Protocol #: 20-1866
Project Title: Understanding Affective Processing of Scientific Evidence to Promote Informed Choice for Breast Cancer Screening
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I. Hypotheses and Specific Aims:

Cancer screening for the right patients at the right level of cancer risk can save lives. However, over the last several years most expert groups have de-intensified many screening recommendations as a result of emerging evidence of net harms for certain populations. Newer recommendations for mammography screening highlight a tailored approach based on age and risk and comorbidities, aiming to minimize harms and target women who could benefit the most.[1] Although there is still widespread disagreement about when and how frequently certain populations of women should receive breast screening, one point of agreement is that women should make an informed choice with their doctor about when to start, when to stop, and how frequently to screen.[2–4]

However, the change in emphasis from uniformly promoting mammography to promoting informed choice constitutes a medical reversal in the sense that this new message is very different from past messages and people's expectations.[1,5–7] The result is a delicate situation in which there is need to convey the evidence to women, but also a need to do it in a way that maintains credibility and trust despite this reversal. Research suggests that many women react negatively to mammography evidence, responding with **R**eactance (e.g., "this is trying to manipulate me", "this is trying to ration healthcare"), self-**E**xemption (e.g., "this doesn't apply to me"), **D**isbelief (e.g., "you can't believe all the research"), or **S**ource derogation (e.g., "I don't trust this source"),[6,8,9] which we refer to together as **REDS**. These responses reflect different ways of rejecting of the evidence, stand in the way of informed choice, and could lead to distrust in future screening health messages.

AIM 1: Identify the prevalence and predictors of REDS in reaction to evidence about mammography benefits and harms, and consequences for decision-making and trust. Research has not yet systematically identified the proportion of women who respond negatively (vs. positively) to mammography evidence, or attempted to explain these responses by examining theory-driven predictors. We will develop and conduct a probability-based nationally representative survey in which we communicate mammography evidence using the current best practices in risk communication, and identify theory-driven predictors of REDS responses, and identify consequences of these responses for decision-making and trust.

II. Background and Significance:

A1. Screening recommendations have changed considerably over recent years.

Breast cancer is the second leading cause of cancer death among women in the U.S., and early detection can result in a cure before it spreads. For many years mammography was strongly promoted, with the aim of maximizing screening uptake.[10–12] However, mammography guidelines have changed considerably as a result of accumulating evidence showing that screening has less benefit for some populations of women, and can cause harm.[13–15] Harms include false positive results requiring follow-up tests and biopsies, and overdiagnosis—the diagnosis of asymptomatic cancer that will not cause symptoms or harm in a person's lifetime—and resultant overtreatment.[16–18] Although routine mammography is still strongly recommended for women in specific age ranges

and with certain risk factors, many expert groups, including the United States Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS), have de-intensified screening recommendations and expanded the role of informed choice.[2,4] Most guidelines now emphasize that women should receive balanced information about the benefits and harms of mammography so that they can engaged in shared decision making (SDM) and make an informed choice with their doctor about when to start, when to stop, and how frequently to screen.[19]

A2. A balanced presentation of both screening benefits and harms is very different from previous unequivocal recommendations to screen, and can strongly contradict women's preexisting beliefs. Controversies about breast cancer screening continues to receive attention in the news media but many women are still unaware of the evidence.[20,21] Most women greatly overestimate their lifetime breast cancer risk,[22] and overestimate their risk even after they have been counseled on their objective risk.[23] A recent systematic review found that in 8 of 9 studies reviewed, a majority (i.e. >50%) of women overestimated the benefit of mammography.[24] Most people (women and men) have little or no prior knowledge of harm from overdiagnosis, which is a counterintuitive concept that contradicts common beliefs about how cancer grows and spreads.[5,25–28] In a 2016 survey, only 16% of women were aware of overdiagnosis as a harm of mammography.[6] Screening is rarely discussed in clinical encounters in a balanced way; for example, in one survey only 19% of women reported that their provider had discussed the harms of screening in addition to the benefits.[29] The public is also very enthusiastic about cancer screening.[10,30,31] For example, in a recent study we found that 43% of women and men expressed a desire for breast/prostate cancer screening even if it would not reduce the chance of cancer death or extend the length of life.[30]

A3. Mammography evidence and revised guidelines can be emotionally charged. "*It feels like just when it became okay to talk about breasts and screening, and we convinced insurance to pay for it, and we started getting it to low income women, now we're told that it's maybe not that great and it should be a choice. How are we supposed to believe that?*" (personal communication with PI Scherer). Given that many women overestimate their breast cancer risk and the benefits of screening, are unaware of the harms of screening, and are very enthusiastic about screening, it should come as no surprise that mammography evidence and the recommendation for informed choice can elicit negative reactions. Qualitative research has shown that some women are suspicious and resistant to screening evidence, particularly the notion of overdiagnosis.[32] In a 2016 U.S. survey less than 1-in-4 women thought both overdiagnosis and overtreatment were "believable".[6] The notion of risk-based screening—that is, creating a screening plan tailored to a woman's objective cancer risk—is concerning for some women, and can raise suspicions of healthcare rationing.[20] In a recent study, women rated a leaflet that described the balance of benefits and harms as less helpful than one that promoted only the benefits, which the authors interpreted as potentially indicating a reluctance to accept information about harms.[33] In recent focus groups involving 42 U.S. adults, participants placed enormous value on cancer screening and expressed hostility toward guidelines suggesting doing less screening.[34] Recently we conducted 16 patient interviews in anticipation of this proposal in which we showed women a breast cancer screening decision support tool[35] and asked how they felt about the benefits and harms presented. Here is how one woman responded to the idea of harm from overdiagnosis: ***"I think this might give people a false sense of security. Like it's giving them permission to not do screening. So I don't think that this is reassuring, and I don't think it accurately represents the actual risk. This whole thing kinda makes me mad. I find it very frustrating because it, it feels like…it feels like propaganda."***

Altogether, the weight of the evidence suggests that communicating mammography screening evidence can elicit negative reactions. The types of negative reactions that we are particularly concerned about include **Reactance** (i.e. perceived manipulation or influence, e.g. "this is trying to ration healthcare"), **self-Exemption** (e.g., "this doesn't apply to me"), **Disbelief** (e.g., "you can't believe all the research anyway"), and **Source derogation** (e.g., "I don't trust this source"), which we shorten to **REDS**.[8,9] These responses are sometimes referred to collectively as "defensive coping",[36] although we prefer "REDS" to refer directly to the four types of responses. To date, no research has examined REDS systematically to assess their prevalence and causes in the context of communicating mammography screening evidence. And even though many women

react negatively to screening information, many women also want to be informed and be able to make a choice.[37] The result is a delicate situation in which there is need to convey the evidence to women, but also a need to do it in a way that maintains credibility and trust.

III. Preliminary Studies/Progress Report:

IV. Research Methods

A. Outcome Measure(s):

The primary outcome measures in this survey are REDS responses and screening intentions. See Table 1 below for all survey measures. [35,55,56,61,66,72,96–99]

	Measure description	Source
Primary DVs	REDS responses	See appendix
	Screening intentions	Schapira et al. 2019
Secondary DVs	Change in trust in provider and healthcare system, pre vs. post BCS-DA	Egede et al. 2008
	Positive responses, e.g. appreciation of information	Ad hoc
	Change in screening knowledge, pre vs. post BCS-DA	Schapira et al. 2019
IVs: primary	Breast cancer risk perceptions: affective, deliberative, experiential	Ferrer et al. 2016
	Perception of net screening benefit (benefits minus harms) at pre-test	Scherer et al., 2018
	Objective breast cancer risk	Schapira et al. 2019
	Cognitive responses to information	See appendix
	Medical Maximizing-Minimizing orientation	Scherer et al., 2016
	Perceived norms	Hersch et al., 2015
	Past screening experience	Petrova et al., 2015
Secondary IVs and control variables	Perceived barriers to screening	Hyman & Baker 1992
	Friends/family experience with breast cancer	Petrova et al., 2015
	Subjective numeracy	Fagerlin et al., 2007
	Health literacy	Chew et al., 2008
	Demographics	Standard questions

Table 1. Aim 1 measures.

B. Description of Population to be Enrolled:

Inclusion:

- Female
- Between 39-49 years of age
- No history of breast cancer
- No known BRCA1/2 mutation

Exclusion:

- Non-English or Spanish Speaking
- Persons unable to provide informed consent (e.g. severe dementia or cognitive disability or illiterate)
- History of breast cancer
- Known BRCA1/2 mutation

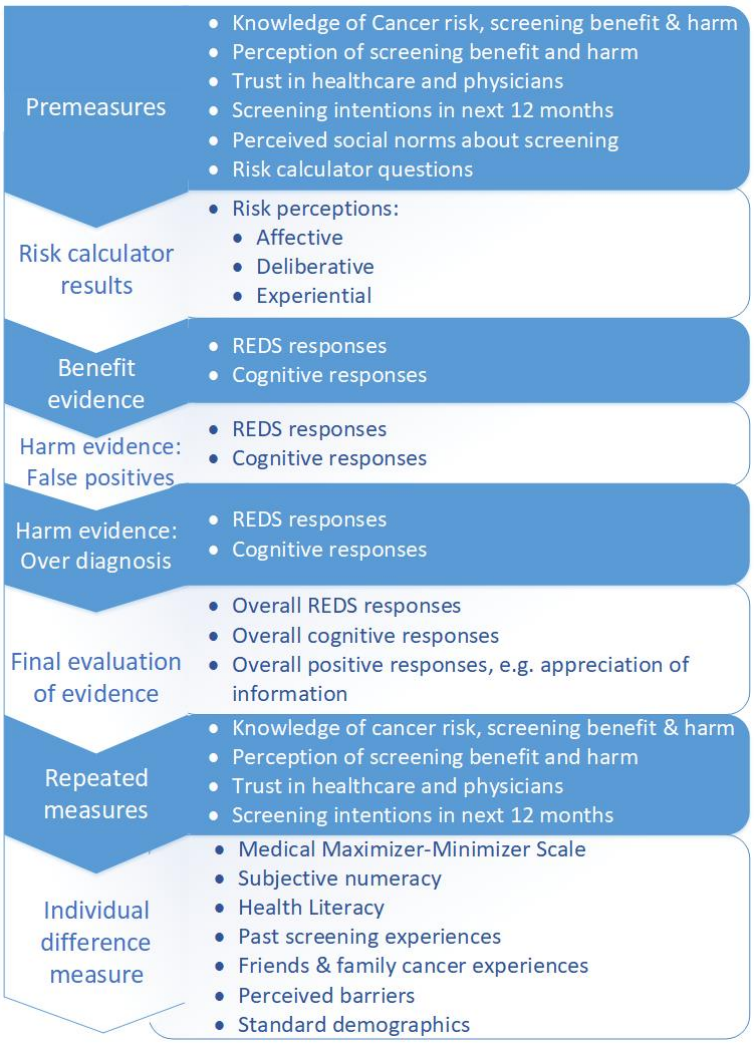
Pilot Survey: We will pilot test questions to measure REDS and cognitive reactions to assess item variability, internal consistency, and reduce the total number of items. We will recruit 700 women through Dynata. Dynata manages an online participant panel of millions of adults across the United States. Participants who are part of Dynata's panel have agreed to participate in surveys in exchange entry into lotteries for small cash prizes.

Pilot Interviews: We will recruit up to 15 women from Carmen Lewis's Internal Medicine clinic at UCHealth. These interviews will focus on assessing overall knowledge and understanding of the information presented in the decision aid. Participants will receive a $25 gift card for participating in the interview.

Nationally Representative Survey: We will recruit 700 women age 40-49 through Ipsos Public Affairs. Ipsos manages an online participant panel allowing population inferences using probability sampling methods and providing Internet access to households that do not have it.

Nationally Representative Interviews: We will recruit up to 40 women from the Ipsos survey who agreed to be contact for a follow-up phone interview. We will specifically recruit women who expressed negative reactions to mammography evidence, so that we can assess how to improve the BCS-DA using insights from those who were negatively affected. We will attempt to recruit at least 25% non-White participants for these interviews.

C. Study Design and Research Methods



The survey flow is displayed in the figure below and will unfold as follows: First, women will be asked premeasure questions displayed in the figure below. Second, women will learn their objective cancer risk estimate, and will report their affective, deliberative and experiential risk perceptions.[56] Third, women will react separately to the three distinct components of mammography evidence (benefits, false positives, overdiagnosis). The purpose of assessing reactions to each component of the evidence is to identify how positively or negatively each part is received. We anticipate that overdiagnosis may be received most negatively. Measured reactions will include REDS responses, and cognitive reactions as previously described (i.e. whether the information is compatible or not with other knowledge). Finally, after all of the information has been presented, women will provide overall reactions to the evidence using the same measures. Next women will report overall positive responses, e.g., the extent to which they appreciated receiving the information, felt empowered by it, and

want to talk to their provider about it. Lastly, women will repeat some of the pre-measures (e.g. knowledge, trust) and report demographics and individual differences.

Pilot Survey: Recruitment and survey distribution with be done by Dynata. All data will be collected electronically using Qualtrics.

Nationally Representation Survey: Recruitment and survey distribution with be done by Ipsos. All data will be collected electronically using Qualtrics.

All Interviews: Patients will be invited to schedule a phone call for the interview (using a regular phone or using Zoom), and audio will be recorded and transcribed.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Benefit from participating in the research cannot be claimed. Women will learn about mammography benefit and harm, which may lead to more informed screening decisions. Learning how to help communicate more effectively about counterintuitive and surprising medical evidence is an area in great need of attention. The intervention is designed to improve communication and decision quality and enhance the overall decision making. Given that the risks are minimal and the benefits great (to both patients, clinicians, and society as a whole) we believe that the benefits of the proposed project outweigh any risks.

E. Potential Scientific Problems:

The length of the survey may be an issue since we are recruiting through Ipsos.

There is a possibility that not a sufficient amount of subjects with voluntarily self-identify for the follow-up interviews.

F. Data Analysis Plan:

Pilot Survey: We will check the variability of each questionnaire item to assess suitability for exploratory factor analysis. Exploratory factor analysis will be used to identify the factor structure of the REDS items. Items that do not load onto any factor will be dropped. Reliability of the remaining items

Nationally Representative Survey: Summary statistics will estimate the prevalence of REDS to each part of the BCS-DA. Simple within-subjects tests (e.g. ANOVA) will compare REDS in response to screening benefits, false positives, and overdiagnosis.

All Interviews: We will conduct exploratory content analysis of these qualitative interviews using the analytic program Dedoose to extract themes in patients' reactions to the presented information.

Safety Oversight:

The principal investigator will be responsible for the conduct of this study, overseeing participant safety, executing the data and safety monitoring (DSM) plan, and complying with all reporting requirements to local and federal authorities. This oversight will be accomplished through additional oversight from the Data and Safety Monitoring Committee (DSMC) at the University of Colorado Cancer Center (CU Cancer Center). The DSMC is responsible for ensuring data quality and study participant safety for all trials at the CU Cancer Center. A summary of the DSMC's relevant activities is as follows:

- Conduct of internal audits

• Has the authority to suspend studies for safety or conduct issues
• May submit recommendations for corrective actions to the CU Cancer Center's Executive Committee

Study audits conducted by the DSMC will consist of a review of the regulatory documents, consent forms, and source data verification. Documentation of the audit conducted by the DSMC will then need to be submitted to the IRB of record at the time of the IRB's continuing review of this trial (if applicable).

G. Summarize Knowledge to be Gained:

Our preliminary data suggest that there are important problems with current approaches to communicating screening evidence. The proposed studies are designed to generate knowledge that will lead to improved communication strategies and real-world improvements in informed patient choice. Because virtually little work has systematically studied this issue, a deeper understanding of how women respond to screening evidence will have widespread clinical applicability.

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