

# Quality of Life: An Outcomes Perspective

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**ABSTRACT.** Kaplan RM. Quality of life: an outcomes perspective. *Arch Phys Med Rehabil* 2002;83 Suppl 2:S44-50.

This article compares a traditional biomedical model with an outcomes model for evaluating medical and rehabilitation care. The traditional model emphasizes diagnosis and disease-specific outcomes. In contrast, the outcomes model emphasizes life expectancy and health-related quality of life (QOL). Although the models are similar, they lead to different conclusions with regard to some interventions. For some conditions, diagnosis and treatment may reduce the impact of a particular disease without extending life expectancy or improving QOL. Older individuals with multiple comorbidities may not benefit from treatments for a particular disease if competing health problems threaten life or reduce QOL. Overall outcomes and benefits of treatment can be summarized by using measures of life expectancy that adjust for QOL. The quality-adjusted life year (QALY) has been proposed as a comprehensive summary index. QALYs have gained widespread usage in many areas of medicine. The outcomes model has been applied widely in rehabilitation research, but few studies estimate the benefits of treatments using QALYs. These methodologies can also serve as a basis for approaches to sharing medical decisions between patients and providers. Opportunities to apply these new methods are discussed.

**Key Words:** Health status indicators; Outcomes research; Quality-adjusted life years; Quality of life; Rehabilitation.

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**T**HIS ARTICLE HAS 3 objectives: (1) to differentiate an outcomes model from a traditional biomedical model; (2) to determine whether the traditional model leads to overdiagnosis and, perhaps, to excessive costs in health care; and (3) to propose that new methods of medical decision making, involving both patients and providers, can contribute to the solutions for these problems.

## MODELS

### The Biomedical and Outcomes Model

Medicine and clinical psychology are based on the art of diagnosis and treatment. Preventive health care is often re-

garded as a specialty for the early detection of treatment of disease. The traditional biomedical model, which is oriented toward disease, depends on measures of disease process. Diagnosis typically involves identification of pathology through physical examinations and psychologic tests. Successful intervention occurs when a disease is eradicated. We sometimes refer to this model as the find it—fix it approach<sup>1</sup>—diagnosis is used to find disease pathology and treatment is used to fix it.

The traditional model reflects traditional thinking. Since the time of Sir Isaac Newton, linear thinking has been the predominant worldview. Linear thinkers have focused attention on discrete components of the world and assumed that these components operated with independence from one another. Complex machines exemplify linear function because each component operates independently of each other.

### The Outcomes Model

An alternative conceptualization argues that the goal of health care is to make people live longer and feel better. This approach, known as the outcomes model, is similar to the traditional biomedical model in many ways. However, finding and fixing disease does not necessarily lead to the best patient outcomes. There may be occasions when diagnosis does not contribute to improved life expectancy or quality of life (QOL). In fact, there are occasions when diagnosis and treatment may lead to losses in health status.

One of the important distinctions between the traditional biomedical model and the outcomes model is the value placed on patient self-reports. The traditional biomedical model arose from attention to acute disease.<sup>2</sup> Acute diseases can typically be diagnosed and successfully treated (or sometimes they will get better on their own). These problems are often identified through a biologic test. With good testing, how patients report the experience may be of little value. Most of the information required to diagnose and treat the condition can be identified in the laboratory. The acute disease model dominates how we have developed health care, including the construction of hospitals, the development of training programs, and the creation of medical subspecialties.<sup>2</sup> The difficulty is that, since about 1950, the major burden on our health care system has been chronic disease.<sup>3</sup>

Chronic diseases typically have multiple causes, and most people who have 1 chronic condition typically have other chronic diseases as well. The Medical Outcomes Study, for example, recruited patients who had 1 of 6 chronic disease states. However, over 90% of the participants had other chronic conditions in addition to that which placed them in a category for the study.<sup>4</sup> In contrast to acute diseases that last for a brief time, chronic conditions are usually not cured. As a result, patients must adapt to these problems, and psychologic or social factors are of key importance. Patient interpretation of the condition and adaptation to the problem cannot be ignored.

The outcomes model also places greater emphasis on epidemiologic data. In contrast to the traditional biomedical model, which emphasizes identification of a basic disease mechanism, the outcomes model focuses on determinants of patient outcome. Sometimes, the exact pathology of a health condition is unknown. For example, some people challenge the existence of a disease unless they understand its pathophysiology. Fibro-

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myalgia, a painful disabling condition with unknown pathophysiology, is an example.<sup>5</sup> The outcomes model recognizes that biologic pathways may never be fully understood.<sup>6</sup> Further, some behavioral risk factors affect health outcomes through different biologic pathways.

One of the most important differences is in how the models define a unit of benefit. The traditional model usually links benefit to changes related to a diagnosis. For example, outcome might be assessed by changes in blood pressure, tumor size, or death from a specific disease. The traditional biomedical model often focuses on the small picture at the expense of avoiding the big picture. Much of contemporary preventive cardiology is based on observations from the Coronary Primary Prevention Trial (CPPT).<sup>7</sup> In this experimental trial, men were randomly assigned to take either a placebo or a drug known as cholestyramine. Cholestyramine can significantly lower serum cholesterol and, in this particular trial, produced an average total cholesterol reduction of 8.5%. In comparison to men using placebo, men in the treatment group experienced 24% fewer heart attack deaths and 19% fewer heart attacks.

One of the crucial features that differentiate the outcomes model from the traditional biomedical model is how each measures the outcome. The CPPT showed a 24% reduction in cardiovascular mortality in the treated group. The absolute proportion of patients who died from cardiovascular disease was similar in the 2 groups. In the placebo group, there were 38 deaths among 1900 participants (2%). In the cholestyramine group, there were 30 deaths among 1906 participants (1.6%). In other words, taking medication for 6 years reduced the chances of dying from cardiovascular disease from 2% to 1.6%.

The diagnosis-specific medical model focuses on cardiovascular deaths because the medicine was designed to reduce deaths from heart disease. Considering all causes of death, there was essentially no benefit of treatment. At the end of the study, 3.7% of those in the placebo group had died and 3.6% of those in the cholestyramine group had died. Cholesterol lowering by using cholestyramine may reduce the chances of dying from heart disease, but it is less clear that it reduced the chances of dying prematurely. The outcomes model does not take cause of death into consideration. From the outcomes perspective, the focus is on whether the patient is alive.<sup>8</sup> If a medication reduces the chances of dying from 1 disease while increasing the chances of dying of another, it is not regarded as effective.<sup>9</sup> Because virtually all treatments have the potential to produce harm as well as benefit, the outcomes model may be the most appropriate to evaluate benefits of treatment.

The outcomes model is consistent with the *Healthy People 2020* report. The primary public health objective for the United States is to decrease disability and increase longevity.<sup>10</sup> Many of these approaches attempt to summarize health by using 1 overall index number. Several approaches to measuring health outcome attempt to aggregate measures of morbidity and mortality into a single index of quality-adjusted life expectancy (QALE).<sup>11</sup> The outcomes model is consistent with several decades of work in rehabilitation medicine. Keith<sup>12</sup> outlined the need for a new model for rehabilitation nearly 35 years ago. Over the years, Keith<sup>13,14</sup> has argued for greater use of functional status outcome measures. Whiteneck et al<sup>15</sup> offered the Craig Handicap Assessment Reporting Technique as a method for evaluating outcomes of rehabilitation programs for people with handicaps. The value of related methods have been described in several important lectures and publications.<sup>16-18</sup> Many of the approaches have been consistent with the World Health Organization guidelines and have attended to performance of role activities. One important review<sup>19</sup> considered the

areas of coverage, respondent burden, and psychometric properties for various measurement approaches. Other recommendations have been offered by the National Center for Rehabilitation Research and the Agency for Health Care Policy and Research.<sup>20</sup>

One approach consistent with both the outcomes model and the rehabilitation research tradition is the estimate of benefits in terms of quality-adjusted life years (QALYs). However, despite the popularity of QALYs in many areas of medicine, there have been relatively few applications of it in rehabilitation medicine. For example, a recent search using PubMed identified about 1500 publications concerning QALYs. Among these, only a handful was relevant to rehabilitation medicine. QALYs are used in quality-adjusted survival analysis, which is a refinement of generic survival analysis. In traditional survival analysis, those who were alive are statistically coded as 1.0, whereas those who are dead are statistically coded as 0.0. Mortality can result from any disease, and survival analysis allows comparisons between different diseases. For example, the life expectancies for those who will die from stroke can be compared with the life expectancy of those who may die as a result of spinal cord injury (SCI). The advantage of these generic measures over disease-specific measures of brain or central nervous system function is that general comparisons of life expectancy can be considered. The disadvantage is that all individuals who are alive are considered equal. A person confined to home because of severe cognitive limitations is scored just as someone who is active and participating in activities. Utility assessment allows the quantification of levels of wellness on the continuum anchored by death and wellness.<sup>21</sup>

In the 1990s, the US Department of Health and Human Services (DHHS) convened an expert panel to set standards for cost-effectiveness analysis in medicine and health care. The panel suggested that outcomes be measured by using QALYs, which are measures of life expectancy with adjustments for QOL.<sup>11,22</sup> QALYs integrate mortality and morbidity to express health status in terms of equivalents of well years of life. If a woman dies of stroke at age 50 and one would have expected her to live to age 75, the disease was associated with 25 lost life years. If 100 women died at age 50 (and also had a life expectancies of 75y), 2500 (100×25y) life years would be lost.

Death is not the only outcome of concern in stroke. Many adults continue to suffer from the disease, leaving them somewhat disabled over long periods. Although still alive, the quality of their lives has diminished. QALYs take into consideration the QOL consequences of these illnesses. For example, a disease that reduces QOL by 50% will take away 0.5 QALYs over the course of 1 year. If it affects 2 people, it will take away 1 QALY (2×0.5) over a 1-year period. A rehabilitation treatment that improves QOL by 0.2 for each of 5 individuals will result in the equivalent of 1 QALY if the benefit is maintained over a 1-year period. The basic assumption is that life years can be adjusted for QOL by multiplying the time in each health state by its QOL preference weight to estimate QALYs. QALYs can be added together and estimated over multiple patients and multiple years. This system has the advantage of considering both benefits and side effects of treatment programs in terms of the common QALY units.

Another strength of using QALYs is that they incorporate changes in symptoms and functioning that traditionally have been components of rehabilitation evaluations. By measuring a wide spectrum of symptoms and concentrating on function, the proper assessment of QALYs includes global well-being, including psychologic aspects.

In addition to health benefits, programs also have costs. Resources are limited, and good policy decisions require allo-

cation that maximize life expectancy and health-related QOL (HRQOL). Methodologies for estimating costs have now become standardized. From an administrative perspective, cost estimates include all costs of treatment and costs associated with caring for any side effects of treatment. From a social perspective, costs are broader and may include costs of family members not working to provide care. Comparing programs for a given population with a given medical condition, cost effectiveness is measured as the change in costs of care for the program compared with the existing therapy or program, relative to the change in health measured in a standardized unit such as the QALY. The difference in costs over the difference in effectiveness is the *incremental cost-effectiveness* and is usually expressed as the cost/QALY ratio. Because the objective of all programs is to produce QALYs, the cost/QALY ratio can be used to show the relative efficiency of different programs.

A few recent examples of the application of QALYs in rehabilitation medicine include an evaluation of the effectiveness of aggressive care for patients with nontraumatic coma. One study<sup>23</sup> compared the cost-effectiveness of continuing aggressive care with withholding cardiopulmonary resuscitation and ventilation support after 3 days of coma. The analysis suggested that aggressive care produced relatively little health benefit but significantly increased cost. As a result, the cost/QALY ratio was very high.

Another example of the use of QALYs is provided by the Stroke Treatment Anecdotal Trial. Anecdotal is a product developed from the venom of the Malaysian pit viper. The product may produce rapid defibrinogenation and, therefore, may have value for the treatment of stroke. In 1 randomized clinical trial,<sup>24</sup> 248 patients with acute ischemic strokes received anecdotal, whereas a control group of 252 patients received placebo. Both groups were treated within 90 days poststroke. The analysis showed that anecdotal treatment both produced health benefit and reduced cost. In other words, the analysis clearly favored the anecdotal treatment.<sup>24</sup>

A third example is an evaluation of the impact of hip and vertebral fractures. In observational data,<sup>25</sup> women free of hip or vertebral fractures obtained scores of .91 on the 0 to 1.0 scale. Those with 1 or more vertebral fractures obtained scores of .82, whereas those with hip fractures scored .63. Vertebral fracture was equivalent to losing 20 to 28 days a year, whereas hip fracture was associated with an estimated loss of 23 to 65 days a year. The combination hip and vertebral fracture was estimated to be the equivalent of losing 115 to 202 days a year.<sup>25</sup>

In summary, QALYs combine measures of morbidity and mortality and do not require medical diagnoses. The measures include time or prognosis and incorporate preferences for health outcomes. A consensus conference with the DHHS recommended the use of QALYs to evaluate health programs.<sup>11</sup> A recent Institute of Medicine report<sup>26</sup> on the measurement of population health came to similar conclusions.

### The Disease Reservoir Hypothesis

The outcomes model sometimes leads to very different suggestions about the use of resources than does the traditional biomedical model. Perhaps the best examples concern screening for disease. According to the American Cancer Society (ACS), it is necessary to screen for cancers so that they can be detected early.<sup>27</sup> It is believed that there is a reservoir of undetected disease that might be eliminated through more aggressive intervention. Screening guidelines have been proposed, and patients who fail to adhere to these guidelines are regarded as uninformed.<sup>28,29</sup>

To understand the problem better, it is necessary to understand the natural history of disease. Public health campaigns often conceptualize disease as binary. Either persons have the diagnosis or they do not. However, most diseases are processes. It is likely that chronic disease begins long before it is diagnosed. For example, autopsy studies consistently show that most young adults who died early in life from noncardiovascular causes have fatty streaks in their coronary arteries that indicate the initiation of coronary disease.<sup>30</sup> Not all people who have the disease will ever suffer from the problem. With many diseases, most of those affected will never even know they are sick.

Among those who do have problems, some may not benefit from treatment. This problem is well recognized in rehabilitation outcomes research.<sup>14</sup> However, it may be less well known in other areas of medicine. For example, if smokers are screened for lung cancer, many cases can be identified. However, clinical trials have shown that the course of the disease is likely to be the same for those who are screened and those not subjected to screening, even though screening leads to more diagnosis and treatment. Although screening identifies cases earlier, there may be large reservoirs of disease that can be detected through screening.<sup>31</sup> Very high proportions of elderly women have ductile breast cancer in situ (DCIS), and nearly 40% of elderly men (>75y) have prostate cancer.<sup>32</sup> The harder we look, the more likely it is that cases will be found. However, only about 3% of elderly men will die of prostate cancer, and only about 3% of elderly women will die of breast cancer.

A very sensitive test for prostate cancer may detect disease in 10 men for each 1 man who will eventually die of this condition. These problems are not limited to cancer. Recent autopsy studies suggest that nearly all young men (age range, 15–34y) who die of noncardiovascular causes have some evidence of coronary disease.<sup>30</sup> Advanced magnetic resonance imaging technology has revealed surprisingly high rates of stroke. One cross-sectional study<sup>33</sup> of 3502 men and women over age 65 found that 29% had evidence of mild strokes and that 75% had plaque in their carotid arteries.

Black and Welch<sup>34</sup> make the distinction between disease and pseudodisease. Pseudodisease is disease that will not affect life duration or QOL at any point in a patient's lifetime. When the disease is found, it is often "fixed" with surgical treatment. However, the fix has consequences, often leaving the patient with new symptoms or problems. Many surgeries for patients with SCI, for example, offer few benefits in terms of patient outcomes. The outcomes model considers the benefits of screening and treatment from the patient's perspective. Often, using information provided by patients, we can estimate the QALE for a population and determine if they are better off with or without screening and treatment.<sup>22</sup>

### Medicine as a Cognitive Science

The traditional biomedical model treats disease as a binary variable. People are sick or they are not. However, most chronic diseases are gradual processes. The threshold for deciding whether someone has the disease can be ambiguous. This occurs not only in the definition of the disease, but also in the interpretation of clinical data.<sup>35</sup> By using their experience, clinicians examine and interpret clinical information. Like any judgment, these perceptions are not always reliable. For example, it is known that physicians are highly variable in their interpretation of clinical data. They disagree with one another when examining the same clinical information.<sup>36–38</sup> For example, 1 study<sup>39</sup> evaluated the reliability of pathologist-assessed DCIS. Six pathologist subjects were given written guidelines and examples of each of the problems for which they were

looking. After this training, these experienced pathologists were given 24 high-quality slides of breast tissue. There was considerable variability in the propensity to see DCIS. For example, 1 pathologist saw cancer in 12% of the slides, whereas another saw DCIS in 33% of the same slides. Among 10 slides when at least 1 pathologist saw DCIS, no 2 pathologists had the same pattern of identification. One pathologist saw cancer in 8 of the 10 cases, whereas another saw DCIS in only 3. One case was diagnosed by only 1 pathologist, and only 2 cases were seen by all 6.<sup>39</sup> These variations in diagnostic patterns imply that patients with the same problem who go to different doctors may get different diagnoses.

### Clinical Implications

The disease reservoir model suggests that disease is common, particularly for older people. If we look for it, we will find it. Once disease is identified, treatment is typically indicated. The outcomes model regards disease as a process. Although biologic abnormalities might be detected, they are not considered problematic unless they threaten the life expectancy or potentially reduce HRQOL. Biologic abnormalities that will not affect either life expectancy or life quality are called pseudodisease.<sup>34</sup> Pseudodisease is very common. As a result, efforts to screen populations for health problems will result in a lot of "disease" and may produce significant expenditures on treatment. However, it is not clear that population health will improve. Organizations such as the American Heart Association, American Lung Association, and ACS argue that mass screenings for disease are necessary because observed disease represents only the tip of the iceberg. Clearly, greater screening will produce more cases. On the other hand, what will be detected includes both true disease and pseudodisease.<sup>27,40-47</sup>

### Individual Decision Making

Perhaps the best example of contrast between the 2 models concerns the diagnosis and treatment of prostate cancer. Prostate cancer is an important health problem. The epidemiology is interesting because there may be a large reservoir of undetected cases.<sup>43</sup> The National Center for Health Statistics reports that there were 132,000 new cases in 1992.<sup>48</sup> However, ACS reported that there were 334,500 new cases in 1997.<sup>27</sup> National data suggest that there were 34,000 deaths from prostate cancer in 1996, whereas ACS projected 41,000 expected deaths in 1997.

Prostate cancer is the second leading cause of cancer death among men (behind lung cancer). Significant differences of opinion exist about whether the public should invest in screening programs for prostate cancer. The American Urological Association and ACS have promoted large-scale screening of all men older than age 50.<sup>49</sup> These organizations suggest a yearly screening using digital rectal exams or prostate-specific antigen (PSA). The State of California enacted legislation in 1998 requiring physicians to advise men about the benefits of prostate cancer screening. Other organizations, including the American College of Physicians, argue that such screening programs may be of limited benefit<sup>32,50</sup> and that they may be costly, accounting for about 5% of all health care costs.<sup>51</sup>

One of the challenges is in determining whether there really is an epidemic of prostate cancer. Figure 1 shows changes in prostate cancer incidence and mortality between 1976 and 1994. The number of reported prostate cancer cases doubled over this interval. Following concern about the value of screening, there has been a recent downturn in incidence. However, mortality from prostate cancer has remained relatively constant. One explanation for this apparent discrepancy is that

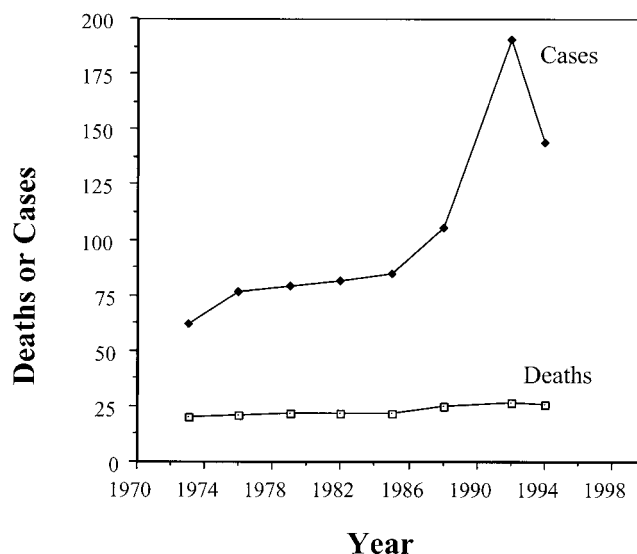


Fig 1. Prostate cancer incidents and mortality per 100,000 men in the US population from 1973 to 1998. Data from Centers for Disease Control and Prevention, Surveillance, Epidemiology and End Results program. Available at [www.cdc.gov/cancer/naticancerdata](http://www.cdc.gov/cancer/naticancerdata).

there is a reservoir of undetected prostate cancer. Many of the undetected cases are unlikely to lead to ill health or death.<sup>42</sup>

**Ambiguity.** The outcomes model recognizes the significant ambiguity with many treatment choices. Although we may be able to detect and attempt to fix prostate cancer, the real challenge is in deciding if diagnosis and treatment is valuable.

There have been several simulations of the benefits of screening and treatment. There are at least 3 methods available to screen for prostate cancer: digital rectal examinations, transrectal ultrasound, and PSA. About 3% of all men will die of prostate cancer. However, autopsy studies show that for men in their mid-seventies, about 40% have prostate cancer.<sup>34</sup> Better diagnostic procedures will identify more men who have the condition. For those who do have disease, there are 3 options: radical prostatectomy (surgical removal of the prostate gland), external beam radiation, and watchful waiting.

For men who choose radical prostatectomy, it is unclear whether there is a survival benefit.<sup>32</sup> They may gain some relief knowing that they have chosen the most aggressive option. However, there are consequences. Among men receiving radical prostatectomy, about 40% will become incontinent, and 30% of these will have incontinence that requires the use of pads or clamps. Sixty percent of the men who will undergo prostatectomy will become impotent, and only about 11% will have had sexual intercourse in the 30 days before the interview.<sup>52</sup>

The traditional model encourages treatment for those with a diagnosis. The outcomes model recognizes another option: watchful waiting, that is, monitoring the condition without treatment. Treatment can be initiated if the disease changes. Understanding the value of watchful waiting requires an understanding of the natural history of disease. Computer simulations of cohorts of 68-year-old men suggest that the risk of distant metastasis is about 5 per 100 patient years. The median time to metastasis is about 14 years. During the 14-year interval, 58% of the men will die of other causes before the development of metastatic problems from their prostate cancer. For those who do develop metastases, hormonal therapy can

provide control of symptoms and delay disease progression long enough that many of the men die of other causes before serious complications from their prostate cancer.<sup>53</sup>

By using QALYs as an outcome measure, simulations suggest the benefits of screening are few. For example, Krahn et al<sup>54</sup> estimated the population benefit for programs to screen 70-year-old men for prostate cancer. They found that the benefits, on average, were improvements in the life expectancy between a few hours and 2 days. However, when they adjusted the life expectancy for QOL, they discovered that screening programs reduced quality-adjusted life days. The reason for this negative impact is that screening identifies many men who would have died of other causes. These men, once identified with prostate cancer, are then likely to engage in a series of treatments that would significantly reduce their QOL. For these men, the treatment causes harm without producing substantial benefits.

### Shared Decision Making

Because resources are often used to treat pseudodiseases, health care in the United States has become very expensive. A central component of the problem is that many decisions are made under conditions of considerable uncertainty. Although patients accept treatment with high expectations of benefit, experienced health care providers may recognize that the potential benefit of many treatments is probabilistic. One approach to this problem is greater patient involvement in decisions about care. This section reviews the emerging study of shared medical decision making, in which choices of treatment pathways are a collaborative effort between provider and patient.<sup>55</sup>

In an ideal world, a patient could approach a physician with a list of symptoms and problems. The physician would identify the problem and administer a remedy. The service should be inexpensive and painless. However, this scenario is uncommon. For most medical decisions, judgments about disease are not perfectly reliable and, even when an early diagnosis is available, it is not always clear that treatment is the best option.<sup>36</sup> Choices about what treatments should be offered have typically been left to the physician. For various reasons, however, patients are becoming activated in the decision process.

Shared decision making is the process by which the patients and physicians join in partnership to decide whether the patient should undergo diagnostic testing or receive therapy. Often, shared decision making involves formal decision aids that provide patients with detailed information about their options. The information is usually presented through interactive video disks, decision boards, descriptive consultations, or through the Internet.<sup>56</sup> By using these decision aids, patients complete exercises to inform them of the risks and benefits of treatment options. Sometimes, they provide preferences for outcomes in the shared decision-making process.<sup>55</sup>

Shared decision making is not patient decision making. In other words, there are technical aspects of medical decisions for which patients are not well equipped. For example, patients are not expected to know what approach to surgery is best or the advantages or disadvantages of particular medications. On the other hand, patients have a perspective that only they fully understand. For instance, surgical treatment for some SCIs may increase risk of additional pain. Some patients might be willing to take the risk, whereas others may prefer to cope with their current condition. The patient provides the perspective that is typically unknown to the physician. Use of decision aids allows these preferences to be expressed. The personal issues brought by the patient can be merged with the technical concerns of their physicians.

Because time in medical encounters is so limited, shared decision making often involves a referral to a decision laboratory. The doctor may advise the patient to use a decision aid, often under the supervision of another health care professional. Once the patient has interacted with the decision aid, he/she can return to the physician prepared to deal with the decision in a relatively short period of time.

Although shared decision making is a relative new field, several decision aids have now been evaluated. In 1 example, Frosch et al<sup>57</sup> considered a decision aid to help men decide whether they should be screened for prostate cancer using the PSA test. The men were all enrolled in a clinic that provides a wide variety of medical screening tests. In an experiment, the men were randomly assigned to 1 of 4 groups in a 2×2 factorial design. One factor was for use of a decision video. Men either watched or did not watch a video that systematically reviewed the risks and benefits of PSA screening. The video featured a debate between a urologist who favored PSA screening and an internist who opposed PSA screening. Further, the video systematically reviewed the probabilities of false positives, false negatives, and the risks of prostate cancer. It also systematically reviewed the evidence for the benefits of treatment for prostate cancer. The other factor in the experimental design was whether men had the opportunity to discuss the decision with others. The design resulted in 4 groups—usual care, discussion alone, video alone, and video plus discussion. All men were asked if they wanted the PSA test, and medical records were obtained to determine whether the test was completed.<sup>57</sup>

The study showed that there was a systematic effect of the video and discussion groups. In the usual care control group, virtually all men (97%) got the PSA test. In other words, with no new information, men will typically take the test. In the other groups, having more information lead to a conservative bias. In contrast to the usual care control, those in the other groups were more sensitive to the risks of the test in relation to its benefits. Among those participating in the discussion group, 82% got the PSA test. For those watching the video, 63% completed the test. Those watching the video and participating in those discussions had only a 50% PSA completion rate. The study showed that, as patients become better informed, they were less likely to take the PSA test. The study also obtained information on patient knowledge. As knowledge increased, the likelihood of getting the PSA test decreased, again, stressing that better informed patients make more conservative decisions.

Shared decision making may be a valuable tool for rehabilitation research and practice. However, a review of the literature failed to identify rehabilitation studies in which the methods had been applied. One exception is a well-evaluated program on surgery for herniated disks. In this well-controlled study,<sup>58</sup> 393 patients with herniated disks, spinal stenosis, or other chronic back problems were randomly assigned to use a shared decision-making aid or to a control condition. Those in the shared decision-making group felt better informed, and elected surgery significantly less often than those in the control condition.<sup>58</sup> Although there have been calls for greater use of shared decision making for those with chronic back pain,<sup>59</sup> actual applications in the rehabilitation field remain few.

### CONCLUSION

The traditional biomedical model and the outcomes model differ. One of the most important distinctions is the focus of attention. The traditional model emphasizes disease pathology and treatment. According to this model, the function of health care is to detect problems by identifying pathology. Once

identified, treatment is initiated. The outcomes model focuses on the impact of detection and treatment. Often, identification of pathology and treatment result in improved patient outcomes. However, there may be cases in which identifying disease does not result in better patient outcomes. For example, there are many circumstances in which disease, if left undetected, has no impact on life expectancy or QOL. As a result of this ambiguity, providers and patients must face difficult decisions about what treatment should or should not be initiated.

The outcomes model has been widely applied in rehabilitation research. However, there are 2 areas of outcomes research that have received relatively little attention. First, few studies in rehabilitation represent outcomes in terms of QALYs. Use of QALYs can help prioritize demands on limited health care resources and allow for the comparison of rehabilitation in relation to other areas of medicine and health care. A second area of outcomes research that deserves greater attention is the use of shared medical decision making. Patient preferences for health outcomes are a very important component of the health decision process. An emerging set of methodologies might be used to increase patient involvement in this decision process.

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