FOUNDATION PROCEDURES FOR DEVELOPMENT OF DECISION AIDS

Introduction

The Foundation for Informed Medical Decision Making is responsible for the content of decision aids that are created jointly by the Foundation and its partner, Health Dialog. The Foundation's decision aids focus on decisions about diagnostic or treatment activities for which patients might legitimately make different decisions based on their own values or preferences. The Foundation's decision aids are intended to accomplish the following:

1. To frame the decision, the options available to patients, in a balanced, unbiased way.
2. To explain what is known and not known about the potential risks and benefits of each of the reasonable options, based on the best available clinical literature.
3. To use interview material from patients who have faced a similar choice to communicate to users both the common alternative ways of thinking about the decision that might lead to different decisions and to share with patients what the experience of the various choices might be like, including what it would be like to experience some of the most frequent side effects or complications of the treatment options.

Overall, the goal is to prepare patients to understand their condition, the options before them and the implications of these options so that they are able to make an informed choice. An underlying premise of the Foundation's decision aids is that it is highly desirable for patients to become informed and take a major role, with their physicians, in making important medical decisions.

In order to create a decision aid of the type that meets the Foundation standards, there are a number of steps that we routinely take.

Focus Groups

As a first step, we think it is critical to talk to a number of patients who have faced the choices that will be presented in the program. We typically do this by gathering groups of patients in groups of six to ten. The groups are recruited from clinical practices and through public strategies such as postings on bulletin boards or advertisements in newspapers. We routinely try to get patients from two or three different communities, in different parts of the country, and we try to include people with various characteristics with respect to age, gender, cultural background, and the kind of choices they made.

Typically, focus group participants are asked to join a group to talk about their experience with the condition and the choices for about an hour and one-half. A trained leader discusses their experiences leading up to the decisions, the rationales for the choices they made, and the consequences and experiences they had after they made their decision. The goal of this discussion is not to reach a consensus. Rather it is to make sure that the Foundation is aware of the range of rationales, perspectives, and experiences that patients have. These group discussions help us to identify information gaps, misperceptions, concerns, and adverse consequences of some of the options that will need to be addressed in any effective decision aid.

These group discussions are video taped, with volunteer permission, of course, and the results are written up in summary fashion and integrated into what we call a content document, which forms the basis for the creation of the decision aid.

Provider Focus Groups

In addition to talking with patients, we also try to gather two or three groups of providers to talk with us about their thoughts on the decision rules that they use and the kind of recommendations they make to their patients. We also like to get their reading on what the pros and cons of the various options are. Invariably, we learn that there is a variety of opinions among providers, sometimes based on specialty, sometimes based on the setting in which they practice. These discussion groups with providers also give us insight into how to structure a decision aid by helping us to understand the context in which patients will be making decisions and the kinds of input that they may be getting from providers.

Evidence Summaries
For every program, the Foundation identifies a Medical Editor. The Medical Editor is almost always a generalist physician, most often in general internal medicine, who has done research in the subject matter being addressed. That Medical Editor works with staff members at the Foundation to produce an evidence document. The evidence document is not a summary of everything ever published on the topic of the decision aid. Rather, it is organized around the kinds of information that a patient making a decision would need or ought to know in order to make an informed choice.

The relevant literature is examined, and the best sources on which to base estimates or generalizations are identified. The results from patient focus groups and provider focus groups are used in some cases to identify additional issues that need to be addressed in the evidence document.

For each decision aid, the Foundation also identifies a set of three to five clinical advisors. Often, they represent various different specialties that are involved in the management or treatment of the target condition. Once the evidence document is complete, it is reviewed by the clinical advisors, comments are made, and revisions and edits are made if necessary.

This evidence document is then integrated with the results from the focus groups to produce what we call a content document, which is the basis on which the decision itself aid is developed.

Production

Once the content document is complete, the production process begins. The content document essentially outlines the main points that need to be communicated in the program. The elements by which this is communicated are essentially four:

1. Graphic illustrations that help users understand the condition and the treatment options.
2. Statistical data about the likelihood of various good or not-so-good things happening that are associated with the choices.
3. Interview material from patients, communicating their rationales for the choices they made and sharing their experiences with the treatments and the consequences of what they decided.
4. Interviews with providers who can explain their perspectives on various aspects of the treatment options and decisions.

The initial production planning focuses on what needs to be accomplished with each of these elements. The development of the script usually involves having a narrator who weaves the elements into a coherent program.

The patient interview material all comes from volunteers. Sometimes they are identified through the original focus groups; in other cases, we identify them in other ways, for example through clinical referrals. However, essentially we find people who have stories to tell, have them tell their stories on camera, and then the writers and producers choose those parts of the interviews that are needed to give a comprehensive and balanced presentation of the patient perspective on the various options that are being discussed. Patients are never scripted, although those patients whose interviews are recorded are chosen because they are known to be able to articulate a particular perspective or experience.

Evaluation

All the materials that end up in the program are subject to several rounds of critical evaluation. Medical Editors and clinical advisors, as well as those responsible for gathering patient perspectives from focus groups, review draft scripts and various examples of interview material and graphical presentation, throughout the production process. Scripts are also reviewed by a literacy expert to identify places where the material can be presented more simply or more clearly. Finally, the elements are put together into what we call a "rough cut." This is essentially the complete program, except the narration is more informal. In some cases the graphics are not in final form. This is the version of the program that receives extensive testing. The testing consists of the following:

First, all of the clinical advisors, as well as the Medical Editor, review the rough cut and provide their comments and feedback. In addition, we identify outside reviewers who have various perspectives we think we want to include in our review process.

The other side of our review is to show the rough cut to would-be users. In general, we do this testing with people who have been through the decision or treatment choices that are addressed in the program. We feel it is inappropriate to test the program on people who are actually facing live decisions. The argument for using "ex-patients" is that they are familiar with the issues, they can report what they needed to know and what they wished they knew, and they can identify with any emotional distress that may be associated with the choice. Admittedly, having such people review the program is not identical to having those facing the choice do the evaluation. However, we think it is the best, most reasonable approach given the alternatives.

Typically we recruit eligible patients from at least two different sites – sometimes from clinical referrals, other times through mass communications such as newspaper ads.

The typical protocol is to gather eight or ten volunteers in a room, show them the program, ask them to do several systematic ratings of the program, and then ask them to participate in a discussion of the program led by a moderator. Right after they see the program, volunteers are asked to rate the program for balance, whether the various options were presented in an appropriately fair and equal way. They also answer a series of knowledge questions that address key issues or facts that we identify ahead of time as important for patients to know when they are facing the choice. Although we learn many things in the review process that can lead to changes in the program, evidence that the program does not treat all the options equally and fairly and evidence that certain messages are not being communicated accurately invariably lead to program revision to try to correct those problems.

Making Final Changes

The material from the various reviews is compiled and summarized. Likewise, the results from the various patient review groups (patients invariably number 30 or more) are summarized in a similar way. Then there is a meeting with the production staff and the key participants from the Foundation to go over the issues and, with guidance from the Medical Editor, to decide which issues need to be addressed and what reasonable strategies are available to solve the problems that are identified.

NOTE: Anytime any of the reviewers identifies a question of clinical or evidentiary accuracy, the issue is carefully evaluated and the "right" answer is found and put in the program.

Based on these steps, the program is put into final form.

The Booklet

In addition to the audio-visual product that is thought of as the decision aid, all Foundation and Health Dialog decision aids also come with a paper booklet. Over time, we have found that this booklet is an invaluable complement to the video tape. The booklet includes:

1. A verbal summary of the framing of the problem,
2. All of the statistical information that is presented in the tape,
3. Any other charts or graphs with long lists,
4. In some cases, additional detail on general issues that are brought up in the program. For example, in the program we might mention a particular class of medications; in the booklet, we might provide a list of the brand names of the medications that fall in that category.

Most of the people who view video tapes cannot remember the numbers that are presented. Having them all reproduced in the booklet gives them an easy way to go back and review such information. The same is true for lists.