

# Effects of Design Features of Explicit Values Clarification Methods: A Systematic Review

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## **Abstract: 258 words (max 275)**

**Background.** Diverse values clarification methods exist. It is important to understand which, if any, of their design features help people clarify values relevant to a health decision.

**Purpose.** To explore the effects of design features of explicit values clarification methods on outcomes including decisional conflict, values congruence, and decisional regret.

**Data Sources.** MEDLINE, all EBM Reviews, CINAHL, EMBASE, Google Scholar, manual search of reference lists, and expert contacts.

**Study Selection.** Articles were included if they described the evaluation of one or more explicit values clarification methods.

**Data Extraction.** We extracted details about the evaluation, whether it was conducted in the context of actual or hypothetical decisions, and the results of the evaluation. We combined these data with data from a previous review about each values clarification method's design features.

**Data Synthesis.** We identified 20 evaluations of values clarification methods within 19 articles. Reported outcomes were heterogenous. Few studies reported values congruence or post-decision outcomes. The most promising design feature identified was explicitly showing people the implications of their values; for example, by displaying the extent to which each of their decision options aligns with what matters to them.

**Limitations.** Due to the heterogeneity of outcomes, we were unable to perform a meta-analysis. Results should be interpreted with caution.

**Conclusions.** Few values clarification methods have been evaluated experimentally. More research is needed to determine effects of different design features of values clarification methods and to establish best practices in values clarification. When feasible, evaluations should assess values congruence and post-decision measures of longer-term outcomes.

## INTRODUCTION

There is widespread acknowledgment among those who develop decision support materials for patients that an effective decision aid should include a mechanism to help people clarify their values relevant to the decision.<sup>1,2</sup> However, consensus in the field ends there. Different concepts of values and divergent ideas of how to clarify them run rampant throughout the literature on decision aids and decision counseling. As new approaches to values clarification are put forward<sup>3</sup> and questioned,<sup>4</sup> there remain no established best practices.<sup>5,6</sup> A sub-analysis (n=13) within the Cochrane review of patient decision aids for people facing health treatment or screening decisions showed that as a whole, decision aids with explicit values clarification methods led to decisions that were more congruent with values.<sup>7</sup> However, evidence of effectiveness of any given values clarification method is limited,<sup>8,9</sup> mixed,<sup>10,11</sup> or lacking.<sup>12,13</sup> Different types of values clarification may lead to different decisions<sup>14</sup> and some values clarification methods may even harm decision quality.<sup>15</sup> Having previously developed a descriptive taxonomy of the different design features that distinguish values clarification methods,<sup>16</sup> the aim of the present paper is to synthesize the nascent evidence base concerning the effects of such design features.

### **Values, Values Clarification, and Preferences**

As described in our previous article,<sup>16</sup> for the purposes of this review, the term *values* refers to the extent to which decision attributes matter to an individual making a health decision. *Values clarification* is the process of sorting out what matters to an individual relevant to a given health decision. *Preferences* are inclinations toward or away from a

given decision option. In other words, values describe how one feels about the attributes of a decision, while preferences refer to how one feels about the different options.

## **METHODS**

### **Inclusion and Exclusion Criteria**

Articles were eligible for inclusion in this review if they described the results of an evaluation of an explicit values clarification method intended to assist someone in making an individual health decision. We defined an explicit values clarification method as one in which the user explicitly interacted with it, for example, by completing a worksheet or a discrete choice experiment. We required that evaluations isolate the effects of the values clarification method, for example, by testing a decision aid with and without a values clarification method included. We excluded articles describing the evaluation of a decision aid containing a values clarification method where the values clarification method was not tested independently.

### **Search Strategy**

Articles in this review are a subset of articles from our descriptive review of the design features of values clarification methods. Our search strategy is therefore described in detail elsewhere.<sup>16</sup> Briefly, with assistance from two medical librarians, we developed a systematic search strategy to identify articles describing values clarification methods. We searched MEDLINE, all EBM Reviews, CINAHL, EMBASE, and Google Scholar, as well as the reference list from the Cochrane systematic review of decision aids,<sup>17</sup> articles citing International Patient Decision Aid Standards,<sup>1</sup> and we performed a reference search and

consulted with experts to identify potentially missed articles. This strategy yielded a total of 2659 articles to be screened.

### Screening Process

At least two authors (HW plus one or more of LS, TG, SCD) independently screened all articles. Discrepancies were resolved by discussion until consensus was reached.

### Quality Appraisal

We conducted a risk of bias assessment on included articles according to the Cochrane Handbook.<sup>18</sup>

### Data Extraction

One author (HW) extracted all data about included evaluations into an evidence table. This table was reviewed by at least one other author (TG, SCD), who identified areas of concern, and resolved issues together with HW, bringing in another author (LS) for consultation when necessary.

We linked this evidence table with data we had previously extracted about the design features of the included values clarification methods.<sup>16</sup> To investigate relationships between design features of values clarification methods and the effects such design features might have, we selected from our taxonomy five design features that have clear differentiation between their levels and also have relationships with theory-based processes of decision making.<sup>6,19</sup> *Tradeoffs* describes whether the tradeoffs in the decision are explicitly presented to the user. *Open-Ended* describes whether or not a user can add attributes of concern to the list of topics covered in the values clarification method, or if

s/he must work within a set of pre-identified attributes. *Values Exploration* refers to extent to which the method supports an iterative discovery process of values clarification.

*Implications* has to do with whether a method explicitly presents the implications of the user's expressed values by, for example, displaying a recommended option or by showing how well or poorly each option fits with the user's expressed values. *Decision Intentions* describes whether or not the method asks users for their decision preference or intentions.

In addition to these design features, we were also interested in exploring the potential effects of *Foundation*, which describes whether a method had a theory, framework or model underlying it, and *Actual/Hypothetical*, which describes whether an evaluation was conducted with people who were actually facing the decision or who were participants in a study assigned a hypothetical context; for example, "Imagine you are faced with the following health decision ..."

## Data Syntheses

Summary statistics were calculated in Microsoft Excel.<sup>20</sup> Cross-tabulations were conducted in R, version 3.2.1.<sup>21</sup> Because the outcome measures within included studies demonstrated significant heterogeneity in the constructs measured as well as the methods and timing of assessing them, we were unable to conduct meta-analyses that would provide meaningful answers to our research questions about the effects of different design features. We therefore synthesized results descriptively, with the goal of observing potential patterns to inform hypotheses for evaluating future values clarification methods.

To describe effects on outcomes, we pooled all experiments that evaluated a values clarification method against no values clarification method or an "implicit" values

clarification method against an explicit method. So-called implicit methods involve presenting information about the potential benefits and harms of options in tables, which facilitates values clarification but does not explicitly require it in any way. The Cochrane review of patient decision aids specifies that all patient decision aids must contain implicit values clarification methods at minimum.<sup>7</sup>

For three-armed studies in which the comparison of a decision aid with and without a values clarification method included a third arm that was not relevant to our comparison of interest (for example, an information booklet serving as a control condition in an evaluation of the decision aid) we ignored the third arm. For three-armed studies containing two different values clarification methods and one arm of implicit values clarification, we considered each comparison of a values clarification method against implicit values clarification, meaning that each of the three-armed studies included in this review contributed two comparisons to the pooled set.

## **RESULTS**

### **Overview of Included Studies**

This review includes 19 articles describing experimental evaluations of explicit values clarification methods. Of these, 14 evaluated a values clarification method against no values clarification method, 2 evaluated an explicit values clarification method against an implicit values clarification method, 2 compared three values clarification methods (two explicit and one implicit) and 1 evaluated two different values clarification methods against each other with no comparison against an implicit method or no values clarification. The latter



study was excluded from pooled reporting below as it addressed a different research question than the others. Therefore, when describing the results of this review we describe the design features and evaluations of 20 explicit values clarification methods that appear within 18 studies. One evaluation (1/20) was a pre-post experiment; the rest (19/20) were randomized experiments. The risk of bias of included articles (Table 1) was low overall. However, lack of registration of protocols for most studies meant that selective outcome reporting was unclear for most studies.

The majority of included evaluations (12/20) were undertaken in people who were actually facing the decision. Diverse populations were included. See Table 2 for details.

Table 1: Risk of Bias of Included Articles about here

Table 2: Summary of Included Articles about here

## Outcome Domains and Findings

To explore and describe potential patterns in a data set with heterogeneous measures, we grouped outcomes into the following domains and sub-domains.

*Decision Readiness* includes four sub-domains: worry, uncertainty about the decision, decision making preparation, and knowledge. As a whole, this domain addresses whether a values clarification method might influence how well- or ill-equipped a person is to make a decision. Outcomes in this domain are assessed prior to making a decision. *Worry* includes non-decision-specific measures related to worry such as anxiety, perceived vulnerability, and concerns about health specific to the clinical context. For example, the latter might refer to concern about prostate cancer, or perceived personal risk of a genetic marker.

*Decision Uncertainty* addresses concern about the decision itself and includes decisional conflict and subscales, measures of decisional uncertainty, strength of preference, ambivalence, and the difficulty of making the decision. *Decision Making Preparation* captures how well or poorly a user is prepared to make a decision. It includes preparation for decision making, decisional self-efficacy, process measures of informed decision making, and stage of readiness to make decision. *Knowledge* describes users' comprehension or recall of their options and attributes of options.

We defined worry and decisional uncertainty as positive when lower, and decision making preparation and knowledge as positive when higher. For all domains, we defined results within a domain as positive if at least one outcome was positive and no outcomes were negative, and vice versa for negative results. Examining all 20 evaluations as a group, we observed that 17/20 reported Decision Readiness. Within these, 5/17 reported a positive outcome, 9/17 a null or mixed outcome, and 3/17 a negative outcome.

*Decision* includes two sub-domains: the choice made and the values congruence of that choice. Thus, this domain addresses whether a values clarification method influences a decision or the quality of the decision. Within this domain, *Choice* captures measures of the decision made, decision intentions, or preference for one option. We defined choice as positive or negative on a case-by-case basis. In most cases, we defined it as neither positive nor negative, as most values clarification methods included in this review address preference-sensitive decisions in which there is no medically optimal choice. Shared decision making approaches and tools can also be used in other types of decisions, and indeed, have been used to address both overuse<sup>22</sup> and underuse.<sup>23</sup> For methods within this

review used in similar such decision contexts, we defined movement towards optimal use as positive. *Congruence* assesses the extent to which a given values clarification method ensures that the values of the person affected by the decision were integrated or able to be integrated into a decision. It includes outcomes such as agreement between individual and proxy decision-maker, agreement between values expressed and decision taken, perception that decision was congruent with values, and agreement between indirect and direct measurement of important attributes of the decision. We defined higher congruence as positive. Fifteen out of the 20 evaluations reported on this outcome; of these, 2/15 were positive and 13/15 were null. Most of these results came solely from assessment of the decision, as values congruence was reported in only 3/20 of the evaluations.

*Post-Decision Effects* includes measures of well-being following the decision, grouped into two sub-domains. *Post-Decision Feelings* includes measures of decision satisfaction, decisional regret, satisfaction with decision process, and strength of preference after making the decision. Timing of such measures ranged from one to two months after the decision to two years after the decision. We defined positive post-decision feelings as higher satisfaction, higher strength of preference and lower regret. *Post-Implementation Health* includes health status, symptoms, quality of life, and depression after the decision has been made and implemented. We considered results in this domain positive if health status was higher, symptoms less frequent or severe, quality of life higher and depression lower. Only 4/20 of evaluations reported on Post-Decision Effects; of these, 3/4 reported a positive outcome and 1/4 a null outcome.

Included studies also reported other outcomes that we did not include in an overarching domain due to infrequent use and lack of fit with the domains we identified. These included, for example, the most important attribute of the decision, users' feelings about a given values clarification method, and reports of costs and time spent on the values clarification method. Such outcomes are described in the summaries in Table 3b.

Table 3: Summary of Evaluation Outcomes about here

### Design Features and Effects

We present cross tabulations between values clarification design features and our three evaluation domains in Figure 1, in which each circle represents one of the 20 evaluations. We do not present the cross tabulation for Values Exploration because only one included evaluation was of a values clarification method that supported a discovery process of values clarification.

Figure 1: Design Features and Evaluation Outcomes about here

Examining the patterns for different design features suggests some potential hypotheses for future study. First, comparing evaluations of values clarification methods that explicitly show implications with evaluations of methods that do not suggests that showing implications may potentially be associated with greater Decision Readiness and more positive Post-Decision Effects. Asking people to indicate their decision intentions within the values clarification method may also be promising, though the potential pattern is weaker. Other design features demonstrate less clear indications of potential relationships. We further note a potential pattern when comparing studies conducted in actual versus

hypothetical contexts. Evaluation outcomes, both positive and negative, may be stronger in studies conducted with people who are actually facing the decision.

### **Comparisons of Values Clarification Methods Against Each Other**

As described in the overview of included studies, one article compared two values clarification methods against each other and two articles compared two explicit values clarification methods with an implicit method. These three articles come from the same research team, and each study offers insights from comparisons between a rating and ranking values clarification method and a discrete choice experiment. One article demonstrated that a rating and ranking method was associated with higher congruence than a discrete choice experiment;<sup>24</sup> the other two did not assess congruence. All three showed differences regarding some measure of participants' most important attribute in the decision.<sup>14,24,25</sup> One of the comparisons showed difference in choice when the name of the intervention (Prostate Specific Antigen) was not given, but there was no difference when the name was given.<sup>14</sup> The other two studies showed no differences in choice.

Another article included a step at the conclusion of the study showing study participants two versions of the values clarification method. Study participants preferred the version displaying a summary of their responses.<sup>26</sup> This result from a within-subjects evaluation is consistent with our observations from the pooled evaluations regarding the potentially positive effect of explicitly showing users the implications of their values.

## DISCUSSION

In examining this set of values clarification methods that have been described and evaluated, we note several key issues. First, out of the large number and wide range of methods that have been developed,<sup>16</sup> relatively few have been evaluated. Having limited empirical evidence about methods for values clarification makes it difficult for developers of decision support tools to make evidence-based design choices. It is critical to analyze the effects of different design features to help guide future designs.

Among values clarification methods that have been evaluated, there is significant heterogeneity of outcomes. There is considerable debate and discussion about which outcomes are appropriate for evaluating values clarification methods and how best to apply them.<sup>5,27,28</sup> In this review, the most common outcome sub-domain was Decision Uncertainty, frequently assessed by the Decisional Conflict Scale.<sup>29</sup> This outcome is somewhat problematic because although we defined lower decisional conflict as positive, such a finding may indicate a lack of awareness of the tradeoffs within a decision, rather than an improved state of decision readiness.<sup>30</sup> As other authors have suggested,<sup>14,31</sup> the most appropriate outcomes for evaluating values clarification methods are likely longer-term outcomes such as decision satisfaction and regret, which were infrequently reported in the included studies. However, these outcomes should be used with caution because they may be influenced by the outcome of the decision rather than the process by which the decision was made.<sup>32-34</sup> The most important short-term outcome is arguably values congruence, since the purpose of values clarification is to help decisions reflect what is important to the person or people most affected by the decision. However, it can be

challenging to measure. Values and preferences may take time to stabilize, meaning that timing of assessment is a critical consideration. This outcome was also infrequently reported. When planning evaluations and choosing outcomes, we recommend that researchers consider the domains outlined in this review and also consult relevant articles by Llewellyn-Thomas and Crump<sup>5</sup> and Winn, Ozanne and Sepucha.<sup>27,28</sup>

The most promising potential pattern from our synthesis is that explicitly showing people the implications of their stated values may be associated with positive outcomes. Although further study will be required to test this hypothesis, this potential finding suggests that values clarification methods may be more helpful when they are designed not only to assist people in sorting out what matters to them, but also in seeing how what matters to them determines which option may be best for them. It is unclear whether the positive effect arises because showing implications may help validate or reinforce the option that people might have chosen anyway. It may also be that showing implications helps clarify preferences, much like the method of decision making in which one flips a coin, and then makes a decision guided by whether one's reaction upon seeing the result is satisfaction or disappointment. It should be noted that values clarification methods within this review presumably aimed to provide accurate implications.

We note that our observation of the potential benefits of showing implications may present some tension, because in patient decision aids, such presentations would be difficult to implement without some sort of underlying model or algorithm to estimate the fitness of an option for an individual given his or her expressed values. In some circumstances, this might be accomplished with decision analytic models using utilities, whose elicitation

presents problems of usability<sup>35</sup> and measurement.<sup>36</sup> Decision analytic models also present other challenges when attempting to use them with patients<sup>37</sup> and have been suggested to be inferior to other forms of values clarification for adequately clarifying and capturing values.<sup>38</sup> Nonetheless, the findings from this review offer some justification for further collaboration between researchers with expertise in models, measurement, and patient-facing decision support tools such as patient decision aids. Future research may also explore ways that health care professionals might use their expertise to help patients better understand relationships between values and options. To the best of our knowledge, although frameworks of shared decision making typically mandate that clinicians should help patients clarify their values and preferences and at least one measure emphasizes the importance of integrating preferences into the decision,<sup>39</sup> no frameworks explicitly require that clinicians help patients understand the connections between what matters to them and which option is best suited to them.

## Limitations

This review was limited by heterogeneity of outcome measures. Because of this heterogeneity, we did not pool outcomes. Neither did we present effect size estimates, as these are not comparable across the many different types of outcomes in the included studies. By presenting only whether or not a statistically significant difference was found in the original study and the direction of any reported effect, our synthesis overlooks differences in studies' power to detect effects. Our approach was ultimately guided by an attitude articulated by statistician John Tukey: "Far better an approximate answer to the *right* question, which is often vague, than an *exact* answer to the wrong question, which can



always be made precise.”<sup>40</sup> We emphasize the preliminary nature of these findings and urge experimental study of the design features described.

In addition, although our development of a taxonomy that includes the design features studied here showed that none of them completely determines any of the others,<sup>16</sup> clustering of design features or overly broad definitions may have obscured effects. For example, for Foundations, we included any theories, frameworks and models, stated or implied, rather than requiring a descriptive theory of values clarification. Additionally, it is possible that we failed to include studies that could have contributed to this synthesis.

## **CONCLUSIONS**

This review demonstrates that few values clarification exercises have been evaluated. Among those that have, there is a lack of consensus concerning outcome measures. Exploring patterns of effects allowed us to suggest some hypotheses, namely that presenting users with the implications of their expressed values may lead to better outcomes. However, we emphasize the exploratory nature of our findings and highlight the importance of conducting further investigations into these research questions using direct experimental evaluations of design features. When evaluating values clarification methods, we encourage researchers to assess and report values congruence and, in the cases of actual decisions, a post-decision measure that reflects longer-term outcomes.

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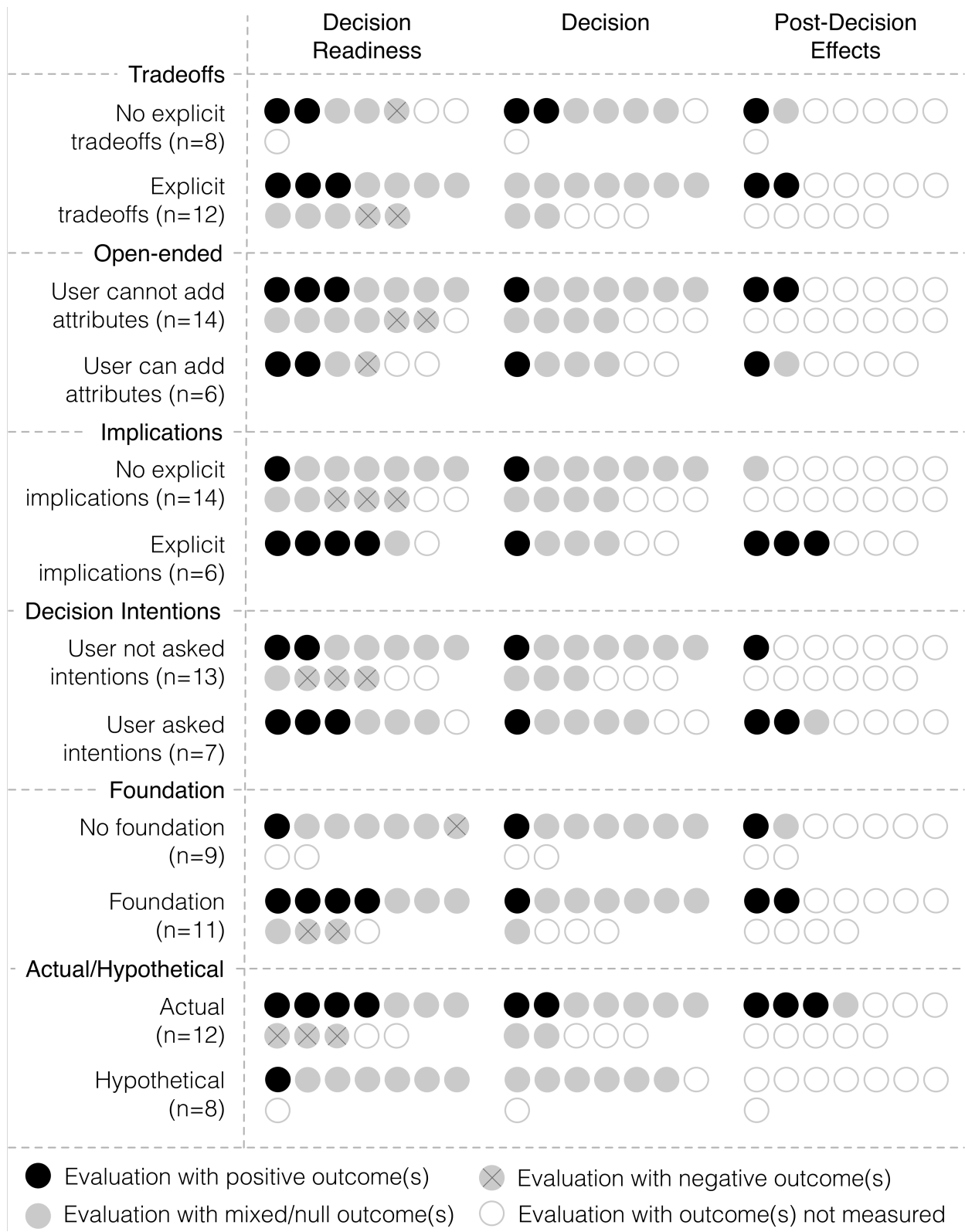
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Figure 1: Design Features and Evaluation Outcomes



**Table 1: Risk of Bias of Included Articles**

Article	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition data)	Selective reporting (reporting bias)	Other bias
Abhyankar et al. <sup>11</sup>	?	?	-	?	+	?	+
Achaval et al. <sup>41</sup>	+	+	+	+	+	?	+
Brenner et al. <sup>25</sup>	+	+	+	?	?	+	+
Clancy et al. <sup>42</sup>	+	?	?	+	?	?	-
Costanza et al. <sup>43</sup>	-	?	?	?	+	?	+
Feldman-Stewart et al. <sup>26</sup>	+	+	?	?	?	?	+
Feldman-Stewart et al. <sup>31</sup>	+	+	?	+	+	?	+
Fraenkel et al. <sup>44</sup>	+	?	?	+	+	?	+
Frosch et al. <sup>45</sup>	+	+	?	+	+	?	+
Kennedy et al. <sup>46</sup>	+	+	?	+	+	?	+
Labrecque et al. <sup>12</sup>	+	+	+	+	+	?	+
Lerman et al. <sup>13</sup>	?	?	?	+	?	?	+
Matheis-Kraft et al. <sup>47</sup>	+	+	?	?	+	?	+
Montgomery et al. <sup>48</sup>	+	+	?	+	+	?	+
O'Connor et al. <sup>10</sup>	?	+	?	+	+	?	+
Pignone et al. <sup>24</sup>	+	+	+	+	?	?	+
Pignone et al. <sup>14</sup>	+	+	+	?	?	+	+
Roosmalen et al. <sup>49</sup>	+	?	-	?	?	?	+
Sheridan et al. <sup>50</sup>	?	+	+	+	+	+	+

Low risk of bias    
 Risk of bias unclear    
 High risk of bias



**Table 2a: Summary of Included Articles**

<b>Article</b>	<b>Decision</b>	<b>Actual or hypothetical?</b>	<b>Study population</b>
Abhyankar et al. <sup>11</sup>	Choice between standard adjuvant chemotherapy for early stage breast cancer and clinical trial testing new chemotherapy.	hypothetical	Healthy women aged 19-60 (mean = 36 years, SD = 13.8), staff or students at a UK university, asked to imagine having been diagnosed with breast cancer, undergone lumpectomy and suggested chemotherapy by their doctor (n=30)
Achaval et al. <sup>41</sup>	Whether or not to have total knee arthroplasty to treat knee osteoarthritis in cases of pain and disability unresponsive to medical treatment	actual	Adults with osteoarthritis of the knee who experience pain that interferes with activities of daily living (n=139)
Brenner et al. <sup>25</sup>	Whether or not to be screened for colorectal cancer, and, if yes, what screening test to use (4 unlabeled screening tests designed to simulate fecal occult blood testing, sigmoidoscopy, colonoscopy, or a radiological test like CT colonography)	hypothetical	Adults 50-75 at average risk of colon cancer (no personal or family history) (n=920)
Clancy et al. <sup>42</sup>	Choice between being immunized for Hepatitis B, screened for antibodies and immunized if negative, or not immunized unless exposed	actual	Physicians who had not been vaccinated against Hepatitis B (n=1027, total 1280 with additional arm not relevant to comparison)
Costanza et al. <sup>43</sup>	Whether or not to have prostate specific antigen (PSA) testing to screen for prostate cancer.	actual	Men 50-70, 45-70 if African American, with no PSA test in previous 12 months and no history of prostate cancer (n=101)
Feldman-Stewart et al. <sup>26</sup>	Choice between four main options for early stage prostate cancer (watchful waiting, surgery, external beam radiation and brachytherapy.)	hypothetical	Men 50+, asked to imagine they had been diagnosed with prostate cancer (n=90)
Feldman-Stewart et al. <sup>31</sup>	Choice between four main options for early stage prostate cancer (surgery, external beam radiation, brachytherapy, or watchful waiting/active surveillance described as "no treatment for now.")	actual	Newly diagnosed prostate cancer patients with low or intermediate risk early-stage disease (Stage T1 or T2, PSA<20, and Gleason<8), visiting the cancer clinic for their first consultation, and faced with a treatment decision (n=156)
Fraenkel et al. <sup>44</sup>	Choice between treatments for knee pain	actual	Adults 60+ with pain involving one or both knees on most days of the month who could successfully perform a choice task with a dominant (objectively preferable) option (n=87)
Frosch et al. <sup>45</sup>	Whether or not to have prostate specific antigen (PSA) testing to screen for prostate cancer.	actual	Men >50 (n=611)
Kennedy et al. <sup>46</sup>	Choice between treatment options for menorrhagia (advice and reassurance, addressing possible iatrogenic causes, drug therapy, or surgery such as hysterectomy or endometrial destruction)	actual	Women with uncomplicated menorrhagia (very heavy menstrual periods) (n=421, total 625 with additional arm not relevant to comparison)
Labrecque et al. <sup>12</sup>	Whether or not to have a vasectomy	actual	Men 25+ considering vasectomy (n=60)
Lerman et al. <sup>13</sup>	Whether or not to have genetic testing for BRCA1	actual	Women 18-75 with family history of breast and/or ovarian cancer (n=236, total 400 with additional arm not relevant)

Matheis-Kraft et al. <sup>47</sup>	Preferences for care in case of decisional incapacity	hypothetical	to comparison)
Montgomery et al. <sup>48</sup>	Whether or not to start drug therapy for hypertension	actual	Competent women, aged 70-94 (mean = 79 years, SD = 6.4) and their family proxy (n=60)
O'Connor et al. <sup>10</sup>	Whether or not to take hormone replacement therapy after menopause	actual	Adults 32-80, 49% female, with newly diagnosed hypertension (n=212)
Pignone et al. <sup>24</sup>	Whether or not to be screened for colorectal cancer and, if yes, which screening test to use	hypothetical	Women 50-69, at least 2 years menopausal, never used HRT (n=201)
Pignone et al. <sup>14</sup>	Whether or not to be screened for prostate cancer.	hypothetical	Adults 48-75 at average risk for colon cancer (no personal or immediate family history of colon cancer, polyps or inflammatory bowel disease) (n=104)
Roosmalen et al. <sup>49</sup>	Choice between intensive screening and prophylactic surgery for breasts and/or ovaries	actual	Men 50-70 of average risk for prostate cancer. (n=911)
Sheridan et al. <sup>50</sup>	Whether or not to initiate behaviours to prevent coronary heart disease (CHD), and, if so, which behaviours	hypothetical	BRCA1/2 mutation carriers, affected or unaffected with breast cancer (n=88)
			Men 45+, Women 55+, likely to be at moderate to high risk for CHD, no prior history of cardiovascular disease (n=137)

\*VCM = Values Clarification Method

**Table 2b: Summary of Included Articles**

<b>Article</b>	<b>Comparison type(s)</b>	<b>Comparison</b>	<b>Summary of findings relevant to VCM</b>
Abhyankar et al. <sup>11</sup>	VCM* vs. no VCM; implicit VCM vs. explicit VCM	Randomized: 1) information only (n=9), 2) information plus implicit VCM (review benefits and risks, add to list if desired, underline events perceived as most likely) (n=11), 3) information plus "explicit" VCM (implicit tasks plus rate importance of each benefit and risk and indicate direction leaning) (n=10)	VCM resulted in more use of personal values when evaluating attributes of options, somewhat less ambivalence, less uncertainty and did not change decision preference.
Achaval et al. <sup>41</sup>	VCM vs. no VCM	Randomized: 1) decision aid without VCM (n=70), 2) decision aid with VCM in the form of adaptive conjoint analysis (n=69) N.B. Study also included a third arm of educational booklet only (control for main study, n=69) that is not relevant to VCM vs. no VCM comparison.	VCM resulted in smaller reduction in decisional conflict compared to decision aid alone, and took more time (2 hours vs. 1 hour).
Brenner et al. <sup>25</sup>	Implicit VCM (balance sheet) vs. rating and ranking vs. discrete choice experiment	Randomized: 1) balance sheet (n=309), 2) rating and ranking task (n=305), 3) discrete choice experiment (n=306)	Different types of values clarification led to different patterns of responses on most important attribute. Namely, people randomized to rating and ranking task were more likely to identify risk reduction as their most important attribute, with 70% of participants who used rating and ranking identifying this as their most important attribute versus 49% who used discrete choice experiment and 55% who used balance sheet. Type of values clarification did not influence unlabeled test preference, nor values clarity.
Clancy et al. <sup>42</sup>	VCM vs. no VCM	Randomized: 1) information only (n=264), 2) information + VCE (decision analysis) (n=753), 3) nothing (control) (n=263, not relevant for VCM vs. no VCM comparison, excluded from sample size)	VCM increased action-taking (screening or vaccination.)
Costanza et al. <sup>43</sup>	VCM vs. no VCM	Before and after counseling session to clarify values	VCM increased knowledge and decisional satisfaction, decreased decisional conflict, and did not change readiness to make a decision nor perceived vulnerability.
Feldman-Stewart et al. <sup>26</sup>	VCM vs. no VCM; VCM with summary vs. VCM without summary	Step 1: Randomized: 1) values clarification with summary (n=30), 2) values clarification without summary (n=30) and 3) control with no values clarification (n=30)	Participants preferred VCM design with summary over VCM without summary and no VCM.
Feldman-Stewart et al. <sup>31</sup>	Implicit VCM vs. explicit VCM	Randomized: 1) structured information only (n=75), 2) structured information plus VCM (n=81)	Explicit VCM increased preparation for decision making and decreased decision regret. Decision conflict decreased in both arms.
Fraenkel et al. <sup>44</sup>	VCM vs. no VCM	Randomized: 1) information pamphlet (control) (n=40), 2) adaptive conjoint exercise (VCM) (n=47)	VCM resulted in higher scores on decisional self-efficacy, preparation for decision making, and arthritis self-efficacy
Frosch et al. <sup>45</sup>	VCM vs. no VCM	Randomized: 1) traditional decision aid without VCM (n=155), 2) chronic disease trajectory model with VCM (n=153), 3) combined traditional decision aid and	VCM had no effect on preferences for PSA testing, preference for watchful waiting, knowledge or decisional conflict.

Kennedy et al. <sup>46</sup>	VCM vs. no VCM	chronic disease trajectory model with VCM (n=152), 4) links to prostate cancer-specific Web sites from credible sources (control condition) (n=151) Randomized: 1) usual care (control) (n=204, not relevant to VCM vs. no VCM comparison, excluded from sample size), 2) information only (n=206), 3) information plus values clarification interview (n=215)	VCM resulted in lower use of a more invasive treatment, more frequent clinician perceptions of "longer than usual" consultations, and lower overall costs. Compared to control, the arm with VCM also resulted in greater patient satisfaction with the decision-making process and minimal improvements in self-reported health status, but this was not relevant to the VCM vs. no VCM comparison. VCM had no effect on decisional conflict, knowledge, decision preferences or certainty.
Labrecque et al. <sup>12</sup>	VCM vs. no VCM	Randomized: 1) decision aid with information and values guidance (n=30); 2) decision aid with information only (n=30)	
Lerman et al. <sup>13</sup>	VCM vs. no VCM	Randomized: 1) education only (n=114), 2) education plus values clarification counseling (n=122), 3) control (n=164, not relevant for VCM vs. no VCM comparison, excluded from sample size)	VCM with education resulted in increased perceptions of risks and limitations of BRCA1 testing, but knowledge was no better than education alone. Perceived personal risk decreased more with education alone, and neither VCM and education nor education alone influenced perceptions of benefits of BRCA1 testing, decision intentions, or decisions.
Matheis-Kraft et al. <sup>47</sup>	VCM vs. no VCM	Randomized: 1) values discussion (n=30); 2) no values discussion (control) (n=30)	VCM resulted in mixed results: its effectiveness or lack thereof depends on which statistic (kappa or percent agreement) is used to measure concordance between older women and their proxies.
Montgomery et al. <sup>48</sup>	VCM vs. no VCM	Randomized: 1) decision analysis + education (n=50), 2) decision analysis only (n=50), 3) education only (n=54), 4) usual care (control) (n=58) N.B. Based on power calculations, paper reports analysis of factorial design: decision analysis (VCM) vs. no decision analysis, and education vs. no education.	VCM increased knowledge and reduced total decisional conflict by significantly reducing scores on uninformed, unclear values and unsupported subscales and somewhat reducing scores on uncertainty subscale. VCM did not influence scores on decision quality subscale, nor did it change state anxiety, decision intention, or ultimate decision.
O'Connor et al. <sup>10</sup>	Implicit VCM vs. explicit VCM	Randomized: 1) decision aid with explicit values clarification via balance scale exercise (n=101), 2) decision aid with implicit values clarification via summary table of risks and benefits (n=100)	VCM had no effect on clarity of values, concordance between values and decision, total decisional conflict, other subscales of Decisional Conflict Scale, nor acceptability of intervention.
Pignone et al. <sup>24</sup>	VCM with explicit tradeoffs (discrete choice) vs. VCM without explicit tradeoffs (rating and ranking)	Randomized: 1) conjoint: discrete choice (n=50); 2) Rating and ranking (n=54)	Different types of VCM led to different patterns of indirect responses about which attribute is most important, but did not significantly affect direct responses, nor were there any observed differences on perceived clarity of values, intent to be screened, or choice of screening test.
Pignone et al. <sup>14</sup>	Implicit VCM (balance sheet) vs. rating and ranking vs. discrete choice experiment (DCE)	Randomized: 1) balance sheet (n=302), 2) rating and ranking task (n=307), 3) discrete choice analysis (n=302)	Different types of values clarification led to different patterns of responses on most important attribute (namely, people randomized to rating and ranking task were more likely to identify reduced chance of death as their most important attribute) and different responses on unlabeled test preference (people randomized to balance sheet task were more likely to prefer PSA-like

Roosmalen et al.<sup>49</sup> VCM vs. no VCM

Randomized: 1) shared decision-making intervention consisting of time tradeoff values clarification exercise (n=44), 2) usual care (control) (n=44). N.B. Randomization took place as second step of a trial in which the first step was randomization to either receive an educational decision aid or have usual care. Participants were pooled and re-randomized for this second step.

Sheridan et al.<sup>50</sup> VCM vs. no VCM

Randomized: 1) decision aid without VCM (control) (n=62), 2) decision aid with VCM (n=75)

\*VCM = Values Clarification Method

test as opposed to no screening). However, type of values clarification did not influence labeled test preference. Values clarity differed statistically significantly among types of values clarification with rating and ranking having the lowest score (indicating greatest clarity), then discrete choice, then balance scale; however, the authors deemed these differences too small to be important.

VCM resulted in lower scores on depression and intrusive thoughts, higher self-rated health, stronger treatment preferences for breasts, increased perceptions of having weighed pros and cons for breast treatments, and perceptions that specialists had a strong preference about breast treatments 9 months post-intervention. There were no significant differences observed for any outcomes at 3 months post-intervention, nor those associated with ovaries at any time point.

VCM increased time spent with online tool, but did not affect decisional conflict, clarity of values, behavioural intentions, perceptions that decision was in line with values, self-efficacy for reducing coronary risk, decision intentions (including number of treatments intended), nor perceptions of tool.

**Table 3a: Summary of Decision Readiness Outcomes**

Article	n	Worry	Decision Uncertainty	Decision-Making Preparation	Knowledge	Decision Readiness
Abhyankar et al. <sup>11</sup>	30	○	●	●	○	●
Achaval et al. <sup>41</sup>	139	○	⊗	○	○	⊗
Brenner et al. RR <sup>25</sup>	614	○	●	○	○	●
Brenner et al. DCE <sup>25</sup>	615	○	●	○	○	●
Clancy et al. <sup>42</sup>	1027	○	○	○	○	○
Costanza et al. <sup>43</sup>	101	●	●	●	●	●
Feldman-Stewart et al. <sup>26</sup>	90	○	●	○	○	●
Feldman-Stewart et al. <sup>31</sup>	156	○	●	●	○	●
Fraenkel et al. <sup>44</sup>	87	○	○	●	○	●
Frosch et al. <sup>45</sup>	611	●	⊗	○	●	⊗
Kennedy et al. <sup>46</sup>	421	○	○	○	○	○
Labrecque et al. <sup>12</sup>	60	○	●	○	●	●
Lerman et al. <sup>13</sup>	236	⊗	○	○	●	⊗
Matheis-Kraft et al. <sup>47</sup>	60	○	○	○	○	○
Montgomery et al. <sup>48</sup>	212	○	●	○	●	●
O'Connor et al. <sup>10</sup>	201	○	●	○	○	●
Pignone et al. RR <sup>14</sup>	609	○	●	○	○	●
Pignone et al. DCE <sup>14</sup>	604	○	●	○	○	●
Roosmalen et al. <sup>49</sup>	137	●	●	○	○	●
Sheridan et al. <sup>50</sup>	88	○	●	○	○	●

● Positive result    ● Mixed or null result    ⊗ Negative result    ○ Outcome not assessed

RR = rating and ranking exercise; DCE = discrete choice experiment

**Table 3b: Summary of Decision & Post-Decision Outcomes**

Article	n	Choice	Congruence	Decision	Post-decision feelings	Post-implementation health	Post-Decision Effects
Abhyankar et al. <sup>11</sup>	30	●	○	●	○	○	○
Achaval et al. <sup>41</sup>	139	○	○	○	○	○	○
Brenner et al. RR <sup>25</sup>	614	●	○	●	○	○	○
Brenner et al. DCE <sup>25</sup>	615	●	○	●	○	○	○
Clancy et al. <sup>42</sup>	1027	●	○	●	○	○	○
Costanza et al. <sup>43</sup>	101	○	○	○	●	○	●
Feldman-Stewart et al. <sup>26</sup>	90	○	○	○	○	○	○
Feldman-Stewart et al. <sup>31</sup>	156	●	○	●	●	●	●
Fraenkel et al. <sup>44</sup>	87	○	○	○	○	○	○
Frosch et al. <sup>45</sup>	611	●	○	●	○	○	○
Kennedy et al. <sup>46</sup>	421	●	○	●	●	●	●
Labrecque et al. <sup>12</sup>	60	●	○	●	○	○	○
Lerman et al. <sup>13</sup>	236	●	○	●	○	○	○
Matheis-Kraft et al. <sup>47</sup>	60	○	● †	●	○	○	○
Montgomery et al. <sup>48</sup>	212	●	○ ‡	●	○	○	○
O'Connor et al. <sup>10</sup>	201	○	● ‡	●	○	○	○
Pignone et al. RR <sup>14</sup>	609	● *	○	●	○	○	○
Pignone et al. DCE <sup>14</sup>	604	● *	○	●	○	○	○
Roosmalen et al. <sup>49</sup>	137	●	○	●	●	●	●
Sheridan et al. <sup>50</sup>	88	●	●	●	○	○	○

● Positive result    ● Mixed or null result    ⊗ Negative result    ○ Outcome not assessed

RR = rating and ranking exercise; DCE = discrete choice experiment; VCM = values clarification method

\* There were no differences in labeled test preference but participants in both VCM arms were more likely to choose to avoid screening compared to participants in implicit arm.

† Depends on measurement method.

‡ Congruence was low for VCM but not measured for no VCM; therefore no comparative results reported.

