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Deciding on breast cancer risk reduction: the role of counseling in individual decision-making – a qualitative study

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Abstract

Objectives—The presentation of risks and benefits in clinical practice is common particularly in situations in which treatment recommendations involve trade-offs. The treatment of breast cancer

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risk with selective estrogen receptor modulators (SERMs) is such a decision. We investigated the influence of health care provider (HCP) counseling on women's decision-making.

Methods—Thirty breast cancer risk counseling sessions were recorded from April 2012 – August 2013 at a comprehensive cancer center and a safety-net, community hospital in the US. Participating women and HCPs were interviewed. A cross-case synthesis was used for analysis.

Results—Of 30 participants 21 received a SERM-recommendation, 11 decided to take SERMs. Counseling impacted decision-making, but did not determine it. Three categories emerged: 1.) ability to change the decision anytime, 2.) perceptions on medications, 3.) proximity of cancer.

Conclusion—Decision-making under conditions of a risk diagnosis such as increased breast cancer risk is a continuous process in which risk information is transformed into practical and experiential considerations.

Practice Implications—Individuals' health care decision-making is only marginally dependent on the interactions in the clinic. Accepting patients' experiences and beliefs in their own right and letting them guide the discussion may be important for a satisfying decision-making process.

1. Introduction

The presentation of risks and benefits in clinical practice is common particularly in situations in which treatment recommendations involve trade-offs. For example, women who are at increased risk of developing breast cancer have the option to take selective estrogen receptor modulators (SERM) to reduce their risk [1–3]. However, the medication increases other risks. Medical guidelines that address the treatment of women at increased risk of developing breast cancer recommend a discussion with the women about the risk and benefits of taking SERMs to reduce primary breast cancer risk [4–6].

Uptake of SERMs in high-risk populations who are cared for in medical centers varies between 11% and 42% [7–10]. A recent systematic review found that atypical cell findings in a breast, provider recommendation, and less concern with side effects were factors associated with higher levels of SERM uptake [11]. Studies that investigated the effect of decision aids on SERM use found that while knowledge about risks and benefits increased decisions were not influenced [12, 13]; rather, the perceived impact that SERM use would have on women's emotional well-being was more predictive of women's willingness to take a medication to reduce breast cancer risk [14]. These women were exposed to a decision aid but not to counseling by a health care provider (HCP). However, the importance of a physician's recommendation for treatment uptake is generally acknowledged [15, 16]. At the same time there is surprisingly scant research that investigates how counseling as part of regular care of an HCP influences health care decision-making. Considering that treatment guidelines for women at increased risk of breast cancer recommend discussion of risks and benefits of SERMs, it should be of interest to see how HCP counseling may influence an individual's health care decision-making. The few findings thus far suggest that views and perceptions prior to counseling guide decision-making more than the counseling itself [17].

In this paper, we investigated how individuals who have discussed SERM use and other strategies for breast cancer risk reduction with an HCP decided for or against treatment

uptake. In particular, we analyzed how counseling on SERM use as part of regular medical care and a physician's recommendation for or against SERMs influenced health care decision-making regarding breast cancer risk.

2. Methods

2.1. Study Design

The research described here was part of the video component of the NSABP/NRG Oncology DMP-1 study (ClinicalTrials.gov: NCT01399359). In the larger study, 1023 women were recruited to examine the social, cultural, and psychological factors involved in decision-making about risk reduction strategies for breast cancer [18] (unpublished results).

All DMP-1 participants received two questionnaires: One after the counselling session (Q1) and a second one after they had made a decision about SERM use or after six months of the counselling session (Q2). The video component substudy recorded patient-HCP conversations on SERM use and breast cancer risk and sought to analyze women's decision-making strategies about whether or not to take a SERM and the role that the HCP counseling plays in the decision-making process. Participants of the substudy participated in the two DMP-1 survey and in a qualitative, in-person interview within two weeks after the counseling about their experiences in the consultation session and their breast cancer risk. See table 1 for the structure of the interview. After participants had made a decision and completed Q2, they received a phone call from the study nurse or the interviewer at the site to inquire about their reasons for the decision made (see table 2 for the information gathered).

The substudy was conducted at two sites in the US: one large comprehensive cancer center chosen to reach a high-risk population and the other a community-based safety-net teaching hospital in an urban setting chosen to include minorities.

For the purpose of the sub-study, study personnel at the study sites screened women prior to their appointment in the clinic to determine with whom a conversation on SERMs was likely to take place. They focused on women who came to discuss biopsy results or/and a family history of breast cancer risk. From April 2012 to August 2013, women who met the eligibility criteria (Table 3) were approached prior to the appointment by telephone and informed about the study. The first thirty women who gave written consent for the appointment to be video-recorded were included in the substudy. The HCP who counseled the participant also signed a consent form with which s/he indicated her agreement to be video-recorded and interviewed. HCPs received no guidance on how to conduct the counseling since the aim was to understand regular medical care.

The study was approved by each site's institutional review board in accordance with assurances filed with and approved by the US Department of Health and Human Services. Informed written consent was required from both the participants and the medical personnel conducting and participating in the recorded consultation sessions and interviews.

2.2. Sample

Table 3 shows eligibility criteria for women and providers. The aim was to video-record 30 consultation sessions. The sample size was determined based on previous qualitative investigations [19–21]. Potential participants were approached by the study nurse, and asked for consent to be video-recorded prior to the consultation session, until the sample size of 30 was reached (Fig. 1). Providers who treated and counseled women with an increased risk of breast cancer at these two sites, and who consented to the video-recording, were included in the substudy.

2.3. Data collection

Consultations between participants and HCPs were video-recorded. Up to six weeks following the counseling, an audio-recorded, semi-structured, qualitative participant interview was conducted. All interviews were in-person and all, except for one, were conducted at the study site. The interviews were conducted by research staff working at the study sites with a background in health research (CG) and clinical psychology (PP). To ensure a cohesive interview style at both sites, the interviewers (CG, PP) were trained to conduct the interviews by the senior researcher (CH). The interview guideline contained two parts, and was developed based on a literature review and the study aim (Table 1). The first part was an open interview about women's understanding of breast cancer risk, decision-making about SERMs, and the counseling experience. In the second part, participants watched their own counseling session, commented on it, and answered tailored questions from an initial analysis of the video.

HCP interviews also contained two parts. The first explored their counseling strategies, while in the second they viewed and commented upon a video recording of consultation sessions that they themselves had conducted.

To learn how the final decision about SERM use was reached, a five-question structured interview guideline was used to conduct telephone interviews with participants after they had decided about whether or not to take a SERM (Table 2).

2.4. Analysis

Interviews were transcribed verbatim, the counseling videos were summarized [22], and the final telephone interview responses were documented. All written data were entered into MAXQDA 10 [23], a software program for qualitative data. Data was analyzed by SB in collaboration with CH using a cross-case synthesis approach [24, 25]. Cases consisted of video data, the interview, and the telephone interview record. Each case was analyzed beginning with the telephone interview. Then the decision-making process was reconstructed through the different documents, identifying salient themes regarding decision-making in each case. To ensure coding consistency, analysis was regularly presented in a qualitative methods working group at the Institute for Public Health, Charité-Universitätsmedizin Berlin and discussed with the project team members, particularly the interviewers (CG, PP). After themes were identified for each case, themes were compared across cases in order to reach a synthesis and to develop categories that could explain the decisions made. Only after all themes had been synthesized into categories did we consider analysis complete.

Themes and categories were corroborated by comparing and contrasting the counseling strategies discussed in the HCP interviews with analysis of the video-recorded counseling interactions [22], in the context of the decision reached. To protect participant anonymity, quotes have been edited to remove any identifying characteristics and names, and have been grammatically altered for ease of reading.

3. Results

3.1. Sample Characteristics

Thirty participants were interviewed. The mean age for participants was 51 years (range 37–73). The sample was ethnically diverse, with 20% identifying as African-American and 63% as White (Table 4). Most participants in the sample had a family history of breast cancer and a high lifetime risk of developing breast cancer (Table 5). One participant did not complete the telephone interview about her decision and was excluded from the cross-case synthesis. Five HCPs counseled the 30 participants. Two providers, one at each site, conducted 25 of the video-recorded counseling sessions for the sample. The remaining three HCPs conducted one to three consultations each. Consultations lasted on average 21 minutes, ranging from 10–37 minutes. Most consultations were one on one, however a second HCP was present at 5 consultations and 6 participants were accompanied by companions. To ensure the anonymity of HCPs, no identifying socio-demographic characteristics are reported. Based on the analysis of the consultation videos, 21 participants received a recommendation from the HCP to take a SERM, 20 with abnormal breast tissue and 11 decided to take a SERM (Table 5). All but one of these 11 women were counseled by the same HCP. Of the 11 women who decided on SERM use, all chose to take tamoxifen, although six could have chosen either raloxifene or tamoxifen based on their menopausal status. Of the 9 women who did not receive a recommendation from the HCP to take a SERM, none decided for SERM uptake (Table 6).

3.2. Description of the Counseling

All HCPs provided detailed information on a range of strategies to reduce breast cancer risk, including lifestyle factors such as diet and physical activity, regular follow-up appointment, and SERMs. All HCPs discussed involved risks and benefits. They all had written information on the participants' breast cancer risk assessment and the risks and benefits of SERM use with them that guided their counseling. In most instances, counseling started with an explanation of the calculated breast cancer risk assessment. This Breast Cancer Risk Assessment Tool (BCRAT) calculates an individual's risk of developing breast cancer over a five-year and lifetime, taking into account the following breast cancer risk factors: age, age of first menstrual cycle, age of first live birth, number of first degree relatives with breast cancer, biopsy history and race/ethnicity. In counseling, the individual's Gail score calculation was compared to the average woman's risk, and an explanation that factored in what led to increased risk in the woman's particular case was given. HCPs differed in terms of how they framed these numbers based on their assessment of the patient. For example, while all providers presented both risks and benefits of SERM intake to the women, some highlighted the potential risks associated with SERM intake more, while others highlighted

the comparable risk levels between contraceptive pills and SERMs with regard to blood clots.

In the interviews the HCPs all presented an idea of whom they considered an ideal candidate for SERM uptake, which was guided by whom they thought would accrue the greatest level of risk reduction. These ideas were quite similar across providers and consisted of a woman who has few co-morbidities, is young enough to experience few serious side effects, has a high level of breast cancer risk, and has atypical cells. The few HCPs in our sample that were new to the risk counseling also mentioned that they discouraged SERM use due to their unfamiliarity with SERMs. HCPs tailored their recommendations based on their assessment of the SERM candidate and on their own familiarity and ease with SERMs as a risk reducing medication.

The HCP who counseled 10 of the 11 women who chose tamoxifen for breast cancer risk reduction had two unique counseling strategies for women with atypical cell findings that were not found in the other consultation videos. First, the HCP framed the temporality of the decision in two ways: the first related to being able to make the decision at a later point, while the second highlighted that the medication could be discontinued at any time if unpleasant symptoms developed. Furthermore, while most HCPs, when counseling women with atypical cell findings, did stress the additional benefits of risk reduction, they did not do so as strongly as the aforementioned HCP.

3.3. Women's decision-making

“I didn't expect [a diagnosis with atypical hyperplasia]! [...] After my visit with [the HCP], I'm asking, I'm looking, I'm trying to find the right decision! I'm still in the middle of that process.”

(Participant X, 5-year Gail score range: 3.01 – 5.00%, age range: 56–65)

While the different presentation of information impacted women's decision-making, the interviews revealed that it did not determine a woman's decision if she was not already open to taking a medication prior to counseling. All participants who considered SERM use individually balanced their personal risks and benefits based on similar themes.

The ability to change the decision at any time (temporality of the decision) played a crucial role for all. How participants perceived medication use also shaped the conditions under which they would be willing to take a pill and how they interpreted side effects. Lastly, the close experiences that participants had with breast cancer more generally (the proximity of breast cancer) impacted how they thought about their own risk. Each of these categories is presented in detail below. Quotations that exemplify how participants expressed them are shown in Table 7.

3.4. Temporality of the Decision

Decisions made in the consultation session were not considered final by many participants, both SERM takers and decliners. Many participants who declined to take a SERM expressed that they might change their decision if their risk level increased. In particular, the youngest

participants were open to reassessing their decision if presented with an increased risk assessment.

Concurrently, those who chose to take a SERM also expressed that they would stop taking the drug if they experienced too many side effects. This sense of control was important in determining how comfortable they felt about taking a SERM.

3.5. Perceptions about Medication Use

3.5.1. Perceived Positive Effects—SERM users emphasized how their risk of breast cancer would be greatly minimized. Some described this reduction using numbers they remembered from the consultation. When given a choice between raloxifene and tamoxifen, all who chose to take a SERM chose tamoxifen. While this was the recommendation of the HCP, most women also talked about a family member's or friends' unproblematic experience with the drug. This clearly influenced and reinforced their drug choice. The continuing risk reduction protection provided by tamoxifen after treatment, as described in the counseling, was also important.

3.5.2. Perceived Negative Effects—The 11 women who had atypical cells but decided against SERM use were typically surprised that they should have an increased risk of breast cancer. Some were more worried about other conditions such as cardiovascular disease. These women were offered and agreed to six month visits for close monitoring.

In sharp contrast, one participant with atypical cells followed the treatment recommendation made by her regular HCP to have a prophylactic bilateral mastectomy. In order to eliminate as much risk as possible, she declined the HCP's recommendation to take a SERM and instead opted for surgery.

Participants who declined a SERM despite a positive recommendation discussed how their fear of cancer was overshadowed by the threat of the SERMs' side effects, such as stroke, which could be immediate, sudden, and fatal.

Overall, SERM decliners were concerned about how potential side effects such as hot flashes and symptoms of menopause might negatively impact their daily life and cited the duration (5 years) and daily pill ingestion as deterrents that could cause unwanted change.

3.5.3. Illness Versus Potential Disease—Some participants stated that they would take a medication for illness, but not for a potential disease. For some participants who chose to start a SERM, the counseling HCP's argument that the side effect profile of the drug was similar to other prevention medications such as the birth control pill was convincing.

3.6. Proximity of Cancer or Other Diseases

Some participants voiced how the experiences of friends or family with breast cancer impelled them to take a SERM. For some, this was a relative to whom they felt particularly close. Cancer within the family or social environment became an important factor for a participant's decision-making if they felt there was a similarity between themselves and the cancer patient in terms of age, behaviors, life circumstances, or a similarity in looks. This

group of participants signaled a strong belief that they were at risk of developing breast cancer.

Conversely, those who declined a SERM and had experience with close friends or relatives with cancer stressed how they differed from the person with cancer. The differences mentioned helped to diminish their sense of the threat of developing breast cancer.

Some participants had close colleagues, friends, or family who had had blood clots or cataracts, some of the serious potential side effects of SERMs. Such experiences influenced decision-making.

3.7. Reaching a Decision: Personal Risk-Benefit Analysis

The three decision-making categories discussed above provided important context for our participants when making a decision regarding SERM use. The HCP's recommendation worked to strengthen their resolve to take a SERM, but only if it aligned with their individual thinking about their own risk. If they had a strong feeling that their risk of breast cancer was a real and imminent threat to their present state of health, then the recommendation to take a SERM was a catalyst to act.

Alternatively, those who declined SERM use stressed that breast cancer need not be a death sentence and felt that living with the possibility of breast cancer was preferable to experiencing SERM side effects. These participants articulated that close monitoring or modifying lifestyle factors (changing diet, exercising, losing weight, and/or lowering alcohol intake) would be a sufficient alternative to medication. The ability to control unwanted side effects was highlighted in the choice not to take a SERM, and this was contrasted with a cancer that may or may not develop.

Some participants, both takers and decliners of SERMs, stressed how they reached their decision independently of the HCP's recommendation and/or described the consultation as a place for discussing risks and benefits.

The vast majority of participants who made a decision for or against SERM use during the consultation expressed that this was the right decision for them. Those who did not make a decision during the consultation, however, remained unsure about their decision afterwards. In general, the decision was easiest for women when their assessment aligned with the HCP's recommendation.

4. Discussion and Conclusion

4.1. Discussion

A physician's recommendation [26] has been shown to be an important factor in SERM uptake, as well as in treatment decision-making in general. However, little research has looked at the influence that counseling in regular medical care on the risks and benefits of a treatment has on an individual's decision-making. Indeed, the few studies thus far have shown that individuals' pre-counseling views of their individual risk status are a strong predictor of their decisions [17]. Studies investigating the effect of presentation of

individualized risk estimates on risk perception have found that risk perceptions remain relatively stable [27–29].

In our study, the framing of the information by the HCP influenced, but did not determine, the decision of the participants. The presented risks and benefits were transformed by participants into an individual risk-benefit analysis that was framed not by the statistical information but by practical and experiential information with regard to the temporality of experiencing side effects (in instances where women chose to take the medication), and personal experiences and views regarding medications and breast cancer in general. Risk needed to be translated into experiential categories, such as how great a risk they felt breast cancer posed to their health, in order to use it for individual health care decision-making. In this respect, the *proximity of cancer* was an important category because it determined how threatened the women felt. The importance of an experiential dimension in understanding and acting on risk information for lay women has been noted by Salant et al. [19], who showed that bodily symptoms are important for an individual to feel at risk. However, as we have shown in this paper, the decision to start SERM treatment often needs a further evaluation, with a focus on others with breast cancer and one's relationship and similarity to them. While for most the decision to take or not take a SERM was reached in the consultation, the experiential process of evaluation and finalizing of the decision took place outside of the counseling setting and is influenced by the environment more than by the counseling.

The importance of bodily-experiential and emotional dimensions in feeling at risk may also explain why other studies have found that cognitive knowledge and numerical risk play only a marginal role in decisions about whether or not to take a SERM [30, 31]. Furthermore, women have not been found to think that the individualized risk information provided to them necessarily correlates with their own individual situation [32]. In this respect, our study shows that the framing of risk information by the HCP became most important to candidates who were positively disposed to prevention medication *before* considering a SERM. In contrast, the decision was most difficult for women who had a misalignment between the risk status presented by the HCP, the HCP recommendation and their own sense of risk of breast cancer and perceptions on medication. For them, the continued conversation HCPs offered women at increased risk of developing breast cancer may be particularly important.

There are several limitations to our study. The study population, recruited from clinics providing high-risk counseling, may have received more extensive counseling on risk and SERM use than women in other care settings. Because of this, it is likely that our sample could have been presented with more options for their risks than in other risk counseling settings and that they reflected more carefully on their decisions than other women in similar situations. Thus the reflections and balancing of personal risks and benefits may be particular to our study sample. The high importance of women's prior experiences may be even more significant in settings where counseling is not as thorough as in our study.

Furthermore, the sample of HCPs in our study included both experienced and inexperienced HCPs, which was reflected in the counseling and interactions with participants. This

particular sample therefore shows how important familiarity with the medications is for HCPs, and thus also for the counseled women.

Finally, most of the women were counseled by two HCPs, which possibly limits our findings to this sample. However, comparing and contrasting the strategies of these two HCPs with the other HCPs, and particularly the decision-making strategies of the women they counseled, does not reveal different decision-making strategies, which suggests that the translation of medical risks and benefits into experiential dimensions may be applicable to other counseling situations.

4.2. Conclusion

The presentation of risks and benefits in clinical practice is recommended and increasingly common. Particularly in situations in which the potentiality of a disease is discussed and prevention treatments offered, the weighing of risks and benefits is paramount. Most importantly, in our research on how counseling on SERM use and an HCP's recommendation for or against SERMs influence decision-making regarding breast cancer risk, three categories were found to play a role. The first is regarding the temporality of the decision, where decision-making is seen as an ongoing process that can be re-evaluated at a future time. Thus, risk counseling in this context is to be understood as a continuous process. The second is an individual's prior perceptions of medication, which determines their decision-making and which, if different from provider's recommendation, may lead to a patient who is uneasy about what to do. Finally, the proximity of breast cancer plays a crucial role, as individuals evaluate the received information in the light of their own or close others' experiences and perceptions. The findings of this study stress that it is important to not only assess patient's beliefs and preferences but to take them seriously in their own right. Our findings and other recent studies [17] may point to the need to develop counseling strategies that are not aimed to change perceptions but instead work with the acceptance of patients' beliefs and understandings and with an understanding that one's social and cultural environment will be a determining factor of decision-making.

4.3. Practice Implications

This study strengthens the importance of addressing individuals' particular experiences and beliefs in health care interactions with HCPs. It also stresses the fact that individuals' health care decision-making is only marginally dependent on the interactions in the clinic. Accepting patients' experiences and beliefs in their own right and letting them guide the discussion may be important for a satisfying decision-making process. Furthermore, the study suggests that counseling in the context of risk conditions needs to be conceptualized as a continuous process in which experiences and decisions may change over time.

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Highlights

- Risk counseling in breast cancer is an on-going process
- Decision-making is continuous in breast cancer risk treatment
- Personal experiences determine one's decision-making
- One's risk evaluated along similarities and differences to other's with disease

Figure 1.
DMP-1 substudy recruitment flow

Table 1

Study participant interview structure and content

Participant Interview topic guideline conducted in-person after the consultation session by staff at the study sites (CG and PP)
1. We would like to first talk about how you experienced the consultation session, what you took away from it and what was important to you about it.
2. We also will talk more generally about being at risk for breast cancer and why you had to come here to talk to the HCP.
3. Finally, we want to watch the video of the consultation session you had with the doctor and I would like you to comment on it. Is it as you remembered it? Do you see something very different from how you remember the consultation with the HCP?

Table 2

Telephone Interview Summary Sheet for participants who decided about SERM use

1. General Information
<ul style="list-style-type: none"> - Study ID - Date of the conversation - Date of counselling session - Date of write-up - Author of write-up
2. Overview of the telephone conversation
<u>Introduction question:</u> <p>Does the participant take a SERM? – yes/no</p>
<u>Additional questions and probes:</u> <p>What made her decide to take/not take a SERM?</p> <p>Was it a difficult decision?</p> <p>Who was included in the decision-making?</p> <p>Is she satisfied with the decision?</p>

Table 3

Eligibility Criteria

Study Recruit	Eligibility	Ineligibility
Participant	<ul style="list-style-type: none"> - Women - Discussion with HCP of SERM use for the prevention of breast cancer - English speaking - 35 years or older - Willingness to be video-recorded 	<ul style="list-style-type: none"> - Invasive or noninvasive breast cancer - Prior use of SERM / osteoporosis medicine - Lumpectomy, mastectomy, radiation lobular carcinoma in situ
Provider	<ul style="list-style-type: none"> - Any medical provider at participating recruitment site giving breast cancer risk counseling - Discussion of SERM use with patient - Willingness to be videotaped 	<ul style="list-style-type: none"> - No consent given

Table 4

Participant characteristics: NSABP DMP-1 video component Substudy

Participant Characteristic ^a	Decision Made ^b			p-value ^c
	Total n=30 N(%)	Yes n=11 N(%)	No n=19 N(%)	
Age, Years (Mean: 51)				
37–45	11 (37)	5 (45)	6 (32)	0.87
46–55	9 (30)	3 (27)	6 (32)	
56–65	9 (30)	3 (27)	6 (32)	
66–73	1 (3)	0 (0)	1 (5)	
Race / Ethnicity				
White / Non-Hispanic	19 (63)	7 (64)	12 (63)	0.27
White, Hispanic	2 (7)	1 (9)	1 (5)	
Black / African American	6 (20)	1 (9)	5 (26)	
Multiracial	1 (3)	0 (0)	1 (5)	
Unknown race, Hispanic or Latina	2 (7)	2 (18)	0 (0)	
Hysterectomy History				
Never had a hysterectomy	18 (60)	6 (55)	12 (63)	0.71
Had a hysterectomy	12 (40)	5 (45)	7 (37)	
Menopausal Status				
Pre-menopausal	11 (37)	5 (45)	6 (32)	0.70
Post-menopausal	19 (63)	6 (55)	13 (68)	
Education				
12 years / high school / general education degree (GED)	6 (20)	2 (18)	4 (21)	0.23
Vocational / technical training / associates degree	3 (10)	0 (0)	3 (16)	
1–3 years of college / junior college (without a degree)	5 (17)	2 (18)	3 (16)	
4 or more years of college / graduated from college	9 (30)	2 (18)	7 (37)	
Graduate / professional degree	7 (23)	5 (45)	2 (11)	
Household Income (US\$)				
<\$20,000	3 (10)	0 (0)	3 (16)	0.31
\$20,000 – <\$60,000	6 (20)	1 (9)	5 (26)	
\$60,000 – <\$100,000	4 (13)	3 (27)	1 (5)	
\$100,000+	14 (47)	6 (55)	8 (42)	
Unknown	3 (10)	1 (9)	2 (11)	
Insurance Coverage				
Private health insurance	24 (80)	11 (100)	13 (68)	0.33
Medicare	3 (10)	0 (0)	3 (16)	
Medicaid	2 (7)	0 (0)	2 (11)	
No insurance reported	1 (3)	0 (0)	1 (5)	

^aDemographic information, self-reported from questionnaire.

^bSelf-reported from the telephone interview, one missing telephone interview considered SERM No.

^cBased on the Fisher's exact test.

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Table 5

Participant breast cancer (BC) risk / history: NSABP DMP-1 video component substudy

Participant Characteristic	Decision ^d			p-value ^e
	Total n=30 N(%)	Yes n=11 N(%)	No n=19 N(%)	
Family History of (BC)^{a,b}				
1 st degree: mother, sister and/or daughter with BC ^a	16 (53)	3 (27)	13 (68)	0.06
Mother diagnosed with BC ^a	12 (40)	3 (27)	9 (47)	0.44
Sister diagnosed with BC ^a	8 (27)	0 (0)	8 (42)	0.01
Daughter diagnosed with BC ^a	1 (3)	0 (0)	1 (5)	1.00
1 st degree and/or 2 nd degree with BC: grandmother, aunt, half-sibling ^{a,b}	20 (67)	4 (36)	16 (84)	0.01
Biopsy History^a				
Never had a breast biopsy	4 (13)	0 (0)	4 (21)	0.27
Breast biopsy with atypical hyperplasia	22 (73)	11 (100)	11 (58)	0.01
Visit with provider (No. previous visits)^b				
1 st consultation	16 (53)	6 (55)	10 (53)	1.00
2 nd consultation	6 (20)	2 (18)	4 (21)	
>2 nd consultation	8 (27)	3 (27)	5 (26)	
BCRAT / Gail Score^c				
Lifetime risk for BC				
<20%	11 (37)	3 (27)	8 (42)	0.47
20%	19 (63)	8 (73)	11 (58)	
5 yr. risk for BC				
<2.00%	6 (20)	1 (9)	5 (26)	0.67
2.01% – 3.00%	10 (33)	4 (36)	6 (32)	
3.01% – 5.00%	8 (27)	4 (36)	4 (21)	
>5.01% –	6 (20)	2 (18)	4 (21)	

^aDemographic information, self-reported from questionnaire.^bVariables from interview transcripts.^cBreast Cancer Risk Assessment Tool (BCRAT) / Gail score calculated from questionnaire responses including: age, age at first menstrual period, age at first live birth, number of 1st degree relatives with breast cancer, biopsy number, biopsy with atypical hyperplasia, and race. High risk is considered to be =20% lifetime, 1.66% 5 yr.^dSelf-reported from the telephone interview.^eBased on the Fisher's exact test.

Table 6

Health care provider (HCP) recommendation and selective estrogen receptor modulator (SERM) choice:
NSABP DMP-1 video component substudy

HCP recommendation to take a SERM ^a	Total n=30 N(%)	Yes to SERM n=11 ^b N(%)	No to SERM n=19 ^b N(%)	p-value ^c
Recommendation Yes	21 (70)	11 (100)	10 (53)	0.01
Recommendation No	9 (30)	0 (0)	9 (47)	

^aAnalyzed in video content logs: Recommendation Yes, provider gave verbal endorsement.

^bSelf-reported from the telephone interview, one missing telephone interview considered SERM No.

^cBased on the Fisher's exact test.

Table 7

Themes of decision-making including quotations

Category	Quotations
Temporality of the decision	
	<p><i>"I don't think that any of the side effects discourage me from taking the drugs, I just didn't think I was at the point where I need to take them right now. Maybe next year ... if [the risk level] increases substantially, that might be a trigger to say [that] we need to start considering this."</i> (Participant A, 5-year Gail score range: <2.00%, age range: 35–45 years)</p> <p><i>"After I left [the consultation session], I thought that I will take tamoxifen because that was the drug the HCP recommended. I got the prescription filled and I haven't taken one yet. I've looked at the bottle a couple of times, but a nurse told me there's no rush to this. I liked that she did that. There's no rush and it's true."</i> (Participant B, 5-year Gail score range: 2.01–3.00%, age range: 56–65 years)</p>
Perceptions about medication use	
Themes	Quotations
Perceived positive effects	<p><i>"I went from a high percentage of getting cancer – I remember the number being 86% – to a percentage of almost not getting it if I'm taking this medication. That's what I'm taking away from it."</i> (Participant D, 5-year Gail score range: <2.00%, age range: 46–55 years)</p> <p><i>"[I had done some research and my mom had also taken it], so the reason why I selected to take tamoxifen is because [the HCP] said that after five year[s], raloxifene has shown to have some decrease in the effect, so I thought that I don't need to do that, because I'm young!"</i> (Participant E, 5-year Gail score range: 3.01–5.00%, age range: 56–65 years)</p>
Perceived Negative effects	<p><i>"[The HCP] kept going over it and everything and at first I said I was probably interested in taking it. But then after mentioning the blood clots and the other things [the HCP] said, 'Have a think about [it]'... [The HCP] just told me to make sure I keep</i></p>
Illness Versus Potential Disease	<p><i>my appointment!"</i> (Participant AD, 5-year Gail score range: >5.01%, age range: 56–65 years)</p> <p><i>Anytime you say blood clot it makes me a little nervous ... because blood clots are serious. Once they travel, all of a sudden it's just kaput. So I could die from a blood clot. On the other hand, I could live and have treatment for cancer."</i> (Participant C, 5-year Gail score range: >5.01%, age range: 46–55 years)</p> <p><i>"I'm strongly against [taking] a pill for five years. I feel deep down that risks are different for different people, and it might affect me [in] a different way [than it affects others] and that bothers me. It seems [like a] very long time to take these pills and have these risks."</i> (Participant F, 5-year Gail score range: 3.01–5.00%, age range: 35–45 years)</p> <p><i>"I just don't want to take the risk of taking a drug. I didn't even take birth control pills. I don't like taking a lot of drugs that are going to alter my internal chemistry... [If] there's a reason, then I will be happy to [take a drug]. But I feel that my risk is low enough that I'm willing to take that slight risk."</i> (Participant G, 5-year Gail score range: 2.01–3.00%, age range: 56–65 years)</p> <p><i>"I think it was the analogy that [the HCP] made to [the cholesterol-lowering medication] Lipitor [or] being on the [birth control] pill. [Those] were things that meant something to me. I could relate to them."</i> (Participant H, 5-year Gail score range: 2.01–3.00%, age range: 46–55 years)</p>
Proximity of Cancer or Other Diseases	
	<p><i>"I had a friend that brought me [to] the [biopsy appointment] who is a breast cancer survivor. ... I get a chance. She didn't have a chance. She's gone through the chemo, she's gone through the radiation, she's gone through the breast surgery. ... I just felt like [taking a SERM] was my chance. Since God gave me the chance, [I] ought to try to prevent it."</i> (Participant K, 5-year Gail score range: >5.01%, age range: 56–65 years)</p> <p><i>"My grandmother was an old woman, and [the progression of the disease] happened really quickly. It was more to see my friend [with breast cancer]. When the doctor told me [about my atypical cell diagnosis], I just went back to her. I was thinking about her, and I think that [this affected how I think about my own risk]."</i> (Participant I, 5-year Gail score range: >5.01%, age range: 35–45 years)</p> <p><i>"I have speculated as to why my daughter, being the youngest in the family, came down with breast cancer. She's not a person [who] eats fruits and vegetables and healthy foods. I am. I've always been a vegetable</i></p>

Category	Quotations
	<p>person: salads, fruits. I've never been a big meat eater. She's a big meat eater. So, you know, there [are] those things." (Participant J, 5-year Gail score range: >5.01%, age range: 66–75 years)</p> <p>"The blood clot just actually came into my head last week when one of our employees passed away from a blood clot. So I got to thinkin', 'Oh wait a minute!' (laughs) ... And then my cousin who had the open heart surgery last week." (Participant X, 3.01–5.00, age range: 56–65 years)</p>
Reaching a Decision: Personal Risk-Benefit Analysis	
	<p>"I just didn't feel like it was a big deal five years ago, because [the HCP] didn't say: 'I really think you need to take this.' But then when I had this [biopsy finding with atypical cells] and with it a doubling of risk. Having this [atypical ductal hyperplasia], I felt like [the HCP] wanted to prevent me having to go through anything else if they could do that." (Participant K, 5-year Gail score range: >5.01%, age range: 56–65 years)</p> <p>"To tell you the truth, [SERMs] really concern me because it's something that happens over a period of time and could cause a lasting effect later on in life, heart attacks and different things like that. I feel like there are some things I can do to help prevent cancer, [but] when it happens it happens." (Participant C, 5-year Gail score range: >5.01%, age range: 46–55 years)</p> <p>"I felt like if it was really a higher risk that [the HCP] would have recommended then that I do that. [The HCP] didn't do that so that kind of gave me some comfort that it wasn't like: 'I really strongly recommend that you do this.' So I took it upon myself then to make my own decision based on that information." (Participant N, 5-year Gail score range: 2.01–3.00%, age range: 46–55)</p> <p>"I don't feel the HCP put any pressure on me. I think [the HCP] explained everything. Laid it all out for me and told me that I was a good candidate for this. And ultimately [that] left it up to me. That made me feel ok ... Even if [the HCP] had pressured me a little bit more, or pushed it, I still don't think I would've. Because, I still know me and I'm not going to do it." (Participant M, 5-year Gail score range: 2.01–3.00%, age range: 46–55 years)</p> <p>"I didn't expect [a diagnosis with atypical hyperplasia]! [...] After my visit with [the HCP], I'm asking, I'm looking, I'm trying to find the right decision! I'm still in the middle of that process." (Participant X, 5-year Gail score range: 3.01 – 5.00%, age range: 56–65)</p>