CHAPTER 2:
A FRAMEWORK FOR ASSESSING THE FEASIBILITY OF ESTABLISHING
NATIONAL OUTCOMES DATA BASES

The design and construction of a national outcomes data base is a substantial undertaking, financially and logistically, and one that may not be appropriate for all clinical conditions. It is therefore important to establish a set of criteria that can be used to help guide decisions about whether a condition is a worthy candidate for such a data base. These criteria can be used as a first-level screen for assessing the likelihood for success of making an investment in data collection that will require long-term participation by a large number of patients and clinicians. Moreover, it is important to examine the nature and extent of existing data collection efforts for the condition of interest, and to determine whether they can be used to produce the information of interest; if they provide a foundation to build on or if a de novo effort is required; and what lessons can be gleaned from the experiences of these prior efforts to collect longitudinal data on the patient and clinical population of interest.

In conducting the assessment, RAND applied a framework that comprised (1) articulating the purpose of a national outcomes data base and defining the ways in which such data can be useful for patients and providers; (2) establishing a set of criteria for selecting candidate clinical conditions; (3) drawing from the shared decision-making literature to guide the construction of a patient-centered national outcomes data bases (see Chapter 3); and reviewing existing data bases (see Chapters 4 and 5).

Purpose of a National Outcomes Data Base

The purpose of creating the proposed People Like Me outcomes data bases is to provide information about experience with a course or courses of treatment, tailored to those demographic and clinical characteristics of patients that are known to influence the outcomes, and to help patients and their physicians make treatment decisions that lead to the best outcomes given patient preferences. This process can occur by making information readily available about the experience of different courses of treatment—whether drawn from clinical trials, treatment registries, or surveys—stratified by key patient characteristics. Depending on the condition selected, the way in which the outcomes data base is built may differ (i.e., a newly created registry versus combining existing data bases from clinical and observational studies); however, the basic data base concept being proposed is observational, following a
cohort of patients who have faced a treatment decision and chosen (or had chosen for
them) one of several available treatments (including watchful waiting). Once the
information is gathered and organized, the information then must be presented in
formats that can assist patients and clinicians with understanding the state of knowledge
regarding different treatment courses for the selected health conditions and patient
experiences with those treatments.

Criteria for Selecting Conditions for Review

The project team, in collaboration with the AHRQ project leader, selected eight
candidate clinical conditions for initial evaluation with the objective of narrowing the
clinical set to two conditions. The two chosen clinical conditions would serve as models
to explore and contrast a range of issues that would influence the feasibility of
establishing national outcomes data bases. We purposely selected two conditions that
would have different design implications to illustrate the range of issues associated with
such a project (e.g., existence or lack of existence of data bases, evidence-based treatment
guidelines versus consensus based guidelines, content). An assessment of all possible
clinical conditions for potential investment in creating outcomes data bases was outside
the scope of this project.

The eight conditions selected for consideration were arthritis, breast cancer,
congestive heart failure, epilepsy, infertility, multiple sclerosis, Parkinson’s disease, and
prostate cancer. Each of these conditions was evaluated against the following criteria,
which were developed to be used as an initial screen for determining whether a given
clinical condition was a good candidate for a data base.

Selection Criteria

1. **Prevalence of the condition in the population.** The condition should affect
a large number of people to ensure a large enough pool of potential
participants and to maximize the use of the data base and their effect on
treatment decisions. A larger pool of patients will also facilitate subgroup
analyses.

2. **Significant impact on health.** The condition should significantly affect the
person’s health and functioning (i.e., mortality, morbidity, and quality-of-
life).

3. **Existence of treatment alternatives.** The treatment course should involve
clear treatment decision points or alternative actions that patients could
take (e.g., medical versus surgical interventions, watchful waiting versus
active intervention)—so that the availability of information would help
patients evaluate and make more-informed treatment decisions with their clinicians.

4. **Variation in treatment experiences.** Although the treatment alternatives may have comparable long-term outcomes (e.g., mortality), differences should exist in the experience (i.e., process, intermediate outcomes) a patient will have. These differences should represent key determinants of patient choices.

5. **Existing data collection efforts.** The existence of a national data base that tracks selected aspects of care, which might serve as a foundation for building a more robust data base to assist with decision-making.

6. **Treatment alternatives that imply different cost profiles.** The different treatment alternatives have different costs and patients face varying out-of-pocket expenditures for care.

7. **Subgroup differences in outcomes.** The conditions are characterized by differences or disparities in treatment patterns for subgroups of the population (subgroups could be defined by demographic and/or clinical characteristics).

8. **An evolving knowledge base.** The conditions should reflect areas where the science of treatment is evolving or changing, so that there is a lack of information on the effectiveness of treatment alternatives (i.e., randomized controlled trials).

9. **Willingness of patients and providers to participate.** A high likelihood exists that clinicians and patients would be willing to participate in supplying information to create the data base.

In addition to these criteria, in our consultative discussions with patients and clinicians, three additional criteria were identified as important factors that would make a condition a good candidate for data base development: (1) A highly mobilized and vocal patient constituency exists that can advocate for the creation of the data base and that can mobilize patients to participate in the effort; (2) The condition is life-threatening or debilitating; and (3) The treatment is ongoing (or potentially recurrent) rather than a single occurrence.

**Condition Selection Overview**

To select two conditions for the People Like Me feasibility assessment, we applied the criteria listed above to eight candidate conditions: arthritis, congestive heart failure, epilepsy, infertility, multiple sclerosis, Parkinson’s disease, prostate cancer, and breast
cancer. Below, we briefly summarize our findings for each condition. In consultation with AHRQ, we decided a priori to examine one cancer condition and one non-cancer condition. We therefore organize our discussion by cancer and non-cancer conditions.

Non-Cancer Conditions

Arthritis. The Centers for Disease Control and Prevention (CDC) estimates that about 43 million Americans, or one out of every six individuals, have some form of arthritis. Furthermore, this number is expected to reach 60 million by the year 2020. In 1999, more than 17 percent of all disability among people over the age of 18 was caused by arthritis (Centers for Disease Control and Prevention, 2001). Osteoarthritis affects about 21 million people, making it the most common form of arthritis (Centers for Disease Control and Prevention, 2001). Arthritis is the leading cause of disability in the United States, and the daily activities of about 7 million Americans are limited by the disease. Arthritis, in all of its various forms, is responsible for 44 million outpatient visits and 750,000 hospitalizations each year. The annual medical cost of treating arthritis is $15 billion, and lost productivity accounts for an additional $50 billion annually in indirect economic costs (Centers for Disease Control and Prevention, 2001).

Depending on the severity of the pain and limitations in movement, patients usually have several different treatments from which to choose. Some patients may find it effective to use only one treatment, while others may need to combine several treatments to relieve pain and increase movement. Physical therapy, exercise, and Transcutaneous Electrical Nerve Stimulation (TENS) have been shown to be effective in reducing pain and increasing the ability to walk (Easton, 2001). Acetaminophen, NSAIDs, and COX-2 inhibitors have all been used successfully in treating osteoarthritis (Easton, 2001). When the pain is extreme or the range of motion is extremely limited, some patients may consider surgery for their osteoarthritis. Hip or knee replacement surgeries are treatment options when less invasive treatments fail. However, both are major surgeries that are expensive and can be dangerous to undergo (Easton, 2001).

While a number of the medications used to treat osteoarthritis have been studied in randomized controlled trials, the various treatments have never been compared against one another (i.e., medication versus surgery) and combination treatments have not been studied. Given a wide variety of available treatments and the lack of comparative information on the outcomes of these various treatments, it can be very difficult for patients to choose a treatment best suited for their circumstances.

Congestive Heart Failure. About 4.8 million Americans suffer from congestive heart failure (CHF), and about 400,000 new cases develop each year. In 1993, there were 42,000 deaths directly related to CHF (a four-fold increase from 1968) as well as another
219,000 deaths that were indirectly related to the disease. CHF is the most prevalent diagnosis among hospitalized patients over the age of 65: Approximately 20 percent of hospitalized patients in this age group have CHF as either a primary or secondary diagnosis. Between 1980 and 1993, the number of physicians’ office visits for the condition increased by 70 percent. As the elderly population grows in size, these numbers are expected to increase (National Heart, Lung, and Blood Institute [NHLBI] Fact Sheet, 1996).

In 1993, the annual direct medical costs of treating congestive heart failure were estimated at $17.8 billion. This figure includes hospitalizations, doctor visits, home care, nursing home care, and medications; however, it does not take into account indirect costs attributable to the condition such as lost wages for caregivers or the emotional toll that the disease can have on a family (NHLBI Fact Sheet, 1996).

Many decisions need to be made in treating CHF, especially given new, experimental and very costly treatments that continue to be developed. Decisions about CHF treatment are frequently made by the doctors in emergency situations with little input from the patients. Many of the treatments are backed by data from multiple randomized control trials (i.e., the use of ACE inhibitors, beta-blockers, digitalis, etc.). In other cases, there is evidence from a single RCT or consensus on the part of physicians (i.e., use of calcium channel blocking drugs, routine use of nutritional supplements) (Gomberg-Maitland et al., 2001). The American College of Cardiology (ACC) and the American Heart Association (AHA) revised their guidelines concerning the evaluation and management of CHF in 2001 (American College of Cardiology and American Heart Association, 2001). The ACC and AHA guidelines do provide treatment guidance for subgroups of the population, including groups defined by gender, race, age, and comorbidities. A People Like Me data base could help clinicians and patients grapple with decisions about the array of new treatments.

Because a number of treatments are available to patients with CHF, including many that are still experimental, an outcomes data base could provide an opportunity to track and compare outcomes. However, because treatment decisions often have to be made immediately in an emergency or urgent situation, it is unclear whether patients would be able to use the information effectively to influence their course of treatment.

**Epilepsy.** Epilepsy is a syndrome of susceptibility to repeated seizures. Nearly 1.4 million people in the United States have epilepsy and most are under the age of 45 (Epilepsy, 1996). The prevalence of epilepsy is higher for African-Americans than whites in every age group except those ages 15 - 24. For persons ages 35 - 44, the prevalence among African-Americans is about 13 per 1,000 compared to four per 1,000
for whites. For persons ages 45 - 55, the prevalence among African-Americans is 10 per 1,000 persons compared to four per 1,000 for whites. The disease is also slightly more prevalent among women than men with 5.1 cases per 1,000 women compared to 4.2 cases per 1,000 men (Morbidity and Mortality Weekly Report, 1994). The incidence of epilepsy is 30 to 56 new cases per 100,000 persons annually (American College of Radiology, 1999).

Based on information from the Epilepsy Foundation of America (Epilepsy Foundation of America website, 2002), the annual costs approximate $12.5 billion in direct medical costs for all types of treatment and indirect costs resulting from lost wages. Between 20 and 30 percent of epileptic patients are unemployed because their condition prevents them from keeping a job. Many new, effective, and costly medications have become available for treatment in recent years, and medication can cost patients thousands of dollars a year. In addition to drug therapy, treatments are available for recalcitrant cases—these treatments include vagus nerve stimulation, which generally costs about $15,000, and neurosurgery, which is even more expensive.

The recommended initial treatment once a diagnosis of epilepsy has been made is the standard dose of a first-line antiepileptic drug. A number of randomized controlled trials have been conducted that demonstrate the effectiveness of certain drugs for different types of seizures, thus providing evidence-based guidance for making treatment decisions (Browne and Holmes, 2001). If the medicine does not control the seizures, causes too many side effects, or is too toxic, then the dosage may need to be adjusted. If the dosage cannot be increased enough to control the seizures without causing unacceptable toxicity, then a new medication will need to be prescribed. Patients and physicians may consider discontinuing anti-epileptic drugs under certain circumstances when the patient is seizure free. The probability of recurrent seizures once medication is discontinued is between 25 and 50 percent (Browne and Holmes, 2001). Vagus nerve stimulation is a procedure whereby an electrode is attached to the left vagus nerve and a generator is implanted in the chest wall. Regular pulses of electricity prevent or interrupt seizures. Brain surgery to remove the area of the brain that causes the seizures or interrupts the nerve pathways along which the seizure impulse travels is also an option (Benbadis and Tatum, 2001).

Although epilepsy affects a significant number of people and can have a profound impact on the lives of the people it affects, with appropriate clinical management it can usually be controlled to the point that the person can live a normal life. In many cases, the person can discontinue the medications entirely after a few years.
Infertility. Infertility is generally defined as the inability to conceive after a year of intercourse without the use of birth control. In 1995, 15 percent of all women of reproductive age (15 - 44 years), or about 9.3 million women, reported ever receiving infertility services, and about 6.7 million of them (10 percent of women of reproductive age) were found to have infertility problems. Infertility rates vary widely by age group. About four percent of women ages 15 - 24 had infertility problems compared with 13 percent of women ages 25 - 34 and 21 percent of women ages 35 to 44 (Mosher and Bachrach, 1996). The population with fertility problems is very similar to the general population in terms of race and socioeconomic status. Infertility problems disproportionately affect older women of childbearing age (Stephen and Chandra, 2000).

In 1984 dollars, a successful pregnancy achieved through any form of infertility treatment cost an average of $10,700. However, the costs of treating infertility vary greatly depending on the underlying cause of the infertility and the treatment necessary (Cooper, 1986). A 1996 study found similar costs for the insurance company (about $10,500) in addition to about 35 percent more in patient cost-sharing for diagnosis and simple treatments. More-complex procedures such as in vitro or other assisted reproductive techniques were not included (Bates and Bates, 1996).

If it is possible to define the cause of infertility, then treatment will depend on the reason for infertility. If the problem is with the male, then intrauterine insemination or intracytoplasmic sperm injection are usually attempted. If the woman is not ovulating, then drugs are used to attempt to induce ovulation and intrauterine insemination can still be tried. If this does not work, there are other ovulation-inducing therapies as well. If ovulation is confirmed and semen analysis is normal, then the couple may try the drug therapy combined with intrauterine insemination anyway. If none of these therapies are successful, diagnostic testing with laproscopy is usually continued. If everything looks normal, these procedures are usually attempted again. However, if the fallopian tubes are blocked, the treatment may be a surgical attempt to open the blocked tube or to begin assisted reproductive techniques (Battacharya and Hall, 2000).

Infertility is an important health problem affecting approximately 10 percent of couples of reproductive age. It has a significant effect on quality-of-life including sexual problems, marital problems, depression, and potential financial hardship if treatments are pursued. There are clear patient-centered issues regarding complex treatment decisions for infertility, such as whether to be treated versus whether to adopt a child, which make it a good candidate for shared decision-making and patient-physician discussion.
Multiple Sclerosis. Nationwide, there are approximately 250,000 to 350,000 cases of multiple sclerosis (MS). The prevalence of multiple sclerosis is between 57 and 140 per 100,000 and geography is a key factor in the observed variation in prevalence rates. The observed prevalence of MS is higher (110 to 140 per 100,000) among the population in areas above the 37th parallel, which runs from Newport News, VA, to Santa Cruz, CA, compared to areas below the 37th parallel (57 - 78 per 100,000). MS is more common among Caucasians, especially those of northern European descent. It is practically non-existent in the Inuit population, however. It affects two to three times as many women as men (National Multiple Sclerosis Society, 2001).

In 1994 dollars, the cost per person per year for treating multiple sclerosis was about $34,000 (Whetten-Goldstein et al., 1998). Annual direct and indirect costs for treating multiple sclerosis in the United States are estimated at $6.8 billion, and the lifetime cost of treating one person with multiple sclerosis can be as high as $2.2 million. These costs include personal health services, paid or unpaid care from professionals or relatives and friends, retraining, equipment, and earnings loss. There is also the emotional cost of dealing with the disease, since it often prevents the person from working and there is a high likelihood that a person with MS will be in a wheelchair (Whetten-Goldstein et al., 1998).

Many MS patients show signs of recovery without treatment after a relapse, though most clinicians recommend treating each episode. Clinicians have successfully used corticosteroids to shorten relapses and speed recovery, even though there is no strong evidence that they aid in long-term recovery (Polman and Uitdehaag, 2000). Eventually, relapsing/remitting multiple sclerosis develops into a secondary progressive stage, in which the attacks are less pronounced and the remissions occur less often. Interferon beta is the usual course of treatment for this phase as well (Polman and Uitdehaag, 2000).

The impact of multiple sclerosis on quality-of-life for those who suffer from it is severe. Most persons with the disease will be forced to quit their job after only one year and will find themselves in a wheelchair within 15 years. In addition, the costs per patient may be as high as several million dollars over the course of a lifetime, placing a large burden both on health insurance companies and the patients and their families. However, there are few treatment options and most of the treatments are through drug therapy. Given limited choices of therapy and the fact that the disease affects many fewer people than the other conditions evaluated for study, MS would rank lower among the various conditions as a good candidate for a People Like Me data base.
**Parkinson’s Disease.** The estimated number of people with Parkinson’s disease in the United States is between 500,000 and 1,500,000. Based on information from the Mayo Clinic, the prevalence of Parkinson’s is about 200 cases per 100,000 people and the incidence of new cases is about 20 per 100,000 per year. The average age of onset of Parkinson’s is 60, although about 5 percent of cases occur before the age of 40 and are classified as early-onset Parkinson’s. While there is some indication that the prevalence of the disease is lower among Africans, Japanese, and Chinese, it is unclear whether this translates into lower prevalence among African-Americans, Japanese-Americans, and Chinese-Americans. There also seems to be a slightly higher prevalence among men than women, since six in 10 cases are male (Koller, 1993).

According to the Parkinson’s Action Network, the annual cost of drug therapy for early-stage Parkinson’s is about $2,000 - $7,000. For more advanced stages of the disease, the costs can run much higher. Treatment for Parkinson’s-related falls, which occur in about 38 percent of those with Parkinson’s, can be up to $40,000 or more, including hospitalization. In addition, about 30 percent of those with Parkinson’s will lose their jobs within a year, so disability subsidies can be as much as $30,000 annually. With progressive Parkinson’s, the patient often requires assisted living and nursing home care, which can cost more than $100,000 per patient (Parkinson’s Action Network, 1999).

Parkinson’s results from a severe shortage of dopamine, a substance that allows people to move normally. The main treatment for Parkinson’s is pharmacological, but there are several classes of drugs that can be used in treatment of the disease. In addition to these basic treatments, physicians will usually treat some of the symptoms of Parkinson’s, such as the tremors normally associated with the disease. While the ideal treatment would slow the progression of Parkinson’s, the main treatment goals are often to relieve the symptoms, so that they do not interfere with the patient’s daily life, and to reduce the chances of complications (Young, 1999). Surgery is considered a last resort, and is utilized only when the patient fails to respond to pharmacological treatment and does not have any cardiopulmonary risk factors for surgery. Several different surgeries may be appropriate for treating Parkinson’s (Young, 1999).

Parkinson’s disease affects a large number of people and significantly affects quality-of-life. As the disease progresses, it can lead to the need for assisted living, which can be very difficult and costly. Although there are some choices in treatment, the main treatment is pharmacological. Surgery is used only as a last resort. Therefore, patients have few decision-making options. While the costs of treating the disease are high, they are less than those of osteoarthritis and prostate cancer.
Cancer Conditions

Breast Cancer. Approximately 192,000 new cases and 40,000 deaths from breast cancer occur annually in the United States. Breast cancer is the leading cancer diagnosis among women and ranks second after lung cancer for all deaths from cancer among women. Overall, American women have a one-in-eight lifetime chance of being diagnosed with breast cancer. However, the probability of this diagnosis increases with age. A woman between 30 and 40 has a one-in-257 chance of being diagnosed with breast cancer as compared to a one-in-24 chance for a woman between 70 and 80 (National Institutes of Health, 2001).

The American Cancer Society estimates that expenditures for breast cancer treatment in the United States are about $6 billion annually in direct medical costs. The cost of breast cancer treatment is significantly lower when it is detected early. A 1996 study estimates that treating breast cancer in a preinvasive stage costs $30,000 to $40,000 less compared to treating it in a later invasive stage (Legorreta et al., 1996).

With a diagnosis of lobular carcinoma in situ (LCIS-stage 0), the preferred treatment is observation, since LCIS is not considered cancer but a risk factor. For stage I or II breast cancer (primary tumors less than 5 cm), a number of randomized clinical trials have shown that mastectomy or lumpectomy followed by radiation treatment is clinically and medically equivalent with regard to outcomes. For women whose breast cancer is metastatic, hormonal therapy is indicated if her hormone receptors are estrogen- and/or progesterone-positive. If not, chemotherapy will often be of benefit (National Comprehensive Cancer Network, 2000).

Prevalence, cost of treatment and impact on quality-of-life are all significant for breast cancer. Treatments for breast cancer have generally been well evaluated in clinical trials. In addition, at most stages of treatment, clear evidence-based guidelines exist on the course of treatment, and there is very little controversy over what works, except at very late stages when the cancer has metastasized. However, at various points in the treatment course, patients may be asked to make a choice about treatment that may involve different side effects, duration, and difficulty of treatment. The main choice a woman given a diagnosis of breast cancer may be faced with is whether to undergo a lumpectomy with subsequent radiotherapy or a mastectomy, where the radiotherapy is probably not indicated. These two choices have been shown to have clinically equivalent outcomes. Most of the other treatment choices (i.e., tamoxifen versus chemotherapy) have more to do with what will work for the woman’s particular clinical profile. It is also important to note that breast cancer patients are highly interested in
complementary and alternative medicines, none of which has been rigorously evaluated to guide treatment decisions.

**Prostate Cancer.** Prostate cancer is the most common cancer diagnosis and is second only to lung cancer in cancer-related deaths among American men. The American Cancer Society projects that in 2002, 189,000 new cases of prostate cancer will be diagnosed (American Cancer Society website, 2002). In 2000, there were roughly 32,000 deaths attributable to prostate cancer. Approximately 70 percent of all cases are diagnosed in men age 65 years and older. Prostate cancer is about twice as common in African-American men as in white men.

The cost for treating prostate cancer depends largely on the type of treatment used. A 2000 study of over 10,000 men treated for early-stage prostate cancer found that the average costs of the initial work up for diagnosis, treatment, and six-month follow up ranged from $12,000 to $30,300, depending on the type of treatment (Brandeis et al., 2000). Treating with radical prostatectomy and adjuvant radiation is the most expensive, with an average cost of $30,300. Radical prostatectomy alone had a mean cost of $18,300, and the adjuvant radiation alone typically had costs of $15,100. The least expensive form of treatment for early-stage prostate cancer was brachytherapy (radiation through radioactive seeds implanted directly in the tumor), at about $12,000 (Brandeis et al., 2000). Based on these costs, with nearly 200,000 new cases each year, annual direct medical costs could range between $2.4 and $6 million. All of the above costs are for treating early-stages of prostate cancer. When the cancer is discovered in later stages, it is likely to be much more expensive since extended treatments may be necessary. For metastatic disease, costs could include extended rounds of hormone treatments, chemotherapy, and palliative care, which could lead to even higher treatment costs.

For localized and regional disease, the most common treatments are radical prostatectomy or radiation therapy, although some physicians may recommend “watchful waiting” or hormone therapy depending on patient characteristics (such as age). Once the cancer has metastasized, there is no longer a choice in treatments. At this point, androgen ablation, either with hormone treatment or through orchiectomy, is the recommended treatment. If the androgen ablation ceases to contain the disease, then chemotherapy is used as a treatment of last resort (Pienta et al., 2001).

The prostate-specific antigen (PSA) screening test is now widely used, and an increasing share of prostate cancers are being detected at earlier stages where men have more options for treatment. At most stages of the disease, at least two treatment choices may be equally effective in terms of long-term outcomes but may have markedly
different intermediate outcomes on sexual, urinary, and bowel functioning. In contrast to breast cancer, for which there have been multiple randomized controlled trials to compare alternative treatment therapies, studies to compare the benefits of various treatment options for prostate cancer are almost entirely lacking. The exception is a recent study that randomly assigned newly diagnosed prostate cancer patients to watchful waiting versus radical prostatectomy and compared patients in the two groups on mortality, metastasis-free survival, and local progression (Holmberg et al., 2002). This study found no significant difference between surgery and watchful waiting in terms of overall survival, while radical prostatectomy significantly reduced diseasespecific mortality.

Prostate cancer represented an excellent candidate for exploring the range of issues associated with creating an outcomes data base because of the size of the population affected, the fact that prostate cancer can result in death, that there are treatment choices with varying consequences for the patient, and that little or no information is available to compare these choices.

Conclusions

Each of these clinical conditions meets many or all of the selection criteria enumerated above. For the purposes of this study, however, we were requested to narrow the list to two conditions as a means to explore the range of issues related to creating People Like Me outcomes data bases. Based on our review of the eight candidate conditions against the selection criteria, RAND, in consultation with AHRQ, selected prostate cancer and osteoarthritis as the conditions to use to examine the feasibility of establishing outcomes data bases for use by patients and providers.

These two conditions are very different in terms of the types of treatment choices and the consequences of those choices on the health and functioning of the patient, as well as the costs to the patient. Prostate cancer results in significant mortality among men, and while osteoarthritis is not a life-threatening situation it can cause severe disability over a person’s lifetime. Data bases exist for prostate cancer, (e.g., SEER, CaPSURE, PCOS) which may offer potential platforms on which to build a larger data base, although they are currently not structured to produce and make available information for use by patients. Some arthritis data bases exist, but they do not focus on osteoarthritis (the subset we selected for study), and most look at medications rather than surgical treatments. With respect to osteoarthritis, there has been a proliferation of surgical procedures and some of them are perceived to be underused.
Both prostate cancer and osteoarthritis have several treatment options that require patients and their doctors to make complex decisions. Additionally, once diagnosed with the condition, patients have time to engage in shared-process for both conditions. Few of the treatments for either condition have undergone randomized controlled trials to compare differences in outcomes (intermediate or long-term), so there is need for additional information on outcomes that patients are likely to experience. For both conditions, there are disparities in outcomes for subgroups of the population. Prostate cancer is about twice as common in African-American men as in white men. Arthritis is more common among women, older people, those in rural areas and those with low education or income levels. Both diseases present challenges for establishing an outcomes data base; however, there is ample opportunity to expand our understanding of the effects of different courses of treatment for two medical conditions that have little existing comparative outcomes information.

**Process for Conducting the Feasibility Assessment**

Once the two model conditions were selected, the project team did the following:

1. Identified examples of existing longitudinal data bases as well as data tools that were being used with patients to help them understand treatment outcomes.

2. Interviewed project staff within each of the identified data bases to examine what information they were collecting, how the data were used, and what the issues were in developing and maintaining a longitudinal data base to track patient outcomes.

3. Identified a list of physician leaders and patient advocates in each clinical area who could speak to the problems of existing information on which to base treatment decisions.

4. Held meetings with the physician and patient advocate leaders to reflect on the need for a People Like Me data base, articulate the questions the data base should be designed to answer, and explore the range of issues and challenges in collecting data.

5. Summarized the information from these discussions, interviews, and reviews of existing data collection efforts to guide future work on developing national outcomes data bases tailored to address the questions of People Like Me.

Chapters 4 (prostate cancer) and 5 (osteoarthritis) describe the work and findings from the feasibility assessment. Another important step in our assessment process was
an examination of the literature on shared decision-making (Chapter 3) to identify issues that have implications for using a People Like Me outcomes data base to provide decision support tools for patients and physicians.