CHAPTER 3:
SHARED DECISION-MAKING: A REVIEW OF THE LITERATURE

Introduction

Shared decision-making has gained greater relevance for clinical medicine in recent years. When treatment alternatives are available but none is clearly superior, there is greater recognition that patient values and preferences should factor into decision-making (Barry, 1999). However, incorporating shared decision-making into clinical practice has been challenging, owing to: (1) the lack of role models and training for clinicians; (2) the limited time available during clinical encounters; (3) the complexity of evaluating and clearly communicating to patients the tradeoffs in the risks and benefits of treatment; and (4) the lack of good, relevant data to inform decision-making (Dunn et al., 2001; Braddock et al., 1999; Barry, 1999).

Shared decision-making programs and decision aids offer an opportunity to address some of these problems by providing information and decision assistance to patients outside the clinical encounter. While their specific goals and content vary, these aids generally aim to inform patients about likely outcomes of therapeutic options, incorporate patient values in weighing the benefits and risks of treatment, and encourage patient participation in care decisions. Evaluations of these programs suggest that they can increase patient knowledge, reduce decisional conflict, influence patient behavior, and affect treatment choice (Hersey et al., 1997; O’Connor et al., 2003). However, the reliance of many decision aids on using clinical trial data for their probabilities of therapeutic risks and benefits (Murray et al., 2001a, 2001b; O’Connor et al., 1999) raises several concerns. First, the currency of the data used in the decision aid will determine their utility for informing treatment decision-making, especially for conditions in which available treatments change rapidly. Second, if the study intervals for trials used to calculate probabilities in the decision aid are not sufficiently long, the long-term consequences of treatment exposure and complications may not be well described. Finally, the stringent eligibility criteria imposed by most randomized clinical trials may make their results less applicable for patients who do not fit their eligibility profile (e.g., patients with multiple health problems or those who take a number of different medications). Many developers have responded to these concerns by adopting update policies for their products (O’Connor et al., 1999; O’Connor et al., 2003). In addition, a transparent evidence base can help users gauge the usefulness and generalizability of a particular decision aid. However, a lag time is still likely to exist.
between when new data, whether for new treatments or from new studies, become available and when they are incorporated in updates. Data banks or data bases may offer an alternative strategy for treatment decision support by providing a dynamic stream of data on the therapeutic experiences of a broad range of patients and serving as a repository of outcomes for existing and novel therapies.

However, experience with the use of data bases for this purpose is limited, and an assessment of the market for these outcomes data bases, potential implementation strategies, and the practical issues associated with incorporating their use within the flow of clinical care—including facilitators and barriers—is necessary before additional steps can be taken to develop them for decision support. To identify user and design issues that should be considered when evaluating the feasibility of developing a data base to assist patients in treatment decision-making, we reviewed the literature to identify the characteristics of patients who are most likely to participate in shared decision-making, what information patients want and what format they want it in, and the likelihood of physician support for these data bases. We also reviewed the evidence on the use and effectiveness of shared decision-making programs and decision aids for informing patient decision-making.

The State of Patient Involvement in Clinical Decision-Making

For many patients, their physicians are the primary source of information about treatment options. However, evidence to date suggests that the degree of information-sharing and collaborative decision-making in clinical practice is often quite low. For example, when presented with hypothetical patients with no significant medical history and normal physical examinations, most physicians participating in a study of clinical decision-making indicated that their decision to order mammograms or prostate-specific antigen (PSA) tests was independent of patient preference (Dunn et al., 2001). In fact, one-third of the participants would not discuss cancer screening with the patients at all. These physician attitudes are confirmed by the experience of real patients. In a study of preferred and perceived decision-making roles in 233 cancer patients, 45 percent preferred a shared role, but only 24 percent felt that decision-making was shared. In addition, patients who perceived their role as being more passive than they would have liked indicated that they wanted more information on treatment options and their side effects, a chance to voice their concerns, and greater reassurance that they would be well looked after (Gattellari et al., 2001).

In an effort to critically evaluate the quality of information-sharing during the clinical encounter, Braddock et al. (1999) analyzed audiotapes from 1,057 patient-
physician encounters for elements of informed decision-making, using preestablished criteria. The authors found that only 9 percent of decisions met the definition of completeness for informed decision-making. Even when the least stringent definition was applied, only 20 percent of discussions were considered complete. Basic decisions were most often completely informed (17 percent), but few intermediate or complex decisions were (less than 1 percent), despite the fact that intermediate and complex decisions made up nearly half of the decisions observed. Across the three levels of decision complexity, the nature of the decision was discussed most frequently (66-84 percent). Treatment alternatives (6 - 30 percent), pros and cons (2 - 26 percent), or uncertainties associated with the decision (1 - 17 percent) were rarely discussed. Physicians sometimes discussed patients’ role in decision-making (5 - 18 percent) and elicited patients’ preferences (18 - 27 percent), but rarely explored whether patients understood the decision (1 - 7 percent).

Lack of time was cited as one reason physicians limit patient involvement in decision-making (Dunn et al., 2001). Indeed, Braddock et al. (1999) found that during visits averaging between 14 and 17 minutes, about two to three patient concerns were addressed. However, physicians do include more elements of informed decision-making for complex decisions (Braddock et al., 1999). Other factors, such as language barriers, may offer partial explanations for why some decisions were poorly informed (Dunn et al., 2001). Overall, these results raise concerns regarding whether patients are adequately involved in clinical decision-making. However, these studies are cross-sectional, and it is possible that many patient concerns had already been addressed in prior visits or that resources (e.g., nurse practitioners, health educators, and decision aids) providing necessary information for informed decision-making were available to patients outside the clinical encounter.

Patients’ Need for Information

The Level of Patient Information Need

While the degree of information-sharing during the clinical encounter appears limited, patients consistently report a high demand for information. Strull et al. (1984) reported that 41 percent of 210 patients with hypertension wanted more information about their condition. Similarly, Kennelly and Bowling (2001) found, in focus groups with 38 cardiac patients (aged 56 and older), that participants did not feel they received sufficient information from their doctors to make informed choices.

Patients and their families appear to fill some of the information gap by accessing health websites on the Internet. A report on the use of online health resources, funded
by the Pew Charitable Trusts, estimated that 52 million Americans, or 55 percent of those with Internet access, used the Web to get health or medical information (Fox and Rainie, 2000). Of those who sought health information for themselves, 47 percent indicated that the material they found influenced decisions made about treatment or care. However, the quality (i.e., accuracy and completeness) of the information on these websites is not monitored, and a recent study reported that coverage of important clinical information has been poor (Berland et al., 2001). For example, the authors reported an average of 16 percent, 20 percent, 27 percent, and 35 percent of key questions about breast cancer, depression, childhood asthma, and obesity, respectively, received no coverage at English-language sites and 49 percent, 61 percent, 33 percent, and 69 percent of the elements for these four conditions received no coverage at Spanish-language sites. Despite these quality concerns, however, the popularity of Internet health resources reflects the strong demand patients and their families have for readily available information about clinical conditions and treatment options.

**What Kinds of Information do Patients Look For?**

Fox and Rainie (2000) found that among those using online health resources, 70 percent reported that their last online search was for a specific condition. Of those who looked for medical information for a specific condition, 48 percent looked for information on symptoms, 30 percent sought information about treatments or medicines, and 29 percent looked for information on what happens to people who contract a specific illness. Kennelly and Bowling (2001) found that participants in their focus groups wanted more information about their condition as well as balanced information about treatment options and their associated health outcomes. Similarly, Gattellari et al. (2001) found that cancer patients wanted feedback on the progression of their disease, information about their prognoses, and the risks and benefits associated with different treatment options and side effects.

**Patient Preferences for a Decision-Making Role**

While the demand for information was uniformly high, the level of involvement patients desire in decision-making is less predictable (Robinson and Thomson, 2001). Studies have reported that a large proportion of patients want to participate in therapeutic decisions (69 percent of 439 interactions between hospitalized cancer patients and oncologists in Blanchard et al., 1988; 45 percent of 233 cancer patients in Gattellari et al., 2001). However, these studies also found a sizable minority who preferred to delegate responsibility for treatment decisions to physicians (31 percent in Blanchard et al., 1988; 37 percent in Gattellari et al., 2001). This variability in patient
preferences for involvement has led researchers to search for factors that can predict the role patients want in treatment decision-making.

Demographic and Socioeconomic Effects on Decision-Making Preferences

A number of demographic and socioeconomic factors, including age, gender, and education, have been observed to influence patients’ preferences for participation in treatment decision-making. In particular, younger age is associated with a desire for greater involvement. For example, Vertinsky et al. (1974) observed that the desire for participation decreased with age (Spearman $r = -0.23$, $p = 0.001$, $N = 200$, randomly sampled from the community). Similarly, Blanchard et al. (1988), Degner and Sloan (1992), and Deber et al. (1996) reported that younger cancer patients expressed a greater desire for an active role in decision-making and that being older was associated with a desire to delegate treatment decision responsibilities to physicians. However, it is possible that the observed association with age may be partially or primarily due to a cohort effect. Females were also more likely to desire an active role in decision-making, although the effect was less consistent. Vertinsky et al. (1974) reported that females were less likely to want to delegate decision-making responsibilities to physicians, and Blanchard et al. (1988) observed that female cancer patients were more likely to want an active role. However, McKinstry (2000), who studied 410 patients’ preferences for a shared or directed approach in five hypothetical clinical scenarios, found no major association with gender. Degner and Sloan (1992) observed that a higher level of education was associated with a desire for greater responsibility for decision-making in a newly diagnosed cancer sample, and McKinstry (2000) found that higher social class was associated with a desire for a shared style of decision-making. Despite these effects, demographic and socioeconomic variables accounted for only a small proportion of the variance in decision-making preferences (15 percent in Degner and Sloan, 1992). Furthermore, the relationship between these variables and role preferences are likely to be complex, and neither Vertinsky et al. (1974) nor Degner and Sloan (1992) believed that these variables could adequately predict decision-making preferences in patients.

Health Status Effects on Decision-Making Preferences

Studies have found that patient preference for involvement declines as they move along the spectrum from wellness to illness. For example, Vertinsky et al. (1974) reported that greater frequency of visits to the physician ($r = -0.31$, $p = 0.001$) and longer hospitalizations ($r = -0.22$, $p = 0.003$) were associated with a lower desire for an active role in decision-making. Similarly, Degner and Sloan (1992) reported that 59 percent of 428 cancer patients, but only 9 percent of 271 subjects among the general public wanted a passive role in decision-making. The authors noted that recent diagnosis in the cancer
patients might have contributed to their desire to delegate decision-making responsibility, while the hypothetical scenario posed to the public might have led these subjects to overestimate their desire for an active decision-making role. However, Blanchard et al. (1988) also found that patients with advanced disease and lower functional status were less likely to want involvement in decision-making. On the other hand, Degner and Sloan (1992) reported that neither symptom distress levels nor stage of disease (cancer) were associated with patient role preference in decision-making. In addition, 51 percent of cancer patients and 46 percent of the general public wanted their physician and family to share responsibility for decision-making if they were too ill to participate. Finally, Gattellari et al. (2001) reported that patients with metastatic cancer were twice as likely to perceive that their role was more passive than they would have liked (adjusted odds ratio: 2.01; 95% CI: 1.13, 3.59).

Despite evidence of demographic, socioeconomic, and health effects, the variability in decision-making preferences remains largely unexplained. It is important to note that the cross-sectional nature of this research makes it difficult to determine if different preference sets reflect types of patients or states of interest that may be influenced by experience or education. For example, it has been suggested that patients may be reluctant to participate in decision-making because they are overwhelmed by the amount of information, the complexity of different choices, and the anxiety associated with the need to make the “right” decision (Frosch and Kaplan, 1999), a reluctance that could be overcome by a well-designed decision support aid. Furthermore, a positive experience in collaborative decision-making or greater knowledge about their condition may lead patients to desire a more active role in the future. However, without adequate follow up, the nature of such effects is unknown. This issue has particular relevance for patients with chronic diseases who become increasingly knowledgeable about their illness and must make multiple decisions over time (Watt, 2000). Furthermore, preferences for decision-making roles may be influenced by factors, such as the dynamics of the patient-physician relationship, that can change over time or are amenable to change through patient and physician intervention (Guadagnoli and Ward, 1998).

Contextual Influences on Shared Decision-Making

Contextual factors, such as organizational structure and the nature of the patient-physician relationship, can affect the propensity of patients and physicians to engage in shared decision-making. As part of a study of shared decision-making in medication use, Stevenson et al. (2000) asked 20 general practitioners to identify factors that would
hinder or facilitate shared decision-making. In these discussions, physicians’ beliefs about their patients’ ability to understand medical language and medical problems was identified as a barrier to patient participation in decision-making. However, the physicians in the study also believed that an organizational shift toward greater teamwork with other health care professionals would generate more opportunities for shared decision-making. The nature of the patient-physician relationship may also affect the likelihood of patient involvement in treatment decision-making. One recent study with asthma patients suggests that the longer the patients’ relationship with their doctor, the more their doctor will involve them in decision-making (Adams et al., 2001). Although these studies suggest that contextual factors can influence whether shared decision-making takes place, few studies have explicitly examined the effect of these factors on patient involvement in treatment decision-making.

**Shared Decision-Making Programs and Decision Aids**

**Use of Shared Decision-Making Programs**

Decision aids and shared decision-making programs have been developed for a variety of conditions including cancer, hypertension, and HIV/AIDS (Hersey et al., 1997; O’Connor et al., 2003; Hing et al., 2000; Montgomery et al., 2000; Murray et al., 2001a; 2001b). However, their rates of use appear to vary substantially (Hersey et al., 1997). For example, the PC-based Comprehensive Health Enhancement Support System (CHESS), placed in the homes of breast cancer (N = 400, Gustafson et al., 1996) and HIV/AIDS (N = 116, Boberg et al., 1995) patients, was heavily used. The program offered patients the opportunity to communicate with and share personal stories with other patients, as well as the ability to ask questions, retrieve information, and obtain assistance in decision-making tasks. Seventy-five percent of breast cancer patients referred to the CHESS program utilized the system and all of the HIV/AIDS patients used some aspect of the program, with services associated with enhancing social support being the most popular. Hersey et al. (1997) suggested that the breadth of offerings provided by CHESS might be a major factor promoting its acceptance because lower rates of use were observed for programs with narrower offerings.

Ease of access may also be important in enhancing rates of use. One study reported that only 14 percent of patients with low back pain used a tool that required an additional visit (Kamas, 1995). Programs that are readily accessible in patients’ homes, either on a personal computer (e.g., CHESS) or through the Internet, might produce the highest levels of use. Finally, active promotion of the shared decision-making tool at the organizational level is likely to be necessary for continued use of the tool by patients; the
use of an interactive videodisc system on benign prostatic hyperplasia dropped from 41 percent to 13 percent when the tool was no longer promoted by the care system (Wagner et al., 1995).

**Patient Attitudes and Knowledge**

Despite variability in rates of use, evaluations of shared decision-making programs and decision aids suggest that these aids are viewed positively by patients and can influence treatment decisions and patient behavior. Frosch et al. (2001) found, in a cross-sectional study of shared decision-making interventions for PSA tests, that 70 percent of all participants (N = 176) felt “somewhat positive” or “very positive” about participating in shared decision-making interventions. A greater percentage of those in the intervention groups expressed a desire for shared decision-making than in the usual care group (discussion: 55 percent; video: 67 percent; discussion + video: 70 percent; usual care: 47 percent). Those in the intervention groups were much less likely to want their physician to be the primary or only decision-maker (discussion: 2 percent; video: 4 percent; discussion + video: 8 percent; usual care: 49 percent). O’Connor et al.’s (2003) systematic review also found patients were more likely to take an active role in decision-making (pooled relative risk = 1.83, 95% CI = 1.02, 3.27).

The literature on decision-making programs and decision aids also suggest that these aids can increase patient knowledge of their condition and its treatment. Hersey et al. (1997) found that in eight of nine randomized trials of interactive videodiscs, videotapes, or brochures/fact sheets, users of these aids reported greater knowledge. O’Connor et al. (2003) estimated in their systematic review that average knowledge scores improved 9 to 28 points out of 100 (weighted mean difference = 19, 95% CI = 13, 25) when decision aids were used compared with usual care. They also found that patients who received a detailed decision aid that included descriptions of probability estimates were more likely to have realistic expectations of treatment risks and benefits than those who were given usual care (pooled relative risk = 1.48, 95% CI = 1.3, 1.8).

**Treatment Selection**

The effects of decision aids on treatment selection were variable. O’Connor et al.’s (2003) systematic review did not find that decision aids affected patients’ decisions to circumcise male newborns or to get genetic screening for breast cancer. However, a 76 percent increase in preference was observed for hepatitis B vaccine in one study (Clancy et al., 1988) and a 25 percent reduction in the use of warfarin was observed in another (Man-Son-Hing et al., 1999). The review also noted a nonsignificant trend, between 21 and 42 percent, toward reducing patient preference for invasive procedures in studies of patient preference for major surgery.
Although these results suggest that decision aids can sometimes influence treatment selection, it is unclear whether these aids actually help patients achieve better downstream effects, such as persistence with choice or fewer regrets with treatment decisions (O’Connor et al., 1999). One study found that a substantial proportion of men who were previously treated for metastatic prostate cancer (23 percent of 201) regretted their choice (Clark et al., 2001). However, the limited empirical data currently available suggests that decision aids can do little to improve these downstream outcomes (Goel, 2001; O’Connor et al., 2003).

**Overall Effects of Decision Aids**

In general, decision aids appear to make patients be more knowledgeable about treatment options and have more realistic expectations about the risks and benefits of different therapies. Furthermore, there is evidence to suggest that decision aids can encourage more active participation in treatment decision-making and lead to decisions that are more informed and consistent with patients’ personal values. However, their utilization rate and effects on treatment selection have been variable, and limited evidence is available to indicate that decisions made after using these aids produce greater persistence with chosen therapy or reduce decisional regret. Furthermore, more research is needed on how patients’ sociodemographic characteristics, literacy level, and personal predisposition affect the way they access, use, and benefit from decision aids (O’Connor et al., 2003).

**Patient Perspectives on Risk Information: Content and Format**

**In What Format Do Patients Want the Information?**

Health information may be perceived as more useful when it is tailored to the patient. Jones et al. (1999) conducted a randomized clinical trial of 525 cancer patients that compared the effect of health information tailored to a patient’s medical record with general information. The authors found that two-thirds of subjects who were given access to both personalized and general health information chose the personalized system first. Those in the personalized system group were also more likely to be satisfied, to think that the information was relevant, and to feel that they had learned something new. Patients in the personalized information system group were also more likely to use the computer in the follow up visits (20/169 versus 4/155, p = 0.002). Finally, a systematic review by Edwards et al. (2000) indicated that individualized risk estimates produced stronger intervention effects, suggesting that probability estimates can be effective for improving outcomes, particularly if tailored to the individual.
Treatments often produce adverse events, which can range in severity from a mild rash to death. Relating the severity of these events and the likelihood they will take place is known as risk communication. Research on risk communication suggests that patients can find risk information difficult to understand, especially when expressed in numeric terms (Edwards and Elwyn, 2001; Kennelly and Bowling, 2001; Lloyd, 2001). These studies have also found that although some prefer quantitative presentation of risks, many prefer to reinterpret numeric risks presented qualitatively (e.g., high or low).

It is important to note that how the information is framed and the complexity of the data display can determine whether the information gets used in decision-making, particularly for decisions that are difficult and unfamiliar, yet of importance to the individual (Hibbard et al., 2002; Vaiana and McGlynn, 2002). Furthermore, individuals may not be aware that the weight they place on a particular attribute, such as cost or quality, may not be accurately reflected in how they make their decisions (Hibbard et al., 2002). Edwards and Elwyn (2001) noted that stand-alone risk estimates can lead to overweighting low probabilities and underweighting high probabilities; framing the same risk information in terms of survival rather than mortality can affect perception and choice behaviors so that individuals have a more favorable impression of survival estimates (Tversky and Kahneman, 1981). In general, those attributes that are easy to assess, familiar, and have a precise frame of reference tend to get greater weight during decision-making than attributes that are less familiar or have a more fluid frame of reference. For example, in health plan decisions, costs may become a more important driver of choice because they are more familiar and precise than quality information, which is more complex and difficult for people to understand (Hibbard et al., 1997). In addition, integrating information on multiple attributes, such as costs and quality or side effects and quality-of-life, is challenging for individuals to tackle on their own, especially if tradeoffs are necessary to arrive at a final decision. Cognitive testing studies suggest that different ways of presenting the same information can be influential in changing how attributes or outcomes information are used in decision-making (Hibbard et al., 2002). Therefore, further research on efforts to help individuals gain greater familiarity in evaluating outcomes information and to identify information displays that facilitate this process will likely be very helpful for patient decision-making (Vaiana and McGlynn, 2002; Hibbard et al., 2002).

**Physician Perspectives on Tailored Information for Patients**

Physicians will likely welcome new technology that can help them tailor treatment recommendations to their patients’ needs. Deber and Thompson (1987) noted that the
main difference between physicians who recommended conservative breast surgery and those who recommended modified radical mastectomy for a hypothetical patient appeared to be their views on the relevancy of group-level results for individual patients. In their survey of 228 oncologists and surgeons, the authors found that physicians recommending aggressive treatments were more likely to agree with the statement: “Clinical trials do not allow the physician to take sufficient account of the uniqueness of the individual patient.” Similarly, in a focus group study by Edwards et al. (1999), the physicians indicated that group-level information is less useful in clinical practice.

The importance of tailoring extends beyond the clinical characteristics of the patient. Physician participants in the Edwards et al. (1999) study also highlighted the need for a diversity of data presentation formats to tailor to the experience and comfort level of the patient. Physicians tended to view graphs as a good way to concretely present data (including both absolute and relative risks) without being too “scientific” or too time-consuming. However, they also recognized that graphic presentation might not work for all patients, some of whom may find chances or odds ratios more useful.

**Data Banks or Data Bases**

*Opportunities and Challenges*

The concept of using data banks or data bases to assist physicians in tailoring treatment recommendations for individual patients is not new. In his 1976 editorial, Fries suggested that data from patients closely matching the characteristics of the patient being seen by a physician be located in a data base. He gave an example listing characteristics of four patients with comparable clinical variables. For each patient, the 30 most similar patients were selected from the data base. Frequencies of adverse outcomes (e.g., mortality, rash) were presented along with the therapy associated with the best outcome. He noted that despite similar clinical characteristics, the data base produced four different prognoses and four different therapeutic recommendations. Hlatky et al. (1984) noted the complementary roles of data bases and randomized clinical trials, citing the importance of data bases for the vast majority of patients which randomized trials, with their stringent inclusion criteria, may not adequately represent.

However, concerns with the use of data bases have also been raised. Mantel (1983) cited the simple case in which the selectivity of treatment is often associated with disease severity, so that the most effective treatments may be given to the sickest patients—who in turn are most likely to suffer the worse outcomes, making the treatment appear to perform poorly. The idea of matching patient characteristics, as
suggested by Fries (1976), may alleviate some of this problem. However, the size and
balance of the pool of matching candidates and the consequent level of matching
achieved in the data base would likely vary for patients with different characteristics
and affect the reliability of the statistics produced. In fact, the reliability of the data base
estimates would likely be lowest in extreme cases for whom available matching
candidates is limited. For the data base to be useful as a decision aid, mechanisms for
limiting selection and other forms of bias must be devised to ensure the reliability and
representativeness of the information produced.

**Data Bases as Decision Support**

Published studies of the utility of data banks for decision support are rare. One
study (Li et al., 1984) examined the influence of estimates from the Duke-Harvard
Collaborative Coronary Artery Disease Data Bank on physicians’ treatment
recommendations. The authors found that physicians agreed on the recommended
treatment course for 68 percent of the 60 patients and their recommendation for these
patients rarely changed when presented with the estimates from the data bank.
However, in the 19 patients for whom physicians’ initial recommendations were
divided, 10 percent of the recommendations did change. It is interesting to note that
physicians who changed their recommendation subsequently placed greater value on
the data bank, suggesting that physicians’ perception of a decision or information aid
may be improved if they feel that it can provide relevant new information for a clinical
problem they faced.

**Lessons from the Literature**

The relevance of shared decision-making for clinical medicine has gained greater
recognition in recent years. However, evidence suggests that patients are often not fully
informed about treatment choices during the clinical encounter. Furthermore, the level
of patient involvement in treatment decision-making is low. Contextual factors, such as
the length of the patient-physician relationship, may influence the extent to which
patients are involved. However, there is limited empirical evidence available to support
this claim.

While patients’ interest in treatment decision-making varies, their information
needs are consistently high and they are likely to be active information seekers. Shared
decision-making programs and decision aids offer opportunities to fulfill some of
patients’ need for information and decisional assistance. While continued evaluation of
such aids is necessary, evidence to date suggests that they can increase patient
knowledge, influence treatment decisions, and encourage patient involvement in
decision-making, although their long-term effects are still unclear.

Research suggests that personalized information would most likely be popular
among patients and physicians. Furthermore, individualized risk estimates are likely to
be effective in influencing treatment choice. An outcomes data base offers a flexible
strategy for providing individualized information to assist patients in treatment
selection. However, several design issues should be considered:

• **Level of Patient and Physician Participation and Potential for Bias.** The
  level and selectivity of participation will directly affect the ability of the
data base to provide unbiased individualized estimates. Therefore, it is
important that the data base be inclusive of patients with different
sociodemographic and clinical characteristics and of all available
treatments, including watchful waiting.

• **Sample Size and Reliability of Estimates.** It will be important to assess
  how the number of matching candidates affects the quality of the
information produced. Particularly if an individual’s clinical
characteristics are uncommon, the number of available matches may
become quite low and the reliability of the estimates will deteriorate. It
may be helpful to determine a threshold for matches below which
estimates should not be considered useful.

• **Privacy and Confidentiality Concerns.** To enhance the breadth of
  participation and the cooperation of participants, it will be important to
put in place safeguards to protect the confidentiality of patients and
physicians who provide data for the data base.

• **Information Tailored to the Patient.** Patients prefer to see information
  that is personalized to their situation rather than generic results that may
or may not apply to their unique profile. However, integrating
information for multiple dimensions such as different side effects and
quality-of-life outcomes is a difficult task. Therefore, it may be necessary
to provide training or assistance to help patients and physicians develop
skills and gain familiarity in incorporating different types of information
during treatment decision-making.

• **Format and Content Considerations.** The ability of patients and clinicians
to understand and use risk information can vary. Furthermore, their
comfort level with different presentation formats (e.g., qualitative
descriptions of risk, numeric estimates, graphical displays), also appears to
vary. Therefore, it will be important to develop a flexible system of data presentation in which users can specify a mode of presentation and reading level with which they are comfortable. Creating options that allow a patient easy access to the information (e.g., at home via the computer or Internet) is likely to promote use; however, depending on the complexity of information shown, this may need to be balanced with information that is jointly reviewed and discussed by the patient and physician.

- **Cognitive Testing of Different Presentation Formats.** Research has shown that the weight given to different factors during decision-making can be influenced by presentation formats. It may be necessary to incorporate a cognitive testing stage to identify important presentation features that will facilitate the process of integrating information from multiple outcomes during decision-making.

- **Promotion of Data Base.** Use of the shared decision-making programs are influenced by patient and physician awareness of their availability. For the data base to achieve widespread use by the patient and clinical community, it will be important to actively promote or advertise the availability of the information, and this promotion will likely need to be ongoing.

- **Physician Attitudes and the Structure of the Patient Encounter Represent Potential Barriers that Must Be Addressed.** The current degree of information-sharing in clinical practice is poor, and physician attitudes of “knowing what is best for the patient” or “the information is too complex for the patient to fully grasp” are factors in the limited sharing of information that occurs today. Additionally, patient encounters are brief, hindering the ability of clinicians to take the time to fully educate their patients. These factors will need to be addressed if an informational data base is to achieve widespread use in clinical practice.