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COST-UTILITY ANALYSES IN ORTHOPAEDIC SURGERY

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Background: The rising cost of health care has increased the need for the orthopaedic community to understand and apply economic evaluations. We critically reviewed the literature on orthopaedic cost-utility analysis to determine which subspecialty areas are represented, the cost-utility ratios that have been utilized, and the quality of the present literature.

Methods: We searched the English-language medical literature published between 1976 and 2001 for orthopaedic-related cost-utility analyses in which outcomes were reported as cost per quality-adjusted life year. Two trained reviewers independently audited each article to abstract data on the methods and reporting practices used in the study as well as the cost-utility ratios derived by the analysis.

Results: Our search yielded thirty-seven studies, in which 116 cost-utility ratios were presented. Eleven of the studies were investigations of treatment strategies in total joint arthroplasty. Study methods varied substantially, with only five studies (14%) including four key criteria recommended by the United States Panel on Cost-Effectiveness in Health and Medicine. According to a reader-assigned measure of study quality, cost-utility analyses in orthopaedics were of lower quality than those in other areas of medicine ($p = 0.04$). While the number of orthopaedic studies has increased in the last decade, the quality did not improve over time and did not differ according to subspecialty area or journal type. For the majority of the interventions that were studied, the cost-utility ratio was below the commonly used threshold of \$50,000 per quality-adjusted life year for acceptable cost-effectiveness.

Conclusions: Because of limitations in methodology, the current body of literature on orthopaedic cost-utility analyses has a limited ability to guide policy, but it can be useful for setting priorities and guiding research. Future research with clear and transparent reporting is needed in all subspecialty areas of orthopaedic practice.

Level of Evidence: Economic and decision analysis, Level III. See Instructions to Authors for a complete description of levels of evidence.

Clinical programs for patients with musculoskeletal disorders are faced with numerous harsh realities: an aging population requiring more medical intervention, rapidly emerging newer and often more expensive technologies, and fixed budgets. Economic evaluation of orthopaedic surgical treatments is an important area of study that requires high-quality information if it is to be useful to surgeons and policy makers.

Cost-utility analysis is a type of economic analysis that is used to assess the value of an intervention in terms of improving both quality and quantity of life. (This term as well as many others used in this field is defined in a glossary at the end of this article.) "Utility" refers to an individual's or society's preference for a particular set of health outcomes. Many tools have been developed to aid researchers in estimating a patient's preference for a specific health state, which is then used to calculate quality of life. These tools include generic instruments (e.g., the EQ-5D¹, the Health Utilities Index [HUI]²,

and the Quality of Well Being [QWB] Index³), which link information from general questionnaires with separately derived preferences for health states, and direct measurement techniques, with which a group of subjects is asked directly to provide information about their preferences for a set of health states with use of time-trade-off, standard-gamble, or rating-scale methods (see Glossary). The goal of all of these approaches is to derive measures that can then be used in utility and cost-utility analyses.

Cost-utility analysis is useful for comparing health treatments or programs that may differ in terms of their effects on morbidity as opposed to only mortality. The incremental cost of an intervention is compared with the incremental health effects of the intervention, and the result usually is expressed as a cost per quality-adjusted life year gained (see Glossary). By combining quality and duration of life into a single metric, the quality-adjusted life year allows for comparisons across a broad array of interventions for the same condition and across different condi-

tions. Consequently, cost-utility analysis is considered the gold standard for reporting the results of economic evaluations in the medical literature^{4,7}.

We are not aware of any systematic and comprehensive audits of the cost-utility literature in orthopaedics. We therefore conducted a systematic review of original cost-utility analyses of orthopaedic surgery in the medical literature. Our objectives were (1) to provide a resource listing published cost-utility ratios that can be used by clinicians and policy makers for decision-making, (2) to identify areas within orthopaedic surgery that may benefit from further economic evaluation, and (3) to critically review the conduct and reporting of cost-utility analyses of orthopaedic surgery to identify opportunities for improvement as these studies play an increasing role in informing health policy decisions.

Materials and Methods

This study was part of a larger study in which all cost-utility analyses in medicine were reviewed^{8,9}. Study details, including information on the cost-utility ratios⁹, utility values¹⁰, and reporting practices⁸, are described elsewhere in detail, and a comprehensive registry of these studies is available as a public-use data file at www.hsph.harvard.edu/cearegistry.

As part of this larger study, a computerized search restricted to the English-language literature was performed with use of the medical subject headings and/or text keywords "quality-adjusted," "QALY," and "cost-utility." The search was conducted with use of Medline, for the years 1976 through 2001. We validated our search findings with use of the Health Economic Evaluations Database maintained by the British Office of Health Economics¹¹. One of us (C.A.B.) then reviewed the articles to determine whether they were orthopaedic-related and appropriate for inclusion. Two trained reviewers independently abstracted data on whether or not the intervention, comparison, study perspective, and funding source were clearly defined; on the utility measurement technique and source; on whether or not incremental analyses, discounting, and sensitivity analyses were appropriately reported; and on the collection and presentation of the cost data and the cost-utility ratios (see Glossary). The journals were divided into three groups: general medical or surgical, medical or surgical subspecialty, and methods or policy. The reviewers met to reach a consensus on the results, and a third reviewer adjudicated any discrepancies.

The quality of each paper was subjectively rated on a 7-point Likert scale on the basis of criteria derived from selected recommendations of the United States Panel on Cost-Effectiveness in Health and Medicine^{5,6}. The panel recommended the use of a societal perspective, community or patient sources for utility estimates, appropriate incremental comparisons, sensitivity analysis, and appropriate discounting of costs and health benefits at the same rate^{5,6}. To allow comparisons across countries and between different years, all cost-utility ratios were converted into real 2002 United States dollars with use of the foreign exchange factor (Federal Reserve Bank of St. Louis, St. Louis, Missouri) appropriate to each particular coun-

try for each particular year and with use of the general Consumer Price Index inflator from the United States Bureau of Labor Statistics. Cost-utility ratios were rounded off to two-digit precision. An unpaired Student *t* test assuming unequal variances was used to compare group means, and the Fisher exact test was used for comparisons between proportions.

A table was constructed that included a description of each intervention, the alternative with which it was compared, and the appropriate target population. This table was sorted by level of cost-utility, which was divided into five categories: (1) cost-saving (in terms of money and benefit), (2) cost-utility ratio of <\$20,000 per quality-adjusted life year (considered to be an excellent value for money—i.e., very cost-effective), (3) cost-utility ratio between \$20,000 and \$100,000 per quality-adjusted life year (generally considered to be a good value), (4) cost-utility ratio of >\$100,000 per quality-adjusted life year (not the best value, but many interventions with such a ratio are still funded), and (5) dominated (the intervention is less effective and more costly than the alternative).

Results

Our search revealed thirty-seven studies of interventions dealing with the musculoskeletal system and orthopaedic surgery published between 1989 and 2001, and these analyses provided a total of 116 cost-utility ratios. Table I lists the characteristics of these articles.

Total joint arthroplasty was the most commonly studied intervention. Of the eleven studies dealing with this subject, five were investigations of the cost-utility of primary total joint arthroplasty (total hip arthroplasty in four articles and total knee arthroplasty in one), three articles dealt with the economic impact of antibiotic prophylaxis for prevention of infection at the site of an arthroplasty, one focused on strategies for managing infections at the site of a total hip arthroplasty, and the remaining two dealt with perioperative issues (autologous blood donation and duplex venous surveillance). Nine articles dealt with osteoporosis prevention with pharmaceutical intervention: three assessed hormone replacement therapy; two, bisphosphonates; one, calcium and vitamin D; and three, other pharmaceutical interventions. Spine surgery was the topic of five papers, with two papers dealing with the management of lumbar disc herniation, one involving lumbar spinal fusion, one dealing with clearance of trauma patients for cervical spine surgery, and one focusing on neurosurgical interventions. The last paper was included because it presented a cost-effectiveness ratio for spinal surgery. One or two papers each represented the remaining orthopaedic subspecialties, with none in pediatric orthopaedics.

Table II lists the key methodological features of the articles, and a more comprehensive table providing the methodological features of each study is presented in the Appendix. Adherence to good methodological practices varied: only nine studies (24%) dealt with utility from a societal perspective by including some measure of indirect costs (see Glossary). Six of those studies included costs in terms of patient time and/or productivity; one included transportation costs; one, costs in

TABLE I Characteristics of Orthopaedic Cost-Utility Analyses Identified in Literature Review

Characteristic	% of Articles (N = 37)
Year of publication	
1989-1997	43
1998-2001	57
Country of study	
United States	54
Sweden	19
Canada	8
United Kingdom	8
Other*	11
Journal type	
General medical or surgical	19
Medical or surgical subspecialty	62
Methods or policy	19
Orthopaedic subspecialty	
Total joint arthroplasty	30
Osteoporosis	24
Spine	14
Trauma	8
Tumor	5
Foot and ankle	5
Sports medicine	5
Hand and upper extremity	3
Other†	5
Sponsorship‡	
Government	43
Foundation	19
Industry (pharmaceutical or medical device company)	24
Could not be determined	27

*France, Netherlands, Israel, or Australia. †Medical management of osteoarthritis or health policy. ‡More than one response was allowed for each article.

terms of caregiver time and productivity; and two, home-care costs. (Two measures of indirect costs were used in one study.) Of the thirty-seven studies, thirteen used a Markov model, which allows for transitions between health states over time. In eighteen studies (49%) the investigators discounted both costs and health benefits (see Glossary), and in thirty (81%) they performed incremental analyses, comparing the costs and benefits with those of an alternative therapy.

Studies varied with regard to the reporting of costs and preference weights. The economic data were gathered from a primary source in only seventeen studies (46%). In most (twenty-one) of the studies, the models of health benefit were based on primary sources, and three of these studies were carried out alongside randomized controlled trials. A number of different methods were used to generate utilities for health

states. The authors of most (nineteen) of the studies relied on clinical estimates of utilities, derived from the input of clinicians, decision analysts, experts, or authors without the use of any formal methodology. The time-trade-off or standard-gamble technique was used in three studies, and pre-existing generic tools such as the EQ-5D¹ were employed in eleven. The general community or the patients themselves were the most common sources for utility estimates (twenty-seven studies); health care professionals and/or the authors were the source in fourteen (38%).

The mean subjective quality score (assigned on a Likert scale ranging from 1 [low quality] to 7 [high quality]) improved from 3.4 points prior to 1998 to 4.1 points after 1998; however, this difference was not significant ($p = 0.15$). There was no difference in the quality of articles among the different journal types (mean scores, 4.5 points for the seven general medical or surgical articles, 3.7 points for the twenty-three orthopaedic subspecialty articles, and 3.0 points for the seven methods or policy articles). The orthopaedic papers had a lower average quality rating (3.7 points) than did the non-orthopaedic cost-utility analyses in our larger database, which had an average quality rating of 4.2 points ($p = 0.04$). Because these quality ratings were subjectively assigned (albeit by well-trained reviewers), a comprehensive chart of key methodological practices extracted from each article is presented in the Appendix to help readers to independently judge the quality of each study.

Although previous authors have found that studies supported by industry are more likely to yield favorable results^{12,13}, we did not find this to be the case for the orthopaedic articles that we reviewed. The industry-funded studies were as likely as the government or foundation-funded studies (63% in both cases) to provide cost-utility ratios of <\$50,000 per quality-adjusted life year (a common threshold below which studies are considered to be cost-effective). Only five articles (one on spine surgery and four on total joint arthroplasty), which presented a total of eight cost-utility ratios, met four key recommendations of the United States Panel on Cost-Effectiveness in Health and Medicine^{6,7,14} (use of a societal perspective, utility estimates based on community or patient sources, appropriate incremental comparisons, and appropriate discounting of costs and health benefits at the same rate). Of the eight ratios (marked with double asterisks in a table in the Appendix) in these studies, five were <\$50,000 per quality-adjusted life year (considered to be cost-effective), and none of the articles were funded by industry.

A cost-utility "league table" in the Appendix groups the interventions in the thirty-seven studies into five categories ranging from "cost-saving" (less costly and more effective than the alternative) to "dominated" (more costly and less effective than the alternative). As noted earlier, the lower the cost-utility ratio, the better the value of an intervention as it costs less money to gain a quality-adjusted life year. Eight interventions were cost-saving (cost per quality-adjusted life year of <\$0). Most interventions fell within the ranges of cost-effectiveness that have commonly been used as thresholds

TABLE II Reporting Practices in Orthopaedic Cost-Utility Analyses

Item	% of Articles (N = 37)
Study funding source disclosed	73
Framing	
Clearly defined intervention	89
Adequate description of comparator	60
Study perspective clearly stated	43
Discount rate for future costs and quality-adjusted life years reported	49
Reporting costs	
Economic data collected alongside a clinical trial or another primary source	46
Authors clearly stated the year of monetary units	70
Reporting of preference weights	
Preference measurement technique reported	68
Source of preferences listed	76
Preference source was patients*	41
Preference source was general community*	32
Reporting of results	
Incremental analyses appropriately reported	81
Sensitivity analyses reported	87
Authors discussed an explicit "cost-effective" cutoff	49

*More than one preference source may be used in each study.

(\$20,000 to \$100,000 Canadian dollars)¹⁵. Thirty-four interventions were estimated to have a cost-utility ratio of ≤\$50,000, and another nine interventions cost between \$50,000 and \$100,000 per quality-adjusted life year. The median was \$15,000 per quality-adjusted life year.

Several controversial procedures were found to have relatively high cost-utility ratios (i.e., poorer value), including antibiotic prophylaxis in certain situations, venous surveillance with phlebography or ultrasound after total joint replacement, hormone replacement therapy in relatively young patients, and laminectomy with fusion and instrumentation as compared with laminectomy with fusion but no instrumentation in patients with spondylolisthesis and spinal stenosis. Some procedures in common practice, such as the use of bisphosphonates for the treatment of osteoporosis in certain patients and for patients with metastatic breast cancer, had ratios as high as \$360,000 per quality-adjusted life year, a value usually considered to be cost-ineffective. Autologous blood donation, a common practice in many centers, had a ratio of \$51,000 per quality-adjusted life year for patients undergoing bilateral or revision total joint replacement in a center with no change in transfusion practices relative to allogeneic blood. In

a center with increased transfusion of autologous blood (compared with that of allogeneic blood) for patients treated with primary unilateral total hip replacement, the cost-utility ratios of autologous donation ranged from \$310,000 to \$950,000 per quality-adjusted life year.

Discussion

Although the volume of published economic evaluations in the field of orthopaedic surgery is lower than that in other clinical areas, payers are increasingly demanding evidence of cost-effectiveness. This type of research reflects the increasing importance of assessing both the costs and the benefits of an intervention. There has been growth in the number of published economic analyses, and clinicians are being increasingly exposed to these studies. A general understanding of economic evaluations and a specific awareness of the published studies in orthopaedics will be increasingly important to orthopaedic surgeons as they weigh in on reimbursement and other policy decisions that affect the field.

Total joint arthroplasty is the most commonly studied area in the field of orthopaedic surgery. We found six cost-utility ratios for comparisons of total hip arthroplasty with the alternative of observation only, and all of the ratios are considered to indicate cost-effectiveness (below a threshold value of \$50,000 per quality-adjusted life year) by today's standards. Osteoporosis is the next most commonly studied area, and, surprisingly, many of the published ratios indicate that treatment may be cost-ineffective. Half of the cost-utility ratios for osteoporosis treatment are >\$100,000 per quality-adjusted life year. Additional investigation is required as osteoporosis is a major public health problem and it will probably continue to be an area of interest to policy makers.

Spinal surgery, trauma, oncology, pediatric orthopaedics, and sports medicine are underrepresented in the orthopaedic cost-utility-analysis literature. Given the burden of disease and societal costs, there is a need for more information to guide resource allocation decisions within these areas of orthopaedics.

The quality of published cost-utility studies is variable and often poor. The majority of the orthopaedic articles did not clearly define a perspective; 40% did not explicitly define the comparison; and, in 24% of the studies, the source of the health-outcome preferences could not be determined. Most authors performed sensitivity analysis, reported the method of cost estimation, discounted appropriately, used incremental analyses, and stated the threshold that they used. Our findings suggest the need for improvement in methodology in several areas. Concerns about the credibility of orthopaedic analyses may persist in the absence of such improvements.

The modified league table in the Appendix allows clinicians and policy makers to quickly view descriptions of the existing cost-utility analyses in orthopaedic surgery in order to assess where the reported cost-effectiveness of an intervention falls. We do not report the actual dollar amount per quality-adjusted life year for each ratio; such exact numbers might be misleading, given the variability of the methods that were used in the studies. The studies in the league table can be examined

in the context of the methodological practices (also listed in the Appendix) with which they were performed, allowing the reader to form his or her own judgment about the validity of a study's cost-effectiveness results.

A number of limitations of the present study deserve mention. The search strategy was limited to selected key words, and we only included studies in which the cost-utility ratio was expressed as cost per quality-adjusted life year; therefore, some well-designed studies may have been omitted¹⁶⁻¹⁹. Reviewers were not blinded to the journal in which the article appeared or to the authors of the article, and this may have biased the results. The merits of the clinical or economic model assumptions were not judged; we sought to determine only whether procedural guidelines for conducting and reporting the analysis were followed. Finally, while the methodological practices varied among the studies, this fact is not reflected in the league table presented in the Appendix. The differences among ratios in league tables can be explained by looking more closely at key elements of each study. Perspective, population, the comparison, the method of utility measurement, the country in which the study was performed, the source of the cost data, and discounting can all affect the resulting ratio. Because of the variability of study methods, the cost-effectiveness ratios presented in league tables must be viewed with caution; they provide an aid to health policy makers but not sufficient evidence on which to base important health policy decisions. We addressed this limitation, to some extent, by placing interventions within a range of cost-effectiveness values (rather than providing exact cost-utility ratios) and providing data on study methods for readers who wish to use that information.

Applying economic evaluation methods to orthopaedic interventions is a complex undertaking. It requires several different types of expertise, and a number of methodological issues are still unsettled. There are many interventions that have not yet been studied, and many of those that have been studied need to be investigated further. The aging of the population and the development of newer, more expensive technologies ensure that health care costs will increase. In the past few years, more explicit considerations of costs have come to the fore. In some cases, policy makers have explicitly used cost-effectiveness analysis to make decisions regarding coverage of interventions; however, in most countries in which cost-utility analyses are used in policy making, they are applied to the evaluation of drugs, not devices.

Some private managed-care plans in the United States have developed and used guidelines²⁰, and the Centers for Medicare and Medicaid Services have debated the addition of cost-effectiveness analysis to technology assessment; however, the regulation has yet to be finalized. In the United Kingdom, cost-effectiveness analysis is explicitly being used to determine which new technologies should be introduced into the National Health Service, and this process is not limited to pharmaceuticals. The lack of level-I evidence regarding most interventions in orthopaedic surgery makes it more difficult to perform high-quality cost-utility analyses. In the future, or-

thopaedists and industry should be encouraged to provide better-quality data for health technology assessment with well-designed prospective, randomized, controlled trials.

There is an urgent need for improving economic evaluation in orthopaedic surgery by using standardized methods and transparent reporting. As the field develops, it will be important to assess both the clinical and the economic assumptions when one reads the economic literature. It also must be emphasized that economic analysis should be used to inform decisions about clinical practice and policy; it should not dictate them¹⁴.

Appendix

eA A table presenting the key methodological criteria of each study that was analyzed and a cost-utility league table are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

Glossary

Definitions are adapted in part from reference 14.

Cost-utility analysis: A form of economic evaluation that focuses on the quality, not just the quantity, of life resulting from a clinical intervention.

Cost-utility ratio: The ratio is calculated as: (cost of intervention – cost of alternative)/(benefit of intervention – benefit of alternative). Only the ratios expressed as cost per quality-adjusted life year were included in the present study. A lower cost-utility ratio indicates better value. (Less is paid for an increase of one quality-adjusted life year.)

Direct health-care costs: The cost of medical resources consumed (e.g., for physician visits, surgery, and so on).

Discounting: The process of adjusting future costs and future health benefits to their present value. This is done because future costs and benefits are assumed to be worth less to individuals than are present costs and benefits. For example, \$10 spent during the second year of a patient's treatment is worth less than \$10 spent in the present. The \$10 spent in the future needs to be discounted to the present value. If a discount rate of 5% is used, then the present value would be: $\$10 \times [1/(1 + 0.05)^2] = \9.07 .

Generic index of health-related quality of life: A standardized instrument for measuring health outcome that is constructed by determining preferences for various health states with direct measurement techniques such as the time-trade-off, standard-gamble, and rating-scale methods. Some commonly used instruments include the EQ-5D¹, the Health Utilities Index (HUI)², and the Quality of Well Being (QWB) Index³.

Incremental cost: The difference between the cost of an intervention and the cost of the alternative with which it is being compared.

Indirect costs: Costs such as lost productivity due to time off from work during treatment.

Quality-adjusted life years: A generic outcome derived by using a quality-adjustment weight on the duration of time for which the patient is affected by an intervention. In the conventional approach, the utility (the quality-adjustment weight) is multiplied by the time spent in that health state, and then those values are summed to calculate the number of quality-adjusted life years. For example, if the patient spends one year after the surgery in a state that is 50% of perfect health (a utility value of 0.5) and then has a return to perfect health for the next year, the gain in quality-adjusted life years at two years would be $(0.5 \times 1) + (1 \times 1) = 1.5$ quality-adjusted life years.

Sensitivity analysis: Analysis that determines the impact of changing variables on the results (e.g., what effect does changing the hospital costs of an intervention have on the results?).

Standard gamble: A method of determining utility/preference weights. The respondent is asked to compare life in a given suboptimal health state with a gamble between two alternate outcomes: perfect health (denoted as probability p) and death (denoted as $1 - p$). The probabilities in the gamble are varied until the respondent is indifferent regarding the choice between the given suboptimal health state and the gamble. The utility for the given health state is then calculated as: $[p \times \text{utility (perfect health)}] + [(1 - p) \times \text{utility (death)}]$. For example, a person may be told that he or she can choose to live for his or her remaining ten years with limited mobility and pain or risk a therapy (perhaps surgery) that may restore perfect health (utility = 1) or cause death (utility = 0). If the risk of death is varied until the person is indifferent regarding the choice between limited mobility and a 15% chance of death (the gamble), the utility = $(0.85 \times 1) + (0.15 \times 0)$, or 0.85.

Time trade-off: A method of determining utility/preference weights. The respondent is asked to choose between life in a given suboptimal health state for a fixed amount of time (such as limited mobility for ten remaining years of life) and life in perfect health for a shorter period of time (such as perfect mobility for eight years). The life expectancy in perfect health is varied until the respondent is indifferent regarding the choice

between the two states, and the utility is then calculated as: life expectancy in perfect health/life expectancy in suboptimal health (in this example, the utility is 8/10 or 0.8).

Utility states (also referred to as "preference weights"): A measure of an individual's or a society's preference for a particular set of health outcomes. For example, if a construction worker and a computer programmer who have sustained a calcaneal fracture are each asked to rank "having a broken foot" on a scale of 0 (defined as death) to 1 (defined as perfect health), their rankings might differ considerably because of the importance that each attaches to the use of the lower limb. Utilities can then be used to calculate quality-adjusted life years by multiplying the utility for a health state by the duration of time spent in that health state. This allows comparison of outcomes (in quality-adjusted life years) across different interventions and different diseases. ■

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