

**2012 UPDATED CHAPTER B:
Providing Information About Options**

**SECTION 1:
AUTHORS/AFFILIATIONS**

Deb Feldman-Stewart (lead)	Queen’s University, Kingston	Canada
Mary Ann O’Brien (co-lead)	University of Toronto, Toronto	Canada
Marla Clayman	Northwestern University, Chicago	USA
Joyce Davison	University of Saskatchewan, Saskatoon	Canada
Masahito Jimbo	University of Michigan, Ann Arbor	USA
Michel Labrecque	Laval University, Quebec City	Canada
Richard W. Martin	Michigan State University, Grand Rapids	USA
Heather Shepherd	Family Planning New South Wales, Ashfield	Australia

**SECTION 2:
CHAPTER SUMMARY**

What is this dimension?

In patients’ decision aids, information should be provided pertaining to the patient’s health condition and all medically reasonable options to address the health condition. The information should be based on the best available evidence, patient information needs, and the ethical/legal principles of informed consent, and be presented in a balanced manner.

What is the theoretical rationale for including this dimension?

Patients choosing among various screening / diagnostic / treatment options need this information in order to arrive at an informed choice. Ethical and legal obligations along with decision-making theory make clear that patients require information in order to ensure that the decision made is consistent with their values and preferences.

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

At least 60 RCT studies have evaluated the effect of patient decision aids on knowledge; knowledge is measured in a variety of ways in these trials. However, the evidence indicates that well-designed decision aids generate improvement in mean knowledge scores. Issues that need to be studied in greater depth include questions about information presentation, population-specific effects, and information media.

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

a) Updated Definition

Patient decision aids aim to facilitate informed, value-based decisions about health. This is accomplished by helping each patient determine what is personally important so that they can participate in the decision to the extent that they would like. Therefore, information should be provided pertaining to the patient's health condition and to all medically reasonable options to address the health condition. The information should be based on the best available evidence and be presented in a balanced presentation (both of potential harms and potential benefits, and of the options). The selection of information to provide should be guided by a) patients' identification of the information that they need in order to make the decision (which may include psychosocial needs—e.g., extent I can manage on my own after treatment--- logistical concerns, or other non-biomedical matters), in addition to b) the legal and ethical obligations of informed consent.

b) Changes from Original Definition

The updated definition includes the same fundamental concepts as the old, but it now places more emphasis on patients' information needs that are beyond that typically identified in the "informed consent" paradigm. Further, the new definition specifies qualities that should characterize the information that is selected – that is, be based on best-available evidence and be balanced across both a) harms and benefits, and b) options.

c) Emerging Issues/Research Areas in Definition

None.

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

a) Updated Theoretical Rationale

Patients' Information Needs

Patients' information needs for decision making often differ from the information priorities of their healthcare providers (Capirci et al., 2005; Turner et al., 1996). Therefore, it is important to identify empirically the information that patients need in order to make their decisions. In addition, because the needs often vary considerably from one patient to the next (Feldman-Stewart, Brundage, Nickel, & Mackillop, 2001; Jenkins, Fallowfield & Saul, 2004; Sheridan, Felix, Pignone, & Lewis, 2004; Feldman-Stewart et al., 2010), it is important to quantify the prevalence of each need in a population of the patients of interest—e.g., through a survey.

Further, both prescriptive theories of decision making (e.g., Expected Utility Theory, von Neuman and Morgenstern, 1953) and descriptive theories of decision making (e.g., Behavioral Decision Framework, Frisch & Clemen, 1994; Conflict Model, Janis & Mann, 1977; Differentiation and Consolidation, Svenson, 1992; Fuzzy Trace Theory, Reyna, 2008; Image Theory, Beach & Mitchell, 1987; Parallel Constraint Satisfaction, Glöckner & Betsch, 2008; and Search for Dominance Structure, Montgomery, 1994) suggest that to make a decision, the decision maker needs to establish their preference for particular aspect(s) of the options or for an option as a whole. For patients to determine their values and preference(s), they need to have the relevant information. Hence, the implication of all these theories is that for patients to make decisions, they need to be provided with appropriate information.

Legal and Ethical Obligations of Informed Consent

In most jurisdictions, there is a legal obligation of informed consent, making the healthcare professional responsible for ensuring that the patient understands their condition, the procedure being recommended, its potential benefits and harms, and any alternate procedures that are available. Healthcare professionals are also bound by the ethical doctrine of informed consent, which is founded on three principles: 1) autonomy (which obligates the professionals to ensure that the patient can act in her or his own best interest without undue pressure); 2) benevolence and non-malevolence (which obligates the professionals to choose to do good and to avoid doing harm to patients); and 3) justice (which obligates the professionals to treat all patients equally) (Appelbaum, Lidz & Meisel, 1987; Faden & Beauchamp, 1986).

Legal and ethical obligations require that healthcare professionals explain, for treatment decisions, how the untreated condition is expected to develop, the procedures involved in the treatment(s), the potential benefits of the treatment(s), and the severity and likelihood of the various treatment side effects. For screening or diagnostic tests, additional information should be provided about the frequency of true/false positive and true/false negative results, and about the recommended follow-up actions that could include treatment options for true positive results. Patients' information needs that are outside these content areas should be addressed.

b) Changes to Original Rationale

The fundamental rationale currently provided is the same as the original. Recent evidence highlights, in particular decision-making contexts, a) the extent of difference between patient information needs and the priorities of their health-care professionals, and b) wide differences in information affecting the decisions amongst the patients.

c) Emerging Issues/Research Areas in Theory/Rationale

Identifying Information Details

Research is emerging that focuses on details that affect patient decisions, and clarifies what information should be provided. For example, patients with early-stage prostate cancer concerned about “the cancer spreading” (when choosing between watchful waiting and active treatment) are often concerned about one of two very different issues: some patients are

concerned about the *chances* of the cancer spreading while others are concerned about *where* the cancer will spread (i.e., wanting to avoid brain metastases more than metastases to other parts of the body). For each decision, investigation of the details that affect patients' decisions will help clarify the information that should be provided in a patient decision aid for that decision.

Identifying Prevalence of Information Needs in Patient Populations

Research is emerging that prevalence estimates of individual information needs are required within a population of patients in order to determine a) which needs are most prevalent, and b) the extent of variability in particular needs across patients. Further research is needed in individual decisions to establish the prevalence of particular information needs amongst a population of patients.

How Best to Address the Information Needs of Individual Patients

Because patient decision aids are intended to help the individual patient with her/his decision, it is important to be able to accommodate wide variability in information needs when it occurs within a patient population. Research is needed to determine best ways of tailoring patient decision aids to address the information needs of the individual patient.

SECTION 5: EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION

a) Updated Evidence Base

The following evidence comes from the updated Cochrane Collaboration Review of patient decision aids (Stacey et al., 2011), which includes publications until the end of 2009, augmented by a search of OvidSP, including all databases (e.g., Medline, AMED, EBM Reviews, EMBASE, Global Health, Ovid Healthstar, PsycExtra, PsychInfo) for 2010 publications. The following search terms were used for the 2010 search: (“decision aid” or “decision support” or “decision making”) AND (“randomized trial” or “controlled trial” or “comparison”).

RCTs Involving Patients Facing Actual Choices

The 2011 Cochrane Review identified 50 randomized controlled trials and the 2010 search identified an additional 10, totaling 60 trials that evaluated the effect of patient decision aids on knowledge. Of the 60 comparisons, 39 compared a patient decision aid to “usual care”, which we defined as no intervention beyond that usually given in the study setting. Twenty-one of the 60 compared a simpler to a more detailed patient decision aid; we defined “more detailed” as providing information (with or without other additions) that was not provided in the “simple decision aid”.

Knowledge Scores –Decision Aid versus Usual Care

Stacey et al. (2011) reported that 39 trials compared patient decision aids to usual care. They conducted a meta-analysis of 26 studies and found that patients using decision aids had mean knowledge scores that were, on average, 14 out of 100 points higher (95%CI 11 to 16) than the mean scores of patients who received usual care. They also identified an additional 8 studies that could not be included in the meta-analysis. Of these, 5 reported statistically significant improvement in knowledge scores in DA groups compared to usual care, although one (Weymiller, 2007) only showed the advantage if the DA was used during the consultation but not when used prior to it. The other 3 studies reported a statistically significant improvement from baseline for DA groups. Of the five additional trials published in 2010, all reported statistically significantly improved knowledge for the DA group compared to the usual care group: 2 studies reported higher mean knowledge scores (Evans et al., 2010 and Mathieu et al., 2010), 2 reported larger mean improvement from baseline scores (Rubel et al., 2010 and van Peperstraten et al., 2010). The fifth study reported that a larger percentage of DA patients as compared to usual care patients improved their knowledge scores, and the mean improvement in scores was larger for DA group compared to that in the usual care group (Allen et al., 2010). Thus, overall, it appears that providing patients with a decision aid results in higher knowledge scores than those who just receive usual care.

Knowledge Scores - Simple versus More Detailed Decision Aids

Stacey et al. (2011) reported that 20 studies compared more detailed patient decision aids to simpler versions. Their meta-analysis of 14 trials suggested that, on average, the more detailed decision aids resulted in an improvement in mean knowledge scores over usual care of 5 out of 100 points (95% CI 3 to 7), which is considered a small effect. One study that could not be included in the analysis found no difference between the groups (Volk et al., 2008). Of the five 2010 reports, three found some statistically significant evidence of higher knowledge scores for the more detailed decision aid but often the difference was limited: one found a higher mean knowledge score (Raynes-Greenow et al., 2010), one found a significant improvement in the more detailed decision aid group but not in the simpler decision aid group (Jibaja-Weiss et al., 2010), and one found no difference in mean overall knowledge scores but the more-detailed group had more accurate perceptions of the risks deemed most important to the decision (Mann et al., 2010). One study reported no difference in mean knowledge scores between the groups (Labrecque et al., 2010). The final study was designed for low literacy patients, so the intervention decision aid actually had less information but also used simpler language and graphic illustrations compared to the standard information provided to the control group. The authors also reported that the group who received less information (in simpler language with graphics) had higher mean knowledge scores and a larger proportion who reached the knowledge threshold the authors defined for “informed decision making” (Smith et al., 2010). Thus, generally, it appears that the more detailed decision aids seem to result in slightly higher knowledge scores than the simpler decision aids, but the differences are very small, often isolated and it appears that they can be eliminated by presentation strategies.

Feeling Informed Scores – Decision Aids versus Usual Care

Although the evidence related to objective knowledge scores is considered the gold standard, evidence around how informed patients feel leads to the same conclusions as those of objective data. Most frequently the subjective feelings have been measured by the “feeling uninformed” subscale of the Decisional Conflict Scale (DCS, O’Connor et al., 1995). The Cochrane Collaboration Review (Stacey et al., 2011) identified 25 studies that reported the Decisional Conflict Scale subscale. Sixteen of those studies compared DA to usual care, and a meta-analysis of those data suggests a reduction in feeling uninformed of -7 out of 100 points (95% CI -9 to -4). Of the five 2010 decision aid versus usual care comparisons, none reported the “feeling uninformed” subscale even if they used the Decisional Conflict Scale.

Feeling Informed Scores – Simple versus More Detailed Decision Aids

The Cochrane Collaboration Review’s (Stacey et al., 2011) meta-analysis of the 9 studies that compared a more detailed patient decision aid to a simpler version suggests that the more detailed decision aids resulted in a slight reduction of feeling uninformed of -3 out of 100 points (95% CI -5 to 0). Of the five 2010 reports comparing simple to more detailed decision aids, two found the more detailed decision aid reduced feeling uninformed scores significantly more than the simple one (Jibaja-Weiss et al., 2010 & Mann et al., 2010). In the study of patients with low literacy patients, the decision aid had less information with simpler language and graphic illustrations in the intervention. Use of the decision aid resulted in patients feeling more informed on the low-literacy version of the subscale (65% versus 52%) (Smith et al., 2010). Two studies did not find a difference between the groups’ scores on the DCS Feeling Uninformed subscale (Labrecque et al., 2010, Raynes-Greenow et al., 2010). However, one of those studies did find that a significantly higher percentage of the more-detailed decision aid group reported having enough information to make a decision (89% versus 80%) (Raynes-Greenow et al., 2010).

b) Changes from Original Evidence Base

The types of evidence have not changed from the original. Studies from 2005 until the end of 2010 have been added.

c) Emerging Issues/Research Areas in Evidence Base

Information Presentation

Evidence suggests that many aspects of how the information is presented can affect patients’ ability to use it. Many aspects of text presentation can affect comprehension including its structure (Vaiana & McGlynn, 2002; Hartley & Burnhill, 1977), layout (Wilson & Wolf, 2009; Sanfey & Hastie, 1998), language (Rudd, Kaphingst, Colton, Gregoire, & Hyde, 2010), and font (Vaiana et al., 2002). See also IPDAS Chapter J “Addressing Health Literacy”. Presentation of quantitative information, including potential benefits and risks, is addressed in IPDAS Chapter C “Presenting Probabilities”. Aspects beyond how the text itself is presented can affect comprehension. Text and numeric presentations can interact to affect comprehension (Fagerlin et al., 2005). And, if graphics do not directly reinforce the textual information, they can distract

from core information and reduce recall accuracy (Martin, Brower, Gerald et al., *in press*). Finally, although evidence presented above suggests that more detailed decision aids, generally, can result in small improvements in the amount of relevant information understood by patients, there are times when less information results in greater comprehension (Peters, Dieckmann, Dixon et al., 2007). See Population-Specific Effects, below, for further information.

Presentation format can also affect decision-making processes. Presenting information in table format helps readers make direct comparisons which, in turn, helps decision making (Sundstroem, 1989; Feldman-Stewart & Brundage, 2004). It should also be noted that, when options are presented sequentially (i.e., one after the other), the order in which they are presented can shift preferences (Ubel et al., 2010).

Further research is needed to clarify how to present information in patient decision aids to assist patients' understanding and their decision making processes.

Population-Specific Effects

While some generalities appear around how information presentation affects its potential to be understood, there is evidence suggesting that these effects may be population-specific. In addition to literacy levels being an important consideration [see also IPDAS Chapter J “Addressing Health Literacy”], age may also be an important consideration, such as when using illustrations (Liu C-J et al., 2007). Further research is needed to clarify what population-related factors are important considerations for how information is presented.

Medium

Medium-specific considerations can also affect how well information is understood by patients. For example, multi-media presentation can result in poorer comprehension than when the information is presented in a single medium (Sundar, 2000). Evidence from a systematic research program on multi-media learning provides guiding principles on how to maximize the effectiveness of multi-media presentations (Mayer, 2001). Multi-media can be used to implement “entertainment education” which has resulted in higher knowledge gains for low literacy patients than audio-booklet presentation; it has no apparent differential impact on high-literacy patients (Volk et al., 2008) [see also IPDAS Chapter J “Addressing Health Literacy”]

b) Bibliography

Below we list some references that provide evidence as specified in that section. Readers can find a more complete list of papers reporting randomized controlled trials of patient decision aids in the Cochrane Collaboration Review identified at the top of the list.

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**APPENDIX:
ORIGINAL CHAPTER B**

Original Authors

Deb Feldman-Stewart (lead)	Queen's University, Kingston	Canada
Joan Austoker	University of Oxford	UK
Agathe Charvet	Psychologue à l'Institut de Médecine Sociale et Préventive à Genève	Switzerland
Paul Hewitson	University of Oxford	UK
Sara Knight	University of California, San Francisco	USA
Karen Sepucha	Harvard Medical School, Boston	USA
Tim Whelan	McMaster University, Hamilton	Canada

Original Rationale/Theory

Patient decision aids aim to facilitate informed, value-based decisions about health. This is accomplished by helping each patient determine what is personally important so that they can participate in the decision to the extent that they would like. Therefore, the patient needs to understand their health condition, and all medically reasonable options to address the condition, including each option's potential benefits, harms and side effects. The selection of information to be included is guided by patients' identification of their needs, in addition to the legal and ethical obligations of informed consent.

Patients' Information Needs

Although information needs vary widely from one patient to the next, in general all patients require information that includes how the untreated condition is expected to develop, the procedures involved in the treatment(s), the potential benefits of the treatment(s), and the severity and likelihood of the various treatment side effects (e.g. Feldman-Stewart, Brundage & Van Manen, 2004). For screening or diagnostic tests, additional information should be provided about the frequency of true/false positive and true/false negative results, and about the recommended follow-up actions that could include treatment options for true positive results.

Legal and Ethical Obligations of Informed Consent

In most jurisdictions, there is a legal obligation of informed consent making the practitioner responsible for ensuring that the patient understands their condition, the procedure being recommended, its potential benefits and harms, and what alternate procedures are available.

Health professionals are also bound by the ethical doctrine of informed consent that is founded on three principles: (1) autonomy (which obligates the professionals to ensure that the patient can act in their own best interest without undue pressure); (2) benevolence and non-malevolence (which obligates the professionals to choose to do good and to avoid doing harm to patients); and (3) justice (which obligates the professionals to treat all patients equally) (Appelbaum, Lidz & Meisel, 1987; Faden & Beauchamp, 1986). Ensuring that patients understand their condition, all medically reasonable options, and the potential outcomes of each option is intrinsic to all of these principles.

Original Evidence

Inventory Of Available Patient Decision Aids

Information about options was assessed in patient decision aids registered in the Cochrane Review inventory (O'Connor et al., 2003).

Of 131 patient decision aids that were available and updated within the last 5 years:

- 100% (of 131) presented information about options and their potential benefits and harms.

RCTs Involving Patients Facing Actual Choices

The Cochrane Review identified 18 randomized controlled trials that evaluated the effect of patient decision aids on knowledge. Nine of these compared a patient decision aid to usual care, and nine compared a simpler to a more detailed patient decision aid (O'Connor et al., 2003). Of the 9 trials that compared patient decision aids to usual care, all (100%) showed statistically significantly higher mean knowledge test scores in the patient decision aid group compared to those of the usual care group. Of the 9 that compared more detailed patient decision aids to simpler versions, 8 (89%) showed a trend toward higher mean knowledge test scores in the group receiving the more detailed patient decision aid; however, only 4 studies had the power to detect a statistically significant difference.

Similar results were observed in the trials that measured “feeling uninformed” on a subscale of the Decisional Conflict Scale. Compared to usual care, patients using a patient decision aid in all six RCTs (100%) had a statistically significant reduction (ranging from mean of 5 to 16 points out of 100) in feeling uninformed about options, benefits, and harms. Four RCTs compared a more detailed patient decision aid to a simpler version. Of the four, three (75%) showed a reduction in feeling uninformed (from 3 to 5 points out of 100), that was not statistically reliable due to insufficient power.

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