2012 UPDATED CHAPTER A: USING A SYSTEMATIC DEVELOPMENT PROCESS

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SECTION 2: CHAPTER SUMMARY

What is this dimension?

While authors differ in the emphasis they place on particular aspects, key features common to all patient decision aid (PtDA) development processes include scoping and design, development of a prototype, 'alpha' testing with patients and clinicians in an iterative process, 'beta' testing in 'real life' conditions (field tests), and production of a final version for use and/or further evaluation.

What is the theoretical rationale for including this dimension?

It is important that PtDAs are carefully developed, user-tested, and open to scrutiny, with a well-documented and systematically applied development process. Users require assurance that the development process has been carried out to acceptable standards. Because poor quality decision aids have the potential to cause harm to patients and cause doubt to be cast on the concept of shared decision making more broadly, it is essential that those not involved in developing them are provided with sufficient documentation to check the validity and reliability of their development processes.

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

To date, only about half of patients' decision aids appear to have been field tested with patients, and even fewer had been reviewed or tested by clinicians not involved in the development process. Very few described a distribution strategy, and surprisingly few (17%) described a method for reviewing and synthesizing the clinical evidence. In many cases it was difficult to gauge from the trial reports whether a development process along the lines recommended in IPDAS had been followed or not. However, it is important to bear in mind that most of the PtDAs described in the RCTs included in the Cochrane Collaboration's review were developed before the publication of the IPDAS criteria.

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

a) Updated Definition

Patient decision aids (PtDAs) aim to provide evidence-based information to help people make health decisions. They are usually developed when there is more than one reasonable treatment, prevention, screening, or care management option. They take a variety of forms, including leaflets or booklets, computer programs, DVDs, or interactive tools for use online or in the clinic. Some include extensive information and filmed interviews to illustrate options and outcome probabilities, while others use decision analytic tools to elicit reactions to specific features and trade-offs. Some use face-to-face discussions or educational methods in combination with written material. All aim to present outcomes, risks, and uncertainties in a clear, comprehensible, scientifically valid and unbiased manner to help people make personally relevant value-based health decisions.

The PtDA development process has been described in a number of trial reports and associated articles (see below). In addition, several organizations developing suites of decision aids for commercial use have described their development processes. While different authors tend to place greater or lesser emphasis on particular aspects, key features common to all include scoping and design, development of a prototype, 'alpha' testing with patients and clinicians in an iterative process, 'beta' testing in 'real life' conditions (field tests), and production of a final version for use and/or further evaluation (see model development process below, in **Figure 1**).

The process is often overseen by a multidisciplinary steering group that includes patient and clinician representatives and other relevant stakeholders. Further detail on each of the elements is included below in **Table 1**.

Figure 1: Model Development Process for Decision Aids

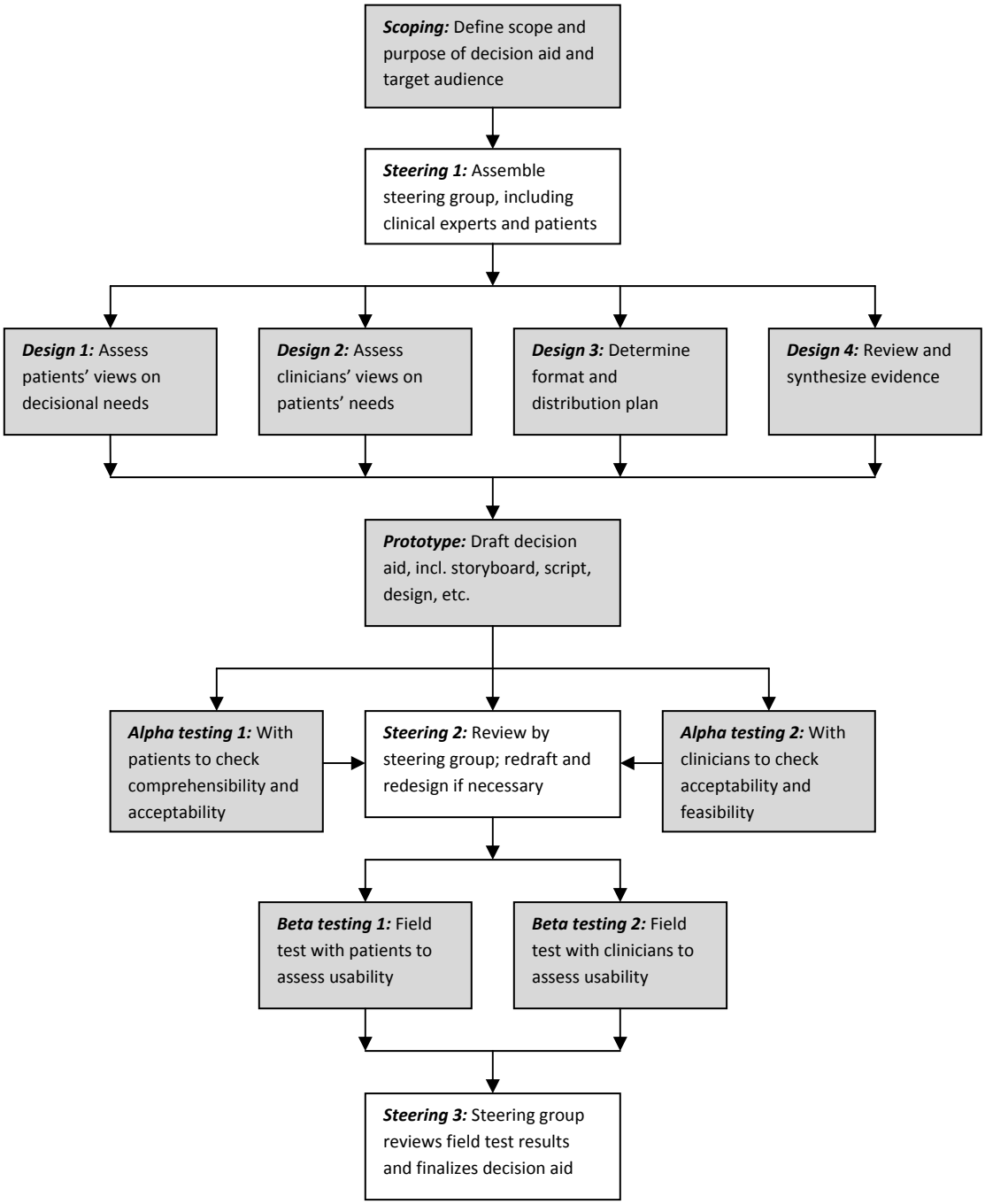

Table 1: Key Elements of Decision Aid Development Process[1]			
Element	**Definition**	**Methods**	**Comments**
Scoping	Describe health condition or problem; state the decision that needs to be considered; specify target audience	Developer advised by multi-disciplinary steering group, ideally involving topic experts, clinicians, and patients Likely to be informed by specific theoretical approach which may be explicit or implicit.	Explicit statement should be included in PtDA. All decision aid RCTs in Cochrane review included a description of the purpose and scope of the aid they were evaluating. Theoretical framework often unstated.
Steering group	A team of stakeholders who advise on the development, evaluation, and implementation of the PtDA	Steering group members will have relevant expertise in decision making for the specific topic: patient representatives, clinicians, patient educators, shared decision making expertise, policy makers.	Members should be familiar with and/or sympathetic to the concept of SDM.
Design 1 and 2 – Assess decisional needs [see Chapter B for further details]	Elicit patients' and clinicians' views on patients' information and decision support needs	Focus groups Stakeholder interviews Surveys Systematic literature review (including qualitative and quantitative studies) Direct observation	Few recommendations regarding optimal approaches to assessing decisional needs. RCTs included in Cochrane review reported patients' perspective on decisional needs more frequently than clinicians' perspective (43% vs 15%).

[1] Collated from a review of papers reporting trials that were included in the latest Cochrane Collaboration's review of decision aids (Stacey et al., 2011) plus associated papers describing 84 decision aids evaluated in randomized controlled trials (RCTs).

Design 3 – Determine format and distribution plan [see Chapter H for further details]	Includes choice of media and format of decision aid, setting, timing of introduction into patient pathway, how and when decision aid will be distributed to patients and/or clinicians	Formats may include print media, audio recordings, DVDs, videos, websites, computer programs, decision boards, face-to-face discussions, group education, and any combination of these. Distribution methods include handing out in clinic, mailing, telephone coaching, or direct-to-patient via websites or other means. Settings include primary care, secondary care, health coaches, community	Should be considered early in the development process. Some RCTs report complex methods that may not be suitable for widespread use. Less than a third (31%) of RCTs in Cochrane review included a description of how the decision aid would be distributed and used in routine clinical practice.
Design 4 – Review and synthesize evidence [see Chapters C, I, and K for further details]	Summary of clinical evidence relevant to the decision and options	Comprehensive literature search with emphasis on systematic reviews (when available). The evidence may include empirical studies of patients' experience and/or preferences. Use quality criteria to assess clinical practice guidelines when these are used as evidence source. It may be more efficient to develop PtDAs alongside clinical practice guidelines, since they draw on the same evidence base.	Frameworks provide little guidance on selection of relevant outcomes, how to minimize bias, address potential financial conflicts of interest, reach consensus, or deal with poor-quality or inadequate evidence. How clinical evidence was appraised and selected for inclusion in the decision aid was reported in only a small minority of RCTs included in Cochrane review (17%).

Prototype development	Draft decision aid, including storyboard, script, graphics, web design, video, etc.	Ranges from basic to highly sophisticated.	This aspect of the development process is rarely reported in any detail.
Alpha testing	Direct feedback from 'typical' users sought during the development process. This may include members of the steering group and others involved in the development process.	Review by key stakeholders (patients, clinicians) via focus groups, cognitive interviews, direct observation, usability, and acceptability testing. Feedback may be sought at various stages in an iterative process.	Specific methods, observations, and results often not reported. RCTs included in Cochrane review reported patient testing more frequently than clinician testing (37% vs 21%).
Beta (field) testing	Testing with patients (and occasionally providers) in 'real-world' settings to assess feasibility.	Small-scale observational pilot studies often precede larger randomized controlled trials. Review and field testing should be carried out with patients and clinicians who have not been involved in the development process. Offering clinicians the opportunity to review and comment on the materials may be essential if they are to be persuaded to recommend the PtDAs to their patients.	Field testing often focuses on use of tool in settings that may not reflect 'real-world' use; provider reactions not routinely assessed. RCTs included in Cochrane review reported results of field tests with patients more often than clinicians' reactions to decision aid (51% vs 19%).

b) Changes from Original Definition

The new definition includes all the elements of the original, but they have been renamed and reordered to clarify the different phases of the development process. The description of PtDA design has been expanded to include consideration of format and distribution plans, and we have also added a section on prototype development. Our aim was to provide a clearer overview of the entire development process. Where appropriate, we have included pointers to other sections in the updated IPDAS document where more detailed descriptions will be found.

c) Emerging Issues/Research Areas in Definition

- Optimal methods for determining decisional needs require further development and testing.
- There may be much to be learnt from development processes and quality standards in related areas; examples include general information materials, user-centred web design, or guidelines for evaluating complex interventions (McGee, 2010; Cato, 2001; Craig et al, 2008).
- Comparison of PtDAs and clinical practice guidelines and the scope for developing these in parallel should be evaluated.
- There is no consensus on how to select material for inclusion in decision aids. Studies should evaluate how much information patients want/need and how much detail is required.
- Studies should compare the effectiveness of different PtDA formats and delivery mechanisms.
- More guidance is needed to inform PtDA alpha- and beta- tests, including user-centred design methods, acceptability, usability, and feasibility testing. The process of designing the PtDA remains rather subjective. When does the iteration stop? What is saturation?
- There is little evidence on the relative importance of each of the above-mentioned features of the development process. Most have emerged from practical experience supported by consensus, but we do not claim they are evidence-based.

SECTION 4: THEORETICAL RATIONALE FOR INCLUDING THIS QUALITY DIMENSION

a) Updated Theoretical Rationale

It is important that PtDAs are carefully developed, user-tested, and open to scrutiny, with a well-documented and systematically applied development process. Some decision aids have been designed for one-off use in studies to advance knowledge, while others are intended for wider use in a range of real-life clinical settings. Some have been developed by academics, some by clinicians, some by voluntary organizations, and some by commercial companies. Whatever their provenance or purpose, users require assurance that the development process has been carried out to acceptable standards. Poor quality decision aids have the potential to cause harm to patients and they could also cast doubt on the concept of shared decision making more broadly, so it is essential that those not involved in developing them are provided with sufficient documentation to check the validity and reliability of their development processes.

b) Changes to Original Rationale

Wording changes only.

c) Emerging Issues/Research Areas in Rationale

- There is a need to assess the strengths and limitations of different theoretical frameworks and their usefulness or otherwise in designing and implementing PtDAs.

- Better understanding of the barriers and facilitators to adoption of shared decision making and the needs of the various stakeholders will be essential to ensure successful development and implementation of high quality, useful, and relevant decision aids.

- There are efforts under way to develop systems for certifying patient decision aids in both the US and the UK, for example, as part of regulations supporting widespread use of certified PtDAs in routine practice. Any accreditation scheme will require a set of agreed-upon standards and careful documentation of the processes by which the PtDA was developed. These schemes should be monitored and evaluated to see if they help to raise standards in decision aid development.

SECTION 5: EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION

a) Updated Evidence Base

Despite the proliferation of patient decision aids, detailed information on the processes by which they are developed is limited. Some groups that have developed multiple PtDAs have proposed guidelines for their development (Elwyn et al., 2011; O'Connor et al., 1998; Raats et al., 2008), or described insights generated by a particular approach (Montori et al., 2007). The following is a brief overview of selected approaches to decision aid development.

Ottawa Decision Support Framework: O'Connor (1998) is among the earliest authors to describe the development of a PtDA, and the Ottawa Decision Support Framework (ODSF) guided the development of at least 22 of the PtDAs included in the Cochrane Collaboration review. Based on expectancy value, decisional conflict, and social support theories, the framework includes three key elements: 1) assessment of determinants of decisions (both patients' and providers'); 2) provision of decision support interventions to prepare the patient and provider to make and implement a decision; and 3) evaluation of the success of the interventions at improving the quality and outcomes of the decision process. Additional detail is provided to define determinants of decisions, such as sociodemographic and clinical characteristics; patients' and providers' perceptions of the decision and of what important others think about the decision; and resources (both personal and external) available to make the decision. The authors note that the goals of decision support are to address modifiable and suboptimal decision determinants, such as inadequate knowledge, unrealistic expectations, unwanted pressure, and inadequate support, and they encourage the use of tailored outcome probabilities, detailed descriptions of benefits and risks, and information on the opinions and perspectives of others (both clinicians and patients) on the decision.

Using the example of a decision aid aimed at helping women decide about use of postmenopausal hormone therapy, O'Connor (1998) outlines an iterative development process involving the research team and panels of patients and experts, with the PtDA content based on clinical guidelines, and structured guidance in clarifying values and implementing a decision is provided by a personal worksheet.

Commentary: The Ottawa Framework is particularly relevant to 'preference-sensitive' decisions, which involve careful deliberation and consideration of tradeoffs among options. Perhaps because the PtDA developed by O'Connor was based on an existing high-quality clinical guideline, the framework provides little advice for how developers should review and synthesize the relevant clinical evidence. The framework also does not address how developers might deal with conflicts of interest, achieving consensus on the evidence, maintaining the PtDA content over time, or implementation outside research settings.

Cardiff University: Based on their experience developing three web-based PtDAs over a seven-year period, Elwyn and colleagues (2010) proposed a development process for web-based decision support interventions. This systematic "process map" includes 3 main steps: 1) content specification, with an emphasis on ensuring that patients' perspectives on the proposed options are sought and included in addition to synthesis of the scientific evidence; 2) design, including storyboarding, an iterative phase of trial and experimentation called "sandpit" testing, and usability testing; and 3) field testing with patients facing the decision and clinicians who are interacting with them. The process calls for key documentation, including: a protocol document that explains the decision and highlights the rationale for developing a PtDA; evidence synthesis based on systematic reviews or comprehensive literature searches; storyboard; and technical specification document to guide the website development. Their projects were overseen by a project management group, which retained editorial control, and included involvement at all steps by key stakeholders including clinicians, patients, and policymakers. Unique challenges faced by developers of web-based tools are highlighted, including decisions regarding navigation (free vs. mandated) and use of interactivity (audio, video, gaming, avatars, etc.) in ways that add value and enhance ease of use yet avoid over-engineering. The authors find little evidence to inform best practices in these areas.

Commentary: The process outlined by Elwyn and colleagues is widely applicable across a range of situations for which decision support interventions may be developed (i.e., screening, treatment, etc.) and a variety of media (although some of the concepts included, such as storyboarding, are adapted from film production). However, as the authors acknowledge, the process is time-consuming and costly: three PtDAs developed using this process each took two to three years to develop and test. Insights gained from early efforts could be generalized to create templates to allow more efficient, less costly future development. The process outlined does not offer recommendations regarding conflict of interest, processes for achieving consensus on the evidence, maintenance of PtDA content over time, or implementation outside research settings.

Dutch Institute for Healthcare Improvement: Researchers at the Dutch Institute for Healthcare Improvement reported on the development over a 12-month period of 6 decision aids based on existing evidence-based clinical guidelines (Raats, 2008). Citing the Ottawa Decision Support Framework (O'Connor, 1998) and the IPDAS standards, the authors followed four key steps: 1) establishment of criteria and selection of topics; 2) assessment of patients' information needs via literature review and focus groups; 3) drafting of the aid, including iterative review by a

multidisciplinary working group of health professionals, guideline developers, decision-making experts, and patients, and with reference to existing aids on the topic; and 4) endorsement of the aid and establishment of ownership and responsibility for the maintenance and updating of both the supporting guideline and the decision aid itself. With regard to implementation, the authors call for concomitant development and coordinated release of clinical practice guidelines and accompanying PtDAs that support their application, and for identifying and acknowledging early in the guideline development process any so-called 'grey zones' of uncertainty regarding patient preferences.

Commentary: The outlined process appears efficient and scalable when high-quality evidence-based practice guidelines are available. However, the authors acknowledge that additional research is needed to evaluate the effect of the aids in practice within the Dutch health care system. The evidence synthesis step used by other developers is addressed by use of national evidence-based guidelines; the authors note that these should also meet internationally accepted quality criteria (e.g., AGREE, 2003). The resulting tools include a values-clarification method, but the process by which the method was selected and 'populated' with non-directive, standardized questions is not defined.

Mayo Clinic: Montori and colleagues describe insights gleaned from the pragmatic process they followed to develop the Statin Choice decision aid for patients with diabetes (Montori, 2007), which was evaluated in an RCT included in the Cochrane Collaboration review. In particular, the authors highlight how deliberate observations of how patients and clinicians make decisions during office visits, and of early prototypes in use during patient-provider encounters can inform the ultimate format, design, and content of the final PtDA. Similar to other developers, their experience reinforces the importance of flexibility, iteration, and involvement of patients and clinicians throughout the process.

Commentary: This article does not recommend a particular development process, but rather offers insights unique to the approach their research group chose. The direct observation methodology that Montori and colleagues describe may complement more traditional needs assessment approaches for informing developers about what patients and physicians need from a PtDA. Observing early prototypes in the setting they are being designed for can also be an important step in ensuring that the intervention will work as intended and have the desired effect on the decision making process. These insights also highlight the importance of flexibility during the early stages of design and development.

Informed Medical Decisions Foundation: Developers that produce PtDAs for both research purposes and for public distribution, such as the Informed Medical Decisions Foundation (IMDF), provide details of their development process on their organization's website. Ten of the RCTs included in the most recent Cochrane Collaboration review were conducted using PtDAs developed that used this process. IMDF lists the following elements in their PtDA development process: 1) involvement of healthcare providers representing key clinical specialties, overseen by a clinician who divests him or herself of any potential financial conflicts of interest; 2) involvement of patients at several stages, including needs assessment via focus groups and literature reviews; and 3) review and evaluation of PtDA drafts by providers and patients prior to their release for general use. The approach outlines processes for evidence review and synthesis, disclosure of funding source and conflicts of interest, and periodic review and updates.

Healthwise: Healthwise has almost certainly developed more PtDAs than any other organization. They provide details of their tools and development process on request, but their PtDAs have not

been evaluated in published trials. Their materials are developed by multi-disciplinary project teams using a four-step process: planning, research, writing, and review, following guidelines that ensure the content is accurate, easy-to-use, and easy to understand (K. Baker, personal communication). Ongoing surveillance and updating is a key step in the process, and hundreds of patients provided input during a recent redesign of the organization's decision aid portfolio. However, few details are available regarding how the developers select and synthesize the relevant clinical evidence or deal with conflicts of interest.

Review Methods for this Update

We reviewed papers describing 84 decision aids that had been evaluated in RCTs and included in the latest update of the Cochrane Collaboration review of decision aids (Stacey et al., 2011). Our review focused on descriptions of the development process. These were assessed against a specially designed checklist that included the original IPDAS description of a systematic development process as well as additional components drawn from the various processes described above and illustrated in our model. Since many trial reports included only cursory descriptions of decision aid development, we also reviewed linked papers cited in the trial reports, of which the following were the most useful (Kasper et al., 1992; Barry et al., 1995; Spunt et al., 1996; Sawka et al., 1998; Green & Fost, 1997; O'Connor et al., 1999; Kasper et al., 2006; Breslin et al., 2008; Nassar et al., 2007; Vandemheen et al., 2010; Whelan et al., 1995; Whelan et al., 1999).

As indicated above, only about half of the PtDAs appear to have been field tested with patients, and even fewer had been reviewed or tested by clinicians not involved in the development process. Very few described a distribution strategy, and surprisingly few (17%) described a method for reviewing and synthesizing the clinical evidence. In many cases it was difficult to gauge from the trial reports whether a development process along the lines recommended in IPDAS had been followed or not. However, it is important to bear in mind that most of the PtDAs described in the RCTs included in the Cochrane Collaboration's review were developed before the publication of the IPDAS criteria.

An analysis of data from the iCoCo study carried out for the purposes of this review showed that PtDAs that scored highly on having a systematic development process also scored highly against other IPDAS criteria. However, there was no evidence from the small sub-sample of studies in iCoCo to support the hypothesis that a systematic development process results in a demonstrably better gain when using PtDAs in randomized trial conditions (Joseph-Williams, 2011).

b) Changes from Original Evidence Base

This section has been completely rewritten. The original described evidence on patients' information needs which is now covered in Chapter B.

c) Emerging Issues/Research Areas In Evidence Base

See above.

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APPENDIX:
ORIGINAL CHAPTER A

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Original 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

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.

Original 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.

RCTs 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.

Original References

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