

Longitudinal Study of the Influence of False-Positive Mammography Results on Psychological Outcomes and Subsequent Screening Behavior

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ABSTRACT

JESSICA T. DEFRANK: Longitudinal Study of the Influence of False-Positive Mammography Results on Psychological Outcomes and Subsequent Screening Behavior

(Under the direction of Noel Brewer, PhD)

If screened regularly, over one-half of U.S. women will have abnormal mammography results that require additional follow-up but in which cancer is not detected (false-positive result). This dissertation presents and tests a model, informed by theoretical and empirical evidence, of the relationship between receipt of false-positive mammography results and adherence to subsequent mammography screening. To test study hypotheses, I analyzed longitudinal data ($n=2406$), gathered through medical claims records and telephone interviews, as part of the PRISM (Personally Relevant Information on Screening Mammography) intervention trial to increase repeat mammography adherence among insured North Carolina women. About 8% of women received false-positive mammography results within 14 months of their interviews. Among women who said their physicians had not advised them to get mammograms in the past year, those who received false-positive results were more likely to have no subsequent mammogram on record compared to women whose results were normal (18% vs. 7%, $OR=3.17$, 95% $CI=1.30,7.71$). However, among women who reported physician recommendations, receipt of false-positive results was not associated with adherence to subsequent

screening. Receipt of false-positive results was associated with greater breast cancer worry ($p < .001$), the belief that mammography test results were less accurate ($p = .003$), and thinking more about the benefits of regular screening ($p < .001$), regardless of physician recommendations. In mediation analyses, none of these variables explained the association between false-positive test results and subsequent screening behavior. Findings suggest that women who receive false-positive mammography results, coupled with lack of physician recommendations for screening, are at risk for non-adherence to future screening. Abnormal mammograms that do not result in a cancer diagnosis are opportunities for physicians to emphasize the importance of regular screening. Findings provided only partial support for the proposed model, perhaps due to characteristics of the PRISM study design, where all women received annual reminders for their mammograms and received mammograms prior to study enrollment.

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CHAPTER 1: A MODEL OF THE INFLUENCE OF FALSE-POSITIVE MAMMOGRAPHY RESULTS ON SUBSEQUENT SCREENING

Inherent in any screening exam is the possibility for false-positive test results. Given ongoing efforts to increase regular use of medical screening, the growing number of screening tests becoming available to patients, and emergence of new technologies that improve existing tests' sensitivity for detecting disease while increasing false alarms¹ false-positive results are becoming ever more common. They present a significant public health concern because of their demonstrated impact on well-being and behavior.^{2,38} While decades of empirical research have investigated psychosocial consequences of false-positive mammogram results,^{2-7,38} a theoretically-informed understanding of how they influence return for breast cancer screening is lacking. The purpose of this chapter is to present a model of how false-positive mammography results influence subsequent mammography screening. While this model may be applicable to other types of false-positive test results, I focus on the example of screening mammography because false-positive results on screening mammography exams are a common experience,⁸ and the preponderance of research on psychological and behavioral effects of false-positives comes from the mammography literature.

Breast cancer is the most commonly diagnosed non-skin cancer among U.S. women with an estimated 194,000 new breast cancer cases in 2009 and 40,000

deaths.⁹ Mammography is the single most effective method of detecting breast cancer early, and results of numerous studies show it reduces breast cancer morbidity and mortality.¹⁰⁻¹² Despite these benefits, false-positive mammography results are common⁸ and can have lasting effects on women.²

For the purpose of this dissertation, I define a false-positive as an abnormal mammogram requiring any form of further follow-up in women not found to have breast cancer within the next year. This broad definition of false-positives is consistent with current behavioral research.² Between 6% and 15% of screening mammograms in the U.S. are abnormal; most of these are false-positives.¹³⁻¹⁵ About one-half of U.S. women aged 40-75 can expect to have a false-positive mammogram result if screened biennially over 10 years,⁸ and this rate should increase with annual mammography use. U.S. rates of abnormal, and thus false-positive mammograms, are higher than those of any other country that promotes regular breast cancer screening, yet U.S. women die from breast cancer at rates similar to those of other countries.¹⁶

In the absence of clear benefit from so many false-positive mammography results, the question of harms becomes more pressing. Consequences of false-positive mammograms include substantial financial costs associated with follow-up testing, estimated to be over \$100 million annually in the U.S. alone.¹⁷ Two recent meta-analyses showed that false-positive results can affect women's well-being and future screening behavior.^{2,38} Findings from meta-analyses also offer potential insight into what a plausible theory might look like. The theory must account for psychological processes that increase likelihood of return for screening after a false-

positive experience, as typically found for U.S. studies. The model would also have to account for psychological processes that have the opposite effect on return for screening, as typically found for European and Canadian mammography studies. Although several system-level factors offer potential explanations for conflicting geographical findings, this model focuses on psychological reactions that motivate or interfere with subsequent screening and is not intended to explain geographical differences in return for screening rates.

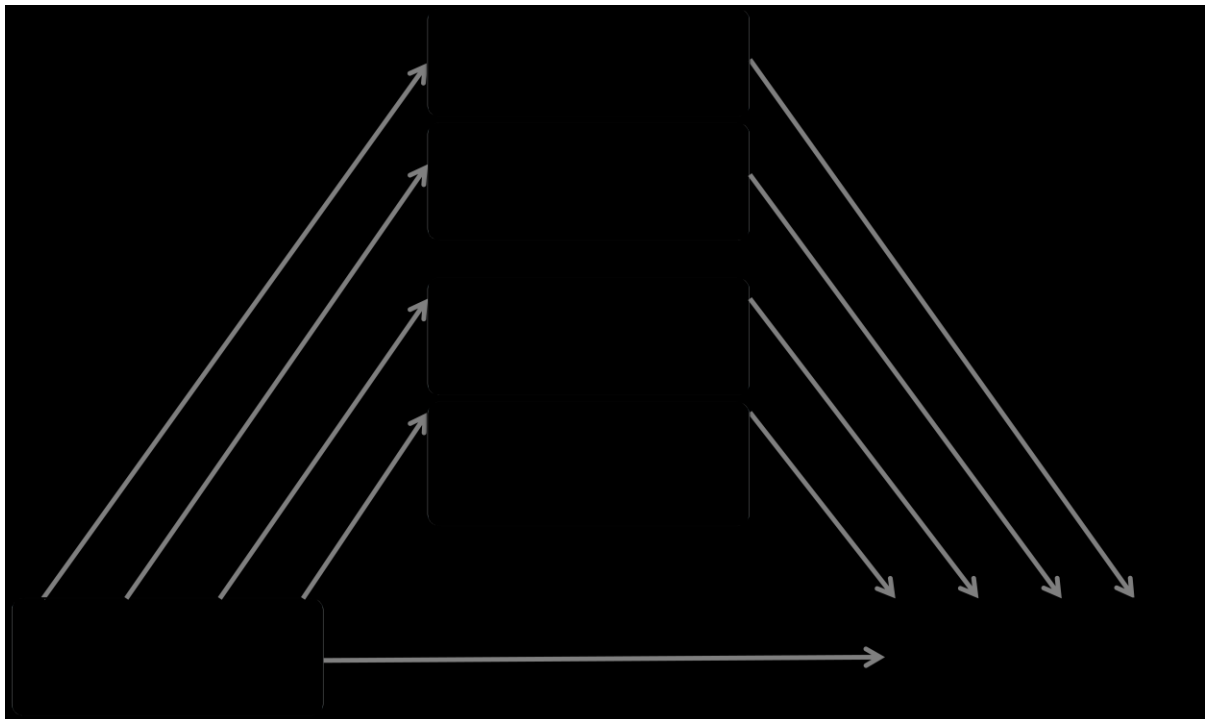
This chapter first briefly introduces a theoretical model of the relationship between receipt of false-positive mammography results and adherence to subsequent mammography screening. The chapter then presents empirical and theoretical support for the main pathways of the model and derives novel predictions. I also discuss methodological considerations for statistically testing models clarifying the relationship between false-positive test results and behavior.

Overview of Theoretical Model

I propose that false-positive mammography results cause women to think differently about themselves and the screening test. I hypothesize that false-positive mammography results cause women to have elevated breast cancer-related worry, anxiety and perceptions of being more likely to get breast cancer in the future. These beliefs, in turn, motivate vigilance about future mammography screening. I also hypothesize that women may experience positive consequences after receipt of false-positive results, such as thinking more about the benefits of regular screening. Increased thought about the benefits of mammography should make women more likely to adhere to future screening. False-positive results may also cause women to

think differently about the accuracy of mammography screening, which in turn could deter them from returning for routine screening exams. Thus, the proposed model suggests that women's thoughts about themselves and screening should mediate the relationship between receipt of false-positive mammography results and return for subsequent mammography screening.

Figure 1: Model of effects of false-positive mammography results



Influence of False-Positive Mammography Results on Return for Subsequent Screening

Empirical studies show that false-positive results of screening tests influence health behaviors. Most evidence for this relationship comes from the breast cancer screening literature, but false-positive test results also affect return for prostate,¹⁸ lung,¹⁹ and cervical cancer screening.²⁰ Brewer and colleagues meta-analyses of

over 300,000 women from the U.S., Canada and Europe examined the effect of false-positive screening results on return for routine mammograms.² Findings differed by geographic region. In the United States (5 studies), women who received false-positive results were slightly (7%) more likely to return for subsequent screening mammograms compared to women who had normal mammogram results. The largest of these studies that included over 40,000 women enrolled with the Vermont Mammography Registry found 63% of women with previous false-positive results returned for a subsequent, on-schedule screening, whereas 57% of women who had previous mammograms that were normal returned for subsequent, on-schedule screening ($OR=1.29$; 95% $CI=1.20,1.38$).²¹ Although the effect size was small, this difference remained statistically significant after control for sociodemographic and medical variables. In contrast, studies conducted in European countries (5 studies) generally found no effect of false-positive mammograms on return for screening, though fixed effects statistical analysis of the data suggested a small reduction in return for screening with false-positive results.²² Studies conducted in Canada (2 studies) also found that women who received false-positive results were less likely to return for subsequent screening. Studies published after the meta-analysis generally confirm these findings.²³⁻²⁵

False-Positive Mammograms and Women's Thoughts about Themselves

Early studies assessing psychological effects of receiving abnormal mammograms generally found that large proportions of women experienced moderate increases in anxiety, distress, and intrusive thoughts in the short-term period immediately after receipt of test results. Extreme or clinically pathological

levels of anxiety were rare.^{4, 5} More recent research, both in the U.S. and abroad, has focused on the long-term effects of false-positive mammography results - commonly defined as being at least a month after doctors determine that the abnormal mammogram does not indicate cancer. Meta-analyses by Salz and colleagues' concluded that false-positives had a moderate but consistent effect on anxiety and worry about breast cancer that persisted months and even years beyond receipt of false-positive results.³⁸ They also showed that women who received false-positive test results perceived themselves to have a higher likelihood of getting breast cancer compared to women whose results were normal.³⁸

Breast cancer worry and anxiety

False positive test results, worry and anxiety: Worry is defined for purposes of this research as ruminative thinking about a negative or potentially dangerous event. Researchers also describe worry as being a combination of “unwanted cognitive activity” and emotion.²⁶ Although some use the terms worry and anxiety interchangeably, anxiety is a distinct phenomenon characterized by intense and uncontrollable emotional and physiological responses to a perceived threat.²⁶ Thus, worry and anxiety both are characterized by negative cognitive and emotional reactions, with worry having a more deliberative cognitive quality and anxiety a less voluntary and more emotional quality. While worry and anxiety may be conceptually separable, their associations with false-positive mammogram results are similar, and thus I discuss them together here.

Worry after false-positive mammography results can take many forms. Women might worry about getting future mammograms and the uncertainty of a

cancer diagnosis.²⁷ They might also worry about potential consequences of having cancer, such as progressively debilitating illness or death, side-effects of cancer treatment, and the impact of a cancer diagnosis on one's family, job, finances or quality of life.^{28, 29} The systematic review by Brewer and colleagues found many studies where false-positive mammograms caused worry about breast cancer that endured long after cancer had been ruled out.² Studies by Lerman and colleagues,^{27, 30} among the earliest to investigate long-term effects of false-positive mammograms, showed higher levels of worry for women who received false-positive test results compared to those who received normal test results 3 months after the screening exam. Aro and colleagues followed women prospectively and found moderately-elevated worry for women who had false-positive mammography results compared to those who had normal test results both at 2 and 12-months.³¹ A study in the United Kingdom, where routine screening is recommended every 3 years, found that women who received previous false-positive results continued to experience psychological distress in the month prior to their next routine screening exam.³²

Association between false-positive mammography results and breast cancer-specific anxiety are similar to those for worry.^{27, 33-35} For example, Gram and colleagues found 29% of women who had false-positive mammography results reported breast cancer-related anxiety 18 months after screening compared to 13% of women who had normal results.³³ However, many studies relying on generalized measures of anxiety (such as the Hospital Anxiety and Depression Scale) have not demonstrated long-term effects for women who received false-positive mammography results.³⁴⁻³⁶ These findings suggest that the anxiety experienced

after false-positive results is breast cancer-specific rather than general.^{37, 38} The breadth of generalized anxiety measures may prevent them from detecting important and breast-cancer-specific reactions to false-positive mammograms.³⁹

Consequences of worry and anxiety: While worry and anxiety elicit negative thoughts, their influence on behavior is not necessarily deleterious. Although not formally embedded in commonly used models of health behavior,⁴⁴ the motivating influence of worry parallels constructs in theories about the relationship between emotion and protective behavior⁴⁵ and also models of stress and coping where emotional responses are proposed to motivate problem-focused coping.⁴⁶ That is, theory suggests that non-pathological levels of worry and anxiety should motivate protective health behaviors.

Studies also suggest that worry and anxiety are strong motivators of many protective health behaviors, including condom use⁴⁰ and smoking cessation.⁴¹ Worry and anxiety about breast cancer motivates breast cancer screening in the general population^{28, 42} as well as in women who received false-positive mammography results. Lerman and colleagues showed that worry caused by false-positive mammograms had a positive, linear relationship with return for screening.²⁷ That is, higher worry about breast cancer after a false-positive experience was associated with a greater likelihood of return for women's next screening mammograms. The authors speculated that women might seek to resolve their feelings of worry through heightened vigilance about breast screening. While it is plausible that worry after false-positive test results could deter future screening,^{3, 28} or might have a curvilinear

relationship with screening,⁴³ the research literature does not offer much support for these predictions.

Perceived likelihood of disease

False-positive test results and perceived likelihood of disease: Perceived likelihood of disease, sometimes referred to as perceived susceptibility or perceived vulnerability, refers to one's belief about chances of personal harm. Several factors might influence how individuals assess their own likelihood of breast cancer or other diseases including their previous health experiences, health beliefs, and family history.^{47, 48} While perceptions of one's chances for getting cancer likely is linked to worry about the disease, evidence suggests perceived likelihood and worry are distinct constructs and have unique influences on behavior.⁴⁹

Many women who have received false-positive mammography results perceive they have higher chances for getting breast cancer compared to those whose mammography results were normal. Aro and colleagues found 54% of women who received false-positive results described their likelihood of future disease as "high" or "very high" a year after the false-positive experience, higher than the percentage of women with normal mammogram results (43%).³¹ Lipkus and colleagues reported similar findings such that women who had false-positive mammography results perceived their lifetime breast cancer risk as higher than women whose results were normal, regardless of when the false-positive results occurred.⁵⁰ While some women who receive false-positive test results may truly have a higher risk for breast cancer (Evidence suggests that women who received multiple breast biopsies may be at greater risk for breast cancer.),⁵¹ most abnormal

mammograms do not indicate substantial breast cancer risk. Thus, women's belief that they have an increased likelihood for getting breast cancer because of their false-positive test results is often inaccurate.

Consequences of perceived likelihood of disease: The link between perceived likelihood of disease and protective behavior is central to several theories of health behavior⁵² including the Health Belief Model,⁵³ Extended Parallel Process Model⁵⁴, and Precaution Adoption Process Model.⁵⁵ These models generally propose that the greater people perceive their susceptibility to disease to be, the more likely they will be to engage in protective behavior. Theorists also argue the reverse - that behavior can affect perceptions of susceptibility.⁵⁶ That is, perceived susceptibility might be both a determinant and a consequence of behavior. For example, women who do not receive regular mammography screening might perceive their likelihood of getting breast cancer as low as a way to justify their behavior.⁵⁷ I will return to this point later, as it is an important consideration when testing for mediational effects (see Testing Mediational Hypotheses).

Empirical research supports the claim that the of being susceptible to disease motivates many protective behaviors, including vaccination⁵⁸ and condom use.⁵⁹ Findings from two large meta-analytic reviews found that greater perceived risk of breast cancer was associated with a greater likelihood of screening in the general population, although effect sizes were small.^{47, 60}

Persistence of psychological outcomes after a false-positive test result

Implicit in the proposed model is the assumption that psychological effects of false-positive mammograms, such as worry, anxiety and perceptions of risk, are persistent. That is, the model requires that psychological effects after false-positive test results persist long enough to motivate or deter subsequent mammography screening, which in the U.S. is typically recommended 1 year after the test that produced the false-positive result.^{61, 62, 87} One explanation for this phenomenon is that people may have considerable difficulty revising their beliefs once they are formed. This is true even when presented with credible information contrary to those beliefs.^{63, 64} In the context of mammography screening, abnormal test results might cause women to believe they have an underlying medical problem. Upon learning they do not have cancer, some women may have difficulty undoing thoughts of worry, anxiety and susceptibility to disease elicited by the abnormal test results.

False-Positive Mammograms and Thoughts about the Screening Test

Perceptions of screening's accuracy

One potentially important but largely ignored area of research is the impact of false-positive results on women's thoughts about the accuracy of screening tests. I focus on two objective measures of accuracy: the test's sensitivity and positive predictive value. The following paragraphs provide detailed explanations of these concepts. However, what is more important are women's perceptions of the test's accuracy – a point I will return to later.

Widely-used measures of test accuracy include sensitivity and positive predictive value. Sensitivity is the probability an individual with disease will receive a positive test result. Mammography’s sensitivity is generally between 83% and 95%.¹³ That is, mammography will detect between 83% and 95% of breast cancers in women who have the disease and undergo screening. Another measure of screening accuracy, positive predictive value, is the probability a positive test result means there is an underlying disease. Mammography’s positive predictive value is very low - about 10% in the U.S.⁶⁵ This means only about 10% of abnormal readings result in a cancer diagnosis. As shown in the hypothetical example in Table 1, the low positive predictive value results from there being few women with breast cancer. Thus, the resulting ratio of true positives to total positives (positive predictive value) is low. Conversely, the ratio of false-positives to total positives is high.

Table 1: Hypothetical example of mammography accuracy

	Have breast cancer (n=11)	No breast cancer (n=1000)
Abnormal mammogram	10 (<i>true positive</i>)	100 (<i>false-positive</i>)
Normal mammogram	1 (<i>false-negative</i>)	900 (<i>true-negative</i>)

Note. Sensitivity is 91% (10/11). Positive predictive value is 9% (10/110).

False-positive test results and perceived accuracy: I hypothesize that false-positive mammography results will influence the way women think about the accuracy of abnormal test results (test’s positive predictive value), but not the test’s

sensitivity. That is, women who have experienced false-positives should be more likely to think that abnormal results are often inaccurate. However, women should remain confident in mammography's ability to detect breast cancer when it exists (test's sensitivity) regardless of whether or not they've had a false-positive experience. This belief is rational because a false-positive result gives no information about whether a test is accurate in detecting cancer when it is present (see Table 1). False-positive results also should not influence women's beliefs about the effectiveness of mammography for reducing deaths from breast cancer. That is, false-positive experiences should not interfere with how women value the importance of early detection and treatment for decreasing breast cancer deaths.

Few studies have explored perceptions of screening accuracy and effectiveness after false-positive experiences.^{31, 66, 67} While some evidence suggests that false-positives do not impact women's perceptions of mammography's sensitivity or effectiveness for reducing deaths from breast cancer,^{31, 66} no study has investigated women's perceptions of the accuracy of abnormal test results and the impact of these perceptions on future use.

Consequences of perceptions of test accuracy: Perceptions of a screening test's accuracy should be associated with its use. Research shows that women who believe mammography's sensitivity is high are more likely to use it.⁶⁸ I hypothesize that women who believe abnormal test results are less accurate might avoid subsequent screening, although no study has tested this hypothesis. This may be because, women who believe abnormal test results are inaccurate may have

feelings of distrust about the test or the medical system.²⁹ Studies show that medical mistrust is associated with underutilization of health care services.^{69, 70}

The hypothesis that perceptions of test accuracy should influence use of mammography is similar to the perceived efficacy construct in the Extended Parallel Process Model (EPPM).⁵⁴ EPPM defines “perceived response efficacy” as the belief about whether or not a response (e.g., return for routine mammography screening) can effectively address a health threat (e.g., breast cancer). EPPM posits that decisions to seek protective behaviors in the presence of a health threat hinge, in part, upon the availability of an effective response. Perceived response efficacy could tap into women’s perceptions of mammography’s accuracy. That is, women who believe abnormal test results are inaccurate might perceive return for screening as an ineffective response to their breast cancer threat and thus will avoid future screening. What is unique about perceived response efficacy in the context of this research is that the protective response individuals are contemplating (return for mammography screening) is the same behavior that caused the breast cancer threat (false-positive mammography result).

Positive consequences of false-positive mammography results

False-positive test results and thinking about the benefits of screening: Few studies have explored the possible positive effects of having false-positive mammograms. Some evidence suggests that false-positive experiences cause women to think more about the benefits of regular screening.^{50, 71, 72} Commonly reported benefits to getting regular mammograms are that they offer the possibility of early detection and provide “peace of mind.” Studies by Lipkus⁵⁰ and Pisano⁷² found

that while women who received false-positive mammography results had greater breast cancer-related distress, they also thought more about the benefits of mammography compared to women who received normal test results. Meta-analyses also support the presence of both positive and negative reactions to false-positive mammograms.³⁸

Consequences of thinking about the benefits of screening: The increased consideration of the potential benefits of screening should make these beliefs more accessible in memory and thus improve their ability to affect subsequent behavior.^{73,}
⁷⁴ Studies show that women who understand more about the benefits of mammography are more likely to be screened regularly.⁷⁵⁻⁷⁷ As a result, many interventions designed to increase mammography use focus on having women think about the test's benefits.^{75, 78, 79}

Theory also suggests that thought about the benefits of mammography may serve as a coping response for women who experienced false-positive test results. Models of stress and coping conceptualize “coping responses” as thoughts and behaviors individuals use to offset or overcome adversity and manage stressful aspects of their environment.⁴⁶ Problem-focused coping involves using adaptive strategies, such as problem solving and information seeking, to manage a stressful situation. Problem-focused coping may be one strategy individuals use to offset negative feelings caused by a false-positive test result. That is, women who have had false-positive mammograms might counterbalance the worry and anxiety about getting breast cancer elicited by their experiences by thinking more about how they might benefit from regular screening.

Predictions from the Model

The proposed model allows us to test several predictions about how false-positive mammography results should affect subsequent breast cancer screening.

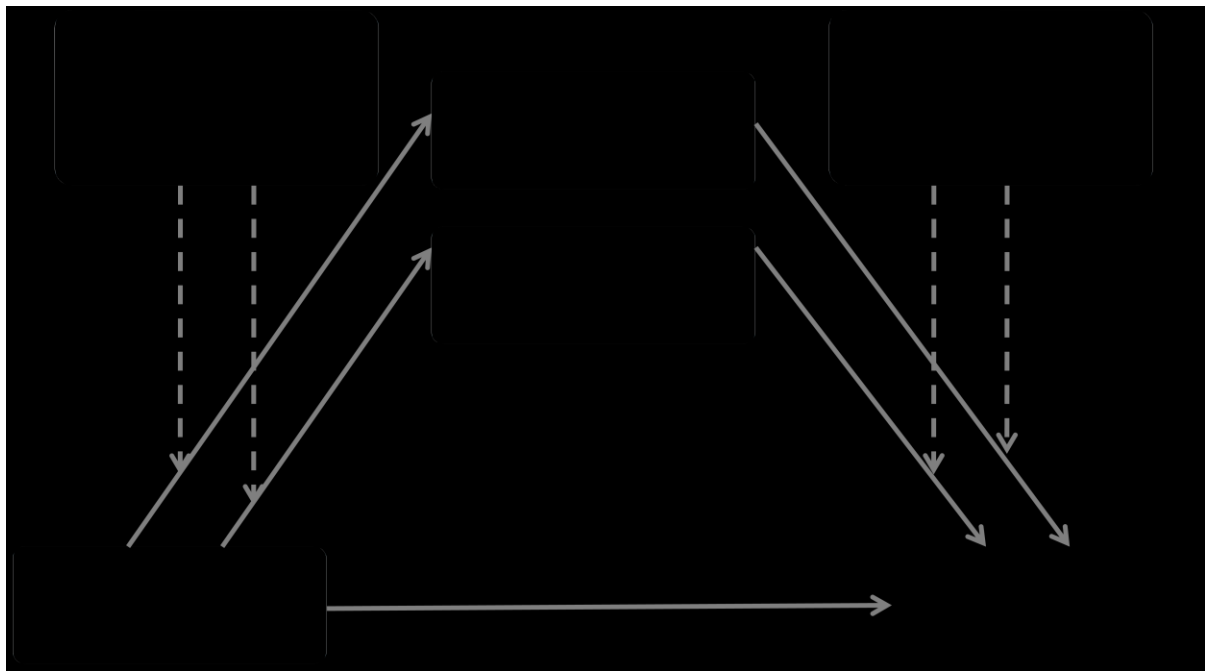
- 1. False-positive mammography results should affect subsequent screening behavior.** Findings from U.S. studies suggest that women who receive false-positive mammography results should be more likely to return for subsequent mammography screening.²
- 2. Thoughts elicited by a false-positive experience should mediate the relationship between receipt of false-positive test results and adherence to subsequent screening.** Women whose previous mammograms were false-positive will have elevated breast cancer-related worry and will believe they are more likely to get breast cancer compared to women whose previous mammograms were normal. In turn, these thoughts will motivate vigilance about regular screening. Women might also think more about the benefits of regular mammography after receipt of false-positive results, which in turn would also increase their likelihood of return for screening. No published studies have examined these mediational pathways.
- 3. Beliefs about mammography's accuracy should suppress the relationship between receipt of false-positive mammography results and adherence to subsequent screening.** Women who receive false-positive mammography results may believe that abnormal test results are less accurate. This belief might cause women to distrust screening, off-setting the

positive influences of worry, perceived likelihood of disease and thoughts about the test's benefits. Few studies have examined the prediction that false-positive test results affect perceptions of test accuracy, and no published study has examined suppression effects.

Moderating Influences

While I hypothesize that false-positive mammography results influence subsequent screening - as mediated by thoughts about the person and thoughts about the test - there may also be important subgroup differences. Decisions to return for subsequent mammography screening after receiving false-positive results may be conditional upon various factors, including women's educational level, literacy, income, and interactions with health care providers, to name a few (see Figure 2). I classify these factors as "predisposing" or "enabling" factors as is commonly done in health behavior research.^{80, 81} Predisposing factors in this model refer to socio-demographic characteristics, such as education level, that might modify the way that false-positive test results affect how women think about themselves or the screening test. Enabling factors refer to financial or health care resources that, when unavailable, might deter women from acting on feelings elicited by false-positive results, breaking the mediational chain.

Figure 2: Moderating factors on association between false-positive mammography results and subsequent screening



Financial and health-care resources

Abnormal mammogram results require potentially costly and time consuming follow-up procedures. One U.S. study estimated that for every \$100 spent on screening mammograms on a population level, an additional \$30 was spent on follow-up procedures due to abnormal test results⁸, although actual costs borne by individual women was not known. U.S. women who receive false-positive mammography results are likely burdened with some costs from follow-up testing (although this may be less of an issue in other countries where costs are not a barrier to mammography screening). Other costs associated with false-positive test results may include missed work hours, transportation, childcare needs or other inconveniences.⁸² Therefore, women who receive false-positive test results and lack sufficient financial resources may be less likely to act on thoughts and feelings

elicited by their test result compared to women who receive false-positives but have no financial hardship.

Similarly, women who receive false-positive test results and do not have a usual source of health care, or opportunities to communicate with their physicians about their false-positive experiences, may be less likely to comply with future mammography screening compared to women who receive false-positive results but have these resources. Physicians are important sources of information for women contemplating the benefits and risks of screening.^{83, 84} Thus, physician recommendations may prompt women who receive false-positive results to act on feelings of worry and anxiety, thus facilitating return for future screening. Additional predictions of the model are:

4. **The effects of false-positive mammography results on subsequent screening depend on women's ability to understand the results.** While not a specific aim of this study, women with lower education levels might understand less about the complexities of screening and their test results. As a result, they might be less likely to experience worry, perceive themselves as more likely to get breast cancer, or think about the benefits of screening, breaking the mediational chain. Similar predictions could be made for factors such as numeracy and health literacy.

5. **The effects of false-positive mammography results on subsequent screening depend on the presence of financial and health care resources.** Women who lack financial or health care resources may not

show the pattern of mediation proposed in the previous models. Lack of these resources may interfere with women's ability to act on thoughts and feelings elicited by a false-positive experience, breaking the mediational chain.

Testing Mediational Hypotheses

The model of false-positive test results proposes several mediational hypotheses. That is, the model seeks to clarify the causal pathways through which a false-positive test result exerts its effect on future behavior. While researchers have used a variety of study designs to test mediational hypotheses, strong tests of mediation should establish a temporal chain among predictor, mediator and outcome variables.⁸⁵ The predictor (X) should occur before the mediator variable (M), and M should occur before the outcome (Y). Because measurement of constructs is unlikely to coincide with their occurrence, researchers should take special care in understanding the limitations and challenges inherent in the approach they choose. In this section, I use the example of false-positive mammography results and adherence to subsequent screening to illustrate several key considerations when testing the model's mediational hypotheses.

Cross-sectional study designs

Researchers sometimes test for mediation using cross-sectional study designs that rely on retrospective recall of constructs and behaviors. However, such studies usually preclude establishing a temporal timeline among variables, making them undesirable for testing mediational hypotheses. Thus, findings from cross-sectional studies can only be considered as exploratory or suggestive of mediation.⁸⁶

In the context of false-positive mammography results and return for screening, use of cross-sectional study design is potentially problematic because the outcome - Y (whether or not women returned for a subsequent screening and the result of that screening exam) could plausibly influence subjects' report of potential mediators (M). For example, women who returned for subsequent screening mammograms (Y) and received normal test results may report less worry about breast cancer (M) compared to women who had not yet returned for screening. Similarly, women who had not returned for subsequent screening (Y) might minimize their perception of breast cancer risk (M) as a way to justify their behavior. As a result, effects of M on Y would be biased because of this reverse causal pathway, and the basis for causal inference would be seriously undermined.

Longitudinal study designs

Longitudinal designs are preferable for testing mediation models because they better allow researchers to establish a temporal timeline among variables.⁸⁶ In the context of false-positive mammography results and return for screening, longitudinal designs offer many advantages, but also introduce some complexities. One important consideration regards the ideal timing for assessment of mediators. This length of time should not be so long that psychological effects of the false-positive result would have dissipated. Studies have found false-positive test results impact psychological outcomes anywhere from a few weeks to 3 years after the false-positive experience, though effects may last even longer.² Assessing potential mediators more than 3 years after the false-positive test result may not yield meaningful findings as effects of the false-positive result might have dissipated. A

related consideration is that time between the false-positive and assessment of mediators should not be so great such that a subsequent screening mammogram (Y) occur prior to assessment of the mediators (M). For example, if researchers allowed several years to elapse between the false-positive and assessment of mediators, women are likely to have returned for a routine screening by this time (most U.S. women are advised to return for screening 12 months after the screening that produced the false-positive result).^{61,62,87} In these cases, occurrence of Y would precede measurement of M. As discussed previously, this is problematic, because women's return for screening (Y) would have influenced responses to questions regarding mediator variables (M).

It is also possible that the degree to which false-positive test results impact psychological outcomes (M) will vary over time. As a result, the strength of the effect of X on M might not be the same for all time intervals. For studies where the influence of X on M might not be stationary, researchers suggest the inclusion of a variety of time intervals over which the mediation process unfolds.⁸⁶ That is, rather than assessment of a time-specific mediated effect (the degree to which M at exactly Time 2 mediates the effect of X at exactly Time 1 on Y), researchers will be more interested in an overall mediated effect - the degree to which M at any time within a specified window mediates the effect of false-positive test results on behavior.

A final consideration in longitudinal mediation research is that occurrence of a construct might differ from when a researcher measures it.⁸⁶ That is, measures of Y and M might actually assess conditions that began long before the occurrence of X. As a result, the temporality among variables could be compromised. In the context of

false-positive mammograms, some mediators (such as worry about breast cancer) will have existed prior to the occurrence of X (false-positive test result). Women may have worried about breast cancer even before receipt of the mammogram that produced the false-positive result. Therefore, prior levels of M should be controlled if researchers want to determine if *changes* in the mediating variables influence the outcome. Another possible scenario is that the behavior represented by Y might precede X. Women who consistently return for routine screenings might be more likely to have received false-positive test results. That is because, women who are screened regularly will have undergone more screening exams. They, therefore, will have had more opportunities for false-positive results.⁸⁸ Studying a population of homogenous women with respect to their previous screening histories or statistical adjustment for previous screening behavior would control for this potential source of bias.

Significance and Implications of the Research

Understanding the influence of false-positive mammography results is increasingly important as we rethink screening guidelines and implement new screening technologies. Researchers estimate that about one-half of U.S. women will receive false-positive mammography results if tested regularly.⁸ This proportion should increase if women adhere to annual (rather than biennial) screening guidelines. Wider implementation of digital mammography might also contribute to higher rates of false-positive results because research suggests digital technology detects larger proportions of breast cancers at the expense of an increased false-positive rate.¹ A better understanding of the long-term psychological and behavioral

consequences of receiving false-positive results on screening exams should be a public health priority. While research suggests that small elevations in worry and anxiety elicited by false-positive experiences may be good for motivating future screening, these psychological effects are unnecessary and should be addressed. Findings from this study should have implications for intervention and will guide future research on other types of screening exams and behaviors. I discuss these implications later in the dissertation.

CHAPTER 2: SPECIFIC AIMS AND HYPOTHESES

Aim 1: To assess effects of false-positive mammography results on adherence to subsequent mammography screening.

Hypothesis 1: Women whose previous mammography results were false-positives will be more likely to obtain their subsequent, on-schedule screening mammograms than women whose previous mammography results were normal.

Aim 2: To assess effects of false-positive mammography results on women's thoughts about themselves and thoughts about the test.

Hypothesis 2.1: Compared to women whose previous mammography results were normal, women whose previous mammography results were false-positives will have more breast cancer worry.

Hypothesis 2.2: Compared to women whose previous mammography results were normal, women whose previous mammography results were false-positives will believe they are more likely than other women to get breast cancer.

Hypothesis 2.3: Compared to women whose previous mammography results were normal, women whose previous mammography results were false-positives will think more about the benefits of regular mammography.

Hypothesis 2.4: The relationship between receipt of a previous false-positive mammography result and beliefs about effectiveness of mammography in reducing deaths from breast cancer will be non-significant.

Hypothesis 2.5: The relationship between receipt of a previous false-positive mammography result and perceptions of mammography's ability to detect breast cancer (test's sensitivity) will be non-significant.

Hypothesis 2.6: Compared to women whose previous mammography results were normal, women whose previous mammography results were false-positives will believe abnormal test results are less accurate (test's positive predictive value).

Aim 3: To determine if the relationship between receipt of false-positive mammography results and adherence to subsequent mammography screening is mediated by women's thoughts about themselves and thoughts about the screening test.

I state mediation hypotheses only for variables hypothesized to be associated with receipt of false-positive mammography results in Aim 2.

Hypothesis 3.1: Women whose previous mammography results were false-positives will have more breast cancer worry and, in turn, will be more likely to

obtain their subsequent, on-schedule screening mammograms than women whose previous mammography results were normal.

Hypothesis 3.2: Women whose previous mammography results were false-positives will believe they are more likely than other women to get breast cancer and, in turn, will be more likely to obtain their subsequent, on-schedule screening mammograms than women whose previous mammography results were normal.

Hypothesis 3.3: Women whose previous mammography results were false-positives will think more about the benefits of regular mammography and, in turn, will be more likely to obtain their subsequent, on-schedule screening mammograms than women whose previous mammography results were normal.

Hypothesis 3.4: Women whose previous mammography results were false-positives will believe abnormal test results are less accurate (test's positive predictive value) which, in turn, will suppress the hypothesized positive relationship between receipt of false-positive mammography results and subsequent, on-schedule screening.

Aim 4: To determine if financial or health care-related factors moderate the relationship between receipt of false-positive mammography results and adherence to subsequent mammography screening.

Hypothesis 4.1: Report of financial hardship will moderate the relationship between receipt of false-positive mammography results and adherence to subsequent screening.

Hypothesis 4.2: Report of cost barriers to obtaining mammograms will moderate the relationship between receipt of false-positive mammography results and adherence to subsequent screening.

Hypothesis 4.3: Receipt of physician recommendations for mammograms will moderate the relationship between receipt of false-positive mammography results and adherence to subsequent screening.

CHAPTER 3: RESEARCH DESIGN AND METHODS

To address the study aims, I used data from a large, prospective study of repeat mammography use among insured North Carolina women aged 40-75.

Parent Study for Secondary Data Analysis

PRISM (Personally Relevant Information about Screening Mammography), part of the National Institutes of Health (NIH) Health Maintenance Consortium, is a randomized controlled trial to increase rates of repeat mammography. Barbara K. Rimer, DrPH, is the principal investigator. Institutional review boards for the University of North Carolina School at Chapel Hill and Duke University approved the research study.

Study sample and recruitment

PRISM researchers identified potential participants through the North Carolina Teachers' and State Employees' Comprehensive Major Medical Plan, also known as the State Health Plan (SHP). DeFrank and colleagues described recruitment and data collection methods.⁸⁹ Briefly, the sample included North Carolina female residents who were between the ages of 40 and 75, enrolled with the SHP for two or more years prior to sampling, and had recent mammograms within a designated time period. Researchers identified 9,087 women who met initial eligibility criteria.

PRISM study enrollment occurred between October 2004 and April 2005. Researchers sent invitation letters to all potential participants with instructions for opting out of the study. Trained telephone interviewers from Battelle Centers for Public Health Research and Evaluation made as many as 12 attempts to obtain consent and administer baseline interviews. Of those invited, 3,547 women completed baseline telephone interviews, 2,051 refused to participate, and 747 were ineligible due to answers on screening interviews (e.g., breast cancer history)(see Figure 3, Analytic sample). The remaining 2,742 women were of unknown eligibility because call attempts were exhausted ($n=2,570$) or their enrollment was no longer needed ($n=172$) to reach the target sample size. The range in baseline response rates, based on the American Association for Public Opinion Research (AAPOR) Standard Definitions, was 47% to 64%.⁹⁰ The lower response rate excludes a portion of those with unknown eligibility from the response rate calculation; the higher response rate excludes all those with unknown eligibility. These response rates are typical for participation in national telephone surveys, which have declined in recent years.⁹

Data collection

Following consent, women completed 30-minute baseline telephone interviews that assessed socio-demographics and mammography-related beliefs and practices. Subsequent telephone interviews occurred at about 12, 24, 36 and 42 months (see Appendix A, PRISM Data Collection Timeline) and lasted about 30 minutes. Women who completed 36-month telephone interviews comprised the

analytic sample for this study. Women not reached for 12- or 24-month interviews were still eligible to participate in 36-month interviews.

Intervention

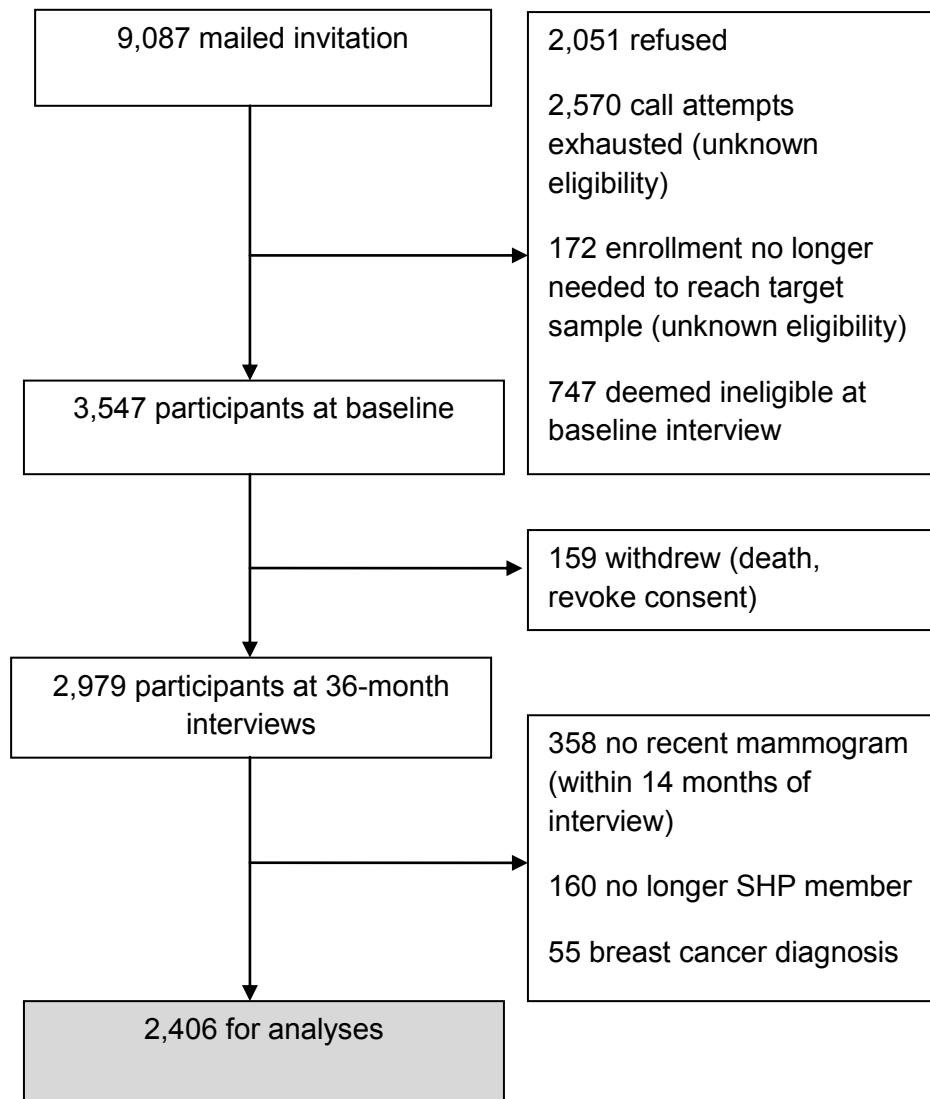
Although not the focus of this research, I describe PRISM interventions because it is plausible that receipt of PRISM interventions may have diminished effects of false-positive mammography results on key study variables. PRISM researchers pre-randomized women to 1 of 9 intervention strategies prior to study recruitment (see Appendix B, PRISM Study Design). PRISM did not include a non-intervention control arm for ethical reasons. PRISM used a two-step intervention design where after delivery of a first round of interventions, women who became non-adherent to mammography received supplemental interventions. The first round of intervention involved randomization to 1 of 3 reminder types: printed enhanced usual care reminders, printed reminder booklets guided by behavioral theory (enhanced letter reminder), and automated telephone reminders. Supplemental interventions were a combination of printed reminder letters (priming letters) and telephone counseling, both tailored to women's self-reported barriers and knowledge deficits regarding mammography. In addition to addressing barriers, some supplemental interventions also elaborated on positive consequences of getting regular mammograms or negative consequences of not getting regular mammograms. Delivery of reminders occurred 2-3 months prior to women's mammography due dates. Study staff mailed priming letters approximately 3 months after women's due dates (once they became overdue for their next screenings); counseling calls followed 2-5 weeks later. Researchers timed delivery of subsequent

intervention over the 4-year study period according to due dates for women's next mammograms. PRISM findings showed that supplemental intervention (priming letters plus any form of telephone counseling) was more effective in reducing cumulative days of non-adherence during the 4-year study period than PRISM reminders only, although effect sizes were small.⁹²

Analytic Sample

The analytic sample included 2,406 participants who completed 36-month interviews. Only the 36-month interviews included items on perceived test accuracy - a key study construct. Women with a previous breast cancer diagnosis did not participate in the interviews. The sample included respondents to 36-month telephone interviews ($n=2,979$) and excluded those who did not have recent mammograms in the last 14 months ($n=358$), were no longer members of the State Health Plan ($n=160$) and therefore information on subsequent mammography screening was not available, or had a breast cancer diagnosis subsequent to their interviews ($n=55$) indicating their abnormal test results were "true positives" (Figure 3). The analytic sample included women in all PRISM intervention arms to provide sufficient sample sizes to detect potentially small effects.

Figure 3: Analytic sample



Measures

Predictor

Receipt of false-positive mammography results: The primary predictor variable for analyses is women’s recent mammography test result self-reported during 36-month interviews. The interview item states: “*Since we last spoke, have you had a mammogram when you were told the results were not normal, but no cancer was found?*” Response categories were *Yes*, *No*, and *Don’t Know*. Missing

values were small ($n=2$) and were coded as *No*. Women did not receive this interview item if they reported a recent breast cancer diagnosis or if they did not have mammograms since their last interview date. These exclusion criteria helped to ensure that women's abnormal mammograms were not true-positives and that occurrence of false-positive results was recent (within 14 months of the 36-month interviews). False-positive results occurring more than 14 months prior to the 36-month interviews were coded as *No*, because a subsequent screening mammogram may have occurred prior to the 36-month assessments. PRISM researchers relied on self-report of abnormal test results, because SHP medical claims data did not include information about screening test results. Previous research indicates that self-report of abnormal mammogram results corresponds highly with medical records, but may be less accurate for minority or low-education groups.⁹³

A second predictor variable was the number of self-reported false-positive test results since PRISM study enrollment. This number came from responses to 12-, 24-, and 36-month interviews and ranged from 0 to 3. I used this variable for exploratory analyses assessing effects of receiving multiple false-positive results.

Outcome

Adherence to subsequent screening mammography: The primary dependent variable for analyses was adherence to subsequent mammography screening. PRISM researchers used SHP claims information, verified by self-report for most women, to determine women's previous and subsequent mammogram dates. Women coded as "adherent" obtained their subsequent screening mammograms 10 to 14 months after their previous screening mammograms at 36-month interview

assessments. All women in the study sample had an opportunity to return for subsequent screening within 14 months of their previous mammograms and thus be adherent. Women coded as “non-adherent” either received mammograms that were delayed or had no subsequent mammogram on record for this study. The 10-14 month window is consistent with previously published PRISM research.⁸⁹ Researchers chose the lower boundary of 10 months to exclude mammograms that were likely diagnostic or short-interval rescreening mammograms. Thus, mammograms occurring within 10 months of women’s previous mammograms were not used to determine the outcome. The upper boundary of 14 months reflects American Cancer Society recommendations for yearly mammograms plus a 2-month window for scheduling.⁹⁴ At the time of the study, women who received false-positive mammography results typically should have returned for regular screening 1 year from the date of the screening exam that produced abnormal results (as opposed to 1 year from the date of follow-up or diagnostic exams).^{61, 62}

Analyses used 2 versions of the adherence outcome. A dichotomous outcome classified women as adherent vs. non-adherent to subsequent mammography screening. A nominal outcome further classified the non-adherent women as either having received a subsequent but delayed mammogram or having no subsequent mammogram on record, thus resulting in a 3-level variable.

Mediators

Mediator variables come from 36-month interviews. Responses to mediator variables were recoded such that higher scores reflected more of the variable of interest (e.g., higher scores reflected more breast cancer worry). Missing values

were relatively uncommon and ranged from 0-4%. Missing values were not associated with false-positive status for any proposed mediator variable.

Worry about breast cancer was measured with two items and combined to create a single continuous measure ranging in score from 2 to 9. The first item read: *Having yearly mammograms causes you worry or anxiety about breast cancer.* I coded responses of *strongly agree* as=4, *somewhat agree*=3, *somewhat disagree*=2, and *strongly disagree*=1. The second item read: *How worried are you about getting breast cancer in your lifetime?* I coded responses of *not at all* as =1, *a little*=2, *some*=3, *a lot*=4, *a great deal*=5, and *refused/don't know*=missing.

Perceived likelihood of breast cancer was measured with one item assessing women's comparative perceptions of risk that read: *How likely are you to get breast cancer in your lifetime compared to the average woman your age and risk?* I coded responses of *more likely* as=3, *about as likely*=2, *less likely*=1, and *refused/don't know*=missing.

Thought about the benefits of mammography was measured with a single item that read: *In the past week, how often have you thought about the benefits you can gain by getting a mammogram when you are due?* I coded responses of *none of the time* as=1, *a little of the time*=2, *a moderate amount of time*=3, and *most of the time*=4.

Perceived accuracy of mammography was measured with two items. The first item assessed women's perceptions of the test's sensitivity and read: *How much do you trust mammograms to give accurate information about whether you have breast*

cancer? I coded responses of *not at all* as=1, *a little*=2, *a moderate amount*=3, *completely*=4 and *refused/don't know*=missing. The second item assessed women's perceptions of the test's positive predictive value and read: *How often do you think an abnormal mammogram result means a woman has breast cancer?* I coded responses of *always* as=4, *most of the time*=3, *some of the time*=2, *rarely*=1 and *refused/don't know*=missing.

Perceived effectiveness of mammography was measured with one item: *Thinking of women your age and race, how effective are mammograms for reducing deaths from breast cancer?* I coded responses of *very effective* as=4, *somewhat effective*=3, *somewhat ineffective*=2 and *very ineffective*=1.

Moderators

Moderator variables came from 36-month surveys. Missing values were uncommon and did not exceed 1% for any variable. Missing values were not associated with false-positive status for any proposed moderating variable.

Financial barriers were assessed with two items and tested separately as potential moderators. The first item read: *Without giving exact dollars, how would you describe your household's financial situation right now?* Responses were: *after paying the bills, you still have enough money to buy special things* as=1, *you have enough money to pay the bills, but little spare money to buy extra or special things*=2, *you have money to pay the bills, but only because you have to cut-back on things*=3, *you are having difficulty paying the bills no matter what you do*=4, and *refused/don't know* =missing. Due to low frequency of some responses, I

dichotomized this variable as no financial hardship=0 (*after paying the bills, you still have enough money to buy special things*) and 1=financial hardship (other responses). The second item was from a list of reasons why women delay mammograms and read: *The cost of the mammogram: Do you agree or disagree that this could delay your getting a mammogram*. Responses were *strongly agree* as=4, *somewhat agree*=3, *somewhat disagree*=2, *strongly disagree*=1, and *refused/don't know*=missing. I retained this item as a continuous variable. Missing values were small and did not exceed 1% for either item.

Physician recommendation for mammograms was assessed with a single item and read: *In the last year, has a doctor advised you to have a mammogram?* I coded responses as *yes*=1, *no*=0 and *don't know/refused*=missing. Missing values on the physician recommendation variable (12; 0.5%) were not associated with false-positive status (p -value for Fisher's exact test=1.00).

Data Analysis

I assessed effects of false-positive mammography results on adherence using logistic regression for the dichotomous outcome and generalized logit model (GLM) analyses for the 3-level nominal outcome.⁹⁵ Preliminary analyses rejected the proportional odds assumption ($p=.05$), confirming that the 3-level outcome should be treated as a nominal rather than ordinal measure. GLM analyses first produced a Wald chi-square statistic for the overall association between false-positive status and the outcome and then produced 2 sets of regression parameters comparing each category of non-adherence to the adherent category. I assessed effects of

false-positive test results on potential mediating variables using linear regression and correlation analyses.

I conducted mediation analysis using bootstrapping techniques described by Preacher & Hayes.⁹⁶ Mediation analysis tested the hypothesis that the product of paths a and b ($a*b$) differed significantly from 0, where path a represented the association between the predictor and mediator variables, and path b represented the association between the mediator variables and outcome adjusting for the predictor.^{96, 97} In brief, bootstrapping involved resampling from the dataset and estimating the mediated effect thousands of times. This information was used to build an empirical approximation of the sampling distribution of $a*b$, providing bias-corrected standard errors and 95% confidence intervals. Bootstrapping provides higher power to detect mediated effects compared to more traditional approaches (such as the Sobel test). Bootstrapping is also preferred when including covariates or multiple mediators.

Tests of moderation involved inclusion of an interaction term that crossed the predictor variable and moderator (e.g., receipt of false-positive mammography result*physician recommendation for a mammogram) along with both the predictor and moderator variables in the regression models. Power analyses suggested that the available sample size was sufficient to detect potentially small effects of false-positives on mediating variables and the outcome. Sample sizes exceeded recommended numbers to test for potentially small mediated effects.⁹⁸

I conducted analyses using SAS v9.1.3. Tests were two tailed, using a critical alpha of .05.

CHAPTER 4: RESULTS

Participants

The mean age for women in the study sample was 55 years (Table 2). Most women were white (88%), married (79%), and had a college education (65%). About one-third (31%) reported some level of financial hardship, but few reported they “somewhat agreed” or “strongly agreed” that cost was a barrier to future screening (9%). Most (70%) reported their physicians advised them to get mammograms in the past year. Over one-half of women (60%) were adherent to repeat mammography screening prior to study enrollment.

About one-half of women (51%) reported ever having received a false-positive mammography result prior to 36-month interview assessments. About 17% (403/2406) of women received false-positive mammography results since study enrollment (1214/2406). A small percent of women (3%) reported multiple false-positive results since study enrollment (69/2406). About 8% of women (184/2406) reported a *recent* false-positive result in the 14 months prior to their 36-month interview assessments, which is the main predictor variable for these analyses.

Table 2: Demographic and medical characteristics of the sample

	Total (n=2406) n(%)	Recent mammogram was false-positive (n=184) n(%)	Recent mammogram was normal (n=2222) n(%)	<i>p</i>
Age (mean)	55.1	55.2	55.1	.83
Race				.67 ^a
White	2118 (88.0)	166 (7.8)	1952 (92.2)	
Black	249 (10.4)	16 (6.4)	233 (93.6)	
Asian	8 (0.3)	0 (0.0)	8 (100.0)	
Native Hawaiian/Pacific Islander	1 (0.04)	0 (0.0)	1 (100.0)	
American Indian/Alaska Native	24 (0.5)	1 (4.2)	23 (95.9)	
Refused or "other"	6 (0.3)	1 (16.7)	5 (83.3)	
Marital status				.55
Married	1910 (79.4)	143 (7.5)	1767 (92.5)	
Not married	495 (20.6)	41 (8.3)	454 (91.7)	
Missing	1 (<0.1)	0 (0.0)	1 (100.0)	
Education				.57
≤High school	358 (14.9)	27 (7.5)	331 (92.5)	
Some college	478 (19.9)	42 (8.8)	436 (91.2)	
≥College	1569 (65.2)	115 (7.3)	1454 (92.7)	
Missing	1 (<0.1)	0 (0.0)	1 (100.0)	

^a *p*-value for Fisher's exact test

Table 2 cont.

	Total (n=2406) n(%)	Recent mammogram was false- positive (n=184) n(%)	Recent mammogram was normal (n=2222) n(%)	<i>p</i>
Financial status				.39
No financial hardship	1649 (68.5)	120 (7.3)	1529 (92.7)	
Some financial hardship	748 (31.1)	62 (8.3)	686 (91.7)	
Missing	9 (0.4)	2 (22.2)	7 (77.8)	
Cost a barrier				.073 ^a
Strongly disagree	2049 (85.2)	155 (7.6)	1894 (92.4)	
Somewhat disagree	162 (6.5)	12 (7.4)	150 (92.6)	
Somewhat agree	114 (2.7)	5 (4.4)	109 (95.6)	
Strongly agree	81 (6.5)	12 (14.8)	69 (85.2)	
Doctor or provider advised mammogram in the past year				.006
No	721 (30.0)	39 (5.4)	682 (94.6)	
Yes	1673 (69.5)	145 (8.7)	1528 (91.3)	
Missing	12 (0.5)	0 (0.0)	12 (100.0)	
Adherent to repeat screening prior to study enrollment				.95
No	962 (40.0)	74 (7.7)	888 (92.3)	
Yes	1444 (60.0)	110 (7.6)	1334 (92.4)	
Previously received a false- positive result				<.001
No	1192 (49.5)	66 (5.5)	1126 (94.5)	
Yes	1214 (50.5)	118 (9.7)	1096 (90.3)	

Assessment of Potential Control Variables

Some characteristics varied by recent false-positive status (Table 2). Women who previously received false-positive mammography results were more likely to have received recent false-positive results (10%) compared to women who had not previously received false-positive results (6%; $p < .001$). However, this variable was not associated with adherence to subsequent screening ($p = .27$). Women who received physician recommendations for mammograms were more likely to have received recent false-positive results (9%) compared to women who did not receive physician recommendations (5%; $p = .006$). Physician recommendation for mammograms was marginally associated with adherence to subsequent screening ($p = .06$). Inclusion of physician recommendation for mammograms as a control variable did not change study findings. Therefore, I report bivariate relationships unless otherwise noted. Analyses did not control for intervention type, because proportions of women who reported recent false-positive mammography results did not differ by PRISM intervention arm ($p = .15$).

Adherence to Subsequent Mammography Screening

The following sections describe findings for the dichotomous adherence outcome (adherent vs. non-adherent) and nominal adherence outcome (adherent vs. delayed mammogram vs. no subsequent mammogram on record). As discussed previously, the two outcomes are computationally similar except that the nominal outcome expands non-adherence into two categories. I hypothesized women who received recent false-positive mammography results would have higher rates of

adherence to subsequent screening compared to women who received normal results (Hypothesis 1).

Findings showed women whose previous mammography results were false-positives were equally likely to be adherent to their subsequent screening mammograms (69%; 127/184) compared to women whose previous mammography results were normal (75%; 1667/2222) ($OR=0.74$, 95% $CI=0.54, 1.03$; $p=.07$). I also tested whether categories of non-adherence (delayed mammogram vs. no subsequent mammogram on record) varied for women who received false-positive compared to normal test results and found no overall association (Wald $X^2=4.3$; $p=.12$)(Table 3). Subsequent screening mammograms that were delayed occurred for 22% (40/184) of women who reported recent false-positive results and for 16% (355/2222) of women who reported their recent mammography results were normal. No subsequent screening mammogram was on record for 9% (17/184) of women who reported recent false-positives and for 9% (200/2222) of women who reported their recent mammography results were normal. The number of false-positive test results since study enrollment was not associated with either adherence outcome ($p=.71$ and $p=.84$ for dichotomous and nominal outcomes respectively).

Table 3: Association between false-positive status and adherence to subsequent screening

	Adherent <i>n (%)</i>	Delayed mammogram <i>n (%)</i>	No subsequent mammogram on record <i>n (%)</i>
Recent mammogram was false-positive	127/184 (69.0)	40/184 (21.7)	17/184 (9.3)
Recent mammogram was normal	1667/2222 (75.0)	355/2222 (16.0)	200/2222 (9.0)

Women’s Thoughts about Themselves and Thoughts about the Screening Test

False-positive test results and thoughts about the person

I hypothesized receipt of recent false-positive test results would be associated with more breast cancer-related worry (Hypothesis 2.1) and a higher perceived likelihood of getting breast cancer (Hypothesis 2.2). As hypothesized, women who received recent false-positive mammography results had more breast cancer worry compared to women whose mammography results were normal ($r=.07$; $p<.001$) (Table 4). The amount of breast cancer-related worry did not vary with the number of days elapsed since women’s recent mammography exam (mean 196 days) for either the false-positive or normal test results group ($p=.97$). That is, amount of worry was stable over time for women in both groups. Also contrary to my hypothesis, receipt of recent false-positives was not associated with women’s perceived likelihood of getting breast cancer in their lifetime ($r=.01$; $p=.63$) (Table 4).

Greater number of false-positive mammography results since study enrollment was associated with more breast cancer-related worry ($r=.10$, $p<.001$), but was not associated with greater perceived likelihood of getting breast cancer ($r=.03$, $p=.24$).

Table 4: Association between false-positive status and women's thoughts about themselves

	Recent mammogram was false- positive (n=184)	Recent mammogram was normal (n=2222)	<i>r</i>	<i>p</i>
	<i>n</i> (%)	<i>n</i> (%)		
Breast cancer-related worry			.07	<.001
<i>How worried are you about getting breast cancer in your lifetime?</i>				
Not at all	22 (12.0)	328 (14.8)		
A little	73 (39.7)	1027 (46.2)		
Some	72 (39.1)	719 (32.4)		
A lot	15 (8.2)	102 (4.6)		
A great deal	2 (1.1)	43 (1.9)		
Missing	0 (0.0)	3 (0.1)		
<i>Having yearly mammograms causes you worry or anxiety about breast cancer.</i>				
Strongly disagree	128 (69.6)	1701 (76.6)		
Somewhat disagree	24 (13.0)	281 (12.7)		
Somewhat agree	20 (10.9)	193 (8.7)		
Strongly agree	12 (6.5)	43 (1.9)		
Missing	0 (0.0)	4 (0.2)		
Perceived likelihood of getting breast cancer in lifetime			.01	.63
<i>How likely are you to get breast cancer in your lifetime compared to the average woman your age and race?</i>				
Less likely	39 (21.2)	518 (23.3)		
About as likely	112 (60.9)	1338 (60.2)		
More likely	25 (13.6)	300 (13.5)		
Missing	8 (4.3)	66 (3.0)		

False-positive test results and thoughts about the screening test

I hypothesized women who received recent false-positive mammography results would believe abnormal test results were less accurate (test's positive predictive value) compared to women whose mammography results were normal (Hypothesis 2.6), but that false-positive status would have no effect on perceptions of the test's sensitivity (Hypothesis 2.5) or effectiveness (Hypothesis 2.4). I also hypothesized women who received recent false-positive mammography results would think more about the benefits of regular screening (Hypothesis 2.3).

As hypothesized, women who received false-positive mammography results believed abnormal test results were less accurate (test's positive predictive value) than women who received normal test results ($r = -.06$; $p = .003$) (Table 5). Receipt of false-positives was not associated with thoughts about the test's sensitivity for detecting disease ($r = .01$; $p = .67$) or the test's effectiveness for reducing deaths from breast cancer ($r = -.02$; $p = .34$). As hypothesized, recent false-positive results also were associated with thinking more about the benefits of regular mammography ($r = .07$; $p < .001$). Commonly reported benefits for both groups of women were that having regular mammograms provided "peace of mind" (50%) and allowed for the early detection of breast cancer (27%).

Greater number of false-positive mammography results since study enrollment was associated with beliefs that abnormal test results were less accurate ($r = -.10$; $p < .001$) and with thinking more about the benefits of regular mammography ($r = .05$; $p = .021$).

Table 5: Association between false-positive status and thoughts about the test

	Recent mammogram was false- positive (n=184) n(%)	Recent mammogram was normal (n=2222) n(%)	r	p
Test's positive predictive value			-0.06	.003
<i>How often do you think an abnormal mammogram result means a woman has breast cancer?</i>				
Rarely	12 (6.5)	131 (5.9)		
Some of the time	159 (86.4)	1686 (75.9)		
Most of the time	10 (5.4)	372 (16.7)		
Always	2 (1.1)	12 (0.5)		
Missing	1 (0.5)	21 (1.0)		
Test's sensitivity			.01	.67
<i>How much do you trust mammograms to give accurate information about whether or not you have breast cancer?</i>				
Not at all	0 (0.0)	4 (0.2)		
A little	4 (2.2)	79 (3.6)		
A moderate amount	111 (60.3)	1315 (59.2)		
Completely	68 (37.0)	820 (36.9)		
Missing	1 (0.5)	4 (0.2)		
Test's effectiveness			-0.02	.34
<i>Thinking of women your age and race, how effective are mammograms for reducing deaths from breast cancer?</i>				
Very ineffective	3 (1.6)	23 (1.0)		
Somewhat ineffective	2 (1.1)	10 (0.5)		
Somewhat effective	48 (26.1)	561 (25.2)		
Very effective	131 (71.2)	1610 (72.5)		
Missing	0 (0.0)	18 (0.8)		
Thought about benefits of regular mammograms			.07	<.001
<i>In the past week, how often have you thought about the benefits you can gain by getting a mammogram when you are due?</i>				
None of the time	105 (57.1)	1483 (66.7)		
A little of the time	39 (21.2)	431 (19.4)		
A moderate amount of time	28 (15.2)	237 (10.7)		
Most of the time	12 (6.5)	71 (3.2)		

Association of Potential Mediators and Subsequent Mammography Screening

Breast cancer-related worry was not associated with adherence to subsequent screening ($OR=1.02$, 95% $CI=.95,1.10$; $p=.63$). Individual items measuring breast cancer worry also were not associated with adherence to subsequent screening. I tested for a possible curvilinear relationship between the item asking women how worried they were about getting breast cancer in their lifetimes and the outcome, because of the potentially curvilinear pattern of responses. However, the quadratic term was not associated with adherence ($p=.62$).

Adherence to subsequent mammography screening was not associated with women's perceived likelihood of getting breast cancer ($OR=1.08$, 95% $CI=.92,1.26$; $p=.35$), thinking more about the benefits of regular screening ($OR=.98$, 95% $CI=.88,1.09$; $p=.70$) or belief in the accuracy of abnormal test results ($OR=.99$, 95% $CI=.82,1.20$; $p=.91$). Thoughts about the test's sensitivity ($OR=1.07$, 95% $CI=.91,1.27$; $p=.43$) and effectiveness for reducing deaths from breast cancer ($OR=1.08$, 95% $CI=.91,1.23$; $p=.40$) were not associated with adherence to subsequent screening. Findings were the same for the nominal adherence outcome.

Mediation

I hypothesized that women's thoughts about themselves and thoughts about the screening test would mediate the relationship between receipt of false-positive test results and adherence to subsequent screening (Hypotheses 3.1-3.4). While receipt of a recent false-positive test result was associated with breast cancer-related worry, beliefs about accuracy of abnormal test results and thinking about the benefits of regular screening, none of these variables was associated with

adherence to subsequent screening. Regardless, I conducted statistical tests of mediation, because mediation may exist in the absence of statistically significant pathways.⁹⁹ The bootstrapped estimate of the mediated effect was not significantly different from 0 for worry (95% *CI* = -1.99, 2.16), beliefs about test accuracy (95% *CI* = -1.59, 1.74), or for thinking about the test's benefits (95% *CI* = -1.69, 2.35). Bootstrapped estimates also did not differ from 0 when simultaneously including these variables in a single model, when controlling for baseline values of the mediator and outcome variables, or when controlling for physician recommendation for screening. Thus, none of the hypothesized variables mediated (or suppressed) the relationship between receipt of false-positive mammography results and adherence to subsequent screening. I return to these issues later in the dissertation, because it is possible that lack of association may have been due to characteristics of the PRISM study and sample.

Moderation

I hypothesized that financial factors would moderate the relationship between receipt of false-positive mammography results and adherence to subsequent screening (Hypotheses 4.1-4.2). Contrary to my hypothesis, reporting cost barriers to mammography screening or financial hardship did not moderate the relationship between receipt of false-positive mammography results and adherence to subsequent screening ($p=.50$ and $.53$ respectively). Other contextual factors did not moderate the relationship between receipt of a recent false-positive test result and adherence to subsequent screening: age ($p=.51$), ever having received a prior false-positive mammography result ($p=.23$), adherence to regular mammography

screening prior to study enrollment ($p=.99$), and education ($p=.41$). Findings were also null for the nominal adherence outcome.

As hypothesized, influence of recent false-positive mammography results on adherence to subsequent screening was conditional upon receipt of a physician's recommendation for mammography screening (Hypothesis 4.3). This modifying effect was statistically significant for the nominal adherence outcome ($p=.02$), but not for the dichotomous adherence outcome ($p=.38$). Thus, only findings for the nominal outcome are reported here. Post-hoc analysis showed that among women who reported physician recommendations, receipt of recent false-positive results was not associated with adherence to subsequent screening ($p=.054$). However, among women who said their physicians had not advised them to get mammograms, those who received false-positives were more likely to have no subsequent mammogram on record compared to women who received normal test results (18% vs 7%, $OR=3.17$, 95% $CI=1.30,7.71$)(Table 6). Thus, receipt of a physician recommendation for mammograms buffered the negative effect of false-positive mammography results on return for subsequent screening.

Table 6: Association between false-positive status and adherence to subsequent screening by physician recommendation for mammograms

	Adherent <i>n (%)</i>	Delayed mammogram <i>n (%)</i>	No subsequent mammogram on record <i>n (%)</i>
Physician recommendation for a mammogram ^a			
Recent mammogram was false-positive	101/145 (69.7)	34/145 (23.4)	10/145 (6.9)
Recent mammogram was normal	1137/1540 (73.8)	248/1540 (16.1)	155/1540 (10.1)
No physician recommendation for a mammogram ^b			
Recent mammogram was false-positive	26/39 (66.7)	6/39 (15.4)	7/39 (18.0)
Recent mammogram was normal	530/682 (77.7)	107/682 (15.7)	45/682 (6.6)

^a Comparison of no subsequent mammogram vs. adherent: *OR*=0.73, 95% *CI*= 0.37,1.42; *p*=.054

^b Comparison of no subsequent mammogram vs. adherent: *OR*= 3.17, 95% *CI*=1.30,7.71; *p*=.038

Sensitivity Analyses

I conducted sensitivity analyses to assess whether receipt of PRISM intervention might have diminished the influence of false-positive test results on adherence. I could not test this hypothesis directly, because all PRISM participants received study interventions. Researchers did not include a non-intervention control group for ethical reasons. However, study interventions ranged in intensity from simple reminders (mailed or automated telephone messages) to reminders plus individually-tailored priming letters and telephone counseling. Women randomized to a PRISM “control” arm received reminders only whereas the remainder received

reminders and tailored interventions if they became overdue for their mammograms. It is possible that the effect of false-positive test results on subsequent adherence was weaker for those randomized to receive the tailored interventions, because these interventions were more intensive and designed to help women overcome barriers to screening. Previous PRISM analyses showed that tailored interventions were more effective in reducing non-adherence compared to reminder interventions over the 4-year study period.⁹² However, the interaction between false-positive status and intervention type (simple reminders vs. tailored interventions) on adherence to subsequent screening was not statistically significant ($p=.97$), indicating that the influence of false-positive results on adherence was similar regardless of the intensity of PRISM intervention. Also, effects of false-positives on adherence to subsequent screening were null for the PRISM “control” arm ($n=1024$; $p=.23$).

While sample sizes for the described analyses were large ($n=2406$), I addressed the possible lack of statistical power to detect associations by conducting additional analysis using a continuous adherence outcome measure. This measure counted the number of days between recent and subsequent screening mammograms (mean=457 days, $SD=183$; range 305-993). Consistent with the previously reported findings, the effect of false-positives on number of days between screenings was null ($p=.23$) as were associations between proposed mediating variables and days between screenings. The interaction with physician recommendations for mammograms remained statistically significant ($p=.04$).

Findings also did not differ by method of imputation (mode or median) for missing data on proposed mediating or moderating variables.

CHAPTER 5: DISCUSSION

My dissertation had two overarching goals. The first was to describe a model, guided by theory and empirical evidence, explaining the relationship between receipt of false-positive mammography results and adherence to subsequent screening. While influence of false-positive mammography results on future screening behavior and psychological outcomes is well-established, a theoretically-informed model clarifying these relationships is lacking. The second aim of this dissertation was to statistically test pathways of the model using longitudinal data from the PRISM (Personally Relevant Information on Screening Mammography) study and to assess for mediational and moderation effects. The purpose of this chapter is to describe where study findings support and deviate from the model described earlier in this dissertation. I also discuss study limitations, strengths, and implications for intervention and future research.

Do False-Positive Mammography Results Influence Future Screening?

Contrary to my hypothesis, receipt of false-positive mammography results did not influence return for subsequent screening in this study. Among women who received false-positive mammography results, 69% returned for screening within 14 months compared to 75% of women whose mammography results were normal. This finding conflicts somewhat with a recent meta-analysis showing that, among

U.S. women, receipt of false-positive mammography results typically motivates adherence to future screening.²

U.S. studies that have assessed this relationship - conducted between 1991 and 2003 - found that false-positives either had no effect or a small positive effect on subsequent mammography use. The slight, but negative null effect for this study is notable for not having been documented previously in any U.S. study. Rather, this trend is more consistent with Canadian and some European findings where false-positives have been shown to interfere with subsequent mammography screening.² Given slight declines in mammography use for some groups of U.S. women¹⁰⁰ coupled with controversy concerning the benefits and harms of screening for breast cancer,¹⁰¹ monitoring the effects of false-positive test results should remain a public health priority.

While not the focus of this dissertation, I briefly speculate why findings from this study more closely resemble those from European studies. Many European countries have screening programs that automatically schedule women into appointments to attend their regular mammograms and send reminders for these appointments. European programs thus require women to “opt-out” of mammography screening should they choose not to attend. In the U.S., women must “opt-in” to undergo regular screening; no national program automatically invites women to attend regular mammography screening. In essence, PRISM created an “opt-out” program for study participants similar to that of European systems. Researchers sent PRISM participants annual reminders for their mammograms and contacted women who became delayed by telephone. While “opt-out” programs that

invite women to attend screening produce higher rates of mammography compliance,¹⁰² it is also plausible that women in these programs might have more distrust or disappointment in mammography screening if they receive false-positive results, which in turn might deter future screening.

While false-positive mammography results had no overall effect on subsequent screening, interesting subgroup differences emerged. Among women who said their physicians had not advised them to get mammograms, receipt of false-positive test results interfered with their return for subsequent screening. For women who lacked physician recommendations, 67% who received false-positives returned for timely subsequent screenings compared to 78% of women who received normal test results. This finding suggests that abnormal mammograms that do not result in a cancer diagnosis can be opportunities for physicians to stress the importance of regular screening. Women who do not receive this advice could be at risk for not returning for future mammography screening. While we might expect that most patients and physicians communicate about the benefits and harms of breast cancer screening following a false-positive experience, few women report having such conversations.¹⁰³ I discuss implications for intervention later in this chapter.

Influence of false-positive mammography results on subsequent screening did not vary by other factors, including presence of financial barriers, women's age, education level, whether they received prior false-positive mammography results and whether they were already adhering to regular mammography screening prior to study enrollment. It is plausible that women who have lower incomes might be less likely to return for timely screening after receiving false-positives because of the

costs and inconveniences associated with follow-up testing. While study findings did not lend support for this hypothesis, all women in the sample were insured, and few reported cost barriers to getting their mammograms. Testing this hypothesis in a more socioeconomically diverse population might yield different findings. Other research suggests that financial costs associated with follow-up testing can be substantial.^{8, 104} In the U.S. alone, such costs are estimated to exceed \$100 million annually.¹⁷ However, the extent to which women are burdened with these financial costs is not known and should be the topic of further investigation. In addition to financial costs, women who undergo follow-up testing for abnormal test results are likely burdened with other costs, including missed time from work, meeting transportation and childcare needs, and other inconveniences.^{29, 82}

[Do False-Positive Mammography Results Affect the Way Women Think about Themselves or the Screening Test?](#)

Findings showed limited support for other proposed pathways of the model. Receipt of false-positive mammography results influenced the way women thought about themselves. Women who received false-positives worried more about breast cancer compared to women who received normal test results - even about a year after receiving the "all clear" from cancer. Moreover, levels of breast cancer worry were higher for women who received multiple false-positive results. The finding that false-positive mammography results cause breast cancer-related anxiety, worry and distress that endures over the long-term is well-documented in the research literature.^{2, 27, 31, 38, 50} Studies both in the U.S. and abroad consistently have shown moderate but reliable elevations in breast cancer-specific distress anywhere from a few weeks to 3 years after cancer had been ruled out. While elevations in breast

cancer-related distress are rarely pathological or require medical attention, these symptoms are unnecessary byproducts of screening and should be minimized.

Breast cancer-related worry did not influence future mammography use in this study. This peculiar finding conflicts with research suggesting that worry about breast cancer increases vigilance about mammography screening.^{27, 28, 42} and with theorists' positions that non-pathological worry motivates self-protective behaviors.^{26,}
⁴⁵ There also was no support for an alternative hypothesis positing a curvilinear relationship between worry and screening (that is, some research suggests that moderate levels of worry motivate screening, whereas extremely high or low levels of worry deter future screening).⁴³ Rather than conclude that worry about breast cancer has no influence on screening behavior, I attribute this lack of association to characteristics of the study sample and design, discussed later in this chapter.

Study findings supported the hypothesis that false-positive mammography results change the way women think about the screening test. While receipt of false-positive test results had no effect on beliefs about mammography's sensitivity for detecting breast cancer, women who received false-positive mammograms believed abnormal test results were less accurate. That is, these women were more likely to understand that abnormal test results do not necessarily indicate cancer (the test's positive predictive value). This belief is rational because women's false-positive experiences would have debunked the misperception that positive test results mean cancer is present. Whether or not these beliefs reflected distrust or dissatisfaction with screening could not be addressed by our study. It is plausible that feelings of distrust would inhibit women who receive false-positives from returning for future

screening exams, although this hypothesis remains untested. Qualitative research by Padgett and colleagues suggests that some women who receive false-positive mammography results leave the screening experience feeling suspicious or distrusting of the health care system.²⁹ While our study did not assess influence of distrust on screening per se, we found that believing abnormal test results are often inaccurate had no effect on future screening. This finding might suggest that receipt of false-positive test results caused women to have more realistic expectations about the accuracy of abnormal test results. Research shows people generally are willing to accept false-positive results and that this experience does not dampen enthusiasm for cancer screening.¹⁰⁵ Given the paucity of research assessing perceptions of test accuracy and feelings of distrust after false-positive screening results, this topic warrants further research.

Findings showed positive consequences of receiving a false-positive results, which is consistent with other research.^{38, 50, 71, 106, 107} Women in this study who received false-positives spent more time thinking about the benefits of regular mammography, such as the possibility for early detection of breast cancer and feeling “peace of mind” when results are normal. Increased thought about the benefits of regular mammography use may have served as a coping response for women who experienced false-positive test results. Models of stress and coping conceptualize “problem-focused coping” as thoughts and behaviors individuals use to offset adversity, such as information seeking or problem solving.⁴⁶ Thus, women who had false-positive mammography results might have counterbalanced the worry and anxiety elicited by this experience by thinking more about the potential positive

aspects of regular screening. While the increased consideration of mammography's benefits did not influence return for screening in this study, several other studies show that women who understand and think about the benefits of screening exams are more likely to get them.⁷⁵⁻⁷⁷

Contrary to my hypothesis, receipt of false-positive mammography results did not cause women to believe they had a greater likelihood of getting breast cancer. This finding conflicts with a recent meta-analysis that found false-positive test results had a small but significant effect on perceived likelihood of disease.³⁸ That is, women who received false-positive mammography results generally believed they had a higher chance of getting breast cancer compared to women who received normal test results, although effects were often small. Discrepancy between our study's findings and previous research might be due to differences in measurement. Our study used a measure of "comparative risk" that assessed how women perceived their own likelihood of getting breast cancer compared to other women of their age and race. However, previous research has relied heavily on measures of perceived absolute risk, that is, how likely women think they are to get breast cancer in their lifetimes (for example, on a scale from 1-5). A study by Lipkus and colleagues used both types of perceived risk measures and showed that receipt of false-positive mammography results was associated with perceptions of absolute risk, but not comparative risk.⁵⁰ Other research also supports the claim that perceived susceptibility measures are not interchangeable.¹⁰⁸

Is There Support for the Model?

Consistent with the proposed model, false-positive mammography results affected both the way women thought about themselves and about the test. That is, receipt of false-positive mammography results caused elevated breast cancer worry (thoughts about the person), coupled with the belief that abnormal test results were less accurate and increased thought about the benefits of regular screening (thoughts about the test). Findings also showed support for the presence of both negative and positive reactions to false-positives. While the majority of studies on false-positives have assessed negative reactions, such as worry, anxiety and distress, fewer have explored potential positive reactions to this experience.

Findings from this study do not offer support for a key study hypothesis that thoughts and feelings elicited by false-positive experiences explain return for subsequent screening. While it is possible that the model simply is incorrect, this interpretation is implausible given the large body of empirical and theoretical evidence supporting the association of these beliefs and health behaviors, including mammography screening. I turn to alternative explanations for why there was a lack of association among these key variables. As described in other sections of this dissertation, women who participated in PRISM all had previous mammograms (per the study's eligibility criteria) and agreed to take part in a 4-year trial where they would receive yearly telephone interviews and study interventions. It is possible that women who agreed to participate in PRISM were already highly motivated about getting regular mammograms and, therefore, perceptions of worry and test accuracy would have had little influence on decisions to get mammograms. Another

explanation is that PRISM participants received yearly reminders for their mammograms, and some received telephone counseling designed to help them overcome their barriers to screening. Thus, receipt of PRISM interventions may have diminished the effect of key variables on adherence to subsequent screening. I was unable to test this hypothesis directly, because PRISM did not include a non-intervention control group for ethical reasons. However, sensitivity analyses showed that the influence of false-positive results on return for screening was similar regardless of the intensity of PRISM intervention. A worthwhile area of future research would be to test a theoretical model of false-positives outside the context of an intervention trial.

Other Limitations and Considerations

PRISM researchers did not have access to medical records to determine which mammograms were false-positives. Rather, this study relied on women's self-reports of whether they had a recent mammogram that was abnormal but where no cancer was found. While research suggests that self-report is a highly accurate method of determining whether people had false-positive screening results,⁹³ it is possible that rates of false-positives were under-reported slightly in this study. Some women may not have known or understood that their test results were abnormal. Yet, false-positive rates for this study (8%) were very similar to national averages.¹³⁻

¹⁵ Proportions of women who inaccurately reported receipt of normal test results that were in fact false-positives should not have differed for women who were subsequently adherent or non-adherent to screening. Thus, it is unlikely that underreporting of false-positive mammograms would have biased study findings.

Information on the type of follow-up women underwent for abnormal test results (e.g., rescreen, ultrasound, biopsy etc.) was not available for this study. This information may have been useful, because some research suggests that invasive follow-up procedures, such as biopsy, cause stronger effects on women's perceptions of worry and risk compared to less invasive procedures or rescreening.^{27, 30, 106} However, regardless of the type of follow-up procedure, women who receive false-positive mammography results generally report worse psychological outcomes compared to women whose mammograms are normal. Also, studies show that rates of return for regular screening after receipt of false-positive results are the same regardless of type of follow-up.²⁷ Therefore, it is unlikely that control for type of follow-up women received for their abnormal test results would have influenced key findings.

Another limitation is that the study population was insured, highly educated and predominately white. Generalizability of findings to non-insured populations and those with diverse socioeconomic and racial/ethnic backgrounds should be the topic of future research.

Study Strengths

The greatest strength of this study was use of prospective data to test theoretically-driven hypotheses about the relationship between false-positive test results, psychological outcomes and subsequent screening behavior. Although study findings did not show evidence of mediational effects, I discuss methodological considerations when testing for mediation and recommend cutting-edge statistical techniques for future researchers seeking to clarify the relationship between false-

positive test results and future health behavior. Other strengths included a large population-based sample and access to health claims information to confirm most women's mammogram dates.

Implications for Future Research

Expanding the proposed model to other behaviors and populations would be a worthwhile area of future research. For example, effects elicited by false-positive mammography results for women are likely to be similar to those experienced by men undergoing screening for prostate cancer. False-positive prostate cancer screening test result (PSAs) likely influence men's perceptions of cancer risk, worry, and perceptions of test accuracy, although these topics have received little research attention.¹⁸ However, unlike mammography screening, the one published study on this topic suggests men who receive false-positive results on PSAs are *less* likely to return for subsequent prostate cancer screening compared to men whose results are normal.¹⁸ While it is possible that perceptions of test inaccuracy or distrust might explain this finding, other factors, such as the risk of sexual side effects that can result from biopsy procedures for positive PSAs, should be considered. Another population of future interest is breast cancer patients who have survived their disease and are undergoing regular screening and surveillance. False-positive results on routine mammography exams likely have a tremendous impact on cancer survivors' thoughts, well-being and screening behavior, although no research I am aware of has explored these issues.

Implications for Intervention

False-positive mammography results cause small but reliable elevations in breast cancer-related distress that can endure for months or even years after cancer has been ruled out. While some might argue that a little worry can serve as a good motivator for future adherence to screening, clinicians have a responsibility to minimize distress caused by false-positive test results. As one physician commented “experience from daily life teaches us that nothing is so corrosive and enervating as a persisting uncertainty about the possibility of serious illness or upset.”¹⁰⁹

Research from a large controlled trial shows that by offering immediate follow-up and reading of test results, women’s anxieties after abnormal mammograms can be greatly reduced.¹¹⁰ This may be, because women receiving same day follow-up for abnormal test results may not have time for anxiety and worry to settle in. However, same day follow-up for abnormal test results is far from common practice. Clinics that cannot provide these services could intervene by providing women with written information about the recall process,¹¹¹ or with counseling from nurses after receipt of abnormal test results that addresses the benefits and harms of regular screening.¹¹² Both strategies have been shown to reduce women’s concerns. Findings from our research suggest that women who receive multiple false-positive mammography results might deserve more careful clinical attention, because they experience higher levels of breast cancer-related distress.

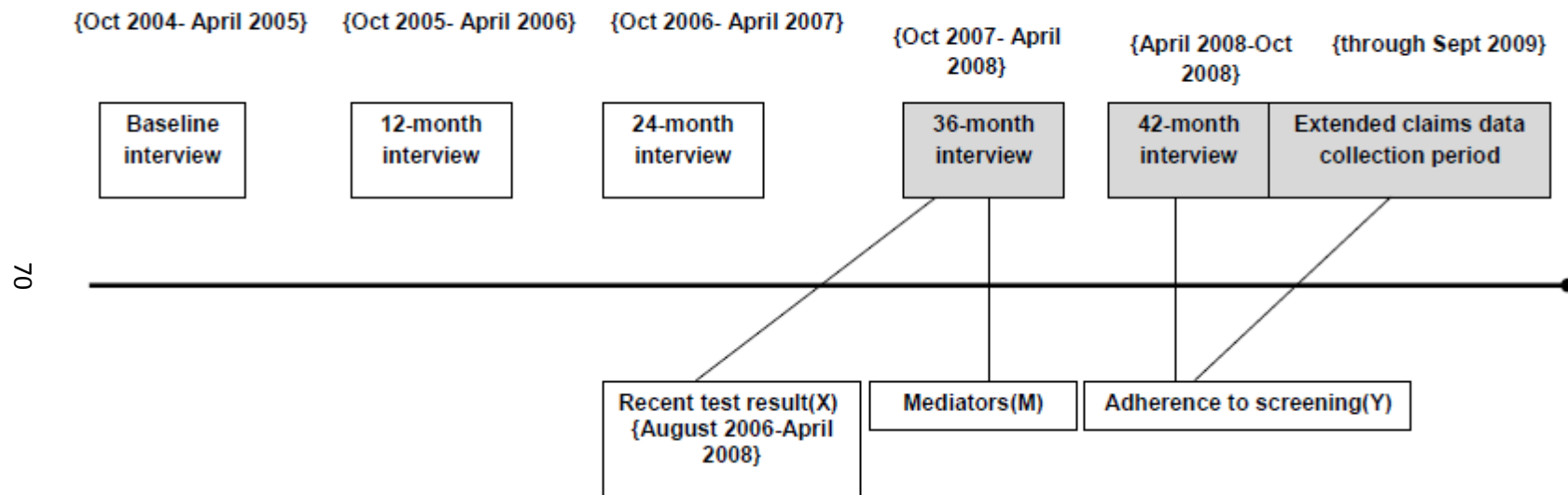
False-positive mammography results, coupled with a lack of communication between patients and their physicians about these results, could lead to non-compliance with future screening. Primary care physicians and staff are important

sources of information about breast cancer screening and are well-positioned to provide advice and reassurance after false-positive results. Best practices in communicating with patients who have had false-positive test results about the balance of benefits and harms of regular screening are needed.

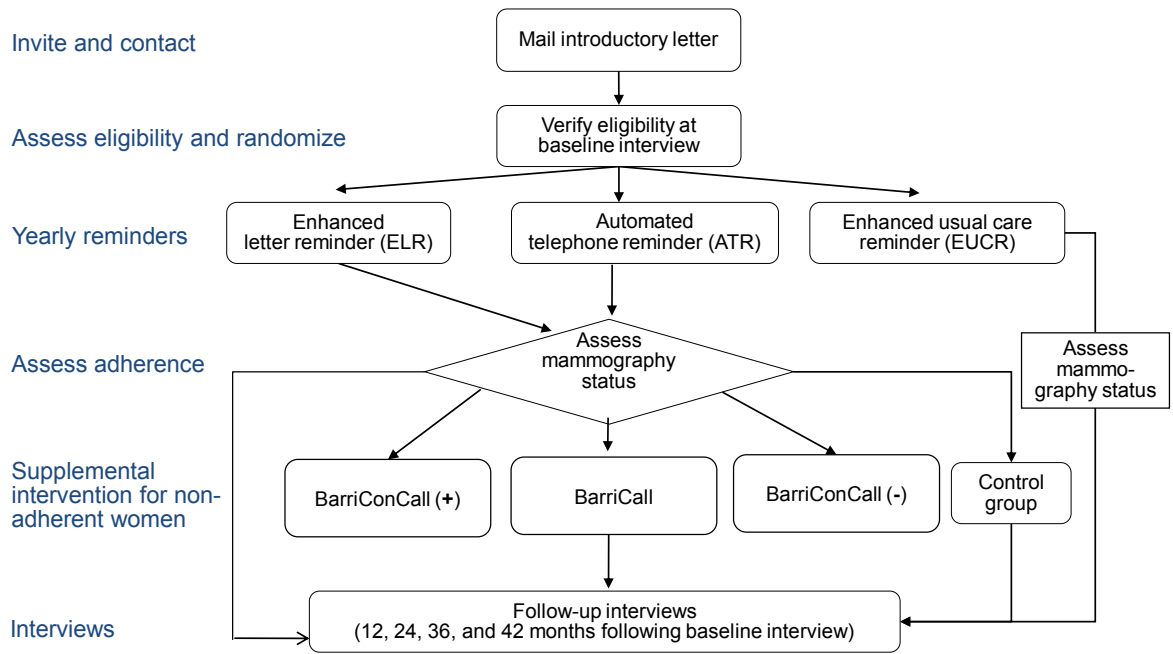
Conclusion

To conclude, understanding potential harms from mammography is important as we contemplate new screening guidelines. If screened regularly, as many as one-half of U.S. women will have false-positive mammography results in their lifetimes. Although most experts still agree that the benefits of regular mammography use outweigh its negative consequences, despite current controversy, minimizing distress caused by false-positive results should be a public health priority. Interventions to alleviate these concerns, as well as the role of physicians in promoting future screening after a false-positive experience, should be a focus of future intervention research.

APPENDIX A: PRISM Data Collection Timeline



APPENDIX B: PRISM Study Design



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