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Methodologic Evaluation of the Radiology Cost-effectiveness Literature[1]

PURPOSE: **To evaluate the methodologic quality of cost-effectiveness and cost-benefit analyses reported in the radiology literature.**

MATERIALS AND METHODS: **Original investigations of cost-effectiveness and cost-benefit analysis were identified from an on-line search of the radiology literature from 1989 to 1995. The articles were evaluated for adherence to minimum methodologic standards for economic analysis research. Major criteria assessed were (*a*) provision of comparative options, (*b*) statement of perspective of analysis, (*c*) presentation of cost data, (*d*) measurement of outcomes, (*e*) use of a summary measure of economic efficiency, and (*f*) performance of sensitivity analysis. Minor criteria assessed were inclusion of (*a*) source of cost data, (*b*) long-term costs, (*c*) discounting, and (*d*) incremental computation of the summary measure.**

RESULTS: **Forty-four economic analysis articles were identified. The median numbers of major and minor principles adhered to were three and one, respectively. Five studies used all six major criteria, and three used all 10 criteria. The median number of criteria adhered to did not increase during the study period.**

CONCLUSION: **Adherence to methodologic standards in the radiology cost-effectiveness literature is not optimal. There are several examples from radiology journals, however, where such standards are met.**

Because of the continued increase in health care costs, there has been growing emphasis on cost-effectiveness and economic analysis in discussions of health care policy. Cost-effectiveness analysis offers promise as a method of containing costs by means of efficient allocation of resources. Australia has passed legislation requiring that new drugs must be shown to be cost-effective before approval (1). Similar guidelines have been proposed for Ontario, Canada (2). In the United States, cost-effectiveness has been introduced as a criterion for Medicare coverage (3), and Oregon has used cost-effectiveness as a basis for Medicaid coverage of medical procedures (4). In the medical literature, the publication of cost-effectiveness and cost-benefit–related articles has increased 50-fold since the 1960s. Even since 1979, the number of published economic analysis articles has almost quadrupled (5).

Economic analysis encompasses both cost-effectiveness and cost-benefit analysis. In cost-benefit analysis, all costs and outcomes are reduced to dollar equivalents. For example, a lost-wages or willingness-to-pay approach might be used to assign a specific dollar value to a year of life. The dollar cost of the medical intervention needed to save that year of life is then compared with the dollar value of the year of life saved. If the intervention costs more than the dollar value of the year of life saved, then the intervention would not be recommended. The difficulties associated with this type of analysis result from the ethical and methodologic considerations that are inherent in the attempt to assign a dollar value to a health outcome. This difficulty is avoided in cost-effectiveness analysis by using different scales for costs and outcomes. Costs are usually expressed in dollars, while outcomes are measured in some form of health outcome units, such as lives saved or quality-adjusted life years. The results of a cost-effectiveness analysis are then expressed as a ratio, such as dollars per year of life saved. These cost-effectiveness ratios can be used to compare the relative value of different interventions.

As in other forms of research, possibilities for bias exist in economic analyses. This concern has led to the publication of a number of calls for standardization of methods used in performing and reporting cost-effectiveness research (6–8). In radiology, several articles detailing cost-effectiveness analysis methods have appeared recently (9–11). To our knowledge, in

Index terms: Cost-effectiveness • Economics, medical • Radiology and radiologists, outcome studies • Radiology and radiologists, research • Radiology and radiologists, socioeconomic issues

Radiology 1997; 203:87–91

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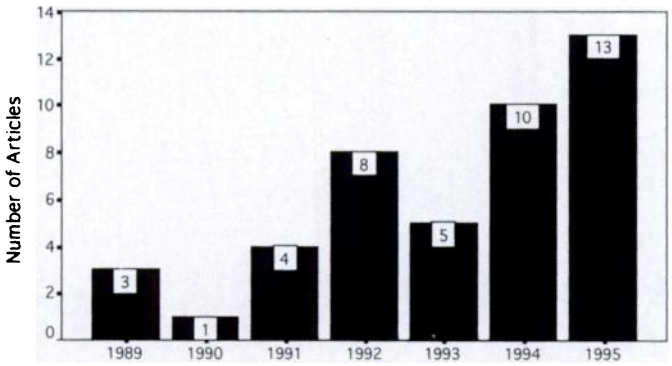
See also the editorial by Reinus (pp 13–15) in this issue.



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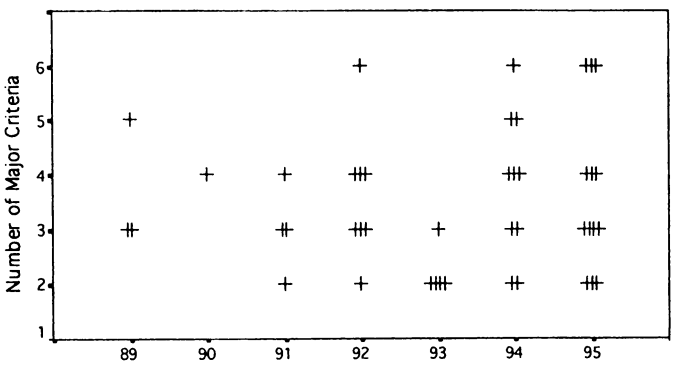

2.

Figures 1, 2. **(1)** Graph depicts the number of articles reviewed for each year. The number of articles increased significantly during the study period (r = .89, P = .007). **(2)** Graph shows the number of major criteria versus year of publication for the 44 articles reviewed. Linear regression analysis revealed no significant increase in the number of criteria during the study period (r = .06, P = .69).

all of medicine to date, however, there have been few formal methodologic evaluations of the economic analysis literature (12,13) and none that included articles from the radiology literature. The purpose of our study was to assess the methodologic quality of the cost-effectiveness and cost-benefit analyses published in peer-reviewed radiology journals.

MATERIALS AND METHODS

Article Selection

A Medline search of 21 major peer-reviewed diagnostic radiology journals was conducted for the years 1989–1995. The journals included in the literature review were *Abdominal Imaging, Academic Radiology, American Journal of Neuroradiology, American Journal of Roentgenology, Australasian Radiology, British Journal of Radiology, Clinical Radiology, European Journal of Radiology, Gastrointestinal Radiology, Investigative Radiology, Journal of Computer Assisted Tomography, Journal of Ultrasound in Medicine, Journal of Vascular and Interventional Radiology, Magnetic Resonance Imaging, Magnetic Resonance in Medicine, Neuroradiology, Pediatric Radiology, Radiology, Seminars in Roentgenology, Skeletal Radiology,* and *Urologic Radiology*. The search was conducted for the terms "cost-effectiveness," "cost-effective," "cost-benefit," or "benefit-cost" in the title or in the abstract. In addition, the search was conducted under the National Library of Medicine subject heading "cost-benefit analysis," which includes cost-effectiveness analysis. This search yielded 173 articles, which were analyzed in greater detail. Review articles, letters, technical notes, and editorials were excluded to limit the study to original research articles.

We then subjected the remaining 60 articles to a preliminary review to determine whether the use of the terms "cost-effective" or "cost-benefit" was casual or if such analysis was a primary goal of the study. Use of "cost-effective" or "cost-benefit" in the title or an explicit statement that such analysis was a purpose of the study was a criterion for inclusion. In addition, we considered cost-effectiveness to be a primary focus of studies that presented any form of economic analysis and drew conclusions about cost-effectiveness or cost-benefit. A simple statement concluding that an intervention was or was not cost-effective without any supportive documentation was considered casual use of the term. Full methodologic review was conducted of the 44 articles (14–57) that did not use "cost-effective" or "cost-benefit" in a casual manner.

Critical Analysis

Before review of the research articles, we defined six major and four minor criteria that should be considered a minimum standard for performing and reporting cost-effectiveness and cost-benefit studies. These criteria were derived by means of extensive review of the radiology and general medical literature on methodologic standards for economic analysis (2,6,8–10,58–62) and represent areas in which there is general agreement. These methodologic criteria selected represent a modified version of the standards proposed by Udvarhelyi et al (13) and parallel the recommendations of the American College of Physicians Task Force on Principles for Economic Analysis of Health Care Technology (7). The minor criteria were subsets of the major criteria. Areas of controversy in the methods of economic analysis were specifically excluded.

Each article in the final set was reviewed independently by two individuals (C.C.B., D.J.M.) and graded for the presence of each of the methodologic standards. Agreement between reviewers was calculated by using the κ statistic (63). Disagreements between reviewers were then resolved by consensus, and percent adherence to the methodologic criteria was calculated. The relation between year of publication and number and quality of published articles was explored by using simple linear regression. The total number of published articles in the included journals was determined from Medline information. The χ^2 statistic was then used to compare the change in total number of published articles with the change in number of economic analyses between the first 3 years and the final 3 years of the study.

In all cases, these criteria were designed to be minimum standards. We did not attempt to critique the rigor of the analyses performed in individual studies. Rather, if a given criterion was addressed at all, it was considered to be included. If a methodologic criterion was neither included in the analysis nor explanation for its absence explained, then this criterion was considered to be absent.

Methodologic Principles

Principle 1.—An explicit statement of the diagnostic or therapeutic options considered should be provided. Cost-effectiveness and cost-benefit analyses are comparative studies that measure simultaneously the costs and outcomes of two or more interventions. Since the relative cost-effectiveness of any medical care will depend on what it is being compared with, this comparison should be made explicit to the reader. Sometimes the comparator for a given test or intervention will be no intervention. However, even the absence of action will almost always have some subsequent cost and/or benefit that must be quantified.

Principle 2.—An explicit statement of the perspective of the analysis should be provided. The cost and effectiveness of an intervention may vary when evaluated from different perspectives (ie, society, provider, payer, patient). For example, costs from a societal perspective might include indirect costs from lost productivity, while costs from a payer's perspective might be limited to the direct costs of medical care. Similarly, benefit to the individual might be prolongation of his or her life, while benefit to society might be added life years spread out among many individuals.

Compliance with Methodologic Standards

Criteria Used	No. of Articles*
Major	
Comparative options	43 (98)
Perspective of analysis	6 (14)
Cost data	43 (98)
Outcome data	35 (80)
Summary measure or dominant strategy identified	18 (41)
Sensitivity analysis	8 (18)
Minor	
Source of cost data	31 (70)
Long-term costs	9 (20)
Discounting	5 (11)
Incremental computation method	9 (60)†

* Total number of articles reviewed = 44. Numbers in parentheses are percentages.
† Only considers cases in which a summary measure was provided (n = 15).

Principle 3.—Cost data should be provided. A clear statement of the estimated cost of a test or intervention served as the major criterion. In addition, three minor criteria related to cost were considered: (*a*) statement of the source of the cost data, (*b*) inclusion of long-term costs, and (*c*) use of discounting. The criterion source of cost data required a statement of what method was used to estimate costs (accounting costs, reimbursements, or charges). Long-term costs, the second minor criterion, may accrue with an intervention, and these costs should be considered in an analysis. If the investigators in a study considered long-term costs or explained the exclusion, this was considered sufficient for this criterion to be met.

The third minor criterion concerned the use of discounting. Discounting is an economic construct used to adjust future costs to their present value and is usually considered to be in addition to inflation (59,60,64). Money that is available in the present is considered to be worth more than money that might become available in the future. For example, if an individual were offered $1,000 today or $1,000 5 years from now, that individual would almost certainly choose to have the money today. This is the case even if the future money were adjusted for inflation. The reason is that the money, if available today, can serve some useful function (eg, earning interest). This is known as the time value of money. Costs that accrue 1 or more years from the base year of the analysis should be discounted. Use of discounting or discussion of why discounting was not included was necessary for this minor criterion.

Principle 4.—Outcomes should be explicitly stated. Health outcomes are the measure of effectiveness of the two interventions being evaluated. These health outcomes are measured by using such standards as mortality statistics, indexes of morbidity, and quality-adjusted outcomes such as quality-adjusted life years. In cost-benefit analysis, health outcomes are converted into dollar equivalents. Ideally, the selection of outcome measures should be justified, and all potential outcomes should be included in the analysis. For purposes of our study, any explicit statement describing an outcome measure was considered sufficient.

Principle 5.—A summary measure of economic efficiency should be calculated or the dominant strategy should be identified. For cost-benefit analysis, the summary measure is a cost-benefit ratio or a dollar figure representing the difference between the costs and benefits of an intervention (58,59). In cost-effectiveness analysis, a ratio of cost to effectiveness should be stated. For example, a commonly used summary measure is dollars per year of life. Since the logical outcome measures for various interventions may differ, provision of any summary measure was considered sufficient. However, when one strategy is dominant, the summary measure is not necessary. A strategy is dominant if it is both less costly and equally or more effective than the alternative intervention. A strategy is also dominant if it is equal in cost and produces superior health outcomes. Identification of a dominant strategy was also sufficient for the major criterion.

For the fourth minor criterion, when a summary measure was provided we evaluated use of the incremental method of calculation rather than the average method. The incremental method enables determination of additional cost per unit of additional benefit of one intervention over another. Since the purpose of cost-effectiveness analysis is to compare different strategies, the incremental method is preferred (58,59,62).

Principle 6.—Sensitivity analysis should be performed. Health economic analysis involves the use of assumptions for both costs and outcomes. These values are often uncertain and may vary with different patient populations. In addition, the discount rate is chosen somewhat arbitrarily and may be uncertain. The strength of an economic analysis is related to the stability of the conclusions despite different assumptions for each variable. As in other types of research, the reader needs to know how stable the results are or if they can be attributed to chance. In cost-effectiveness or cost-benefit analysis, the sensitivity analysis partially addresses these questions. In sensitivity analysis, each assumption is tested over the range of possible values, and the effect on the conclusions is determined. If the conclusions change with a sensitivity analysis, then the stability of the conclusions should be questioned. The sensitivity analysis serves some of the same functions as statistical analysis, although with less foundation in mathematical theory.

Methods of actual determination of 95% confidence limits for sensitivity analysis have been proposed, but no consensus for them exists, to our knowledge (65). An additional role for the sensitivity analysis is to determine which uncertain variables are important so that they may be targeted for future research. Provision of any sensitivity analysis qualified for compliance with this criterion.

RESULTS

The number of economic analysis articles increased significantly during the study period (r = .89, P = .007), ranging from one study in 1990 to 13 studies in 1995 (Fig 1). The total number of published articles increased slightly from 12,358 in the first 3 years to 13,895 in the final 3 years. However, the proportional increase in number of economic analyses was significantly greater (P < .001) than that in the total number of articles. The majority of articles were found in the *American Journal of Roentgenology* and *Radiology* (14 and 12, respectively), which accounted for 59% of the total.

Only five (11%) of the 44 articles included all six major criteria (23,39, 47,48,53), and only three (7%) included all 10 major and minor criteria (23,47, 53). The median number of major criteria fulfilled was three, and the median number of minor criteria was one. There was no correlation between year and total number of criteria (r = .06, P = .69), year and major criteria (r = .08, P = .62), or year and minor criteria (r = .03, P = .84). A scatterplot of the number of major criteria versus the year of publication is shown in Figure 2. A summary of compliance with each of the individual methodologic standards is shown in the Table. The major criteria of comparative options and cost data were followed in almost all studies (98% for each). However, the perspective of the analysis (14%), sensitivity analysis (18%), and discounting (11%) standards were followed only infrequently.

Agreement between the reviewers' independent evaluation of the articles was excellent, with κ values of 0.79 for the major criteria and 0.86 for the minor criteria (63). The most frequent disagreement occurred in the major criterion summary measure or dominant strategy identified, which accounted for five of the 13 major disagreements. The κ value for this criterion was 0.77.

DISCUSSION

In a broad sense, the methodologic standards of economic analysis parallel those of traditional radiology research. The methods of analysis need to be presented in a clear manner that can be understood by editors, review-

ers, and readers. There should be sufficient detail in the description of the methods so that the study could be replicated by a reader. Also, the computations involved in cost-benefit and cost-effectiveness analyses may necessitate decision analysis computer models or spreadsheet-type programs. The net result of such an analysis will be dependent mainly on the nature of the inputs, which therefore must be clearly described. Finally, when comparing the results of two economic analyses, the reader needs to be able to determine if the methods are comparable and, therefore, the comparison is valid.

Cost-effectiveness and other health economic analyses are important methods of evaluating health care interventions. For example, in a setting of limited health care resources, the marginal cost-effectiveness ratios can be used to prioritize interventions for funding. For such comparisons to be valid, however, the method used must be standardized (2,7). Unfortunately, we have found that only a minority of the health economic analyses in the radiology literature conform to even basic methodologic standards. The lack of improvement in the methods used in articles since 1989 is equally disturbing.

Casual use of the term "cost-effective" also warrants discussion. Our final data set excluded studies in which the term "cost-effective" was used in the abstract of the article but no apparent form of economic analysis was performed. However, it is unfortunate that such casual use occurred in 16 of the original research articles that were identified. The term "cost-effective" has a specific meaning, defined as analysis of the trade-off between medical benefit and cost (66,67). Use of the term in a casual manner should be discouraged.

In 1992, in a study similar to ours, Udvarhelyi et al (13) reviewed 77 cost-effectiveness and cost-benefit analyses from the general medical, general surgery, and medical subspecialty literature. However, none of the reviewed articles were from the radiology literature. Udvarhelyi et al found that only three of the 77 articles followed all six of what they defined as fundamental principles for cost-effectiveness or cost-benefit analysis. Although the criteria are not identical, our findings from the radiology literature are actually somewhat better than the results of Udvarhelyi et al. We found that 11% of the radiology cost-effectiveness and cost-benefit analysis articles comformed to all six major criteria versus 4% of the articles in the study by Udvarhelyi et al. Fortunately, there are several studies of cost-effectiveness in the radiology literature where such standards are met and that may be used as examples for those undertaking cost-effectiveness research (23,47,53).

Our study does have several limitations. Our search method was based on the National Library of Medicine subject heading and specific words in the title or abstract. A cost-effectiveness analysis performed but not explicitly stated in the title or abstract may have been missed. Also, a different word pattern with a similar meaning may have been missed. However, we believe that we have included most articles in which the economic analysis was a major focus. It is probable that articles missed by our search would use even fewer of the methodologic standards, as cost-effectiveness or cost-benefit analysis was not the major focus of the project. Further, the reviewers were not blinded to author, journal, or year of publication. However, neither of the reviewers participated in any of the studies being evaluated. Finally, the criteria were designed to be objective to maximize agreement and minimize bias.

We have attempted to evaluate only the presence or absence of general methodologic standards, and these principles should not be considered a comprehensive methodologic guide to writing about or performing health economic analysis. Other factors that will determine the validity of a cost-effectiveness or cost-benefit analysis include the validity of the comparators, the inclusion of all realistic benefits and costs (or at least a discussion of any exclusions), methods and statistics of any meta-analysis or pooling of data that was performed, and the validity of the individual assumptions. Several more detailed discussions of the principles and methods of cost-effectiveness and cost-benefit analysis are available (8,10,60,64).

In the spectrum of radiology outcomes research, economic analyses are in the highest level, societal efficacy (level 6), in the spectrum proposed by Thornbury (68). Traditional radiology research has centered on issues of technical efficacy, diagnostic-accuracy efficacy, or diagnostic-thinking efficacy. Because of the often indirect or temporally distant connections between imaging and outcome, it can be difficult to measure the effect of a given imaging study on patient health. This fact compounds the difficulty in performing higher-level efficacy studies such as economic analyses. Further, economic analyses often require multidisciplinary teams and may be expensive. Finally, the methods used in cost-effectiveness and cost-benefit analysis are complex and require skills not generally included in the radiology training curriculum.

It is commendable that despite these difficulties, radiology investigators are showing increased interest in health economic analysis. However, when the methods are inadequate, the results may be questioned. It is disturbing that few of the radiology economic analyses met even the minimum criteria for which we evaluated. If cost-effectiveness analysis is to play a role in how radiologic procedures are evaluated, then radiology investigators should become better trained in use of the proper methods (69) or collaborate with investigators who have this type of expertise.

In conclusion, cost-effectiveness analyses and cost-benefit analyses found in the radiology literature are frequently deficient in adherence to basic methodologic standards. As cost-effectiveness analysis may have important policy implications, the quality of these reported analyses must be improved. ■

Acknowledgment: We thank Jeffrey J. Jarvik, MD, MPH, for constructive comments during preparation of the manuscript.

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