Health Economic Issues Related to Adult Lumbar Scoliosis

22

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Introduction

This chapter discusses key concepts for understanding how to assess the value of health care interventions. Value has been defined as a comparison of the outcomes achieved to the costs incurred related to an intervention [1]. Evidence-based medicine has emerged as a field designed to satisfy increasing needs to balance benefits of treatment with health care

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R. Hostin, MD (⊠) Department of Orthopedic Surgery, Baylor Scott and White, 4708 Alliance Blvd #810, Plano, TX 75093, USA e-mail: rhostin@swscoli.com interventions to rising health care costs. A gradual shift toward a value-driven rather than resource utilization-based health care system has occurred. There have been increased demands to contain costs with greater focus on outcomes (rather than process), which require the application of appropriate methods of economic evaluation. Cost-effectiveness analysis is increasingly used by health care decision makers to allocate scarce resources in an increasingly value-maximizing, patient-centered health care system that considers outcomes (effectiveness) in relation to resources (cost). This chapter introduces several basic concepts regarding the economic measurement of health benefits, costs, and cost-effectiveness methods applicable to spine care.

Measuring and Valuing Health Outcomes

Clinical or biomedical measures and outcomes such as survival, mortality, remission, and complications are routinely collected and readily available. However, these measures are unable to quantify a patient's quality of life, which includes aspects such as physical, mental, and social wellbeing. A large and growing literature exists on the theory and practice of quantifying health outcomes and the burden of illness. Health-related quality of life (HRQOL) tools reliably measure changes in the overall health status of a patient.

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There are four types of commonly used HRQOL measures: generic or general, disease specific, pain scales, and health utilities.

Generic measures are attractive because they can be applied to broad ranges of diseases and allow comparisons among patients with different types of health conditions. A standard health index includes two components: a health state classification instrument and a formula to assign a utility/score to any unique set of responses to that instrument [2]. The score measure may either be based on people's preferences or on arbitrary scoring algorithms. The most widely used generic measures are the EuroQol (EQ-5D), the Medical Outcomes Short Form-36 (SF-36), and the Health Utility Index (in versions HUI-I, HUI-II, HUI-III). Studies have shown that these measures are reliable and valid in large patient populations [3-11]. One downside of generic measures is they might misrepresent important changes in health outcomes related to specific diseases or treatments.

Disease-specific measures are tailored to the symptoms associated with a given medical condition. The spine-specific instruments are designed to capture disease pain, disability, spine-related function, and other relevant attributes to spine health; however, these instruments provide a limited ability to compare outcomes across unrelated diseases. The most commonly used spine-specific outcome measures are the Oswestry Disability Index (ODI), the Roland Morris Disability Questionnaire (RMDQ), and the Scoliosis Research Society Questionnaire (SRS-22).

Health-Related Quality of Life (HRQOL)

HRQOL are measures designed to quantify health status across different health states. The majority of HRQOL are commonly assessed through self-reported questionnaires, capturing responses in domains such as physical function, social function, mental health, and general health.

Generic Measures

EuroQol (EQ-5D)

EQ-5D is a five-dimension measure of health status developed by a consortium of European researchers using a mailed survey to collect information about health and functional states being experienced by individuals [12-20]. EuroQol is a brief, easy-to-use questionnaire that allows self-completion or interviews in a matter of minutes [18]. Preference weights have been developed for the various health states described by the EQ-5D, making the measure suitable for use as quality adjustments to compute qualityadjusted life years (QALYs). The five dimensions of the EQ-5D are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each of the five dimensions has three levels resulting in a combined total of 243 possible health states. The instrument contains a visual analog scale calibrated from 0 (the worst possible state) to 100 (the best possible state).

Health Utilities Index

The Health Utilities Index questionnaire has three versions (HIU-I, HUI-II, HUI-III). The latest, HUI-III, classifies health status along eight dimensions: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain [21, 22]. HUI-III defines 972,000 possible health states, and a utility value is obtained by inputting weights for each dimension into a multiplicative formula. The dimension weights have been estimated from valuation data obtained from a sample of patients from Hamilton, Ontario, Canada.

Medical Outcomes Short Form-36

The SF-36 is a questionnaire composed of 36 questions to be answered by the patient. It assesses health status across seven different health domains: physical function, social function, limitations in role because of physical

health, limitation in role because of mental health, vitality, bodily pain, and general health [23]. Responses in each domain are combined in order to compute a score between 0 - "worst health" and 100 "best health." Two composite measures can also be computed: a mental composite summary score and a physical composite summary score. Using a norm-based scoring algorithm, all domain scales have a mean of 50 and a standard deviation of 10 based on the general 1998 US population. Thus, scores >50 are above the general population mean. Many validation studies have confirmed the SF-36's use in measuring general health across a variety of diseases populations, including spine deformity [23–29].

Spine Disease-Specific Measures

Oswestry Disability Index

The ODI was developed to measure lower back pain [30]. The questionnaire includes questions regarding functional abilities, daily living activities, and social life in relation to spine deformity. The questionnaire includes topics regarding personal care, lifting, walking, sex life, sitting, standing, and sleeping. In the USA, a modified version of ODI was endorsed by the American Academy of Orthopaedic Surgeons as a part of the Musculoskeletal Outcomes Data Evaluation and Management System Initiative [31].

The ODI has been validated in numerous studies [31–34]. The ODI instrument has also been modified to create the Neck Disability Index (NDI) [35]. See Fig. 22.1, which illustrates the scoring chart created as an aid to show all possible ODI scores.

Roland-Morris Disability Questionnaire

The RMDQ consists of 24 statements related to daily physical activities such as dressing, walking, and using of stairs [36, 37]. The patient is asked to put a check mark that corresponds to his

or her current situation. The check marks are added up with a total score of 24, with a higher score representing greater disability. Studies document that RMDQ and ODI have a high level of correlation to each other [38–40].

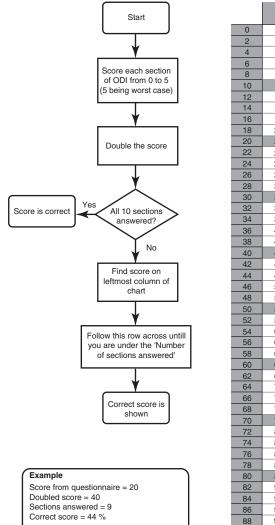
Scoliosis Research Society Questionnaire

The SRS-22 is a scoliosis-specific HRQOL questionnaire. The questionnaire comprises 22 items with five domains – pain (5 items), appearance or self-image (5 items), activity or function (5 items), mental health (5 items), and satisfaction and management (2 items) [41]. Each domain score ranges from 1 to 5, with higher scores indicating better outcomes. For example: question 8 asks the respondent: "Do you experience back pain when at rest?"; question 17 asks: "In the past three months, have you taken any sick days from work/school due to back pain and, if so, how many?"

The SRS-22 is the most widely used tool to measure changes in health-related quality of life in patients with scoliosis [8, 42–47]. The SRS-22R instrument is a refinement of the SRS-22 and was created to assess quality of life following surgery in patients with adolescent idiopathic scoliosis [48]. Additionally, the SRS-22R assesses patient's self-image; however, studies suggest that the questionnaire might not accurately assess the health status of younger patients or those with milder forms of scoliosis [49, 50].

Quality-Adjusted Life Years

QALYs remain the most popular measure of health benefits used in economic evaluation of health care interventions [51]. QALY measures were introduced to create a standard unit of health utility measure in order to value the length and quality of life on a single scale [52–54]. The advantage of the QALY as a measure of health outcome is that it can simultaneously



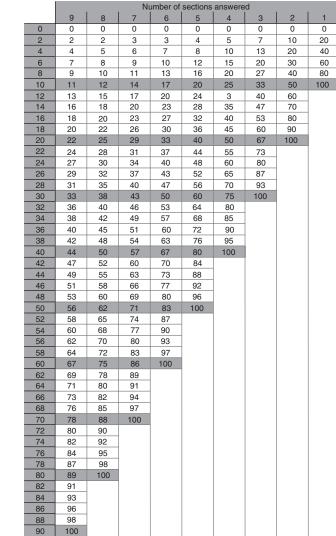


Fig. 22.1 ODI scoring system. *Note*: Scoring chart was created as scoring aid to show all possible ODI scores (Mehra et al. [95])

capture gains from reduced morbidity (quality gains) and reduced mortality (quantity gains) and combine both into a single measure [55]. The QALY measure assumes that an additional year of life has the same value regardless of the age or other characteristics of the person who receives it, assuming that the different life years are of comparable quality [56]. A year of life extension for an infant or a 35-year-old all have the same value in QALYs and, in turn, in a cost-effectiveness analysis using QALYs, which

assumes no difference in the quality of the year of life extension.

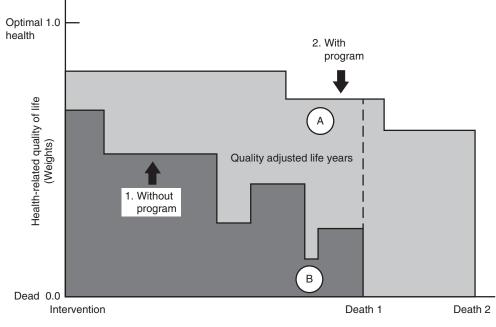
QALYs are a measure of health outcome that assigns to each period of time a weight, ranging from 0 to 1, corresponding to the health-related quality of life during that period, where a weight of 1 corresponds to optimal health and a weight of 0 corresponds to a health state judged equivalent to death; these are then aggregated across time periods [57]. QALYs are computed using Health Utilities Indexes such as the EQ-5D, or SF-6D, and estimates of the length of time a treatment benefit will last. For example, consider a patient with spinal deformity who has a health state of 0.6. Without the surgery, the patient lives for 10 years. With the surgery, the patient's health state improves to 0.9, and his life expectancy is increased by 5 years. Thus, QALY gained with surgery = quality of life years with the surgery – quality of life years without the surgery = 0.9 * 15 - 0.6 * 10 = 7.5QALYs. See Fig. 22.2, which exemplifies QALYs gained from an intervention.

QALYs are primarily used as an outcome of interest in cost-effectiveness analysis and are typically expressed as costs divided by the QALYs gained from a treatment or intervention (cost/QALY). However, other quality-adjusted measures available in the literature are Disability-Distress Index (DDI) [58], the Quality of Well-Being (QWB) Scale [59], and disability-adjusted life years (DALYs) [60].

Costs and Resource Use

It is important to consider not only the clinical outcomes of care but also the costs required to achieve the outcomes associated with treatment. Over the last decade, total charges for spine deformity surgery have increased dramatically with over 20,000 discharges associated with ICD-9 diagnosis codes 737.0–737.9, which is defined as "curvature of the spine," in 2013 [61]. See Fig. 22.3, which shows discharges and costs per year for spine deformity surgeries related to curvature of the spine.

There are multitudes of spine deformity treatments available; some treatments may be very expensive but very beneficial, while others may be inexpensive but do little to improve clinical or quality of life outcomes. Standardized methods of calculating the costs of operative and nonoperative treatments for spine disorders are necessary for value-driven decision making. Therefore,



Duration (Years)

Fig. 22.2 Health-related quality of life with and without treatment. *Note*: The figure illustrates QALYs gained from an intervention. *Circle B* indicates the quality of life without the intervention, while *Circle A* indicates the

additional QALY gained from the intervention (Reproduced from Gold et al. [57], Figure 4.2, p. 92, Copyright © 1996, with permission of Oxford University Press, USA)

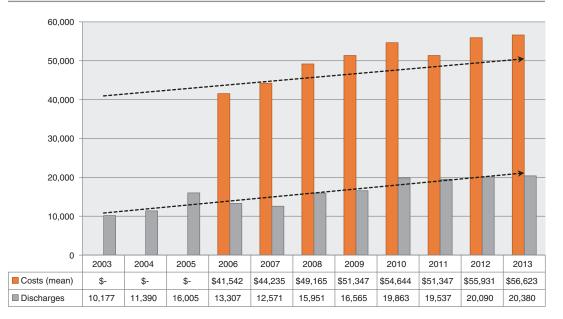


Fig. 22.3 Discharges and costs per year for spine deformity surgeries ICD-9 diagnosis codes related to curvature of the spine (ICD-9 codes 737.0–737.9). *Note*: Spine deformity defined as ICD-9 primary diagnosis codes

737.0–737.9 (Data from Healthcare Cost and Utilization Project, National Inpatient Same, Available at www. hcupnet.ahrq.gov)

determining the value of surgical treatment requires both the clinical, patient-specific, or societal outcomes and the associated costs to provide those outcomes. In addition to determining which costs to include, appropriate methods to measure and analyze costs are all equally important considerations in health economic evaluation.

Identifying all relevant costs associated with treatment is vital in the economic evaluation of a health care intervention. Accurate measurement of costs requires estimation of the amount of resources used in natural and comparable units of measurement. Costs related to health care interventions can be categorized into several types, including direct and indirect costs, operative and non-operative costs, and formal and informal costs. Direct costs are costs that are directly associated with the illness, procedure, or treatment or in addressing the side effects of treatment. These include costs of implants, operating room staff, tests, medications, and supplies. Indirect costs are not directly associated with the illness or treatment and may not be incurred by the individual who is receiving treatment. These often include overhead costs, such as administrative

costs, as well as productivity losses associated with illness or death. It is important to note that some of these resources are challenging, if not impossible, to accurately quantify and capture. For example, how can we quantify a reestablished family routine due to reductions in pain?

The appropriate estimation of costs is varied in the literature, due to scope and specific research question being answered, not to mention the cost data that are available to the researcher. Costs have been analyzed using charges, reimbursements, payments, direct cost, total costs, allowable rates, relative value units, etc. Each of these provides some interesting information, but alone, each often fails to provide the complete cost of care.

Defining Costs

Total hospital costs: Direct and indirect costs.

Direct costs: Direct resources used for the intervention.

Indirect costs: Opportunity costs, patient and family burden due to disease or intervention. Charges: Seldom represents true costs due to markup and contracting.

Payments: Expense incurred for the treatment, amount paid by insurer, not easy-to-access managed care claims data.

Allowable rates: Public data is easily accessible but differs dramatically from managed care payments.

Cost data and measurement are also constrained by the confidentiality among competing health care providers and insurers as well as by differences within the US health care system [62]. From whose perspective costs are considered is an important concept in cost evaluation. The perspective of the one performing the cost evaluation influences the methodologies incorporated and ultimately can lead to very different conclusions. For example, a health care consumer deciding whether to pay for a generic or more costly prescription may be willing to pay more or less for the medication than a hospital, insurance company, or another patient would do [63].

There are two broad categories of cost perspective, the health service perspective and the societal perspective. These can be broken down into more specific categories such as providers, payers (e.g., insurance companies and employers), patients, and policy makers. The health service perspective usually considers costs incurred by the provider or payer, while a societal perspective considers broader costs to society at large and is usually indifferent to who incurs the expense. For example, a societal perspective may consider patient expenses, including productivity loss and family disease burden. Alternatively, an individual hospital may be interested in its internal costs to treat a diseasespecific population [64].

Another important concept in cost assessment is the time horizon considered. Assessment of the cost of spine deformity surgery should consider not only the cost of the surgery itself but future costs and outcomes that are realized or avoided as a result of the surgery [63]. This is also related to the durability of treatment, i.e., how long an intervention will continue to provide benefits. This often manifests itself in repeat revision surgeries for spinal deformity patients. Future costs may be very substantial, and analyses may underestimate the cost if it is not incorporated in the assessment. For example, the cost of surgery includes not only the inpatient stay but preoperative visits, pain medication, postoperative followup, time off from work, etc. In this same vein, it is not only the costs incurred but the avoided costs of forgoing treatment (i.e., the continued disease burden on family and work life, comorbidities that were exacerbated due to spinal deformity). Nonoperative costs include pain management, physical therapy, and post-acute care. Although surgery involves expensive inpatient costs, the reduction of expensive non-operative treatment may outweigh the costs of the surgery, when considered over an extended period of time. Therefore, what appears to be the more expensive initial treatment may reduce total costs over the long run.

After determining appropriate costs to include and how best to accurately capture the costs of care, analyzing cost data comes with its own pitfalls [62].The distribution of costs for surgical treatment tends to be skewed instead of normally distributed.

Due to the skewed nature of the distribution, careful consideration of the statistical approach is necessary. Frequently used methodologies include log transformation of the costs variables and generalized linear models that consider the statistical distribution. A multitude of literature has been written for those interested in learning more about these models and their assumptions [65–71].

In this section we have covered the importance of defining, accurately capturing, and modeling costs for the surgical care of spinal deformity. Ultimately the continual pursuit of the true cost of care will allow for accurate comparisons and help define value and best practices in spine deformity.

Discounting

As a rule, all costs and benefits of health care programs are observed over different points in time. For example, the benefits to the individual and society of adult lumbar scoliosis surgery are incurred over the patient's lifetime after the procedure. However, individuals value the benefits sooner rather than later in life and prefer to incur costs later in life.

Discounting accounts for the differential timing of health care costs and benefits. All future costs and benefits associated with an intervention should be discounted by computing the present value of these [72]. To calculate the present value of future costs and benefits (both monetary and nonmonetary), the following formula is applied:

$$PV = \sum_{t=0}^{N} \frac{\$a_t}{\left(1+r\right)^t}$$

where PV is the present value, $\$a_t$ is the dollar amount of cost or benefit in period *t*, *r* is the discount rate, and *N* is the maximum time periods. A discount rate of 5 % is prevalent in the existing literature. The US Public Health Service Panel on Cost-Effectiveness in Health and Medicine recommended that a 3 % rate be applied for health interventions [55]. Moreover an inflationadjusted discount rate should be used if it is expected that inflation might impact health care costs and benefits.

Types of Economic Evaluation of Health Care Programs

Economic evaluation is used to describe a range of methods that investigate the costs and consequences of different treatments or interventions [73]. These methods are designed to identify and appropriately quantify all costs and benefits of health care interventions. There are three main types of economic evaluations: cost-utility analysis, cost-effectiveness analysis, and cost-benefit analysis.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is a type of economic evaluation in which both costs and consequences of health treatments are examined. The health outcomes of interest are measured and presented in the most appropriate natural, physical, or clinical units, such as symptom-free days, lives saved, complications avoided, or cases of illness avoided [55]. While monetary valuation of outcomes is not always performed, the total net costs of an intervention are calculated and then divided by the number of health outcomes averted to yield the total net cost per unit of health outcome.

Another form of this type of analysis considers the cost of the intervention in relation to the change (effectiveness) from a pre- to post-intervention state of health as from a value perspective. For instance, McCarthy et al. (2013) estimated that the marginal cost of a 1-point improvement in the SRS-22 self-image domain was approximately \$5,700 for adult spinal deformity surgery patients, while the average estimate on a similar 1-point improvement in the SF-36 Physical Component Score incurred a cost of approximately \$26,000 [74].

Cost-Utility Analysis

Cost-utility analysis (CUA) is a special form of CEA, in which the health outcomes in the denominator are valued in terms of utility units [55]. The consequences are measured in quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs). The result of a CUA is usually expressed as the total net cost per unit of utility or measure of quality (net \$ cost or savings per QALY gained). The results of a cost-utility analysis are expressed in terms of cost per QALYs. CUA has become the standardized method to allow comparisons across different health care interventions and medical conditions.

Meaningful comparisons based on relative cost-effectiveness may be made between competing health care interventions using QALY league tables [75, 76] and construction of costeffectiveness league tables.

Cost-Benefit Analysis

Cost-benefit analysis lists all the costs and benefits that might arise as a result of a health care treatment over a specified time horizon [55]. These costs and benefits are converted to present value terms by discounting. If the total discounted benefits are greater than the total discounted costs, the intervention is said to have a positive net present value. The implication is that any intervention deemed to have a positive net present value should be pursued.

Incremental Cost-Effectiveness Ratio (ICER)

ICERs are used to compare two or more competing health care interventions and represent the incremental cost of one unit of outcome gained by a health care intervention when compared to an alternative. An ICER is estimated using [2]:

ICER =
$$\frac{C_1 - C_0}{E_1 - E_0} = \frac{\Delta C}{\Delta E}$$

where C_1 and C_0 are the mean values of the costs using Interventions 1 and Intervention 0; E_1 and E_0 are effectiveness values yielded by Intervention 1 and 0, respectively; and ΔC and ΔE are incremental costs and incremental effectiveness gained/lost. For CUA, ΔE is computed in terms of QALYs. ICER is increasingly used in many countries to determine which interventions to fund. An ICER of \$50,000 per QALY is the conventional threshold for cost-effectiveness [77]. In the literature, health care interventions valued below this threshold are considered "cost-effective" and those above are not [78, 79]. However, the World Health Organization suggests a threshold of three times a nation's gross domestic product per QALY, which in the USA in 2014 would be closer to \$140,000 per QALY [80]. Either of these thresholds may be higher or lower than what a decision maker may deem as their true willingness to pay. Therefore, there is no clear consensus on a universal cost-effectiveness threshold [63, 81]. Instead of the threshold, a cost-effectiveness acceptability curve (CEAC) may be created to allow for different willingness to pay thresholds. For example, for the treatment under consideration in Fig. 22.4 below, if the decision maker's willingness to pay threshold is under \$100,000 per QALY, there is almost a 100 % probability the

intervention is cost-effective at that threshold. If the willingness to pay threshold is \$80,000, there is about a 40 % probability that the intervention is cost-effective at that threshold. See Fig. 22.4, which shows the incremental cost-effectiveness acceptability curve.

ICERs reported for spine interventions are becoming increasingly available. For example, evaluation of cost-effectiveness of surgical vs. nonsurgical treatment of lumbar disk herniation revealed that cost/QALY gained for the surgical cohort in the Medicare population was \$34,355, and for general populations, it was \$69,403 [82]. A cost-utility analysis comparing surgical with nonsurgical care for a lumbar disk herniation reported an ICER of \$4,648 [83]. Periacetabular osteotomy performed with the goal of preventing or delaying the need for total hip arthroplasty reported an ICER of \$7,856 [84].

However, this measure has its limitations mainly because value assessments are inherently subjective, and there are oversimplifications of complex processes [85]. The National Institute for Health and Clinical Excellence in England was criticized for refusing to cover four kidney cancer medications in 2008 based largely on assessments of ICERs that exceeded the \$50,000 (£30,000) threshold [86]. However, despite its limitations, QALY remains the main tool for cost-effectiveness research methodology.

Simulation Modeling

Decision models or trees are used formally to model a decision problem. A model reflects the question to be answered and a graphical representation of the main elements (variables and their relationships) of a clinical decision. Figure 22.5 illustrates a basic decision model related to spine surgery.

Sensitivity Analysis

Sensitivity analysis is an essential part of economic evaluation that allows the assessment of how sensitive a study's results are to variations in

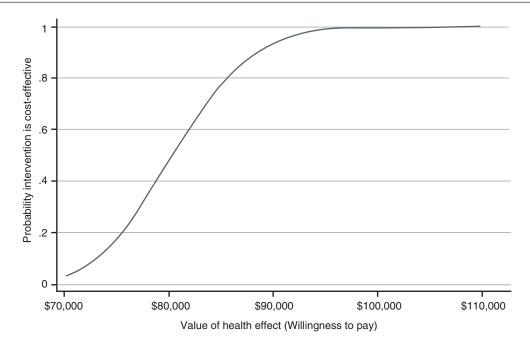
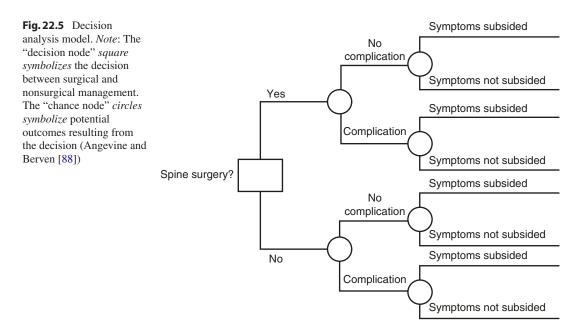


Fig. 22.4 Incremental cost-effectiveness acceptability curve. *Note*: Cost-effectiveness acceptability curves illustrate the probability that the dollar per QALY improve-

ment falls below a given threshold value, i.e., the "willingness to pay" for surgical treatment for spine deformity (McCarthy et al. [92])



key parameters (transition probabilities, costs, utility values) that were used in the primary analysis. The goal of sensitivity analysis is to find out which variables in the model most impact the results and whether changes in parameters will result in savings or costs. Several methods to deal with uncertainty are employed: simple sensitivity analysis, threshold analysis, probabilistic sensitivity analysis, and value of information analysis. In a simple sensitivity analysis, one or more parameters are varied across a range of possible values. The purpose of threshold analysis is to identify the critical value of a parameter above or below which will change the conclusions of the study. The probabilistic sensitivity analysis (PSA) treats all input parameters as random variables with known probability distributions. PSA measures the uncertainty around a prediction of cost-effectiveness. Value of information analysis uses PSA to examine the effect of reducing the uncertainty around the model's parameters [87].

Issues in Cost-Effectiveness Research Related to Spine

Spine disorders are extremely expensive to treat surgically. In particular, the disorders of the lumbar spine such as lumbar stenosis, lumbar degenerative spondylolisthesis, and lumbar disk herniation are expensive to treat and cause significant disability. The evidence around costeffectiveness of operative vs. non-operative treatment of the lumbar spine disorders is inconclusive, and the studies that suggest that surgery is advantageous over nonsurgical treatment fail to report that surgery is actually cost-effective.

Short follow-up periods are one of the main reasons the cost-effectiveness of operative vs. non-operative treatment has been difficult to quantify. For example, the cost-effectiveness data from the Spine Patient Outcomes Research Trial used a 2-year follow-up period. For lumbar disk herniation, the study reported several ICERs both under \$100,000 depending on two different ways direct surgical costs were estimated [82]. Considerations over a longer time horizons might improve calculated cost-effectiveness estimates [88–94]. The choice of time horizon and costing methodology greatly affects the results and must be determined thoughtfully when undertaking cost-effectiveness research or reviewing published work. For example, the short follow-up cost-effectiveness studies are more likely to underestimate the improvements in utility which would reduce ICERs. However, studies with longer time horizon might not necessarily yield more favorable ICERS as these are more likely to account for reoperations following surgery for spinal deformity and thus increase the costs.

Summary

It is becoming increasingly important for clinicians to weigh costs and benefits of competing health care interventions. Formal methods of economic analysis are required to assess the costeffectiveness of health care interventions. This chapter introduced several basic concepts regarding the economic measurement of health benefits, costs, and cost-effectiveness methods necessary to define the value of spine care. We expect that spine care providers will increasingly use costeffectiveness analysis methods in their own practice given the overall shift toward a patient-centered and value-driven health care environment.

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