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Title: Project Insight: Feasibility of a Breast Cancer Screening Decision Support Tool

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Protocol Revision History

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Amendment #2 Version	**07/02/2021**

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1.0 BACKGROUND AND RATIONALE

Breast cancer is the leading cause of cancer and the second leading cause of cancer-related death in U.S. women.[1,2] Screening mammography is a contested strategy for reducing breast cancer mortality. There are considerable differences across guidelines for age of initiation and frequency of screening among women at average risk for breast cancer. [3-5] The U.S. Preventive Services Task Force (USPSTF) recommends against routine screening for women aged 40-49 years, and recommends biennial screening for those aged 50-74 years.[6] Conversely, the American Cancer Society (ACS) provides a qualified recommendation for the opportunity to initiate annual screening mammography for women aged 40-44 years, strongly recommends annual screening for women aged 45-54 years, and suggests annual or biennial screening for those 55 years and older. [2] These conflicting guidelines highlight concerns about the benefits and harms of screening, and may impact women's decision making.[2,3,7-10]

Women with an immediate family history or personal history of breast cancer, genetic risk factors, or prior thoracic or chest wall radiation therapy, and those older in age and with certain modifiable risk factors are likely to benefit from screening mammography. [3-5]Conversely, women at average risk may be more vulnerable to certain harms (i.e., physical and psychological harm, financial strain, opportunity costs) associated with screening.[11]Physical harm may result from unnecessary follow-up tests (e.g., biopsies) following the detection of false-positive results (detection of a cancer in error) or from unnecessary treatment due to overdiagnosis (detection of cancer through screening that would not have caused symptoms or death).[11] Most estimates of incidence rates for overdiagnosis in screening mammography range from 19%-31%.[2,5,12-20] Women may also experience psychological harm, such as stress or anxiety,[21] and financial strain might stem from unexpected costs of follow-up tests, loss of income, and concerns about future possible costs.[11,22- 24]Finally, women may experience opportunity costs by having to forgo activities (e.g., self-care, leisure, professional) for further testing, treatment, or symptom management. [11] Differing guidelines and tradeoffs between the benefits and harms of screening may affect women's ability to make informed decisions about whether or not to undergo screening, when to initiate screening, and screening frequency.[2,5,25] Women from underserved populations (e.g., racial/ethnic minority, low socioeconomic status [SES]) and those with low health literacy are at greater risk of misunderstanding screening guidelines,[11-14] and are more likely to experience disparities in screening mammography and breast cancer incidence and mortality. [26-34]

Little is known about the best ways of communicating information about the benefits and harms of breast cancer screening mammography to racially/ethnically diverse women with varying levels of SES and health literacy. There is an urgent need for formative research to better understand these issues. Findings will inform strategies to support clinicians in communicating and individualizing discussion of the benefits and harms of screening, and will ultimately help enhance women's ability to make informed decisions about screening mammography. This is critical, as informed decision making takes into account empirical evidence and individuals' values and preferences, and is associated with better knowledge about screening guidelines and the benefits,

risks, and limitations of screening, less decisional conflict and anxiety, greater satisfaction with the decision making process or the decision, and active participation in the decision making process.[35,36]

The goal of this project is to create decision support tools for Latina, Black, and non-Latina White women under age 50 with varying levels of health literacy who are considering breast cancer screening mammography.

2.0 OBJECTIVES

To evaluate the potential for implementing the developed decision support tools with Latina, Black, and non-Latina White women in order to collect feasibility data, including acceptability, usability, and limited-efficacy, to prepare for a larger randomized controlled trial.

3.0 PATIENT SELECTION

3.1 Inclusion Criteria

1. Latina, Black, or non-Latina White woman
2. Age between 40 and 49 years old (inclusive)
3. Able to write, read, and understand English

3.2 Exclusion Criteria

1. Greater than average self-reported risk of breast cancer, defined as any of the following:
   a. Self-reported personal history of breast cancer (invasive, ductal carcinoma in situ [DCIS], or lobular carcinoma in situ [LCIS])
   b. Self-reported personal history of atypical hyperplasia
   c. Self-reported first degree family member with history of breast cancer (parent, sibling)
   d. Self-reported known underlying genetic mutation (such as BRCA1/BRCA2 gene)
   e. Self-reported prior thoracic or chest wall radiation therapy

3.3 Inclusion of Women and Minorities

Latina, Black, or non-Latina White women are eligible for this trial. Women of other races are not eligible.

4.0 REGISTRATION PROCEDURES

This study will register summary accrual statistics to the Siteman Cancer Center OnCore Database. On a quarterly basis, accrual should be grouped according to the demographic data collected. Demographic information includes gender, age, ethnicity, and race. If any piece of demographic information was not collected for those categories, choose unknown.

1. In OnCore, navigate to the PC Console for this study and enter the dates of the quarter for which you are entering accrual statistics. (These dates must be inclusive of the same year, e.g. 1/1/2020 – 3/31/2020, not 12/31/2019 – 3/31/2020.)
2. Then, enter the accrual number for any subjects who are in the same demographic groups of race, ethnicity, gender, and age group. For example, if you have accrued two white non-Hispanic males in their 50s, you will enter that demographic as an accrual group of 2. If you have also accrued an Asian female in her 40s, you will enter her as a separate accrual group (you would enter "1" for the accrual number).
3. In addition, you will enter "Research Center" in the drop-down field for "Internal Accruing Reporting Group" and "No disease" in the drop-down field for "Disease Site."

Complete instructions can be accessed in the OnCore Users' Manual:
https://cbmiapps.wustl.edu/confluence/display/OSS/6.+Summary+Accruals

5.0 STUDY PLAN

5.1 Study Design

To conduct a preliminary evaluation of the decision support tool, up to 36 women will be recruited to review the decision tool and complete questionnaires to assess informed choice, decisional conflict and confidence, and acceptability. To inform the feasibility testing, 36 women will be randomized to test randomization, measures, and recruitment.

Following this preliminary evaluation of the decision tool and feasibility testing, 198 participants will be randomized on a 1:1 basis to review the decision support tool or control condition of standard breast cancer screening education. Black, Latina, and Non-Latina White participants will be assigned to either the control or intervention condition using 4 and 2 varying block size. They will complete the pre-questionnaire, review the decision support tool/control condition, and complete the post-questionnaire.

5.2 Study Procedures

5.2.1 Recruitment and Consent

Qualtrics Online Research Panels will be used to recruit participants. Qualtrics utilizes samples from traditional, actively managed, double-opt-in market research panels. For hard-to-reach groups, Qualtrics utilizes niche panels brought about through specialized recruitment campaigns. Qualtrics leverages their partner networks to gain access to many hard-to-reach groups. Qualtrics' sample partners randomly select respondents for surveys where respondents are likely to qualify. All strategic sample partners use deduplication technology to provide the most reliable results and retain the integrity of the survey data.

Written informed consent is not required; participants will receive an information sheet, and continued participation (completion of questionnaires, review of materials) will be construed as consent.

5.2.2 Randomization

The sample will be stratified by racial/ethnic subgroups (Black, Non-White Latina, White) for randomization purposes. Participants in these subgroups will be randomized to either the intervention or control arm on a 1:1 basis using 4 and 2 varying block size. The Washington University School of Medicine research team will create the randomization table. Qualtrics will program the randomization table into the survey.

5.2.3 Participation

Measures will elicit participants' perceptions of the tool (Appendix A)/control condition (Appendix B). These measures assess acceptability and informed choice using knowledge, attitudes, intentions, priorities, and values.

Pre-tool/control condition questionnaires are:

- Sociodemographic characteristics (Appendix J)
- Knowledge of Screening Mammography Guidelines and Perceived Benefits and Harms of Screening Mammography (Appendix D)
- Decision Conflict Scale (which collects feelings of being fully informed and clear about the importance of the components for making informed decisions) (Appendix E)
- Decision Self-Efficacy (Appendix F)

Post-tool/control condition questionnaires are:

- Acceptability (Appendix G)
- Preparation for Decision Making Scale (Appendix H)
- Decision Conflict Scale
- Decision Self-Efficacy
- Knowledge of Screening Mammography Guidelines and Perceived Benefits and Harms of Screening Mammography
- Health literacy and health numeracy (Appendix I)

5.2.4 Data Scrubbing

After data collection, records will be removed from the final data set if they meet any of the following criteria as determined by members of the research team. Members of the research team will keep track of how many records were removed and for what reason(s).

Criteria for removal from the final data set:

- The participants do not meet all of the inclusion criteria; or
- The time to complete the questionnaire is less than half of the median time to complete the questionnaire across the full data set; or
- Participants do not respond to, provide nonsensical or incomprehensible answers to, or give responses in a language other than English to at least

four of the eight following knowledge questions:

- 2.12 Tell me in your own words, what is a mammogram?
- 2.24. What is meant by the term "overdetection" (also called “overdiagnosis”)? Please answer in English. If you are not sure, just guess.
- 2.26. What are some of the benefits of breast cancer screening mammograms? Please answer in English.
- 2.27. What are the risks or downsides of breast cancer screening mammograms? Please answer in English.
- 3.49. Tell me in your own words, what is a breast cancer screening mammogram? Please answer in English
- 3.61. What is meant by the term "overdetection" (also called “overdiagnosis”)? Please answer in English. If you are not sure, just guess.
- 3.63. What are some of the benefits of breast cancer screening mammograms? Please answer in English.
- 3.64. What are the risks or downsides of breast cancer screening mammograms? Please answer in English.

If a participant completes the questionnaire in less than half the median time, it is reasonable to believe that they were unable to process the decision aid(s) in sufficient detail to provide accurate responses to the questions.

Failing to adequately complete the knowledge questions (4 of which are pre-tool/control and 4 post-tool/control) limit the research team’s ability to accurately analyze the feasibility, acceptability, usability, and limited-efficacy of the tool/control.

6.0 STATISTICAL CONSIDERATIONS

Stratification will be based on racial/ethnic groups (e.g., Latina, Black, non-Latina White). For adequate power, 66 participants from each racial/ethnic group will be enrolled and randomized (198 total).

For knowledge, previous research shows that mean knowledge score is 57 out of 100.[36] Compared to usual care, decision aids increased knowledge 13 points (mean difference 13.34 out of 100; 95% CI [11.17,15.51]).[36] For decisional conflict scale (0-100), those using a decision aid were more informed by 7 points (mean difference: -7.26 of 100; 95% CI [-9.73, -4.78]), and were more clear

about their personal values by 6 points (mean difference: -6.09; 95% CI [-8.50, -3.67]).[36] Finally, fewer were passive in decision-making (risk ratio 0.66; 95% CI [0.53 to 0.81]).[36] Using a one-sided Mann-Whitney Test, a sample size of 33 provides 80% power at the 0.05 significance level (alpha) to detect a mean knowledge difference of 13 with an estimated standard deviation (SD) of 20, and to detect a mean decision conflict score difference of 6.5 with an estimated SD of 10. Additionally, using a Mantel-Haenszel test, a sample size of 33 provides 80% power at the 0.05 significance level (alpha) to detect a risk ratio of 1.66 assuming the proportion of the informed values-based choice of 0.45 and 0.75 in the control and intervention groups, respectively. Subsequently, to detect the differences between groups with 80% power and 5% Type I error, 33 participants in each control and intervention group will yield a statistically significant preliminary effect. We are making multiple comparisons and recognize that the overall Type I error rate in this study will be greater than 5%. However, this study will allow us to collect adequate data, for planning future large scale studies.

7.0 PROTECTION OF HUMAN SUBJECTS

Participation in this study does not entail any physical or medical risks that are greater than those ordinarily encountered in daily life. It is possible that the participant may feel uncomfortable completing the questionnaires. If a participant becomes upset, they may exit the study at any time.

There is also a risk of breach of confidentiality. All reasonable steps will be taken to ensure that patient privacy is maintained, including not collecting any identifiers with the research data set. Electronic data will be stored on a Washington University password-protected server and never stored on a portable hard drive or laptop computer. Data will be accessed through the Washington University School of Medicine Qualtrics portal through a university-wide site license.

7.1 Adverse Event Reporting

Participation in this study entails the completion of questionnaires and review of educational materials. We expect that the occurrence of a serious adverse event as it relates to these study interventions to be extremely rare. If a breach of confidentiality were to occur, it would be reported to QASMC and HRPO within 10 days of notification.

7.2 Data and Safety Monitoring Plan

The study principal investigator and study coordinator will monitor for breaches of confidentiality and other adverse events on an ongoing basis. Once the PI or study coordinator becomes aware of a reportable adverse event, the event will be reported to HRPO and QASMC according to institutional guidelines. This study does not require QASMC audit or submission of DSM reports.

7.3 Remuneration

Participants will be compensated through Qualtrics for being a research participant.

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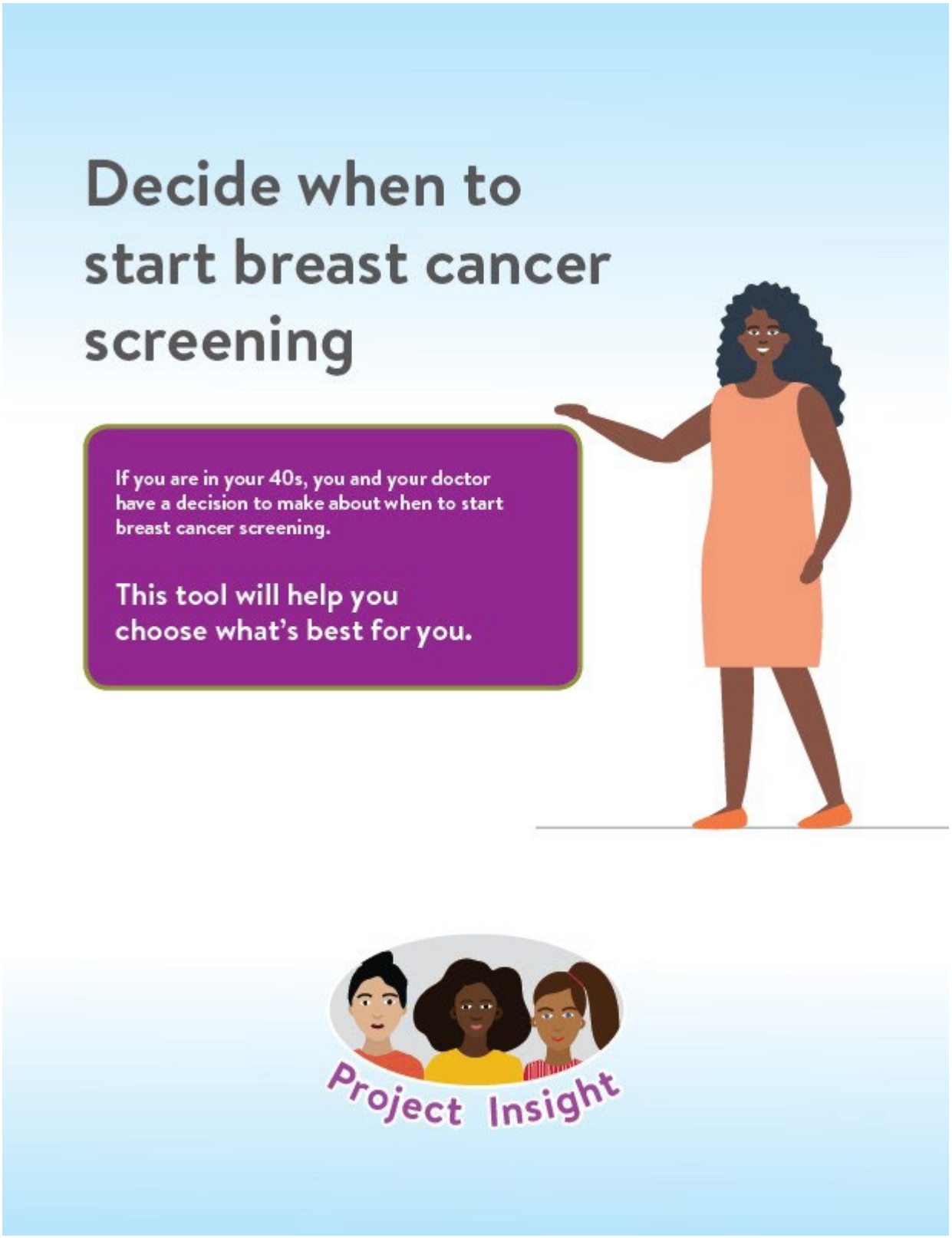
APPENDIX A: Project Insight Decision Tool



Here's what you'll learn in this tool:

Is this tool for me?

This tool is for women who are at average risk for breast cancer. You are considered at average risk for breast cancer if you have:

- ☐ Never had breast cancer before
- ☐ Never been told you have a high-risk lump after having a **biopsy** (a doctor takes out part of your breast tissue to look at it under a microscope to test for breast cancer)
- ☐ Never had radiation treatment to your breast before age 30
- ☐ No family history of your mother, sister, or daughter having breast cancer before age 50
- ☐ Never been told you or your family have a **mutation** (change) in BRCA breast cancer genes

If you didn't check all of the boxes above, or are unsure if you're at average risk, talk with your doctor about breast cancer screening.

The goal of breast cancer screening is to find breast cancer before you have signs or symptoms. When doctors find breast cancer early, it may be easier to treat or cure and can lower your chance of dying.

What test is used for breast cancer screening?

A **mammogram** is the most common screening test for breast cancer. It's an x-ray that takes a picture of the inside of your breast. Mammograms help find breast cancer early, but they do not prevent breast cancer.

During a mammogram:

1. You will place one breast at a time between 2 plastic plates in a machine.
2. The plates will press together to flatten your breast and take pictures. Some women may find this uncomfortable.
3. An expert will look at the pictures.
4. If they see something that may be cancer, you may need more testing. The only way to know if you have breast cancer is a biopsy.

What about other breast exams?

Other breast exams are not a substitute for mammograms.
A **self-breast exam** (examining your breasts on your own by looking and feeling for changes) and a **clinical breast exam** (a doctor or nurse uses their hands to feel for lumps) have not been found to lower the chance of dying from breast cancer. It is important to notice changes in your breasts, and talk about any changes with your doctor.

When do women start screening?

Experts recommend that all women at average risk for breast cancer have a mammogram every 1-2 years until they are 74 years old. Every woman can talk to her doctor to decide how often and at what age to start having mammograms: when they are in their 40s or when they reach age 50.

The guideline comes from a group of experts in the U.S. who make recommendations based on the best information we have for the whole U.S. population.

Keep in mind, this is a guideline for all women at average risk. You and your doctor can decide together when you should start breast cancer screening.

You and your doctor can decide together

You can decide to start screening at any time in your 40s or at age 50. This is a personal decision.

Some women decide to start breast cancer screening in their 40s because they feel the possible benefits are more important to them than the possible downsides.

Other women decide to wait until age 50 because they are more worried about the possible downsides of screening in their 40s.

Women feel different ways about screening

When we made this tool, we asked women ages 40-49 for their thoughts. We've restated their thoughts here.

I have visited my doctor, but we haven't talked about when to start screening. Now, I'm going to ask.

I have always wondered about the recommendation. Do they have enough diversity of participants? Are they focused on women's health? Would my doctor make the same recommendation to me? I guess that is why I want to talk to my doctor about this.

Possible benefits and downsides of starting screening in your 40s

To estimate the chance of possible benefits and downsides, we compared 1,000 women who started screening every other year at age 50 to 1,000 women who started screening every other year at age 40. Women who started in their 40s had:

- A slightly greater chance of finding and surviving breast cancer
- A slightly greater chance of downsides

	Started screening in their 40s (out of 1,000 women)	Started screening at age 50 (out of 1,000 women)		Difference between starting in 40s vs. age 50
Benefits				
Number of women **diagnosed with breast cancer**	154 women (about 15%)	151 women (about 15%)	this means →	Find and diagnose breast cancer in **3 more women**
Number of women who **avoid death** from breast cancer	8 women (less than 1%)	7 women (less than 1%)	this means →	Save **1 more woman** from dying of breast cancer
Downsides				
False alarms (a woman can have more than one)	1,529	953	this means →	Find **576 more false alarms**
Women with **overdetection**	21 women (about 2%)	19 women (about 2%)	this means →	Overdetect **2 more cases of breast cancer**
Biopsies that find **no cancer**	213 women (about 21%)	146 women (about 15%)	this means →	Have **67 more biopsies** that find no cancer

This data is from the Agency For Healthcare Research and Quality (AHRQ, September 2017)

Learn more about the possible downsides:

False alarm: a screening suggests a woman has breast cancer when she does not. It can lead to more, unneeded testing, such as biopsies.

Overdetection (overdiagnosis): a screening that finds breast cancer that would not have caused symptoms or harm. It can lead to unneeded treatment, called **overtreatment**. Women do not benefit from overtreatment.

Women's thoughts about the possible benefits

Early detection is very important to me, even if there is just a small benefit to my health. Mammograms are something I'm used to, they're routine. I don't want to be someone who says 'I have something and I didn't do anything', so it's very, very important to me.

For me, I think about my health. And, well, my whole family. They're the people who depend on me.

Women's thoughts about the possible downsides

I always seem to get abnormal results so I would expect follow-up tests. But, I would be upset about the time and cost to go back in because that's a whole lot of extra that I didn't have to deal with.

When I heard the word abnormal and that they needed to do more testing, I thought it must be cancer and I thought the worst. What if something happens to me? They told me not to be afraid but I was really stressed and worried.

Women's thoughts about making the decision

It's good to be informed about the benefits and harms of breast cancer screening so that you know what to ask. Sometimes when you get to the doctor, it's hard to remember stuff.

I now understand why the doctor told me I could wait. I asked her why and she said we can talk about when the best time is for me to have a mammogram. She knows me and the guideline. I wanted to make the choice with her.

Questions to help you decide

Questions to ask yourself

- **How important is lowering my chance of dying from breast cancer as much as possible, even if it's just a small amount lower?**

not very important	a little important	somewhat important	very important
O	O	O	O

If you answered "somewhat important" or "very important", you may care more about the possible benefits of screening than the possible downsides.

- **How would I feel about having:**
  - A false alarm?

not very worried	a little worried	somewhat worried	very worried
O	O	O	O

  - A biopsy or other tests if my mammogram suggests I may have breast cancer?

not very worried	a little worried	somewhat worried	very worried
O	O	O	O

  - Treatment for breast cancer that would never cause me harm (overtreatment)?

not very worried	a little worried	somewhat worried	very worried
O	O	O	O

  - To pay for extra tests if insurance didn't cover them?

not very worried	a little worried	somewhat worried	very worried
O	O	O	O

If you answered "somewhat worried" or "very worried" to most of the questions above, you may care more about the possible downsides of screening than the possible benefits.

More questions to ask yourself

- If I make the decision to be screened and the results show I have breast cancer, how would I feel about the decision I made to be screened?

- What would I do with the results of my breast cancer screening?

- How might my results change the way I feel or my views about other things in my life?

- What do my family or loved ones think about me starting breast cancer screening in my 40s vs. age 50?

Questions to ask your doctor

- **What is my risk for breast cancer?**

- **Knowing what I told you about myself and my history, can we talk about when I should start breast cancer screening?**

- **Does my insurance cover the cost of breast cancer screening?**
  Most insurance plans cover mammograms every 1 to 2 years at no cost to you, starting at age 40.

- **If I need follow-up testing after breast cancer screening, does my insurance cover the cost?**

- **What can I do to help prevent breast cancer?**

Talk to your doctor about how to prevent cancer by:

Keeping a healthy weight

Being active

Eating healthy fruits and vegetables

Not smoking

My decision

On _____ (date), I am leaning toward the decision that:

(check one)

- ☐ Screening in my 40s is right for me. I'll start at age ____ .
- ☐ Screening starting at age 50 is right for me
- ☐ I am unsure about screening

Keep in mind, this is not a one-time decision. You can talk to your doctor many times and change your decision.

Learn more about breast cancer screening

National Cancer Institute: www.cancer.gov/types/breast/patient/breast-screening-pdq

Centers for Disease Control: www.cdc.gov/cancer/breast/basic_info/screening.htm

Learn about options for a free or low-cost mammogram

https://nccd.cdc.gov/dcpc_Programs/index.aspx#/results/1/36

This work was supported through the National Institute on Minority Health and Health Disparities (R00MD011485) and the Agency for Healthcare Research and Quality.

APPENDIX B: NCI Breast Cancer Screening – Patient Version (Control Condition)

Located at: https://www.cancer.gov/types/breast/patient/breast-screening-pdq

APPENDIX C: Measures

Questionnaires including screening questionnaires and measures, have been removed from this protocol and provided to PRMC as a separate document with track changes