]"Good" traits = Average woman who takes a drug to prevent breast cancer perceived as: brave, or smart, or healthy, or takes good care of her health.

[e]The postmenopausal model interaction between "'Good traits" and "Talked about testing results" was found to be statistically significant. The corresponding "main effects" section of the table for these two covariates is shown by dashes to indicate that they are not applicable for the postmenopausal model. The corresponding "interaction" section of the table for these two variables is shown by dashes to indicate that it is not applicable for the overall and premenopausal models.

gene mutation. The DMP-1 study is the largest to date of U.S. women counseled on SERM use as part of their regular care, investigating women's decision making about SERM use for breast cancer prevention prospectively after counseling.

DMP-1 is also the first study to quantify social and cultural beliefs and understandings that may influence decisions about SERM use. As a result, light has been shed on the complex issue of how women who have received counseling about SERM use

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in clinical practice make their decisions, as well as on the importance of their attitudes, experiences of their peers and family, and on the interaction of these factors with an HCP recommendation in this process.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Disclaimer

The study sponsor played no role in the design, collection of data, analysis or interpretation of the study, or in the writing of the manuscript, or in the decision to submit the manuscript for publication.

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