

An explicit values clarification task: Development and validation

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Abstract

Objectives: (a) To determine which of two values clarification exercises (VCE), based on theoretical decision rules used naturally by people, would be more helpful to patients making a treatment decision and (b) to evaluate the convergent validity of the most helpful VCE when part of a decision aid for the treatment of early-stage prostate cancer.

Methods: Two studies were completed. Study 1: Ninety community volunteers were assigned at random to one of three groups and all made a hypothetical treatment decision. Two groups received VCEs, one with a summary and one without, and the third was a control group. Study 2: In a multi-centre phase II trial, 69 patients used the decision aid that included the exercise ranked most helpful in Study 1. Decision aid assessments included the decisional conflict scale, treatment valuation assessment and regret.

Results: Study 1: Most participants in each group ranked the VCE with the summary as most helpful. Study 2: VCE outputs, such as the size of the summary, were associated in predictable ways with the decision aid assessments.

Conclusion: The VCE ranked most helpful in Study 1 showed convergent validity with decision aid assessments.

Practice implications: With the interpretation of the VCE outputs now validated, a randomized controlled trial is required to determine if the exercise helps patients more than the aid without the exercise.

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1. Introduction

Many patients now want to be involved in decisions about their health care but some of the decisions are particularly challenging. Decision aids (DAs) are interventions that are designed to assist patients with such decisions. These interventions differ from educational interventions, in that they are focussed on a particular decision and endeavour to help the patient make a decision that is consistent with his/her values [1]. “Values” refers to qualities that the individual considers desirable or not, and in these situations

they often relate to quantity or quality of life (e.g., Ref. [2]) To achieve consistency with values, DAs include values clarification exercises, either implicitly or explicitly, as part of the aid. Explicit exercises require that the patient do an action, such as move bars, add weights to a scale or produce numbers, to reflect the relative impact of particular values on her/his decision; implicit exercises do not require any actions but by focussing on information only related to the decision, it is expected that the patient is doing a similar sort of weighting process in his/her head.

Interest in values clarification began in the 1960's within the context of conflict resolution [3]. Though hundreds of exercises were developed in the ensuing years, interest waned during the 1980's without having defined criteria or guidelines for what constitutes a values clarification intervention, and without an operational definition of, and a measure for, the state of being “clarified” [3].

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Within the context of decision aids, values clarification is more than conflict resolution. Because decision aids address decisions that are typically new to the patient, part of the patient's challenge is to discover which values are relevant and important to her or him [4]. Empirical evidence confirms the need for value discovery, for example, as part of the experience of men diagnosed with early-stage prostate cancer [5]. The patient then needs to integrate those values to arrive at a single preferred option; if the values include some that favour opposing options, then resolution of the conflict is required.

There are only a few studies that have attempted to assess the impact of values clarification exercises on the expression of values. These studies compared the consistency between expressed values and the choices made. Of four such studies, two found that the intervention that included values clarification resulted in decisions that appeared to be more consistent with expressed values than the interventions that did not include the tasks [6,7]. The other two studies did not find a reliable impact of the values clarification task [8,9]. Interestingly, two of the studies [7,9] studied the same weigh-scale values clarification exercise but in different situations, different cultures and different languages, and arrived at different conclusions about the effectiveness of the task. Thus, the potential benefit of this values clarification task is not clear. The exercises in the other two studies involved eliciting utilities [6] and a counselling session [8] that directed the patient to thinking about the anticipated impact of various potential outcomes. Both the studies also evaluated the strength of participants' decision; the first study showed that the intervention increased the proportion of participants who were certain about their decision (either to have or to not have HRT) while, in the second study, the intervention appeared to alter participants' perceptions of the limitations and risks of BRCAI testing but did not impact participants' intention to be tested. Because none of the studies were designed to provide analytic insight into the operations of the tasks, it is not clear what makes tasks effective or why.

We are interested in developing a theoretically based values clarification exercise that can be incorporated into our decision aid focussed on treatment for early-stage prostate cancer [2,10]. This is a challenging medical decision for patients because there are four standard treatments for the disease: surgery (radical prostatectomy), external beam radiation therapy, brachytherapy and "watchful waiting" [11]. Recent evidence suggests that surgery confers a modest survival benefit over watchful waiting [12,13] but the relative benefits of external beam radiation and brachytherapy remain unclear because they have not been studied in a randomized controlled study. The choice of treatment, therefore, is heavily dependent on the patient's values related both to quantity and to quality of life.

Before we could evaluate whether or not a particular values clarification exercise is helpful to patients, we needed to be clear about how to interpret its outputs. In this paper,

we report the developmental process and some validation assessments of a values clarification exercise.

2. Development

Two points were important to us, as we began developing the values clarification task. First, we wanted to capitalize on "normal" processing, that is, the processing strategies that are regularly identified in descriptive studies of decision making as processes being used; and which we, therefore, believe are strategies that humans are naturally inclined to use. In part, we hoped this strategy would make it as easy and intuitive as possible for patients to use the aid and obtain benefit. Second, we were aware that people's limited cognitive resources, such as limited energy and memory [14], often leads to the use of shortcuts when processing demand is heavy [15]; and, that the shortcuts involve ignoring some of the information. We took the perspective that it is in the best interest of the patient to reduce their processing demands in order to allow them to actively consider all of the information that he/she identifies as important to their decision.

Following our intent to capitalize on "normal" processing, we noted that there are two strategies that people typically use to integrate all relevant information in a decision – i.e., when no shortcuts are employed – called the "additive" and the "additive-difference" rules [16]. The difference between the two rules relates to the order in which particular pieces of information are considered and in exactly what they affect. The additive rule involves thinking about one option at a time, evaluating all of its attributes and deciding how much it makes that option more or less attractive. The additive-difference rule involves thinking about one attribute at a time, deciding which of the two options it makes more attractive and by how much before thinking about the next attribute.

We started our development by building tasks in parallel based on each of the two rules. The tasks provided bars that were to be adjusted manually to reflect the impact of the attributes being considered. The additive exercises focus on one option at a time. Thus, for each option, one bar was presented on a computer screen for each attribute that the patient identified as being important to this decision. The bars are anchored at each end with "want" and "do not want". The additive-difference exercises focus on one attribute at a time. For each attribute, one bar is presented for each attribute the patient identifies as important. The bar is anchored at each end with one of the two treatment options being considered. For each rule, we built two versions of the exercises: one version included the additional presentation of a "summary" bar (described in more detail later) and the other version did not have a summary bar.

The summary bars (two bars for the additive group, one for each option; and only one bar for the additive-difference group) were based on a linear underlying scale and were

updated by the computer automatically as the participant adjusted their individual bars. The summary bars reflected the arithmetic average of the individual bars set to that point, as the participants had already weighted the impact of the attribute in their setting of the individual bars.

In an initial pilot study, the helpfulness of the resulting four exercises was compared to a control condition that did not include any explicit values clarification. The study had university students – a population that could be recruited easily to help us evaluate, in part, the feasibility of doing the exercises – making hypothetical treatment choices in each of three different medical scenarios: knee surgery, laser eye surgery and chemotherapy treatments for Hodgkin’s disease [17]. The study was run on a computer and for each decision, the participant was provided with information about their situation, listed as attributes of the procedure involved, the potential benefits and the potential harms.

Participants in the four experimental groups were then provided with the list of attributes and asked to identify each one that they felt would affect their decision. The identification was then followed by the value clarification exercise appropriate to their group, with bars being presented for each of the identified attributes. So in the additive groups, the participant considered option 1 and adjusted each bar sequentially moving a pointer from a central neutral position, the extent that attribute pushed them either toward or away from wanting that option. They then repeated the exercise on option 2. In the additive-difference groups, participants adjusted each bar, indicating which option that attribute “pushed” them toward and by how much. Participants in all groups then indicated their decision and answered knowledge questions about the information provided to them.

Results of the study showed no difference among the support conditions in the primary outcome of interest: a helpfulness rating [seven-point Likert scale]. However, participants in the two additive groups (a) produced fewer choices that were consistent with their expressed values than those in the additive-difference groups and (b) had lower knowledge scores than participants in all three other groups

[17]. Thus, we decided to focus continued development on the exercises based on the additive-difference rule.

2.1. Assessment of exercises in cancer-decision context

Building on the above study, we then compared the two exercises based on the additive-difference rule to a control condition without any values clarification exercise, in a study that used participants more like the ultimate population of interest (prostate cancer patients) making the decision of interest (treatment decision for early-stage disease). Fig. 1 shows an example situation, in which the patient is choosing between surgery and radiotherapy, thus, the anchor at one end of each bar is “want surgery” and at the other end “want radiotherapy”. The figure shows the version of the exercise with the summary bar; the other version of the exercise looks the same with the exception that nothing appears in the space of the summary bar. As in the earlier experiment, the summary bar displays the average of the individual bars, and to do so, assumes a linear scale underlies each of the individual bars. There are, however, no distance markings on the bars. Thus, the next study addressed the questions (a) whether the summary bar, given its linear underlying scale assumption, seemed valid, (b) whether the summary bar “made” sense to participants and (c) which forms of support seemed most effective.

2.2. Method

2.2.1. Participants

Ninety male volunteers, at least 50 years old, were recruited via an ad in the local newspaper. No other demographic information was obtained as our interest was the relative performance of the three types of value clarification conditions. Participants were asked to imagine that they had just been diagnosed with early-stage prostate cancer. They were assigned at random to one of three groups: values clarification with summary, values clarification without summary and control with no values clarification.

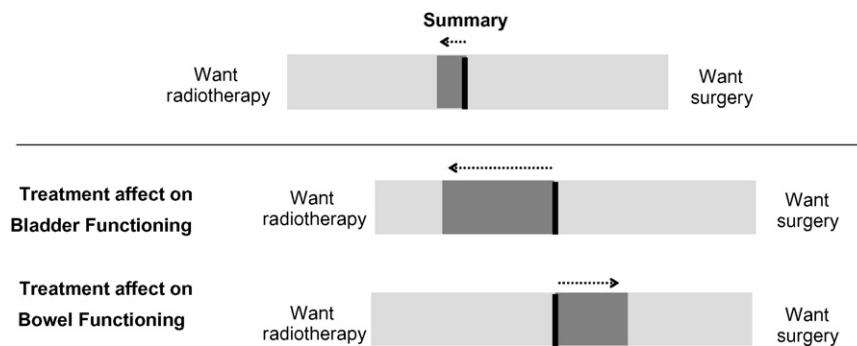


Fig. 1. The figure shows the visual presentation of the values clarification exercise with a summary bar. The example shows two attributes affecting the decision. The treatments’ affect on bladder functioning is pushing the patient to choose radiotherapy while the treatments’ affect on bowel functioning is pushing him to choose surgery. The push from concerns about bladder functioning is larger than the push from the concerns about bowel functioning. The summary bar shows the arithmetic average of the two pushes. The individual bars of the values clarification exercise without the summary bar are also presented as they appear in the figure.

2.2.2. Procedure

Using a computerized exercise on an individual basis, each participant was provided with the information about the disease and treatment options that we include in our decision aid [2,10]. All groups saw the same information and it was presented in a table with attributes in the rows and treatment options in columns. Twenty attributes were presented, such as “Effect on bladder functioning”, “Chances of dying from the disease”, etc. Thus, each attribute was described for those treated with each treatment. The participant selected each attribute (of either the treatments or of the disease) that was important to his decision by clicking the mouse on it from the list of what was presented in the table; the instruction was “Please select the attributes that affect which treatment option you prefer”. Each participant then completed a knowledge test answering a multiple choice question on each attribute identified. For example, the question related to effect of radiation treatment on bladder functioning was: how many men (out of 100) treated with radiation will have scar tissue eventually interfere with their flow of urine? The two groups receiving values clarification exercises then completed their respective exercise. All participants indicated their treatment choice at the end.

After making their treatment decision, participants answered questions about the process they had experienced. All participants rated how easy/hard it was to make the decision on a 10-point Likert scale. In addition, participants who received the exercises with the summary bar were asked if the summary bar made sense (yes/no) and asked to rate how helpful it was (10-point Likert scale).

Finally, all participants in all three groups were shown all three forms of assistance—(a) information only, (b) values clarification without a summary bar and (c) values clarification with a summary bar. They were then asked to rank them in order of expected helpfulness.

2.3. Results

2.3.1. Bars

We checked to see if the total of the bar lengths, assuming a linear underlying scale, was consistent with their treatment choices: in each group with bars (values clarification with and without the summary), 97% (29/30) made a treatment choice consistent with their bars, assuming the linear underlying scale.

2.3.2. Summary bar

Participants who received the values clarification exercise with the summary bar were asked if the summary bar “made sense” to them: 27 (90%) reported “yes”. When asked to rate the effect of the summary bar on a 10-point Likert scale (1 = made decision easier, . . . , 10 = made decision harder), the mean was 4.10, (neutral point 4.5) with 57% of participants rating it 4 or less indicating that it made the decision easier to some extent; 23.4% rated the bars as 1 or 2 (extreme “easier” ratings), 6.7% rated them at 9 or 10 (extreme “harder” ratings).

2.3.3. Comparison across all three groups

Participants in all groups answered knowledge questions on each of the attributes they identified as important to their decisions. Mean percentage of questions answered correctly did not differ among the groups; the means were 45.6%, 43.3% and 46.8% for the information only, bars with no summary, and bars with summary groups, respectively, $F < 1$.

Participants rated how hard it was to make the decision (1 = very easy, . . . , 10 = very hard): there was no difference among the groups: information only group’s mean rating 4.63, bars with no summary group mean 4.53 and bars with summary mean 4.33, $F < 1$.

Finally, participants ranked the three forms of support in terms of their expected helpfulness. Overall, bars with summary was ranked as “most helpful” by the largest portion of participants in each of the groups, 56%, 43%, 73% by information group, bars no summary group and bars with summary group, respectively, $F(2,27) = 17.75$, $p < 0.001$.

3. Validation

This section examines the convergent validity of the values clarification exercise outcomes when the exercise ranked highest on expected helpfulness in the above study was incorporated into our decision aid and used by patients actually facing their treatment decision for early-stage prostate cancer. The decision aid involves three fundamental components: the systematic presentation of information, listing exercises to help the patient identify which attributes of the treatments and of the disease are important to his decision, and the values clarification exercise to help integrate all that is important. The aid is implemented on a computer on an individual basis. Each patient is presented only the treatment options offered to him by his doctor, and the patient then chooses from amongst those options—a strategy that reflects our view that the decision aid is intended to facilitate the patient’s ability to participate in his treatment decision as it is. The risk information provided is tailored to the individual patient’s risk group. The entire process typically takes 1–1.5 h. More detail about the aid’s design and theoretical basis can be found elsewhere [10], as can a phase II report of patients using an earlier version of the aid [2]. The current examination focusses on a multi-centre phase II trial of a second version of the aid.

3.1. Method

Patients from three *Canadian* centres used the decision aid, and later made their actual decisions with their doctors. As part of the decision aid process, each participant identified attributes important to his decision three times: before receiving information about treatment options (T1), after the information (T2) and if he was offered more than two options after eliminating his least preferred treatment(s)

and focussed only on his two most preferred options (T3). After identifying attributes at T3, the men did the values clarification exercise.

For each identified important attribute at T3, a horizontal bar anchored with the participant's two most preferred treatment options was presented. He adjusted each bar to show how much that attribute "pushed" his choice toward one treatment or the other. As each bar was set, the summary bar presented at the top of the screen, provided an arithmetic average of all bars set to that point. Fig. 1 shows an example display.

At each time point men also rated their preference for each treatment option (treatment value assessment, TVA) on a five-point Likert scale. In addition, decisional conflict – distress caused by making the decision – was measured by O'Connor's decisional conflict scale [18,19] and regret – sorrow or repentance for the choice made – was measured by Ottawa's regret scale [20].

3.1.1. Analyses

To evaluate our assumptions, we examined the following:

- (a) Evidence suggesting that participants had a continuous scale underlying their bar settings—we expected that most participants would use intermediate bar positions rather than only extreme bar positions, such as the neutral centre position or bar ends.
- (b) Convergence between summary bar and actual treatment choice—we expected that most patients would select the treatment favoured by the summary bar.
- (c) Convergence between summary bar and decisional conflict—we expected that smaller summary bars would be associated with higher decisional conflict.
- (d) Convergence between bars pushing in competing directions and treatment valuation assessments—we expected that more patients with bars pushing in competing directions would have TVA ties at T3 than those who did not have competing bars.
- (e) Convergence between bars pushing in competing directions and regret—we expected that patients with bars pushing in competing directions would have higher regret scores.

3.2. Results

Sixty-nine men from the three centres participated in the study, although due to technical difficulties, we have complete data sets from 57 participants, missing usually only one outcome (most often the knowledge test) from the data set of the other 12 participants. We include the *N* in each analysis to make clear the proportion of participants who contributed that information. Of the 64 from whom we had age information, most men were aged 60–69 (56%); 67 patients provided marital status and 89% were married; and of the 67 we have treatment information for, 75% had been offered three or four treatments options.

3.2.1. Evidence suggesting a continuous underlying scale

In an attempt to gain some insight into whether patients appeared to have any type of continuous scale underlying their bar settings, we were interested to know the proportion of patients who did not use any intermediate positions when setting their bars. Of the 63 patients from whom we had full bar data, only 5 (8%) did not use intermediate bar settings: one patient used the neutral zero-position and the bar-end positions only, the other four used only the bar ends. The patient who used both the neutral and end positions, also had one bar that favoured one treatment but nine additional bars that favoured the other. One patient who used only the extreme settings had only one important attribute. The other three patients who used only the extreme positions had between 3 and 10 attributes affecting their decisions, but in each case all bars favoured the same treatment. An additional interesting observation is that 25 (40%) of all the patients set at least one of their bars at the neutral (0) position in addition to setting others at intermediate positions.

3.2.2. Convergence between summary bar and actual treatment choice

Of 61 patients for whom we had all relevant data, actual treatment decisions were predicted for 48 (79%) of patients by their summary bar. We obtained reasons for the decision from some of the 13 patients whose summary bar did not predict their actual choice: 5 (38%) actually selected watchful waiting when that was not included as one of their preferred options with the decision aid. Reasons obtained for the actual choice suggested it was a strategy to postpone selecting an active treatment because of circumstances at home, such as a wife being sick.

Of 14 patients whose highest TVA ratings at T3 were tied, 9 (64%) had summary bars that predicted their actual treatment choice. All five of the other patients chose their other "most preferred" option.

3.2.3. Convergence between summary bar and treatment valuation assessments

Of the 62 patients with TVA scores at T3 and the summary bar, those whose highest TVA scores were ties had smaller summary bars than the patients with no ties (respective means: 49.8 versus 119.23) [$t(60) = 2.90$, $p = 0.005$]. Larger differences between the TVA score of the most preferred option and that of its closest competitor were associated with larger summary bars [$r(60) = 0.51$, $p = 0.00$].

3.2.4. Convergence between summary bar and decisional conflict scale

For the 63 patients from whom we had both decisional conflict and summary bar scores, higher decisional conflict scores were associated with smaller summary bars [$r(61) = -0.27$, $p = 0.03$].

3.2.5. Convergence between bars pushing in competing directions and treatment valuation assessments

Of the 62 patients from whom we had both TVA scores at T3 and bar scores, more patients with TVA ties at T3 had bars that pushed in competing directions than patients with no TVA ties (80% versus 44%) [$\chi^2 = 5.70$, $p = 0.02$].

3.2.6. Convergence between bars pushing in competing directions and regret

Of the 60 patients from whom we had both bar and regret scores, patients with bars pushing in competing directions had higher regret scores than patients with bars pushing in only one direction (means: 1.44 versus 1.21) [$t(58) = 2.11$, $p = 0.04$].

4. Discussion and conclusion

4.1. Discussion

The issue of values clarification exercises and whether or not they are helpful in decision aids is still an unanswered question. We believe that our theoretically based approach would lead to developing an exercise that would have amongst the greatest potential to be helpful to patients. Although we have not yet addressed the issue of whether or not patients consider the exercise helpful, these validation assessments of the outputs of our exercise seem to suggest our interpretation of the outputs is valid.

We are cautious, however, not to over-interpret where patients set each bar. Although our assessment seems to imply that assuming a linear underlying scale is valid, we do not suggest that the setting of one bar should be compared precisely to the setting of another bar. When using visual analogue scales – similar to our bars – Aitken cautioned long ago about different people using different underlying scales [21]. Nonetheless, our data suggest that even if patients are using different underlying scales, our linear scale estimate led to summary bars, which appear to be convergent with other outcomes across the group.

One interesting observation is the number of patients who set at least one bar at the neutral position. Almost one-half of our patients appeared to realize only at the point of setting the bars, that some of the attributes they had selected as affecting their decision, actually did not help to discriminate between their two most preferred treatments. We have been sensitive to distinguishing between attributes important to the person and attributes that can help people make their choice. A common example that demonstrated the difference in this study is that “chances of dying from the disease” was often selected as an important attribute by our participants at the beginning of the decision aid process. When they then received the information about each of their offered treatments, they discovered that the two treatments they were considering had the same expected cure rates, and with that realized that this attribute was not helpful to their

choice. In spite of trying to clarify throughout the decision aid instructions that it is the second type of selection that the patients should be making, these data suggest that almost half of our patients only realized through the values clarification exercise that some of their selected attributes would not help them make their choice.

The observation that the exercise may help patients become clearer about which values influence their decisions is what excites us most. Rather than focussing on the detail of the bar settings, our focus is much more on whether or not the process of using the bars is considered helpful by the patients. A randomized controlled trial comparing the decision aid including the values clarification exercise to the aid without the exercise is required to clarify its benefit.

4.2. Conclusion

It appears that the outputs of the values clarification exercise that we developed based on the additive-difference decision rule can be interpreted by assuming that a linear scale underlies the positioning of the pointers on each bar. While we do not suggest that means that every person is actually using a linear scale, the convergence we have observed suggests that the scale is generally a close approximation of the individual scales actually used.

4.3. Practice implications

Now that we understand how to interpret the outputs of the exercise, the next step is to determine if the exercise is helpful to the patients. It, therefore, needs to be tested in a randomized controlled trial that compares how helpful the decision aid is with the exercise to how helpful it is without the exercise.

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