

WORKBOOK ON DEVELOPING AND EVALUATING PATIENT DECISION AIDS



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WORKBOOK OBJECTIVES

OBJECTIVES:

1. To understand the process of developing and evaluating aids that facilitates the health-care decision making of clients and their health care professionals.
2. To identify sources of existing decision aids.
3. To understand the efficacy of aids to support decision making in health.
4. To plan the development and feasibility testing of a decision aid.

DECISION AIDS TO ASSIST PATIENTS TO PARTICIPATE IN CHOICES ABOUT PROFESSIONAL CARE OPTIONS

A. What is a decision aid?

Patient decision aids or “shared decision making programs” are interventions for preparing patients for decision making about professional care options. They are meant to supplement rather than to replace the counselling provided by health practitioners. According to the Cochrane Collaboration (1), decision aids for professional care options are defined as:

..interventions designed to help people make specific and deliberative choices among options by providing (at the minimum) information on the options and outcomes relevant to the person’s health status. Additional strategies may include providing: information on the disease/condition; the probabilities of outcomes tailored to a person’s health risk factors; an explicit values clarification exercise; information on others’ opinions; and guidance or coaching in the steps of decision making and communicating with others. Decision aids may be administered using various media such as decision boards, interactive videodiscs, personal computers, audiotapes, audio-guided workbooks, pamphlets, and group presentations.

Excluded from the definition of decision aids are passive informed consent materials, educational interventions that are not geared to a specific decision, or interventions designed to promote compliance with a recommended option rather than a choice based on personal values.

Decision aids have been developed for: a) medical therapies for atrial fibrillation, benign prostatic hypertrophy; low back pain, cancers of the breast and lung, leukemia, lymphoma, circumcision, and ischemic heart disease; b) diagnostic tests such as amniocentesis and screening for colon and prostate cancers; c) preventive therapies such as Hepatitis B vaccine and hormone therapy at menopause; d) clinical trial entry decisions; and e) end-of life decisions such as resuscitation in seniors (1,).

B. When do you need a decision aid?

The need for a decision aid may depend on whether the potential health care strategy is considered a “standard of care”, a “guideline”, or an “option”. For example, insulin for Type I diabetes or antibiotics for a bacterial infection would be considered **standards of care** because there is strong evidence of their effectiveness and strong agreement among patients that these are valued interventions. Therefore, there is relatively less discussion about *whether* the patient should take this intervention and more discussion on *how* they should take it. In the case of guidelines, there may be more uncertainty for patients and practitioners. Although the evidence about the outcomes of the interventions is known, there is less agreement among patients regarding values: not everyone agrees that the benefits outweigh the risks. For example, there is good evidence that amniocentesis for pregnant women over 35 is effective in detecting abnormalities, but not all women choose the procedure because their values differ. Interventions are classified as **options** of care when evidence on outcomes is known or unknown, and agreement on values may be even more variable, or unknown. An example of an option that emerged in 1998 is Tamoxifen to prevent breast cancer in healthy but high risk women. One

large trial showed a benefit in reducing the risk of breast cancer and two smaller trials did not show a benefit. Moreover, the benefits in the large trial were also accompanied by an increased risk of endometrial cancer and vascular events such as thrombophlebitis and pulmonary embolism. When the large trial results were published by the U.S. National Cancer Institute on the Internet, the following information was provided:

“Based on the [trial] ..results, should women who are at increased risk of breast cancer take tamoxifen? Women at increased risk of breast cancer now have the option to consider taking tamoxifen to reduce their chances of breast cancer. ...the decision is an individual one in which the benefits and risks of therapy must be considered. The balance of these benefits and risks will vary depending on a woman’s personal health history and how she weighs the benefits and risks. Even if a woman is at increased risk of breast cancer, tamoxifen may not be appropriate for her”.

C. Do decision aids work?

Evaluation studies from a Cochrane systematic overview of trials (1) and two general reviews (2,3) have shown that decision aids improve decision making by:

- reducing the number of patients who are uncertain about what to do;
- increasing patients’ knowledge of the problem, options, and outcomes;
- creating realistic personal expectations of outcomes;
- improving the agreement between choices and patients’ values;
- reducing decisional conflict and the factors contributing to decisional conflict such as feeling informed, clear about values, and supported in decision making; and
- increasing participation in decision making without adversely affecting anxiety.

The impact of decision aids on satisfaction with decision making is more variable. More research is needed on which decision aids work best with which decisions and which types of patients. We also need to evaluate their acceptability to practitioners and diverse groups and cultures, their impact on client-practitioner communication, and their effects on compliance with choice, health-related quality of life and appropriate use of services.

D. How do you develop and evaluate a decision aid?

Steps in Developing and Evaluating a Decision Aid

1. Assess *need*.
2. Assess *feasibility*.
3. Define the *objectives* of the aid.
4. Identify the *framework* of decision support.
5. Select the *methods of decision support* to be used in the aid.
6. Select the *designs* and *measures* to evaluate the aid.
7. Plan *dissemination*.

As summarized above, there are seven steps we use when developing our decision aids in Ottawa (4). When considering each step, there are several questions developers need to ask themselves and there are certain methods that can be used to answer the questions that are posed. These are described briefly below.

1. Is there a need for a decision aid?

Needs assessment involves the compilation of evidence about the nature of the decision difficulty, the numbers affected, practice and preference variation, availability of aids elsewhere, and demand for the aid. Methods for needs assessment are varied and data are obtained from primary and/or secondary sources. It is important that needs are defined from the perspective of potential users, both patients and practitioners. The perspective of managers and third party payers may also be necessary. Useful questions here include:

What are the decision making needs of patients and practitioners?

Needs are assessed using key informant interviews, focus groups, or surveys. They elicit patients' and practitioners' perceptions of: decisions perceived as important & difficult; usual roles and decision making practices; barriers & facilitators in providing or accessing decision support, and potential strategies for overcoming barriers.

What makes the decision difficult?

This can be determined by examining published systematic overviews, decision analyses, and preference studies. These types of studies may indicate whether the decision is characterised by: small or uncertain benefits; uncertain or material risks; the need to make value tradeoffs between benefits and risks; and variation in patients' preferences for outcomes

Are sufficient numbers affected and how are they affected?

This question can be answered by reviewing data bases, population surveys, and statistics on demographic characteristics of the population, morbidity, and mortality.

Is there sufficient variation in utilization?

Utilization information can be obtained from practice atlases (5, 6), utilization data, and practice variation studies

Are there decision aids available to meet these needs?

The answer to this question is obtained from a review of published overviews and reports. It is also useful to preview the Cochrane Register of Decision Aids (7).

Is there a demand for decision aids and what methods are preferred?

Market surveys of practitioners and patients are useful to determine demand for an aid.

2. Is it feasible to develop a decision aid?

Feasibility is assessed to determine that the aid can be developed with available evidence and resources and delivered and updated in a timely, accessible and acceptable manner. Useful questions here include:

Are there adequate resources?

Developers need to assess their financial resources to undertake such work. They also need to ensure they have experts with the external credibility, access to dissemination networks, and commitment to ongoing update. If these are lacking, developers need to link to established evidence evaluation and dissemination networks.

Is there enough evidence of benefits and risks to incorporate into a decision aid?

Information is obtained from systematic overviews with appraisals of the quality of evidence. It is also helpful to review ongoing trials and talk to experts to determine how quickly the evidence expected to change.

Can delivery be accessible and acceptable to users?

These questions can be elicited in focus groups and market surveys.

3. What are the objectives of the decision aid?

The objectives of the decision aid should be stated explicitly. They influence the selection of the framework, intervention strategies and evaluation methods. The objectives of the decision aid should identify what will be achieved. The objectives should be clear, specific, and measurable, and relevant for the situation. Preferably, they should be stated from the perspective of the user. They can range from general to specific and from short-term to long-term.

An example of a broad general objective is: “To improve the decision making of patients and their practitioners who are considering options for treating benign prostatic hypertrophy.”

An example of a specific objective is: “To improve patients’ knowledge of options and outcomes regarding treatments for benign prostatic hypertrophy.”

The short-term or long-term objectives depend on what ends are viewed as desirable (2). Some see “evidence-informed patient choice” as the desired end. This means that patients make a choice that is informed by the scientific evidence about the potential benefits and harms of the available options. It is based on the belief that we have a basic moral obligation to provide individuals with sound information as well as choice about their health care. Therefore if a person makes a choice based on adequate knowledge of options and realistic expectations of potential benefits and harms, then the desired end has been achieved.

Some would argue that evidence-informed choice is not sufficient unless it leads to other beneficial outcomes such as greater clinical effectiveness, health gain, individually appropriate utilization, reduced expenditures on inappropriate interventions, reduced litigation etc. The short-term objective of making an informed choice is therefore viewed as a means to another desirable end.

Reflection Exercise: What is a good decision?

Think about your views on this issue.

What would convince you that a person had made a good decision?

What would convince you that a person had used a good decision making process?

Note: For further readings on what experts have to say, reference (8) has several points of view.

Now consider the objectives you would like to achieve in your decision aid.

DEFINING THE OBJECTIVES OF A DECISION AID

Write the objectives of your decision aid in your own words:

Are there any objectives listed below (✓) that apply to your situation.

- ☐ **Improve decision making of patients and practitioners.**
 - ☐ Improve patients'/practitioners' knowledge of the clinical problem, options, outcomes, variation in patient/practitioner opinions and practices.
 - ☐ Create realistic expectations of outcomes, consistent with available evidence.
 - ☐ Clarify patients' personal values for outcomes and promote congruence between patients' values and choice.
 - ☐ Reduce patients'/practitioners' decisional conflict (uncertainty) about the course of action to take.
 - ☐ Promote implementation of choices.
 - ☐ Improve patients'/ practitioners' satisfaction with decision making.
 - ☐ Other, specify
- ☐ **Improve outcomes of decisions.**
 - ☐ Promote patients' persistence or compliance with choice.
 - ☐ Reduce patients' distress from consequences of decision.
 - ☐ Improve patients' health-related quality of life.
 - ☐ Promote informed use of resources by patients/practitioners.
 - ☐ Other, specify

4. Which framework will drive its development?

Depending on the objectives, several frameworks are available to guide decision aid development. Compete references to these frameworks are provided in the annotated bibliography at the end of this section.

Charles, Gafni and Whelan focus on features distinguishing shared decision making from other models of decision making (9).
Entwistle defines evidence-informed choice and outlines different criteria for evaluation (10).
Llewellyn-Thomas places decision support in a broader sociopolitical context and expands on the types of preferences one can elicit from patients (11).
Mulley places shared decision making in the context of outcomes research (12).
The Ottawa framework emphasizes the preparation of both the patient and practitioner using a decision making behaviour framework that separates the effects of each decision support method (13).
Rothert et al also describe the mutual roles of patients and practitioners in decision making, with a focus on information and values (14).

These 'decision support' frameworks may need to be supplemented by others. For example, if decision making behaviour is strongly influenced by biological factors (e.g. addictions), other constructs need to be added. If a key challenge is not only deliberating about options, but also implementing options and maintaining behavioural change, models of change and behaviour such as Prochaska's stages of change or the Precede Precede Model may be relevant.

THE OTTAWA FRAMEWORK OF DECISION SUPPORT

The Ottawa Framework identifies several determinants of health care decisions that may be suboptimal and are potentially modifiable by decision aids. Patients and practitioners may have problems with:

- a) *perceptions of the decision* (e.g. inadequate knowledge, unrealistic expectations of outcomes, unclear values, high uncertainty or decisional conflict);
- b) *perceptions of others* (e.g. biased or limited perceptions of the variation in others' opinions and practices; social pressures, inadequate support), and
- c) *personal and external resources* to make the decision (e.g. limited skills in shared decision making).

Decision aids are designed to address these problematic determinants of choice by providing accurate, balanced, and tailored information, clarifying patients' values, and augmenting skills in shared decision making. For example,

-*inadequate knowledge* may be improved by providing information on options and outcomes;
-*unrealistic expectations* (perceived probabilities of outcomes) may be re-aligned by presenting probabilities of outcomes that are tailored to the patient's clinical risk and by describing outcomes so that they are easy to imagine and identify with;
-*unclear values* are addressed by describing outcomes in familiar, simple, and experiential terms so as to better judge their value and by providing the opportunity to weigh the benefits versus the risks;
-*biased perceptions of the variation in others' opinions* may be corrected by presenting all options, and in some cases, by providing examples of others' choices and statistics on variation in choices;
-*limited skills in shared decision making skills* may be improved by providing structure, guidance or coaching in deliberating about the personal issues involved in the choice and in communicating preferences.

These methods of decision support need to be adjusted to another important determinant of decisions, the patients' and practitioners' characteristics

As a consequence of these interventions, patients presenting with uncertainty or decisional conflict caused by these problems may become more certain about what to choose and may be more likely to implement these choices.

Based on the Ottawa framework, one can hypothesize that decision aids will improve the determinants of choice so that decisions are more likely to be: 1) informed (i.e. based on better knowledge and realistic expectations); 2) consistent with personal values; and 3) implemented. Moreover, patients' comfort with the decision making process (e.g. decisional conflict, self-confidence and satisfaction with decision making) may be improved.

Based on the results of other educational interventions designed to promote realistic expectations of outcomes and informed active involvement in one's care, it is also reasonable to hypothesize that patients may be more likely to persist with decisions, to report less distress with the consequences of their decisions, and to experience improved health-related quality of life.

5. Which methods will be included in the decision aid?

In selecting the decision support methods, the developer needs to determine how much emphasis will be placed on preparing the patient and the practitioner. The specific decision support methods, content, and delivery methods depend on the nature of the decision, the needs of the users, feasibility constraints, and the objectives of the decision aid. The 'essential content' in decision aids is still a matter of debate.

Information about clinical condition, options and outcomes. Most decision aids start with a description of the clinical situation that has stimulated the need to consider certain options and outcomes. Patients need to know about the conditions or diseases they face, common manifestations and complications.

Then, the health care options are described including: what they include, the method and duration of delivery, and the patient's involvement in their use.

Next, the outcomes of each option are described in sufficient detail for patients to understand what it is like to experience such an outcome. This is important because people will often underestimate the likelihood of an option that they cannot imagine or identify with it. Moreover, people cannot judge the value of an outcome that is unfamiliar. In many decision aids, the functional impact of the outcome is described (e.g. how the patient can be expected to respond physically, emotionally, and socially). The evidence to support the description of outcomes can be found in quality of life studies. We usually select the impacts that are most frequently reported and most important to the patients. In the absence of quality of life data, a panel of experienced patients and clinicians can be helpful in describing outcomes. Some decision aids that are delivered by video include interviews of patients describing what it is like to experience the outcomes.

Presenting Probabilities of Outcomes. One of the consistent benefits of decision aids is to create realistic expectations of outcomes. This is achieved by presenting probabilistic

information about the likelihood of benefits and risks. Patients who are unaware who have unrealistic expectations (e.g. overestimate the benefits and underestimate the risks) can be helped with this information.

The numerous issues in presenting risk information are summarized in a recent monograph of the National Cancer Institute (2). Generally, it is advisable to use numbers to describe probabilities because people do not agree on what is meant when words are used (e.g. high probability, small chance). Numbers are better at creating realistic expectations.

Whether numbers should also be accompanied by graphic illustrations (100 faces, bar charts, pie charts) is still being examined. We find 100 faces most helpful. The pie charts do not distinguish between small probabilities associated with various options (e.g. 50% versus 60%). The bar charts are difficult to interpret by people with less education. When displaying the 100 faces, we shade the number expected to experience an outcome and leave the other faces unshaded. This allows us to frame the message about chances of outcomes in both positive and negative terms. Many studies have shown that one gets different responses depending on whether you emphasize the chances of something happening (5% will get this complication) versus not happening (this complication may occur, but in 95% of cases a person will remain free of complications). We shade the numbers in a row rather than randomly because it is difficult for people to notice small differences in probabilities between options using random shading.

Values Clarification Exercises. Patients clarify their values in two possible ways. First the descriptions of outcomes provided vicarious experience from which to judge their value. Second, some decision aids ask patients to explicitly consider the personal importance of each benefit and risk.

In those that use explicit valuing approaches, some handle probabilities and values for outcomes separately, asking patients to value each outcome via formal utility assessments and then combining the values for outcomes with their associated probabilities using expected utility decision analysis to arrive at a recommendation for the patient. Others ask patients to value treatments, by considering both probabilities and values together, using probability trade-off tasks; relevance charts; and "weigh scale" exercises. The purposes of these valuing exercises are to structure and provide insight into how values affect personal decision making.

Whether it is necessary to have an explicit values clarification exercise has not been determined. One study showed that the addition of a 'weigh scale exercise' did not benefit women who were not going to change their current practices. Whether it is beneficial as a communication tool between patients and practitioners and whether it is beneficial in patients who are planning to change practices remains to be seen.

We usually use a values clarification exercise in our decision aids, usually in the personal worksheet. The benefits and risks are placed on a balance scale so that patients can: 1) add other potential benefits and risks that are important to them; 2) indicate the personal importance of each by shading or checking those that are affecting their decision making; and 3) communicate their values efficiently to their practitioners and others involved in decision making.

Information About Others' Opinions. Whether decision aids should include information about others is still open for debate. One survey of patients' decision making needs indicated that some but not all thought this information was essential for decision making. Some developers of decision aids include no examples in order to remain neutral. Others provide balanced information on different points of view.

We usually include examples of how different patients deliberate about options. The examples are composites of cases in our clinics. The decision aid presents a situation

exemplifying a patient choosing each of the options, including one in which no treatment/testing is chosen. Patients learn not only what others choose, but also the reasoning behind the choices. The different cases reinforce the notion that decision making is variable and should be individualized according to a person's own situation and personal values.

Guidance and Coaching in Decision Making and Communication. Guidance and coaching has been found to be helpful in promoting better coping strategies, health practices, and outcomes. Whether it is helpful in decision aids is still under investigation. We provide structure and guidance in decision making by showing patients the steps in decision making and by providing suggestions for what to do in a follow-up discussion with their practitioner. The steps are usually presented after patients receive the general information on options. This helps them to personalize the information in their own situation. The steps usually include:

- Considering personal benefits and risks;
- Clarifying personal values;
- Listing current health practices;
- Listing questions;
- Indicating preferred role in decision making; and
- Indicating current leaning or predisposition toward the options.

We usually use a personal worksheet for patients to consider these steps and illustrate with examples how others complete the worksheets. The worksheet provides a focus for communication and discussion at a follow-up visit. It can also be used to discuss varying views among family members.

Methods of Delivering Decision Aids. Decision aids can be delivered in various forms: decision boards, interactive videodiscs, personal computers, audiotapes, audio-guided workbooks, pamphlets, and group presentations. The method used depends on the preferences of the users and the resources and expertise of the developers. The efficacies of different methods are under active investigation. Most developers use more than one delivery method.

Preparing the Practitioner There are several methods of preparing the practitioner. We usually use a manual or practice guideline that summarizes the scientific information regarding the decision. The practice guidelines are those developed by a provincial or national group (e.g. Cancer Care Ontario, Society of Obstetrics and Gynecology). We have also held or contributed to local and national continuing education workshops that summarize the evidence regarding the options and efficacy of the decision aid in preparing patients for decision making.

Now it's time to consider the methods you wish to include in your decision aid. These charts may be helpful in summarizing your views for discussion with other members of the team.

PATIENT DECISION SUPPORT METHODS

check ✓ those you wish to include

Information

☐ *About Clinical Problem*, specify _____

☐ *About Options*, specify _____

☐ *About Consequences of Options*, specify _____

_____ detail in describing outcomes:

☐ define outcomes; ☐ describe physical, emotional, social impact; ☐ use narrative/scenario styles

☐ *About probabilities of Outcomes*: , specify _____

display? ☐ numerical; ☐ frequencies/ percents; ☐ graphic pie charts; ☐ 100 people ☐ qualitative (low, moderate, high);

tailoring?: ☐ not tailored; ☐ stratified by personal risk factors;

☐ Evidence for statements: ☐ level of evidence; ☐ references included/not

☐ Suggested readings: ☐ included; ☐ not included

Values Clarification

☐ implicit only; ☐ explicit, specify: _____

☐ marking important pros/cons (stars, circling, highlighting); ☐ weigh scale exercise; ☐ decisional balance sheets;

☐ other

Information on Others specify _____

☐ none; ☐ cases of different choices; ☐ statistics on variation in patients' decisions or practitioners' opinions;

☐ recommendations from clinical societies

Guidance/Coaching specify _____

☐ steps of decision making; ☐ communicating with practitioners

☐ tips on managing consequences of choices; ☐ tips on maintaining behaviour change

Delivery specify _____

☐ person to person counselling; ☐ telephone counselling; ☐ group counselling

☐ generic tools; ☐ decision board; ☐ audio-guided workbook; ☐ interactive videodisc; ☐ linear video

☐ computer based tool; ☐ other

PRACTITIONER DECISION SUPPORT METHODS

check ✓those you wish to include

Type of Decision Support

- ☐ clinical algorithms;
- ☐ patient materials
- ☐ other

Information:

- ☐ scientific evidence re decision;
- ☐ rationale for decision aid;
- ☐ efficacy of decision aid;
- ☐ timing and use in practice;
- ☐ scientific references.
- ☐ other

Delivery

- ☐ manual; ☐ video; ☐ lecture; ☐ workshop; ☐ hot-line; ☐ academic detailing
- ☐ other

6. Which designs and measures will be used to develop the decision aid?

Development and evaluation depend on the objectives of decision aids. Developers need to decide on: the sampling and design architecture; the criteria for evaluation; and the measurement tools that will be used to operationalize the criteria.

In previous papers we have made the following comments about development design and evaluation. The standard methods we use to develop decision aids include: 1) drafting and redrafting by an expert inter-disciplinary panel of health services researchers, education and communication specialists, and practitioners; 2) assessment and revision by panels of practitioners and patients who are experienced with the decision; 3) pilot testing with practitioners and patients at the point of decision making; 4) conducting evaluative studies using before/after and randomized trial designs.

Our evaluations of decision aids distinguish between improved decision making and improved outcomes of decisions because: a) decisions that depend on client's values cannot be judged as right or wrong; and b) good decisions can still result in bad outcomes due to variable nature of clinical outcomes. Therefore, we define a good decision as one that is informed, consistent with personal values, and acted upon, in which participants express satisfaction with decision making. We are also evaluating the impact of decision aids on compliance with choice, quality of life, and appropriate use of resources.

Base on completed reviews, we have the following insights and recommendations for evaluative studies.

Gaps in Research. There are several gaps in research on decision aids. More research is needed on: a) how decision aids perform for different clinical decisions; b) their acceptability to practitioners; c) their acceptability to diverse patient groups; d) their impact on patient-practitioner communication; e) their downstream effects on persistence with the decision, distress, regret, and health-related quality of life; and f) their optimal strategies for disseminating and implementation strategies.

Methodological Problems. Most evaluation studies are fraught with methodological difficulties. They cannot be double-blind. Those that randomize patients rather than practitioners have contamination problems that narrow the differences that will be detected. Those that randomize practitioners need to be

very large, because of cluster sampling. Moreover, they may have selection biases because clinicians, knowing their assignment, may: a) be more or less enthusiastic about recruiting patients; and b) recruit different types of patients. Despite the researchers' best efforts, it is very difficult in a real world setting to present the decision aid at the appropriate time to patients who are eligible to consider all of the options in the aid. Furthermore, efficacious interventions may have no impact if either patients or practitioners, or both, are extremely polarized toward one of the options at baseline. When post-intervention measures are administered after the consequences of the choice are known, it is very difficult to avoid having the outcome colour their evaluation of satisfaction with the decision making process and the decision.

Recommendations:

Future studies should:

- examine the impact of decision aids on a broader range of decisions with a more comprehensive range of patient and practitioner outcomes;
- select patients who are at the point of decision making for whom the choices in the aid are relevant;
- measure patients' and practitioners' baseline predispositions toward the choices; c) have sample sizes large enough to detect clinically meaningful differences in decisions among the undecided subgroup of patients;
- measure patients' perceptions of practitioners' opinions;
- have a usual care arm and describe clearly what usual care comprises;
- describe clearly what was in the decision aid and how it was used in the diagnostic/treatment trajectory.

With this background, it is time to consider designs and evaluations. These charts may be useful to identify the stage you are in and to record your views for discussion with the team.

AT THIS STAGE, WHICH DESIGN IS APPROPRIATE?

Development Panel

Participants: researchers, clinicians, educators, patients, opinion leaders;

Methods: iterations of drafts, feedback, revisions, feedback etc.

Review Panels

Participants: potential users (practitioners, patients who have already made decisions)

Methods: focus groups, personal interviews, questionnaires to elicit acceptability, etc.

Sample size: n = 10 per group

Pilot Studies

Participants:

patients at the point of decision making

Designs where: X=decision aid intervention; C=control intervention; O=observation of effects; R=randomization

post-test only, usually with pre-established criteria for success (e.g. 70% find aid acceptable)

sample size about 10

X O

before/after study- baseline questionnaire, decision aid, post-test questionnaire

sample size about 30 per group

O X O

Trials

Participants: patients at point of decision making; practitioners

Designs

quasi experiment

OCO

OXO

Randomized trial

unit of randomization □ patient; □ practitioner

ROXO

ROCO

AT THIS STAGE, WHICH MEASURES ARE APPROPRIATE

Criteria For Evaluation

Measurement Tools

EARLY STAGE (e.g. post-test only)

Acceptability

Acceptability Questionnaires–Barry tool, Ottawa tool

PILOT STUDIES (e.g. before/after)

Knowledge

Knowledge/Comprehension test

Expectations of outcomes

Probability scales- numbers and words

Clarity of values

Values subscale of Decisional Conflict Scale

Decision

Choice Question (option x, option y, unsure); choice predisposition

Decisional conflict

Decisional conflict scales for patients and providers

TRIALS

Knowledge, Expectations, Clarity of Values, Decision, Decisional Conflict as above

PLUS

Realistic perceptions of others

Perceptions of % of practitioners/patients choosing options; subjective norms

Skill in decision making

Self-efficacy scale, Implementation data

Satisfaction with decision making

Decision Satisfaction Inventory; Satisfaction with Decision); Satisfaction with Preparation for Decision Making

Use of decision aid

Diary, Utilization data

Participation according to needs

Congruence between preferred and actual role in decision making Degner scale, Strull Question, Deber questionnaire

Persistence with decisions

Survey of decision over time; Refills, implementation data

Health related quality of life

Generic (e.g. SF 12) and Condition-specific

Use of resources

Analysis of utilization data

Costs

Consult health economist. See Hersey and Lohr Framework and Nease & Owens cost-effectiveness model

A description of the ‘Evaluation Measures’ we use and samples are available at

www.ohri.ca/decisionaid

7. How should the decision aid be disseminated?

Dissemination involves the targeted distribution and promotion of the use of the decision aid. Six key elements of research transfer and use (2) are presented: potential adopters; practice environment; the evidence-based innovation (e.g. the decision aid); strategies for transferring the evidence into practice; evidence adoption; and outcomes. These elements are systematically monitored prior to, during, and following any research transfer efforts.

The data generated by monitoring is used to:

- 1) identify potential barriers and supports to research use associated with the potential adopters, the practice environment, and evidence based innovation;
- 2) provide direction for selecting and tailoring transfer strategies;
- 3) track the progress of the transfer effort, and
- 4) assess the adoption of the evidence and its impact on outcomes of interest.

Although dissemination is identified as a final step, it should be addressed early in the development process so that the aid is acceptable to potential users and has a greater potential for adoption. Therefore, dissemination questions can be posed during the needs and feasibility phases. Development and review panels can include potential users (practitioners and patients) and partners who may assist with dissemination (consumer groups, health professional organizations, disease foundations, and public education agencies).

APPENDIX Example of How to Apply the Steps

Example of Developing a Decision Aid for Postmenopausal Hormone Therapy (See Reference 8, 13, 15, 16)

1. Need.

In terms of need, there was general agreement that:

- the decision was difficult, due to the uncertainty of outcomes with long-term use, the need to balance benefits against risks, and variation in opinions of whether the benefits outweighed the risks;
- sufficient and growing numbers were involved in making this decision (at least 10% of the population);
- there was considerable variation in utilization and preferences both from the practitioners' and clients' perspectives;
- there was sufficient demand for an aid; and
- women and practitioners wanted a balanced presentation of the benefits and risks based on current evidence and a guide to help streamline the process of deliberation between women and practitioners.

2. Feasibility.

In terms of feasibility, there was general agreement that:

- we had the resources, expertise, and networks to develop, evaluate and disseminate the aid;
- we had commitment to update the evidence via our linkage to the International Cochrane Collaboration which has an ongoing process of summarizing evidence of benefits and risks;
- although the evidence was expected to change as new studies emerged, we extended the shelf life of the aid by using pooled evidence from meta-analyses and letting users know of upcoming trials in 10 years which will provide higher quality evidence of long term benefits and risks; and
- we could deliver the aid in a manner that was acceptable and accessible to women and practitioners.

3. Goals and Objectives.

The goals of the decision aid were to improve decision making and the outcomes of the decisions from both the patient and practitioner perspective. The specific objectives were to improve:

- decision making so that it is informed (based on adequate knowledge and realistic expectations), consistent with personal values and implemented
- satisfaction with decision making
- persistence with choice
- health related quality of life
- appropriate use of health care resources.

4. Framework of Decision Support.

We used the Ottawa Decision Support Framework

5. Decision Support Methods

Content and delivery methods. We structured the content of the decision aid according to the Ottawa framework and American College of Physician counselling guidelines. There were two parts, a woman's take-home audio-workbook, and a practitioner manual.

The woman's take-home audio-workbook prepared the women for a follow-up visit to discuss the issue with her practitioner. A 40 minute audiotape guided a woman through a 32-page illustrated booklet and personal worksheet providing information on:

I. General Information on Diseases of Aging, Alternatives, Benefits, and Risks

- CHD, osteoporosis, endometrial cancer, and breast cancer including definition, incidence, median age of onset, mortality rates, and the physical, emotional and social impact of these diseases; and major risk factors;
- prevention and early detection strategies;
- HRT regimens; benefits and risks including effects on CHD, osteoporosis, menopausal symptoms, endometrial cancer, breast cancer, side effects, contraindications, and other reasons women decide not to take HRT;
- probabilities of disease with and without HRT according to risk of disease and hysterectomy status;

II. Steps in Weighing Her Own Benefits and Risks

Guidance in completing a Personal Worksheet to:

- identify her personal lifetime benefits and risks of HRT tailored to her hysterectomy status, and risk of CHD, osteoporosis and breast cancer; review her menopausal symptoms status and menstrual history; and consider other issues important in the decision;

- clarify her values using a "weigh scale" to rate her perceived importance of each benefit and risk;
- identify her current health practices in promoting healthy bones, heart, and breasts;
- list her questions;
- identify her preference for participation in decision making; and
- indicate her predisposition or "leaning" toward taking HRT.

III. Suggested Steps for a Follow-up Visit with her Practitioner

The completed Personal Worksheet provides a focus for discussion for the woman to:

- Review possible benefits and risks with her practitioner to verify & fill in gaps
- Discuss personal values by showing the practitioner her weigh scale
- Make a decision considering benefits, risks, personal values, and preference for decision participation
- Plan the next steps

The booklet included illustrative icons to represent each concept. The text was adjusted to a grade 8 reading level, but was comprehensible to those with less than Grade 8 reading because of the accompanying audiotape and illustrations. The data describing lifetime risks and benefits were those used in the ACP guidelines from the overview of Grady et al. A woman used the aid in a self-paced, active way, responding to checklists and writing in her opinions. In order to familiarize herself with the steps in weighing the benefits and risks, she was shown how four other women completed the steps before being asked to complete her own assessment. The four different cases also reinforced the notion that decision making is variable and can be individualized according to a woman's health history, values, current health practices, and preferences for decision participation.

The practitioner's decision support materials included: 1) a guidelines for using the decision aid; 2) a manual describing the scientific evidence of benefits and risks; practice guidelines; and suggested counselling strategies; and 3) a prescription and management algorithm for those choosing HRT including patient assessment; selection of hormonal treatments; and follow-up surveillance.

6. Development and Evaluation Design and Measures.

We developed and evaluated the decision aid in several phases. The early prototypes of the decision aid for hormone replacement therapy (HRT) were developed using an iterative process with a: 1) development panel of interdisciplinary researchers, educators, and practitioners; and 2) review panels comprising of potential users including post-menopausal women, medical and nursing practitioners, and educators. These groups guided its development using criteria such as need, feasibility, and appropriateness and acceptability of the objectives, content, and decision support methods. The methods used to elicit the review panel's opinions included focus groups, meetings, interviews, and surveys.

We then proceeded to evaluate the acceptability of the decision aid with 40 women. Based on their comments we revised the aid.

Next we conducted a before/after study of 94 postmenopausal patients from 6 family practices in downtown Ottawa Canada. We found that compared to baseline, patients who used the take-home aid significantly ($p < 0.001$): improved their general knowledge of alternatives, benefits, and risks; had more realistic personal expectations of outcomes with and without HRT; and reduced their decisional conflict scores, with the greatest improvements observed in feeling certain, informed, clear about values, and supported in decision making.

We then conducted a randomized controlled trial of an audioguided workbook versus a general educational pamphlet briefly describing HRT benefits, risks, side effects and likely beneficiaries in general terms. We found that women exposed to the decision aid had significantly ($p < 0.04$): more realistic personal expectations; and less decisional conflict, particularly in the area of feeling informed, clear about values, and supported in decision making. They also found the intervention more acceptable ($p < 0.05$). There were no differences between groups in general knowledge about HRT.

We are just completing a randomized controlled trial of involving 40 family practitioners and 200 women. We randomized 40 Ottawa family physicians to prepare women for counselling using either: 1) a pamphlet briefly summarizing options and outcomes and likely beneficiaries in general terms; or 2) an audio-guided workbook with detailed information on options, steps in decision making, examples, and personal worksheet summarizing personal: outcome probabilities; values; practices; questions; preferred participation roles; and predispositions. Patient and physician questionnaires were administered at baseline, after the take-home intervention, and 1 week, 2 months and 9 months after counselling. Evaluation measures include: the quality of patient-practitioner communication; efficiency and satisfaction with the decision support process; knowledge and expectations; decisional conflict; satisfaction with the decision; persistence with decisions; distress from treatment side effects; and quality of life.

We found that both intervention groups were comparable at baseline. Post-intervention, both groups had improved knowledge, but those using the complex decision aid reported more: realistic expectations, shared decision making, and satisfaction with decision making. Physicians using the audio-workbook were also more

satisfied with women's preparation for decision making. Other outcomes are being analysed. Our conclusions is that simpler aids are not as useful as complex aids in preparing patients for decision making about hormone therapy.

6. Disseminate

Guess what, the evidence on hormone therapy changed with the completion of the HERS Study and Women's Health Initiative. We are revising our decision aids to accommodate this new information. Our dissemination strategy is currently in the planning stages. We have begun to assess the barriers/facilitators of use and are evaluating potential implementation strategies.

References

1. O'Connor A, Rostom A, Fiset V, Tetroe J, Entwistle V, Llewellyn-Thomas H, Holmes-Rovner M, Barry M, Jones J. Decision Aids for Patients Facing Health Treatment or Screening Decisions: A Cochrane Systematic Review. British Medical Journal 1999;319:731-734. See updates in cochrane collaboration library.
2. O'Connor AM, Fiset V, DeGrasse C, Graham I, Evans W, Stacey D, Laupacis A, Tugwell P. Decision aids for patients considering health care options: Evidence of efficacy and policy implications. Journal of the National Cancer Institute Monograph No 25., 1999 p.67-80. Overview of decision aids-points to gaps, methods issues, policy issues.
3. O'Connor AM Annotated Bibliography on Decision Aids. Can be found at www.ohri.ca/decisionaid under the 'Resources' section.
4. O'Connor A, Edwards A. the role of decision aids in promoting evidence-based patient choice. In: Edwards A, Elwyn G, editors. Evidence-based patient choice. Oxford: Oxford University Press; 2001. p. 240-242.
5. ICES Practice Atlases & Atlas Reports Series <http://www.ices.on.ca/> Can be found under 'Publications'.
"Practice Atlases", developed by the Institute for Clinical Evaluative Sciences, use maps and charts to show regional differences in health care delivery. They include indepth, disease-specific atlases and "Atlas Reports", which are shorter issue-specific documents that are produced periodically in three areas: "Health of Ontarians," "Uses of Health Services," and "Indicators of Hospital Performance." These reports are available in PDF format and can be downloaded free-of-charge.
6. Dartmouth Atlas, <http://www.dartmouthatlas.org/>
The Dartmouth Atlas describes how medical resources are distributed and used in the United States. It has been developed by the faculty of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School.
7. O'Connor AM, Stacey D, Rovner D, Holmes-Rovner M, Tetroe J, Llewellyn-Thomas H, Entwistle V, Rostom A, Fiset V, Barry M, Jones J. Decision aids for patients facing health treatment or screening decisions. (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003.
8. O'Connor AM, Drake ER, Fiset V, Graham I, Laupacis A & Tugwell P. The Ottawa Patient Decision Aids. Effective Clinical Practice 1999;2(4):163-170. Describes the Ottawa Approach and summarizes results to date. Part of a special edition focused on decision making.
9. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: What does it mean? Soc Sci Med, 1997;44:681-692. **McMaster** Approach. Useful examination of what constitutes shared decision making.
10. Entwistle VA, Sowden AJ, Watt IS. Evaluating interventions to promote patient involvement in decision making: By what criteria should effectiveness be judged? J Health Serv Res Policy 1998; 3(2):100-7. From the **York University** Center for Dissemination, UK. Illustrates that evaluation criteria depend in part on the type of involvement of the patient and practitioner. For an examination of the **ethical underpinnings** of informed choice, see also: Entwistle VA, Sheldon TA, Sowden A, Watt IS. Evidence-Informed patient choice. Int J Technol Assess Health Care 1998;14:2.

11. Llewellyn-Thomas, H. Presidential Address. *Med Dec Making*. 1995;15(2):101-6. A framework for understanding the factors that influence decisions and preferences, placed in a broader sociopolitical context. **Toronto Approach**. Very good for distinguishing between preferences for outcomes, time, treatments, control in decision making etc.
12. Mulley A. Outcomes research: Implications for policy and practice. In: Smith R, Delamother T, editors. *Outcomes in Clinical Practice*. London: BMJ Publishing Group: 1995. p. 13-27.
Foundation for Informed Medical Decision Making approach. Focus on outcomes research.
13. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Bunn H, Graham I, Drake E. A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. *Patient Education and Counselling*, 1998;33(3):267-279. **Ottawa** Framework to guide decision support strategies used in decision aids and their evaluation. Illustration of how to operationalize the framework using a HRT decision aid. Defines determinants of decisions, decision support interventions addressing determinants, and potential effects on the quality of the decision process, the decision, and outcome of the decision.
14. Rothert M, Talarczyk GJ. Patient compliance and the decision making process of clinicians and patients. *J Compliance Health Care* 1987;2:55-71. **From Michigan State University**. Describes the mutual roles of patients and practitioners.
15. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, McPherson R, Bunn H, Graham I, Drake E. A decision aid for women considering hormone therapy after menopause: Decision support framework and evaluation. *Patient Education and Counselling*, 1998;33(3):267-279.
16. O'Connor AM, Tugwell P, Wells G, Elmslie T, Jolly E, Hollingworth G, McPherson R, Drake ER, Hopman W, MacKenzie T. Randomized trial of a portable, self-administered decision aid for post-menopausal women considering long-term preventive hormone therapy. *Med Dec Making*. 1998;18 (3):295-303.

Developing a schedule

You have considered many of the issues about using decision aids. Now its time to plan the next steps.

Below is a chart to summarize some of the tasks that need to be done in making progress toward achieving your goal. Think about what need to be done, who should do it, and when the task should be started and completed.

Schedule			
Task	Person Responsible	Projected Start Date	Projected Completion Date