

# Treatment decision aids: conceptual issues and future directions

Cathy Charles PhD,\*† Amiram Gafni PhD,\*† Tim Whelan BM MSc FRCP (C)§¶\*\* and Mary Ann O'Brien MSc BHSc (PT)\*¶

\*Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, †Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, ON, §Department of Medicine, McMaster University, Hamilton, ON, ¶Supportive Cancer Care Research Unit, McMaster University and Juravinski Cancer Centre, Hamilton, ON and \*\*CCO, Juravinski Cancer Centre, Hamilton, ON, Canada

## Abstract

### Correspondence

Cathy Charles  
Centre for Health Economics and Policy  
Analysis (CHEPA)  
Department of Clinical Epidemiology  
and Biostatistics  
McMaster University, HSC 3H5  
1200 Main Street West  
Hamilton  
ON L8N 3Z5  
Canada  
E-mail: charlesc@mcmaster.ca

### Accepted for publication

25 February 2005

**Keywords:** medical encounter, shared decision-making, treatment decision aids, values clarification exercises

**Background** In the last 10 years, there has been a major growth in the development of treatment decision aids. Multiple goals have been identified for these tools. However, the rationale for and meaning of these goals at the conceptual level, the mechanisms through which decision aids are intended to achieve these goals, and value assumptions underlying the design of aids and associated values clarification exercises have often not been made explicit.

**Objective** In this paper, we present ideas to help inform the future development and evaluation of decision aids.

**Results** We suggest, (i) that the appropriateness of using any decision aid be assessed within the context of the wider decision-making encounter within which it is embedded; (ii) that goal setting activities drive measurement activities and not the other way round; (iii) that the rationale for and meaning of goals at the conceptual level, and mechanisms through which they are intended to have an impact be clearly thought through and made explicit; (iv) that value assumptions underlying both decision aids and associated values clarification exercises be communicated to patients; (v) that taxonomies developed and used to classify various types of decision aids include a section on value assumptions underlying each tool; (vi) that further debate and discussion take place on the role of explicit values clarification exercises as a component of or adjunct to treatment decision aids and the feasibility of implementing valid measures.

**Conclusion** Further debate and discussion is needed on the above issues.

## Introduction

In the medical literature there has been an increasing interest in the development and evaluation of treatment decision aids.<sup>1-9</sup> The term decision aid is a general label that has been applied to different kinds of tools/instruments used to inform patients about available treat-

ment options and their benefits and risks, and to structure the decision-making process in order to encourage patients to express their treatment preferences. The number, type, purpose and contexts of their use have proliferated over the last 10 years.

The literature on the development and evaluation of decision aids derives from a variety of

different areas of study including, for example, clinical (primarily medicine and nursing), educational, decision sciences, psychology and health economics. The frameworks used and major issues of concern to researchers in these different areas vary. Our purpose in writing this paper is not to present a comprehensive literature review or critical systematic overview of this literature. This has already been undertaken through the Cochrane Collaboration (for articles on decision aids used in decision-making and screening<sup>2</sup>) as well as by others.<sup>8,10</sup>

Our goal is more focused and selective – to explore a number of critical conceptual and methodological issues relating to the development and evaluation of decision aids that we feel are problematic and to make some suggestions for addressing these issues. Specifically, we will discuss the importance of examining the fit between any given decision aid with the type of treatment decision-making context within which it is embedded; explore the relationship between goals and outcome measures in the development and evaluation of decision aids; suggest some conceptual criteria for identifying relevant goals for decision aids and their application; examine value assumptions underlying both decision aids and explicit values clarification exercises; and explore the feasibility of validly measuring the latter. We start by discussing the importance of context.

### **The importance of context**

Treatment decision-making typically takes place within the context of a doctor/patient encounter. Decision aids are tools designed to assist one or both parties with treatment decision-making. For this reason, we start our discussion by emphasizing the importance of understanding the wider treatment decision-making context when evaluating the appropriateness and helpfulness of any given decision aid. This goes beyond simply identifying the type of decision-making approach within which the tool will be embedded. It includes, in addition, examination of the fit or match between the type of decision-making approach used (e.g. shared, informed,

paternalistic) and the design of the decision aid (if any) most suited to facilitate this approach. As Dowie has pointed out,<sup>11</sup> the decision-making approach is distinct from the mode of decision-making (i.e. which mode of judgement and decision-making are to be adopted within the selected approach) and different combinations of these two variables are possible. Further, potential mismatches between the two may have negative consequences that are, as yet, unknown.

As we have pointed out in earlier work, the treatment decision-making process is both complex and dynamic. We have identified three ‘pure types’ of decision-making processes: the paternalistic, shared and informed approaches with a myriad of in-between approaches that combine components of different models.<sup>12,13</sup> We noted that the type of approach used by the same participants can shift, both within a single encounter and over time. We also identified several analytical stages of treatment decision-making, including: information exchange, deliberation of treatment options and negotiation of a treatment to implement.

Insofar as decision aids are intended to help participants in the medical encounter to make treatment decisions, then such aids could be developed and targeted to help implement one or more of the different types of decision-making approaches, one or more of the different stages in the decision-making process, and within stages, one or more specific goals. An aid developed to help achieve the goals of one type of decision-making approach or stage (e.g. information exchange) may not be the most appropriate tool for helping to achieve the goals of other approaches or stages (e.g. deliberation about the treatment to implement). In reality, most decision aids developed to date have been designed, at a minimum, to help communicate information from doctor to patient on treatment options and their benefits and risks. However, this type of information is not a necessary feature of all decision aids. An aid, for example, developed to help patients to negotiate with their doctor would be aimed at the deliberation stage of the process and may focus on communication

strategies that are unrelated to technical information on treatment benefits and risks.<sup>13</sup>

The decision-making context also includes the severity and stage of the disease. Disease severity may influence the amount and type of support that patients want in the clinical encounter and the role of decision aids in this process. For example, in the context of breast cancer conservation therapy vs. mastectomy, it may be important to ensure that aids can be used in the medical encounter as an integral part of the communication and support process undertaken by the doctor to help women express their treatment preferences. Where the clinical problem is less severe in its health consequences, e.g. hormone replacement therapy (HRT), it may be less important to embed the use of a decision aid within the context of the medical encounter, especially if the patient prefers an informed approach to treatment decision-making without doctor input.

The treatment decision-making context also varies in terms of the number and types of decision-makers involved. In a pure paternalistic encounter, the doctor alone makes the decision, with little patient input other than consent. In more complex cases, in terms of the number and variety of participants, there may be several types of health-care providers as well as the patient, family members or friends involved. Theoretically, decision aids could be developed to help any participant engage in any stage of the decision-making process although, in practice, these tools have been targeted to patients.

In some clinical contexts, patients and doctors may hold different assumptions about such a basic issue as whether there is a treatment decision to be made, even when treatment options are presented by the doctor. For example, in an earlier study of women with early stage breast cancer we found that some women reported that 'doing nothing was no choice'.<sup>14</sup> These women felt that the diagnosis of breast cancer instilled in them an obligation to do everything possible to cure the disease, which, for them, translated into an obligation to accept all treatments offered by the doctor to assist in their own cure. In this context, estimates that could be

provided in a decision aid about the risks and benefits of treatment vs. no treatment would not be particularly helpful because these women did not perceive that there was a choice to be made.

The generic point we want to emphasize here is that the treatment decision-making context, e.g. the approach used to make treatment decisions and the clinical situation vary considerably. The question of which decision aid is best cannot be divorced from the wider context in which it is used. To do so, would be to deny the fundamental situational nature of treatment decision-making and the importance of tailoring this process to the individual needs of participants in any given clinical encounter.

Developing decision aids which are universalistic in nature,<sup>11</sup> which, it has been argued, characterizes current work in this field, may not longer be tenable precisely because specific attributes built into a given aid in order to maximize achievement of outcomes in one type of decision-making approach or stage may not be as well adapted to maximizing goal attainment in other types or stages. This issue is even more complex when one considers that the type of decision-making approach (e.g. a shared approach) used at the beginning of a given medical encounter may change as the encounter evolves (e.g. to an informed approach). The fit between the decision-making approach used and the most appropriate decision aid design to facilitate this process requires further attention, including consideration of potential barriers (e.g. feasibility constraints) of a more custom tailored approach. This is an important area for future research. In the next section, we turn to the issue of goal setting for decision aids and explore two issues: the relationship between goals and outcome measures and conceptual criteria for evaluating the appropriateness of various goals.

## Goal setting for decision aids

### Goals vs. outcome measures

There has been considerable interest in the literature in defining both goals and outcome

measures for decision aids.<sup>15–21</sup> In terms of goals, different authors have different ideas about what the primary goals should be, but, increasingly two key goals are identified: to provide patients with information on the benefits and risks of various treatment options and to help patients clarify their values so that they will make treatment choices that are consistent with their values.

In terms of actual outcome measures used in evaluations of decision aids, these are numerous, diverse, and fall into multiple conceptual categories. One way to think about these is in terms of the following taxonomy, although other researchers have also developed somewhat different classification systems.

The most predominant category of outcomes relates to information transfer and includes such variables as impact on patient knowledge and understanding of treatment risks and benefits.<sup>20–23</sup> Another category of outcomes relates to the impact of the decision aid on the decision-making process and on the treatment decision, including the extent to which patients want to participate in the process, the specific decision made, satisfaction with the decision-making process and with the decision.<sup>24,25</sup> A third category of outcomes relate to the psychological impact of decision aids on, for example, decisional burden, decisional conflict and decisional regret.<sup>26–29</sup> A fourth category of outcome measures relates to health status and includes the impact of decision aids on various measures of health status and quality of life.<sup>30–34</sup> Finally, the effects of decision aids on overall health-care system costs have been measured by examining the global financial impact of changes in individual patients' treatment choices (either to more expensive or less expensive treatments) after using some form of decision aid.<sup>35</sup> The financial cost of actually using a decision aid in the medical encounter in terms of time required to administer the instrument has also been of interest.<sup>36,37</sup>

Despite the extensive attention given to goals and outcome measures, we feel that there is some ambiguity in discussions about the relationship between the two. The first issue relates to whether goals should drive the development

of outcome measures or whether empirical measures should drive the development of goals.

As the above taxonomy of outcome measures illustrates, researchers in this field are able to generate an ever growing type and number of outcome measures for decision aids. But, just because a particular variable can be operationalized and measured before and after use of a decision aid to assess change in an attitude or behaviour, does not mean that such a variable ought to be defined as a goal of this intervention. We see measurement as an aspect of methods and methodological rigour, not a criterion for goal setting. To use what we can measure as the basis for determining what we ought to measure is to put the cart before the horse. Goal setting ought to drive measurement and not the other way round.

The second issue relates to the measurement of outcome measures that are not attached to any pre-defined goals. Some researchers argue that it is important to measure certain outcomes of decision aids even if these are unrelated to pre-specified goals. The rationale is that some new and interesting information might be obtained (particularly unanticipated findings) that could inform future policy regarding the use of such aids in practice.

The problem with such 'stand-alone' outcomes lies in how to interpret the results and what implications can be drawn from these for future policy. Examining the impact of decision aids on costs is one example. Let us assume that research results show that, in a given study, those patients using a decision aid, on average, have lower treatment costs than those not using the aid. If we do not know, or have not thought about the mechanism by which such a result might be obtained, then it is impossible to identify empirical measures that will enable us to test in the future whether what we observe in a specific study supports or refutes our hypothesis and whether our findings are generalizable. Furthermore, if this is really the result we want to achieve (i.e. the goal is to reduce costs), then the most efficient method for doing so would be not to offer patients a choice in the first place but rather to offer only the less expensive alternative,

obviating the need for use of the decision board. Otherwise the temptation will be to use decision aids as a way of steering patients to choose lower cost treatment options over higher cost ones rather than their original intent which was to offer patients an informed choice. We feel that any goal set for decision aids has to be consistent with the concept of choice because a fundamental principle underlying decision aids is that several options exist and there is no universal right or wrong choice. In other words, choosing the more expensive treatment does not constitute a wrong choice.

#### Conceptual criteria for determining goals of decision aids

If we accept that outcome measures for decision aids should derive from goals, then how do we determine what are appropriate goals? Here, we are interested not so much in the content of particular goals but in the criteria by which appropriateness should be judged. We suggest three basic criteria at the conceptual level prior to any consideration of measurement issues.

First, we argue that researchers should have a clear and explicit rationale for why any particular goals selected for decision aids are seen as important within a particular decision-making context, including the clinical context, the participants making the decision and the type and stage of the decision-making process. This criterion follows from our earlier discussion.

Secondly, there is a need to clearly define whatever constructs are selected as goals and to clearly operationalize the various dimensions of these constructs up front.<sup>38</sup> Otherwise, there is no way of knowing whether the empirical measures used are actually capturing the meaning of the construct, especially if the latter has multiple dimensions. Unclear constructs will also hinder interpretation of empirical results because even though statistical associations between two measures may be significant, their meaning at the conceptual level will remain unclear if the constructs themselves are fuzzy or open to multiple interpretations. Two illustrations are given below.

As our first example, we note that many developers of decision aids are interested in measuring the impact of these instruments on what is variously called patient knowledge or understanding. But these are actually different constructs and require different forms of empirical measures. The measurement of knowledge acquisition can be undertaken fairly simply by asking patients if they remember accurately information contained in a decision aid such as the percentage of patients at risk for a certain side-effect or the percentage of patients who will survive beyond 5 years if given a particular treatment.

But measurement of recall of information gives no indication of whether the patient understands the meaning of probability statements at the aggregate level and their relevance to individual decision-making. To demonstrate understanding, patients would need to realize that 80% survival means that if you were to take many samples of patients like the group that was studied in a randomized-controlled trial (RCT) from which this estimate was derived, you would find that on average and within certain pre-specified confidence intervals, 80% would survive and 20% would not. The patient would have to understand that in her particular case, there is no way of knowing in advance whether she would end up in the 80% survival group or the 20% non-survival group; further she would need to recognize that these percentages do not mean that she has an 80% probability of survival and a 20% chance of non-survival; or that her doctor can predict the future outcome of treatment in her particular case.

Our second example illustrates a less than ideal match between the conceptual definition of a particular construct of interest in evaluating the impact of decision aids and the outcome measure used to represent this construct in assessing potential attitudinal change. The concept in question is 'decision regret' and has been defined in terms of a particular domain: 'the aspect of regret stemming from the knowledge that the treatment choice made was non-optimal...'.<sup>26</sup> In this case, it would appear that the conceptual definition is not based on regret of

the decision but rather regret of a non-optimal health status outcome which the patient assumes (perhaps incorrectly) results from that decision. Yet the Likert scale used to measure the construct of decision regret is based on questions that relate to the patient's perception of the 'rightness' of the decision rather than to the outcome of that decision. Hence, the outcome measure is not well matched to the conceptual definition.\*

The final conceptual criterion for helping to decide on particular goals appropriate for decision aids relates to *the need for a theoretical foundation or basis for making hypotheses about the mechanisms by which particular design features of a given decision aid can be expected to produce a particular outcome*. Developers and evaluators of decision aids ought to be able to make transparent and explicit their analytical reasoning for making predictions about how decision aids can be expected to achieve their goals. This sets up the expectation of conceptual plausibility, akin to biological plausibility in predicting the impact of a given treatment on the course of a disease. In terms of goal setting, this third criterion logically follows from the first two above. It requires developing hypotheses about the potential connections between hypothesized independent and dependent variables, constructs that will subsequently be empirically measured to explore the impact of the intervention on defined outcomes.

For example, what are the mechanisms through which a decision aid might be expected to improve quality of life? If we have some *a priori* hypothesis about the process or mechanisms by which we think the change will take place, we will be more likely to gain insight into particular design features of decision aids that will produce desired results.

---

\*The definition of decision regret also suggests other conceptual issues. For example, what is meant by the term 'non-optimal' and how would we measure this? Can one only measure decision regret after the outcome is known, and if so, will there not be a confounding of what it is the patient is really regretting? Regret over the decision and regret over the outcome can vary independently, raising the issue of whether it is appropriate to define regret over one (the outcome) in terms of regret over the other (the decision).

We recognize that in the case of a decision aid with several stated goals, it may well be useful to distinguish between those that are primary and those that are secondary. What we are advocating is that, whether primary or secondary, the rationale for selection of decision aid goals ought to be well thought through as should the mechanisms by which such aids are intended to produce anticipated results.

In conclusion, we see a need to make explicit and standardize not the structure, goals or content of decision aids, but rather the conceptual criteria used to identify appropriate goals. We also argue that the application of conceptual criteria is different than the methodological exercise of critically appraising the research methods used to empirically evaluate their success. The latter is not a substitute for the former. Both are necessary to promote rigour in the design and evaluation of decision aids.

#### Application of conceptual criteria

There is likely to be considerable variability in the extent to which the three conceptual criteria outlined above for defining goals (i.e. providing a clear rationale for the goals defined for decision aids, providing clear definitions and operational measures of the various dimensions of constructs chosen for goals, and providing hypotheses about the mechanisms by which particular design features of a given aid can be expected to produce a particular outcome), are currently used. In the best case scenario, all three criteria would be discussed in publications describing the development of decision aids. In reality, few studies (including our own), use all three criteria, and, in particular, criterion 3. The worst case scenario would encompass those articles which (i) empirically measure selective outcomes of decision aids (while not identifying these explicitly as goals up front), (ii) fail to offer any description of the conceptual definitions of key variables to be measured or a rationale for choosing these and (iii) fail to discuss mechanisms by which specific impacts of decision aids are expected to be achieved. We now turn to

explore value assumptions underlying both decision aids and values clarification exercises associated with them.

### **Value assumptions underlying decision aids**

Value assumptions underlie all forms of decision aids and can operate at different levels. For example, at the most basic level, developers of decision aids assume that patients may not know how to make treatment decisions and need help in doing so. Developers of decision aids offer these tools to patients as a way of assisting them in structuring the process of treatment decision-making in what they consider to be helpful ways. This contrasts, for example, with the more usual approach whereby patients make a treatment decision based on their own preferences, as they define them, once relevant information is given to them.

A fundamental issue of key importance in relation to such normative approaches to treatment decision-making is the extent to which patients are given and understand the assumptions underlying conceptual frameworks used to develop decision aids and the extent to which they buy into these assumptions as a basis upon which to make their treatment decision. In this context, it is important to highlight the word 'offer' in the above paragraph. By offer we mean that the subscriber to this approach needs to explain to the patient the underlying value assumptions of the approach offered and ask her whether she wants to change her behaviour to be consistent with these assumptions, once she knows what they are. If the individual says yes, then it is appropriate to continue with the next steps involved in using this approach. If she says no, then this approach is not appropriate for her. This is also the case if the individual is not asked at all if she subscribes to these assumptions because in this case, she will not have an opportunity to say either yes or no but rather will simply be told to structure her thinking in a particular way.

To illustrate this point with a practical example, let us take the case of decision tree analysis. Decision tree analysis is a type of

normative decision aid which is based on an underlying conceptual framework called expected utility theory.<sup>39</sup> The assumptions underlying this theory have been explicitly described and are readily available in the relevant literature to doctors wanting to use this approach. 'Offering' this decision-making approach would mean that doctors should be able to and should in fact be explaining the assumptions underlying this approach in a simple manner to their patients. Hence, doctors would make clear that decision tree analysis prescribes an explicit method for how patients should go about making treatment decisions under conditions of uncertainty, for identifying the factors to be considered and the process to be used for the specific weightings of each. As long as both the doctor and patient buy into the value assumptions underlying this aid in the form of expected utility theory and subscribe to the view that use of decision trees is the best way to make treatment decisions than this method would be appropriate for them to use.

It is interesting to note, however, that leading authors and empirical evidence find that most people do not subscribe to the behavioural assumptions of expected utility theory when making decisions.<sup>40,41</sup> This finding raises several issues for further research in relation to the use of decision aids based on this theory. First, are health-care providers who use decision tree analysis aware of the assumptions underlying this approach, secondly, do they communicate these to patients and thirdly, do patients understand and accept these as well? If the answer to one or all of these questions is no, this means that health-care providers may be inappropriately using decision analysis in invalid ways by imposing on patients rather than 'offering' to patients a normative approach to treatment decision-making when the latter do not understand or subscribe to the behavioural assumptions they are assumed to have bought into. Under these conditions, use of this type of analysis for this patient is problematic, no matter what other appealing features this approach might offer.

Value assumptions are built into the structure of decision aids in other less subtle ways. For

example, if decision aids contain information comparing two different treatment options and their benefits and risks when there are, in reality, more than two, this assumes first that only two options are worth considering and second, that the only relevant information worth reviewing in order to make the decision is information on treatment benefits and risks.

Value assumptions also underlie the development and use of specific measures to assess the outcomes of decision aids. As seen above, a wide range of variables have been measured as potential outcomes of decision aids. Implicitly these activities cultivate a value assumption that the more outcomes that are influenced positively by a given decision aid, the better the tool, regardless of whether the tool was designed to affect change in these areas, how important change in these areas is when compared with other potential goals, and in the absence of explicit independent criteria to judge whether these goals are worth pursuing either as ends in themselves or as objectives specifically designed for decision aids to achieve.

It is not possible to eliminate all value assumptions built into the structure and processes underlying decision aids. But if these value assumptions are not made explicit, and/or no attempt is made to minimize their number and strength, these assumptions may direct or channel patients into using decision-making processes which they do not fully understand or buy into, as well as potentially putting premature closure on whatever usual decision-making process they feel most comfortable with.

### **Value assumptions underlying values clarification exercises**

One goal of decision aids which is increasingly advocated is the clarification of patients' values so that they can maximize their ability to make treatment choices that are consistent with their true values or preferences. Specific values clarification processes<sup>26,27,42</sup> have been structured into some decision aids that involve asking patients to value the importance of various potential treatment risks and benefits and, then

to make, either implicitly or explicitly, trade-offs (e.g. how important is body image vs. survival?) among them to come up with a preferred decision. There are many variations on this exercise. It is believed that this process will help the patient see if the final treatment decision she makes is consistent with the priorities she has identified in the exercise. These types of exercises assume that undertaking a preference-based trade-off is the best method for determining individual level treatment decisions.

To illustrate the problem with the trade-off assumption, let us imagine that a decision aid of whatever type is developed comparing two treatment options for addressing the same disease. The research information presented in the decision aid shows that, on average, patients treated with option A have a 5% higher survival rate than patients given option B but the side-effects (or risks) associated with option A are also greater; for example, the risk of hair loss is also higher with option A than with option B. As a result, the patient is encouraged to think about the importance of survival vs. side-effects to help choose a treatment.

But these are aggregate level estimates, and as noted earlier, do not apply in the same way at the individual level. At the individual level, for each treatment there are (for simplicity) four possible categories of outcomes: (i) survival beyond a specified time period and no hair loss (the best case scenario), (ii) survival and hair loss, (iii) no survival benefit and no hair loss and (iv) no survival benefit and hair loss (the worst case scenario). We cannot predict which category an individual patient will end up in following either treatment, but it is possible that an individual could choose option A and achieve both longer survival and no hair loss. In other words, in the individual case, desirable outcomes are possible that do not result in a trade-off.

The use of probability statements about trade-offs at the aggregate level is likely to channel patients into thinking (erroneously) that the same magnitude of trade-off is also a feature of decision-making at the individual level. But, as noted earlier, we do not know the exact probabilities that an individual faces; hence, it is



impossible to convey the magnitude of the potential trade-offs they face. Further, to the extent that individual patients may differ from those included in the studies from which aggregate data are derived, individuals may want to apply the aggregate level probability information in different ways to inform their own decision-making rather than conforming to a single and prescribed method of interpretation. For an empirical example where assuming an expected utility type of preference for all patients wrongly predicted their true choice of treatment following a myocardial infarction (see Heyland *et al.*).<sup>43</sup>

Values clarification exercises are aimed at helping the patient reveal her true preferences. A key issue with this type of trade-off exercise, however, is that it may distort or be inconsistent with the way that the patient usually makes decisions. If this is the case, the exercise itself becomes a form of intervention which rather than clarifying or revealing the patient's value structure actually imposes on her a different way of processing information rather than allowing her to clarify and articulate her values in her own way. This, in turn, may result in her expressing preferences that do not reflect her true values but rather are shaped by the (artificial) process she has just undergone to formulate them.

It is important to note that values clarification exercises deviate from the economic agency model of the doctor/patient relationship in an important way. In the agency model the doctor is supposed to put herself in the patient's shoes, to try to think like the patient and provide a mirror for the patient's values without superimposing her own values or favoured process of digesting and articulating these. As we explained in an earlier paper,<sup>44</sup> this requirement is not feasible. This is because the number of preference mapping methods (ways of valuing) is unlimited and there is no way (known to us) to find the patient's preference mapping method without an empirical enquiry. This type of enquiry is not easy and is time-consuming. Simple questions like, what do you think is important, or how important is hair loss vs.

survival are not sufficient. As explained above, these questions are only useful if we assume a specific type of preference mapping method, but this contradicts our goal of finding out what the preference mapping method is of the patient who is facing the decision.

It can be inferred that those who advocate the need for values clarification exercises assume that patients, on their own, have difficulty making treatment decisions which are consistent with their true values, and that patients need help in processing and articulating these values, but we have not seen any evidence to support this assumption. How do we know that this is a problem that requires an intervention? Further, assuming for the moment that there is a problem, how do we know that explicit values clarification exercises will help patients to make 'better' decisions (i.e. decisions that are more congruent with their true values) than implicit approaches used by patients and which they define?

We wonder whether it is even possible to construct a valid test to assess the superiority of an explicit values clarification process over implicit methods. To do so would require that we first know what the patient's true values are so that we could use these as the 'gold standard' by which to judge which approach resulted in a treatment decision most congruent with these values. But this line of thinking does not get us any further ahead. If we knew what the patient's true values were in the first place, we would not need any explicit exercise to help the patient define these.

The argument that explicit values clarification exercises ought to be included as an essential goal of decision aids suggests that providing relevant information on treatment benefits and risks to patients is a necessary but not sufficient condition for enabling them to make treatment decisions. One implication of this position is that the so-called informed model of treatment decision-making is not feasible in practice without some form of prior values clarification process being administered to the patient – not because the patient lacks the relevant technical information to make the decision but because she cannot, on her own, understand or apply her own values to

treatment decision-making without first undergoing some form of values clarification step. To date, this step has not been considered in the literature to be a necessary component of an informed approach to treatment decision-making. Even if it were to be advocated as a necessary component in the future, it would remain difficult, if not impossible to implement in a valid way because it is not feasible to help patients clarify their values without the risk of changing them through the exercise itself.

We know of no similar type of exercise designed to help clarify doctor values. This suggests that either doctor values are presumed to be much more easily accessible to the doctor than are patient values to the patient and/or that in a shared process, the doctor needs to know the patient's values but the patient does not need to know the doctor's values. The first assumption appears to lack empirical evidence while the second contradicts the very definition of a shared approach, at least as we have defined it.<sup>10,11</sup> In the latter, the patient needs to know the value assumptions underlying a doctor's treatment recommendation so that she can assess whether what is important to the doctor as an underlying rationale for making the decision is as important to her (the patient) as other considerations that she might want to think about.

Values clarification exercises developed to date have been designed to be universalistic (one type fits all patients) rather than individualistic (tailored to specific patients). However, this assumption gets in the way of finding out how patients themselves value different risks and benefits and the approach they use for combining this information to arrive at an overall treatment decision. Whether or not explicit values clarification exercises can be devised to enable the measurement of the patient's true values is an open question. We think this issue needs more debate before closure is reached on the status of this type of exercise as a key goal and feature of decision aids not because the goal itself is misplaced but because of feasibility issues in devising a valid exercise to elicit patients true values without inadvertently shaping these.

Interestingly, when reviewing various classification systems developed to summarize and compare key dimensions of decision aids, we did not find any (including our own) that incorporated the range and type of value assumptions underlying each tool's development as a key classification variable or the extent to which such value assumptions were made explicit. We think that this might be a useful adjunct to currently used classification systems because an explicit statement about value assumptions underlying design features would enable potential users to assess whether or not they buy into these assumptions, and hence, whether any given tool is appropriate to their needs.

## Conclusion

We recognize that some of our arguments above may be controversial. Our purpose is not to suggest that ours is either the first or final word on any of the issues raised but rather to open these up for further discussion. We welcome challenges to our arguments that would help to stimulate further debate and move forward conceptual thinking about key issues in the field. The key arguments we have raised can be summarized as follows: (i) that the appropriateness of using any decision aid be assessed within the context of the wider decision-making context within which it is embedded; (ii) that goal setting activities drive measurement activities and not the other way round; (iii) that the rationale for and meaning of goals at the conceptual level, and mechanisms through which they are intended to have an impact be clearly thought through and made explicit; (iv) that value assumptions underlying both decision aids and associated values clarification exercises be communicated to patients; (v) that taxonomies developed and used to classify various types of decision aids include a section on value assumptions underlying each tool; (vi) that further debate and discussion take place on the role of explicit values clarification exercises as a component of or adjunct to treatment decision aids and the feasibility of implementing valid measures.

We think the above issues are important to reflect on. They are complex and not easy to resolve. But unless we continue to grapple with them, we risk glossing over rather than clarifying some fundamental, and, we would argue, problematic assumptions and issues underlying current thinking and research in this field.

## Acknowledgements

The authors would like to thank two anonymous reviewers for their very thoughtful and insightful comments on an earlier draft of our paper. These comments were extremely helpful to us in revising and, we think improving, the quality of this final version.

## References

- Whelan T, Levine M, Gafni A *et al.* Breast Irradiation post-lumpectomy: development and evaluation of a decision instrument. *Journal of Clinical Oncology*, 1995; 847–853.
- O'Connor A, Stacy D, Entwistle V *et al.* *Decision Aids for People Facing Health Treatment or Screening Decisions. The Cochrane Database of Systematic Reviews. The Cochrane Library.* Oxford: Cochrane Collaboration, 2003; 1: 1–213.
- O'Connor A, Drake E, Fiset V, Page J, Curtin D, Llewellyn-Thomas H. Annotated bibliography of studies evaluating decision support intervention for patients. *Canadian Journal of Nursing Research*, 1997; 29: 113–120.
- O'Connor A, Rostom A, Fiset V *et al.* Decisions aids for patients facing health treatment or screening decisions: systematic review. *British Medical Journal*, 1999; 319: 731–734.
- O'Connor A, Fiset V, DeGrasse C *et al.* Decision aids for patients considering options affecting cancer outcomes: evidence of efficacy and policy implications. *Monograph of the National Cancer Institute*, 1999; 25: 67–80.
- Estabrooks C, Thiel E, Pinfold S, Goel V, Sawka C, Williams J. Consumer decision aids: where do we stand? A systematic review of structured consumer decision aids. *Technical Report, Institute for Clinical Evaluative Sciences* (00-01-TR), 1999. Toronto, Ontario.
- Molenaar S, Sprangers M, Oosterveld P, de Haes J. The evaluation of an interactive computer programme on treatment options in early stage breast cancer: reactions of patients and surgeons. *Psycho-oncology*, 1998; 7: 175.
- Whelan T, O'Brien MA, Villasis-Keever M *et al.* *Impact of Cancer-related Decision Aids: An Evidence Report.* Unpublished Report. Contract No. 290-970017, 2001.
- Snowden AJ, Forbes C, Entwistle V, Watt I. Informing, communicating and sharing decisions with people who have cancer. *Quality in Health Care*, 2001; 10: 193–196.
- Molenaar S, Sprangers MA, Postma-Schuit FC *et al.* Feasibility and effects of decision aids. *Medical Decision Making*, 2000; 20: 112–127.
- Dowie J. The role of patients' meta-preferences in the design and evaluation of decision support systems. *Health Expectations*, 2002; 5: 16–27.
- Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (Or, it takes at least two to tango). *Social Science and Medicine*, 1997; 44: 681–692.
- Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: revisiting the shared treatment decision-making model. *Social Science and Medicine*, 1999; 49: 651–661.
- Charles C, Redko C, Whelan T, Gafni A, Reyno L. Doing nothing is no choice: lay constructions of treatment decision-making among women with early stage breast cancer. *Sociology of Health and Illness*, 1998; 20: 71–95.
- Entwistle V, Sowden A, Watt I. Evaluating interventions to promote patient involvement in decision-making: by what criteria should effectiveness be judged? *Journal of Health Services Research and Policy*, 1998; 3: 100–107.
- Entwistle V. The potential contribution of decision aids to screening programs. *Health Expectations*, 2001; 4: 109–115.
- Kennedy ADM. On what basis should the effectiveness of decision aids be judged? *Health Expectations*, 2003; 6: 255–268.
- Holmes-Rovner M. Evaluation standards for patient decision supports. *Health Expectations*, 1995; 15: 2–3.
- O'Cathain A, Thomas KJ. Evaluation of decision aids – where next? *Health Expectations*, 2004; 7: 98–103.
- Levine M, Gafni A, Markham B *et al.* A bed-side decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Annals of Internal Medicine*, 1992; 117: 53–58.
- Laurie M, Elit M, Levine M *et al.* Patients' preferences for therapy in advanced epithelial ovarian cancer: development, testing, and application of a bedside decision instrument. *Gynecologic Oncology*, 1996; 62: 329–335.
- Whelan T, Gafni A, Charles C, Levine M. Lessons learned from the decision board: a unique and evolving decision aid. *Health Expectations*, 2000; 3: 69–76.

- 23 Whelan T, Levine M, Willan A *et al.* Effect of a decision aid on knowledge and treatment decision making for breast cancer. *Journal of the American Medical Association*, 2004; **292**: 435–441.
- 24 Wills CE, Holmes-Rovner M. Preliminary validation of the satisfaction with decision scale with depressed primary care patients. *Health Expectations*, 2003; **6**: 149–159.
- 25 Moumjid N, Carrere MO, Charavel M *et al.* Clinical issues in shared decision-making applied to breast cancer. *Health Expectations*, 2003; **6**: 222–227.
- 26 Brehaut J, O'Connor A, Wood T *et al.* Validation of a decision regret scale. *Medical Decision Making*, 2003; 281–292.
- 27 O'Connor A. Validation of a decisional conflict scale. *Medical Decision Making*, 1995; **15**: 25–30.
- 28 O'Connor A, Tugwell P, Wells G *et al.* A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Education and Counseling*, 1998; **33**: 267–279.
- 29 Goel V, Sawka C, Thiel E, Gort E, O'Connor A. Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer. *Medical Decision Making*, 2001; **21**: 1–6.
- 30 Greenfield S, Kaplan S, Ware J, Yano M, Frank H. Patient's participation in medical care: effects on blood sugar control and quality of life in diabetes. *Journal of General Internal Medicine*, 1988; **3**: 448–457.
- 31 Barry M, Cherkin D, Chang Y, Fowler F, Skates S. A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. *Disease Management and Clinical Outcomes*, 1997; **1**: 5–14.
- 32 Murray E, Davis H, Tai S, Coulter A, Gray A, Haines A. A randomized controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care. *British Medical Journal*, 2001; **323**: 493–496.
- 33 Murray E, Davis H, Tai S, Coulter A, Gray A, Haines A. A randomized controlled trial of an interactive multimedia decision aid in hormone replacement therapy in primary care. *British Medical Journal*, 2001; **323**: 490–493.
- 34 Bernstein S, Skarupski K, Grayson C, Starling M, Bates E, Eagle K. A randomized controlled trial of information-giving to patients referred for coronary angiography: effects on outcome of care. *Health Expectations*, 1998; **1**: 50–61.
- 35 Kennedy A, Sculpher M, Coulter A *et al.* Effects of decision aids for menorrhagia on treatment choices, health outcomes and costs. a randomized controlled trial. *Journal of the American Medical Association*, 2002; **288**: 2701–2708.
- 36 O'Connor A, Mulley A, Wennberg J. Standard consultations are not enough to ensure decision quality regarding preference-sensitive options. *Journal of the National Cancer Institute*, 2003; **95**: 570–571.
- 37 Graham ID, Logan J, O'Connor A *et al.* A qualitative study of physicians' perceptions of three decision aids. *Patient Education and Counseling*, 2003; **49**: 1–5.
- 38 Norman G, Streiner D. *Health Measurement Scales: A Practical Guide to Their Development and Use*. Oxford, UK: Oxford University Press, 2003.
- 39 Fishburn PC. Expected utility: an anniversary and a new era. *Journal of Risk and Uncertainty*, 1988; **1**: 267–288.
- 40 Kahneman D, Tversky A. Prospect theory: an analysis of decision under risk. *Econometrica*, 1979; **47**: 263–291.
- 41 Gafni A. When does a competent patient make an irrational choice (letter)? *New England Journal of Medicine*, 1990; **323**: 1354.
- 42 O'Connor A, Wells G, Tugwell P, Laupacis A, Elmslie T, Drake E. The effect of an explicit values clarification exercise in a women's decision aid regarding postmenopausal hormone therapy. *Health Expectations*, 1999; **2**: 21–32.
- 43 Heyland D, Gafni A, Mitchell A, Levine M. Do potential patients prefer tissue plasminogen activator (TPA) over streptokinase (SK)? An evaluation of the risks and benefits of TPA from the patient's perspective. *Journal of Clinical Epidemiology*, 2000; **53**: 888–894.
- 44 Gafni A, Charles CA, Whelan T. The physician-patient encounter: the physician as a perfect agent for the patient versus the informed treatment decision-making model. *Social Science and Medicine*, 1998; **47**: 347–354.