



**International Patient Decision Aid
Standards (IPDAS) Collaboration**

IPDAS Collaboration Background Document

February 17, 2005

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Note: This collection of papers is intended to supplement the summarized information provided in the IPDAS Collaboration Voting Document: Draft VIII, February 1, 2005.

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Section A: Using a systematic development process

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Rationale/Theory

Patient decision aids are meant to support informed values-based decision making. They are usually developed when there is more than one reasonable option and there is considerable variation in how patients value the features of different options. Practitioners and patients may find it challenging to arrive at a good decision without advance preparation using a patient decision aid that helps patients understand the options and clarify the personal value of their different features.

Patient decision aids take considerable effort to develop, and can have an important effect on decision quality and the use of health services. Therefore, it is important that they are developed using a systematic and replicable process.

Specific developmental steps common to many patient decision aids (O'Connor et al., 2003; Bekker et al., 1999) include:

Assessing decisional needs. Groups with relevant perspectives and expertise are assembled and engaged in a rigorous social process to analyze:

- *The characteristics of the decision* such as: all potentially relevant health care options; protocols involved in each option; evidence regarding outcomes, probabilities, and variation in patients' values for different features of options; sensitivity of the decision to variation in values and probabilities; and other characteristics such as the burden of condition and costs.
- **Patients' information needs.** Although, information needs vary widely from one patient to the next, in general all patients require information that includes the natural course of the condition, the procedures involved in the treatments or tests, the potential consequences, their severity, and their likelihoods of occurring (e.g. Feldman-Stewart, Brundage & Van Manen, 2004).
- **Patients' decisional needs** such as: current perceptions of options; salience of outcomes, probabilities, and values in decision making; the degree of difficulty making the decision and factors contributing to that difficulty; usual and preferred

decision making roles; decisional barriers and facilitators; feasibility and local attitudes regarding the use of patient decision aids.

Formation of groups to develop and review patient decision aids. Patient decision aid developers usually include experts in clinical care, evidence-based decision making, patient education, and patient experience. Patient decision aid reviewers usually include potential users such as patients who are experienced with the decision and the practitioners who counsel them about the decision.

Drafting, reviewing, and revising. The elements included in patient decision aids (e.g. information about the condition, options, and outcomes; values clarification; examples of others' experiences with decision making; and guidance in decision making and communication) are described elsewhere. Through an iterative process, a patient decision aid is drafted, reviewed, and revised until it is ready for field testing. At this stage, part of the review may include acceptability questionnaires eliciting, for example: reviewers' perceptions of the appropriateness and amount of information; ability to help patients decide what is most important to them; appropriate length; balanced presentation of options and outcomes; ability to hold their interest; ability to help them understand the various patient roles in decision making; and usefulness for decision making.

Field testing is conducted with patients at the point of decision making. The objectives focus on feasibility, acceptability to users, potential to improve knowledge, and potential to clarify personal values regarding the features of options.

External peer review. The patient decision aid undergoes critical appraisal by those who were not involved in its development and evaluation.

Evidence

Patients' information needs. Of the 14 screening patient decision aids verified by the Cochrane Review (O'Connor et al., 2003), 10 developers described how they arrived at the content of their aids. Of these 10, 5 (50%) consulted their respective patient populations about their information needs using interviews (with individual patients and/or focus groups) or through surveys. Of these 5 populations, 20% wanted information about the health condition, 83% on the "no test" option, 83% on the test procedure(s), 80% on the risks of the procedures, 80% on the rates of true/false positives and of true/false negatives, 67% on the potential consequences of a positive test result, and 40% on the potential consequences of a negative test result.

Of the 45 treatment patient decision aids verified by the Cochrane Review (O'Connor et al., 2003), 32 developers described how they arrived at the content of their aid. Of these 32, 21 (66%) developers consulted their respective patient populations about their information needs, using interviews (either with individuals and/or focus groups) or surveys. Of these 21 populations, 96% wanted information about the health condition, 81% on the multiple options, 50% on the 'no treatment' option, 100% on the treatment procedures, 100% on the potential benefits, and 100% on the potential risks of the various treatment options.

RCT's involving patients facing actual choices. Of the 29 individual patient decision aids, evaluated in the 34 RCTs included in the Cochrane Review, 19 were available for review (O'Connor et al., 2003). Of these:

- 89% (17 of 19) listed the credentials of developers; and
- 58% (11 of 19) reported a published or easily accessible description of the development process.

Overall, there is limited evidence about how these development processes affect decision quality.

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Section B: Providing information about options

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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.

- 4.4.1 ***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.

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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Section C: Presenting probabilities

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Rationale/Theory

A key objective of patient decision aids is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur. Since no intervention is 100% effective in all patients without harms (including side-effects), probabilities must be presented in patient decision aids. However, presenting risk information (probabilities) is problematic because most individuals -- including patients and professionals -- have difficulty in processing and accurately evaluating probabilities and statistics. The evidence suggests that individuals would rather use a heuristic such as someone else's evaluation of the risks than attend to the figures in order to make a decision. Some strategies for effectively communicating probabilities in health have been proposed (see, for example, Schwartz, 1999), but few have been tested empirically in patient decision aids. Therefore, recommendations in this document are largely made on theoretical grounds, borrowing heavily from work in clinical epidemiology and evidence based health care, psychology (prospect theory, Tversky & Kahneman, 1974;1981), risk communication and risk perception research (Loewenstein et al., 2001; Slovic et al., 2002), and decision theory (theory of expected utility, Neumann & Morganstern).

Presenting numbers. Although many patients prefer to read words rather than numbers, numerical probabilities improve the accuracy of understanding. Event rates (natural frequencies) are the recommended way to present these probabilities. Event rates for all relevant options and for each relevant outcome should be given, and appropriate time frames and denominators should be provided. For example, a patient decision aid on stroke prevention in atrial fibrillation should give the number out of 100 men who will have a stroke over 10 years if they take warfarin, the number out of 100 men who will have a stroke over 10 years if they take aspirin, and the number out of 100 men who will have a stroke over 10 years if they take no treatment. For situations in which risks are small, such as screening and other preventive interventions, denominators of 1000 or 10,000 may be needed.

Events rates are intuitively interpretable because they are natural frequencies with clearly stated reference classes. Some patient decision aids use other presentation formats including relative risk reduction, absolute risk reduction, number needed to screen, or number needed to treat. These may help when patients have to compare many options, because they allow summarization of data but they are less likely to be well understood. Furthermore, none of these formats (relative risk reduction, absolute risk reduction, number needed to screen, or number needed to treat) make the baseline risk of disease as explicit as simply presenting event rates for all intervention options being compared.

Constant denominators (e.g. 1 in 100, 5 in 100) rather than constant numerators (e.g., 1 in 100, 1 in 20) are more readily understood (Woloshin et al., 2000). For information to be meaningful, it is important to present the timeframe over which events occur, and to use a timeframe that patients find useful for planning health management -- for example, “Imagine 1000 patients. Over the next 10 years, 150 of them will die of ...”. Although lifetime risk is often used, 10 year time frames are often more appropriate (Woloshin et al., 2002).

Visual aids. Presenting event rates with visual aids such as 100 faces diagrams, bar charts, human figure representations, or flow diagrams may aid accurate understanding of probabilities. By using more than one presentation format, patients are able to choose the format that works best for them. As well, analogies may be especially useful for presenting small risks – e.g. one person in a football stadium crowd, etc (Edwards, 2003). Any visual aids to be used should be pilot tested for understanding, and developers should take care to avoid using misleading images (such as graphs with misleading scales) or using different scales within the same patient decision aid. There is evidence that the formats which are perceived most accurately and easily by patients are vertical bars, horizontal bars and systematic ovals. Pie charts and random ovals lead to slower and less accurate estimates (Feldman-Stewart et al., 2000).

Probabilities for tests and screening decisions. The mortality benefit from screening should be presented as the probability of death with and without screening; e.g. the probability of dying of breast cancer in 1000 women who regularly participate in screening and in 1000 women who decline screening. It is very important that the survival times are NOT used as these are likely to be affected by lead time bias (Barratt et al., 1999; Welch et al., 2000).

Patient decision aids for screening should also present the probability of having the target condition detected with and without screening, because many cancer screening programs lead to over-detection of disease. Disease aids should therefore alert readers to the possibility of screening leading to detection and treatment of disease that might never have caused symptoms had it not been for screening. For example, the chance of having breast cancer or prostate cancer diagnosed is substantially higher in screened compared to unscreened populations because some or many of these cancers would never have become symptomatic (and therefore diagnosed) in the absence of screening.

Patient decision aids about tests or screening programs also need to present information about the chances of receiving a false positive (false alarm) or false negative result. Although these data have traditionally been presented as specificity and sensitivity, these are not readily understood. Such conditional probabilities should be avoided and natural frequencies (event rates) used instead. For example, “over 10 mammography screening rounds, 160 out of 1000 women participating in screening will experience a false positive result” is more readily interpreted than the specificity (the proportion of patients who test positive among those who do not have disease) of mammography screening.

Screening may lead to a cascade of events (including follow-up tests and treatments), and the probability of each of these events occurring should also be presented.

Tailoring probabilities. Whenever possible, individualised risks should be used. Although there is little evidence specifically examining the degree to which individualised risk information facilitates patients’ understanding and decisions, it is likely that personally relevant risks will be evaluated more accurately in accord with a patients' values than less relevant risk information. For example, individualized risk estimates (using tables, computerized algorithms, or risk estimates for groups of patients) depending on important risk factors such as age, gender, family history, smoking status might be used. As a minimum, it should be clear to the user of the patient decision aid whether the probabilities apply to them based on their gender, age, medical history, or other risk factors.

Framing probabilities. The way information is framed can affect preferences and decision making (Edwards et al., 2001; Tversky et al., 1981). Thus, patient decision aid developers should be aware of potential framing effects. Framing effects are minimized if visual aids such as 100--faces diagrams are used, because they show the number of patients experiencing the outcome and the number of patients not experiencing the outcome for each option being considered all at once. Simply giving the percentage (x %) of patients who experience an event (e.g., death) does not achieve this as clearly, because the reader has to do mental arithmetic (100-x) to calculate the percentage who do not experience it (e.g., survive). Event rates presenting both positive and negative frames can be used, but may lead to information overload. An alternative is for writers to acknowledge explicitly the frame used and encourage patients to reformat the information for themselves.

Formats such as relative risk reduction, absolute risk reduction, and numbers need to treat can be misleading, because they do not make explicit the baseline risk of the target condition. For example, a 50% reduction in risk sounds very impressive, but it might refer to a treatment that reduces the risk of death from 40 out of 100 to 20 out of 100 OR to a treatment that reduces the risk of death from 4 out 10,000 to 2 out of 10,000. Relative risk reduction generally is more impressive -- and potentially misleading -- than absolute risk reduction, particularly for rare events.

Probabilities in context. Disease-specific probabilities (or the benefits of various disease-specific interventions) are hard to understand in isolation. Therefore, patient decision aids

need to help patients put disease- (or intervention-) specific information into context. One way is to provide estimates of the 10-year chance of developing or dying from various diseases (or dying from any causes) for men/women, smokers/non-smokers at various ages. Other anchors, such as commonly and not so commonly occurring events, have been used.

Conveying uncertainty. It's very important to acknowledge uncertainty in probability estimates. Often the uncertainty is large, especially if evidence is scarce or events are rare. It's probably wise to do simple things such as rounding off numbers (to avoid false illusions of precision), using phrases like "our best guess is...", give ranges, or provide 95% confidence intervals.

Even with the best evidence from large studies (thus with high accuracy and precision), the issue of stochastic uncertainty remains (Edwards, Elwyn, Mulley, 2002). Essentially, we never quite know who are the patients who are going to be affected, and who the treatment is going to be most useful for. One way to deal with this uncertainty might be to say: "If 100 patients like you are given no treatment for five years, 92 will live and eight will die. Whether you are one of the 92 or one of the eight, I do not know. Then, if 100 patients like you take a certain drug every day for five years, 95 will live and five will die. Again, I do not know whether you are one of the 95 or one of the five." (Skolbekken, 1998)

Despite these limitations from uncertainty, practitioners generally feel that we can still try to make decisions about what the best treatment plan is for an individual person, based on what happens to these groups of patients in the studies. Hence the value, it is thought, of presenting the information about benefits and harms to aid the decision making process. Both sources of uncertainty should be acknowledged in comprehensive discussions of risks in patient decision aids.

Evidence for probabilities used. To enhance transparency and allow patients and practitioners to see for themselves where the probabilities come from, a technical appendix or something similar should be provided. This can outline the data sources, the populations from which the probabilities were obtained, and any calculations or modeling that was done to derive the probabilities in the patient decision aid. Developers may want to include a decision analyst or other experienced modeler on their team to help obtain useful probability estimates. In some instances, developers may use decision analysis to structure the patient decision aid. In such cases, if the probabilities used in the decision analysis are presented, they should be presented in accordance with these criteria.

Evidence

RCTs involving patients facing actual choices. Of 29 individual patient decision aids evaluated in the 34 RCTs included in the Cochrane Review, 19 were available for content review (O'Connor et al., 2003). Of these, 19, 17 (89%) patient decision aids contained some sort of information about outcome probabilities. There were some differences in the way this information was provided:

- 11 of 19 (58%) patient decision aids provided numerical data with outcomes reported as “x out of 100” and/or percentages (with consistent denominator of 100).
- 5 of 19 (26%) patient decision aids provided numerical data with outcomes reported as “x out of y” (denominators were not necessarily consistent).
- 4 of 19 (21%) patient decision aids provided graphical display of the data using pie charts, bar charts, or line graphs.
- 3 of 19 (16%) patient decision aids provided graphical display of the data using 100 faces diagram.
- 1 of 19 (5%) patient decision aids provided numerical data using a tabular format.

The Cochrane Review identified 7 randomized controlled trials that evaluated the effect of patient decision aids on patients’ perceived probabilities of outcomes: 4 of these compared a patient decision aid to usual care and 3 compared a simpler to a more detailed patient decision aid (O’Connor et al., 2003). Perceived outcome probabilities were classified according to the percentage of individuals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar patients.

All 7 studies (100%) showed a trend toward more realistic expectations in patients who received a detailed patient decision aid (i.e., included descriptions of outcomes and probabilities) compared to those who did not receive patient decision aids with this information included. However, only 6 of the studies had the power to detect a statistically significant difference (RR ranged from 1.3 to 2.3).

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Section D: Clarifying and Expressing Values

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Rationale/ Theory

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

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

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

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

Some patient decision aids not only encourage patients to clarify their values, but also to *share* them with others involved in the decision. Strategies may range from recording values, guiding/coaching patients in values communication, training practitioners in values communication, or sending recorded values to providers. Strategies that facilitate communication may increase the chances that they are discussed in counselling sessions and that patients receive the most valued option (Dodin et al., 2001; Guimond et al., 2003; Holmes-Rovner et al., 1999; O'Connor et al., 1999; Rothert et al., 1997).

Evidence

RCTs Involving Patients Facing Actual Choices (O'Connor, et al., 2003). Data were obtained from the Cochrane Systematic Review of patient decision aids in which 29 different patient decision aids were evaluated in 34 trials. Of these 19, 11 measured the match between personal values and choices (n = 3), and self-reports about feeling clear about the personal importance of benefits versus harms (n = 10). One trial explored the effects on practitioner's discussion of values.

Ways to clarify values. The most frequently used values clarification techniques in patient decision aids are:

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

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

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

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

Primary endpoints:

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

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

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

Feeling clear about personal values. Ten trials used a subscale of the Decisional Conflict Scale (O'Connor, 1995) to measure the extent to which patients feel clear about personal

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

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

Are more methods or more detailed methods better than fewer or less detailed methods? Of the 4 trials making this comparison (O'Connor et al., 1999; Dodin et al., 2001; Goel et al., 2001), 3 showed no significant differences and 1 showed differences in favour of more methods (O'Connor et al., 1998). When the results of all 4 trials were combined, the overall improvement was not statistically significant. The one trial that did show improvement (7.5 points out of 100) had feature descriptions that were very brief. In three trials whose basic feature descriptions were more detailed, there was no significant improvement.

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

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Appendix: Technical Descriptions

Values Clarification: Detailed Concepts:

Overall value attributed to options: A holistic judgment of the relative desirability / undesirability that an individual assigns to an option.

Values attributed to specific features of options: The relative desirability/undesirability that an individual assigns to an option's specific elements, including: i) the procedure/process involved; ii) the consequences or outcomes; and iii) the probabilities of the consequences.

Value of Procedure/Process: The relative desirability / undesirability that an individual assigns to the procedures, mode of delivery, timing, and/or duration involved in undergoing a particular option.

Value of Consequences/Outcomes: The relative desirability / undesirability that an individual assigns to the expected physical, emotional, and social effects of an option.

Value of Probabilities: The relative desirability / undesirability that an individual assigns to the chances of experiencing a particular physical, emotional, or social outcome if a particular option is chosen.

Evaluative *scores* can be elicited to indicate the *strength* of desirability / undesirability assigned to an option or its attributes.

Values Clarification Methods: Specific Types

Implicit Methods: Non-interactive. Balanced illustrative examples of what it is like to experience specific features of an option, including the procedures involved, the consequences (e.g., physical, emotional, and social functioning), or the probabilistic uncertainties. Underlying assumption is that these examples allow viewers to formulate personal value judgments. Viewers' values are not revealed as collectible data points.

Descriptive "Scenarios" Illustrative examples provided in text form. E.g. patient decision aid audio-guided booklets produced by the Ottawa group or decision boards provided by the McMaster group (e.g. O'Connor et al., 1998; Whelan et al., 2004).

"Patient Testimonials" Illustrative examples provided in video form. E.g. patient decision aid videos produced by the Foundation for Informed Medical Decision Making (e.g. Barry et al., 1997).

Explicit Methods: Interactive. After considering the relevant information about each option, the viewer engages in judgment tasks deliberately designed to reveal the viewer's overall evaluations and/or attribute evaluations as collectible data points.

Utility assessments: Relies on axioms of rationality. A person's values for outcomes are elicited [using standard gamble (yields SG utilities), time tradeoff (yields TTO utilities), or visual analogue scales (yields VAS scores)] (Kupperman et al., 2003).

Social Matching: Like implicit Patient Testimonials, but: a) illustrative examples show how other patients evaluate options' protocols, consequences, and probabilities, as well as how other patients use evaluations to arrive at choice; and b) viewer then asked to explicitly indicate which person's evaluations most closely match their own.

Balancing Techniques: Simplest form involves evaluating whether or not to select option 'A'. Steps:

- a) Standard features of option 'A' are visually displayed on a "weighing scale" in which the 'benefits/pros/advantages/reasons to choose Option A' are listed on the left, and the 'harms/cons/disadvantages/reasons to forgo Option A' are listed on the right.
- b) Person reviews standard features and adds others that are important in their situation.
- c) Person rates desirability / undesirability of each feature by shading or assigning stars (0 stars = not at all important to me; 5 stars = very important to me).
- d) Person makes an overall value judgment using a "leaning scale" anchored by 'Yes A' and 'No A', with 'unsure' situated in the middle.

More complex forms involve evaluating option 'A' relative to other option(s) B, C, etc. E.g. patient decision aid audio-guided workbooks produced and evaluated by the Ottawa group (e.g. O'Connor et al., 1998).

Threshold Techniques: Simplest form involves evaluating whether to choose option 'A' or option 'B'. Steps:

- a) Standard features of both options (their procedures, consequences, chances) are visually displayed in parallel columns.
- b) After considering this information, the viewer indicates initially preferred option.
- c) Then relative strength of preference for initially preferred option is gauged by hypothetically altering the level of one of the features (e.g., probability of a positive or a negative outcome) in either the preferred or the rejected option, until viewer gives up initially preferred option and switches to other option.

E.g. patient decision aids evaluated by Llewellyn-Thomas (1996; 1997).

Analytic Hierarchy Process: Steps:

- a) Begins with explicit definitions of the decision goal, the alternative options, and the criteria used to compare the options' abilities to meet the goal.
- b) These elements then organized into hierarchical decision model with the goal at top, alternatives at bottom, and criteria in middle.
- c) Elements on each level then compared relative to the element(s) on next higher level to derive ratio-level scale: for criteria, ratio-level scale indicates their importance relative to the decision goal; for options, ratio-level scale indicates how well they can be expected to meet the criteria.
- d) Finally, the information about the relationships among the elements on each horizontal level of the hierarchy is combined vertically to determine the relative abilities of the alternative options to meet the decision goal.

E.g. patient decision aids produced and evaluated by Dolan (1995).

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Section E: Using personal stories

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Rationale/Theory

Examples of others' experiences with decision making are used for four main reasons:

- to provide factual information to help patients understand the options and their associated outcomes;
- to demonstrate how patients value decisions differently;
- to share a range of opinions; and
- to exemplify the steps others have used to make decisions.

Traditionally, it has been argued that, to achieve informed consent, patients need evidence-based information about outcomes associated with all of the options and an opportunity to weigh up these outcomes in the context of their own values and lives. This approach assumes that information about outcomes is meaningful to patients. However, patients who are unfamiliar with a health state may find it difficult to imagine that health state, and the extent that it may affect their lives. An important part of processing evidence-based information is developing a vivid and authentic picture of the health states under consideration. A primary method that patients use to develop such a picture is to read about or listen to the stories of others who have experienced that state.

Most patients find such stories easier to process and recall than statistics. For example, facts and figures -- such as the mean number of times side-effects occur and the average intensity or severity of these side-effects -- are harder for many patients to understand than the stories of patients who have experienced these side-effects. The stories of patients who have actually experienced a health state are seen as having a level of authenticity that health professionals who have never experienced that health state cannot provide, even if they have particular expertise in that health state. For example, women with breast cancer suggested that the severity of lymphoedema was under-represented for many years by health professionals, who did not measure it correctly, or follow-up women for long enough to perceive the true prevalence of lymphoedema-related distress.

Furthermore, provision of balanced examples of how and why other patients have chosen certain options is seen as important for effective decision-making. It allows patients to learn not only what others choose, but also the reasoning or values behind these choices, with the different cases reinforcing the notion that decision-making is variable. As well, stories can exemplify the steps or process others have used in making the decisions. Whether or not stories are provided in patient decision aids, patients are likely to seek individuals who have experienced the decision

Although we know very little about the role of patient stories in patient decision aids compared to the many other sources of patient experiences' available, the inclusion of these stories in patient decision aids appears to be widely supported. However, a number of concerns about the inclusion of patient stories have been expressed. These include:

- The stories of a few individuals can never represent the experience of the majority, and yet these may over-ride consideration of more representative facts and figures.
- The selection of patient stories may provide a biased view. For example, only patients who are articulate, have strong motivations to tell their story, and speak the same language may be included. As well, even a “balanced” presentation of views can potentially give false impressions that there is an equal split in opinion about treatment, when in fact 90% of patients recommend or accept a particular option.
- Patients who have chosen a particular option are committed to supporting that option, for fear of regret. This has been called “cognitive dissonance” (i.e. the description of negative experiences arising from an option would be in conflict with the patients’ desire to believe that they had chosen the best option). Thus, the accounts of any patients who have already chosen a treatment option are likely to be biased.
- Long-term experiences when the disease is life-threatening can only be provided by patients who survived; by default, the experiences of those who benefited less are not available because these patients are no longer alive.
- Some patients’ stories may be elicited by unethical means. For example, drug companies may pay patients to provide a positive description of the outcomes of certain treatment options.
- There is often a mismatch between the rigor involved in the collection and presentation of evidence-based information about the effects of treatments, and limiting “patient stories” to a very few accounts from patients who are available, photogenic, or sufficiently literate to share their experiences.

Finally, appropriate, rigorous methods exist for researching and selecting patients’ experiences with health and illness (e.g. Popay, Rogers, & Williams, 1998) to ensure that the stories are evidence-based, cover the full range of experiences, disclose the context in which the decision was made, minimize the potential limitations of using patient stories, and maximize their value. With attention to the rigorous methods used to select patient stories, patients should find a perspective akin to their own that can facilitate rather than impede high quality decision making.

Evidence

Patients’ decision making needs. A cross-sectional telephone survey of 635 Canadians was conducted to describe decision-making needs of patients when faced with complex health decisions characterized by the need to balance benefits versus risks of various options (O’Connor, Drake et al., 2003). Over half of the participants reported obtaining support and information about what others decided. Of these, most cited their personal doctor (32%), friends (29%), *other patients* (27%), or other doctors (27%). Respondents were also presented with eight factors (including knowing what others decide or recommend) that could be considered essential criteria for concluding that a decision is satisfactory. Interestingly, all factors were strongly endorsed by participants (>89%), except for the factor referring to “others’ experience” (22%) (O’Connor A, personal communication, January 26, 2004). These observations suggest that, although patients value and desire others’ experiences to be included in patient decision aids, other aspects of patient decision aids -- such as knowing the main options and their pros and cons, or being satisfied with the choice made -- are considered more important patient decision aid components.

RCT’s involving patients facing actual choices. Of 29 individual patient decision aids evaluated in 34 RCTs in the Cochrane Review, 19 were available for review of their content (O’Connor, Stacey et al., 2003).

- 74% (14 of 19) included examples of others' experience. Of these 14, 8 provided testimonials, 4 provided examples of balance scales completed by others, 1 used group discussion, and 1 supplied regression weights.

Available evidence concerning inclusion of others' experience in patient decision aids is sparse, though increasing (Ubel, 2002).

Use of narratives. The use of narratives can make information more salient, easily imaginable, memorable, and more readily evaluated (Price & Czilli, 1996; Sanfrey & Hastie, 1998; Satterfield, 2001). Michielutte et al (1992) reported that a narrative style of text significantly improved comprehension, particularly among readers with low literacy skills.

Use of patient testimonials. Ubel, Jepson & Baron (2001) investigated whether the inclusion of patient testimonials in patient decision aids affects patients' treatment choices. Prospective American jurors were presented with hypothetical statistical information about the percentages of angina patients who benefit from angioplasty and bypass surgery (50% and 75% respectively). This information was supplemented by written testimonials from hypothetical patients, which had benefited or had not benefited from each of the two treatments. The numbers of patients benefiting/not benefiting were varied to be either proportionate or disproportionate to the statistical information. It was found that the percentage of participants expressing a preference for bypass surgery over angioplasty varied from 58% (among participants receiving no testimonials) to 30% (among participants receiving 1 positive and 1 negative testimonial for each treatment), even though all participants received identical statistical information about the effectiveness of the treatments. It was concluded that inclusion of written patient testimonials, when presented with statistical summary data on treatment effectiveness, significantly influenced hypothetical treatment choices. The number of testimonials in favour of either option strongly influenced choice.

Current research. Since the majority of studies concerning the inclusion of others' experiences have been conducted with non-patient populations, outcomes of similar studies within clinical settings still need to be ascertained. Associate Professor Peter A. Ubel and co-investigators are currently conducting a study to delineate the effect of patient testimonials on patients' treatment choices, and to find ways to minimize the chance that testimonials will distract patients from probabilistic information.

Simon Whitney and Michael Crouch, funding by a K-08 Career Development Award from AHRQ, are currently conducting a randomized controlled trial of a patient decision aid for statin therapy ("Statin Therapy Informed Choice"). In the self-administered version, a section entitled "What would my experience be like if I took a statin cholesterol medicine?", ten "mini-stories" depict the main foreseeable outcomes of the statin therapy decision. The likelihood that an individual's experience would be like that of the person in each mini-story is provided in terms of odds and "chances in 1,000" (based on data from the large statin trials). Thus, the investigators have tried to combine the hypothesized value of stories (for making possible scenarios seem more real) with a fact-based estimate of the likelihood that the stories are applicable to the individual.

In conclusion, the current evidence about this topic is limited and conflicting. It remains to be clarified whether it is possible to identify a 'best strategy' for the inclusion of others experiences in patient decision aids. It is likely that different conditions and types of decision will require different combinations of material, suggesting that the evidence will never be applicable to all, even if based on appropriate clinical populations. However, common issues include how to present balanced patients'

stories representing each outcome, and how to integrate the priorities expressed in the patients' stories with the statistical information about health outcomes.

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Section F: Guiding/Coaching in deliberation and communication

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Rationale/Theory

The objective of a patient decision aid is to help patients make a good decision — one that is well-informed, reflects the patients’ values, and is implemented. To support this goal, guidance and coaching methods may seek to do one or more of the following:

- Improve understanding by providing information, tailoring information, brainstorming and answering questions, and checking understanding;
- Clarify values by facilitating reflection, taking someone through values clarification exercises, and sharing others’ experiences;
- Improve deliberation by anticipating and avoiding common pitfalls (e.g. anchoring, mis-imagining, etc.) that can undermine effective decision-making, and taking someone through the steps of decision making.
- Improve patient - practitioner communication by helping patients prepare questions and concerns, by teaching skills for raising difficult subjects, and by providing a worksheet or list to share with doctor;
- Improve follow-through by helping patients anticipate and overcome barriers to implementing desired options
- Reduce emotional distress and anxiety and improve ability to use skills for coping and problem solving.

Avoiding decision traps. Patients and practitioners do not naturally follow the axioms of normative decision theory; however, when inconsistencies are highlighted, many willingly change their choices to be more aligned with the principles. Thus, explicit guidance in the steps of deliberation is often beneficial to help overcome some of common decision-making traps.

Quality of patient-provider communication. Open communication is essential for shared decision making. However, many studies have documented that, the quality of communication between patients and providers is poor. Good communication and strong patient-provider relationships have been linked to greater satisfaction and positive health outcomes. Poor communication, conversely, has been linked to dissatisfaction, conflict, and worse outcomes. Patients and practitioners may benefit from guidance in more open communication.

Ways of learning. Patients learn in different ways. Many patients prefer and find it more effective to learn from others as opposed to a book, video or pamphlet. Many researchers argue that learning and skill acquisition does not happen when individuals simply receive factual information but happens most effectively by actually engaging in the process, often with support of a mentor or coach.

Emotional distress. A new diagnosis can cause significant distress and anxiety, and can disrupt coping and problem solving skills. Coaching or counselling that can help patients reduce this emotional distress. Furthermore, anxiety may increase patients' desire and capability to participate effectively in decision making.

There is no single theory or method that has been used consistently or evaluated extensively to address all of these goals. Theories of decision making often do not address emotional or communication needs. Likewise, theories of communication, coping, and self-efficacy do not address issues of decision making under risk and uncertainty. Most guidance/coaching with patient decision aids has a limited focus – for example in, either enhancing understanding of information or clarifying values. There are very few data on the relative impact of the different methods on the quality of decisions, and thus limited evidence to support or refute any of the different theories for using guidance or coaching methods in patient decision aids.

Evidence

RCT's involving patients facing actual choices. Of the 29 individual patient decision aids, evaluated in the 34 RCTs included in the Cochrane Review, 19 were available for review of their content (O'Connor et al., 2003). Of these, 17 (89%) patient decision aids contained some sort of guidance/coaching in deliberation and/or communication. The amount of guidance varied considerably:

- 4 patient decision aids with a worksheet only were evaluated in 9 trials (Barry et al., 1997; Bernstein et al., 1998; Holmes-Rovner et al., 1999; Kennedy et al., 2002; Murray et al., 2001a; 2001b; Morgan et al., 2000; O'Connor et al., 1998; O'Connor et al., 1999; Rothert et al., 1997)
- 5 patient decision aids with a list of the steps of decision making and a worksheet were evaluated in 5 trials (Dodin et al., 2001; Goel et al., 2001; Man-son-Hing et al., 1999; McBride 2002; Rostom et al., 2002)
- 2 patient decision aids with a worksheet plus coaching were evaluated in 3 trials (Kennedy et al., 2002; Rothert et al., 1997; Holmes-Rovner et al., 1999)
- 6 patient decision aids with coaching only were evaluated in 7 trials (Davison et al., 1999; Davison et al., 1997; Dolan et al., 2002; Green et al., 2001; Holmes-Rovner et al., 1999; Lerman et al., 1997; Rothert et al., 1997)

The Cochrane Review found that more complex patient decision aids produced higher gains in knowledge, more realistic expectations, and a greater match between patients' values and choice. One trial found that patients in the study arm involving a patient decision aid plus coaching by a nurse had fewer hysterectomies and incurred lower costs than either of the other two study arms (patient decision aid only and control) (Kennedy et al. 2002). For the most part, the trials of patient decision aids do not compare varying intensities of coaching/guidance, and therefore the relative effectiveness of these methods is not clear.

Other evaluative studies. Many studies have documented poor quality of communication during medical consultations (Braddock et al., 1999; Marvel, Epstein et al. 1999). Examples of poor communication include: a) physicians tend to dominate the discussion and patients tend to withdraw; b) the focus is on medical facts, not thoughts or feelings; and c) the traditional medical interview that gets documented with the SOAP note does not leave room for shared decision making (Donnelley, 1992; Lipkin et al., 1995; Singer, 1992). A systematic review of RCTs found that the quality of patient-physician communication influences health outcomes

such as emotional status, symptom resolution, functional and physiologic status, and pain (Stewart, 1995). Some of the characteristics of quality communication included engaging patient in discussion of problem, encouraging questions and participation in decision-making about management, and discussion of emotions and feelings. Interventions designed to increase these behaviours have been shown to positively affect outcomes. (Greenfield et al., 1985; 1988) Without good communication, patients tend to become dissatisfied and disenroll from health plans (Davies et al., 1986), to change physicians (Kasteler et al., 1976; Kaplan et al., 1996), to initiate complaints against physicians (Roter, 1977), and to be non-compliant with medical recommendations (Korsch et al., 1968; Francis et al., 1969).

However, interventions that focus only on patients (such as many patient decision aids) or only on physicians (Keller & Carroll, 1994; Joos et al., 1996; Fallowfield et al., 1998) may have limited impact. Studies that engage both patients and physicians may have the biggest impact (Brown et al., 1999; Sepucha et al., 2000).

A review of psychosocial interventions in cancer care found that different psychosocial interventions (including education, behavior training, coping techniques and group support) may positively affect psychosocial outcomes, and increase participation in decision making (Fawzy et al., 1995).

Other relevant literature. The adult learning literature, as well as theories in organizational behavior and management science, suggests that learning is a social process, not merely the receipt of knowledge. Patients are more apt to learn when messages and information are targeted or tailored to their situation, their needs, and their concerns (Knowles, 1990; Knowles et al., 1998; Krueter & Ricardo, 2003). In addition, patients may be more apt to learn when helped by others, and when actually engaged in actions. (Argyris & Schon, 1978; Argyris et al., 1985; Bandura, 1982; Knowles et al., 1998; Lave & Wenger, 1991; Lewin, 1952).

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APPENDIX: Technical Descriptions

Detailed Concepts:

❖ Theories – Specific Types:

a) Normative Decision Theory (i.e. expected utility theory or subjective expected utility theory) posits a set of axioms to which decision makers should subscribe, in order to ensure that their actions are most likely to generate the results they desire (Fishburn, 1988; Howard & Matheson 1989).

b) Psychological Decision Theory attempts to explain the cognitive pitfalls that can lead to decisions that violate one or more of the axioms of rationality. One pitfall involves the heuristics commonly used by patients when they make judgements about events (Kahneman & Tversky, 2000; Redelmeier et al., 1993; Russo & Schoemaker, 1989; Tversky & Kahneman, 1981). Another pitfall involves the preference reversal phenomenon, which is a fairly pervasive inconsistency in patients' choices under uncertainty. The preference reversal phenomenon is explained by Prospect Theory (perhaps the most commonly-cited psychological decision theory), which argues that these inconsistencies depend on whether the options in a choice situation are framed in terms of the prospect of relative gains or relative losses.

c) Decisional Conflict Theory: Although the majority of behavioral decision theory highlights how often patients stray from the normative ideals, Decisional Conflict Theory took a slightly different approach by trying to define those conditions under which decision makers seem to follow a more vigilant process. Janis and Mann (Janis & Mann, 1977) studied emergency decision making, and found that decision makers tended to be more vigilant when they (a) realized a threat if they stay with the status quo, (b) realized a threat if they changed to the first alternative, (c) hoped that they could find some better options, and (d) believed that they have sufficient time to search and deliberate. This means that there needs to be some anxiety or conflict in order to motivate patients to deliberate, but not too much, or else it will interfere with cognitive processing. Anis and Mann also developed some interventions designed to promote vigilance and improve the quality of decisions. Some patient decision aids incorporate these techniques (e.g. balance sheet exercise).

❖ Methods – Specific Types:

a) Health Coaching: Greenfield, Kaplan, and colleagues (1985; 1988) pioneered the concept of health coaching. In their model, the coach's goals are to encourage patients during their clinic visit with their practitioner to: (1) ask questions, (2) recognize relevant medical decisions, and (3) negotiate these decisions with their provider. In addition, techniques were taught to have patients overcome potential barriers in discussions with their provider such as embarrassment, fear of appearing foolish, forgetting to bring up an issue, and intimidation by the provider. In several controlled trials of patients with different conditions (such as diabetes, hypertension, and cancer), they found that patients who underwent an intervention to better understand their medical condition and were coached to better talk with their provider were more active in the conversation with their provider, more assertive during these conversations, and elicited twice the number of factual statements from their provider. Patients in the intervention group also expressed a significantly stronger desire to participate in the medical decision making process.

b) Consultation Planning and Recording: Sepucha, Belkora and colleagues developed and evaluated a series of interventions designed to facilitate deliberation and improve communication in

medical consultations concerning decisions about treatment of breast cancer. The interventions (called Consultation Planning (CP) and Consultation Recording (CR)) are based in three disciplines: decision analysis, action research, and action science. They use a trained facilitator to elicit and structure a patient's questions and concerns (in CP), to share them with the practitioner, and then to use them as an agenda to guide the consultation, which is also facilitated and recorded (in CR). A notable aspect of these decision support methods is that the focus is not on information provision; instead, the goals are to uncover, order, and prioritize the understanding of patients and practitioners, to promote more open communication, and to facilitate a consensus that addresses the patient's values and needs. Two small controlled trials suggest that these methods significantly increase the quality of communication, the quality of decisions, and both patient and practitioner satisfaction with the process. (Sepucha et al. 2000; 2002) A large, multi-site randomized trial will evaluate CP/CR with or without shared decision making videos (developed by the Foundation for Informed Medical Decision Making), to explore the relative impact of information-focused and communication-focused support for patients with breast cancer.

c) The "E4" model rejects paternalistic and consumer-driven roles for physicians, and embraces the interpretive and deliberative visions of how patients and physicians should interact (Keller & Carroll, 1994). Further, this model encourages physicians to engage the patient, empathize with the patient, educate the patient, and enlist the patient. Keller and Carroll prescribe a specific class of interpretive and deliberative responses and run workshops to teach empathic communications to physicians (Platte & Keller, 1994). Physicians find these workshops useful; however, there is no evidence that their intervention improves the quality of communication in consultations with patients, or improves the quality of the patient-physician relationship.

Section G: Disclosing conflicts of interest

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Rationale/Theory

Patient decision aids should present unbiased information about the pros and cons of different management options for a medical problem. Bias can influence a patient decision aid's content either intentionally or unintentionally. Often, decisions about screening, diagnostic testing or treatment have financial implications for practitioners, their institutions, and for commercial companies that make and sell diagnostic or therapeutic products. These financial interests have the potential to bias the content of a patient decision aid, particularly when individuals or groups who stand to gain (or lose), depending on the management decision, are involved with the development and production of the patient decision aid. Ideally, individuals and groups with a financial interest in the management decisions addressed by a patient decision aid should not be involved in the development and production of that patient decision aid. However, at minimum, individuals or groups who had a potential financial interest in the content of the patient decision aid should be clearly and prominently acknowledged to users (patients and practitioners).

A definition of conflict of interest that is commonly used by medical journals is, "a set of conditions in which professional judgment concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by secondary interest (such as financial gain)"(Thompson, 1993). Practitioners and scientists who read research reports and reviews in medical journals represent a relatively well-educated audience, yet journal editors remain concerned about adequate disclosure of potential conflicts of interest by the authors of those papers. Users of patient decision aids often come from the lay public, and their ability to detect and evaluate the influence of potential conflicts of interests on the content of the programs they use may be poorer compared with medical professionals. Thus, patients may be more vulnerable to any bias incorporated into patient decision aids than medical professionals are to biases that may enter into scientific papers in medical journals. Moreover, patient decision aids may be developed and disseminated for use by patients or members of the public without the benefit of scrutiny by independent peer reviewers or an independent editor, as would generally be the case for papers in most peer-reviewed medical journals. Therefore, it seems reasonable that requirements for disclosure of potential conflicts of interests should be at least as stringent as disclosure requirements for medical journals. In addition, for a lay audience, explaining how the financial interests of any commercial funders relate to the patient decision aid's content seems like a reasonable approach to help patients and practitioners decide whether a program is likely to be biased by such interests. While a professional viewer might know that a particular funder makes or sells a product described as an option in the patient decision aid, a lay viewer might not.

Financial interests and professional biases may not be the only concerning influences on the content of patient decision aids. Practitioners-investigators may have built their academic careers by espousing a particular point of view that may then be reflected in a patient decision aid. Moreover, the scientific content on which a patient decision aid is based is itself subject to myriad potential conflicts of interest. However, these subtler forms of bias may be harder for lay viewers of patient decision aids to evaluate and understand based on an increasingly complex disclosure statement.

Evidence

Inventory of available patient decision aids. One of the CREDIBLE criteria for the evaluation of patient decision aids asks, “Was sponsorship free from perceived conflicts of interest?” In the most recent Cochrane review inventory of patient decision aids, reviewers rated 131 recently updated patient decision aids on this criterion. The ratings were as follows: ‘yes’ 96.2%, ‘no’ 0.8%, ‘not ascertainable’ 3.1% (O’Connor et al., 2003). These data suggest the reviewers usually found enough information about the funding sources of the patient decision aids to make a judgment regarding potential conflicts of interest, and that it was unusual to identify potential conflicts when funders were identified.

There are essentially no data on the impact of funding sources or specialty orientation on the perceived balance of patient decision aids. In fact, in the Cochrane review, data on ratings of patient decision aid balance could not be ascertained for 90.8% of patient decision aids.

Other evaluative studies. However, data from the world of medical scientific publishing and the relationships between professional specialty and variations in medical practice strongly suggest that financial interests or specialty-specific management preferences could bias patient decision aids. For example, in scientific articles, an analysis by Stelfox and colleagues (1998) found that journal articles about the use of calcium channel blockers were more positive about those uses when the authors had financial relationships with pharmaceutical companies that make and sell calcium channel blockers. While Barnes and Bero (1998) found that authors of reviews about the health effects of passive smoking were less likely to describe a negative relationship if the authors were funded by tobacco companies. Most remarkably, in both these cases, only the minority of relevant financial relationships on the part of the original authors were actually disclosed as part of the publication process; the authors of systematic reviews usually had to root them out through direct contact with the original authors. Specialty perspective can also have a strong effect on views regarding optimal medical management. For example, for clinically localized prostate cancer (a common topic for patient decision aids), urologic surgeons are much more positive about radical prostatectomy while radiation oncologists are much more positive about radiation therapy as a treatment option (Fowler et al., 2000). In cardiovascular care, cardiologists are more likely to recommend diagnostic modalities such as exercise tests and coronary angiography than primary care physicians are for the same patients.

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Section H: Delivering decision aids on the Internet

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Rationale/Theory

The Internet is one of several ways in which patient decision aids are made available. Other methods include video-cassettes, computer programs, decision boards, booklets, and audio-guided workbooks. The use of the Internet for making patient decision aids available is becoming more popular because of the increased accessibility for patients and the decreased costs for producing and distributing them. Patients go increasingly to the Internet to find answers to their health concerns and to get assistance in making health related decisions. However, information on the Internet needs not only to be valid and reliable, but also easily accessible and comprehensible. The design, usability, interface, logical organisation, and interactivity of an Internet site are crucial factors to enable patients to obtain the information they need.

Evidence

Inventory of available patient decision aids. Although patient decision aids have been available since the early 1980's, the use of the Internet as the medium of delivery has dramatically increased over the last 5 years. However, there has been little evaluation of the effectiveness of the Internet as the medium of delivery.

Of 131 patient decision aids that were available, updated within the last 5 years, and registered in the Cochrane Review of patient decision aids inventory (O'Connor et al., 2003):

- 73% (of 131) were available only on the Internet. Several other patient decision aids developed and evaluated as booklets or leaflets were also available on the Internet.

RCTs involving patients facing actual choices. None of the 29 individual patient decision aids that were evaluated in 34 RCTs included in the Cochrane review used the Internet as the medium of delivery in the study (O'Connor et al., 2003).

A recently published trial by Frosch and colleagues (2003) compared men considering prostate cancer antigen (PSA) screening a) who viewed a patient decision aid video in the clinic immediately prior to their practitioners' appointment with b) those who accessed the Internet-based patient decision aid at home. There was no difference between the groups in terms of participants' ratings of the convenience, effort, or satisfaction related to using the patient decision aids. Compared to the Internet group, men in the video group were more likely to use the patient decision aid (98.2% versus 53.5%), had significantly improved knowledge, and were more likely to decline PSA screening. Men in the Internet group who reviewed the entire online patient decision aid showed knowledge improvements similar to the video group.

Other relevant literature. The National Cancer Institute (NCI) provides Web design and usability guidelines based on research studies and supporting information from the field. Each guideline provides:

- A brief statement of the overarching principle that is the foundation of the guideline
- Comments that further explain the research/supporting information
- Source(s) of the research/supporting information
- A score indicating the "Strength of the Evidence" that supports the guideline
- One or more graphic examples of the guideline in practice.
(<http://usability.gov/guidelines/intro.html#1>)

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Section I: Balancing the presentation of options

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Rationale/Theory

The goal in patient decision making is to enable the patient to make an informed autonomous decision that reflects their personal preferences. To this end, patient decision aids provide patients with information about options and their consequences (benefits/harms) to help them clarify personal preferences. However, the goal of an autonomous decision also implies that the presentation of information should not favor a specific option (Hope, 1996). There is empirical evidence that variations in the presentation of information affects how health is perceived, and how therapeutic choices are made and acted upon (Herrin, 2001; Jorgensen & Gotzsche, 2004). For example, depending on the framing of the data (e.g. using mortality or survival rates), patients make different treatment choices (Bohmer & Sepucha, 2003). Furthermore, the way in which information is presented influences patients' satisfaction, knowledge, understanding, participation in decision-making, continuance of chosen options, coping with their situation, and search for further information (Christensen-Szalanski et al., 1987; Broyles et al., 1992; Inglis & Farnill, 1993; Phatouros & Blake, 1995; Michie et al., 1999).

When unbalanced, information can create therapeutic expectations that are impossible to meet, and can lead patients to unwittingly undertake interventions that carry chances of harms that they would not willingly accept. Since it is not only dishonest but unethical to create unrealistic expectations or to obscure the chances of harm (Raffle 1997; 1999; 2001), patient decision aids must aim to present information in a balanced manner that does not inadvertently persuade the user to accept or reject a particular option.

Evidence

- Inventory of available patient decision aids.*** Balanced presentation of information 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:
- 97.7% (of 131) presented potential harms as well as potential benefits;
 - 8.0 % (of 131) measured the degree of balanced presentation of benefits and harms from the user perspective; of these, the majority of patients found the patient decision aid balanced;

RCT's involving patients facing actual choices. Of the 29 individual patient decision aids, evaluated in 34 RCTs included in the Cochrane Review, 19 were available for review of content (O'Connor et al., 2003). Of these:

- All 19 (100%) presented potential harms as well as potential benefits;
- 4 (21%) measured the degree to which patients thought the presentation of benefits and harms was balanced. Three of these four reported that more than 2/3 of patients found the information balanced (see table 10.1). All four studies used a scale that was similar to the scale first reported by Barry and colleagues (1995).

Other evaluative studies. In 1995, Barry and colleagues asked men to indicate whether the information in a patient decision aid about the treatment of benign prostatic hyperplasia was slanted toward surgery, balanced, or slanted toward watchful waiting. Ratings were obtained on a five-point scale. As reported in table 10.1, 74% thought the patient decision aid was completely balanced. Of those who thought it was slanted, most indicated that it was slanted in the same direction to which they were leaning, which raises questions about the ability to accurately measure patients' perspective of information balance.

Barry et al.'s acceptability tool was also used in developing breast screening patient decision aids for women in out-of-target age groups (women 40 to 49 and women 70 and older) (O'Connor, Stacey, Barratt, Mai, 2003). Women within the target age group as well as practitioners affiliated with breast screening programs reviewed the patient decision aids. About half of the women found the patient decision aids slanted in favour of starting screening (40 to 49) or continuing screening (70 and older), while the others found them balanced. In contrast, several practitioners thought the patient decision aids were slanted against screening. These conflicting observations reinforce the uncertainty about whose perspective "counts" when assessing information balance and the challenges in obtaining an objective measure of balance.

Jorgensen & Gotzsche (2004) conducted a cross sectional study of mammographic screening information presented by major interest groups on 27 Scandinavian and English websites to determine if there were balanced accounts of screening's possible benefits and harm. They found that most websites omitted information about important harms and emphasised benefits in a way that would be expected to increase uptake of screening. For example, 12 sites mentioned the lifetime risk of developing breast cancer, usually followed by the annual number of diagnoses. In contrast, only three sites mentioned that women have a more than 50% chance of surviving breast cancer and only four stated that the lifetime risk of dying from breast cancer is about 3-4%.

Results of evaluations of balanced presentation of information presented in patient decision aids

Author (year)	Evaluation	Clearly slanted to favour most invasive intervention	Slightly slanted to favour most intensive	Completely Balanced	Slightly slanted to no favour	Clearly slanted to NOT favour invasive intervention
Barry et al., 1995 BPH treatment	N=373; prospective cohort study	1%	7%	74%	14%	4%
O'Connor et al., 1998; HRT	n=81 ; with in RCT	Not reported	Not reported	76%	Not reported	Not reported
Phelan et al., 2001; Back surgery	n= 41; with in RCT	Not reported	Not reported	60%	Not reported	Not reported
Volk et al., 1999; PSA testing	n=80 with in RCT	6%	10%	79%	4%	1%

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Appendix: Measuring balanced presentation

- a) When measuring the degree of balance in the presentation of options and consequences (benefits, harms), the users (patients, practitioners) personal predisposition towards an option should be elicited at baseline.
- b) For only two options:
A single question can be used to ask users (patients/practitioners) to rate whether the decision aid is slanted from strongly favouring option A through completely balanced to strongly favouring option B. For example:
How balanced and fair did you find the information presented in the decision aid (please check one)?
- Clearly slanted to option A
 - Slightly slanted to option A
 - Completely balanced
 - Slightly slanted to option B
 - Clearly slanted to option B
- c) For three or more options, there are two approaches that could be used to measure balance.
- i) For each option presented, ask users to rate whether the decision aid is strongly in favour of that one specific option through balanced to strongly in favour of the other options. For example:
How balanced and fair did you find the information presented in the decision aid (please check one)?
- Clearly slanted to option A
 - Slightly slanted to option A
 - Completely balanced
 - Slightly slanted to the other options
 - Clearly slanted to the other options
- ii) Ask users to respond to a single question as an indication of biasing the user in one direction. For example:
Did the program present one option as the best overall choice?
- Yes
 - No

Appendix: Interpreting the Results of Balance

- a) Calculate the percentage of users who rate it as completely balanced.
- b) Check the distribution of options that were identified as not balanced.
If the users are roughly equally scattered, this implies that the patient decision aid offers a balanced presentation. If there is agreement that the patient decision aid is slanted either consistently toward or consistently against an option, it is likely that the presentation of information needs to be revised. However, before making revisions, it is important to consider users baseline choice predisposition. Previous evaluation has found that users who already have a preferred option in advance of seeing a patient decision aid are more likely to rate it as “slanted” either in the same direction or away from their own preferences. They may have found the arguments that support their views to be more compelling or they may not have wanted to be made aware of or reminded of facts that are counter to their choice.

Section J: Using plain language

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Rationale/Theory

Patient decision aids are designed to present medical evidence that assists patients to identify screening, diagnostic testing, and treatment options, to determine their values associated with the potential harms and benefits of these options, and to participate in medical decisions. It is therefore, crucial that the text and graphics used to present this information are written in language that is easily understood. Ideally, patient decision aids should be comprehensible to everyone in the target audience, regardless of literacy level. However, medical detail required to describe harms and benefits is, by definition, technical language that is more challenging for readers to understand and particularly difficult for readers with limited literacy skills. These types of resources can be improved by applying the principles of plain language to a document's design, and by measuring readability.

Plain language. There is no gold standard for what constitutes plain language, although there is wide agreement about many attributes, based on research evidence, about reading, cognitive psychology, social marketing, usability, and document design. The 3 major categories of attributes are: 1) the use of everyday language and other clear writing styles; 2) well-structured, logically sequenced, and focused information; and 3) effective document design. When these attributes are used, even good readers have demonstrated improvements in speed and accuracy of reading. As well, in medical situations many adults lack the context necessary to understand and apply the information which further impairs the use of new information. Finally, patients faced with health decisions frequently experience heightened emotional stress which interferes with cognitive abilities. Therefore, developing patient decision aids using attributes of plain language is important for patients of all literacy levels.

Readability. The most valid and reliable measure of the level of a text's comprehension difficulty is its readability. Patient decision aids need to be as transparent as possible in describing the literacy level required to read or listen to the information provided. The majority (50% or more) of "the target population" should be able to understand the patient decision aid. Therefore, in general, the readability of patient decision aids should be at the level equivalent to grade 7 or 8 in the US. However, when patient decision aids are specifically targeted to lower

literacy populations, the readability level should be adjusted accordingly. Finally, the method used to assess readability should be reported with the readability levels.

Evidence

Literacy rates. According to the 1992 National Adult Literacy survey, about half of US adults read at or below the 7-8th grade level. The issue of literacy is of ongoing concern across many countries that include Australia, Canada, Germany, New Zealand, Sweden, the United Kingdom, and The US.

Plain language. There is some evidence that increasing reading ease improves comprehension, and emerging evidence of the effect on health outcomes. Poor literacy has been found to be related to lack of preventive health behaviors (e.g., cervical and breast cancer screening, influenza and pneumococcal immunization), increased risk of hospitalization, decreased ability to follow medical instructions (e.g., use of inhaler), and less control of chronic illness (e.g., glycemic control). However, several studies have shown that health outcomes can be responsive to interventions designed to improve the readability of materials. While the evidence is weak, and it is unclear whether interventions directed at improving readability will lead to better health outcomes, low literacy may be part of a complex of problems relating to poor health outcomes. A recent review identified 24 studies that examined interventions to improve health for persons with low literacy. These studies found mixed results about the interventions' ability to affect knowledge, intermediate markers of disease, disease prevalence and incidence, health behaviors, and use of health services. Few studies examined each type of literacy intervention (text, videotape, computer, oral presentation), therefore it is not clear which types of tools are most effective. Additional limitations included variability in the study designs, the interventions tested, and the outcomes assessed.

Readability measurement. There are well-validated tools for readability (e.g. SMOG, Fry). However, the easily accessible readability measures in word processing software are not very accurate or acceptable. Readability measures focus on the text, while more recent work on health literacy has focused on the abilities of the persons reading the text. Despite their limitations, these existing tools are helpful to good document design and should be used; in the meantime, investigators should re-validate them with various populations and develop more sensitive and specific tools to predict informed decision-making and health outcomes.

Inventory of available patient decision aids. There is no evidence found on the assessment of readability of patient decision aids and their suitability for particular audiences. Most of the 131 patient decision aids, in the Cochrane review inventory, were developed for general audiences (O'Connor et al., 2003). Further research should focus on: a) demonstrating which characteristics of patient decision aids enhance readability and improve comprehension resulting in better health outcomes; b) examining the use of patient decision aids in both low and high literacy groups to determine whether the intervention ameliorates differences according to literacy status; and c) determining whether interventions work directly to improve patients' knowledge and understanding or indirectly through other mechanisms.

Current initiatives. The research agenda in health literacy should be enhanced by the work of the Institute of Medicine in this field. The Institute of Medicine's report Health Literacy: A

Prescription to End Confusion, released in April 2004, highlights the scope of the problem and outlines a research and policy agenda with key recommendations.

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Literacy status of populations

National Assessment of Adult Literacy 2003 (NAAL) project will produce several published reports that address the status of literacy among adults in the U.S. and literacy trends over time. The working title of the principal NAAL 2003 national and state reports is: *Literacy Skills of America's Adults in Workplace, Family, and Community Settings*. Available at: <http://nces.ed.gov/naal/>

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Appendix: Measuring readability

Using a readability formula is a good first evaluation of any patient decision aid. The result, usually expressed in a grade level, gives an estimate of the level of reading difficulty. The formulas (e.g. SMOG, Fry) are generally valid within 1-2 grade levels and have good inter-formula correlation. Variation is largely due to different assumptions about level of reader comprehension. All formulas, however, are just indicators of reading ease or difficulty and should be used within a larger context of using plain language writing and design techniques.

Directions for using the SMOG are at this Harvard School of Public Health website: www.hsph.harvard.edu/healthliteracy. Directions for using the Fry are in “Doak, Doak, and Root (1996). Teaching Patients with Low Literacy Skills.”

If developers of patient decision aids want to use their computers to assess readability, they need to purchase software designed especially for this purpose (see references). The assessment software built into MS Word is not accurate and the Flesch-Kincaid formula as programmed in the software does not report a grade level above grade 12.

If using a computer program, the document must be “cleaned up” prior to running the readability analysis program. This includes deleting all titles and subtitles, extraneous periods (for example, after “Dr.”), and all bulleted lists. There may be other software instructions to follow as well.

Appendix: Resources for plain language writing

The following are several governmental and not-for-profit organizations’ guidelines for plain language that would be helpful to patient decision aid developers:

- www.plainlanguagenetwork.org
- www.plainlanugage.gov
- www.cdc.gov/publications.htm (publication at end of list titled “Simply Put” for CDC standards)
- http://oc.nci.nih.gov/services/Clear_and_Simple/HOME.HTM (These are NIH guidelines)
- www.usability.gov/guidelines/usability/guidelines.pdf (federal standards for website usability)
- www.discern.org.uk
- www.clear.nald.ca

Section K: Basing information on up-to-date scientific evidence

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Rationale

Use of accurate information. There is an expectation by patients and health professionals that patient decision aids are based on the most accurate information available. For a particular clinical decision, the patient decision aid should use the best available evidence to describe all the relevant health care options and their associated outcomes (benefits and risks). Ideally, the patient decision aid's evidence should be based on data from a systematic review(s), in which the published and unpublished literature is systematically searched for the highest quality studies, then summarized, if applicable, using meta-analyses. Normally, practice guidelines will carefully outline the quality of evidence of the benefits of different health care options. Ideally, the harms associated with the health care options described in the patient decision aid should also be supported by the highest quality of evidence available. On occasion, patient decision aid developers will have to perform their own systematic reviews to adequately identify the best available option/outcome evidence. In this situation, details of these reviews should be described in the patient decision aid's background material.

Source for accurate information. The quality of the information used in the patient decision aid has implications for the level of certainty placed on that information; patients have a right to know the limitations of the evidence supporting the effectiveness of different options. The best available option/outcome evidence should be characterized in terms of its quality, so that users (patients and practitioners) can appreciate the level of uncertainty regarding the likelihood that a particular screening/treatment option causes a particular therapeutic/harmful outcome. There are many rating systems for quality of evidence, ranging from high grade (usually a meta-analysis or randomized trial) to relatively low grade (often a cohort study or a case series) (Oxman et al., 2005). For example, data from a non randomized comparison cohort study regarding the efficacy of treatment is likely to be less certain than data from a large randomized trial.

- For studies of treatments, the highest quality of evidence regarding effectiveness comes from rigorous meta-analyses or large randomized trials.
- Observational studies (e.g. cohort studies or case control studies) are less likely to provide high quality evidence about the relationship between a particular screening/treatment option and a therapeutic effect.
- Descriptive studies, including case series, provide lower quality evidence about the relationship between an option and an outcome.
- With respect to the incidence of adverse effects, observational and descriptive studies may provide as good or better evidence than data from randomized trials.

Relevance of evidence. Information describing the therapeutic effectiveness of different treatment options in the patient decision aid should be directly applicable to the patients and practitioners who use it. This pertains not only to the population who will use the instrument, but also, in particular, to the intervention being described. For example, a patient decision aid describing the benefits and harms of adjuvant chemotherapy in women with breast cancer should be based on data from randomized trials or systematic reviews involving patients of similar age and stage of disease as the women who will be using the patient decision aid.

Tailored information to individual characteristics. When outcome probabilities are tailored to the clinical risk for different patient populations, evidence for the different risk groups or the risk assessment tool employed in the patient decision aid should be provided. Such evidence might include data from those studies and any secondary validation studies.

Regular updating of evidence. Information supporting different health care options can quickly become out-dated. Ideally, evidence supporting the information contained in the patient decision aid should be regularly updated at least every two to three years and preferably on a yearly basis. The process used for the update (i.e. whether a systemic review was performed) should be described. By providing a statement regarding the update policy, patients and practitioners can form their own opinions about the degree of confidence to be placed in the patient decision aid's information.

Evidence

RCTs involving patients facing actual choices. Of 29 individual patient decision aids, evaluated in 34 RCTs included in the Cochrane review, 19 were available for review of their content (O'Connor et al., 2003). Of these,

- 13 of 19 (68%) of DAs provided specific citation either within the patient decision aid (3 of 13) or in a separate resource (10 of 13).
- 5 of 19 (26%) described the quality of the evidence with 3 patient decision aids that were based on clinical practice guidelines
- 3 of 19 (16%) described the uncertainty in the evidence presented within the patient decision aid.

Two studies described how different risk groups used in the patient decision aid were identified.

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Oxman A, et al and the GRADE Working Group. Grading evidence and formulating recommendations.
Submitted for publication

Section L: Establishing the effectiveness

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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.

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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