#### 2012 UPDATED CHAPTER D: CLARIFYING AND EXPRESSING VALUES

# SECTION 1: AUTHORS/AFFILIATIONS

Angela Fagerlin (co-lead)	University of Michigan	USA
Michael Pignone (co-lead)	University of North Carolina	USA
Purva Abhyankar	University of Stirling	UK
Nananda Col	University of New England	USA
Deb Feldman-Stewart	Queen's University, Ontario	Canada
Teresa Gavaruzzi	University of Padova & University of Leeds	Italy & UK
Jennifer Kryworuchko	University of Saskatchewan	Canada
Carrie A. Levin	Informed Medical Decisions Foundation	USA
Arwen Pieterse	Leiden University Medical Center	The Netherlands
Valerie Reyna	Cornell University, New York	USA
Anne Stiggelbout	Leiden University Medical Center	The Netherlands
Laura Scherer	University of Michigan	USA
Celia Wills	Ohio State University	USA
Holly Witteman	University of Michigan	USA

#### SECTION 2: CHAPTER SUMMARY

#### What is this dimension?

Values clarification methods (VCMs) are best defined as methods to help patients think about the desirability of options or attributes of options within a specific decision context, in order to identify which option he/she prefers.

#### What is the theoretical rationale for including this dimension?

Several decision making process theories were identified that can inform the design of values clarification methods, but no single "best" practice for how such methods should be constructed was determined.

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# What is the evidence to support including or excluding this dimension?

Our evidence review found that existing VCMs were used for a variety of different decisions, rarely referenced underlying theory for their design, but generally were well described in regard to their development process. Listing the pros and cons of a decision was the most common method used. The 13 trials that compared decision support with or without VCMs reached mixed results: some found that VCMs improved some decision-making processes, while others found no effect.

# SECTION 3: DEFINITION (CONCEPTUAL/OPERATIONAL) OF THIS QUALITY DIMENSION

# a) <u>Updated Definition</u>

Values clarification methods (VCMs) include any methods that are intended to help patients evaluate the desirability of options or attributes of options within a specific decision context, in order to identify which option he/she prefers. Although the methods can be either implicit and non-interactive (e.g., the patient thinks about what's important to his decision) or explicit and interactive (e.g., the patient sets a rating scale for each attribute to reflect the importance of each to his decision) (O'Connor 2005; Llewellyn-Thomas 2009), this chapter is focused on the more studied and better understood explicit values clarification methods.

# b) <u>Changes from Original Definition</u>

Our revised definition differs somewhat from the previous chapter's definition, which referred to "values clarification exercises": "[Exercises to] help patients to clarify and communicate the personal value of options, in order to improve the match between what is personally most desirable and which option is actually selected." (O'Connor 2005)

The rationale for our new definition of VCMs is as follows:

- It focuses on attributes of the situation (e.g., the option that the doctor recommends, the option that my partner/children prefer), attributes of options (e.g., the probability of cure, impact on bladder functioning) and of options as a whole (e.g. holistic comparison of surgery to radiotherapy), because VCMs are intended to ultimately help clarify which option an individual prefers and any of the above aspects of the situation may be helpful in that process.
- It does not include the communication of values to others- this is considered to be a different aspect of decision support interventions.
- It employs the more general term "methods" rather than "exercises."

# c) <u>Emerging Issues with Definitions</u>

See Section 6.

#### SECTION 4: THEORETICAL RATIONALE FOR INCLUDING THIS QUALITY DIMENSION

# a) Original Theoretical Rationale

In the original chapter (see **Appendix**), different types of VCMs were described, including the mechanisms by which these methods may help patients to clarify their values. These descriptions did not refer to underlying theories. The mechanisms that were described in the original chapter include clarifying values by:

- Considering detailed information about the options and their outcomes, which helps to promote understanding of what it means to undergo the procedures involved and to face the physical, emotional, and social consequences;
- Considering how others value features of options and whether the participant is similar to others (social matching);
- Rating or ranking features of options or trading off features of options, which may give insight into one's personal values and/or the tradeoffs underlying the choice for one versus other options.

# b) Updated Theoretical Rationale

Considerable evidence suggests that individuals facing new and complex decisions often do not have stable or clear preferences (Fischhoff 1991; Simon 2008). For example, Feldman-Stewart et al. (2004) showed that almost all early-stage prostate cancer patients who made use of a decision aid made changes to the attributes that they identified as affecting their decision. Importantly, these were patients who had already talked to their urologist and their radiation oncologist, and may have become clearer about what was important to them during those discussions.

Values clarification methods are deemed to be helpful to patients because they provide assistance with particular decision processes. Decision-making process theories imply that those processes can include:

- Identifying options, which can include either the narrowing down of options, or the generation of options that were not offered at the outset
- Identifying attributes of the situation and/or the options which ultimately affect the patient's preference in a specific decision context
- Reasoning about options or attributes of options
- Integrating attributes of options using either compensatory or both compensatory and non-compensatory decision rules
- Making holistic comparisons
- Helping decision makers retrieve relevant values from long-term memory

A specific VCM need not aim to address all of the above decision-making processes, but should aim to facilitate, explicitly or implicitly, at least one or more of these decision-making processes.

The theories presented in **Table 1** (and described in greater detail in **Table 2**) were selected because they specify particular decision-making processes, and hence provide the basis from which the subset of processes that VCMs may be able to assist were derived. (Because some theories, such as Expected Utility Theory (EUT) and theories of behavioral change (e.g.,

Transtheoretical Model), do not specify particular decision processes, they cannot guide identification of the processes that VCMs might be able to help.)

**Table 3** uses the context of decision making about prostate cancer treatment to provide examples of these decision-making processes, and to indicate which theories address these processes.

# c) <u>Emerging Issues/Research Areas in Theory/Rationale</u>

See Section 6.

#### SECTION 5: EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION

# a) <u>Original Evidence Base</u>

In the original version of this chapter, the authors found 19 studies that employed VCMs. (O'Connor 2005) They noted that most (72%) offered examples of how others' values led them to make different choices, and almost half (42%) incorporated some explicit means of measuring one's values (e.g. rating, trade-offs, balance scales). Few studies examined the specific effects of VCMs: the trial by O'Connor and colleagues (O'Connor 1999) did not find important effects of VCMs compared with a listing of the features of the decision. (See **Appendix** for further details).

# b) <u>Updated Evidence Base</u>

We organized our review into 2 major areas: A. Characteristics; and B. Evaluation

# A. Characteristics

Witteman et al. conducted a rigorous systematic review of the characteristics of values clarification exercises, and identified 61 studies that included an explicit VCM within a decision aid (Witteman 2012). In their review, Witteman and colleagues examined a large number of characteristics of the values clarification methods and of the decision aids in which they were embedded.

We present a sub-set of these data here. Our goal was to describe the state of the science of studies that include values clarification methods. Thus, the factors we ultimately decided to highlight were based on the following principles:

1) characteristics of the studies in which the VCMs were presented (e.g., decision context),

2) characteristics influencing the design of the VCMs (e.g., development process),

3) characteristics of the VCMs (e.g., type of VCM utilized).

Our review is therefore limited to "higher level" characteristics of the VCMs and the studies in which they were included. These key characteristics are summarized below and in **Table** 2. (Witteman and colleagues' full paper provides additional details on these—and other characteristics.)

1. Characteristics of Studies in Which Values Clarification Methods were Presented

#### • What was the decision context?

Types of decisions were catalogued by the decision context: whether the decision addressed 1) treatment, 2) prevention, 3) screening (other than genetic screening), or 4) genetic testing. Forty-six percent of VCMs focused on treatment decisions, 25% on prevention decisions, 33% on screening behaviors (not including genetic testing), and 10% on decisions about genetic testing. Three VCMs addressed two of the above decision contexts; one addressed three contexts, and one addressed all four.

#### • What medium was the VCM designed for?

The values clarification methods reviewed were designed to be completed on paper (49%), using a computer (38%), or verbally (15%); two VCMs used two different media, thus numbers do not sum to 100%.

#### • Where was the VCM located within the larger decision aid?

Values clarification methods can be placed before or after the presentation of the relevant information needed to make a decision. The vast majority (85%) of the VCMs were presented after the information section.

#### • Were decision intentions measured?

Over a third of the tools (38%) did not ask participants any questions about their decisions (intentions or actual). Thirty-four percent of the tools asked participants which way they were leaning, while 28% asked for their actual decision.

#### 2. Characteristics Influencing The Design of The VCM

• What theory, framework, model, or mechanism underlie the development of the VCM? The theory, framework, model, or mechanism underlying the development of the VCM was reported or apparent in only 36% of publications. Some theoretical framework was presented in the description of the underlying decision aid for 64% of studies. Twenty-five percent did not report any theory, framework, model, or mechanism. It should be noted that some studies reported theory for both the VCM and the overarching decision aid, thus the numbers presented in Table 2 do not sum to 100%. The most common theory was expected utility theory (18%), even though this theory makes no predictions about how VCMs can improve the process of medical decision making.

• Was the development process described and what was the development process? Most of the articles (74%) described, in some way, the development process of either the decision aid or the values clarification method. Of those that did include details, the development process used included literature reviews (42%), expert reviews (51%), and/ or testing (80%). Those involved in the development process included health professionals (53%), academic experts (31%), and patients who have previously faced the decision (38%). Because many of the articles used multiple processes and participants in their development of the tool, the numbers in Table 2 do not sum to 100%. Less than half (39%) of the VCMs in decision aids were developed and evaluated using established guidelines, most often the IPDAS standards (28% of VCMs).

# 3. Characteristics of the VCM

# • What type of VCM was used?

Ten categories of VCMs were utilized. The most common types were considering the pros vs. cons (46%), utility assessment with or without decision analysis (18%), prioritization (11%), and rating scales (11%). See **Table 4**.

# • Were the results of the VCM presented to participants?

Thirty-nine percent explicitly showed participants the result of the VCM, most of which occurred before the patient was asked to indicate their decision. Fifty-seven percent did not explicitly provide feedback to participants.

# **B.** Evaluation

The committee reviewed 13 studies that compared the effects of decision support with and without VCMs (see **Table 5**). The selected articles were derived from the Witteman et al. review. However, only studies that included VCMs within the context of a decision aid are included here.

The identified studies examined a range of health conditions, with cancer-related topics being the most common (6 of 13). Sample sizes ranged from small (5 of 13 with less than 100 participants) to moderately large (4 with 400 or more participants). Most examined actual patients facing decisions but 3 studies asked participants to evaluate hypothetical decisions. Several different types of VCMs were employed. Available studies examined a wide range of outcomes, and no outcomes were assessed in the same manner across all or most studies. Reported outcomes included likeability of the VCM, knowledge, decision making processes, decisional conflict, uncertainty, satisfaction, decision preference, treatment intent, actual health behaviors, regret and, in a few cases, health outcomes or cost.

The effects of VCMs were mixed: decision processes were improved in 5 of 8 studies, but other outcomes were not measured frequently enough to reach conclusions about whether VCM had mainly positive or mainly neutral effects; no trials, however, suggested VCMs led to worse outcomes. See **Table 6**.

# c) <u>Emerging Issues/Research Areas in Evidence Base</u>

See Section 6.

#### SECTION 6: EMERGING ISSUES / RESEARCH AREAS IN DEFINITION, THEORY, AND EVIDENCE BASE

Although the number of studies of values clarification methods (VCMs) and decision aids is growing rapidly, our review highlights that many questions about the effects of VCMs remain unanswered. We outline several such issues here.

# 1. Proposed Theories

A number of decision-making process theories were suggested without intending to establish agreement about a single theory, or a set of theories, that should be viewed as most promising in providing guidance for the design and evaluation of VCMs. More research is needed across contexts (e.g., healthcare settings) and cultures to better understand how VCMs might be designed to contribute to decision-making. Such understanding requires testing VCMs based on specific theory, including theory-based predictions of anticipated effects on outcomes and consideration of how such VCMs might contribute to effective decision-making.

# 2. Intuitive Processes

There is a debate currently about the value of intuitive processes in decision making. Intuitive processing is typically characterized by a lack of overt cognitive effort and the implicit integration of available information. In contrast, deliberative processing generally involves effortful, conscious and analytical thought (Betsch 2010). Importantly, intuitive and deliberative processes should not be conflated with implicit versus explicit VCMs. Although explicit VCMs are often effortful, and thereby require deliberative thought, an implicit VCM may also be quite effortful and activate analytical thought processes.

From research outside of health care (Wilson & Schooler 1991), deliberative reasoning about pros and cons may cause people to focus on attributes that are obvious, accessible, and easy to articulate, and these attributes may not be the ones that are actually the most important factors in the decision. Therefore, in contexts outside of health care, there is evidence to suggest that deliberation can cause people to ignore attributes that lead to long-term satisfaction. There is also evidence to suggest that intuitions can accurately reflect the integration of a large amount of information (Betsch 2010). However, the decisions that have been studied in the psychology literature are typically hypothetical and/or familiar decisions. There is little research yet to assess to what extent these results are expected to hold for users facing new, complex, preference-sensitive health related decisions. Until more research is available on the value of intuitive processes in such decision contexts, it is unclear to what extent a VCM that encourages intuitive processing of options would be effective to help people sort out what is most important to them, in comparison to a VCM that encourages explicit processing or no VCM.

An increasing number of theories of decision making assume both intuitive and deliberative decision making processes. Importantly, intuition and deliberation are not mutually exclusive. A given decision may employ extensive use of both.

# 3. How VCMs Fit with Patient-Provider Shared Decision Making

Researchers and practitioners need to better understand how values clarification relates to shared decision making (SDM). Is values clarification a pre-requisite to, or an element of, SDM? Does it improve SDM? Through the process of SDM, health care providers may elicit patients' and their families' values. Patients and their families may not necessarily be clear about their own values before the conversation with the health care team and may, on the contrary, be guided to become clear in the SDM process. Whether a VCM should precede the conversation with the health care provider, be used within the consultation, follow that conversation, or even used at all requires further study.

# 4. Use of VCMs with Surrogate Decision Makers

More evidence is needed to determine whether VCMs would also be helpful for others involved in decision making processes. That is, what is the impact of VCMs designed to support the clarification of values of those who influence the treatment decision and who are affected by the outcome of the decision (e.g., caregivers or partners of patients), or of surrogate decision makers, such as family members deciding on behalf of the patient and trying to construct that patient's values from their past experience with that patient and their knowledge about the patient?

# 5. Use of VCMs to Reach a Decision Involving Multiple People

More research is needed to examine how VCMs can be used to help multiple people (such as health care providers and family members) who are working together to support the patient's decision. Specifically, little is known about how VCMs can help clarify the values that influence the advice of others to patients, as well as how VCMs could be used in a process leading to consensus about the choice (when consensus does not violate the autonomy of the patient).

# 6. The Role of Distal Outcomes

Attempts to develop measures of the effectiveness of VCMs have often focused on decision making processes, likely because such processes are directly affected by the VCMs. More distal outcomes, including effects on regret, satisfaction, behaviors, actual decisions, and measures of health may also be important measures of the effect of VCMs, but are often affected by many other factors. How best to incorporate these more distal outcomes into evaluation of VCMs warrants further study.

# 7. Implicit versus Explicit VCM

More research is needed to ascertain the "active ingredients" of VCMs -- that is, the components that make independent contributions to facilitating good decision making processes that the VCMs aim to facilitate. In particular, more research is needed to clarify (a) what is required for implicit values clarification, and (b) if the use of strategies to encourage implicit values clarification is helpful, compared with explicit VCMs and also compared with no VCM.

# 8. How to Handle More Than Two Options

More research is needed to examine whether, in the case of multiple options, it is necessary to present all of the options and whether multiple options should be considered simultaneously or in series. For example, it may be more helpful to identify attributes and then present only the options that match the attributes the individual who faces the decision considers most important. Or rather, it may be more helpful to present all options prior to the VCM and then identify preferred option(s) for further consideration. However, patients require sufficient knowledge of options to realize that certain attributes or values are relevant (Reyna 2008).

# 9. Assessing Capacity of The Patient For VCMs

More research is needed to identify which types of patients are able to benefit from VCMs, how cognitive deficits (e.g. age-related loss of executive functioning) and/or mental illness or other conditions might adversely affect the use of VCMs, and which types of VCMs are best suited for these populations.

# **10. Empirical Evidence Base**

Our systematic review found that the research questions and outcome variables being tested vary widely across studies. It may be helpful for studies to use at least a subset of standard measures so that study results can be more easily compared. We found that reporting of results is quite consistent, with the exception of the development process for values clarification methods. We recommend succinct reporting of: 1) the rationale for the design used (theory, previous designs, literature), 2) who was involved in its development (e.g., clinical experts, patients, advisory panel, etc.), and 3) how was stakeholder input incorporated (focus groups, individual interview, pilot testing, etc.). We also refer authors of reports of VCMs to Witteman et al.'s systematic review where we report a more thorough set of categories for reporting.

We chose to include studies that used either hypothetical or actual clinical decisions. It is unclear whether and how differences in the population used will affect results when comparing decision aids with and without VCM. Hypothetical samples may be preferred in early developmental work to reduce the possibility of causing harm to actual patients; conversely, actual patient populations are needed for evaluating more distal outcomes and to increase generalizability.

As described above, the theoretical and empirical basis for values clarifications research has changed significantly since the last IPDAS Background Document. Yet, there are still many areas that need considerable research before we can make strong conclusions about the use of VCM in decision aids.

Theory	Brief Description	Ident ifying Options	Ident ifying Attrib utes of Situation And/Or Options	Reasonin g About Options or Attrib utes of Options	Integ rating Attrib utes of Options	Making Holistic Compari sons	Helping Retrieve Relevant Values
Behavioral Decision Framework (BDF) Fischhoff, 2008	(Descriptive & Prescriptive theory): Good decision- making is characterized by: a) focusing on the consequences of options; b) identifying all options and assessing their consequences and desirability; and c) making trade-offs to select the alternative with the highest overall evaluation on a set of choice criteria (compensatory).	yes	yes		yes		
Conflict Model of Decision Making (CM) Janis & Mann, 1977	(Prescriptive theory): Decisions create stress which can interfere with good decision making process, characterized by: a) systematic information search; b) thorough consideration of all alternatives; c) sufficient time to evaluate each alternative; and d) reexamining and reviewing data in an unbiased manner			yes		yes	

 Table 1: Decision Process Theories: Extent to Which They Address Specific Decision-Making Processes

Differentiation and Consolidation Theory (Diff Con) Svenson,1992	(Descriptive theory): Decision making involves a process of gradually identifying differences between options (differentiation); these processes continue after the decision is made (consolidation) to minimize cognitive dissonance and future regret.	yes	yes	yes	yes	yes	
Fuzzy Trace Theory (FTT) Reyna, 2008	(Descriptive & Prescriptive theory): People encode both verbatim and gist representations ("traces") of information. However, decision making is mainly determined by the gist (basic meaning for that individual) and by the social and moral values that are retrieved in context, a highly cue-dependent process.			yes	yes	yes	yes
Image Theory (IT) Beach & Mitchell, 1987	(Descriptive theory): Decision making includes two stages: a) pre-choice screening using rapid, simple, emotionally mediated and non-compensatory strategies; followed by b) the choice, using more deliberate and compensatory strategies with the goal to pick the option with the most attractive expected consequences.	yes	yes	yes	yes		

Parallel Constraint Satisfaction Model (PCS) Glockner and Betsch 2008	(Descriptive theory): Decision making involves: a) deliberative processes for information search and production focused on actively constructing the decision problem using different decision rules for searching, editing and changing information; and b) automatic processes for integrating information using an all- purpose, parallel constraint satisfaction rule.	yes	yes		yes	
Search for Dominance Structure Model (SDS) Montgomery, 1983	<ul> <li>(Descriptive theory): Decision making involves a search for a perspective that leads to optimal differences between a to-be-chosen option and other available options, in four stages: a) identifying important attributes and options;</li> <li>b) selecting an initially favored option; c) identifying disadvantages of the initially favored option; and d) neutralizing disadvantages of the initially favored option.</li> </ul>	yes	yes	yes	yes	

# **Table 2: Detailed Descriptions of Selected Decision Processing Theories**

The *Behavioral Decision Framework* (BDF, Frisch & Clemen, 1994; Fischhoff, 2008; Payne et al, 1992; Payne et al, 1998) describes the foundations of a model of a good decision making process (for an early precursor of this model, see Janis & Mann, 1977). That is, good decision making can be characterized by the following three basic features:

- 1. Consequentialist decision strategies: i.e., explicitly focussing on consequences of different options/actions as opposed to non-consequentialist ones such as imitation, habit or other heuristic processing (e.g. I prefer option A because my good friend had it or my doctor seems to prefer it).
- 2. Thorough structuring: Identifying possible options (option generation), anticipating the consequences of options accurately (beliefs about probabilities), and determining the personal desirability of those consequences (value structuring).
- 3. Using compensatory decision rules: Making trade-offs using compensatory rules (e.g., trading off probabilities and consequences) rather than non-compensatory rules.

The *Conflict Model* (CM, Janis & Mann, 1977) of decision making assumes that the most thorough and ideal way of coming to a decision is by way of vigilant information processing. It is characterized by (a) systematically searching information, (b) thoroughly considering all available alternatives, (c) devoting sufficient time to evaluate each alternative, and (d) reexamining and reviewing data in an unbiased manner before making a decision.

*Differentiation and Consolidation* (Diff Con, Svenson, 2003) theory views decision making as a process over time in which one option is gradually differentiated from competing alternatives until one alternative is sufficiently superior. A preliminary option is selected. The differentiation of alternatives subsequently occurs through structural differentiation, that is, changing mental representations of options in support of the preliminary choice, and process differentiation, that is, applying one or more compensatory or non-compensatory decision rules. The theory suggests that the goals of decision makers' processing are to protect themselves against cognitive dissonance and later regret. It suggests that differentiating processes continue after the decision is made, called consolidation. That is, after a decision has been made the relative attractiveness of the chosen alternative is further altered in an attempt to consolidate the choice's superiority.

*Fuzzy Trace Theory* (FTT, Kuhberger & Tanner, 2010; Reyna, 2008) proposes that people simultaneously encode mental representations (traces) of information that vary in precision. Verbatim traces preserve precise detail, but 'gist' traces preserve basic meaning and are the answer to the question "What does this information mean?" to an individual. Essential elements of a decision consist of knowledge, gist of information, retrieval (how knowledge and values are accessed when needed), and processing (how what is perceived is put together with what is retrieved to make a decision). In processing, values and principles are retrieved that are then applied to mental representations of gist. However, retrieval is highly cue-dependent (i.e., sensitive to reminders in the immediate environment), even when values and principles are strongly endorsed (Bartels, Bauman, Skitka, & Medin, 2009). Main implications of FTT for values clarification would be to (a) ensure that patients understand the essential meaning of information (because different gists cue different values) (b) remind patients of an array of

values, some of which might be contradictory; and (c) assist patients in applying their values to their mental representations by disentangling overlapping sets (Reyna, 2008; Reyna & Lloyd, 2006).

*Image Theory* (IT, Beach & Mitchell, 1987) assumes two stages in making decisions: prechoice screening of options to narrow the pool of options, followed by the choice. In screening, unacceptable options are eliminated based on their incompatibility with the decision maker's guiding principles, which underlie the adoption of goals to pursue for a specific decision. It is a rapid, simple, emotionally mediated and non-compensatory strategy that does not necessarily take place consciously. Choice of an option is accomplished by a more deliberate and compensatory strategy that evaluates both the positive and negative attributes of options. It will select the option which potentially offers the most attractive consequences. Depending on the number of options, the decision strategy will be non-compensatory followed by compensatory or compensatory alone.

The *Parallel Constraint Satisfaction* model (PCS, Glöckner and Betsch, 2008) proposes that decision making involves deliberative processes for information search and production, and automatic processes for integrating information and making choices. Processes of deliberation in decision making are mainly concerned with actively constructing the decision problem using different decision rules for search, editing and changing information regarding the decision situation. These rules are under individuals' deliberate control, can be verbalized and give individuals the feeling that they are deciding based on reasoning. The model further assumes that individuals integrate and structure information using an automatic all-purpose decision rule, the parallel constraint satisfaction rule.

The *Search for Dominance Structure* (SDS) model (Montgomery, 1994, 2006) proposes that when available options carry both advantages and disadvantages, decision making involves a search for a perspective that leads to an optimal differentiation between a to-be-chosen option and other available options, that is, the search for dominance. A dominance structure is achieved when the individual perceives one option to be superior to all other options on at least one attribute and is not inferior to any other option on any attribute. The search for dominance includes four stages: selecting important attributes and options (i.e., pre-editing); finding an initially favored option for the final choice; checking disadvantages of the initially favored option (dominance testing); and neutralizing disadvantages of the initially favored option (dominance structuring).

Decision-Making Processes	Example Using The Clinical Context of Treatment of Early Stage Prostate Cancer	Theories Utilized
110005505	Treatment of Darry Stage Prostate Cancer	Utilizeu
Identifying options	Recognizing active surveillance, surgery, and	IT, SDS, Diff
	radiation as potential options	Con, BDF
Identifying attributes	Identifying effectiveness of the treatments; risk of	IT, SDS, Diff
of the situation and/ or the options	adverse effects such as impotence or incontinence; anxiety related to potential for cancer progression or metastasis	Con, BDF
Reasoning about	Evaluating the potential distress of not having	CM IT SDS
attributes of options	immediate treatment in the context of other life stresses. Recognizing the patient can change his mind about active surveillance at any time and opt for active treatment, whereas the converse is not possible.	Diff Con, FTT
Integrating attributes	Trading off fear of living with cancer vs. how	BDF, IT, SDS,
of options	important it may be to avoid adverse effects such as incontinence.	Diff Con, PCS, FTT
Making holistic	Desiring to avoid surgery or radiation per se;	CM, Diff Con,
comparisons	valuing an "active" approach vs. one that feels reactive or passive	FTT
Helping retrieve relevant values	A value that is often retrieved initially concerns survival (life is better than death) and having cancer	FTT
	is often equated to death. A patient retrieving only this value would likely choose immediate surgery.	
	However, a decision aid could elicit retrieval of	
	additional values, such as values concerning sexual	
	to you?") that are sometimes not easily retrieved	
	despite their relevance.	

<b>Table 3: Examples</b>	of Decision-Making	Processes in	<b>Choosing Prosta</b>	te Cancer Treatment
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Abbreviations:

BDF: Behavioral Decision Framework CM: Conflict Model of Decision Making Diff Con: Differentiation and Consolidation theory FTT: Fuzzy Trace Theory IT: Image Theory PCS : Parallel Constraint Satisfaction model SDS: Search for Dominance Structure model

# Table 4: Characteristics of Values Clarification Methods and the Studies in Which They Were Presented

\*This table was adapted with permission from Witteman et al.

1. Characteristics of Studies In Which VCMs Were Presented	N (%)
Decision Context	Overlapping (Note: Three VCMs address two decision contexts; one addresses three contexts; and one addresses all four.)
Treatment	28 (46%)
Prevention	15 (25%)
Screening (non-genetic)	20 (33%)
Genetic testing	6 (10%)
Medium	<b>Overlapping</b> (Note: Two VCMs used two different media)
Computer-based	23 (38%)
Online/Web	9 (15%)
CD-ROM	1 (2%)
With Multimedia	8 (13%)
Audio	3 (5%)
Video	6 (10%)
Other	2 (3%)
Decision board	1 (2%)
Paper	30 (49%)
With Audiotape	5 (8%)
With Verbal component	5 (8%)
Verbal	9 (15%)

With Visual Aids	6 (10%)
With Paper Exercises	1 (2%)
With Personal Data Assistant	1 (2%)
Position in Larger Decision Aid	
After information section	52 (85%)
Before information section	2 (3%)
Between information sections	1 (2%)
Throughout: As add-on to DA	3 (5%)
Throughout: VCM formed the entirety of the tool	3 (5%)
Unclear from article	1 (2%)
Measurement of Decision Intentions	
Asked which way leaning	21 (34%)
Asked which decision taken	17 (28%)
Not asked	23 (38%)
2. Characteristics Influencing The Design of The VCMs	N (%)
Theory, Framework, Model, or Mechanism	
None	15 (25%)
Underlying the VCM	
Expected utility theory	11 (18%)
Conjoint Analysis	1 (2%)

Differentiation and Consolidation Theory	2 (3%)
Multiattribute Utility Theory	2 (3%)
Other	6 (10%)
Underlying the Overall Decision Aid	
Ottawa Decision Support Framework (ODSF)	19 (31%)
Precaution Adoption Model	3 (5%)
Edutainment Decision Aid Model (EDAM)	2 (3%)
Elaboration Likelihood Model	2 (3%)
Stages of Change	2 (3%)
Other	11 (18%)
Development Process	
Development Process Described in Article	
Yes	45 (74%)
No	16 (26%)
What Aspect of Development Process was Described	N.B. Percentages out of 45 with descriptions
Literature review	19 (42%)
Modification, adaptation, translation of tool	5 (11%)
Model validation	2 (4%)
Needs assessment	9 (20%)
Observation of existing processes	1 (2%)

Individual sessions, interviews	9 (20%)
Focus groups	13 (29%)
Consultations, expert review	23 (51%)
Feasibility testing	2 (4%)
Iterative process, iterative steps	9 (20%)
Prototype testing, usability testing, pilot testing	36 (80%)
Who was Involved in the Development Process	N.B. Percentages out of 45 with descriptions
Clinical experts, health care professionals	24 (53%)
Experts in counseling, patient education, patient advocates	9 (20%)
Experts from relevant academic fields (e.g., epidemiology, decision-making, health communication)	14 (31%)
Plain language experts	3 (7%)
Technical experts, design experts	2 (4%)
Policymakers	1 (2%)
Consumer representatives, people from community-based groups, advocacy groups	6 (13%)
Patient experts (those who have previously faced decision)	17 (38%)
Prospective users	22 (49%)
Healthy volunteers, people recruited from community	6 (13%)
Patient advisory groups	1 (2%)
Committees, steering committees, advisory panels, multidisciplinary teams	6 (13%)

What Development Guidelines were Used	
CREDIBLE	3 (5%)
IPDAS	17 (28%)
IPDAS cited, but not used	2 (3%)
National Health and Medical Research Council guidelines for presenting information to consumers	2 (3%)
American College of Physicians Guideline for counselling postmenopausal women about preventive hormone	1 (20/)
therapy	1 (2%)
None	37 (61%)
3. Characteristics of the VCMs	N (%)
Type of VCM	
Type of VCM       Decision analysis	11 (18%)
Type of VCM         Decision analysis         Conjoint analysis	11 (18%) 1 (2%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy process	11 (18%) 1 (2%) 1 (2%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffs	11 (18%) 1 (2%) 1 (2%) 4 (7%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbability	11 (18%) 1 (2%) 1 (2%) 4 (7%) 1 (2%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbabilityTime	11 (18%) 1 (2%) 1 (2%) 4 (7%) 1 (2%) 1 (2%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbabilityTimeAttributes	11 (18%)         1 (2%)         1 (2%)         4 (7%)         1 (2%)         1 (2%)         2 (3%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbabilityTimeAttributesPros vs. cons	11 (18%)         1 (2%)         1 (2%)         4 (7%)         1 (2%)         1 (2%)         2 (3%)         28 (46%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbabilityTimeAttributesPros vs. consWith weighting	11 (18%)         1 (2%)         1 (2%)         4 (7%)         1 (2%)         1 (2%)         2 (3%)         28 (46%)         23 (38%)
Type of VCMDecision analysisConjoint analysisAnalytic hierarchy processTradeoffsProbabilityTimeAttributesPros vs. consWith weightingWith binary response	11 (18%)         1 (2%)         1 (2%)         4 (7%)         1 (2%)         2 (3%)         28 (46%)         23 (38%)         4 (7%)

Prioritization	7 (11%)
Rating scales	7 (11%)
Lists of concerns	5 (8%)
List only	2 (3%)
List and discuss	3 (5%)
Social matching	1 (2%)
Other	1 (2%)
Presentation of Results	
Yes	24 (39%)
Yes, after decision intention	3 (5%)
Yes, prior to decision intention	21 (34%)
Possibly shown explicitly (depends on options selected)	1 (2%)
No	35 (57%)
No, not at all	10 (16%)
No, not explicitly, though it may be inferred	25 (41%)
Unclear from article	2 (3%)

Reference	VCM used	Decision or	Summary of Results
		Context	Relevant to VCM
Abhyankar	Pros and	Choice between	VCM resulted in more use of
2010	Cons with	standard	personal values when evaluating
(n = 30)	weightings	adjuvant	attributes of options, somewhat less
hypothetical decision		chemotherapy	ambivalence, less uncertainty, and
		for early stage	did not change decision preference.
		breast cancer	
		and clinical	
		trial testing new	
		chemotherapy	
Clancy	Decision	Choice	VCM increased action-taking
1988	analysis	between being	(screening or vaccination).
(n = 1280)	with visual	immunized for	
	analogue scale	Hepatitis B,	
		screened for	
		antibodies and	
		immunized if	
		negative, or	
		not immunized	
		unless exposed	
Feldman-Stewart	Rating	Choice between	Participants preferred VCM design
2006	(sliders)	four main	with summary over VCM without
(n = 90)		options for	summary and no VCM.
hypothetical decision		early stage	
		prostate cancer	
		(watchful	
		waiting,	
		surgery,	
		external beam	
		radiation and	
		brachytherapy)	
Feldman-Stewart	Rating	Treatment of	VCM users reported higher
2012	attributes	early stage	preparation for decision making
(n = 156)		prostate cancer	retrospectively and had reduced
	~	~	regret at 1 year.
Fraenkel	Conjoint	Choice between	VCM resulted in higher scores on
2007	analysis	treatments for	decisional self-efficacy, preparation
(n = 87)		knee pain	for decision making, and arthritis
			self-efficacy.

# Table 5: Trials Examining Effect of VCM Versus No VCM Within Decision Aids

Frosch 2008 (n = 611)	Time Trade- off and Visual Analogue Scale	Whether or not to have prostate specific antigen (PSA) testing to screen for prostate cancer	VCM had no effect on preferences for PSA testing, preference for watchful waiting, knowledge or decisional conflict.
Kennedy 2002 (n = 894)	List of concerns and discussion	Choice between treatment options for menorrhagia (advice and reassurance, addressing possible iatrogenic causes, drug therapy, or surgery such as hysterectomy or endometrial destruction)	VCM resulted in minimal improvements in self-reported health status, lower use of a more invasive treatment, higher patient satisfaction, more frequent clinician perceptions of "longer than usual" consultations, and lower overall costs.
Labrecque 2010 (n = 63)	Rating Scales	Whether or not to have a vasectomy	VCM had no effect on decisional conflict, knowledge, decision preferences or certainty.
Lerman 1997 (n = 400)	List of concerns with discussion	Whether or not to have genetic testing for BRCA1	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.

Montgomery 2003 (n = 217)	Decision analysis with standard gamble	Whether or not to start drug therapy for hypertension	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 1999 (n = 201)	Balance Scale (Pros and Cons)	Whether or not to take hormone replacement therapy after menopause	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.
Sheridan 2010 (n = 137) hypothetical decision	Rating and ranking tasks (prioritization)	Whether or not to initiate behaviors to prevent coronary heart disease (CHD), and, if so, which behaviors	VCM increased time spent with online tool, but did not affect decisional conflict, clarity of values, behavioral 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.
van Roosmalen 2004 (n = 88)	Time Trade- off	Choice between intensive screening and prophylactic surgery for breasts and/or ovaries	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.

# Table 6: Outcomes of VCM Trials

Study	Likeab ility	Knowl edge	Deci sion Ma king Process es	Decis ional Conflic t	Decisio n Satisfa ction	Regret	Preferen ce	Intent	Behavior	Health Outcome
Abhyankar 2010 (n = 30)			Improved	Improved			No effect			
Clancy 1988 (n = 1280)									Increased	
Feldman- Stewart 2006 (n = 90)	Improved									
Feldman- Stewart 2012 (n = 156)			Improved			Improved				
Fraenkel 2007 (n = 87)			Improved							
Frosch 2008 (n = 611)		No effect		No effect			No effect			

	Likeab	Knowl	Deci	Decis	Satisfa	Regret	Preferen	Intent	Behavior	Health
	ility	edge	sion	ional	ction		ce			Outcome
			Ma	Conflic						
Study			king	t						
			Process							
			es							
Kennedy					Improved				Reduced	No effect
2002										(reduced
(n = 894)										costs)
Labrecque		No effect	No effect	No effect			No effect			
2010										
(n = 63)		No offect	Improved					No offect	No offoot	
1997		No effect	Improved					No effect	no effect	
(n = 400)										
Montgomery		Improved		Improved			No effect	No effect	No effect	No effect
2003										
(n = 217)										
O'Connor	No effect		No effect							
1999			(concor-							
(n = 201)			dance)							
Sheridan	No effect		No effect	No effect				No effect		
2010										
(n = 137)			Immerced				Changed			Immercad
Vall Roosmalen			Improved				Changed			Improved
2004										
(n = 88)										

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# APPENDIX: ORIGINAL CHAPTER D

# **Original Authors**

Annette O'Connor	University of Ottawa, Ontario	Canada
(co-lead)		
Hilary Llewellyn-Thomas	Dartmouth Medical School, Dartmouth	USA
(co-lead)	College, New Hampshire	
James Dolan	University of Rochester, New York	USA
Miriam Kupperman	University of California at San Francisco	USA
Celia Wills	Michigan State University	USA

# **Original Rationale / Theory**

A key objective of patient decision aids is to help patients to clarify and communicate the personal value of options, in order to improve the match between what is personally most desirable and which option is actually selected. Several mechanisms explain how patient decision aids may accomplish this goal.

Most patient decision aids describe the options and outcomes in sufficient detail for decision making (O'Connor et al., 2003). This helps patients understand what it is like to undergo the procedures involved and to face the physical, emotional, and social consequences. Fishhoff and colleagues (1980) found that patients are better able to judge the value of consequences when they are familiar, simple, and directly experienced. Providing detailed descriptions of experiences makes the features of an option more vivid for individuals.

Some patient decision aids use balanced examples of how others value the features of each option, in order to illustrate how different values may lead to different choices. Patients may be able to sort through their personal values by considering which examples most closely match their own and which do not.

Some patient decision aids explicitly measure values. They guide patients to rate or trade-off different features of options. This engaging process may increase awareness of personal values and provide insight into the trade-offs that need to be made in choosing one option over another.

Some patient decision aids not only encourage patients to clarify their values, but also to share them with others involved in the decision. Strategies may range from recording values, guiding/ coaching patients in values communication, training practitioners in values communication, or sending recorded values to providers. Strategies that facilitate communication may increase the chances that they are discussed in counseling sessions and that patients receive the most valued option (Dodin et al., 2001; Guimond et al., 2003; Holmes-Rovner et al., 1999; O'Connor et al.,

1999; Rothert et al., 1997)

# **Original Evidence**

# RCTs Involving Patients Facing Actual Choices (O'Connor, et al., 2003).

Data were obtained from the Cochrane Systematic Review of patient decision aids in which 29 different patient decision aids were evaluated in 34 trials. Of these 19, 11 measured the match between personal values and choices (n = 3), and self-reports about feeling clear about the personal importance of benefits versus harms (n = 10). One trial explored the effects on practitioner's discussion of values.

# Ways To Clarify Values

The most frequently used values clarification techniques in patient decision aids are: <u>Describing features</u>: 100% (19 of 19) patient decision aids described the features of options and their outcomes. However, there was considerable variability in the level of detail about what it is like to undergo the procedures and to live with the physical, emotional, and social consequences. Some used detailed scenarios or testimonials; others briefly described key features.

Examples of others' values: 72% (13 of 18) provided examples of how other patients' values led them to make different choices;

<u>Measuring values of features</u>: 42% (8 of 19) explicitly guided patients to rate or tradeoff different features of options using: personal balance scales (4 of 8); non-directive counseling with standardized questions (2 of 8); relevance charts (1 of 8); and the analytic hierarchy process (1 of 8).

<u>Communicating values</u>: 47% (9 of 19) of patient decision aids used strategies to facilitate the communication of values, such as personal worksheets (5 of 9); and personal coaching or encouragement to communicate values (4 of 9).

# Primary Endpoints

#### Match between values and choices

3 randomized trials (Dodin et al., 2001; O'Connor, Wells et al., 1999; Rothert et al., 1997), all focused on menopause hormone decisions, evaluated the effects of a basic method of clarifying values in a DA (feature description) compared to DAs with multiple methods (feature description + examples; feature description + examples + rating, feature description + examples + rating + guidance in communicating values). All three studies measured the match between values and choices differently.

# *Are more values clarification methods better than the single method of feature description*?

All three trials found that more methods are usually better than a single method. When the single method of describing experience with options was brief, there was an overall benefit of adding one other method (examples) or several other methods (examples, rating values, guidance in communicating values). However, when the single method of describing consequences was a detailed description of physical, emotional, and social consequences, the benefit was large but of borderline statistical significance (p = 0.06), and was confined only to those who were considering changing from not taking hormones to taking them. In those who were not on hormones and would remain that way, there was no added benefit from having more than one method.

# Feeling clear about personal values

Ten trials used a subscale of the Decisional Conflict Scale (O'Connor, 1995) to measure the extent to which patients feel clear about personal values (Davison et al., 1999; Dodin et al., 2001; Dolan et al., 2002; Goel et al., 2001; Man-Son Hing et al., 1999; Morgan, 1997; Murray et al., 2001a; 2001b, O'Connor et al., 1998; O'Connor et al., 1999). Scores that combine 3 items (e.g., "I am clear about the personal importance of positive versus negative features of the options") in the subscale can range from 0 ("strongly agree") to 100 ("strongly disagree").

*Are values clarification methods better than usual practices*? 6 trials compared patient decision aids with one or more values clarification methods to usual practices (Davison et al., 1999; Dolan et al., 2002; Man-Son Hing et al., 1999; Morgan et al., 1997; Murray et al., 2001a; 2001b). In 3 of these 6 trials, there were statistically significant differences in favor of patient decision aids. The overall improvement, combining results from all 6 trials, was statistically significant (the weighted average difference in favor of patient decision aids was 5.48 points out of 100; we are confident that if this study were repeated several times, 95% of the time the improvement would fall between 1.44 and 9.53 points). The importance of this small improvement in scores needs to be evaluated further.

Are more methods or more detailed methods better than fewer or less detailed methods? Of the 4 trials making this comparison (O'Connor et al., 1999; Dodin et al., 2001; Goel et al., 2001), 3 showed no significant differences and one showed differences in favor of more methods (O'Connor et al., 1998). When the results of all 4 trials were combined, the overall improvement was not statistically significant. The one trial that did show improvement (7.5 points out of 100) had feature descriptions that were very brief. In three trials whose basic feature descriptions were more detailed, there was no significant improvement.

#### Communication of values in discussions with others

One trial (Guimond et al., 2003) involved tape recording the dialogue between patients and doctors after patients were either prepared with: 1) a patient decision aid with brief information about consequences (n = 18); or 2) a patient decision aid with detailed information about consequences, examples of others' values, rating of values, and guidance in recording and communicating values (n = 16). The group prepared using the simpler patient decision aid had less discussion of values (median = 16) than did the group prepared using the more detailed patient decision aid with a written record of values (n = 22), but the difference was not statistically significant from 0 (p=0.10).

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