

**2012 UPDATED CHAPTER L:
ESTABLISHING THE EFFECTIVENESS**

**SECTION 1:
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**SECTION 2:
CHAPTER SUMMARY**

What is this dimension?

In order to establish the effectiveness of a patient decision aid (PtDA), it is critical to provide evidence that the PtDA improves i) the quality of the decision-making process and ii) the quality of the choice that is made (i.e., “decision quality”). The *quality of the decision-making process* refers to the extent to which a PtDA helps patients to: recognize that a decision needs to be made; feel informed about the options and their characteristics; be clear about what matters most to them in this decision; discuss goals, concerns, and preferences with their health care providers; and be involved in decision making. The *quality of the choice that is made* (i.e., “decision quality”) is defined as the

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extent to which patients' eventual choices are consistent with their informed values and are actually implemented.

What is the theoretical rationale for including this dimension?

There are a number of complex reasons for assessing the effectiveness of PtDAs. In this chapter, we have organized this rationale into scientific, ethical, conceptual, and health policy sub-sections. We have also clearly indicated the different rationales for measuring the quality of the decision-making process and the quality of the choice that is made (i.e., "decision quality").

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

This updated overview of the evidence incorporates: a) the results of the 2011 Cochrane Collaboration's review of the 86 randomized controlled trials of PtDAs; b) an examination of the reported performance of instruments used to measure primary process and outcome variables in studies included in the 2011 Cochrane Collaboration's review; and c) good practice examples of how investigators should report on the performance of instruments used to measure decision making process and outcomes. This overview raises a number of issues to be addressed in future conceptual and empirical investigations. For example, when and how should we measure the effects of PtDAs on the decision-making process and on decision quality? Are we overlooking important measurement constructs? Are decision-making process variables predictive of decision quality? Can we develop a minimum "tool-kit" of key theory-based measures of PtDA effectiveness? In what ways do options' behavioral-change characteristics (e.g., diet and exercise versus surgery for obesity/weight management) change our strategies (if at all) for the evaluation of PtDAs?

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

a) Updated Definition

In order to establish the effectiveness of a patient decision aid (PtDA), it is critical to provide evidence that the PtDA improves i) the quality of the decision-making process and ii) decision quality – that is, the quality of the choice that is made.

The Quality of the Decision-Making Process

The core areas/domains about the decision-making process that should be captured, and some details about how each area/domain might be measured, include the extent to which PtDAs help patients to:

- Recognize that a decision needs to be made (e.g., one approach is to assess whether the patient understands that there is more than one reasonable approach to the situation).

- Feel informed about the options and the risks, benefits, and consequences of the options (e.g., the uninformed subscale of the Decisional Conflict Scale (O'Connor, 1995)).
- Be clear about what matters most to them for this decision (e.g., the unclear values subscale of the Decisional Conflict Scale).
- Discuss goals, concerns, and preferences with their health care providers.
- Be involved in decision making (e.g., adaptation of Degner's Control Preferences Scale that assesses who made the decision (Degner, 1992)).

Decision Quality -- The Quality of the Choice That is Made

The quality of the choice that is made is referred to as “decision quality” and, for the purposes of the prior round of IPDAS voting, was defined as the extent to which patients' decisions are consistent with their informed values (Elwyn 2006). Other definitions of decision quality emphasize the additional need for the choice to be implemented (O'Connor 1997, Sepucha 2004). It follows from the definition that the impact of PtDAs on the following outcomes should be measured whenever possible:

- *Informed patient*: This is most commonly measured by assessing patients' knowledge of the options and outcomes. Note that this is not assessed with patients' perceptions; instead, factual items are used to assess their understanding of the information. This may include an assessment of accurate risk perceptions, when applicable.

and

- *Concordance between what matters most to the patient and the chosen option*: Despite considerable variation in assessment of this construct, most approaches require the following: (1) elicitation of patients' goals and/or treatment preferences; (2) identification of the patient's chosen or implemented option; and (3) calculation of the extent to which the chosen option best meets the stated goals.

Many other process and outcome variables that are related to decision quality have been used to evaluate PtDAs; these include decision self efficacy, percentage of patients who are able to state a clear preference (as opposed to being unsure), decision regret, and patient satisfaction with decision making and choice of option. Further, there are many surveys and scales that cover some, but not all, of the process and outcome domains presented above. The definition presented here focuses on the core set of domains that are critical and some examples of scales that have been used; it does not imply that these are the only aspects that should or could be measured.

b) Changes from the Original Definition

The core of the original definition has been retained; however, we have edited the details

to make it consistent with the definition used in the Cochrane Systematic Review of PtDAs, and to more clearly differentiate between decision quality as an outcome variable and the key domains for the decision-making process variables (Stacey et al 2011).

c) **Emerging Issues/Research Areas in Definition**

See Section 6.

**SECTION 4:
THEORETICAL RATIONALE FOR INCLUSION OF THIS QUALITY
DIMENSION**

a) **Updated Theoretical Rationale**

Scientific Rationale

Establishing the effectiveness of any health care intervention, including decision aids, is critical. There is a strong consensus and scientific evidence that PtDAs: a) improve the quality of the decision-making process; and b) increase decision quality or the likelihood that individuals choose and/or receive health care interventions that are most consistent with their informed and considered values (Briss et al., 2004; O'Connor et al., 1997; O'Connor, Stacey et al., 2003; Ratliff et al., 1999; Sepucha et al., 2004, Sepucha 2008, Stacey et al., 2011; Elwyn et al., 2006). However, the field needs to continue to generate high-quality evidence regarding the benefits and harms of these tools to improve our understanding of their impact across various populations, health conditions, and healthcare systems, including across countries and cultures.

The best study design, when applicable, for determining effectiveness of health care interventions is the double blind randomized controlled trial that attempts to minimize risk of bias between groups to allow for head-to-head comparisons. However, these types of studies are limited as they tend to include a fairly homogeneous sample of well-educated, white, middle income patients, and less is known about the impact PtDAs have on disadvantaged patients (e.g., individuals with low literacy, or low incomes). In the case of decision aid trials, it is also challenging (or impossible) to blind participants (patients or providers) to the intervention. Furthermore, there is the challenge of taking the results observed within such trial conditions and applying them to real world settings, especially when the issues of implementation, such as the timing of the use of the decision aid, are difficult to standardize.

Ethical Rationale

Whilst this chapter focuses on the effectiveness of PtDAs, these are commonly seen as a means of supporting a shift from paternalism to informed and shared decision making (SDM). SDM is a process by which a decision is made between the patient, with or

without his/her family, and one or more healthcare professionals. It offers a model to approach patient engagement, particularly in preference-sensitive decisions – decisions in which there are reasonable options and in which the choice among those options is likely to be influenced by patient preferences and values.

Furthermore, not only is there a very clear ethical imperative to engage patients in decisions about their own care, but also PtDAs can support better informed consent. King and colleagues (2006) have argued that traditional informed consent methods are inadequate to engage and inform patients about treatment options in preference-sensitive decisions, and that SDM, because it extends beyond information-giving to supporting the formulation and communication of informed preferences, may offer an ethically and legally supported means for fostering informed choice. Research shows that, when usual care is compared to use of decision aids, current approaches without decision aids are inadequate for ensuring that patients are informed and have realistic expectations (Stacey et al., 2011).

As in any area of the evaluation of interventions, we should be concerned with addressing not only the benefits but also any adverse effects. In the context of PtDAs, the literature is relatively light on the exploration of adverse effects, although such effects have been posited. Adverse effects might include, for example, an increase in inequalities (through being more accessible to, or used by, well-educated patients) or selection of “less-effective” interventions with impact on population health, particularly in preventive health choices (Thomson, 2005). For example, well informed patients may select aspirin rather than (the more effective) warfarin for prevention of stroke in atrial fibrillation as a result of balancing how they value the benefits and risks of these alternatives (Thomson, 2007). Other adverse effects might include increased patient anxiety when patients are faced with clinical uncertainty (Politi et al., 2011), or are offered an unexpected role in decision making and are initially wary of engaging in decision making (Say et al., 2006), or feel unsupported or ‘abandoned’ if decision making is not actually shared but is unduly delegated to patients (Quill & Cassel, 1995). Adverse effects may also occur if PtDAs are neither well developed nor kept up to date, and therefore might bias decisions – hence the importance of standards such as these.

Conceptual Rationale

The measures of “the quality of the decision-making process” and “decision quality” highlighted in this chapter have underpinnings in theories of decision making. Normative theories of decision making, such as subjective expected utility theory, are based on the ideal that all patients can approach decisions rationally and are able to weigh the risks and benefits of various interventions (von Neumann and Morgenstern, 1947). Descriptive theories of decision making, such as prospect theory, demonstrate that humans are subject to cognitive biases that cause decision making to deviate from the normative/rational (Kahneman and Tversky, 1979). For example, a well-known cognitive bias has to do with the effects of framing, where people tend to be risk-averse when statistics are presented as gains and risk-seeking when they are presented as losses

(Tversky and Kahneman, 1974). These kinds of biases can threaten a person's ability to acquire accurate knowledge or to make a decision concordant with their values, thus threatening the quality of their decision. The Dual-Process Theory of decision making (Kahneman, 2003) argues that people make decisions either 'intuitively' (i.e., quickly drawing on past experiences), or 'reasonably' (i.e., using a thoughtful, analytic approach), with the latter being less subject to many of the cognitive biases. PtDAs are designed to encourage a more thoughtful or reasoned process in decision making, thus minimizing the influence of cognitive bias. If a more reasoned, normative approach is pursued, the actual choice will more likely to be informed and value concordant – the key domains of “decision quality”.

Although conceptually many of these theories share similar underpinnings (e.g., an emphasis on information, and the use of deliberative processes to align choices with goals), there is considerable debate about how that gets translated into specific measures (see section 5). The debate involves not only how to measure the construct (e.g., measuring patients' preferences using the standard gamble in formal decision analysis versus using attitude scales), but also the timing of the measurement. For example, some have argued that it is only legitimate to measure the quality of the decision making process before and immediately after exposure to the decision aid, because any later measurement will be prone to potential bias of the practitioner and longer-term measurement, especially after treatments have been experienced, may be influenced by hindsight bias based on health outcomes. (Elywn and Miron-Shatz, 2010)

A key goal of health care is to improve health outcomes, and many outside the field ask about what is the impact of decision aids on health outcomes. There are several challenges to the use of clinical health outcomes (such as quality of life, pain, or mortality) to assess the effectiveness of decision aids. First, the nature of the situation addressed by decision aids requires that there are multiple reasonable options; thus, by definition, there is usually not one clearly superior treatment or intervention. Second, many of these decisions are made under uncertainty, and are essentially making a bet; evaluation of the bet depends on the odds not the outcome. For example, a patient may chose to have surgery, feeling that the benefits outweigh the harms, and yet may suffer a severe, unanticipated complication during the procedure. Using health outcomes to evaluate that decision would suggest it was poor, whereas using decision-making process or decision quality measures would suggest it was strong. A third challenge with using health outcomes as a measure is that studies have shown that patients vary in their willingness to trade off quality of life and quantity of life. For example, patients may elect to forego chemotherapy if their desire to avoid short-term severe side effects outweighs their desire for increasing short-term survival. To the extent that patients feel differently about the potential health outcomes, it is necessary to measure the effectiveness of PtDAs by the extent to which they enable patients to achieve the outcomes they most desire (and avoid those they most dislike).

Policy Rationale

There are several recent, widespread health policy drivers that align with the implementation of PtDAs and SDM, hence emphasizing the need for a robust evidence base. Achieving decisions that are based on informed patients' values and preferences is consistent with the aims of patient-centered care (Institute of Medicine, 2001). Patient and family engagement in care has been identified as one of six national priorities for health care quality by the National Priorities Partnership in U.S. (National Priorities Partnership). The US National Quality Forum has identified SDM as one of top five priority areas for measurement gaps (Table 2 in NQF report to HHS June 11, 2011 Measure Prioritization Advisory Committee Report).

In the UK, SDM (“Nothing about me, without me”) is included within the latest UK Government health policy (Department of Health, 2010), and is embedded in legislation passing through parliament (Health and Social Care Bill 2011). The Department of Health has commissioned an extensive programme of development of PtDAs (NHS, 2012).

Further description on policy developments internationally can be found in the special issue of *The German Journal for Quality in Healthcare*, 2011.

From the policy perspective, however, comes a different pressure for measurement—costs. If health systems are to fund access to PtDAs, then they want to know the intervention is not only effective but also cost-effective. The impact of decision aids on utilization has been demonstrated in a small number of decisions, but, as of yet, there is not strong evidence that the tools are cost-effective or reduce costs. The impact on cost seems to depend on baseline utilisation (NICE, 2011). As implementation efforts expand, examining the impact on costs/cost-effectiveness will be an important outcome to include in those efforts.

b) Changes from the Original Theoretical Rationale

The original chapter did not provide an extensive rationale for including the concept of effectiveness; instead, it focused on proposing methods to operationalize the definition of the outcome concept of decision quality.

We have modified the discussion of the rationale in a number of ways:

- i) we have organized the rationale into scientific, ethical, conceptual, and health policy sub-sections;
- ii) we have more clearly indicated the different rationales for measuring the “quality of the decision-making process” and the “quality of the choice” (i.e., “decision quality”); and
- iii) we have removed most of the section that dealt with operationalizing the measurement of decision quality.

c) **Emerging Issues/Research Areas in Theoretical Rationale**

See Section 6.

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

a) **Updated Evidence**

Cochrane Collaboration Review

The latest update of the Cochrane Collaboration's Systematic Review includes 86 RCTs comparing individual PtDAs for treatment or screening decisions to usual care and/or alternate interventions. The trials were identified by searching through December 2009 on MEDLINE, EMBASE, PsycINFO, and Cochrane databases, and through September 2008 for CINAHL. Fifty-one trials measured knowledge (59%), 16 measured accurate risk perceptions (19%), 13 measured agreement between values and choice (15%), 23 measured feeling clear about values, and 26 measured feeling informed (Stacey et al., 2011).

Evidence About The Quality of the Decision-Making Process

PtDAs resulted in:

- a) reduction in feeling uninformed (MD -6.4 of 100; 95% CI -9.2 to -3.7);
- b) reduction in feeling unclear about personal values (MD -4.8; 95% CI -7.2 to -2.4); and
- c) fewer people passive in decision making (RR 0.6; 95% CI 0.5 to 0.8). There were no studies evaluating the decision-making process attributes relating to helping patients to recognize that a decision needs to be made or understand that their values affect the choice (Stacey et al. 2011).

Decision aids also appear to have a positive effect on patient-practitioner communication in the four studies that measured this outcome. For satisfaction with the decision (number of studies (n) = 12) and/or with the decision making process (n = 12), those exposed to a decision aid were either more satisfied or there was no difference between the decision aid versus comparison interventions. Decision aids do not appear to be different from comparisons in terms of anxiety (n = 20), and general health outcomes (n = 7) or condition-specific health outcomes (n = 9). The effects of decision aids on other outcomes (adherence to the decision, costs/resource use) were inconclusive (Stacey et al., 2011).

Evidence About Decision Quality - The Quality of the Choice That is Made

The latest results indicate that: PtDAs improve knowledge by 14% (mean difference 13.8 out of 100, 95% CI 11.4-16.2), with greater knowledge gains with more complex PtDAs; and improve accurate risk perception by 74% (relative risk 1.7; 95% CI 1.5-2.1) and

more so when the probabilities are expressed in numbers than words. PtDAs also result in fewer people being undecided (more have clear treatment preference) (RR 0.6; 95% CI 0.4 to 0.7); and, in the presence of explicit values clarification, improve agreement between values and choice by 25% (RR 1.3; 95% CI 1.1-1.5) (Stacey et al., 2011). None of the trials measured decision quality defined as decisions based on informed values.

Review of the Reported Performance of Instruments/Measures

There are many different survey instruments and measures used to assess decision-making process and decision quality. It is important to clearly document and appraise the performance of the instruments used to evaluate the effectiveness of PtDAs. A few recent studies exist that examine the properties of instruments such as:

- Kryworuchko et al.'s 2008 appraisal of selected “primary outcome” measures used in decision aid trials, which included some decision-making process and decision quality measures. The study concluded that most publications provided inadequate detail for appraising the included instruments.
- Sepucha and Ozanne's 2009 systematic review of methods to calculate value concordance, which found considerable variability in definitions and methodology and minimal reports of validation of instruments or approaches.
- Scholl et al.'s 2011 review of shared decision making instruments (an update of Simon 2007), which showed that, whilst reliability of most scales is good, they differ in their extent of validation.

To extend this work, we identified all reported outcomes from the 86 studies in the latest Cochrane Collaboration's review, and determined whether they measured one or more of the elements of the “quality of the decision-making process” or “decision quality” as defined earlier. We extracted data on the reported development and performance of each instrument, focusing on the reporting of key criteria for high-performing patient-reported measures including reliability, validity, responsiveness, precision, interpretability, feasibility, and acceptability. The initial review limited the abstraction to the details provided within the published trial papers – based on how a reader might evaluate the measures as described by the trial authors.

We found that the majority measured at least one aspect of decision quality or decision-making process (80/86 trials). Overall, we abstracted 220 measures that mapped onto one or more of the constructs, with knowledge being the most commonly measured construct. There was fairly limited reporting on the performance of the measures used. The studies included information on the psychometrics of only 64/220 or 29% of these measures. The most commonly reported criteria were reliability and validity; however these were reported less than 20% of the time. All the other criteria that we abstracted were reported less than 5% of the time. A little more than half of these measures were previously published or adapted from previously published instruments (129/220 or 58%), and this information may be available in prior publication. However, a significant proportion of the instruments or measures (72/220 or 33%) was new and reported nothing about the

properties of the measure. More detailed analysis of the properties of the measurement is ongoing and will be published separately.

Despite the general lack of reporting on the performance of instruments, there are a few examples of high quality reporting. One instrument that had wide and very strong reporting on its performance was the Decision Conflict Scale (DCS). It is also one of the most widely-used measures (in 39 of the 86 trials). The DCS measures two of the decision-making process domains—whether patients feel that they understand testing/treatment options and outcomes, and whether they feel clear about what matters most to them.

Tables 1 and 2 illustrate notable examples of how investigators included fairly comprehensive but parsimonious reporting on the performance of instruments.

Table 1 reports on the Decisional Conflict Scale.

TABLE 1: Extract from Vodermaier A et al., 2009.

“Measures

Patients were assessed with the following instrumentation:

Primary outcome variable

Decisional conflict. The Decisional Conflict Scale (DCS; O'Connor, 1995) measures patients' uncertainty about which treatment to choose, factors contributing to uncertainty (believing to be uninformed, unclear values, and unsupported in decision making), and perceived effectiveness of decision making. Questions have to be answered on a 5-point Likert scale [*from strongly agree to strongly disagree*]. Higher scores on the scale or subscales reflect higher decisional conflict, uncertainty, and a less effective choice. The German version of the scale demonstrated subscale and total score internal consistencies in the present sample between 0.73 and 0.94. The scale discriminates between patients who make and those who delay decisions (O'Connor, 1995; Bunn and O'Connor, 1996) and is sensitive to change (O'Connor et al., 1998).”

Table 2 reports on a knowledge measure that was developed for the featured study.

TABLE 2. Extracts from Barry et al., 1997.

“The quality of the treatment decisions was examined using a multifaceted approach. First, we determined whether subjects were better informed through a twenty question test of BPH Knowledge ... developed by a panel including a general internist, a urologist, a survey researcher, and a lawyer with a special interest in informed consent. Correct responses were scored +1, incorrect responses -1, and “not sure” responses were scored 0 (total range -20 to +20). The test of knowledge was administered two weeks after exposure to either the [patient decision aid]) or the control brochure.”

and

“Validation of New Outcome Measures

Cronbach’s alpha statistic for the items testing BPH knowledge was 0.68. The criterion validity of this test was assessed by comparing scores for a convenience sample of 12 urologic nurses with the scores of the 167 BPH patients enrolled in the baseline period. The nurses had a mean score of 14.8 [out of 20], compared to 5.6 for the patients ($p < 0.001$). Nurses answered an average of 85% of the questions correctly, compared to 48% for the patients ($p < 0.001$). Furthermore, a modest correlation between these patients’ knowledge scores and their educational levels was seen, $r = 0.23$ ($p < 0.001$).”

Other work that has advanced the measurement of decision quality is not yet reflected in the Cochrane Collaboration’s Review. Sepucha and colleagues have published psychometric analyses of three decision quality instruments (for osteoarthritis of the knee or hip, herniated disc, and breast cancer surgery) that assess the extent to which patients are informed and receive treatments that match their goals (Sepucha, Stacey et al., 2011; Sepucha, Feibelman et al., 2012; Sepucha, Belkora, et al., 2012). In general, these instruments met several criteria for patient-reported outcomes, including test-retest reliability, content and discriminant validity, acceptability, and feasibility. It will be important to further evaluate these as outcome measures in trials of decision aids in order to achieve the outcome of decision quality as defined in this chapter and in previous IPDAS publications (Elwyn et al., 2006).

b) Changes to Original Evidence

The above summary of evidence has been updated, incorporating: a) the results of the 2011 Cochrane Collaboration’s review of the 86 randomized controlled trials of PtDAs; b) an examination of the reported performance of instruments used to measure primary process and outcome variables in studies included in the 2011 Cochrane Collaboration’s

review; and c) good practice examples of how investigators should report on the performance of instruments used to measure decision making process and outcomes.

c) Emerging Issues/Research Areas in Evidence

See Section 6.

**SECTION 6:
EMERGING ISSUES AND RESEARCH AREAS IN THIS QUALITY
DIMENSION**

Inevitably, the revision of this chapter has also identified a number of questions that remain to be answered. A large number emerged in our discussions, which we have reviewed and summarized as high level questions that we suggest are most worthy of pursuit in future research.

How should we measure impact on decision-making process and on decision quality?

- Current measures are almost exclusively patient-reported measures; what advantages/disadvantages would be involved in using provider-reported measures or measures of the patient-provider interaction?
- What are the best measures of decision quality?
- How much, and what type of patient knowledge, is needed to evaluate/support high quality decisions?
- What is the value of decision quality measurement at an individual and aggregate level?
- What is the difference between risk perception and risk understanding?
- What methods are most appropriate for determining concordance? Is it best to focus on the chosen option or the implemented option?
- How do we measure impact on patient-provider interaction?

What else should we measure? Examples include:

- What is the role, if any, for including measurement of health outcomes? Measurement of costs/cost effectiveness?
- Should harms/adverse effects of decision aids be explicitly measured and, if so, how? (e.g., bias, cognitive burden, decision regret)
- What is the impact of PtDAs on health inequalities and literacy?
- What is the role of brief PtDAs compared to complex PtDAs?
- What are the (most) active ingredients of PtDAs? Which components are core to effectiveness?
- What is the impact of decision aids on treatment rates, adherence, service utilization, and service costs?

When should we measure impact? Examples include:

- Measuring knowledge or patients' preferences too long after the decision has been made may lead to hindsight bias in the appraisal of that decision.
- Measuring immediately after a decision aid but before the decision has been made is also problematic as provider consults will likely influence both knowledge and patients' preferences.

Theoretical Issues

- Multiple theories are relevant to the development of decision aids and improving decision quality (decision making theories, information processing theories, communication theories, etc.) – and each may suggest different outcomes. How to reconcile and/or link to each? Can we develop a minimum dataset of measures of decision quality/PtDA effectiveness?
- Increasingly, one or more options in situations covered in decision aids involve a large behavior change component (e.g., surgery versus diet and exercise for obesity/weight management). In what ways does this behavior change component change our strategies (if at all) for the evaluation of PtDAs (e.g., do we need to assess levels of self-efficacy and motivation in addition to knowledge and concordance)?
- Do we have evidence that the decision-making process variables are predictive of decision quality?

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**APPENDIX:
ORIGINAL CHAPTER L**

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Original Rationale / Theory

There is a reasonable consensus that: a) patient decision aids aim to improve the quality of decision making; and b) quality decisions are those that result in individuals choosing and/or receiving the health care interventions that are most consistent with their informed and considered values (Briss et al., 2004; O'Connor et al., 1997; O'Connor, Stacey et al., 2003; Ratliff et al., 1999; Sepucha et al., 2004).

An assessment of the effectiveness of a patient decision aid should, therefore, comprises evaluation of the extent to which it improves the proportion of patients who choose and/or receive health care interventions that are consistent with their individual values. There is, as yet, no approach or metric for measuring the congruence between an individual's values and the health care options they choose and/or receive.

Given the current state of methodological knowledge and experience, two strategies might now be pursued to further the evaluation of the effectiveness of patient decision aids:

- 1) The development of methods and measures for assessing the primary endpoint criterion (e.g., decisions that are consistent with the individual's informed and considered attitudes towards health states that might be affected by the decision; attitudes towards the risks associated with the relevant options; willingness to make trade-offs over time; and position in relation to other value-relevant issues involved in the decision);
- 2) The assessment of process criteria that are likely to support the achievement of the primary endpoint criterion.

First we outline here one promising approach for measuring the primary endpoint criterion. Then we identify some process criteria that are likely to support the achievement of the primary endpoint criterion.

An Approach For Measuring The Primary Endpoint Criterion

For most, if not all, of the decisions that patient decision aid developers seek to support, it will be possible to identify a number of option attributes, risk considerations, time trade off considerations, and other value-relevant issues that are most usually salient for patients facing the decision of interest.

(This identification step would require a rigorous social process involving a group representing all relevant perspectives and sources of expertise relating to the particular decision that the patient decision aid is intended to support).

Then the quality of decision-making could be reasonably estimated for a population of patients facing the decision. This could be done by gauging the (aggregate) proportion of patients for whom the health care option selected and/or received is consistent with their attitudes towards the most usually salient attributes and considerations.

We recognize that there will probably always be some individuals for whom the most usually salient option attributes and value considerations are not the ones on which their decision turns, because other attributes and value considerations are more important to them. However, assuming all other things are equal, when populations of patients that did and did not use a patient decision aid when facing the decision are compared, the odds ratio of the aggregate proportion of patients for whom the option chosen and/or received was consistent with their attitudes towards the most usually salient attributes and considerations should serve as a reasonable measure of the decision quality achieved with and without the patient decision aid.

Methodological development will be needed to refine both (a) the basic approach to this kind of measurement, as well as (b) the decision-specific measures of the options chosen, individuals' knowledge about the most usually salient option attributes (in order to ensure that patients' attitudes are well informed), and individuals' attitudes towards the most usually salient option attributes and value considerations.

Process Criteria Likely to Support the Achievement of the Primary Endpoint Criterion

Process criteria that are likely to support the achievement of the primary endpoint criterion include the knowledge assessment mentioned above and also the extent to which patients: recognise there is a decision to be made; understand that no single option is best for everyone because patients have different values and preferences; appreciate that their own goals, values, and preferences matter in the decision; and have reflected on and discussed their attitudes towards the most usually salient option attributes and value

considerations with the practitioner(s) with whom they are making the decision.

Other Outcome Criteria of Interest

The use of patient decision aids in practice may affect a number of health care processes and outcomes in addition to the ones mentioned above. The focus in this document on decision quality as the primary endpoint criterion is not meant to imply that other outcomes are unimportant. Patients' perceptions of the decision making process and confidence in the decisions made are, for example, important aspects of the quality of health care that may be affected by the use of patient decision aids. However, they are not the best indicators of whether a patient decision aid has fulfilled its aim of improving decision quality; for example, patients who are not well informed about their health care options may express confidence in a particular choice even if it is not consistent with their reported values.

Original Evidence

There is a reasonable consensus that (a) patient decision aids aim essentially to improve the quality of decision making, and (b) good decisions are those that result in individuals choosing and/or receiving the health care interventions that are most consistent with their informed and considered values.

For example, a national survey of the public endorsed the criteria of being informed about options, outcomes and probabilities, having clear values, making a choice that is congruent with values, and being satisfied with the choice (O'Connor, Drake et al., 2003). A survey of oncologists place the highest endorsement (>95%) on the patient criteria of being clear about the values tradeoffs in the decision and being informed of treatment alternatives, harms, and benefits (O'Connor et al., 1997).

Trials of patient decision aids also frequently assess these criteria. In 34 trials of individual patient decision aids, 18 measured knowledge, 10 measured feeling clear about values, and 3 measured agreement between values and choices (O'Connor, Stacey et al., 2003).

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