Breast Cancer Screening: Part B. Systematic Review on Women's Values and Preferences to Inform an Update of the Canadian Task Force on Preventive Health Care 2011 Guideline

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Author contributions

JP wrote the applicable sections to this Part B in the protocol, RF developed and implemented the search strategy and provided text for the applicable sections in the protocol and for this report. TM and LH contributed to discussion with the CTFPHC and PHAC on the scope for this work and critically reviewed the protocol. JP and TM conducted screening, data extraction and quality assessment for the report. JP and LH analyzed the data. JP drafted the report, and all authors provided critical input into the report and approved this version.

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Members of the CTFPHC and staff within the Global Health & Guidance Division (GHGD) of PHAC participated in development of the protocol and approved the final report. The Evidence Review Synthesis Centre (ERSC) is responsible for study selection, data collection, data analysis and interpretation, and preparation of the report while the CTFPHC provided input into the interpretation of the findings. The ERSC takes final responsibility for the content of the review.

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The ERSC conducted this review for the Public Health Agency of Canada [PHAC], however, it does not necessarily represent the views of the Government of Canada.

SUMMARY

Background and Purpose: CTFPHC recommendations are based on a systematic, structured, and transparent assessment of the balance of an intervention's potential benefits and harms, with explicit consideration of other relevant factors and integration of multidisciplinary input including that of stakeholders and patients/public. Our purpose was to systematically review studies providing information on women's values and preferences towards breast cancer screening, in terms of how they weigh the benefits and harms from screening that are considered by the CTFPHC to be most critical for their decision making (Key Question A). We also explored how, and to what extent, women use these outcome valuations when making decisions to undergo screening (Key Question B).

Data Sources and Selection: We searched four databases (MEDLINE, Cochrane Library, CINAHL, PsycINFO; to December 5, 2017), reference lists of systematic reviews and included studies, and several websites for studies, published in English or French and after 2000 (beginnings of increased scrutiny about benefit-to-harm ratio from screening), where women were asked directly or indirectly (via screening intentions) about the relative importance placed on expected benefits and harms of breast-cancer screening using any modality for women at least 40 years of age and not at high-risk for breast cancer. We included studies of any design where authors had women consider at least one benefit (breast-cancer, all-cause mortality) and one harm (false positive recall [FPs], FPs leading to biopsy, overdiagnosis) rated as critically important by the CTFPHC for making decisions. Studies either needed to provide to participants some form of effect estimate for the outcomes, or have the objective of eliciting preference weights or trade-offs between frequencies of benefits and harms. Two reviewers independently screened titles and abstracts, and all citations considered relevant were retrieved in full text for further independent selection with a standard form with consensus or third reviewer input for disagreements. Reasons for exclusion at full text review were documented.

Data Extraction and Analysis: One reviewer independently extracted data into DistillerSR; a second reviewer verified all data. Methodological quality of each included study was conducted using tools applicable for each study design. We grouped studies first by the degree to which the studies provided findings directly related to the outcomes rated as critical for decision making about breast-cancer screening. Studies reporting findings, such as screening intentions by women upon receiving effect estimates for the critical outcomes but also information about other relevant outcomes (e.g. false negatives) or factors (e.g. baseline risk for breast cancer), were consider more indirectly related to Key Question A. Other between-study factors considered during our analysis related to subgroup variables of age (40-49, 50-69, 70+ yrs) and screening history, as well as (when applicable) to our judgements about the benefit-to-harm ratios communicated to the women; these judgements are presented using a 5-point scale from low to high, and attempt to incorporate consideration about completeness of data (e.g. inclusion of all critical outcomes), magnitudes of effect, and how presentation of the data would likely influence perceptions by women (e.g., relative effect estimates were thought to portray higher benefit than were natural frequencies). Lack of information on one or more outcomes (e.g., overdiagnosis or all-cause mortality) was considered most (potentially) influential to findings and specific comments are provided as applicable. After extracting data from studies related to Key Question B, we decided to contextualize the findings within a well-validated theory used to predict and explain human behavior in specific contexts—the Theory of Planned Behavior; related domains include attitudes (including critical and other outcome valuations and underlying beliefs about these outcomes), subjective norms (e.g., influences from family, health providers), and perceived behavioral control (e.g., internal and external barriers). Additional variables beyond those within this model (e.g., screening history, numerical and conceptual understanding of outcomes) were also explored.

Results: Twenty-nine studies were included after screening 4,327 database citations and other sources. Studies were published in 11 countries (1 in Canada) and varied in their sample size (n=6 to 16,000) and design: five qualitative studies, nine randomized controlled trials, one single-arm trial, eight cross-sectional surveys, three uncontrolled pre-post studies, two stated preference studies, and a deliberative jury. Studies varied widely in terms of what critical outcomes were included and how the effects were presented; 24 did not mention all-cause mortality and 4 relied on relative risk estimates while neglecting to provide a reference to baseline risk. Our judgements of the relative benefit-to-harm information presented across studies tried to account for these factors while also accounting for differences in effects between ages. Thirteen studies provided the most direct, and 16 others provided more indirect, findings on how women weigh the benefits and harms of screening.

Key Question A. Provided with data indicating a variation in benefit-to-harm ratios, reductions in breast-cancer mortality appear to outweigh both FPs and overdiagnosis for most women. However, this finding was frequently in the context of incomplete or absent provision of information on all-cause mortality. Two studies indicated that considerable weight may be placed by women on estimates of no reduction in all-cause mortality, although this information seems unlikely to make all women decline screening. Overdiagnosis rates of about 30% of screened-detected diagnoses (e.g., 30% provided together with natural frequency of 11 in 33 [50-59 yrs] or 38 [60-69 yrs] diagnosed in 1000 screened) or even higher appear to be acceptable for many, but not all women especially those in their 40s where the absolute benefits may be reduced substantially because of lower baseline risk. Studies providing insight into benefit-to-harm valuations via screening intentions suggest that information about lower benefit-to-harm ratios will reduce or reverse the perceived benefit-to-harm ratio for screening for a substantial proportion of women in their 40s. Some study limitations and indirectness limit the certainty about the number and characteristics of women in their 40s that may decline screening. Prerequisite information may be a description of possible differences in benefits and harms between age groups, the explicit statement of their being rationale and a need for a choice by women, and accurate knowledge about one's risk for breast cancer during their 40s. The benefits of screening during one's 50s and 60s appear to outweigh the harms for most women regardless of their screening experience, but these findings may be specific to the high estimates of the benefit-to-harm ratios presented in the relevant studies (one small study in this category provided information on all-cause mortality) as well as other information presented within these studies. Based on information of a moderate/low or low benefit-to-harm ratio—even with data on all-cause mortality and competing risks for death—acceptance of continuing to screen may be quite high for women in their 70s, particularly if relatively young and healthy.

Key Question B. Weighing of critical outcomes seems to contribute to some degree, but not entirely, towards women's attitudes/valuations concerning breast-cancer screening and their screening decisions. Other factors likely to influence attitudes and intentions to screening include 1) other outcomes of importance to women (e.g., reassurance, failure to detect all cancers, better treatment for screen-detected cancers, value of information), 2) fear and anxiety about breast cancer stemming from beliefs about high breast-cancer severity, 3) beliefs about harms, for example, viewing overdiagnosis as a treatment rather than screening issue or considering FPs a test feature rather than harm from screening, and, for a minority of women in these studies, 4) importance placed on societal benefit and the high relative benefit in youth based on years of life saved. Some misconception about several of these findings is apparent. Women's intentions to screen appear to be influenced by the attitudes or recommendations from others (e.g., physicians, friends and family). A large proportion of women, but not all women, wants to have a role in making decisions about screening. In some studies, it is unclear to what degree women understood the numerical values presented. Moreover, stated intentions for screening or outcome valuations in some cases may better reflect women's

(mis)beliefs/understanding before being provided with information, which included, for example, a large overestimation of the benefits in one study or beliefs that screening prevents cancer in another. Women without screening experience may be more likely, than those with experience, to change their intentions based on new information on critical outcomes or reflection on other outcomes or beliefs (i.e., revised attitudes), or on factors such as influence of others.

Limitations: There are concerns over the applicability to a Canadian population and the reliability/adequacy of the findings in relation to the CTFPHC's estimates of the absolute and relative benefits and harms. The sample in many studies reflected women having relatively high education levels and good understanding of the applicable country's language; findings may have poor validity when considering low-income and/or foreign-born women residing in Canada. Information on benefits and harms provided in the studies often did not capture all of the outcomes under consideration. The influence that more information on all-cause mortality would make is uncertain, but has likely biased the findings towards higher acceptance of harms (because of beliefs of greater benefit) and overall screening intentions for some, or possibly many, women. Importance placed on benefits, reassurance, and value of information may reflect expectations (i.e., entrenched views) created by media and other health promotional sources, including a long-standing existence of screening programs in many countries, rather than an interpretation of these outcomes within the context of the critical CTFPHC outcomes particularly if poorly communicated or grasped. Our findings for subgroups of age were mostly based on between-study findings because the studies themselves often focused on one age group. Results for the subgroups of 40-49 and 50-69 year-olds are most likely influenced by the benefit-to-harm ratios presented (lower in the former age category), as well as greater explanation about uncertainties and choices about screening, such that the findings of lower screening intentions may have been similar in the older women should the studies have provided the same information.

Conclusions: These findings are intended to inform the importance placed by the CTFPHC on different outcomes when balancing the benefits and harms of breast cancer screening, and factors to consider during guideline implementation. Although the data suggest that women weigh the benefits greater than the harms (with overdiagnosis more critical than FPs) for the most part, the reliability of these findings is likely biased to some degree by the limited exposure in most studies to complete data on all critical outcomes. There is a signal indicating that information on all outcomes (especially when benefits are low) would make a substantial minority of women decline screening. Moreover, the degree to which women use critical outcome valuations (i.e., rationale decision making) during screening decisions appears to be heavily influenced by competing outcomes women may also consider important, beliefs of women about the outcomes that may inflate their valuations, and uncertainty about the ability of women—despite being relatively well-educated for the most part—to fully understand the numerical and conceptual outcome data. High-quality information on outcomes other than those considered critical for decision making (e.g., baseline risks for breast cancer, realistic awareness about reassurance) may help women understand the nuances between different outcomes. There is a need for efforts to increase women's and the general public's awareness and understanding of all outcomes from breast-cancer screening, including their consequences and natural frequencies, to ensure their valuations and decisions are consistent with accurate and complete knowledge. Variations between women's preferences across the outcomes considered suggest that informed decision making, either individually or shared with their providers, is a priority.

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1. Introduction and Purpose

This systematic review forms the second portion of the evidence evaluated to help inform the Canadian Task Force for Preventive Health Care's (CTFPHC) guideline update on breast cancer screening. The results for the effectiveness of breast cancer screening on critical health outcomes are reported elsewhere and were conducted by another Evidence Review Synthesis Centre (ERSC). This report describes the methods and findings from a systematic review on women's values and preferences for breast cancer screening.

CTFPHC recommendations are based on a systematic, structured, and transparent assessment of the balance of an intervention's potential benefits and harms, with explicit consideration of other relevant factors and integration of multidisciplinary input including that of stakeholders and patients/public.[1, 2] There is recognition that, despite having the same information on benefits and harms, different guideline panels, and individuals, may make different choices based in part by their values and preferences.[1] Recommendations aligned with patient values and preferences may be more easily accepted and implemented;[3] those that may not align well with some peoples' values can be implemented with considerations of needs for individual or shared decision-making.

Our purpose was to systematically review studies providing information on women's values and preferences towards breast cancer screening. Incorporation of patient/public preferences and values during guideline development may differ widely between different guideline producers; various strategies may be used in terms of how to collect the data (e.g., literature review and/or direct patient input), how values and preferences are defined, and how the findings are incorporated within the guideline development process or recommendations.[3] For the purposes of this systematic review conducted for the CTFPHC guideline update on breast cancer screening, we are defining preferences and values in a similar manner as have members of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group, in terms of the relative importance ("weight") placed on the benefits and harms ("outcome valuation") of breast cancer screening.[3] Preferences for or against an intervention are viewed as a consequence of the relative importance people place on the expected or experienced health outcomes it incurs. These findings can then be considered as patient input for determining outcome ratings when the CTFPHC is balancing the effect estimates on benefits and harms reported by empirical evidence on the clinical effectiveness of screening programs. This focus on valuation of outcomes considered by the CTFPHC as most critical for decision-making is narrower than what some would consider to encompass patient preferences and values,[4] and we recognize that critical outcome valuations may be influenced by a broad array of other factors (valuation of other outcomes, beliefs, experiences) contributing to values/attitudes[5] of women towards breast cancer screening. Insight related to these factors, within the context of information on the benefits and harms of breast-cancer screening, may provide the CTFPHC with information to consider during deliberations about guideline feasibility, acceptability, and implementation.[3]

2. Methods

This systematic review was completed by the ERSC at the University of Alberta. The review was developed, conducted, and prepared according to the CTFPHC methods (http://canadiantaskforce.ca/methods/methods-manual/). A working group of CTFPHC members was formed for development of the topic, refinement of the research question and scope, and rating of patient-important outcomes considered critical for creating a recommendation. The protocol was registered with the International Prospective Registry of Systematic Reviews (PROSPERO) database (CRD42017058476).

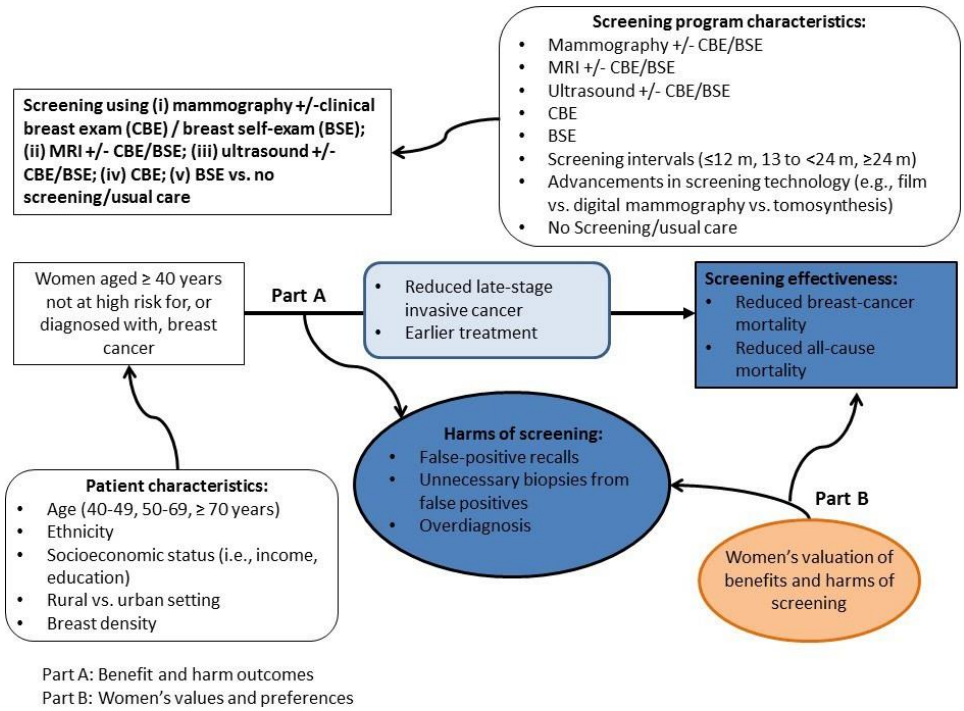
2.1 Key Question

How do women (a) weigh the benefits and harms of breast cancer screening, and (b) use this valuation in their decisions to undergo screening?

2.2 Analytical Framework

An analytical framework was developed for this guideline update. Figure 1 depicts both parts of the evidence review undertaken for this update, including the population and interventions of interest as well as the patient characteristics and outcomes. The outcomes rated by the CTFPHC as most critical for their decision making about breast cancer screening are classified as screening effectiveness and harms of screening.

Figure 1. Analytical Framework



2.3 Literature Search

An information specialist developed and implemented (to December 5, 2017), a peer-reviewed search strategy consisting of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords in four databases: MEDLINE (1946-) via Ovid, Cochrane Library via Wiley, CINAHL via EBSCOhost (1937-present), and PsycINFO via Ovid (1987-present). Methodological filters were not applied to limit retrieval by study design. Searches were restricted by language to include full texts published in English and French, with a publication date restriction of 2000 or later. The date of 2000 was chosen because this timeframe captures the period when the relative magnitude and weighing of both benefits and harms of breast cancer screening came under greater scrutiny.[6-8] The search strategy was adapted to accommodate the controlled vocabularies of each database. All database search strategies are included in **Appendix A**. Reference lists of all included studies and relevant systematic reviews were scanned for further studies. We searched for grey literature using the following websites: provincial cancer screening programs, BC Cancer Agency, Cancer Care Ontario, Canadian Partnership Against Cancers, Canadian Cancer Society, World Conference on Breast Cancer, other relevant stakeholder organization websites.

All results of the database searches were imported into an EndNote® database (Thomson Reuters, New York, NY) for reference citation, and, after duplicate removal, into DistillerSR (Evidence Partners Inc., Ottawa, Canada) for screening and selection procedures.

2.4 Inclusion and Exclusion Criteria

Studies were selected according to the inclusion and exclusion criteria outlined below and in Table 1. The key criterion was that the study must have incorporated an assessment (indirectly or directly) by the participants of the relative magnitude/incidence of benefits and harms determined by the CTFPHC as critical for decision-making about screening for breast cancer (via an independent rating procedure with critical outcomes rated as 7 or greater out of 9 for importance; see CTFPHC Manual for details). Critical benefits included breast-cancer and all-cause mortality reduction, and harms included false positives (FPs; recall after an initial mammogram for further examination or imaging that does not lead to breast cancer diagnosis), FPs requiring biopsy, and overdiagnosis (the diagnosis of disease that will never cause symptoms or death during the patient's normally expected lifetime). Weighing of outcomes may have been explicit within decision analysis/choice experiments or other studies generating ratings on (e.g., preference weights) or trade-offs between benefits and harms under consideration, or implicit such as when women were asked whether or not they intend to (continue to) screen based on information on benefits and harms presented within the study, or based on their past experience of an outcome from screening (e.g., past FP and after getting accurate information on benefits they are asked to decide if they will re-attend screening). Our protocol stipulated that all studies providing information to women in the form of decision aids would be excluded, because the object of our research was not evaluating how well women make decisions or how to best achieve informed decision making (e.g. comparison between different formats, delivery etc.). However, we realized that studies providing women with information in

the form of a decision aid or screening program leaflet could report on relevant outcomes (e.g., importance of benefit and harm information for their decisions, factors influencing outcome valuations) such that our criteria for inclusion was changed to consider these studies.

We used a hierarchy of evidence in terms of, 1) whether the findings represented women's consideration of benefits and harms (rather than harms alone or benefits alone), and 2) to what extent the findings were specific to the benefits and harms considered most critical for decision making by the CTFPHC.

Findings considered most directly related to the Key Question A (KQa) were those that were specific to one or more benefits and one or more harms determined critical by the CTFPHC; screening intentions after receiving information on benefits and harms were used to imply preference for or against screening (i.e., positive intentions implying that benefits were weighted as greater than harms). Studies that provided additional information, usually within decision aids or program pamphlets, on other outcomes (e.g., FNs, radiation) or aspects of decisions (e.g., personalized risk assessment) that may influence screening behaviors/intentions were considered indirect for KQa. Although indirect for KQa which was specific to CTFPHC benefits and harms, information on additional factors contributing to screening decisions from all studies was considered directly applicable for KQb. Studies were included regardless of the screening experience of the participants or their experience of the particular outcomes (e.g., FPs).

Table 1. Inclusion and exclusion criteria

	Inclusion	Exclusion
Population	Women aged ≥40 years of age and not at high-risk for breast cancer Subgroups: age (40-49, 50-69, 70 and older), ethnicity, including whether the women are from an indigenous population, socioeconomic status, geographical location (rural vs. urban settings) **Amendment to protocol during screening/data extraction**: We broadened our age criteria because of the high relevance of some studies enrolling women under 40 (e.g., aged 35-39 while making decisions to screen or not over the next few years) and others enrolled a broader age range yet the majority of participants were of ages considering screening. All studies were conducted with information/data provided on, and findings relevant to, screening women in their 40s or older. An additional subgroup of previous screening experience was also added.	Women with pre-existing or personal history of breast cancer; women considered to be at high-risk for breast cancer on the basis of extensive family history of breast or ovarian cancer or other personal risk factors, such as abnormal breast pathology or deleterious genetic mutations, having previous radiation treatment to the chest (such as Hodgkin's) for cancer. For studies with high-risk and not at high-risk as study groups, we will only use data from the not at high-risk group.
Intervention/Context	Screening for breast cancer using mammography, MRI, ultrasound, clinical breast examination, or breast self-examination Women will usually be provided with information (may not include estimates of effects) on the relative magnitude of critical CTFPHC benefits and harms of screening. Alternatives are when women who have experienced harms (false positives) are provided with information on benefits to make decisions for future screening, or when values for benefits and harms are explicitly elicited by studies. Information can be provided in written form or	

	orally.	
Comparators	Depending on study design, comparator may be no screening/another form of screening, or a different form of information that does not include the magnitude of effects for benefits and harms. Studies may not have a comparison. When only one arm (e.g., screening) of a comparative study is included in the assessment of patient preferences, this study will be classified as a non-comparative study. Comparator may be based on participant characteristics, such as age or socioeconomic status.	
Outcomes	• Willingness to be screened • Acceptability of screening • Uptake of screening • Willingness to pay for screening • Preference weights or utilities for benefits and harms • Relative ranking/rating of benefit and harm outcomes (e.g., ratings based on degree of importance) • Factors related to benefit and harm outcome valuation that contribute to choices for screening (e.g., severity of harm, age of women, availability of treatment, perceived risk for breast cancer) • Other outcomes will be considered (e.g., intent to return for another screen)	
Timing	2000-December 2017	
Settings	Primary care or other settings generalizable to primary care, including referrals by primary care providers	Any setting where it could not be reasonably generalizable to a Canadian screening context
Databases	Medline, Cochrane CENTRAL, CINAHL, PsycINFO	
Study designs	All experimental study designs, examples including: • Direct measurement of outcome utilities, e.g., utility-based stated and revealed preference studies such as contingent valuation studies including discrete choice experiments, willingness to pay • Indirect measurement of outcome utilities, e.g. quality of life or wellbeing measurements, including mapping/transforming of these to utility or health status utilities • Surveys or other studies using questions to rate or rank outcomes (e.g., visual analogue scales or rating scales) • Qualitative studies (These studies may be embedded within randomized controlled trials or other controlled study designs)	Commentaries, opinion, editorials, case reports, and reviews
Language	English and French	

Additional Eligibility Considerations

We did not have a minimum sample size for inclusion, nor did we have a minimum threshold for factors associated with internal validity (e.g., extent of incomplete follow-up or participant attrition). Case reports were excluded, as were papers not reporting primary research (e.g., editorials, commentaries, opinion pieces). Conference abstracts and systematic reviews were not eligible for inclusion, but were examined and served to help identify full study reports.

2.5 Study Selection

For the database searches, two reviewers independently screened the titles and abstracts (when available) using broad inclusion/exclusion criteria. Citations were classified as "include/unsure," "exclude," or "reference" (i.e., conference abstracts, protocols, and systematic reviews). The full text of all studies classified as "include/unsure" from the database searches were independently reviewed by two reviewers using a standard form outlining the inclusion and exclusion criteria. One reviewer examined the "reference" group further, and this reviewer and the librarian conducted all grey literature searches. Disagreements on final inclusion of all studies were resolved through consensus or consultation with a third reviewer. The title/abstract screening and full-text selection processes were conducted and documented in DistillerSR. The flow of literature and reasons for full text exclusions were recorded in a PRISMA Flow Chart.

2.6 Data Extraction and Management

One reviewer independently extracted data into DistillerSR from each included study; a second reviewer verified all data. Disagreements were resolved through discussion or consultation with a third reviewer until consensus was reached.

Study characteristics tables were created for each study and a narrative summary was written to summarize all studies by design, country of origin, sample sizes, population(s) (including subgroups), intervention(s) or survey/interview topics, information provided to participants on CTFPHC benefits and harms and other outcomes, comparator(s) as applicable, and findings, as reported by study authors.

2.7 Methodological Quality Assessment

Tools for assessing methodological quality were chosen based on study design. Critical appraisal tools from the Critical Appraisal Skills Programme (CASP; http://www.casp-uk.net/casp-tools-checklists) and the Centre for Evidence-Based Management (CEBM; http://www.cebma.org/resources-and-tools/what-is-critical-appraisal/) were used for qualitative and cross-sectional/survey studies, respectively. We used the Cochrane Risk of Bias tool[9] to evaluate the risk of bias in controlled trials when the data for both/all groups was relevant to the KQ. We did not use a specific tool for utility/preference based studies but rather comment on key study characteristics which may be associated with biased results.[10] We report on these assessments in summary tables with comments based on individual questions/domains; some questions within the CASP and CEBM tools are more applicable to external validity (e.g., representativeness of study population) and we comment on these separately. Guidance exists for assessing the quality of the body of evidence (i.e., across studies) for outcomes in reviews on intervention effectiveness and qualitative research,[11, 12] but is not yet available for this review type incorporating diverse study designs to address questions on patient preferences. Nevertheless, for each of our findings summary statements we comment as able on the quantity (to reflect, in part, consistency and adequacy), methodological quality (fair, good, or high; based on key domains within tools and judged across the relevant studies), and applicability/relevance of the contributing studies.

2.8 Data Analysis

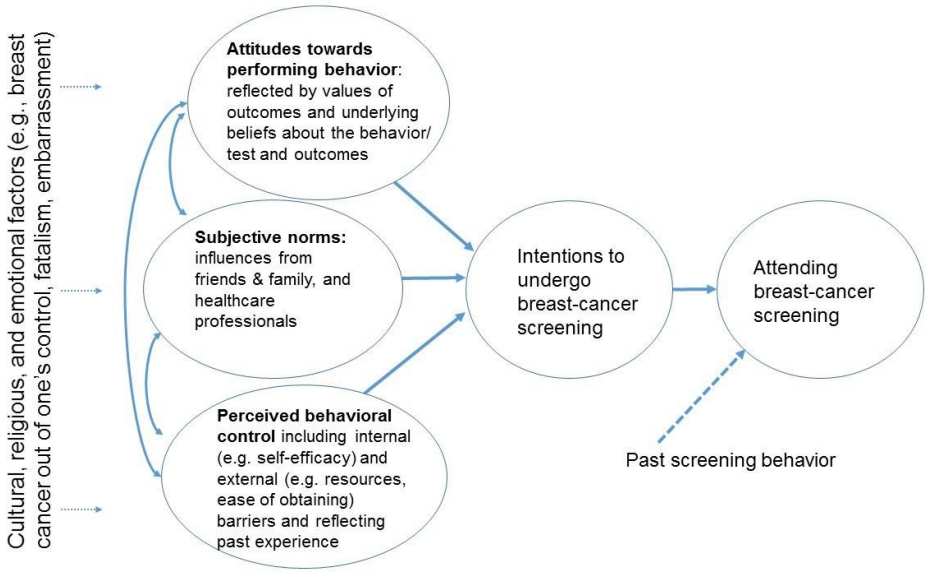
Study characteristics and findings were summarized narratively and are presented in summary tables. They were also extracted into an excel file, with similar findings (e.g., intent to screen, beliefs around screening) grouped into columns and coding for study and population characteristics (e.g., previous screening, age, information provided), to facilitate comparisons between studies. We report qualitative findings alongside quantitative findings when appropriate (e.g., both indicating relative preference for one outcome compared with another) or to help describe quantitative findings (e.g., why women may have chosen a particular outcome as most/least important). Some qualitative findings were used for answering KQb describing factors besides outcome valuation that may be important for decision making by women about breast-cancer screening.

Upon examination of the study characteristics across the included studies—and considering the key subgroup of age (40-49, 50-69, 70+ yrs)—it became evident that key groupings related to important variables of the participants and interventions would be useful for synthesizing the findings. Studies were grouped based on age (of participants and relevancy of information on outcomes provided), breast-cancer screening history of the participants, and the relative magnitude of the benefit-to-harm ratio of screening in scenarios presented to women; we judged the benefit-to-harm ratio information in each study on a 5-point scale (low, moderate/low, moderate, high/moderate, high), while considering its relevant age category as well as the completeness of data (e.g., inclusion of all critical outcomes), magnitudes of effect, and how presentation of the data would likely influence perceptions by women (e.g., relative effect estimates were thought to portray higher benefit than were natural frequencies). Lack of information on one or more outcomes (e.g., overdiagnosis or all-cause mortality) was considered most (potentially) influential to findings and specific comments are provided as applicable. Studies were also grouped according to our previously described hierarchy of the directness of the findings with respect to the CTFPHC critical outcomes. Those that provided findings that were not specific to CTFPHC critical benefits and harms, usually via screening intentions of woman based on effect estimates for these outcomes but also other information within decision aids or program leaflets, are analyzed separately and considered of less direct relevance to KQ2a. Our interpretations of the study findings include critical inferences on the differences between studies in relation to their populations, interventions (numerical data provided to women, other features), and their outcomes; cases where the data provided to women about screening outcomes appeared to differ substantially (i.e., higher benefit-to-harm ratio) from what the CTFPHC might consider more realistic were still considered to provide useful input towards our synthesis.

To interpret the findings for KQb on how and to what extent women use their critical outcome valuation in their decisions to screen, we contextualized the findings within a well-validated theory used to predict and explain human behavior in specific contexts—the Theory of Planned Behavior,[13] as well as empirical evidence explaining how additional factors are predictive of screening behaviors.[5, 14-17] The general framework we used for our synthesis is presented in **Figure 2**. The relative importance of attitudes (overall values), subjective norms (influencers), and perceived behavioral control (internal and external

barriers) in the prediction of intention is expected to vary across behaviors and situations.[13] The Theory of Planned Behavior is open to the inclusion of additional predictors if it can be shown that they capture a significant proportion of the variance in intention or behavior after the theory's current variables have been taken into account.[13] For instance, the theory's focus on cognition may not adequately explain how emotional, religious, and cultural factors contribute to behaviors.[15, 18] Moreover, while past experience of behaviors will influence perceived behavioral control, it may bypass the rest of the model and be so predictive of mammography screening that it merits more attention.[14, 15, 17]

Figure 2. Theory of Planned Behavior applied to breast cancer screening, with extensions for past screening behaviors, and recognition of emotional, religious, and cultural factors (adapted from Ajzen, Griva, Marteau)[5, 13, 15]



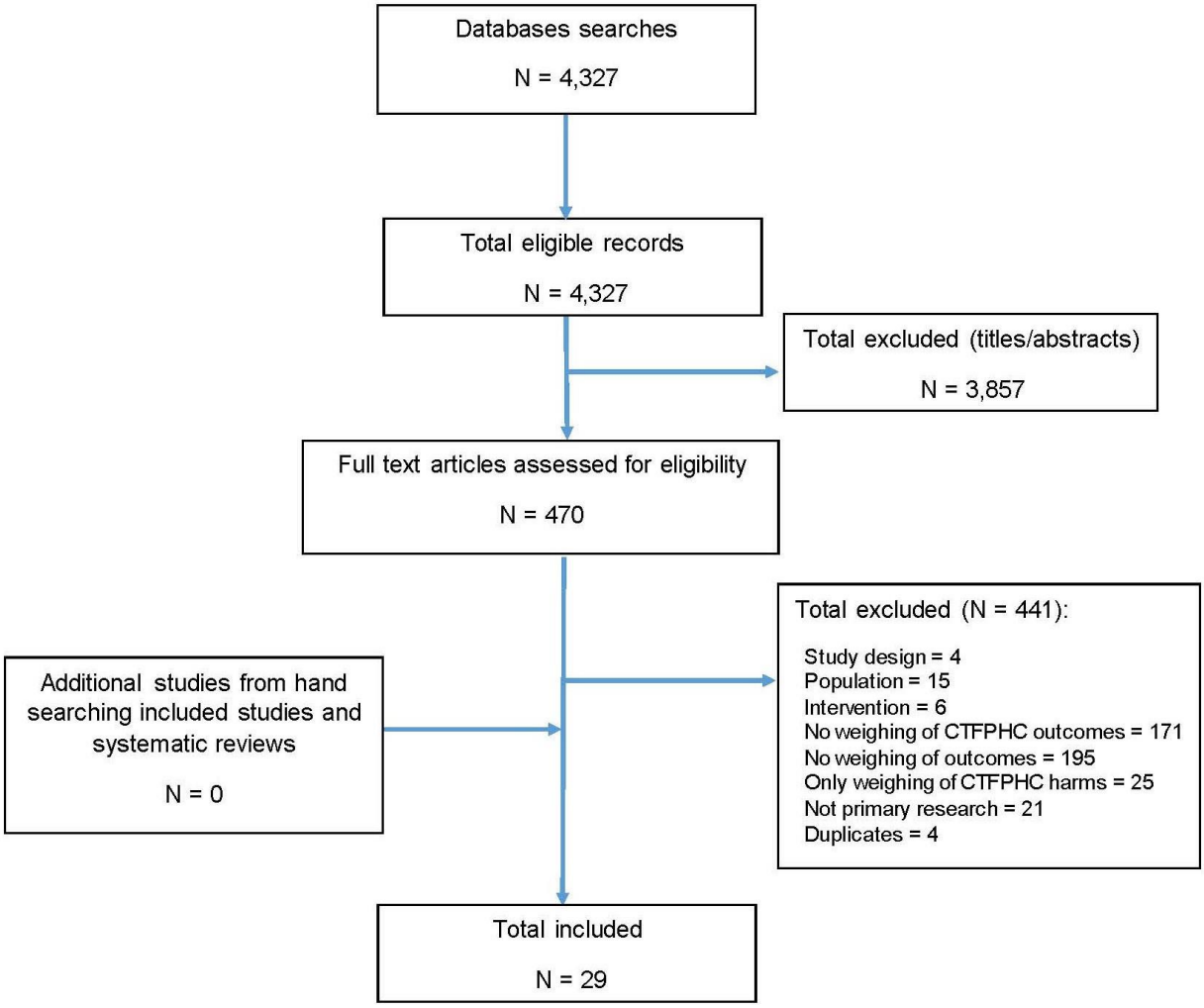
3. Results

3.1 Search Results and Study Selection

Our database searches identified 4,327 citations after removal of duplicates. After exclusion of 3,857 citations during title and abstract review, we assessed the full-text of 441 publications and included 29 studies (**Figure 3**).[19-47] Review of reference lists of all included studies and relevant systematic reviews (n=17) did not locate any additional studies for inclusion; nor did search of websites (n=11) during grey literature searching. The selection process was iterative, such that several studies (n=25) providing findings relevant to harms only (e.g., re-attendance rates or patient-reported outcomes based on FPs with and without biopsy) were initially considered until it was apparent that we had a substantial number of studies evaluating benefits versus harms. Studies only reporting valuation of harms were thought to provide very indirect data because of lack of context around accurate information on benefits. Many studies (n=162) were excluded because they assessed outcome valuation for benefits and harms not rated by the CTFPHC as critical for decision making (e.g., early detection of cancer or reassurance was

frequently evaluated as the only benefit[s] of mammography); several of these studies applied theoretical models such as the Health Belief model to determine why women may or may not screen, in order to design interventions for increasing uptake of screening. Some evaluated decision aids developed using patient and expert and/or stakeholder input on outcomes of importance, but did not include information on breast-cancer or all-cause mortality.[48, 49] Some others evaluated women's attitudes towards breast-cancer screening controversies, or changes to screening recommendations for younger women, but only provided women with general impressions (rather than effect estimates) about the potentially lower benefit-to-harm ratio.[50-53] The CTFPHC Breast Cancer working group provided input during selection, but was unaware of study findings until after final study selection. We contacted authors when there was uncertainty about the information provided to the women. A list of systematic reviews and of excluded studies with reasons for exclusion is supplied in **Appendix B**.

Figure 3. Flow of literature through the screening and selection processes



CTFPHC B&H = benefits and harms rated as critical for decision making by the Canadian Task Force for Preventive Health Care Breast Cancer Screening Working group; N = number

3.2 Study Characteristics

Tables 2 and 3 provide characteristics and findings directly (Table 2) or indirectly (Table 3) relevant to KQa; both tables are considered directly applicable to KQb (see section on Inclusion and Exclusion Criteria for description of directness). Studies were published between 2000 and 2017, with 19 published after 2010. Studies were conducted in 10 countries: United States (US; n=10), Australia (n=5), United Kingdom (UK; n=3), Denmark (n=2), Germany (n=2), Spain (n=2), one each in Canada, France, New Zealand, Hong Kong, and Japan. Study designs and sample sizes varied widely; five were qualitative (n=6 to 50)[23, 28, 30, 42, 44] and 24 were primarily quantitative including nine randomized controlled trials (RCTs; n=35 to 16,000)[19, 21, 25, 27, 29, 33, 34, 38, 41] usually comparing brochures or decision aids having numerical information on outcomes with standard brochures lacking this information, one single-arm trial,[24] eight cross-sectional surveys/questionnaires (n=90 to 4,113), [20, 22, 31, 35, 37, 40, 43, 46] three pre-post studies (n=45 to 2,272),[32, 39, 45] two stated preference studies (n=207 to 397),[26, 47] and a deliberative jury (n=12).[36] Along with quantitative findings, three studies[31, 36, 43] provided some findings based on descriptive analysis of participants' narratives (e.g., free-text answers in surveys). All studies focused on screening with mammography.

Study authors used a variety of information sources for determining what data to present to women in their methods/decision aids. All studies reporting on breast-cancer mortality indicated some degree of benefit (range 0.5 to 5 fewer in 1000 screened over 10 to 20 yrs), while those including all-cause mortality used no effect as their estimate. Differences between the estimates (mainly for breast-cancer mortality) will have largely depended on the assumed breast-cancer mortality control event rate (baseline risk),[54] the choice by some to increase the magnitude of effects to reflect longer screening periods than studied in the available RCTs on screening (i.e., over 20 yrs of screening rather than 5-10 yrs as studied), and the assumption of 100% screening attendance (increasing rates of benefits and harms) that some authors prefer for decision aids supporting individual women's choices.[55] Studies varied widely in terms of what critical outcomes were included and how the effects were presented (Tables 2 and 3). Twenty-four studies (83%) did not present (or elicit) data/information on all-cause mortality. Four studies[21, 27, 46, 47] (14%) used relative rather than absolute effects (natural frequencies) for breast-cancer mortality. Of the 25 studies using absolute effects, 23 applied the same denominator for both benefits and harms; the denominator was usually 1000 or 200, although the study in Canada using the CTFPHC 2011 guideline estimates of effect to communicate screening outcomes (via person diagrams) used number-needed-to-screen values (e.g., 2108 NNS to prevent 1 BC death) but positioned the harms in the same denominator (e.g., 690 FPs and 75 biopsies in 2108 screened).[23] One other study[40] elicited a trade-off for FPs and breast-cancer mortality, and another used different denominators (1 life saved in 400 screened vs. 1-3 of 8 overdiagnosed cancers in 1000 screened).[44] Twenty-two of the 23 studies using absolute effects with similar denominators also provided information using comparisons with women who do not screen. One study only compared outcomes in screened women based on differing ages to start screening (40 vs. 50) and different intervals (annually vs biennially).[24] Descriptions of overdiagnosis were fairly similar across studies (e.g., diagnosis that may never have caused problems during one's lifetime but will usually be treated), although some studies provided verbal explanations and/or illustrations to attempt greater

understanding and no paper explicitly reported that overdiagnosis may cause unnecessary psychosocial consequences due to having a breast cancer diagnosis. Further, in some cases[31, 40, 44, 45] overdiagnosis was primarily discussed/defined in relation to ductal-carcinoma in situ (DCIS) or "slow growing cancers" even though there is overdiagnosis in invasive cancers. One recent study defined overdiagnosis as "suspicious" cells without mention of a cancer diagnosis.[41] FPs were associated with a description of additional tests and possible worry or fear in most studies, although none stated the possibility of adverse effects from surgical biopsies. None of the study findings directly compared FP recalls with FP recalls requiring biopsy in terms of their relative importance.

Our judgements of the relative benefit-to-harm ratio across studies tried to account for these factors while also accounting for differences in effects between ages that are typically reflected in the literature. For example, studies providing data using relative rather than absolute effect sizes were judged as providing high or high/moderate benefit-to-harm ratios, as were those only reporting on breast-cancer mortality (all-cause mortality, when included, was always assumed to be of no benefit) especially when also excluding overdiagnosis. The benefit-to-harm ratio data for most studies was higher than we would judge as resulting based on the findings from Part A of the evidence update (i.e., low benefit-to-harm) (Part A is available at https://canadiantaskforce.ca/). We also provide comments throughout, about specific deficiencies or concerns related to aspects of the presented information that are strongly suspected to bias findings.

Table 2 includes characteristics and findings from 13 studies. [22, 23, 26, 29, 30, 32, 35, 37, 40, 43, 45-47] Five studies provided findings relevant to women in their 40s. Two studies[32, 35] in the US provided data using a survey[35] or videos[32] using estimates on breast-cancer mortality reduction and FPs. One study[35] enrolled women aged 40-44 without screening experience, and in the other in women aged 35-49,[32] 75% had screened. Both samples included a subgroup (20% and 40%) of African American women; otherwise, education and incomes were diverse although 100% and 80% had healthcare insurance and all women spoke English. The Canadian study (in Toronto and Winnipeg) employed maximum variation sampling to recruit women for five focus groups, four of which were stratified by age (35-49 vs 45-59), although ended up with a sample skewed to a higher educational level; most of the women under 45 had not screened while 100% in their 50s had screened previously. No information on participant ethnicity was provided. The authors used presentations and print-outs of person-diagrams of the data (40-49 and 50-59 years) from the CTFPHC 2011 guideline, which included estimates for breast-cancer mortality, FPs and FPs requiring biopsies, to gather input on when women should start screening and the relative importance of breast-cancer mortality versus FPs. A focus group study[30] in Australia included effect estimates (by age) for breast-cancer mortality versus differing rates of overdiagnosis. A proportion (% not reported) of these women had screened, and the authors used a random community sample with purposive sampling for diverse education levels. Wong et al.[46] enrolled Chinese women having diverse education and income levels; previous rates of screening and FPs were not reported although only 19% of this sample had heard about mammography prior to the study. Breast-cancer screening in Hong Kong requires a minimal user charge for all women. No study concerning this age group in Table 2 mentioned all-cause mortality.

Five studies in Table 2 focused on women in their 50s and 60s.[22, 29, 37, 45, 47] Three studies[22, 37, 47] enrolled a sample of women with mixed screening experiences; two employed a sampling method to obtain a fairly representative sample in the US[37] and Japan,[47] and another in Australia[22] used convenience sampling which obtained a diverse sample in terms of socioeconomic status but with a high proportion (91%) of women having previously screened. Two other studies either enrolled women without screening experience[29] or into groups based on experience.[45] Both attempted to obtain a representative sample, although the RCT[29] in Australia recruited women with a high level of education (about 72% college educated) and unknown ethnicity, and the study in the UK did not report their demographics. None of the studies provided information on, or elicited values based on, all of the CTFPHC outcomes; three considered overdiagnosis (but not all-cause mortality),[29, 37, 45] and one considered all-cause mortality (but not overdiagnosis).[22]

The three remaining studies in Table 2[26, 40, 43] elicited values for breast-cancer screening outcomes for women in their 50s rather than obtaining valuations based on specific data. Two of the studies recruited women of varying ages (≥18 years) although oversampled for screening ages such that a majority of participants were older than 40. The sample in the UK study[43] was drawn from a research panel representative of the population for age and sex, but with less ethnic diversity and lower than the national screening history. The US sample of Schwartz et al.'s[40] had relatively higher screening rates (76%; 16% with previous FP biopsy) but was similar to the UK study with respect to limited diversity (90% Caucasian). Gyrd-Hanson's[26] discrete choice experiment with choice sets on breast-cancer mortality and FPs enrolled 50-year old Danish women drawn from the national registry and had a response rate of 82%.

Table 3 contains characteristics and findings from 16 studies providing indirect evidence for KQ2a[19-21, 24, 25, 27, 28, 31, 33, 34, 36, 38, 39, 41, 42, 44] All studies provided numerical data for breast-cancer mortality and FPs, all but three[21, 24, 27] provided information on overdiagnosis, and only four provided information about all-cause mortality.[28, 33, 34, 36] Six studies provided data reflecting what was judged to be a relatively low or moderate-to-low benefit-to-harm ratio.[19, 28, 33, 34, 36, 38]

Younger women were targeted in five studies in the US (n=3), Australia, and New Zealand. Two of these compared decision aids designed for women in their 40s with a control intervention (n=35; ages 40-49)[38] or delayed access to the aid (n=412; ages 38-45).[34] Two studies presented data for women in their 40s and their 50s to find out how many women would wait until they reached 50 to start screening.[24, 41] In another study, the authors conducted a deliberative jury (n=12; ages 40-49)[36] where women were exposed to conflicting and neutral expert views on breast-cancer screening, a decision aid for women in their 40s, and undertook within-group deliberations. Information provided within these studies reflected lower benefit-to-harm ratios (i.e., reflective of lower breast cancer risk for women in their 40s and more FPs from screening) compared with studies of women in older age categories. All studies included some women who had previous screening history, although there was variability in the numbers.

Nine studies focused on women in their 50s and 60s. Three recruited women recently or soon to be eligible for screening in Germany (n=4,466)[20, 25] and Denmark (n=6).[28] In the six other studies,[19, 21, 27, 31, 42, 44] many of the participants (studies in UK, US, Spain) had previous screening experience except for in

one study in France (46% past screening). Only one small study in the 50-59 age category presented data on all-cause mortality. Although it would be expected that these studies present outcome data showing a slightly greater benefit-to-harm ratio than for women in their 40s, all but two studies[19, 28] were still considered to present relatively beneficial data.

Two remaining studies in Table 3 investigated the intentions of women to continue screening in their mid-to-late (n=45)[39] and early (n=734)[33] 70s, living in the US and Australia. One of these[39] explicitly described how women in their 70s may have more overdiagnosis (e.g., because of "slower growing cancers" and competing causes of death); the other[33] also included data for all-cause mortality.

Studies in Table 3 of women in their 40s or 70s were explicitly given the indication that breast-cancer screening was a choice to be made rather than a firm prescription.[33, 34, 36, 39]

3.3 Methodological Quality & Applicability

The methodological quality assessments are presented in **Tables 4 to 6**. In each table, studies are divided by whether they are related to findings in Tables 2 and 3, respectively. The five qualitative studies were generally of high quality. Description of the researcher-participant relationship was either not mentioned or inadequate. One study[28] had a very small sample size (n=6) and there was some concern that the findings may have been influenced by this, particularly with the authors' stated intent to have a diverse sample representing differing socioeconomic status. Two of the nine RCTs were considered to have high risk of bias for lack of blinding[19] and/or incomplete outcome reporting (38% of intervention group withdrew during online decision aid study vs 4% in delayed control group who only completed outcome assessment).[34] Apart from this RCT conducted online, most others recruited, obtained informed consent, and collected outcome data during one contact with participants such that incomplete outcome data was generally low. Issues of main consideration related to internal validity for the 12 survey/cross-sectional studies were lack of pre-determined sample sizes (n=5) and no reporting of confidence intervals (n=5). Response rates were classified as satisfactory when authors obtained ≥50% response (n=5), and unclear when rates were <50% (n=5) or unreported (n=3).

We did not apply a standard tool for the two stated preference studies, or for the deliberative jury. For the utility-based (economic theory-derived) preference studies, we assessed their methods in terms of commonly applied considerations.[10] The discrete ranking study conducted by Gyrd-Hansen et al.,[26] 1) employed structured pre-test procedures to introduce the women to the outcomes described in the cards presented, on which they were asked to rank four scenarios, 2) obtained good representation for the target population (n=207; 82% response from random sampling), 3) applied adequate methods and statistical analysis (lack of factorial design which may have enhanced rigor), and 4) considered important confounders in their analysis (e.g. education, number of screening tests over lifetime); they did not appear to represent the most important outcomes for women, as per alternative motivators/outcomes reported by the women to influence their rankings. Yasunaga et al.'s[47] contingent valuation study, estimating willingness-to-pay, was conducted online and was judged to offer less structured pre-testing procedures

and some concern over representativeness (33% response of random sample), but application of appropriate methods and statistical analysis for this type of study, including exploration of possible confounders. The deliberative jury[36] appeared to be well-conducted with the exception of unknown representativeness of the county's women citizens which is a main feature of this study design (fairness and competence);[56] rather than carefully selecting participants to represent the population demographics, the "first twelve" women within a random sample that agreed to participate were chosen and insufficient data was provided about their socio-demographics to make judgements. Moreover, other factors such as affiliations with special interest groups, or employment in health-care delivery or government, are generally considered as exclusionary for capturing "citizen's" views.[56] In contrast to general principles for citizen juries, the authors clearly state their study did not include a steering group of relevant stakeholders, or delivery of recommendations to those with the authority to recommend them; this may have impacted the findings to some degree if the women participants did not feel their decisions would be seriously considered by key decision makers.

More of an issue for external rather than internal validity, many studies lacked high representativeness with respect to their intended study population; samples recruited were often more educated and less ethnically diverse than would be representative of the country's screening program target audience. Most studies across all designs were conducted using the dominant/official language of the respective country, such that foreign-born women new to the respective country and only speaking another language will not have been represented.

3.4 KQa: How do women weigh the benefits and harms of breast cancer screening?

3.4.1 Weighing Benefits Versus Harms: Data Specific to CTFPHC Critical Outcomes (Table 2)

3.4.1.1 40-49 Age Group

Key Findings:

- **Breast-cancer mortality data was thought more important than that on FPs for making decisions in one's 40s (3 studies, fair-to-good methodological quality).**
- **Overdiagnosis appears to have a greater impact than do FP rates in benefit-to-harm ratio considerations, although the threshold for this harm may be fairly high even when the scenario provided indicates the benefits are relatively small (2 studies, reliance on 1 high-quality study with most applicability and using absolute effects)**
- **Scenarios provided to women indicated relatively higher benefits than harms, with no presentation on the possibility of no reduction in all-cause mortality.**

Detailed Findings:

In focus groups communicating data in verbal presentations and print materials, including icon arrays, representing the outcomes for women in their 40s (NNS 2108 for saving 1 breast-cancer death, and

causing 690 FPs and 75 biopsies) and their 50s (NNS 721 for 1 live saved, 204 FPs and 26 biopsies) reported by the CTFPHC in 2011, Dreidger et al.[23] asked 46 women aged 35-59 to state the age they thought was best for women to start screening. The participants younger than 50 were more likely (41%) than those older than 50 (29%) to choose 50 years for starting to screen; 21% and 35% choose age 40, and 38% and 35% were unclear, respectively. The few women overall (13%; most <50 years) stating that the harms were of greater concern than the benefits for women in their 40s, and the large differential between the outcomes for breast-cancer mortality between age groups (NNS 2108 vs 721), suggest that the women focused more on mortality outcomes when choosing ages to start screening. Based on the discussions within focus groups, a large contributor to the reason for the difference in findings by age was that younger women had less affective attachments to "early detection" messages, fewer screening experiences (making this "routine"), and fewer opportunities to know someone with breast cancer (increasing fear and anxiety).

Nekhlyudov et al.[35] asked 93 women to state the effects of the information provided for various outcomes in terms of whether it made them more likely, no more likely, or less likely to screen; breast-cancer mortality data (1 saved in 1000 screened regularly during 40s) made 56% of women more likely and 4% less likely to screen, whereas when the proportions for FPs rates were presented (using a different denominator [10 in 100 screens]) 29% were more likely and 2% were less likely to screen. Previous screening (75%) did not seem to make a difference in the study by Lewis et al.[32], where 83% of women (n=179) thought benefit data (1 life extended in 1000 over 10 yrs) was more important (75% thought much more important) than harms data (300 FPs in 1000 over 10 yrs), although their experience was likely limited to few screening rounds because of their age. Neither study provided results of statistical tests.

Hersch et al.[30] facilitated focus groups with 50 women of multiple ages in Australia, and provided data indicating a lower benefit-to-harm ratio for the 40-49 age category compared with the 50-59 and 60-69 age categories (0.5 vs. 2 and 3 lives saved in 1000 over 10yrs) together with various possibilities for overdiagnosis (<1 up to 4 [1-10%], 11 [30%] or 19 [50%] of 38 diagnoses in 1000 over 10 yrs); most women agreed that while the 1-10% and 30% numbers for overdiagnosis were negligible and acceptable, respectively, the 50% figure may be unacceptable for some women. Younger women in this study made comments regarding the 50% data, thinking women in their age group would choose to delay screening until an older age where data showed greater benefit. Of note, all quotations within this report cite women using the (larger) percentage values (e.g., 30 or 50%) rather than the natural frequency data (11 or 19 in 1000 screened). In Wong et al.[46] (n=90), data on overdiagnosis (19% without natural frequencies) was not thought to factor much into decisions to screen for many women (important for 5% of women vs. 5% for FPs and 22% for breast-cancer mortality) although the breast-cancer mortality data using a relative risk reduction (20%) may have been perceived as more beneficial than that provided by Hersch et al. The study of Wong, though, also provided information on lower breast-cancer risk for women in Hong Kong which may have further reduced the perceived beneficial effects of screening. Taken together and considering that the Australian population represented in the study by Hersch et al. likely reflects a

population more similar to Canada where women are actively considering screening and more knowledgeable about mammography (e.g., in Wong et al. 88% of women at follow-up still thought that screening prevented breast cancer), the findings suggest that overdiagnosis appears to be of greater importance than FPs and of less importance than expected breast-cancer mortality reductions, unless the rates of overdiagnosis become fairly high (e.g., well above 11 per 1000 screened/30% of diagnoses).

The importance of estimates of overdiagnosis and/or FPs may be underestimated because of lack of data on all-cause mortality which would reduce the overall benefit.

3.4.1.2 50-69 Age Group

Key Findings:

- **Compared with breast-cancer mortality, FP rates of any magnitude may weigh considerably less in decisions of women aged 50-69 to screen (3 studies; good methodological quality).**
- **Presenting data on all-cause mortality reduced intentions to screen for about a third of the women in one good-quality study[22] who initially intended to screen based on a reduced risk for breast-cancer death (2 in 1000) and a small risk for FPs (50 in 1000).**
- **From two high-quality studies[29, 30] that were judged to provide the most extensive descriptions of overdiagnosis, this harm may outweigh breast-cancer mortality benefit for a small but important proportion of women during their 50s and 60s, particularly if rates of overdiagnosis are assumed to be high (e.g., greater than 30% [11 of 38 diagnosed in 1000 screened] of diagnoses).**
- **Previous screening experience likely competes with outcome valuations during decision-making (6 studies; good methodological quality).**
- **Most studies presented data reflecting a high/moderate or moderate benefit-to-harm ratio, with none providing information on all the CTFPHC outcomes (only 1 on all-cause mortality).**
- **Findings from three good-quality studies[26, 40, 43] eliciting data on critical outcomes appeared to agree with those where authors provided data a defined set of outcome estimates. Findings in one study[43] of a high acceptance rate for overdiagnosis (at least 120 for 1 or 250 for 5 saved lives in 1000 screened) may have been influenced by the broader age range in this study and by the brief outcome description. Lack of consideration of all-cause mortality is also of concern.**

Detailed Findings:

Three studies[22, 29, 47] compared **breast-cancer mortality with FP rates** using breast-cancer mortality data more representative for the 50-age category. One of these studies included findings related to all-cause mortality. In a contingent valuation study, Yasunaga et al.[47] presented relatively high benefit-to-harm ratio data to 397 Japanese women in two scenarios using relative reductions in breast-cancer mortality (RRR 20%) with and without FP imaging with biopsy (mostly fine-needle) rates (803 in 10000 screens). These authors found that women were significantly (p=0.02) more willing-to-pay (WTP) for a reduction

in breast-cancer mortality ($16.82) than for this benefit plus the addition of FPs ($12.89). The WTP for the mortality reduction may have been inflated because of provision of information using relative effects. Likewise, a relatively large reduction in WTP when presented with FP data may be in part a reflection of the large numerical (803) presented and the implication that all FPs require biopsy. Women with previous screening history (38%) had a higher WTP in both scenarios and this effect on WTP was greater than the scenario data; regression coefficients for WTP were 0.338 by type of information and -0.632 for previous screening (both $p \leq 0.01$). In Davey et al.[22] where 106 women in Australia were sequentially presented with four scenarios (stated as hypothetical for a new breast-cancer screening test) using different outcome and probability data, breast-cancer mortality (using both absolute [2 fewer in 1000] or relative [34%] reductions and expressed over 10 yrs) and FP recall rates (50 in 1000 screens) were seen as very important or important for 95% and 87% of participants ($p<0.01$), respectively. Willingness to be screened was similar when considering breast-cancer mortality before (78%) and after presentation of FP data (79%). This study also found that women were less willing to be screened after being presented with information on all-cause mortality (no reduction; 53% willing) after that on breast-cancer mortality (2 saved in 1000; 78% willing). Because of this it appears that many women thought breast-cancer mortality is beneficial regardless of no change to all-cause mortality. Based on higher (91%) baseline rates of previous screening compared with stated willingness to screen of around 80% when presented with a "hypothetical" benefit-to-harm ratio, the data suggest that at least 10%, but perhaps more if considering all-cause mortality valuations, of participants may attend screening despite lower personal valuations of the benefit-to-harm ratio actually offered by the programs. The benefit-to-harm ratio presented to participants was relatively high in this study, such that if lower mortality benefit (e.g., 20% RRR or 1 fewer death in 1000), cumulative FPs, or overdiagnosis had been presented there is a possibility this may further reduce their stated willingness. Changing rates of FPs may not be a major factor, though, as suggested by the third study of Hersch et al.[29] The control group in this Australian trial (n=879) received similar data on breast-cancer mortality (4 lives saved in 1000 over 20 yrs) but cumulative FP rates (412 in 1000 over 20 yrs; 27 requiring biopsy), without a significant change in (high) intentions to start screening for the women aged 48-50 without screening experience (pre-test 91% vs post-test 87%). Breast-cancer mortality reduction was thought more important for decision making (79%) than were FP rates (52%).

Previous screening experience may compete with breast-cancer mortality versus FP valuation as a factor during decision-making about screening. In one study,[47] WTP was higher for the study subgroup with previous screening, regardless of the benefit-to-harm ratio. In another study,[22] rates of previous screening were higher than suggested by women's outcome valuations for a "hypothetical" new breast cancer screening test. Moreover, in the Canadian study[23] described above in the 40-49 age category which compared outcomes for women in their 40s and 50s, more participants above the age of 50 (100% previously screening vs. few in those <45 yr group) compared with below 50 favored starting to screen at 40 years. Conversely, women without screening experience in the study by Hersch[29] had high intentions to screen despite a similar benefit-to-harm ratio to other studies The longer timeframe used for the benefits (model estimates for 20 yrs vs. 10 yrs in others) which led to higher absolute numbers of breast cancer deaths saved (4 in 1000) may have led to perceptions of greater overall benefit in this study.

Five studies[29, 30, 37, 45, 46] provided data to women comparing effects for **breast-cancer mortality and overdiagnosis**. As mentioned above in the 40-year age data category, Hersch et al.[30] employed focus groups with women of varying ages with data presented by age for breast cancer mortality (2 lives [50-59] and 3 lives [60-69] saved in 1000 over 10 yrs) and for varying levels of overdiagnosis (<1 up to 4 [1-10%], 11 [30%] or 19 [50%] of 38 diagnosed in 1000 screened). While the 1-10% and 30% overdiagnosis rates were found negligible and acceptable, respectively, many women thought the 50% figure was potentially unacceptable for some women and may lead to avoiding, delaying, or being less rigorous with screening attendance. Regular screenees were less concerned than those with no/less experience. The intervention group in another RCT (n=879) by Hersch et al.[29] was provided with explanation and data (all for 1000 screened over 20 yrs) on overdiagnosis (26% of 73 diagnoses) in addition to that for breast-cancer mortality (4 lives saved) and FP rates (412) also received by the control group. Intentions to start screening (very likely or likely) reduced between pre- and post-testing to a greater extent in the intervention than control group (89% to 74% vs 91% to 87%; $p<0.0001$). The relative importance between the three outcomes were similar between the groups at follow-up (breast-cancer mortality important for 67 vs 79%; FPs 41 vs 52%; overdiagnosis 45 vs 57%; control group only exposed to overdiagnosis concept in follow-up questionnaire as "be(ing) diagnosed and treated for a breast cancer that is not harmful"), although the intervention group thought all outcomes were of less importance to their decision-making which might reflect their overall lower intentions/perceived value to screen. These findings are somewhat similar to those reported by Wong et al.[46], indicating that data on FPs (importance for 5% of women) and overdiagnosis (5% of women) were of similar and considerably less importance than that on breast-cancer mortality (22% of women) for decision making. Lower proportions of women perceiving the outcomes as important in this study versus that of Hersch et al. may reflect the study population in Wong et al. in which many women may not have been actively contemplating screening (<20% had heard of mammography at baseline). Waller et al.[45] provided outcome data for a reduction in breast-cancer mortality-to-overdiagnosis ratio using three different formats (all reflecting a ratio of 1 life saved to 3 overdiagnoses). In both groups of women enrolled based on eligibility for screening in the UK (954 eligible women ≥53yrs [100% screened in past] vs. 1318 not yet eligible 25-46 yrs; excluded 46-52 yrs to avoid overlap in screening experience), there was no difference between pre- and post-testing for overall intentions to screen (probably/definitely) within or between groups (all intentions about 90%). Some women in both groups (eligible 4.5%; not yet eligible 8%) reduced their intentions by at least one level when considering the five levels assessed (yes definitely to no definitely). The women stating reduced intentions were quite likely to be those receiving the basic ratio 1:3 format ("for every 1 life saved, 3 women will be overdiagnosed") because this was found to be a significant factor for reducing intentions (OR, 1.96; 95% CI, 1.33 to 2.89) compared with the other formats using higher numerical values and textual formats (1330 lives saved vs 4000 overdiagnoses and "for every 200 women screened there are 1 life saved and 3 overdiagnoses"). The fifth study[37] employed a larger sampling age frame (n=355, 18-85yrs, mean age 38±14) and used different formats (data text, fact box, visual aid; no differences between findings) for providing information on breast-cancer mortality (1 saved in 1000 screened over 10 yrs) and overdiagnosis (5 in 1000 screened over 10 yrs) with specification that these

applied to people 50 years of age and older in the US. Intentions to screen were moderate (66%), although 21% declined screening based on this information. Comparison with baseline screening attendance is not meaningful for this study where the age range of participants is larger than examined in the study.

Lack of awareness about estimates of no effect in all-cause mortality have likely led to underestimates of the importance for overdiagnosis. Previous screening may also lessen how overdiagnosis is valued. Overdiagnosis data was less concerning (i.e., benefit-to-harm ratio perceived higher) for women with regular versus little or no screening experience in one study,[30] whereas this data was apparently more important than the degree of benefit for approximately 15% of those without experience who changed screening intentions in another study.[29] In contrast, Waller et al.[45] found no difference in screening intentions between the two study groups differing by this variable although the relatively high estimates for benefit (e.g., 1 life saved in 200) may have influenced this finding.

3.4.1.3 Elicitation of Data Not Specific to Age

Three studies[26, 40, 43] were designed to elicit trade-offs or preference weights for benefit and harm outcomes in unspecified age groups and without providing a fixed probability of effect. None of the studies asked women to consider all-cause mortality. Van den Bruel et al.[43] (n=510) elicited trade-offs for breast-cancer mortality and overdiagnosis in the UK using two scenarios employing different magnitudes of effect for breast-cancer mortality (10% vs. 50% relative risk reduction; text also describing absolute values of 1 vs. 5 averted deaths in 1000 women) in an online survey in a research panel. For the 10% and 50% reduction scenarios, respectively, the median number of acceptable overdiagnoses was 150 (95% CI, 120 to 197) and 313 (95% CI, 250 to 364) in 1000 women. Alternatively, 5.1% and 3.5% of the sample would accept no overdiagnosis in each scenario, and 10.2% and 13.9% stated it would acceptable for the entire screening population to be overdiagnosed. The number of acceptable overdiagnoses did not increase five-fold when the number of deaths averted did, suggesting that overdiagnosis rates may substantially influence benefit-to-harm considerations.

Two other studies focused on breast-cancer mortality and FPs. In a mailed survey in the USA (n=479), Schwartz et al.[40] found that 63% of their sample would tolerate 500 or more FPs per life saved and 37% would tolerate 10,000 or more. From other data in this study, the authors reported a fairly realistic knowledge base of their participants (median estimate of FP was 20% for over 10 yrs and RRR for breast-cancer mortality was thought 33% by 25% and 50% by half) suggesting the findings were not greatly influenced/biased by overestimates of benefit (for breast-cancer mortality reduction). When asked how important rates of FPs and overdiagnosis were for their decision-making, 38% wanted to take FPs into account while 61% wanted to account for overdiagnosis. In younger participants, the relevance of overdiagnosis was more important (71% wanting to take into account). Women having had a previous FP biopsy had a similar high tolerance for FPs (71% would accept 500 FPs for each life saved). It is unclear if the findings would be different should the authors have provided estimates using absolute benefit for breast-cancer mortality. In a discrete choice study conducted in 2000 (n=207), Gyrd-Hansen et al.[26] provided choice options based on varying levels of breast-cancer mortality (5 values between 110 to 210 lives saved per 10,000 when screening for 30 years) and FPs (4 values between 1,200 and 4,700 per

10,000 screened over 30 years). The preference weight for breast-cancer mortality was larger (0.01642) than for FPs (-0.000297), although both were significant meaning that they will increase in utility (mortality reduction) or disutility (FPs) as programs get more intense based on total screens/screening intervals. The number of previous breast-cancer screening tests had no influence on preferences.

3.4.2 Weighing Benefits Versus Harms: Data Not Specific to CTFPHC Critical Outcomes (Table 3)

3.4.2.1 40-Age Group

***Key Findings**:*

- **Data reflecting low benefit (0.5 in 1000 fewer breast cancer deaths) and moderate harm (240-330 FPs in 1000 and some [10-50% of diagnosed] overdiagnosis), may reduce or reverse the perceived balance of benefit-to-harms from breast-cancer screening for a substantial proportion of women in their 40s. Some study limitations and indirectness limit the certainty about the number and characteristics of the women that may decline screening (3 studies; fair-to-good methodological quality).**
- **A majority (>50%) of participants in four of the five studies had screening experience.**
- **Findings of reduced screening intentions with the use of decision aids appear to largely reflect critical outcome valuations rather than other information, although it may be necessary to explicitly describe the rationale for there being a need for a choice by women. Opportunity to gain a thorough understanding of the data and having deliberations with other women may influence findings.**

***Detailed Findings**:*

Five studies[24, 34, 36, 38, 41] provided outcome data most relevant to women starting to screen in their 40s. Outcome data for all of the CTFPHC critical outcomes was presented the same way in two studies,[34, 36] using a low benefit-to-harm ratio (0.5 in 1000 fewer breast cancer deaths and no life extension vs. 239 in 1000 FPs and "some" overdiagnosis in 7 extra diagnoses). In an Australian RCT[34] with 412 women aged 38-45 years comparing immediate versus delayed access to a decision aid, the aid did not affect decisions to start screening (43% in intervention vs. 40% in control), but increased the number of women who decided to decline screening (39% in intervention vs 21% in control) rather than remain undecided (18% in intervention vs 39% in control). Although reasons for the women's indecision are unknown, these findings suggest that while some women will still screen despite relatively accurate effect estimates for all outcomes, a similar number may value the harms over the benefits. Additional information on true negative (TN) rates (e.g., reassurance) and reasons why women in their 40s had a decision to make may have influenced findings to some degree. This study had high risk of bias for lack of blinding and for attrition, with many more women not completing outcome data collection in the immediate versus delayed intervention group (38 vs 4%). Baseline characteristics for both groups indicated a relatively educated sample (about 72% with university education).

A deliberative jury was employed in another study[36] where authors asked women (40-49 yrs) to decide on whether or not breast-cancer screening should be publically funded for women in their 40s by the New Zealand government. After 1.5 days of expert presentations (conflicting and neutral), access to a decision aid, and within-group discussion and deliberations, 10 of the 11 women changed their original decisions from *for* to *against* funding although with a caveat that the current funding for women aged 45 years and above should not be reversed despite no evidence provided about differences in outcomes for these women. Reasons cited against funding were due to relatively little benefit in breast-cancer or all-cause mortality compared with the harms of FPs and false negatives (FNs). Because of largely convenience sampling and unreported demographics, there is some concern over selection bias in this study.

Three other studies (all in the US) did not mention all-cause mortality and were varied in their methods and outcome communication. One communicated (via video of physician-patient interaction using numerical data with narrative description to 35 women) a low-to-moderate benefit-to-harm ratio (0.5 in 1000 fewer breast cancer deaths, 330 FPs [with 36 requiring biopsy], and 2 to 10 overdiagnosed in 19 diagnoses in 1000 screened biennially over 10 years).[38] Although previous screening and baseline intention to screen was reported in 91% and 85% of the sample, respectively, after viewing the video only 49% stated their intentions as positive suggesting that approximately 40% of the women felt the harms greater than the benefits. Intentions to screen annually reduced (54% to 14%) and to screen biennially increased (34% to 60%).

Another study (n=168)[24] evaluating an online decision aid compared lifetime deaths in screened women (only) in the 40-49 versus 50-59 age groups (i.e., 22 vs 23 deaths in 1000 screened annually and 24 vs 25 screened biennially) and used the same values for FPs (cumulative over 10 years) in both age groups in annual (60%) versus biennial (40%) scenarios. At follow-up, a similar number of women as reporting previous screening (74%) stated that they had made an appointment for a mammography or were planning to within 6 months (77%). Eighty-three percent strongly agreed that the benefits outweighed the harms. The fact that this aid did not present the relative or absolute differences for women screened versus not screened may have influenced findings (from persistence in overestimate of benefits based on previous perceptions), although the aid did include other features (e.g., personalized risk assessment potentially lowering their expectations about cancer and mortality risk) which would theoretically influence them in the opposite direction.

The last study in this group used online surveys with women randomized to eight possible interventions: two comparators with no or very brief information; three with basic information on personal risk and screening recommendations; and three with extended information using numerical data with explanation. The basic and extended versions also differed in their tailoring and whether they were purely explanatory or using case study approaches, although findings between these versions were not significant in terms of the results used for this report. In the extended versions, data presented for screening versus not screening during one's 40s (3 vs. 2 breast-cancer deaths and 239 FPs in 1000) or 50s (6 vs. 4 breast-cancer deaths and 220 FPs in 1000) were supplemented by information on individualized 10-year and lifetime risks for breast cancer and on cancer diagnoses (both TPs and FNs), as well as brief description that, "in addition

to finding breast cancer, mammograms can sometimes find suspicious cells that would never have spread or become life-threatening and may lead to (unspecified) treatment". While few (6-7%) participants stated they would wait until 50 after viewing either no or very brief information, 14-18% viewing the basic information and 19-24% viewing the extended information reported they would wait.

3.4.2.2 50-69 Age Group

Key Findings:

- **The benefits of screening during one's 50s appear to outweigh the harms for most women without previous or regular screening experience, but these findings account little for weighing in of (possibly no change in) all-cause mortality which may reduce the perceived benefits of screening (3 studies, good methodological quality).**
- **Women who regularly attend screening maintained high intentions to continue screening when provided data representing various benefit-to-harm ratios, although without information on all-cause mortality (5 studies; fair-to-good methodological quality). One large, high-quality RCT in France where screening was less prevalent indicated that even a high benefit-to-harm ratio may not entice all women to screen.**

Detailed Findings:

Nine studies[19-21, 25, 27, 28, 31, 42, 44] presented data on screening intentions after receiving data on benefits and harms relevant to women in this age group; seven[19, 20, 25, 28, 31, 42, 44] contained descriptions and data for overdiagnosis although using differing numerical values and presentations. Only one study (n=6) provided information on all-cause mortality. Studies also differed by their participants' screening experience.

Three studies enrolled women aged in their late 40s or at age 50, prior to having experience in the publically funded breast-cancer screening programs (for women ≥50 yrs) in Germany (n=4114 and 353)[20, 25] and Denmark (n=6).[28] Authors of the two studies in Germany used the same, relatively beneficial, data (50 FPs and 1 overdiagnosis vs 1 life saved in 200 screened over 20 yrs) contained in the 2010-2015 version of the German program leaflet and found that over 80% of participants intended to start screening. The study[25] employing a control group receiving an old leaflet (without numerical data or description of overdiagnosis) found that the new leaflet lowered intentions to a non-significant degree (81.5% vs 88.6%; p=0.06). Moreover, Berens et al.[20] reported that with increasing education level, larger proportions of women intended not to participate (10.5% low, 13.4% medium, and 15.5% high education group; significance not reported). Authors of a small qualitative study in Denmark provided data indicating a lower benefit-to-harm ratio than did the other studies (180 FPs and 10 overdiagnoses vs. 1 life saved in 2000 women over 10 yrs and no change to life expectancy), and reported that one of the six woman reconsidered her decision (to start screening when invited) based on information on overdiagnosis.[28]

Two RCTs compared actual screening attendance rates between groups of women in France[21] and the USA[27] receiving either standard breast-cancer screening program brochures (providing no effect

estimates) or the brochures as well as either a decision aid[21] or two informative brochures.[27] Information provided to the intervention groups indicated a high benefit-to-harm ratio using breast-cancer mortality (26 vs 40 deaths over 10 yrs in 100 women diagnosed via screening or not[21] or 21-30% RRR[27]) versus FPs (94 in 1000[21] or 10-15%[27]) data, yet the information lowered screening attendance to a small degree in the study[21] conducted in France (n=16,000; 40.45% vs 42.15% attendance, p=0.02; 46% of sample had screened previously). No change in attendance at previously scheduled screening appointments was seen for the other study in the USA,[27] although the higher number for mortality reduction (RRR 21-30%) than for FPs (10-15%), and use of relative rather than absolute effects, may have influenced perceptions. Moreover, the sample represented a regularly screening population (n=668; 1.67 vs. 4.03% did not attend, p=0.240; 99% previously screened with 75% annually) in the US where screening is heavily promoted. Data on overdiagnosis was not presented in these two studies.

Four studies[19, 31, 42, 44] using differing study designs evaluated intentions to screen in women based on data on breast-cancer mortality reduction, FPs, and overdiagnoses within either screening information leaflets or a decision aid. In a randomized comparison (n=355)[19] between provision of a standard program brochure in Spain and provision and explanation of the 2008 Cochrane brochure (low benefit-to-harm ratio: 1 death avoided vs. 200 FPs and 10 overdiagnoses in 2000 screened over 10 yrs) to women immediately after a screening mammogram, the authors report that high (100% vs. 98.9%, p=0.24) intentions remained without any difference between groups. Qualitative focus groups[44] with 40 women using the 2011 UK National Health Service's breast-cancer screening program leaflet (1 death avoided in 400 screened; description but no data for FPs) together with additional discussion and data on overdiagnosis (1-3 of 8 diagnoses in 1000 screened) found that screening intentions remained high overall (95% previously screened with 73% regularly) although the reasons provided by the women were related to reassurance, desire to know if cancer is present, and increased chances of better treatment. Similarly, seven focus groups with women aged 40-69 (n=39) discussing a decision aid in Spain (screening biennially for 20 years from 50-69: 1 life saved, 40 FPs, and 2 overdiagnosis in 200) found that the vast majority of women who had already considered screening (90%, 33% with previous FP) would participate.[42] Quotes from women expressing confusion and lack of understanding about the concept of overdiagnosis (e.g., "some will be treated without being necessary…I don't understand it") likely led to greater perceptions of benefit. Finally, a study[31] providing final validation for a decision aid found that a high/moderate benefit-to-harm ratio (3 [50-59 yr] or 4 [60-69 yr] lives saved in 1000 vs. 4 [50-59] or 5 [60-69] more DCIS at diagnosis [treated but with 85% having no recurrence] in 1000 screened and 5% FPs [unclear presentation]) did not change intentions (93% vs. 96% at baseline). Support was provided that intentions matched perceptions of the benefit-to-harm ratio, because 78% (22/28) of the sample changed preference as predicted when removing data on benefits (46% explicitly, 32% implicitly by decreased confidence score).

3.4.2.3 70+ Age Group

Key Findings:

- **Based on a moderate/low benefit-to-harm ratio—including data on all-cause mortality and competing risks for death—acceptance of continuing to screen may be quite high for women in their 70s, particularly if relatively young and healthy (2 studies; good methodological quality).**

Detailed Findings:

The weighing of benefits versus harms for women who regularly screen in their 70s was studied by two groups in the US[39] and Australia.[33] The study in the US provided data indicating a moderate benefit-to-harm ratio, while the ratio in the Australian study was lower because of a statement on no change to all-cause mortality and a more descriptive explanation on overdiagnosis. Both studies employed decision aids providing additional information on competing mortality risks, risk factors and so forth. In the before-after study (n=45) by Schonberg et al.,[39] significantly fewer women (75-89 yrs) decided to continue screening (82% pretest and 56% posttest; p=0.004) although a statistically significant change in screening intentions was only seen for those with <9 years of life expectancy (85 vs 50%) vs >9 years of life expectancy (79 vs 63%). The second study[33] was an RCT comparing a standard brochure with a decision aid in 734 regularly screening women aged 70-71 years. Results showed no difference between groups for those with intentions to continue screening (85.7% vs. 80.6%; both groups appeared to increase slightly in intentions by 6% and 3%) or to stop screening (9.5% vs. 9.3%).

3.5 KQb: How do women use their benefit-to-harm valuations when making decisions to screen for breast cancer?

To understand the degree to which critical benefit-to-harm ratio valuations, in comparison with other factors, contribute to screening decisions, we have used an adapted framework based on the Theory of Planned Behavior (see section on Data Analysis in Methods) and describe (a) the extent to which critical outcome valuation appears to contribute to overall attitudes/valuations of breast-cancer screening, and the influence on attitudes by additional factors apart from critical outcome valuation (e.g., other outcomes of importance, underlying beliefs about breast cancer and screening outcomes) and (b) factors beyond attitudes/values that may influence screening behaviors (e.g., norms/influencers, barriers). We also highlight how understanding of the data and past screening seem to play a key role in decision making.

3.5.1 Contribution of Critical Outcome Valuation to Overall Attitudes Towards Screening and Screening Intentions

Key Findings:

- **The relative magnitude of critical benefits and harms seems to contribute to some degree (5 studies; good-to-high quality), but not entirely (5 studies; good methodological quality), towards women's attitudes/valuations concerning breast-cancer screening and thus their**

screening decisions. Critical outcome valuation was most influential in studies where good understanding of harms was attained by relatively educated women who were contemplating starting screening (4 studies; good-to-high methodological quality).

- **Other outcomes of importance to women (e.g., reassurance, risk for FNs, value of information) likely influence attitudes and intentions (7 studies; fair-to-good methodological quality).**
- **Additional factors contributing to high intentions included:**
  - **Beliefs of high breast-cancer severity (4 studies; fair-to-good methodological quality)**
  - **Beliefs about harms (e.g. viewing overdiagnosis as a treatment rather than screening issue, FPs as a test feature rather than harm from screening) (6 studies; good methodological quality) or,**
  - **For a minority of women, importance placed on societal benefit and relative benefit in youth based on more years of life saved (3 studies; good methodological quality).**

Detailed Findings:

Attitudes towards undergoing screening were measured in several studies, with most employing a version of a validated scale (original [2001] or revised [2006] Dormandy scale).[5, 57] Attitudes are capturing the value of undergoing breast-cancer screening in general, which may encompass attitudes related to the test itself (e.g., painful, time consuming), valuation of patient-important health outcomes such as those focused on in KQ2a but also others seen as important to women, as well as underlying beliefs the women hold about breast cancer and screening.[5] Studies using the Theory of Planned Behavior to describe mammography behaviors have found that attitudes strongly predict intentions to screen and that intentions are highly predictive of screening behaviors;[15] to this extent there appears to be some validity to use attitudes, intentions, or screening behavior when looking at the degree to which critical outcome valuations will predict screening behaviors.

Assuming that information provided by study authors on the critical outcomes reflected a lower benefit-to-harm ratio than previously perceived by the women participants, one would expect attitudes, intentions, and screening to be reduced for women receiving this information if their attitudes are formed largely from this valuation. This was evident in some studies. During the deliberative jury in New Zealand[36] with women in their 40s (55% screened), most women (10 of 11) changed their minds about intending to screen and thinking this was a good idea for women their age; reasons provided for their decision reflected valuation of the benefit-to-harm for critical outcomes. At follow-up in the trial (n=879) by Hersch et al.[29] comparing decision aids with and without information on overdiagnosis, fewer women in the intervention compared with control group had positive attitudes (69% vs. 83%) and intentions to start screening (74% vs. 87%) ($p<0.0001$). Intentions to start screening decreased for some (8.1% of 1318) women in the UK receiving information on breast-cancer mortality and overdiagnosis, although only for those without screening experience.[45] Further, data on all-cause mortality (no effect) compared with breast-cancer mortality (2 fewer in 1000) resulted in fewer women having a positive attitude towards screening (n=106; 71% vs 85%, respectively).[22] A few women (of 40 participants) described a change in

attitude during focus groups with discussions on overdiagnosis in one study.[44] Several other studies, in both screening naïve[20, 25, 28] and previous screenees,[19, 27] failed to support a meaningful contribution of critical outcome valuation to attitudes or screening intentions. No effect of the relative benefit-to-harm ratio between studies was evident.

3.5.1.1 Competing Outcomes Valued by Women

There appear to exist other outcomes that women value to a similar degree to the critical CTFPHC outcomes. In a US study (n=93), data provision on FN rates (20 out of 100 screens) made 8% of women less likely to screen as did data on pain during procedures for 13%. FPs (10 in 100 screens) were cited by only 2%.[35] Peace of mind and reassurance,[24, 30, 44] and similarly elimination of the potential for feelings of regret,[26] were also strong motivators to screen. Some women placed value on having information: "desire to know cancer is present",[44] "knowing about a health condition",[46] "gaining information",[26] and "good to know".[31] Another outcome that appeared to have importance for some women is the chances of better treatment,[44] including a smaller operation.[31] Although many studies did not have findings specific to women's valuation of better breast-cancer treatment outcomes, several decision aids and brochures included a description of this potential benefit and this may have contributed to positive attitudes and intentions.

3.5.1.2 Prevailing Beliefs Contributing to Values

A high perception of breast cancer severity had a major effect on screening decisions in studies in the US[37] and Hong Kong.[46] It also influenced women in a UK study[43] when making trade-offs between breast-cancer mortality and overdiagnosis. Regardless of how well women in the US study understood the evidence on mortality and overdiagnosis, perceptions of breast cancer being extremely severe (e.g., high fatality rate) and of a high personal risk for the disease were predictive of an increase in the perceived benefit of screening and stronger intentions to screen; the information provided to the women resulted in some reassurance.[37] In the Canadian study, fear and anxiety about cancer were frequently brought up in focus groups, especially in those with older women, and were often "intertwined with (analysis of) analytical or rational factors" for choosing when to start screening; younger women in this study had greater concerns about the harms of screening and were more receptive to nuanced messages informed by the evidence. Women in Japan that had more versus less *concern* about their health were more WTP for screening regardless of the benefit-to-harm ratio information provided; WTP was not influenced, though, when looking at the women's self-rated health status.[47] A representative free text response from women stating very high acceptance of overdiagnosis (n=510; 10.2% accepting that the entire screening population be overdiagnosed) also reflected this: "the thought of getting cancer terrifies me."[43] These beliefs and emotions of women are very likely influenced by an overestimation of their personal risk for breast cancer, especially over short-term durations.

Beliefs underlying the evaluation of the critical outcomes may also influence how women weigh their relative importance. During focus groups in Australia, Hersch et al.[30] reported that "the idea of overdiagnosis was surprising and challenged women's beliefs about breast cancer generally being a serious and dangerous disease. Many women expressed surprise or disbelief at distinguishing between

cancers that do require treatment and those that may not… (they) saw overdiagnosis as a treatment issue once diagnosed (e.g., 'wait to deliberate during management decisions')". Similarly, in focus groups in the UK,[44] many women "struggled to see the information on overdiagnosis as relevant to their decision-making about screening but thought it should be part of their decision." Finally, one reason for very high acceptance in Van den Bruels' study[43] eliciting trade-offs between overdiagnosis and breast-cancer mortality also reflected this belief, "if people who are diagnosed fully understand that it may not turn into cancer so have the option to wait for treatment then extra screening can only be a good thing." This belief of overdiagnosis having more relevancy in treatment than in screening decisions, and believing overdiagnosis not to be a true cancer, may explain to some degree why the women in these studies had fairly high thresholds for this outcome and maintained high intentions to screen. Knowledge of uncertainty about which cancers will be overdiagnosed may influence how women weigh this harm. In Schwartz's US survey (n=479),[40] a fairly low threshold of certainty in DCIS becoming invasive was found for deciding on treatment; at a 1% chance of DCIS becoming invasive, 42% of women chose treatment whereas at a 33% chance of invasion, 78% chose treatment.

There was some evidence that women may not consider FPs as harmful but rather a normal consequence of screening tests. For example, 92% of 479 respondents in Schwartz's survey[40] thought that mammography could not harm a woman without breast cancer. To some extent this may be explained when FPs are mentioned in surveys without a description about the possibility of psychosocial consequences for some women after this experience; this effect, though, may be minimal when considering that the women with prior experience of FPs in the Schwartz survey had similarly high tolerance for FPs when weighed against breast-cancer mortality (71% stated tolerance for 500 FPs and 39% tolerated 10,000 or more FPs per life saved). Strong tolerance for harms in experienced women was also evident from other studies.[30, 45, 47] Moreover, several although not all of the studies included information on the possible psychosocial consequences of FPs.

Qualitative findings characteristic of some (2 of 8 representative quotes) European American women during Lawrence et al.'s[31] study indicated beliefs that benefit for others is valued even if no benefits will be gained for oneself. In the deliberative jury where 10 of 11 women decided against funding for breast-cancer screening in younger women, the one dissenting woman supported her view on screening because of a belief that a life saved in youth is more important than a life saved in older ages.[36] There was some indication from the older (50s), but not younger (40s), women in the Canadian study that saving younger lives (especially when young children) is more beneficial than older lives.[23]

3.5.2 Influence on Screening Decisions/Intentions by Factors Other than Attitudes/Values and Beliefs Underlying Outcomes: Potential Barriers and Influencers

Key Findings:

- **Overall attitudes/values towards screening do not always reflect intentions to screen (5 studies; good methodological quality).**

- **Women's intentions to screen appear to be influenced by the attitudes and recommendations from others (e.g., physicians, friends and family) (6 studies; good quality), and also to some extent by barriers (e.g., cost, accessibility) (2 studies; fair quality and indirect for Canadian population).**
- **A large proportion of, but not all, women wants to have a role in making decisions about screening (10 studies; good methodological quality).**

Detailed Findings:

Positive attitudes aligned with high intentions to screen in some studies, such as reported by Baena-Canada et al.[19] with 99.4% and 98% of 355 women having positive attitudes and intentions to screen, respectively. Likewise, fewer positive attitudes (reduced from 87% to 69%) towards screening in the intervention arm (n=440) of the RCT by Hersch et al.[29] were consistent with lower intention to screen (change from 89% to 74%). In other studies, findings were somewhat discrepant, such as in Davey et al.[22] where data on all-cause mortality resulted in positive attitudes towards screening by 71% of 106 women but a willingness to screen in 53%. A high (93.7% of 4113) proportion of women with positive attitudes to screening in one study[20] did not accurately reflect their lower screening intentions (84%). Mathieu et al.[33] reported that older women had very positive attitudes (95% of 734) towards screening, although only 85% had decided to continue screening while 4.9% were unsure. Decisions to attend breast-cancer screening appear to be influenced for some women by factors other than their attitudes and values; the Theory of Planned Behavior would suggest that subjective norms (influencers) and perceived behavioral control are likely to explain the discrepancy to some degree.

External barriers such as personal costs may be of consideration in some countries (e.g., costs made 20% of women less likely to screen in one US study[35] and were important for decision-making by 11% in Hong Kong[46]), although most studies were conducted in countries having publically funded screening. Other perceived barriers are likely also at play for some women, such as reduced accessibility due to geographical location (only two of the studies reported on this variable),[21, 34] inconvenience of having to take time from paid work, or internally derived lack of self-efficacy to attend screening. Few findings related to this theoretical domain (perceived control) from the included studies, although others have found this domain to be a relatively weaker predictor of mammography screening behaviors.[14]

Decisions may be influenced by the roles placed by women on others such as their healthcare providers or friends and family; this model domain has been described to possibly be a stronger predictor of mammography screening than attitudes.[14] Of women considering starting to screen in Germany, more women (48.2% of 353) stated that their doctor's recommendation was likely to influence their decision than was the information in the screening brochure (3.6%).[25] Many US women in one study (n=668; 70.2% and 65.5% in the control and intervention groups, respectively; p=0.21) predominantly relied on physician referrals.[27] Qualitative studies in Spain[42] and Canada[23] also found this explanation through quotes such as "If the doctor says you have to do it, you do it", and findings that "women might fight it impossible to resist the physician's recommendation". For women about to become eligible for screening in Denmark,[28] it was evident that their decision-making process was "dominated by the attitudes of the

circle of acquaintances and to a lesser extent by the information accompanying the screening invitation." Saver et al.[38] also reported that their qualitative work in the US when developing the intervention for their RCT indicated that women are "heavily socialized to value mammography".

The extent to which others influence screening behaviors will be determined in part by preferences of women for an active/autonomous, shared/collaborative, or passive decision-making role. The findings above suggest that some women may rely on passive decision-making and follow recommendations from their physician or acquaintances, although findings from these and other studies show a considerable desire for some involvement in decision-making. Although many women (>65%) predominantly relied on their physician's referral in one study (n=668), overall 96% wanted some involvement in the decision.[27] Three other studies reported similar findings: 80% of women stated a preference for an active role in Hersch et al.[30], 88% wanted a collaborative or active role in Davey et al.[22], and Petrova et al.[37] reported a mean score of 6.81 ± 1.53 (scale 2-12 with 5-7 indicating preference for shared and >7 for autonomous) indicating strong preference for shared decision-making but also a tendency for some towards an active role. While most women appear to want to be involved in decisions to screen, some will not. For example, the study in Hong Kong[46] found that 30% desired a passive role, and one in Denmark[26] found that a "frequently observed motivation to screen was a tendency to accept what is offered or, in other words, do what is recommended". There was large variability in another study.[42]

3.5.3 Other Factors of Influence in Decision-Making: Understanding the Data and Past Screening

Key Findings:

- **The degree of understanding about data provided on expected outcomes from screening probably influences whether or not this information changes attitudes and/or intentions to screen (10 studies; good methodological quality). The direction to which attitudes will change may not be predictable; more accurate knowledge will often reduce attitudes and intentions (i.e., due to full appreciation of lower than anticipated benefits versus harms), but in some cases, such as awareness that most recalls are not diagnosed as breast cancer, may make attitudes more positive (2 studies; fair methodological quality).**
- **It is unknown how accurately women interpreted data on reductions in breast-cancer mortality when no information was also provided around estimates for no extension in life.**
- **Expectations about breast-cancer (e.g., its severity) and screening may compromise perceptions of the balance between screening benefits and potential harmful effects.**
- **Regardless of information provision on evidence-based magnitudes of effect, intentions to screen often remained high for women with previous screening experience (6 studies; good methodological quality).**

Detailed Findings:

The validity of the information provided by women on the relative weight they place on benefits and harms of breast-cancer screening may rely to some degree on the extent of their understanding of the

numerical values (i.e., probability data) provided by the authors as well as the concepts of the harms (including their consequences). In some studies, it is unclear to what degree women understood the numerical values presented and whether or not their stated intentions for screening and values for each outcome reflect this data or their beliefs/understanding before being provided with information, which included, for example, a large overestimation of the benefits in one study (300 to 500 lives saved in 1000 screened[32]) and lack of awareness of harms in another (13% unaware of chances of FPs and FNs[35]). Even on follow-up testing in the study undertaken in Hong Kong,[46] 88% of women still thought screening prevented breast cancer. Several studies evaluated understanding through knowledge questions although there was considerable diversity in the methods used and it was not our intent to evaluate to what degree knowledge gained directly impacted the weighing of benefits and harms. It is also unclear how women interpret estimates for breast-cancer mortality reduction; it is assumed some will believe this to also imply extended lives because of the lack of context around all-cause mortality.

It appears that there is some heterogeneity in whether or not (and in the direction to which) understanding and knowledge influence outcome valuations and intentions to screen. There was some indication in a few studies that good understanding of the data (especially on overdiagnosis) led to lower benefit-to-harm valuations and a reduction in intentions to screen.[29, 36, 37] Other study authors suggested that lack of understanding was thought to result in less change (than anticipated) in intentions to screen;[38] in Waller et al.'s[45] study presenting overdiagnosis and breast-cancer mortality statistics in three different ways, but without much explanation, screening intentions did not reduce very much which may in part be because 43% of women at follow up did not recognize that screening increased cancer diagnoses. Similarly, a higher educational level of participants was associated with lower acceptance of screening in two studies.[20, 25] This finding was not consistent, though, as shown in other studies where women's intentions to screen remained high.[28, 31, 44] On the other hand, better knowledge of the context around harms, for instance the reasons for recalls and that a high proportion of these do not result in a breast-cancer diagnosis, may lower the weight some women place on FPs because of an overall reduction in anticipated anxiety. Upon being provided with information on breast-cancer mortality and FP rates in one study, receiving pamphlets was reassuring and lessened anxiety; about 90% of women said they disagreed or strongly disagreed that the information increased their anxiety about the test.[27] In Petrova,[37] regardless of how well women understood the evidence on breast-cancer mortality versus overdiagnosis, those who perceived breast cancer to be extremely severe reported feeling more assured and relieved upon reading the information about screening; these perceptions of severity and feelings of assurance predicted their increase in the perceived benefit of screening and stronger intentions to screen. One study's authors[28] reported that, "women have expectations about breast cancer screening that are formed before they receive information from the screening programme. These expectations compromise the perception of balance between screening benefits and potential harmful effects. They also influence the perception of the information in the breast screening leaflet." The findings may be as much influenced by the previous screening experience of women, which was shown to be associated with less relative concern over harms in more studies[30, 40, 43, 45, 47] than it was shown to be of more concern (n=0), or to have no impact.[26] The influence that information on all-cause mortality would make is uncertain but likely influenced results

(overestimated benefit valuations) particularly for women in their 50s and 60s where this information was missing the most.

4. Discussion

We reviewed findings from 29 studies evaluating how women weigh the benefits and harms of breast-cancer screening with mammography for women at age 40 and above (KQa), and how they use this valuation in their decisions to undergo screening (KQb). Our findings are intended to inform the relative importance placed on outcomes by the CTFPHC during deliberations about recommendations for screening women in Canada. They may also help with considerations relevant to disseminating and transparently implementing the recommendations. This was not an update of an earlier review, and we are not aware of any review using systematic methodology undertaken by another guideline panel for this topic to date.

How do women weigh the benefits and harms of breast cancer screening?

A reduction in breast-cancer mortality appears to be the largest motivator for screening; a high degree of importance and high intentions to screen often remained despite presentation with data for this outcome that appears to be much lower than previously anticipated by women. However, only five studies provided women with data on estimates of no change in all-cause mortality; from data in two studies[22, 36] it appears that considerable weight may be placed on this outcome, although screening intentions remained as high as 85% in a few other (indirect) studies providing this information to women in decision aids.[28, 33, 34] Based on the evidence directly related to the critical outcomes of interest, overdiagnosis appears to have a much greater impact in benefit-to-harm considerations than do FP rates for women in their 40s, although the threshold for overdiagnosis may be fairly high (e.g., 11 in 1000 screened over 10 yrs) even when the scenario provided indicates the benefits are relatively small. A substantial minority of women in their 50s and 60s may also decline screening because of overdiagnosis. Scenarios using overdiagnosis provided to women in these studies usually indicated a relatively moderate-to-high ratio, with none presenting the possibility of no reduction in all-cause mortality. Studies eliciting acceptable benefit-to-harm ratios, rather than providing fixed estimates of effect, found high acceptance of overdiagnosis (at least 120 for 1 or 250 for 5 lives saved per 1000 screened)[43] and FPs (at least 500 per life saved),[40] but the broader age ranges in the samples and lack of information in one on benefits[40] may limit the reliability of these findings.

Among women in their 40s, when data on all CTFPHC critical outcomes is provided and reflects a low benefit-to-harm ratio (small reduction in breast cancer mortality and no extension in life years vs. reasonable degree of harms), this reduced or reversed the perceived balance of benefits to harms for a substantial proportion. Some study limitations and indirectness limit the certainty about the number and characteristics of women in their 40s that may decline screening. The findings of reduced intentions to screen appear to reflect critical outcome valuations, rather than other information within screening

brochures or decision aids provided in the more indirect studies, although prerequisite information may be a description of possible differences in benefits and harms between age groups, and the explicit statement of their being a need for a choice by women. Accurate knowledge of one's risk for breast cancer during their 40s may also be required to fully appreciate the data. The benefits of screening during one's 50s and 60s appear to outweigh the harms for most women regardless of their previous screening experience, but these findings may be most specific to fairly high estimates of benefit as presented in these studies (one small in 6 providing information on all-cause mortality). One large, high-quality RCT in France, where screening was less prevalent, indicated that even high benefit-to-harm (i.e., no presentation of overdiagnosis or all-cause mortality) may not entice all women in their 50s to undergo screening. Based on information of a moderate/low or low ratio, acceptance of continuing to screen may be quite high for women in their 70s, particularly if relatively young and healthy. The findings for women on their 70s were based on studies of decision aids with multiple information points, so it is difficult to know what specific outcomes they value most and/or least.

As discussed further in findings for KQb, previous screening experience likely competes with outcome valuations as a factor during decision-making about screening. Having the opportunity to gain a thorough understanding of the data—especially on overdiagnosis—and having deliberations with other women may allow for the most reliable findings.

How do women use their outcome valuation in their decisions to undergo screening?

Weighing of critical outcomes seems to contribute to some degree, but not entirely, towards women's attitudes/valuations concerning breast-cancer screening and their screening decisions. The contribution of outcome valuations was most apparent in studies where good understanding of harms was likely attained by relatively educated women who were contemplating starting screening. Other factors likely to influence attitudes and intentions to screen include 1) other outcomes of importance to women (e.g., reassurance, failure to detect all cancers (FNs), better treatment for screen-detected cancers, value of information), 2) fear about breast cancer stemming from beliefs about high breast-cancer severity, 3) beliefs about harms, for example, viewing overdiagnosis as a treatment rather than screening issue or considering FPs a test feature rather than harm from screening, and, for a minority of women in these studies, 4) importance placed on societal benefit and the high relative benefit in youth based on years of life saved. Some misconception about several of these findings is apparent although the studies did not provide rich findings in this regard. When making decisions about breast-cancer screening, women's intentions to screen appear to be influenced by the attitudes or recommendations from others (e.g., physicians, friends and family). A large proportion of women, but not all women, wants to have a role in making decisions about screening.

It appears that overdiagnosis can be broadly conceptualized but it may not be clear to participants that this phenomenon only occurs for women who are screened; because of being a cancer diagnosis its magnitude as a harm from screening appears hard to interpret by women. Despite fairly good efforts to communicate

this harm to study participants, these findings generally agree with two surveys in the UK[58] and Australia[59] which found that the public does not mention screening when defining overdiagnosis, but rather conceptualizes it as "too many diagnoses", "incorrect diagnosis", or "overly negative diagnosis". Beliefs that overdiagnosis is a greater factor for treatment than for screening may not only be held by the lay population. Because the consequence, and thus harm, from overdiagnosis largely relates to treatment harms without any provision of benefit (overtreatment), others have also suggested that the nature and extent of the outcome may be impacted to a greater degree by having better treatment decision tools than reducing screening.[60] Few of the studies portrayed the unnecessary consequences of labelling or stigma, and psychosocial factors that will be assumed with this diagnosis.

Because recommendations to screen for breast cancer persist in most countries where the included studies were conducted, the influence by physicians (assumedly with positive attitudes towards screening especially in women once 50) would not seem to explain a lower intention to screen compared with positive attitudes in some studies. Barriers to screening may be more persistent, although the studies did not provide for many findings in this respect because of their focus on knowledge and attitudes. Lower screening attendance rates in Canada for some populations appear to reflect multiple barriers particularly for immigrant (e.g., language barriers, migration stress) and minority women (e.g., limited knowledge, structural and logistical issues, low perceived risk for breast cancer, lack of trust),[61] rather than their outcome valuations. Barriers to screening in Canada are not exclusive to these population groups.[62]

Women without screening experience may be more likely, than those with experience, to change their intentions based on new information on critical outcomes or reflection on other outcomes or beliefs (i.e., revised attitudes), or on factors such as influence of others. This is supported by other work applying the Theory of Planned Behavior in mammography screening, where past screening behaviors have been shown to directly predict future screening without mediation by intention or other cognitive constructs. In multivariate analysis, Rutter et al.[14] found that once screening attendance was entered into the equation, none of the other variables (model components) played a part. Other authors have reported a sense that ''a woman does not have to rethink her reasons or objections towards attending'',[16] and that screening becomes "routine" maintained by brief self-reminders that sustain the decision. This means that past behavior is "not merely a habitual response, but rather a reflection of those reasoned responses that had contributed to the execution of the same behavior in the past".[15] While this link appears strong, negative feedback from a bad screening experience or extensive media exposure to discrepant views may change intentions.[14, 15]

Other factors not well-described by the Theory of Planned Behavior may influence how critical outcome valuation is used during decision-making. Emotional, religious, and cultural factors (e.g., fatalism/optimism, breast cancer as stigma, cultural beliefs about familism, religious dogma regarding God's control over cancer) have been described to influence decision-making,[15, 18] although the studies we included—which by their nature of data provision were more focused on cognition—did not provide findings to explore any possible relationship between these factors and critical outcome valuation.

Limitations of the Evidence Base

Although we found 29 studies of generally good methodological quality to address our key question, there are concerns over the applicability to a Canadian population and the reliability/adequacy of the findings in relation to the CTFPHC's estimates of the absolute and relative benefits and harms. Only one study was conducted in Canada, and the sample in this and many other studies reflected women having relatively high education levels and good understanding of the applicable country's language; findings may have poor validity when considering low income and/or foreign-born women residing in Canada. The information provided in the studies often did not capture all of the outcomes under consideration—especially all-cause mortality—and as such all findings (especially for KQa) may not be reliable given that benefits estimated by the CTFPHC are smaller than presented in most studies. We assume to some degree that lack of any information on all-cause mortality lends towards interpretations that breast-cancer mortality reductions lead to an increased life span (despite data suggesting otherwise), and thus likely influences/increases valuations of breast-cancer mortality as well. Findings on the relative importance of the outcomes, and especially intentions to screen, may be different than would occur based on the data found in the evidence review on the clinical effectiveness of screening (Part 1). Moreover, it is difficult to interpret how suboptimal understanding of the data (e.g., numerically and conceptually) by women may have influenced our findings. Although several of the decision aids were developed using guidelines (e.g., from the International Patient Decision Aid Standards [IPDAS] collaboration[63], also see guidance white paper by the Canadian Breast Cancer Screening Network[64]) for communicating probabilities, in other cases the findings may have been influenced by presentations of data, for example when using relative risks which do not make the baseline risk explicit and oftentimes inflate perceptions as demonstrated in one of our included studies.[22] Evidence and recommendations are also emerging to support changing terminology when defining low-risk, screen-detected conditions (e.g., use of abnormal cells versus carcinoma or cancer for DCIS) to reduce overdiagnosis.[65, 66]

Importance placed on benefits, reassurance, and value of information may reflect expectations (i.e., entrenched views) created by news media and other disease advocacy groups, as well as a long-standing existence of screening programs in many countries, rather than an interpretation of these outcomes within the context of the critical CTFPHC outcomes particularly if poorly communicated or grasped. A predisposition to consider benefits as more important than harms prevails within the public, despite ongoing controversy within the clinical community. Recent findings from a US survey[67] asking women to rate the relative importance of outcomes (without indication of their relative frequency and with brief outcome descriptions) are similar to ours although they indicate lower importance of overdiagnosis (very important: breast-cancer mortality 67%, reassurance 56%, better treatments 67% vs. FPs 23%, overdiagnosis 22%, and overtreatment 29%). This similarity could support that women's previous expectations of the benefits from screening were largely unchanged based on new information in the reviewed studies. Rather than viewing this only as a limitation of the findings though, we agree with others that it supports a need for improved efforts to increase women's and the general public's awareness and understanding of all of the outcomes, including their consequences and frequencies, to ensure their valuations and decisions are consistent with complete and accurate knowledge.[67] This could be particularly helpful knowing that guideline recommendations may not be perceived by all as aligning with

their values and preferences. Overcoming challenges when communicating harms, and the possibility of overuse of interventions, is difficult as recognized by campaigns such as Choosing Wisely with concern about risks of (mis)perceptions by patients and the public of intents to ration healthcare rather than serve society's interests.[68]

Information on outcomes other than those considered critical for decision making may help women understand the nuances between different outcomes. Although reassurance and/or the value of information for individual women who attend screening programs are attractive outcomes, considering that most women do not experience the reduction in breast-cancer mortality, numerical data commonly reported for these outcomes may be misleading when considering a woman's pre-screening likelihood of not having cancer. For example, should 10 in 2000 (0.5%) women be diagnosed with breast cancer within a screening round, and perhaps 3 of these (0.15%) are overdiagnosed, women who receive a negative result from their screen would have an absolute reduction of 7 in 2000 (0.35%) for the likelihood of potentially lethal breast cancer.[69] Presenting information for screened and non-screened populations in terms breast cancer diagnosis and reassurance may help accurately reflect this data. In a decision aid designed at the University of Sydney for women in their 70s (http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml), the number correctly reassured by screening that they did not have cancer during 10 years (824 in 1000; 959 after further examination) was contrasted with the number of women not screened who would "continue with their daily activities without being affected by breast cancer or attending screening" (974 in 1000). Even though not interpreted as a critical outcome by many guideline panels, providing this information to women may be useful nevertheless.

Limitations of the Review

This review followed rigorous methodological standards, which were detailed a priori in a protocol with deviations made transparent. Nevertheless, several limitations inherent within systematic reviews apply. We focused on studies published in English or French, and studies published in other languages may have differing results. We based our assessments of the methodological quality on study publications and did not contact authors to verify the methods used. Systematic reviews may become outdated, at least in part, if new studies are published that change some or all of their conclusions. We do not think that selective outcome reporting or small study bias was a great concern for this review topic. Our search was highly comprehensive although the major concept of screening may have limited us from including studies having some relevant information but with focus on diagnosis or treatment of breast cancer. Our findings for subgroups of age were mostly based on between-study findings because the studies themselves often focused on one age group. Results for the subgroups of 40-49 and 50-69 year-olds are considered most likely related to the benefit-to-harm ratio presented (lower in the former age category), as well as discussion on choices about screening for women in their 40s, such that findings of lower screening intentions could be similar in the older women should the studies have provided the same information. There were many differences between studies in the populations, number of outcomes presented, magnitude of effects sizes, and how the data were presented; our findings accounted for several of these

variables but we recognize that a complex interplay between variables likely exists. Some important variables, including culture, were not explored in much depth due to both reporting in the studies and the nature of the studies which focused on cognition and knowledge much more than beliefs and attitudes.

Conclusions

Provided with data indicating a wide variation in benefit-to-harm ratios, reductions in breast-cancer mortality appear to outweigh both FPs and overdiagnosis for most women. However, this finding was frequently in the context of incomplete or absent provision of information on all-cause mortality. Two studies indicated that considerable weight may be placed on estimates of no reduction in all-cause mortality, although this information likely will not make all women decline screening. Overdiagnosis rates of 30% of screened-detected diagnoses (e.g., 11 of 38 diagnoses in 1000 screened) or even higher appear to be acceptable for many, but not all, women especially if absolute benefits are reduced substantially as they will be for most younger women. In the context of decision aids reflecting no reduction in all-cause mortality and additional information such as lower estimates of breast-cancer risk (and hence screening benefit) and reasons why a personal decision needs to be made, many women in their 40s may choose not to undergo screening. The benefits of screening during ones 50s and 60s appear to outweigh the harms for most women regardless of screening experience, but these findings may be influenced by providing favourable data on breast-cancer mortality but no information on all-cause mortality. Continuing to screen in ones 70s appears to be quite acceptable, particularly for women who are relatively young and healthy.

The reliability of our findings for how women weigh the critical benefits and harms may be impacted by how the studies portrayed the estimates of effect (i.e., completeness of data, magnitudes and presentation of data), particularly with respect to omission of any comment about possibility of no extension to life years. Because of this there is likely some degree of bias towards higher acceptance of harms and intentions to screen. High-quality information on outcomes other than those considered critical for decision making (e.g., baseline risks for breast cancer, realistic awareness about reassurance) may also help women understand the nuances between different outcomes. Moreover, the degree to which women use critical outcome valuations during screening decisions appears to be heavily influenced by competing outcomes women may also consider important, and by beliefs about the outcomes that may inflate their valuations. There is also some uncertainty about the ability of women in the studies—despite being relatively well-educated for the most part—to fully understand the numerical and conceptual outcome data as presented to them. There is a need for efforts to increase women's and the general public's awareness and understanding of all outcomes from breast-cancer screening, including their consequences and natural frequencies, to ensure their valuations and decisions are consistent with accurate and complete knowledge. These findings may be of relevance for guideline implementation as may other findings relevant to women's expectations, including inflated perceptions about breast cancer risk and severity, and how many factors including barriers and influential people/organizations contribute to decision-making. Variations between women's preferences across the outcomes considered suggest that informed decision making, either individually or shared with their providers, is a priority.

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Table 2. Characteristics and findings from studies providing direct findings on the weight women place on CTFPHC critical benefits and harms

Study, Country Study Description Sample Size, Age, Insured/Funded BC Screening (%), Caucasian (%) Screening History	Communicated Outcomes of Screening, Format of Information and Definitions Provided, Judgement of Benefit-Harm Ratio Considering Age Category and Relative to Others Studies in Category, Other Information Provided	KQ2a: Weighing of benefits and harms	KQ2b: Additional findings related to how women make decisions (other outcomes, attitudes, beliefs, decision making) relative to weighing of benefits and harms
40-49 year data on outcomes			
Nekhlyudov 2008, USA Mailed survey to clinic patients before first automated contact for screening N=93; 40-44, 100%, 67% Previous screening: 0%	**Communicated Outcomes of Screening (during one's 40s):** • BC mortality: 1 fewer in 1000 screened regularly in their 40s • FP: 10 in 100 screens Format & Definitions: statements describing the numerical estimates; BC mortality: will live longer by having regular mammograms in their 40s; FPs: abnormal and will lead to additional tests (sometimes referred to as call-back or false alarm) **B:H Ratio:** High Other information: FN 20 of 100; BC risk lifetime 12 in 100, over 5 yrs <1 in 100, 95 of 100 FPs not diagnosed	**Likelihood of starting to screening based on information on outcomes:** BC mortality: more likely 56%, less likely 4% FP: more likely 29%, less likely 2%	**Other outcomes of importance:** • FN (20 out of 100): more likely 28%, less likely 8% • Some pain during mammography: more likely 14%, less likely 13% • BC risk (12 of 100 during lifetime): more likely 60%, less likely 0% • Cost ($150 if not covered): more likely 10%, less likely 20% **Knowledge at baseline:** 40 (43%) were aware of a woman's lifetime risk of developing BC; 23% were aware of the numerical benefits of screening, 13% were aware of the chances of FN and FP mammograms, (11%) of women were aware of ductal carcinoma in situ
Lewis 2003, USA RCT in clinic sample with differently framed information videos (considering as pre-post one group) N=179; 35-49, 78%, 59% Previous screening: 75%	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 1 life extended in 1000 screened every year • FP & worry: 300 experience (100 continue to worry) vs 700 do not experience (200 will not be bothered by FP), in 1000 screening biennially Format & Definitions: 5-min videos of female MD narrator with text boxes; FP: an abnormal mammogram when there is nothing actually wrong, but the result may require more tests or a biopsy to find out that there was no cancer; more than one third of women with a false positive continue to worry about having breast cancer No significant difference between framing (positive, negative, or neutral) **B:H Ratio:** Moderate	**Relative importance of outcomes**: Baseline: 81% BC mortality more important (75% much more, 6% somewhat more) than FPs and worry Follow-up: 83% BC mortality more important (75% much more; 8% somewhat more) than FPs and worry **Subgroups**: no effect of previous screening or accuracy of knowledge questions	**Knowledge at baseline:** Most (76%) women greatly overestimated the benefit, endorsing incorrect responses that 300 women or 500 women out of 1,000 would live longer because of mammography.
Multiple age data on outcomes & results			

Driedger 2017, Canada (Toronto and Winnipeg) N=46; 35-59 (63% <50); NR, NR Focus groups (n=5) in 2012 with members of the public using presentations and print hand-outs; survey research company recruitment using known survey participants and random-digit dialing, with maximum variation sampling (e.g. wide variation in income and marital status but education skewed to higher) based on questionnaire. 4 of 5 focus groups stratified by age (35-49 and 45-59) Previous screening: 61% (100% in >50 yrs; most <45 had not) Focus groups in men (n=47 ages 45-74) about prostate cancer screening were also conducted but not examined here.	**Communicated Outcomes of Screening (total of 11 yrs):** • BC mortality: 40-49: 2108 would need to be screened to prevent 1 death 50-59: 721 would need to be screened to prevent 1 death • FP: 40-49: 690 in 2108 50-59: 204 in 721 • Unnecessary biopsies: 40-49: 75 in 2108 50-59: 26 in 721 Format & Definitions: Presentation and print hand-outs of plain language descriptions of 2011 CTFPHC guidelines (2180- and 721-person diagrams for BC mortality, FPs, and unnecessary biopsies at 40-49 and 50-69), a summary of the relevant research evidence, and a description of the uncertainties that remained. "Some doctors think that finding a cancer through screening in this age group (40-49) – who are usually pre-menopausal, won't change the available treatment options or the effectiveness of treatments and might expose women to unnecessary risk (including additional testing and anxiety)" Other information: None **B:H ratio:** Low/Moderate (no overdiagnosis or all-cause)	**Age to start screening:** At age 40: 35-49; 21% 50-59; 35% At age 50: 35-49; 41% 50-59; 29% Unclear: 35-49; 38% 50-59; 35% Note: unclear was based on authors' interpretations because using focus group data to quantify **Relative importance of outcomes:** 13% (most under 50) felt the potential harms of screening were too high a price to prevent one 40 -49 yr old from dying	**Affective/emotions vs rationale decision making:** 31% of participants expressed fear about some aspect of cancer or cancer screening. (Including BC and prostate cancer participants); fear of cancer and fear of screening harms were almost mutually exclusive While feelings of fear and anxiety were the most common affective factors driving enthusiasm for cancer screening or testing, participants' strong emotional reactions during the discussions were often intertwined with analytical or rational factors. Younger women had less affective attachments to "early detection" massages, greater concerns about harms of screening, and were more receptive to nuanced messages informed by the evidence. Older participants (50 yrs and older) had greater affective attachments to fear and anxiety about cancer as well as more generalized enthusiasm towards the message that early detection is the best protection against cancer. Heavily influenced those who thought screening should start at age 40. Those 35-49 taking part in focus groups stratified by age were more likely to choose the older age start; those stating age should start at 40 may have been influenced by older women in the group. Indication that saving younger lives (with young children) more beneficial than older lives. Experience in this group leading to "routine" nature of screening and more chance of knowing someone with cancer (increasing their fear). **Decision making:** Some women were more supportive of screening benefits in terms of early detection, others did not unproblematically accept a doctor's recommendation to be screened if they were not at the appropriate age to be invited into the population-based screening program, although they might find it impossible to resist the physician's recommendation.
Hersch 2013, Australia Focus groups using random and purposeful sampling with presentation on data N=50; 40-49: 38% 50-69: 32% 70-79: 30%, 100%, NR Previous screening: 62% (some in all age groups)	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 40-49: 2 vs 2.5 in 1000 50-59: 4 vs 6 in 1000 60-69: 5 vs 8 in 1000 70s: 6 vs 8 in 1000 • Overdiagnosis: 3 scenarios based on "at most 4" (1-10%), 11 (30%) or 19 (50%) of 38 diagnosed with BC of 1000 Format & Definitions: In-depth presentation (text, pictures, plain language) with discussions, clarifications, paraphrasing by women, and assessment of understanding; included portrayal of uncertainty in quantifying and detecting overdiagnosis such that treatments usually given **B:H Ratio:** Various (moderate-to-high benefit effects)	**Overdiagnosis vs BC mortality**: 10% "negligible"; 30% "acceptable and limited impact"; 50% "extremely high" and thought some may decline, delay (especially for younger), or be less concerned or rigorous about attending **Subgroups**: regular screenees less concerned than those with no/less experience	**Other outcomes of importance:** Peace of mind/reassurance highly motivating **Beliefs**: The idea of overdiagnosis was surprising and challenged women's beliefs about breast cancer generally being a serious and dangerous disease. Many women expressed surprise or disbelief at distinguishing between cancers that do require treatment and those that may not. Saw overdiagnosis as a treatment issue once diagnosed ("wait to deliberate management decisions") **Decision making:** • Many women considered it important to take overdiagnosis into account for informed choices, but many others wanted to be encouraged to be screened. • Preference for active involvement: 80%
Wong 2015, Hong Kong Population-based telephone survey using random-digit dialing about print-based decision aid N=90; 54±12.4, 15.5% (minimal user charge), Chinese Previous screening: few (<20% heard	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 20% RRR • FP: 10% • Overdiagnosis: "19% overdiagnosis" (and "30% given a diagnosis and treated, some of which some of which would not be affected in any way had the abnormalities not treated".) Format & Definitions: print-based decision aid (online	**Relative importance for making decisions:** BC mortality: important for 22% FP: important for 5% Overdiagnosis: important 5%	**Other outcomes of importance:** • Know more about health condition 38% • Discover cancer at early age 38% • Concern about risk 20% • Costs 11% **Beliefs:** Older women perceived significantly less severity from a BC diagnosis (b =-0.03, 95% CI = (-0.06, -0.01)) and more educated women reported significantly less anxiety about developing the

of mammography)	version https://brca-screen.sph.hku.hk/adv_en.php) with mainly textual presentation; overdiagnosis are abnormalities that may never become invasive or effect a life in any way; results in further diagnostics and treatment and no gain in post-treatment life expectancy; "major potential harm of mammography"; FPs: benign results from mammography after unnecessary investigations & may lead to anxiety, worry and depression for some **B:H Ratio:** High/moderate Other information: Lower BC incidence in Hong Kong (1 in 19); age-based risk for BC; USPSTF 2009 recommendations & Hong Kong recommendation of insufficient evidence (due to lower baseline rates); possibility for earlier stage & better treatment when diagnosing early, thus may have better quality-of-life after treatment		disease during their lifetime (b = -0.85, 95% CI = (-1.47,-0.24)) **Decision making:** • Baseline and follow-up (46.1% and 50.0%), more women indicated preference for an active role • Pre to post-DA more wanted collaborative (6% to 20%) than passive role (48% to 30%). (p value for kappa 0.99) **Knowledge**: • At followup, 88% thought screening prevented BC
50-69 year data on outcomes			
Petrova 2015, USA Web panel survey with outcomes data in three different formats (data text, fact box, visual aid) for same probabilities N=355; 18-85 (mean 38 ± 14), NR, NR "diverse" Previous screening: 36%	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 4 vs 5 in 1000 • Overdiagnosis: 5 vs 0 in 1000 Format & Definitions: background section & data in different formats via online survey; overdiagnosis: lengthy paragraph in background information on description and uncertainty in detection; with numerical presentation as "diagnosed with breast cancer but treated unnecessarily, often with mastectomy, radiation, or chemotherapy which can cause fatigue and pain" Format using data text, fact box, or visual aid had no significant effect on intentions (p=0.281) **B:H Ratio:** Moderate Other information: general on BC and screening; different treatments and their AEs	**Intentions to screen:** • 5.12 ± 1.94 (scale 1-7; 7 absolutely agree; >4 intended) • 66% yes, 13% undecided, 21% no	**Beliefs:** • 6.27 +/- 1.18 (scale 1-7) perceived severity of cancer had large effect on decisions and reduced degree to which comprehension effected intentions • Those who perceived breast cancer to be extremely severe reported feeling more assured and relieved upon reading the information about screening; these perceptions of severity and feelings of assurance predicted their increase in the perceived benefit of screening and stronger intentions to screen **Decision making:** 6.81 ± 1.53 (scale 2-12; 5-7 preference for shared; >7 autonomous) preferred shared (even if high comprehension of data) **Knowledge**: High comprehension was associated with less intention to get screened for some, but comprehension of the evidence had a limited effect on experienced emotions, risk perceptions, and decision making among those participants who felt that the consequences of cancer were extremely severe.
Yasunaga 2007, Japan Contingent valuation study; WTP (with or without harms data) drawn from random sample of registered internet users with outcomes in two information sheets N=397; 50-59, NR, Japanese Previous screening: 38%	**Communicated Outcomes of Screening:** • Sheet A: BC mortality: 20% RRR • Sheet B: BC mortality: 20% RRR & FP imaging and biopsies (most fine-needle): 803 in 10000 • Cost options were $: 5, 10, 30, or 50, then 2, 5, 10, 30, 50, 70 (higher or lower based on first bid) Format & Definitions: online survey with information sheets with lists of objective facts; FPs: additional close examinations with imaging *and* a biopsy, even if they don't have BC; tests with details on invasive test procedures but	**Willingness to pay for screening:** Sheet A $16.82 (95% CI 14.21-19.42) Sheet B $12.89 (95% CI 10.99-14.79) p = 0.02 **Subgroups**: higher WTP if family history of BC; lower WTP in those without previous screening history	**Beliefs:** Concern about health (a lot vs. not all all) was a significant factor affecting WTP; lower concern lower WTP (coefficient -0.417; p=000); self-rated health not significant

	no risks or psychosocial consequences mentioned **B:H Ratio:** High/moderate Other information: detection rate 22 in 10,000, increasing BC and BC deaths in Japan, screening procedure, detection rates		
Davey 2005, Australia Computer-assisted telephone interviews with convenience sample at clinic using structured questions on all four scenarios with different numerical values N=106; 45-70 (28% <51; 51% 51-60; 21% 61-70); 100%, NR Previous screening: 91%	**Communicated Outcomes of Screening (4 scenarios provided to all women in sequential order):** 1. BC mortality (relative): RRR 34% for biennial for 10 yrs 2. BC mortality (absolute): 4 vs 6 in 1000 for biennial over 10 yrs 3. All-cause mortality: This test reduces the chances of dying from BC. However, having the test will not increase the absolute chance of living a longer life. 4. FP: 50 in every 1000 for biennial for 10 yrs Format & Definitions: telephone narratives of each scenario; all-cause mortality: this test will reduce the risk for dying from BC, but having the test will not increase the absolute chance of living a longer life; FPs: women will eventually be shown through further tests that they do not have breast cancer. However, these women might experience worry, possible discomfort and inconvenience. **B:H Ratio:** Various (high/moderate for BC mortality vs FP) Other information: reassurance 940 in 1000, FN 2 in 1000,	**Relative importance of outcomes:** Very or important: BC mortality (absolute or RRR) 95%, FP 87%, overall benefits (1. to 3. In 2nd column) vs harms (p<0.01) **Willingness to be screened**: 78% using BC mortality absolute effects 53% after for all-cause mortality 79% knowing limitations (FPs and FNs)	**Attitudes/feelings:** Positive or very positive feelings: 85% using BC mortality ARR vs. 71% after ARR for all-cause mortality vs. 79% knowing limitations (harms) **Decision making:** 80% like collaborative or active decision making role
Hersch 2015, Australia RCT drawn from random cohort via electoral register comparing two decision aids +/- data on overdiagnosis N=879; 48-50; 100%, NR use of electoral register Previous screening: NR (not past 2 yrs although 40-49 eligible without invites in AUS)	**Communicated Outcomes of Screening (over 20 yrs):** • BC mortality: 4 avoid dying but 8 still die in 1000 • FP: 412 in 1000 (67 have biopsy) • Overdiagnosis: 19 of 73 (26%) diagnosed with BC in 1000 (IG only) Format & Definitions: booklet with text and visual formats using icon arrays and schematic with screening vs no screening for overdiagnosis; overdiagnosis: "Screening leads to finding some breast cancers that are not harmful; cancers like this may grow very slowly or just stay the same. Without screening, they would never be noticed or cause any trouble. Further checks and examination, doctors cannot be sure which cancers will be harmless. Therefore, treatment is recommended. So, across all the women who have screening, some end up having treatment they do not need." Schematic of women screened vs not screened. Details of treatments and their risks. Differences between FPs and overdiagnosis. FPs: false alarms with extra tests; "women often feel anxious while they are having the extra tests and waiting for their results, and then feel relieved when they are told there is no cancer after all. However, some women find that they	**Intention to start screening (very likely or likely) over next 2-3 yrs.** IG: Baseline: 89%; followup 74% CG: Baseline 91%; followup 87% p<0·0001 at followup; more in IG unsure **Relative importance of outcomes (very important):** BC mortality: IG 67%, CG 79% FP: IG 41%, CG 52% Overdiagnosis: IG 45%, CG 57% p<0.01 for all **Women's values related to benefits and harms:** Lower value in IG vs CG for benefits (4.0 vs 4.3) and harms (4.1 vs 4.3). (closer to 6 more positive values; both p<0.01)	**Attitude:** IG: 69% positive score CG: 83% positive score

	keep worrying about breast cancer for a while afterwards" Data collection 1-4 wks after receiving decision aid via post about 1/3 had discussed with partner or friend but not GP **B:H Ratio:** Moderate (only BC mortality and FP) vs low (all 3 outcomes) Other information: decision aids had additional information but same for both groups; all participants also received national screening brochure without numerical data		
Waller 2014, UK Home-based, computer-assisted survey with data presented in three different forms using stratified random location sampling (considered pre-post study) Eligible for screening (53-70): N=954; mean 62 yrs; 100% Not yet eligible for screening (25-46): N=1318; mean 35.3 yrs NR (50+ yrs eligible in the UK but authors excluded 47-52 to optimize #s not vs screening) % Caucasian NR but random sampling Previous screening: Eligible 91%; Not yet eligible 0%	**Communicated Outcomes of Screening:** • Version 1: 1 life saved to 3 overdiagnosis (ratio) • Version 2: total number of overdiagnoses 4000 compared to lives saved 1300 • Version 3: For every 200 women screened for 20 years there are 3 overdiagnoses and 1 lives saved Format & Definition: narrative during survey questions; overdiagnosis: "some women who have a screening mammography will be diagnosed and treated for breast cancer that would never otherwise have been found and would not have become life-threatening. This is the main risk of breast screening." [If "yes" for needing more information] "The main risk of breast screening is that some women end up having treatment for a cancer that would not have caused them any harm (i.e. they would have died from something else). This is because we can't tell which breast cancers will be harmful and which ones won't, so all women are offered treatment." No significant difference for intentions between versions of data (p=0.45) **B:H Ratio:** High/moderate	**Intentions to screen** (probably/definitely)**:** Eligible: baseline 91.4% vs follow-up 92% Not yet eligible: 90.1% vs follow-up 89% **Change in intentions** (1 level change between 5 yes definitely, yes probably, not sure, probably not definitely not): Eligible group: 4.5% Not yet eligible group: 8.1% Decreased intention was more likely in respondents not yet eligible for screening (OR: 1.96; 95%CI: 1.33–2.89) and exposed to Version 1 vs the other formats (OR: 1.50; 95% CI: 1.02–2.22)	**Knowledge:** 56.7% correct for objective question on overdiagnosis understanding and 64.4% reported no subjective uncertainty in understanding, but 43% failed to understand that screening increased cancer diagnosis (worse understanding than with studies having more explanation, e.g. Hersch 2013)
Eliciting data not specific to age			
Van den Bruel 2015, UK Online survey with two scenarios to elicit trade-offs in research panel representative of UK for age and sex; results specific for BC but prostate and bowel also assessed N=510 women; >18 (mean 46.9); NR	**Scenario 1**: In population of 1000 with 5% incidence of cancer and 1% cancer specific mortality, 1 will not die from cancer because of screening (10% RRR). How many women being overdetected and overtreated would you accept for 1 woman to avoid dying from BC? **Scenario 2**: In population of 1000 with 5% incidence of cancer and 1% cancer specific mortality, 5 will not die from cancer because of screening (50% RRR). How many women being overdetected and overtreated would you accept for 5	**Trade-offs:** Scenario 1: median 150 (95% CI 120 to 197) for 1 averted BC death, accept no overdetection at all 5.1% (3.4 to 7.9), accept overdetection in complete population 10.2% (7.7 to 13.2) 95% CI Scenario 2: median 313 (250 to 364) for 5 averted deaths 95% CI, accept no overdetection at all 3.5% (2.1 to 5.6) 95% CI,	**Beliefs:** Suggest some people would prefer to experience harm from cancer treatment rather than from cancer itself **Reasons for very low or high acceptance of overdiagnosis (most not specific to breast CA):** • *"The thought of getting cancer terrifies me and my mother died of cancer so I would always opt for screening and overdetection. Better to be safe than sorry" (high acceptance)* • *"I think that if people who are diagnosed fully understand that it may not turn into cancer so have the option to wait for treatment then extra screenings in breast cancer can only be a good thing however with bowel cancer its slightly trickier seeing as 1 in 20 people die from*

(100% in ≥50 yrs); NR "less ethnically diverse" Previous screening: 42% (but wide age)	women to avoid dying from BC? *These authors prefer the term overdetection to avoid implications of overdiagnosis meaning misdiagnosis Format & Definitions: written and graphical information; overdiagnosis/overdetection: definition with consequences of unnecessary tests and treatments and their harms Other information: absolute number of cases per year in the UK and a description of the treatment, including its adverse effects	accept overdetection in complete population 13.9% (11.0 to 17.2) 95% CI Acceptability of overdetection did not increase fivefold when benefit increased fivefold (i.e. benefits favor harms) **Subgroups**: people ≥ 50 accepted less overdetection than younger respondents (OR 1.93, 1.43-0.94 for low level of acceptance <30 overdiagnosis per death saved) in both scenarios; people with at least a degree accepted more overdetection in higher benefit scenario	*the treatment (operation) itself" (high and low acceptance for different scenarios)* • *"Surely the end result is to prevent suffering - if overdetection results in people being offered treatment who do not need it, then we need to examine the methods by which we detect rather than not screening and risk even one person dying" (high acceptance)* • *"Hopefully there will be improved detection methods in the future that will eliminate people suffer un-needed screenings." (low acceptance)* • *"It may be a better option to educate people about the symptoms of each disease rather than needlessly make so many people suffer unnecessary treatment" (low acceptance)* • *"It is something which should be highlighted far more than it is, to make people aware of the risks" (low acceptance)*
Schwartz 2000, USA Mailed survey using random selection stratified to oversample screening age N=479; 18+ (25% <40, 10% >70); NR; 90% Previous screening: 76%	No data provided but elicited Format & Definitions: in print survey questions; FP: false alarms where it looks like the women might have cancer when she doesn't; overdiagnosis "We would like to ask your opinion about ductal carcinoma in situ or DCIS, a breast abnormality which can only be picked up by mammograms. Specialists are confused about DCIS because some-times it becomes invasive and sometimes it doesn't. If DCIS does not become invasive, it will not affect how long a person will live even without treatment. Doctors don't know which DCIS will become invasive. Nowadays, almost everyone with DCIS gets treated. Many people receive surgery, chemotherapy, or radiation who would never have gotten sick. For these people, treatment provides no physical benefit." From survey "fairly realistic knowledge": median estimate of FP was 20% for over 10 yrs and RRR for BC mortality thought 33% by 25% and 50% by half; no question on benefits in actual terms	**Relative importance for decision making:** FP: important for 38% Overdiagnosis: important for 60% (71% in 18-39 yr) **Trade-offs:** • 63% would tolerate 500 or more FP per life saved • 37% would tolerate 10 000 or more per life saved • Best estimate 30-200 per life saved assuming 2-6 lives saved over 12 yrs and FP 20-40% **Subgroups:** previous FP (biopsy) similar high tolerance for FPs (35% wanted to take account of; 71% tolerate 500/life and 39% tolerate 10000 or more)	**Uncertainty:** At a 1% chance of DCIS becoming invasive, 42% of women chose treatment whereas at a 33% chance of invasion, 78% chose treatment. **Beliefs:** FP not considered harm: 92% thought that mammography could not harm a woman without BC
Gyrd-Hansen 2000, Denmark Discrete ranking/choice study with conjoint analysis with random sample drawn from register N=207; 50; 100%; NR drawn from national registry Previous screening: NR but starting age for screening	Variables on benefits and harms to calculate preference/ utility weights BC mortality: Risk of dying of BC over lifetime (30 yrs) 340 per 10000 without screening vs. 0, 60,90,120,130 with screening FP: Risk for FP over lifetime 0 per 10,000 without screening vs. to 1,200, 2,300, 3,500, 4,700 with screening (see appendix in Gyrd-Hansen & Sogaard, Health Economics. 2001;10:617-34) Format & Definitions: personal interviews with choice cards; FPs: unnecessary clinical mammography	**Preference weights/coefficients (both significant):** BC mortality reduction 0.01642 FP over lifetime -0.000297 Both significant, i.e., both increase in utility/disutility as program gets more intensified in intervals or # totals screens **Intentions to screen**: 12.9% declined to participate in a BC screening program (in all scenarios) **Subgroups:** number of screening tests over a lifetime had no impact on preferences (i.e.,	**Other outcomes of interest**: The main motivation for participation in 45% was to reduce the risk of dying from cancer. Other frequently observed motivations were to eliminate potential feelings of regret, and to gain information. **Decision Making**: Frequently observed motivation to screen was a tendency to accept what is offered or, in other words, do what is recommended.

		minor inconvenience); no professional training increased the utility for BC mortality reduction (e.g., lower education may increase judgement biases from media and overestimation of small probabilities)	

Table 3. Characteristics and findings from studies providing indirect findings on the weight women place on CTFPHC critical benefits and harms

Study, Country **Study Description** **Sample Size, Age, Insured/Funded BC Screening, Caucasian** **Screening history**	**Communicated Outcomes of Screening, Format of Information and Definitions Provided, Judgement of Benefit-Harm Ratio Considering Age Category and Relative to Others Studies in Category, Other Information Provided**	**KQ2a: Weighing of overall benefits vs harms via screening intentions/attendance**	**KQ2b: Additional findings related to how women make decisions (other outcomes, attitudes, beliefs, decision making)**
40-49 year data			
Mathieu 2010, Australia RCT of immediate vs delayed access to online decision aid for 40s N=412; 38-45 (16% <40); 100%; NR Previous screening**:** 27%	**Communicated Outcomes of Screening (biennially over 10 yrs):** • BC mortality: 2 vs 2.5 in 1000 • All-cause mortality: 12.8 vs 13.3 in 1000 die from any cause (including BC) • FP: 239 vs 0 extra tests in 1000 • Overdiagnosis: 21 vs 14 BC diagnoses in 1000; some will never affect your health Format & Definition: online decision aid with text and diagrams (icon arrays for screened and not screened) http://www.mammogram.med.usyd.edu.au/ ; FPs: "extra tests after an abnormal mammogram. The extra tests will show these women don't have breast cancer. Aside from the inconvenience of attending for these tests, some women will worry long after they have had them"; also in pop-up window that women in the 40s have denser breasts and more recalls than those in 50s; overdiagnosis (link in text to pop-up window when numbers provided for extra cancers diagnosed with screening): some extra diagnoses will lead to less death, some will just be known longer and some would never have effected your health; slow growing such as DCIS (a non-invasive form) that get treated; and not possible to predict which ones will become invasive **B:H Ratio:** Moderate/low	**Intentions to start screening:** Intervention: 43% yes, 18% undecided, 39% no Control: 40% yes, 39% undecided, 21% no **Relative importance/value for decision making**: For women's values related to the benefits and harms (Dormandy scale; closer to 6 more positive values): No difference between groups or between benefits (4.2 vs 4.1) and harms (4.5 vs 4.3).	**None**

	Other information: 7 extra women diagnosed; 9 FNs; 740 TN (reassurance) vs without screening 986 will not get BC or be screened. Information compared screening in 50s (i.e., in 1000 over 10 yrs: FN 10.4, FP 209; BC deaths saved 2; DCIS 4.9 vs 28 invasive) ; background information and reason for a decision in 40s; values clarification exercise (personal worksheet)		
Paul 2008, New Zealand Deliberative jury using random sample from electoral poll for public funding of screening women in their 40s; 1.5 day with expert testimonies (conflicting and neutral) and decision aid provided, discussions and deliberations N=12; 40-49; 100% for ≥45 (55% in study had <45 when not funded); 64% Previous screening**:** 55% (before 45)	**Communicated Outcomes of Screening (over 10 yrs biennially):** • BC mortality: 2 vs 2.5 in 1000 • All-cause mortality: 12.8 vs 13.3 in 1000 die from any cause (including BC) • FP: 239 vs 0 extra tests in 1000 • Overdiagnosis: 21 vs 14 BC diagnoses in 1000; some will never affect your health Format & Definition: presentations, decision aid with text and diagrams http://www.mammogram.med.usyd.edu.au/ , deliberations; FPs: "extra tests after an abnormal mammogram. The extra tests will show these women don't have breast cancer. Aside from the inconvenience of attending for these tests, some women will worry long after they have had them"; also in pop-up window that women in the 40s have denser breasts and more recalls than those in 50s; overdiagnosis (link in text to pop-up window when numbers provided for extra cancers diagnosed with screening): some extra diagnoses will lead to less death, some will just be known longer and some would never have effected your health; slow growing such as DCIS (a non-invasive form) that get treated; and not possible to predict which ones will become invasive **B:H Ratio:** Moderate/low Other information: 7 extra women diagnosed; 9 FNs; 740 TN (reassurance) vs without screening 986 will not get BC or be screened. Information compared screening in 50s (i.e., in 1000 over 10 yrs: FN 10.4, FP 209; BC deaths saved 2; DCIS 4.9 vs 28 invasive)	**Voting about public provision of screening 40-49 yrs:** 10 of 11 women changed their mind from *for* to *against* public provision of screening for 40-49, but the current policy of screening from age 45 should not be changed (back to age 50) The majority felt that mammography is not an accurate enough test for women 40 – 44 (FNs, FPs) and that lack of evidence that screening in this age group really does save lives, compared to starting screening in the 50's.	**Beliefs:** 1 woman took the view that screening was worthwhile if it could save a life, regardless of harms or costs, and that saving a life at a younger age was more important.
Seitz 2016, USA RCT using online survey (by survey company), stratified into 2 groups based on Gail Assessment (<1.5% vs ≥1.5% 10-year risk) then each risk group randomized to 1 of 8 conditions varying according to content (brief	**Brief intervention**: Individual risk for cancer and table summarizing USPSTF and CS recommendations **Extended intervention:** **Communicated Outcomes of Screening (over 10 years, biennially between the ages of 40 and 50):** • BC mortality: 3 in 1000 (without mammogram)	**Intentions to wait until age 50 (% [SD]; OR vs no information):** Comparators: 7.2% (26%) and 6.7% (25%) Brief interventions: 14-18.4% (ORs 2.09-2.89) Extended interventions: 19.4-24.2% (ORs 3.07-4.08)	All women overestimated their risk for breast cancer by approximately 10-15% (e.g. objective risk via Gail at 1-2.5% vs perceived by women before (17-20%) intervention.

[narrative] vs extended [numericals]) and format (expository vs untailored exemplar vs tailored exemplar), vs comparators no or basic (statements of USPSTF and American Cancer Society recommendations) information. We report results for brief and extended versions vs. comparators for women with <1.5% risk for BC (format did not change results) N=1227 (low risk); 35-49, 81.3%, 75.4% Previous screening: 57%	• BC mortality: 2 in 1000 (with mammogram) • FP (tests, biopsies, or surgery): 239 in 1000 women • Overdiagnosis: In addition to finding breast cancer, mammograms can sometimes draw attention to suspicious cells that would never had spread or become life-threatening. Doctors cannot always tell if these will spread or not, which may lead to unnecessary treatment. **Communicated Outcomes of Screening (over 10 years, biennially between the ages of 50 and 60):** • BC mortality: 6 in 1000 (without mammogram) • BC mortality: 4 in 1000 (with mammogram) • FP: 220 in 1000 women Format & Definitions: Online decision aid with text and diagrams, participants were emailed a link to the experiment; FPs: women do not have BC, but have extra tests, biopsies, or surgery following abnormal mammograms **B:H Ratio**: Moderate Other information: Personal and general 1-year and lifetime BC risks. TP and FNs: 12 (40-50 yrs) or 23 (50-60) in 1000 have BC detected by a mammogram; 9 (40-50 yrs) or 10 (50-60) in 1000 women have BC that is not detected by a mammogram, because it develops between mammograms. Statement on radiation. Women under 50 have a decision to make. All numerical data obtained from author contact.	(difference ns between brief and extended)	
Saver 2017, USA Randomized crossover study with a video intervention of slides used using a physician-patient interaction and numerical data and textual descriptions compared with a paper-based patient brochure without any data N=35; 40-49, NR, 60% Previous screening: 91%	**Communicated Outcomes of Screening (over 10 years, biennially between the ages of 40 and 50):** • BC mortality: 4 in 1000 (without mammogram) • BC mortality: 3.5 in 1000 (with mammogram) • FP: 330 in 1000 women (36 biopsies) • Overdiagnosis: Between 2 and 10 in 19 diagnoses in 1000 • Also mentions 1 in 200 women getting mammograms *over their lifetime* will be saved from dying from BC Format & Definitions: Recorded vignettes of physician-patient discussion about mammography based on 2009 USPSTF recommendations. https://youtu.be/6uGy72OCv_Q Overdiagnosis: Sometimes what looks like cancer under the microscope doesn't grow or spread like cancer. So some women go through the stress, possibly surgery and sometimes radiation and chemotherapy BUT they get treatment for something that	**Frequency of screening:** Pre: 54% annually, 34% biennially Post: 14% annually, 60% biennially **Intend to screen:** Pre: 85% yes and 6% unsure Post: 49% yes, 20% unsure Mean change in wanting mammography on 3-point scale (2=yes, 1=unsure, 0=no) -0.06 (p=0.75) control -0.50 (p <0.001) intervention **Benefits>Harms (1=definitely yes, 5=definitely no):** -0.14 (0.38) control	**Decision making:** Intend to discuss mammography with physician (5-point Likert with 1=definitely yes and 5= definitely no): 0.0 (p >.99) control -0.29 (p=0.07) intervention (trend for lower intentions to discuss with physician after receiving the intervention) **Knowledge/Understanding**: Authors report that harms being unclear (anxiety from FP) or poorly understood (overdiagnosis and overtreatment) may be reason for small changes to intentions; the men in the study evaluating prostate cancer were much more likely to reduce intentions (perhaps due to easily understood harms). Also report that their qualitative work when developing the tool indicated that women are heavily socialized to value mammography.

	never would have hurt them. FPs: Mammograms are not perfect. FP can lead to biopsies. Waiting for results can let to unnecessary stress. **B:H Ratio:** Low/moderate Other information: USPSTF recommends every other year and says if done every year, FEW additional lies saved BUT harms almost doubled. Other groups say mammograms should be done every year. Sometimes a biopsy shows something that isn't cancer but has a chance it could later turn into cancer. This is called DCIS.	-0.65 (<0.001) intervention Order of presentation did not make a difference.	
Elkin 2017, USA Prospective, single-arm trial for development and evaluation of a web-based decision aid to help women decide when to start and how often to have mammograms N=168; 40-49; 98%; 80% Previous screening: 74% at least once	**Communicated Outcomes of Screening** **Comparing BC and all-cause mortality, over one's lifetime, based on starting age and intervals (not compared with no screening):** Annually starting at 40: BC mortality: 22 in 1000; 978 in 1000 die from other causes Biennially starting at age 40: BC mortality: 24 in 1000; 976 in 1000 die of other causes Annually starting at age 50: BC mortality: 23 in 1000; 977 in 1000 die of other causes Biennially starting at age 50: BC mortality: 25 in 1000; 975 in 1000 die of other causes **Over 10 years**, annual screening cumulative FP 60%, biennial screening FP 40% **In 1000 screens**, FN 1 vs FP 98 vs TP 2 Format & Definition: online decision aid with text and icon arrays www.breastscreeningdecisions.com framed around decisions on when to start screening (40s or 50s) and how often. FPs: do not have BC despite an abnormal mammogram; may require biopsy and be inconvenient and physically uncomfortable. Overdiagnosis and unnecessary treatment are described qualitatively in plain language, with links to additional information. Also, "many cancers found by screening have a very small chance of causing death". **B:H Ratio:** Moderate Other information: Personal risk assessment and prediction over next 5 years provided. FN: BC that is missed by screening. Values clarification exercise.	**Actual & intention to start or continue screening:** 30% Had a screening mammogram 18% Scheduled an appointment for screening mammogram 29% Plan to make an appointment in the next 6 mos. 18% No plan 5% Unsure **Potential benefits outweigh the potential risks:** 83% strongly agree or agree 10% Neither agree or disagree 7% Strongly disagree or disagree	**Other outcomes:** Having a screening mammogram would help them worry less about BC 70% strongly agreed or agreed 16% Neither agree or disagree 14% Strongly disagree or disagree
50-69 year data			
Berens 2015, Germany	**Communicated Outcomes of Screening (over 20 years,**	**Intentions to start screening:**	**Attitude:**

Survey questionnaire 1 mo after receiving population-based program invite plus 2010-2015 version of German leaflet N=4113; 50; 100%; 90% (10% immigrants) Previous screening**:** 0%	**biennially):** • BC mortality: 1 in 200 women saved • FP: 50 in 200 (10 of these with tissue samples) • Overdiagnosis: 1 additional diagnoses in 10 diagnosis or in 200 screened (1 in 3 becomes dangerous) (Also, of 10 in 200 women with breast cancer, 1 would not have known about it in their lifetime, and 8 would have been treated successfully without screening) Format & Definitions: print brochure; FPs process including needle biopsies in some; 5 of 6 harmless; harm if causes worry; overdiagnosis: tumors found and treated but would never have caused problems Data collection: 1 month after receiving information **B:H Ratio:** High/moderate Other information: incidence of breast cancer (1 of 20 during 50-69; 35 of 1000 women screening for 10 years), cure rate (30%), risk with age and family history, FN results (3 of 200 women over 20 years between 50-69; vs 10 TP from screening); harm if malignancy only extends period of having breast cancer; better treatment sometimes if earlier	84% intended to (start to) participate in program or opportunistic screening over next 3 mos **Subgroups:** With increasing education level, significantly larger proportions of women intended not to participate (10.5% low, 13.4% medium, and 15.5% high education group).	93.7% had positive attitude about screening; less positive in non-immigrant women but most positive in Turkish immigrant women.
Gummersbach 2015, Germany RCT via survey with old vs new (2010-2015 version) German leaflet sent to women before their first invitation for screening program N=353; 48-49; 100%; NR Previous screening: 0%	**Communicated Outcomes of Screening (over 20 yrs):** • BC mortality: 1 in 200 women saved • FP: 50 in 200 (10 of these with tissue samples) • Overdiagnosis: 1 additional diagnoses in 10 diagnosis or in 200 screened (1 in 3 becomes dangerous) (Also, of 10 in 200 women with breast cancer, 1 would not have known about it in their lifetime, and 8 would have been treated successfully without screening) Format & Definitions: print brochure; FPs process including needle biopsies in some; 5 of 6 harmless; harm if causes worry; overdiagnosis: tumors found and treated but would never have caused problems **B:H Ratio:** High/moderate Other information: incidence of breast cancer (1 of 20 during 50-69; 35 of 1000 women screening for 10 years), cure rate (30%), risk with age and family history, false negative results (3 of 200 women over 20 years between 50-69; vs 10 TP from screening)	**Intentions to start screening:** Intervention: 81.5% (95% 75.8%–87.2%) Control: 88.6% (95% CI 83.9%–91.3%) p=0.06 **Subgroups**: Willingness to participate was negatively correlated with their educational level; if experience of BC in themselves or in close relatives (18.7%), receipt of the new leaflet increased the likelihood that they would be willing to be screened (96.6% versus 72.5%; difference, 24.1%; p = 0.009)	**Decision making:** Doctor's recommendation (48.2%); the information leaflet was named less often than any other factor on the list (3.6%) (similar between groups).
Henricksen 2015, Denmark Qualitative interviews on official information and leaflet provided N=6; 45-49; 100%, NR Previous screening: 0%	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 4.4 vs 4.8 in 1000; 15% reduction in risk for dying; 2000 screened over 10 yr to save 1 life • All-cause: no difference in length of life if screened • FP: 180 vs 0 in 2000 • Overdiagnosis: 10 in 2000 have diagnosis that will be over-treated; 25% of BC diagnoses; 1 in 4 diagnoses is a	**Intentions to start screening:** None of the women expressed a wish to seek out more facts, and after being provided with more information, one woman reconsidered her decision (to start screening when invited) based on information on overdiagnosis.	**Attitude:** Information that conflicted with attitudes the women already held was actively disregarded. **Beliefs/Understanding:** Women have expectations about breast cancer screening that are formed before they receive information from the screening programme. These expectations compromise the perception of balance between screening benefits and potential harmful effects. They also influence the perception of the information in the breast screening leaflet. **Decision making:**

	sleeping cancer, 33% more women have surgery than actually have cancer Format & Definitions: print leaflet and interview guide with different formats for numbers with probes and explanations by interviewer; FPs: unspecified findings, but all women talked about anxiety and fear this would cause; overdiagnosis: have a cancer diagnosis "sleeping cancer that may or may not waken" that is over-treated; identified as cancer patients and offered surgery despite their cancer being non-progressive **B:H Ratio:** Low Other information: 50 out of 1000 women will develop cancer (and positive frame 950 women out of 1000 will never develop cancer).		Decision-making process was dominated by the attitudes of the circle of acquaintances and to a lesser extent by the information accompanying the screening invitation.
Bourmaud 2016, France RCT standard leaflet vs decision aid N=16000; 50-74; 100%; random selection of those registered with national health program Previous screening: 46%	**Communicated Outcomes of Screening:** • BC mortality: 26 of 100 cancers die over 10 yrs in those screened biennially over 24 yrs vs 40 of 100 cancers in those not screened • FP: 94 in 1000 (37 more frequent imaging, some biopsies, 2 surgeries for benign anomaly) Format & Definitions: 12-page leaflet with illustrations, text, histograms; FPs; anomalies that are later found to be benign, 37 of 97 will need more frequent imaging, some will need biopsy, 2 will need surgery; abnormal images may lead to additional imaging, anxiety (short-term during examinations), more frequent examinations, having surgery with general anesthetic Data collection: women did not know they were being studied; just provided with either intervention or control then attendance at programs measured. **B:H Ratio:** High Other information including FN (1-2 in 1000), cancer rate 10 in 100; 30% lower rate of chemotherapy.	**Actual screening attendance:** Lower attendance in intervention (3,174; 40.45%) vs control (3,353; 42.14%) in the 12 months following the invitation (p = 0.02). Previous year attendance in program was 50%.	**None**
Toledo-Chavarri 2017, Spain Qualitative study using 7 semi-structured focus groups to evaluate decision-making and acceptability of a decision aid N=39; 40-49 (23%), 50-69 (77%); 100%; NR Previous screening: 90% (33% with previous FP)	**Communicated Outcomes of Screening (50 – 70 yrs olds, biennially until they are 80):** • BC mortality: 1 life saved in 200 • FP: 40 in 200 • Overdiagnosis: 2 in 200 Format & Definitions: print-based decision aid with text and icon arrays for screening. FPs: additional tests to rule out cancer that may be a false alarm. Overdiagnosis: The screening detects harmless cancers. Some types of cancer	**Intentions to screen:** The vast majority of the women who had already considered participating expressed that they would participate.	**Beliefs:** Many overestimated both risks associated with breast cancer and benefits from screening (even with NNS 200) **Attitudes:** Many women had difficulty with the concept of overdiagnosis. Only 2 women had ever heard the term overdiagnosis but were unable to define it. Wording of decision aid was not clear to them. Some women said they would have preferred not to know the information on overdiagnosis, as it caused them anxiety and increased their uncertainty about screening. *"I do not understand this 'some will be treated without being necessary'. I don't really understand it."* (Currently screens due to family history)

	that are detected by screening grow so slowly that they would never have become a health problem. Some even would have disappeared spontaneously without treatment. Drs can't always know if an initial BC can endanger the life of a woman so they offer treatment to all the women diagnosed. This means that some women will be offered treatment they do not need. **B:H Ratio:** High/moderate Other information: 15 in 200 diagnosed, with 8 living (regardless of screening), 4 dying (with screening); 1 in 9 women will have BC throughout their lives and 83% of affected women will survive this disease. Mammography does not prevent you from getting cancer.		*"That is so crazy!"* (Doesn't participate in population screening) *"It is better not to know"* (Does not participate in population screening) **Decision making**: Some women found the information on benefits and risks of screening unnecessary, while others found it helpful for informed or shared decision making. Women against receiving the information considered it unnecessary either because screening was assumed to be positive and therefore participation was seen as a duty or because the decision should be made by a doctor. Other women were in favour of receiving information and consulting with a professional in the form of an informed or shared decision. "*How can I make a decision if it is beneficial to my health? I don't quite understand why you're asking me if I need a tool, when I know it's beneficial"* (Does not participate in population screening). *"If the doctor says you have to do it, you do it"* (Participates in population screening, false-positive result)
Haakenson 2006, USA RCT invitation letter +/- 2 informative brochures in women within large cohort study on mammography and 1 mo before scheduled mammogram N=668; 61.5±11; NR but all scheduled for mammograms; 98% Previous screening: 99%, 75% annually	**Communicated Outcomes of Screening:** • BC mortality: 21-30% RRR • FP: 10-20% total recalls (including FP and TP); 80% of 8-10% biopsies FP Format & Definition: 2 brochures: FPs: call backs quite common (compared with 2-4 per 1000 with diagnosis) often just meaning more imaging needed to look at suspicion area more carefully Data collection: 1-2 after receiving mailed brochures **B:H Ratio:** High Other information: tips about process; recommendations for most people to screen annually; some information on personal risk assessment	**Actual screening attendance:** Intervention: 1.67% did not attend scheduled mammogram Control: 4.03% did not attend scheduled mammogram (p=0.73)	**Beliefs/feelings:** Receiving pamphlets was reassuring and lessened anxiety (~90% said they disagreed or strongly disagreed that info increased their anxiety about test). **Decision making:** 96% of women like to be involved in decision making, but women relied predominantly on their primary care physicians for referral for screening mammography (70.2% and 65.5% in the control and intervention groups, respectively; p=0.21)
Baena-Canada 2015, Spain RCT standard vs Cochrane 2008 leaflet provided and explained to women right after a mammogram in national program N=355; 45-67 (mean 54); 100%; NR Previous screening: 100% just completed	**Communicated Outcomes of Screening (over 10 yrs):** • BC mortality: 1 death from BC avoided in 2000 • FP: 200 in 2000 experience important psychological distress from FPs • Overdiagnosis: 10 in 2000 (30% of diagnosed) screened are diagnosed and treated unnecessarily Format & Definitions: Cochrane 2008 leaflet (translated by Spanish speaker with back translation) provided and verbally explained; FPs: psychological strain until it is known whether or not there is a cancer, can be severe; overdiagnosis: healthy women become cancer patients and will be treated unnecessarily with surgery and usually other treatments (authors mention limited understanding)	**Intentions to continue screening:** Intervention: 175 (98.90%) yes, 2 (1.10%) undecided Control: 178 women (100%) yes (p = 0.240)	**Attitude:** IG: 176 women (99.40%) positive attitude CG: 176 (98.9%) positive attitude (p = 1.000)

	Data collection: 1-month after receiving leaflets **B:H Ratio:** Low/moderate Other information: Possible risks from radiation, pain, false insecurity		
Waller 2013, UK Qualitative focus groups with purposive sampling for ethnicities, marital and socioeconomic statuses; using NHS 2011 leaflet plus description and data for overdiagnosis N=40 (6 FGs); 50-71 yrs; 100%; 67.5% Previous screening: 73% regular, 22% not regular; 5% never	**Communicated Outcomes of Screening:** • BC mortality: 1 BC death prevented for every 400 women screened regularly over 10 years • FP: no #s • Overdiagnosis: between 1-3 of 8 diagnoses in 1000 Format & Definitions: leaflet and additional information verbally in focus groups; overdiagnosis: "screening can find cancers which are treated but which may not otherwise have been found during your lifetime" and "(they are) so slow-growing that they would not have caused any problems. But because we can't yet tell which kind of cancer is the slow-growing kind, the woman receives the usual treatment for breast cancer (e.g., surgery). It's very hard to know what proportion of cancers diagnosed in the screening programme are of the slow-growing type and the experts disagree at the moment." **B:H Ratio:** Moderate Other information in leaflet all descriptive	**Intentions to screen:** Remained high overall; few women felt that they would make different decisions about breast screening in the future	**Other outcomes of importance**: Most women retained their initial perspectives on (95% had screened) attending screening because of reassurance, desire to know if cancer is present, and increased chances of better treatment. **Attitude:** • A few women did describe a change in attitude. • Many women struggled to see the information on overdiagnosis as relevant to their decision-making about screening (compared with false negatives) but thought it should be part of their decision. The risk of undertreatment of cancer was seen as much greater than the risk of overtreatment. • There was trust in doctors, scientists and the NHS breast screening programme to utilise new knowledge or improved technology to ameliorate the risk of overdiagnosis and unnecessary treatment in the future.
Lawrence 2000, USA Decision aid validation study in sample of European and Mexican American women N=28 for quantitative findings, 71 for qualitative findings; 50-80; 100% for quantitative findings, 71 for qualitative findings; European Americans for quantitative findings, European and Mexican Americans for qualitative findings Previous screening**:** 96% in quantitative findings; 82% in qualitative findings	**Communicated Outcomes of Screening (in 1000 over 10 yrs):** BC mortality: 50-59 yrs 4 vs 7 deaths 60-69 yrs 6 vs 10 deaths 18% vs 25% death rate (RRR 30%) FP: 5% (specificity [1- false positive rate = 95%]) Overdiagnosis (DCIS with treatment but 85% having no recurrence): 50-59 yrs 1 vs 5 60-69 yrs 2 vs 7 Format & Definition: decision aid created with multidisciplinary team and piloted with lay people, including focus groups; FPs: description of rates and consequences provided (e.g., additional films, sonograms, possible biopsy, anxiety, occult cancer); overdiagnosis in terms of recurrence risk for DCIS and all receiving lumpectomy; reliability 100% and validity good (22/28 changed preferences after removing benefits); overdiagnosis is implied rather than explicitly stated, using rates of DCIS without recurrence	**Intentions to screen:** 93% chose to have mammogram; 7% chose not to (similar to baseline) Overall, 89% (22/28) changed preference as predicted when removing data on benefits (46% explicitly, 32% implicitly by decreased confidence score).	**Beliefs (qualitative data):** European American women (8 examples): n=1 usually screen because doctor recommends; n=5 might not help them personally but good to know, will help change behaviors, may help others, may help me have smaller operation, n=3 like the information on risks, spread, other information about screening Mexican American women (11 examples): most about improved general knowledge about BC, risks

	B:H Ratio: High/moderate Other information: average risk information, screening process, treatment options; FNs 15%		
70+ age data			
Schonberg 2014, USA Pre-post trial of decision aid in women attending clinics N=45; 75-89; NR (but clinic attendees); 69% Previous screening: 100% within 3 yrs	**Communicated Outcomes of Screening (over 5 years):** • BC mortality: 3 vs 4 in 1000 women age 75 or older • FP: 100 vs 0 in 1000 women age 75 or older • Overdiagnosis: 4 vs 0 pre-cancers and 20 vs 12 early stage in 1000 Format & Definition: decision aid textual and icon arrays for screening vs no screening; FPs: abnormal mammogram but additional tests do not show breast cancer. Some women find this experience causes anxiety and lists of testing with mammograms, ultrasound or biopsies (no numerical data); overdiagnosis: some small breast cancers (pre-cancer or early stage) found on an older woman's mammogram would not have caused problems for at least 5 or 10 years. Some of the cancers may never have caused problems. **B:H Ratio:** Moderate Other information: BC risk, life expectancy, benefits and harms, competing mortality risks, values clarification exercise, treatments and AEs	**Intention to continue screening:** 82% pretest and 56% posttest intend to get a mammogram (p=0.004) **Subgroups:** A significant difference in screening intentions was only seen for those with <9 yrs life expectancy (85 vs 50%) vs >9 yrs life expectancy (79 vs 63%).	**Decision making:** No significant change in the number of women preferring an active role in decision making after reading the DA (shared with physician or only physician pre 61 vs post 56 p=0.75).
Mathieu 2007, Australia RCT standard brochure vs print-based decision aid for women in their 70s using random sample from BC screening program N=734; 70-71; 100%; NR Previous screening: 100% twice in past 5 yrs	**Communicated Outcomes of Screening (over 10 yrs biennially):** • BC mortality: 6 vs 8 in 1000 • All-cause mortality: 204 vs 206 die (including from breast cancer) • FP: 135 vs 0 in 1000 • Overdiagnosis: 41 vs 26 diagnoses in 1000; defined with example in appendix Format & Definitions: print-based decision aid with text and icon arrays for screening and no screening http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml ; FPs: "extra tests after an abnormal mammogram. The extra tests will show these women don't have breast cancer. Aside from the inconvenience of attending for these tests, some women will worry long after they have had them"; overdiagnosis (in appendix): "some of these cancers would never be found without screening (see page 19 for more information, "more breast cancers due to screening because some women die of something else first (because so slow growing), and if not screened would not have had	**Intentions to continue screening:** IG: baseline 77.4% yes, 16% unsure, 6.3% no vs. follow-up mailed questionnaire 85.7% yes, 4.9% unsure, 9.5% no CG: baseline 77.7% yes, 12% unsure, 10.4% no vs. follow-up mailed questionnaire 80.6% yes, 10.1% unsure, 9.3% no OR for stopping 1.28 [95% CI, 0.63-2.61]; P=.50) **Actual re-attendance:** 1-month phone call: no difference in participation between groups (IG 5.9% vs CG 7.0%). Most indicated that they were in the process of arranging to be screened (IG: 75.7% vs CG: 74.7%).	**Attitude:** 95% of all women remained positive toward screening

	treatment (lumpectomy and radiotherapy)") **B:H Ratio:** Moderate/low Other information on why choice to be made, risk factors, competing death risks, FNs (9), reassurance 824 vs 974 with symptoms/diagnosis if not screened, worksheets and examples of other women's sheets		

Table 4. Methodological quality of qualitative studies

Study	Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	Overall assessment of quality
Table 2*										
Dreidger, 2017	Y	Y	Y	Y	Y	U	Y	Y	Y	High
Hersch, 2013	Y	Y	Y	Y	Y	U	Y	Y	Y	High
Table 3										
Toledo-Chavarri, 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	High
Henriksen, 2015	Y	Y	Y	Y	U	U	U	Y	Y	High
Waller, 2013	Y	Y	Y	U	Y	N	Y	Y	Y	Good

*The studies are categorized by whether they are further described in Table 2 or 3.

Y=yes, N=no, U=unclear

Table 5. Risk of bias of randomized controlled trials

Study	Sequence Generation	Allocation Concealment	Blinding of participants and personnel	Blinding of Outcome Assessors	Incomplete Outcome Reporting	Selective Reporting	Other Bias*	Overall assessment of quality
Table 2*								
Hersch, 2015	L	L	L	L	L	L	L	High
Table 3								
Sietz, 2016	L	L	U	U	U	L	L	Good
Saver, 2017	L	L	L	U	U	L	L	Good
Baena-Canada, 2015	L	L	H	H	L	L	L	Fair
Bourmaud, 2016	L	L	L	L	L	L	L	High
Gummersbach, 2015	L	L	L	L	U	L	L	High
Haakenson, 2006	H	U	U	U	U	L	L	Fair
Mathieu, 2010	L	L	H	H	H	L	L	Fair
Mathieu, 2007	L	L	U	U	L	L	L	Good

*The studies are categorized by whether they are further described in Table 2 or 3.

L=low risk, H=high risk, U=unclear risk; *Other biases that were considered included baseline imbalances between groups and inappropriate statistical analysis

Table 6. Methodological quality of cross-sectional and pre-post studies

Study	Did the study address a clearly focused question/ issue?	Is the research method appropriate for answering the research question?	Is the method of selection of the subjects clearly described?	Was the sample of subjects representative with regard to the population to which the findings will be referred?	Was the sample size based on pre-study considerations of statistical power?	Was a satisfactory response rate achieved?	Are the measurements likely to be valid and reliable?	Was the statistical significance assessed?	Are confidence intervals given for the main results?	Have confounding factors been accounted for?	Can the results be applied to your organization?	Overall assessment of quality
Table 2*												
Davey, 2005	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Good
Lewis, 2003	Y	Y	Y	N	Y	Y	U	N	N	Y	Y	Fair
Nekhlyudov, 2008	Y	Y	Y	N	N	U	Y	N	N	U	Y	Fair
Petrova, 2015	Y	Y	U	N	U	U	Y	Y	Y	U	U	Good
Schwartz, 2000	Y	Y	Y	N	Y	Y	U	Y	N	U	Y	Good
Van de Bruel, 2015	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Good
Waller, 2014	Y	Y	Y	U	U	U	Y	Y	Y	Y	Y	High
Wong, 2015	Y	Y	Y	U	N	U	Y	N	N	Y	U	Fair
Table 3												
Elkin, 2017	Y	Y	Y	N	U	U	Y	Y	Y	Y	Y	Good
Berens, 2015	Y	Y	Y	U	U	U	U	Y	Y	U	Y	Good
Lawrence, 2000	Y	Y	Y	U	U	U	Y	U	N	U	Y	Fair
Schonberg, 2014	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	High

*The studies are categorized by whether they are further described in Table 2 or 3.

Y=yes, N=no, U=unclear

APPENDIX A: Search Strategies

MEDLINE: Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid

MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

1. exp Breast Neoplasms/
2. exp Carcinoma, Intraductal, Noninfiltrating/
3. ((adenocarcinoma* or adenoma* or cancer* or carcin* or malignan* or metasta*or neoplas* or sarcoma* or tumour* or tumor*) adj3 (breast? or mamma or mammar*)).tw,kf.
4. (DCIS or (ductal carcinoma adj1 (in situ or insitu))).tw,kf.
5. ((intra-ductal or intraductal) adj1 carcinoma*).tw,kf.
6. or/1-5 [Combined MeSH & textwords for breast cancer]
7. exp *Breast Neoplasms/di, ra, us and screen*.mp.
8. exp Early Diagnosis/ and screen*.mp.
9. False Positive Reactions/ and screen*.mp.
10. exp Magnetic Resonance Imaging/ and screen*.mp.
11. exp Mammography/
12. exp Mass Screening/
13. Physical Examination/ and screen*.mp.
14. exp Self-Examination/
15. Ultrasonography, Mammary/ and screen*.mp.
16. ((breast? or mamma or mammar* or nipple?) adj5 (exam* or selfexam*)).tw,kf.
17. (echograph* or echo-mammogra* or echo-tomograph* or echomammogra* or echotomograph*).tw,kf.
18. (over diagnos* or overdiagnos* or over detect* or overdetect* or over treat* or overtreat* or misdiagnos*).tw,kf. and screen*.mp.
19. false positive*.tw,kf. and screen*.mp.
20. (magnetic resonance imag* or magnetic resonance tomograph* or MR tomograph* or MRI or MRIs or NMRI or NMRIs).tw,kf. and screen*.mp.
21. (mammogram* or mammograph*).tw,kf.
22. screen*.ti.
23. screen*.ab. /freq=2
24. (sonograph* or ultra-son* or ultra-sound* or ultrason* or ultrasound*).tw,kf. and screen*.mp.
25. or/7-24 [Combined MeSH & textwords for screening]
26. and/6,25 [Combined concepts for breast cancer and screening]
27. *Breast Neoplasms/px
28. *Choice Behavior/
29. *Consumer Behavior/
30. Decision Making/
31. Health Care Surveys/
32. Informed Consent/
33. *Mammography/px
34. Patient Acceptance of Health Care/
35. Patient Participation/
36. Patient Preference/
37. *"Quality of Life"/

38. (15D* and (HRQoL or QoL or "quality of life")).mp.
39. ((analys#s or valuation? or value? or valuing) adj3 (conjoint or contingent)).tw,kf.
40. (choice? adj2 (behavio?r* or discrete or experiment*)).tw,kf.
41. ((choice? or choos* or consent* or decision*) adj1 informed).tw,kf.
42. (EQ 5D or EQ5D or EuroQoL 5D or EuroQoL5D).mp.
43. health utilit*.tw,kf.
44. HUI.tw,kf.
45. (multi?attribute or multi?criteria).tw,kf.
46. (pay adj2 willing*).tw,kf.
47. preference*.tw,kf.
48. prospect theor*.tw,kf.
49. (QoL or quality of life).ti.
50. (SF 12 or SF 36 or SF 6D or SF12 or SF36 or SF6D).mp.
51. standard gamble*.tw,kf.
52. (trade off? or tradeoff?).tw,kf.
53. (willing* adj2 pay*).tw,kf.
54. or/27-53 [Combined MeSH & text words for preferences & values]
55. (client* or consumer* or female* or patient* or public or wom#n*).tw,kf.
56. and/54-55
57. ((accept* or consider* or choice? or choos* or chose? or decid* or decis* or input* or involv* or opinion* or participat* or perceiv* or percepti* or perspective? or prefer* or respons* or valuation or value? or valuing or view*) adj3 (client* or consumer* or female* or patient* or public or wom#n*)).tw,kf.
58. or/56-57 [Combined searches for patient preferences & values]
59. and/26,58 [Combined concepts for breast cancer screening and patient preferences/values]
60. Male/ not (Female/ and Male/)
61. (m#n or male*).ti.
62. 59 not (60 or 61) [Male only records excluded]
63. (Adolescent/ or exp Child/ or exp Infant/) not exp Adult/
64. (adolesc* or baby or babies or boy* or child* or fetus or fetal or foet* or girl* or juvenile* or kid or kids or infan* or newborn* or new-born* or neonat* or neo-nat* or paediatr* or pediatr* or preadolesc* or prepubesc* or preteen* or pubescen* or teen* or toddler* or youth*).ti,jx.
65. 62 not (63 or 64) [Child only records excluded]
66. exp Animals/ not Humans/
67. (animal or animal-model* or animals or canine* or cat or cats or dog or dogs or feline or felines or hamster or hamsters or mice or monkey or monkeys or mouse or pig or piglet or piglets or pigs or porcine or primate* or rabbit or rabbits or rat or rats or rodent or rodents or sheep or swine or swines).ti.
68. 65 not (66 or 67) [Animal only records excluded]
69. *Genes, BRCA1/ or (BRCA* or gene* or hereditary).ti.
70. 68 not 69 [Genetic high-risk patient studies excluded]
71. (comment or editorial or letter or news or newspaper article).pt.
72. 70 not 71 [Opinion pieces excluded]
73. case reports.pt.
74. (case report* or case stud*).ti.
75. 72 not (73 or 74) [Case studies excluded]

76. limit 75 to (english or french)
77. limit 76 to yr="2000-Current"
78. remove duplicates from 77

Cochrane Library via Wiley

#1 [mh "Breast Neoplasms"] 9912
#2 [mh "Carcinoma, Intraductal, Noninfiltrating"] 116
#3 ((adenocarcinoma* or adenoma* or cancer* or carcin* or malignan* or metasta*or neoplas* or sarcoma* or tumour* or tumor*) near/3 (breast* or mamma or mammar*)):ti,ab,kw 21324
#4 (DCIS or ("ductal carcinoma" near/1 ("in situ" or insitu))):ti,ab,kw 300
#5 ((intra-ductal or intraductal) near/1 carcinoma*):ti,ab,kw 277
#6 {or #1-#5} 22459
#7 [mh "Breast Neoplasms" [mj]/DI,RA,US] and screen*:ti,ab,kw 262
#8 [mh "Early Diagnosis"] and screen*:ti,ab,kw 887
#9 [mh "False Positive Reactions"] and screen*:ti,ab,kw 167
#10 [mh "Magnetic Resonance Imaging"] and screen*:ti,ab,kw 184
#11 [mh Mammography] 1028
#12 [mh "Mass Screening"] 5525
#13 [mh ^"Physical Examination"] and screen*:ti,ab,kw 142
#14 [mh Self-Examination] 200
#15 [mh ^"Ultrasonography, Mammary"] and screen*:ti,ab,kw 20
#16 ((breast* or mamma or mammar* or nipple*) near/5 (exam* or selfexam*)):ti,ab,kw 764
#17 (echograph* or echo-mammogra* or echo-tomograph* or echomammogra* or echotomograph*):ti,ab,kw 3651
#18 (("over diagnos*" or overdiagnos* or "over detect*" or overdetect* or "over treat*" or overtreat* or misdiagnos*) and screen*):ti,ab,kw 195
#19 ("false positive*" and screen*):ti,ab,kw 517
#20 (("magnetic resonance imag*" or "magnetic resonance tomograph*" or "MR tomograph*" or MRI or MRIs or NMRI or NMRIs) and screen*):ti,ab,kw 490
#21 (mammogram* or mammograph*):ti,ab,kw 1847
#22 screen*:ti 8214
#23 ((sonograph* or ultra-son* or ultra-sound* or ultrason* or ultrasound*) and screen*):ti,ab,kw 1093
#24 {or #7-#23} 16345
#25 #6 and #24 2177
#26 [mh ^"Breast Neoplasms" [mj]/PX] 15
#27 [mh ^"Choice Behavior" [mj]] 398
#28 [mh ^"Consumer Behavior" [mj]] 131
#29 [mh "Decision Making"] 3499
#30 [mh ^"Health Care Surveys"] 353
#31 [mh "Informed Consent"] 605
#32 [mh Mammography [mj]/PX] 58
#33 [mh ^"Patient Acceptance of Health Care"] 2395

#34 [mh ^"Patient Participation"] 1057
#35 [mh ^"Patient Preference"] 525
#36 [mh ^"Quality of Life" [mj]] 4510
#37 (15D* and (HRQoL or QoL or "quality of life")):ti,ab,kw 55
#38 ((analys?s or valuation? or value? or valuing) near/3 (conjoint or contingent)):ti,ab,kw 43
#39 (choice? near/2 (behavio?r* or discrete or experiment*)):ti,ab,kw 11
#40 ((choice? or choos* or consent* or decision*) near/1 informed):ti,ab,kw 7118
#41 ("EQ 5D" or EQ5D or "EuroQoL 5D" or EuroQoL5D):ti,ab,kw 1792
#42 "health utilit*":ti,ab,kw 293
#43 HUI:ti,ab,kw 71
#44 ("multi-attribute" or "multi-criteria" or multiattribute or multicriteria):ti,ab,kw 62
#45 (pay near/2 willing*):ti,ab,kw 629
#46 preference*:ti,ab,kw 8611
#47 "prospect theor*":ti,ab,kw 27
#48 (QoL or "quality of life"):ti 10677
#49 ("SF 12" or "SF 36" or "SF 6D" or SF12 or SF36 or SF6D):ti,ab,kw 5193
#50 "standard gamble*":ti,ab,kw 90
#51 ("trade off?" or tradeoff?):ti,ab,kw 158
#52 {or #26-#51} 38384
#53 (client* or consumer* or female* or patient* or public or wom?n*):ti,ab,kw 721068
#54 #52 and #53 34219
#55 ((accept* or consider* or choice? or choos* or chose? or decid* or decis* or input* or involv* or opinion* or participat* or perceiv* or percepti* or perspective? or prefer* or respons* or valuation or value? or valuing or view*) near/3 (client* or consumer* or female* or patient* or public or wom?n*)):ti,ab,kw 52353
#56 #54 or #55 76295
#57 #25 and #56 423
#58 [mh ^Male] not [mh ^Female] 118
#59 (m?n or male*):ti 19409
#60 #57 not (#58 or #59) 423
#61 ([mh ^Adolescent] or [mh Child] or [mh Infant]) not [mh Adult] 100202
#62 (adolesc* or baby or babies or boy* or child* or fetus or fetal or foet* or girl* or juvenile* or kid or kids or infan* or newborn* or new-born* or neonat* or neo-nat* or paediatr* or pediatr* or preadolesc* or prepubesc* or preteen* or pubescen* or teen* or toddler* or youth*):ti,so 94453
#63 #60 not (#61 or #62) 408
#64 #60 not (#61 or #62) Publication Year from 2000 to 2016 320

Ovid PsycINFO 1987 to October Week 4 2016

1. Breast Neoplasms/
2. ((adenocarcinoma* or adenoma* or cancer* or carcin* or malignan* or metasta*or neoplas* or sarcoma* or tumour* or tumor*) adj3 (breast? or mamma or mammar*)).ti,ab.
3. (DCIS or (ductal carcinoma adj1 (in situ or insitu))).ti,ab.
4. ((intra-ductal or intraductal) adj1 carcinoma*).ti,ab.

5. or/1-4 [Combined subject headings & textwords for breast cancer]
6. Cancer Screening/
7. Health Screening/
8. exp Magnetic Resonance Imaging/ and screen*.mp.
9. Mammography/
10. Physical Examination/ and screen*.mp.
11. "Self-Examination (Medical)"/
12. ((breast? or mamma or mammar* or nipple?) adj5 (exam* or selfexam*)).ti,ab.
13. (echograph* or echo-mammogra* or echo-tomograph* or echomammogra* or echotomograph*).ti,ab.
14. (over diagnos* or overdiagnos* or over detect* or overdetect* or over treat* or overtreat* or misdiagnos*).ti,ab. and screen*.mp.
15. false positive*.ti,ab. and screen*.mp.
16. (magnetic resonance imag* or magnetic resonance tomograph* or MR tomograph* or MRI or MRIs or NMRI or NMRIs).ti,ab. and screen*.mp.
17. (mammogram* or mammograph*).ti,ab.
18. screen*.ti.
19. screen*.ab. /freq=2
20. (sonograph* or ultra-son* or ultra-sound* or ultrason* or ultrasound*).ti,ab. and screen*.mp.
21. or/6-20 [Combined subject headings & textwords for screening]
22. and/5,21 [Combined concepts for breast cancer and screening]
23. *Choice Behavior/
24. *Client Attitudes/
25. Decision Making/
26. *Consumer Behavior/
27. Informed Consent/
28. Preferences/
29. *"Quality of Life"/
30. (15D* and (HRQoL or QoL or "quality of life")).mp.
31. ((analys#s or valuation? or value? or valuing) adj3 (conjoint or contingent)).ti,ab.
32. (choice? adj2 (behavio?r* or discrete or experiment*)).ti,ab.
33. ((choice? or choos* or consent* or decision*) adj1 informed).ti,ab.
34. (EQ 5D or EQ5D or EuroQoL 5D or EuroQoL5D).mp.
35. health utilit*.ti,ab.
36. HUI.ti,ab.
37. (multi?attribute or multi?criteria).ti,ab.
38. (pay adj2 willing*).ti,ab.
39. preference*.ti,ab.
40. prospect theor*.ti,ab.
41. (QoL or quality of life).ti.
42. (SF 12 or SF 36 or SF 6D or SF12 or SF36 or SF6D).mp.
43. standard gamble*.ti,ab.
44. (trade off? or tradeoff?).ti,ab.
45. (willing* adj2 pay*).ti,ab.
46. or/23-45 [Combined subject & text words for patient preferences & values]
47. (client* or consumer* or female* or patient* or public or wom#n*).ti,ab.

48. and/46-47
49. ((accept* or consider* or choice? or choos* or chose? or decid* or decis* or input* or involv* or opinion* or participat* or perceiv* or percepti* or perspective? or prefer* or respons* or valuation or value? or valuing or view*) adj3 (client* or consumer* or female* or patient* or public or wom#n*)).ti,ab.
50. or/48-49 [Combined searches for patient preferences & values]
51. and/22,50 [Combined concepts for breast cancer screening and patient preferences/values]
52. (m#n or male*).ti.
53. 51 not 52 [Male only records excluded]
54. (adolesc* or baby or babies or boy* or child* or fetus or fetal or foet* or girl* or juvenile* or kid or kids or infan* or newborn* or new-born* or neonat* or neo-nat* or paediatr* or pediatr* or preadolesc* or prepubesc* or preteen* or pubescen* or teen* or toddler* or youth*).ti,jx.
55. 53 not 54 [Child only records excluded]
56. (animal or animal-model* or animals or canine* or cat or cats or dog or dogs or feline or felines or hamster or hamsters or mice or monkey or monkeys or mouse or pig or piglet or piglets or pigs or porcine or primate* or rabbit or rabbits or rat or rats or rodent or rodents or sheep or swine or swines).ti.
57. 55 not 56 [Animal only records excluded]
58. (BRCA* or gene* or hereditary).ti.
59. 57 not 58 [Genetic high-risk patient studies excluded]
60. (comment* or editor* or letter).ti.
61. 59 not 60 [Opinion pieces excluded]
62. (case report* or case stud*).ti.
63. 61 not 62 [Case reports excluded]
64. limit 63 to (english or french)
65. limit 64 to yr="2000-Current"
66. remove duplicates from 65

CINAHL via EBSCOhost (1937 to the present)

S1. (MH "Breast Neoplasms")
S2. (MH "Carcinoma, Ductal, Breast")
S3. ((adenocarcinoma* or adenoma* or cancer* or carcin* or malignan* or metasta*or neoplas* or sarcoma* or tumour* or tumor*) N3 (breast* or mamma or mammar*))
S4. (DCIS or ("ductal carcinoma" N1 ("in situ" or insitu")))
S5. (("intra-ductal" or intraductal) N1 carcinoma*)
S6. S1 OR S2 OR S3 OR S4 OR S5 [Combined CINAHL headings & textwords for breast cancer]
S7. (MH "Breast Examination+") and TX screen*
S8. (MM "Breast Neoplasms+/DI/RA/US") and TX screen*
S9. (MH "Cancer Screening")
S10. (MH "Early Detection of Cancer") and TX screen*
S11. (MH "False Positive Results") and TX screen*
S12. (MH "Magnetic Resonance Imaging+") and TX screen*
S13. (MH "Mammography")
S14. (MH "Health Screening")

S15. (MH "Ultrasonography") and TX screen*
S16. ((breast* or mamma or mammar* or nipple*) N5 (exam* or selfexam*))
S17. (echograph* or "echo-mammogra*" or "echo-tomograph*" or echomammogra* or echotomograph*)
S18. (over-diagnos* or overdiagnos* or "over detect*" or "over treat*" or misdiagnos*) and TX screen*
S19. "false positive*" and TX screen*
S20. ("magnetic resonance imag*" or "magnetic resonance tomograph*" or "MR tomograph*" or MRI or MRIs or NMRI or NMRIs) and TX screen*
S21. (mammogram* or mammograph*)
S22. TI screen*
S23. (sonograph* or "ultra-son*" or "ultra-sound*" or ultrason* or ultrasound*) and TX screen*
S24. S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 [Combined CINAHL headings & textwords for screening]
S25. S6 AND S24 [Combined concepts for breast cancer and screening]
S26. (MM "Breast Neoplasms/PF")
S27. (MH "Consumer Participation")
S28. (MH "Consent+")
S29. (MH "Cooperative Behavior")
S30. (MH "Decision Making")
S31. (MH "Decision Making, Patient")
S32. (MM "Mammography/PF")
S33. (MM "Quality of Life")
S34. (15D* and (HRQoL or QoL or "quality of life"))
S35. ((analys?s or valuation* or value* or valuing) N3 (conjoint or contingent))
S36. (choice* N2 (behavio* or discrete or experiment*))
S37. ((choice* or choos* or consent* or decision*) N1 informed)
S38. ("EQ 5D" or EQ5D or "EuroQoL 5D" or EuroQoL5D)
S39. "health utilit*"
S40. HUI
S41. ("multi-attribute" or "multi-criteria" or multiattribute or multicriteria)
S42. (pay N2 willing*)
S43. preference*
S44. "prospect theor*"
S45. TI (QoL or "quality of life")
S46. ("SF 12" or "SF 36" or "SF 6D" or SF12 or SF36 or SF6D)
S47. "standard gamble*"
S48. ("trade off*" or tradeoff*)
S49. (willing* N2 pay*)
S50. S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 [Combined CINAHL headings & text words for patient preferences & values]
S51. (client* or consumer* or female* or patient* or public or wom?n*)
S52. S50 AND S51

S53. (accept* or consider* or choice* or choos* or chose* or decid* or decis* or input* or involv* or opinion* or participat* or perceiv* or percepti* or perspective* or prefer* or respons* or valuation or value* or valuing or view*) N3 (client* or consumer* or female* or patient* or public or wom?n*)
S54. S52 OR S53 [Combined searches for patient preferences & values]
S55. S25 AND S54 [Combined concepts for breast cancer screening and patient preferences/values]
S56. MH "Male" NOT ((MH "Female") AND (MH "Male"))
S57. TI (m?n or male*)
S58. S55 NOT (S56 OR S57) [Male only records excluded]
S59. (((MH "Adolescents+") OR (MH "Child+") OR (MH "Infant+")) NOT (MH "Adult+")
S60. TI (adolesc* or baby or babies or boy* or child* or fetus or fetal or foet* or girl* or juvenile* or kid or kids or infan* or newborn* or "new-born*" or neonat* or "neo-nat*" or paediatr* or pediatr* or preadolesc* or prepubesc* or preteen* or pubescen* or teen* or toddler* or youth*)
S61. S58 NOT (S59 OR S60) [Adolescent/Infant/Child only records excluded]
S62. ((MH "Vertebrates+") NOT MH Human)
S63. TI (animal or "animal-model*" or animals or canine* or cat or cats or dog or dogs or feline or felines or hamster or hamsters or mice or monkey or monkeys or mouse or pig or piglet or piglets or pigs or porcine or primate* or rabbit or rabbits or rat or rats or rodent or rodents or sheep or swine or swines)
S64. S61 NOT (S62 OR S63) [Animal only records excluded]
S65. (MM "Genes, BRCA")
S66. TI (BRCA* or gene* or hereditary)
S67. S64 NOT (S65 OR S66) [Genetic high-risk patient studies excluded]
S68. TI (comment* or editor* or letter*)
S69. PT (Commentary or Editorial or Letter)
S70. S67 NOT (S68 OR S69) [Opinion pieces excluded]
S71. PT "Case Study"
S72. TI ("case report*" or "case stud*")
S73. S70 NOT (S71 OR S72) [Case reports excluded]
S74. S70 NOT (S71 OR S72) Published Date: 20000101-20161231; Language: English, French

APPENDIX B: Lists of Scanned Systematic Reviews and Excluded Studies

Systematic Reviews Scanned for Studies

1. Alcazar-Bejerano IL. Health Behaviors, Disparities and Deterring Factors for Breast Cancer Screening of Immigrant Women - A Challenge to Health Care Professionals. Journal of Lifestyle Medicine. 2014 Mar;4(1):55-63. doi: http://dx.doi.org/10.15280/jlm.2014.4.1.55. PMID: 26064855.

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3. Brett J, Bankhead C, Henderson B, et al. The psychological impact of mammographic screening. A systematic review. Psycho-Oncology. 2005 Nov;14(11):917-38. PMID: 15786514.

4. Brewer NT, Salz T, Lillie SE. Systematic review: the long-termeffects of false-positive mammograms. Annals of Internal Medicine. 2007 Apr 3;146(7):502-10. PMID: 17404352.

5. Mansfield C, Tangka FK, Ekwueme DU, et al. Stated Preference for Cancer Screening: A Systematic Review of the Literature, 1990-2013. Preventing Chronic Disease. 2016 Feb 25;13:E27. doi: http://dx.doi.org/10.5888/pcd13.150433. PMID: 26916898.

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10. Pace LE, Keating NL. A systematic assessment of benefits and risks to guide breast cancer screening decisions. JAMA. 2014 Apr 2;311(13):1327-35. doi: http://dx.doi.org/10.1001/jama.2014.1398. PMID: 24691608.

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12. Trikalinos TA, Wieland LS, Adam GP, et al. Decision aids for cancer screening and treatment. 2014.

13. Fitzpatrick-Lewis D. Breast Cancer Screening. 2011. Available at: https://canadiantaskforce.ca/

14. Havrilesky L, Gierisch, J.M., Moorman, P. et al., Systematic Review of Cancer Screening Literature for Updating American Cancer Society Breast Cancer Screening Guidelines. Atlanta, GA Society AC; 2014. https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/breast-cancer-screening-guidelines.html

15. Nelson HD, Cantor, A., Humphrey, L., Fu, R., Pappas, M., Daeges, M., Griffin, J.,. Screening for Breast Cancer: A Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation Agency for Healthcare Research and Quality. Rockville, MD: 20160219 2016.

16. Wu TY, Bancroft, J.M., Guthrie, B,. An integrative review on breast cancer screening practice and correlates among Chinese, Korean, Filipino, and Asian Indian American women. Health Care for Women International. 2005 20050404 DCOM- 20050524;26:225-46.

17. Edgar L, Glackin, M., Hughes, C., Rogers, K. M. A,, Rogers KM. Factors influencing participation in breast cancer screening. British Journal of Nursing. 2013 20130926 DCOM- 20140128;22(17):1021-6.

Excluded Studies with Reasons

Study Design:

1. Gummersbach E, in der Schmitten J, Abholz HH, Wegscheider K, Pentzek M. Effects of different information brochures on women's decision-making regarding mammography screening: study protocol for a randomized controlled questionnaire study. *Trials.* 2013;14:319.

2. Hafslund B, Nortvedt MW. Mammography screening from the perspective of quality of life: a review of the literature. *Scand J Caring Sci.* 2009;23(3):539-548.

3. Hersch J, Barratt A, Jansen J, et al. The effect of information about overdetection of breast cancer on women's decision-making about mammography screening: study protocol for a randomised controlled trial. *BMJ Open.* 2014;4(5):e004990.

4. Mokbel K, Lirosi F, al-Sarakbi W, Leris C. Women's views on the introduction of Annual Screening Mammography to those aged 40-49 years (a pilot study). *Curr Med Res Opin.* 2001;17(2):111-112.

Population:

1. Artmann A, Gottschalk N, Jacobs VR, et al. Counseling and care: A Breast Cancer Awareness Training to improve participation and adherence to screening recommendations in women with a family history of breast cancer. *Journal of Clinical Oncology.* 2009;27:1530-1530.

2. Barker KK, Galardi TR. Dead by 50: lay expertise and breast cancer screening. *Soc Sci Med.* 2011;72(8):1351-1358.

3. Bittencourt L, Scarinci IC. Training Community Health Workers to promote breast cancer screening in Brazil. *Health Promot Internation.* 2017;26:26.

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5. Borders MH, Cheng L, Fitzpatrick KA, Krupinski EA. Patient Compliance in the Setting of BI-RADS Category 3: What Factors Impact Compliance With Short-Term Follow-Up Recommendations? *Breast Journal.* 2017;23(1):77-82.

6. Buchanan Lunsford N, Sapsis KF, Smither B, Reynolds J, Wilburn B, Fairley T. Young Women's Perceptions Regarding Communication with Healthcare Providers About Breast Cancer, Risk, and Prevention. *Journal of Women's Health.* 2017;04:04.

7. Gray E, Donten A, Karssemeijer N, et al. Evaluation of a Stratified National Breast Screening Program in the United Kingdom: An Early Model-Based Cost-Effectiveness Analysis. *Value in Health.* 2017;20(8):1100-1109.

8. Khokhar A. Study on knowledge, experiences and barriers to mammography among working women from Delhi. *Indian J Cancer.* 2015;52(4):531-535.

9. Kirubakaran R, Chee Jia T, Mahamad Aris N. Awareness of Breast Cancer among Surgical Patients in a Tertiary Hospital in Malaysia. *Asian Pac J Cancer Prev.* 2017;18(1):115-120.

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11. MacDonald DJ. Women's decisions regarding management of breast cancer risk. *Medsurg Nurs.* 2002;11(4):183-186.

12. Prinjha S, Evans J, McPherson A. Women's information needs about ductal carcinoma in situ before mammographic screening and after diagnosis: a qualitative study. *J Med Screen.* 2006;13(3):110-114.

13. Seven M, Bagcivan G, Akyuz A, Bolukbas F. Women with Family History of Breast Cancer: How Much Are They Aware of Their Risk? *Journal of Cancer Education.* 2017;04:04.

14. Timmermans DR, Ockhuysen-Vermey CF, Henneman L. Presenting health risk information in different formats: the effect on participants' cognitive and emotional evaluation and decisions. *Patient Educ Couns.* 2008;73(3):443-447.

15. Tisnado DM, Moore AA, Levin JR, Rosen S. Developing and testing a decision aid for use by providers in making recommendations: about mammography screening in older women. *J Appl Gerontol.* 2015;34(3):343-358.

Intervention:

1. Costa AR, Silva S, Moura-Ferreira P, et al. Cancer screening in Portugal: sex differences in prevalence, awareness of organized programmes and perception of benefits and adverse effects. *Health Expect.* 2016;23:23.

2. Finkelstein J, Wood J, Crew KD, Kukafka R. Introducing a Comprehensive Informatics Framework to Promote Breast Cancer Risk Assessment and Chemoprevention in the Primary Care Setting. *AMIA Summits Transl Sci Proc.* 2017;2017:58-67.

3. Johnson R, Jalleh G, Pratt IS, et al. Online advertising by three commercial breast imaging services: message takeout and effectiveness. *Breast.* 2013;22(5):780-786.

4. Kadmon I, Pierce P, Antonakos CL. Elder women's decision-making in breast cancer care: An Israeli study. *Eur J Oncol Nurs.* 2012;16(3):233-237.

5. Liu YH, Ye JM, Xu L, et al. Effectiveness of dynamic contrast-enhanced magnetic resonance imaging in evaluating clinical responses to neoadjuvant chemotherapy in breast cancer. *Chin Med J.* 2011;124(2):194-198.

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No Weighing of CTFPHC B&H:

1. Allahverdipour H, Asghari-Jafarabadi M, Emami A. Breast cancer risk perception, benefits of and barriers to mammography adherence among a group of Iranian women. *Women Health.* 2011;51(3):204-219.

2. Allen JD, Bluethmann SM, Sheets M, et al. Women's responses to changes in U.S. Preventive Task Force's mammography screening guidelines: results of focus groups with ethnically diverse women. *BMC Public Health.* 2013;13:1169.

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12. Couts TL. Predicting adherence to mammography screening practices among African American women. *Dissertation Abstracts International: Section B: The Sciences and Engineering.* 2015;76(2-B E).

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