CHAPTER 6:
CONCLUSIONS AND RECOMMENDATIONS

Is There a Need for National Outcomes Data Bases?

Based on our review of prostate cancer and osteoarthritis as two candidate clinical conditions that illustrate the complexity of treatment choices faced by patients, we found a very strong desire among patients to have access to an information source that would not only explain what their condition is but would also help them understand what the various treatment options are and what outcomes (i.e., survival, functioning, side effects) people like themselves could expect from each of the various treatment options. Overwhelmingly, patients observed that information on differences between treatment options and outcomes was difficult to obtain, was not synthesized and presented in a way to allow them to understand the tradeoffs, and rarely offered insights as to what their own experience might be given their unique patient characteristics (e.g., age, race/ethnicity, gender, health status, stage of disease). Patients also underscored that they do not have a reliable source for accurate information on alternative treatment therapies and their effectiveness, something that is of high interest to patients. Patients with prostate cancer and osteoarthritis also described relying heavily on other patients for information—in the absence of information that was presented from the patient’s perspective as to what they might experience—as well as the Internet, where they acknowledged it was difficult to assess the accuracy of the information presented.

Patients, perhaps because of their own difficulties in finding information, indicated they would be very willing to participate in a longitudinal outcomes data base, particularly if they understood that it would benefit future patients in their quest for information. While patients wanted to ensure that their own personal data were protected, they did not see privacy issues as an obstacle to their participation. Patients expressed a preference for the federal government (e.g., National Institutes of Health) or a nationally respected and trusted organization (e.g., American Cancer Society) to operate such a system because these parties would have no vested interest in any particular form of treatment and were more likely to present accurate information. Patients noted they would have reservations about participating if the project were sponsored and operated by a pharmaceutical company or medical device manufacturer that produces a treatment. Their concern stemmed from a belief that these types of entities might be less willing to provide objective information and/or might try to market products directly to patients participating in the data base project.
Providers also expressed considerable support for the People Like Me data base concept, particularly as it pertained to obtaining information on the clinical benefits of various therapies for different types of patients. They also seemed interested in finding ways to better organize and present information to help patients understand treatment options because they currently struggle with how best to communicate with patients given a wide range of abilities and patient preferences for information—from “you make the decision, doctor” to “I want to know all my choices and what is going to happen as a result of each choice.” Both providers and patients agreed that a national outcomes data base would provide an important tool for shared decision-making between patients and providers, something that is currently lacking.

Providers did express concern about the validity of the data base depending on how the sample of patients whose data make up the data base were chosen. They underscored the complexity of gaining representative participation by providers and patients in a voluntary data base that reflected a sample of patients with the condition—which could potentially lead to a biased sample. Physicians expressed some reservations about patients being able to view the outcomes information by themselves outside of the doctor-patient consultation; however, they acknowledged that the Internet has greatly transformed the discussions that doctors have with their patients—so that patients often come to the doctor armed with information they want to discuss. Their primary concern regarding the construction of the data base seemed to be with the accuracy and validity of the information contained in the system.

Is It Feasible to Develop a National Outcomes Data Base?

With respect to the feasibility of developing national outcomes data bases, it was clear from our research that efforts have already been made—both in the United States and abroad—to develop data collection systems that longitudinally track patient outcomes. Outside the United States, these are more frequently disease registries that capture 100 percent of the patients with a particular condition or treatment—typically within national health systems. The information derived from the longitudinal data base systems that we reviewed was viewed as extremely valuable for research purposes to understand how patients fare under different forms of treatment—especially as treatments evolve after the clinical trial stage. And, while not yet fully realizing their potential in this regard, the data bases were seen as a valuable tool to support clinicians in their interactions with patients. None of the projects that we reviewed had taken the next step of making the information available for direct use by patients, although the developers noted that this was an important audience for the information, and they
were interested in finding ways to translate existing data for use by consumers and exploring how they might modify their data base efforts in the future to support greater shared decision-making between physicians and patients.

The existing longitudinal data base efforts demonstrate that establishing an outcomes data base is technically feasible and is valued by end users, but that substantial resources are required to design and operate them. The amount of resources required largely depends on the number of patients and providers required to participate in the data base to produce statistically reliable results by different profiles of interest to patients (how many People Like Me demographic and clinical characteristics are accounted for), the amount of data required to be captured (how many data elements), the frequency and intensity of follow up efforts to track patients over time, and the scope of the effort (how many conditions and interventions are being monitored). To establish and operate a national outcomes data base, the investment is likely to range from $5 to $25 million annually—with the costs determined by the factors noted above.

Summary

Based on discussions with patients and clinicians, it is clear that comparative outcome information is lacking for many treatments and that patients make difficult decisions every day with little or poor information to inform those choices. We also know from the studies on shared decision-making tools that the availability of and promotion of the use of such tools can encourage greater information-sharing between patients and providers and help patients make more informed decisions and feel more satisfied with decisions. We also acknowledge that not all medical conditions would be appropriate for developing a longitudinal outcomes data base that could be used by patients and their physicians. As noted in Chapter 2, we outline key criteria that should be evaluated in the process of selecting appropriate conditions for such an effort. It is also important to note that the construction of such a data base will be complex and will benefit from starting with a pilot to test the concept and the design of the systems used to capture the data and then expanding over time to build the information base. Also, it appears that given the broad array of individuals—physicians, medical organizations, patients, and researchers—who will need to be involved, the effort will be most likely to succeed if it is a consortium effort.

There is keen interest among patients to have a People Like Me resource, providers support this activity, and smaller-scale efforts have been successfully designed and implemented. Prior to undertaking the establishment of any national
outcomes data base, we recommend conducting meetings with patient and provider representatives to solicit their support for and input into the design of the system. While various health conditions share similar features, we did identify through the patient-provider discussions some unique factors across different conditions that would affect the design and implementation of an outcomes data base. The patient and provider meetings and ongoing involvement will be essential steps in firmly defining the scope of the project, the goals of the data base, how data will be captured (which outcomes are of interest and how are they measured), how the data are analyzed, and how and what data will be shared with patients and providers—and will increase the chances of successful development and implementation.