

ECONOMIC EVALUATION OF DIAGNOSTIC TESTS

A Review of Published Studies

Johan L. Severens
Gert-Jan van der Wilt

University of Nijmegen

Abstract

Objectives: The purpose of this review was to examine whether studies from the medical literature focusing on efficiency of diagnostic facilities reported economic evaluation methods appropriately, following guidelines for conducting and reporting economic evaluations.

Methods: A MEDLINE search was conducted, and studies that concerned a diagnostic technology and fulfilled the Drummond criteria were selected for methodological review. The reliability of selection and methodological review based on the abstracts was determined by scoring a random sample of both abstracts and full articles. Interrater reliability was determined by scoring a random sample of abstracts by both authors. Kappa values were calculated. Nine methodological aspects were reviewed: study design, the type of economic evaluation, the comparison made, the study's perspective, the cost-effectiveness ratio used, the definition of cost-effective, the types of costs analyzed, the cost calculation method, and the use of sensitivity analysis.

Results: Two hundred fifty studies published between 1992 and 1997 were found regarding efficiency of diagnostic facilities; 134 studies fulfilled the Drummond criteria and were selected for methodological review. Kappa values showed reliability of selection and methodological review and interrater reliability. The existing literature on the economic evaluation of diagnostic facilities does not adhere well to guidelines for economic evaluation. In 95%, no perspective was mentioned, in 50% of the cases no ratio was given, in 82% the cost calculation method was not mentioned, and in 66% no sensitivity analysis was reported.

Conclusions: Our review suggests that to improve the quality of reporting economic evaluations, editorial boards could issue and enforce guidelines for standard reporting of such studies.

Keywords: Review literature, Diagnostic techniques and procedures, Cost-benefit analysis, Technology assessment

The objective of economic evaluations of health care interventions is to provide information concerning the relation between input (resource use) and output (health outcomes) among competing alternatives (16). To interpret the results of these studies, it is essential that explicit information be provided concerning methodological aspects, such as the alternatives that have been considered in the study, the

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perspective from which the study was conducted, the type of costs that were included and that contributed to overall costs, and the methods used to calculate costs. If such information is lacking, results should be interpreted with caution. Comparing figures from different studies is difficult, if not impossible. Several examples exist of widely varying figures of the cost-effectiveness of health care interventions. This variation may be due partly to differences in alternatives selected for comparison, types of costs included, or cost calculation methods. For instance, comparing the results of economic evaluations of the diagnosis of patients with severe esophagitis, costs for an upper endoscopy vary substantially between studies because of differences in the perspectives and cost calculation methods (29). As a result, several attempts have been made to establish guidelines for the conduct of such studies (9;16;22). Moreover, to facilitate literature reviews, guidelines have been set up for reporting these studies (40).

In the past few decades, a growing number of economic evaluations have appeared in the medical literature (2;18). Of the total number of economic evaluation studies reported from 1979 through 1990, approximately one-third concerned diagnostic interventions (19). The current study was undertaken to assess the extent of compliance with guidelines for economic studies of diagnostic tests published in the literature between 1992 and 1997.

METHODS

Search and Selection Criteria

A computerized MEDLINE search was conducted to identify articles published in medical journals regarding efficiency research on diagnostic facilities between 1992 and 1997. We performed the following search: a) exploded the medical subject heading (MeSH) "diagnosis" to include 682 subcategories, then limited to the subheading "economics"; and b) searched the MeSH heading "cost-benefit analyses" as well as the terms "cost-effectiveness" or "cost-effective" in the title or the abstract of the article. These combined results were limited to studies that were published in English, included human subjects, involved comparative studies, and included an abstract. A total of 250 references were obtained from the search.

Before reviewing the abstracts based on the methodological aspects, criteria were used to determine whether the study was relevant for the purpose of our review. Drummond et al. (16) state that, regarding a full economic evaluation, two criteria have to be met. The first of these suggests that an economic evaluation in principle deals with choices. Therefore, the question was whether the study compared two or more alternatives. The second of these criteria is that economic evaluation must deal with either the outcome or consequences and the costs of the alternatives being compared. Therefore, we had to ask whether both costs and outcome of the alternatives were examined by the study. First, we determined whether the criteria from Drummond were fulfilled, regardless of the medical technology that was studied.

Besides the Drummond criteria, the article had to deal with a diagnostic facility. The MEDLINE subject heading "diagnosis" is used whenever diagnostic aspects are mentioned in the study. We excluded references that did not fulfill the criterion that the article concentrated on at least one diagnostic facility.

Selected Articles

Of the 250 references found, 55 did not fulfill the Drummond criteria. Fifteen did not explicitly compare alternatives and 40 did not consider both effects and costs.

An additional 58 studies did not consider a diagnostic facility. The main reason for this relatively large number is because the MeSH heading “diagnosis/economics” includes laparoscopic techniques that can be applied for diagnostic purposes but also for therapeutic use, such as laparoscopic cholecystectomy. After reading the abstracts, another three studies were considered irrelevant for our review. In two cases a study concentrated on quality of care research, and one study contained a mere description of diagnostic techniques. Of the studies found, three fulfilled neither the Drummond criteria nor our review criteria. Ultimately, we excluded 116 of the 250 studies found based on the abovementioned criteria. The remaining 134 studies are referenced in the Appendix.

To assess whether the desired selection of studies could be made reliably based on information provided in the abstracts, 4 months after reading the abstracts 10% of the references were randomly chosen and the full articles read. Of the random 25 articles, three were not available in the Netherlands, so 22 full articles were finally read (1;4;8;10;11;12;21;23;24;25;26;28;30;33;34;36;37;38;41;42;44;45). Again, the Drummond criteria and our review criteria were used to determine whether a study met these selection criteria. Using kappa values, the results of scoring the full articles were compared with the results of the original scoring 4 months earlier based on reading only the abstracts of the same studies.

Methodologic Review

The abstracts of the 134 studies were carefully reviewed regarding methodology. We identified nine methodologic aspects that should be mentioned by the authors:

1. The type of study;
2. The type of economic evaluation;
3. The comparison made;
4. The study's perspective;
5. The ratio between costs and effects used;
6. The use and definition of the term cost-effective;
7. The types of costs analyzed;
8. The methods used for calculating cost; and
9. The use of sensitivity analyses.

These aspects were derived by reviewing recommendations from reports and textbooks that have described valid methods for economic evaluations and made recommendations for reporting study results (9;16;22). According to these recommendations, the methodologic aspects represent basic information and should be mentioned in abstracts (40).

The nine aspects reviewed were each divided into categories. Regarding the type of study, we distinguished five categories: randomized trial, prospective study, retrospective study, modeling study, and other. Within the health economic literature, cost-minimization, cost-effectiveness, cost-utility, and cost-benefit analyses are defined as different types of economic evaluation (16). Because the comparison made in an economic evaluation can be essential to the study results (3), we identified the following types of comparison: test versus test comparison; test versus no test; test versus treatment; other; and no information. The study's perspective should be mentioned explicitly because the choice for using a certain perspective influences the methods used in the analysis, for instance, the relevant cost categories and the

methods used to value the costs (16). Three perspectives were distinguished: a third-party payer perspective, the perspective of the health care provider, and a societal perspective. Several cost-effectiveness ratios can be used in economic evaluation of diagnostic facilities. Cost per patient, per life saved, per life-year saved, per case discovered, per quality-adjusted life-year (QALY), per some other measure, and no information were used. The use of the term cost-effective is often discussed (13). We investigated whether a definition was explicitly or implicitly used in the study, using the categories cost-saving, more effective, cost-saving and more effective, more effective and worth the additional cost, lowest average cost-effectiveness, and no information. The types of costs that were part of the analyses should be specified by the researchers. From the literature we distinguished medical cost, nonmedical cost, and productivity cost. Regarding the methods for calculating the cost, charges, real costs, or both are distinguished. Sensitivity analysis is an important method to investigate uncertainty in economic evaluation (7). Although several types of sensitivity analysis can be defined, we concentrated on whether sensitivity analysis was performed and which variables were subject to this analysis: costs, effectiveness, or other variables.

To assess whether the scoring of the abovementioned methodological aspects could be made reliably based exclusively on the information provided in the abstract, a comparison was made between scoring the articles read in full and the original abstract scoring. Of the 22 articles read in full, 10 fulfilled both the Drummond and our review criteria; the kappa scores regarding the methodological aspects are based on these 10 articles (4;8;10;23;25;26;30;34;38;42).

Besides the comparison of the abstract and full article, reliability of our review was assessed by having both authors review a sample of 10% of the 134 abstracts (R21;R29;R31;R58;R60;R64;R67;R87;R92;R108;R116;R120;R127;R130). Interrater reliability was again analyzed by calculating kappa values.

RESULTS

Results of the Reliability Tests

Reliability of the Selection of Studies. The results of the three distinct reliability tests are as follows. First, comparing the scoring of the abstract and the scoring of the full article, the kappa value for using the Drummond selection criteria was 1.00. The kappa value for selection based on our own review criteria was 0.73. Using both sets of criteria selection based on the abstracts was exactly the same using the full articles (kappa 1.00).

Reliability of the Methodological Review. The reliability of scoring the methodological aspects solely on the basis of the abstracts was assessed by comparing the scoring of the full article. The kappa value for scoring the type of study was 0.68; kappa was 1.00 for the type of economic evaluation and the comparison made; 0.45 for the study's perspective; 0.83 for the ratio between costs and effects used; 0.50 for the definition of the term cost-effective; 0.55 for the methods used for calculating cost; and 0.69 for the use of sensitivity analysis. For the scoring agreement regarding the types of costs analyzed, kappa could not be calculated because an unequal number of categories was used. For this aspect the abstract and full article scoring agreed in 60% of the cases.

Interrater Reliability. Regarding the interrater reliability comparing the scoring by both authors (JLS and VDW) for the nine aspects, for four of the aspects

Table 1. Overview of Scoring the Review Aspects in Different Categories

Review question categories	%	Review question categories	%
<i>Type of study</i>		<i>Type of economic evaluation</i>	
Randomized trial	8.2	Cost-minimization analysis	15.7
Prospective study	32.1	Cost-effectiveness analysis	47.0
Retrospective study	14.9	Cost-utility analysis	6.7
Modeling study	29.9	Cost-benefit analysis	0
Other	3.0	Combination	4.5
Combination	2.2	No information	26.1
No information	9.7		
<i>Comparison made</i>		<i>Study's perspective</i>	
Test vs. test	76.1	Third-party payer perspective	0.7
Test vs. no test	14.9	Health care provider perspective	3.0
Test vs. treatment	4.5	Societal perspective	1.5
Other	2.2	Other	0
Combination	1.5	Combination	0
No information	0.8	No information	94.8
<i>Cost-effectiveness ratio</i>		<i>Definition of cost-effective</i>	
Cost/patient	6.7	Cost-saving	14.9
Cost/life saved	7.5	More effective	1.5
Cost/life-year saved	2.2	Cost-saving, more effective	17.2
Cost/case detected	9.7	More effective, worth the cost	14.2
Cost/"specific measure"	16.4	Lowest average cost-effectiveness	21.6
Cost/QALY	7.5	No information	30.6
Combination	2.2		
No information	47.8		
<i>Types of costs analyzed</i>		<i>Cost calculation methods</i>	
Medical cost	25.4	Charges	6.0
Nonmedical cost	0	Real cost	11.2
Productivity cost	0.7	Combination	0.7
Combination	3.7	No information	82.1
No information	70.2		
<i>Use of sensitivity analysis</i>			
Yes, costs	4.5		
Yes, effectiveness	0.7		
Yes, other variables	12.0		
Combination	16.4		
No information	66.4		

the kappa value was 1.00, and for the remaining five aspects the lowest kappa was 0.77.

Results of the Review

The results of the review questions can be found in Table 1. Regarding the type of study, approximately 10% of the abstracts gave no information. Prospective study designs (randomized trials and nonrandomized prospective studies) comprised a large part of the studies (40.3%). Modeling studies (30%) also played a considerable role in economic evaluation. Other types of studies included literature reviews and an extensive description of diagnostic technologies.

Cost-effectiveness analysis was the type of economic evaluation most frequently used. Although cost-utility and cost-benefit analyses theoretically would render a comparison between different studies possible (27), these types of evaluation were

seldom found. A considerable number of studies did not mention the type of economic evaluation. It is possible in nearly all cases to determine the comparison made in the studies. Test versus test is most common.

Although the choice of the perspective of the study is highly relevant for the results and therefore the interpretation of the study results, in nearly 95% of the 134 studies the perspective was not mentioned in the abstract. For those studies where such information was provided, the perspective of the health care provider was used most often.

To make comparison between studies possible, the final outcome of a study can be expressed in cost-effectiveness ratios using endpoints such as life saved, life-year saved, or QALYs. Such endpoints are used to calculate ratios 17.2% of the time. Cost per case detected seems to be a ratio that could make the comparison of different studies possible. However, detecting a case can be of varying importance regarding the disease that is suspected. In half of the cases, no ratio was calculated or no information was given on this topic.

Whenever a definition of the term cost-effective was explicitly given or could be inferred from the abstract, in more than 20% of the abstracts average cost-effectiveness ratios were used. The two options, simultaneously cost saving and more effective (which in fact reflects dominance) and more effective and worth the costs, reflect the calculation of an incremental cost-effectiveness ratio. This was used in 31% of the abstracts. A definition of cost-effective where costs and effects were not related to each other at all was used in 16.4% of the studies.

No information on types of costs that are analyzed in the study appeared in the majority of abstracts. Moreover, in about 82% of the abstracts the calculation method of determining the costs was not mentioned explicitly.

In more than 66% of the studies sensitivity analysis was not used to investigate robustness of the study findings. Besides costs and effectiveness variables, 12% of the studies used other variables such as prevalence and prior probability of disease.

DISCUSSION

Reliability of the Review

The reliability of our review was determined regarding three aspects: the reliability of the selection, the reliability of the methodological scoring, and the interrater reliability. Given the kappa values of comparing selection based on the abstract only or after the full article had been read, we conclude that excluding 116 of the 250 studies based only on the abstracts was reliable. Considering the kappa values regarding the reliability of the methodological scoring, it can be concluded that most of the methodological aspects can indeed be judged exclusively from the abstract, because agreement was substantial or almost perfect (31). Only the study's perspective and definition of the term cost-effective turned out to be difficult to score based on the abstract. The discrepancy can be explained by the fact that these aspects are often not mentioned in the abstract in contrast to the article in full. However, in cases where these aspects are mentioned in the abstract, the scores based on the abstract and the article fully agree. Given the lowest kappa value of 0.77 regarding the interrater reliability, we concluded that reviewing all 134 abstracts by only one author (JLS) was reliable.

The Review

Trials are considered to be a natural vehicle for economic evaluation (15), which explains the considerable number of studies that are based on prospective trials.

Modeling studies are used often in economic evaluation. They may help to extrapolate results of short-term prospective studies, adjust study findings for a different health care system, or be used whenever a trial is not practical (14;32). The main purpose of economic evaluations is to make the relationship between input (costs) and outcome (effectiveness) explicit. Average cost-effectiveness ratios were used most often as the final outcome of a study. Although these ratios do give information about the different diagnostic facilities under consideration, the incremental cost-effectiveness ratio should be calculated, because decisions about the choice of alternatives should be made at the margin (5). As in all trials, uncertainty of study results is present in an economic evaluation. Besides variability in sample data, which encourages use of formal statistical methods, sensitivity analysis is an important tool to handle uncertainty related to data inputs for which no clear sample exists, for instance, cost and effectiveness estimates (7). For this purpose sensitivity analyses are recommended to be performed; however, in two-third of the studies this method was not used to investigate robustness of the study findings.

Our review suggests that the existing literature on the economic evaluation of diagnostic facilities does not adhere well to basic guidelines for reporting economic evaluations. Previously, reviews on both general and specific methodological issues of economic evaluations have reached the same conclusion (6;20;43). However, since the publication of these reviews and despite the recommendations that have been made, the situation has not improved. An important finding of our review is that, between 1992 and 1997, many abstracts concerning diagnostic tests still failed to report the study's perspective, the types of costs analyzed, calculation methods of costs, and the use of sensitivity analysis. The methodological aspects that were adequately reported were the type of study and the comparison made.

Our study has several limitations. The literature search was conducted using only MEDLINE. Although it can be expected that most of the medical literature is covered in this database, other databases might have resulted in additional studies. Moreover, we used subject headings to find studies concerning diagnostic facilities instead of using key words in the title or abstract, possibly resulting in missing studies. Furthermore, the limits used to decrease the number of studies found (published in English, human subjects, comparative study, and abstract indicated), might have led to selection. However, there is no reason to assume that our sample of studies differs systematically from the total pool of studies regarding economic evaluation of diagnostic tests.

Although some of the guidelines on economic evaluation are more recent than the studies considered in this review, earlier textbooks give sufficient instructions on how to perform and report economic evaluations (17). In addition, earlier reviews recommended clear reporting of methodological aspects (20;43). Over the past three decades the methodology of performing economic evaluations has developed, and recently specific major methodological challenges for the economic evaluation of diagnostic technologies have been identified again (39). Despite this ongoing methodological discussion in performing economic evaluations, standardization of reporting economic evaluations is particularly important because it allows comparison of the costs and health outcomes of alternative methods of improving health (22;35). Apparently, as is the case with health care guidelines, the mere publication of these methodological guidelines is not sufficient to bring about the desired changes. Therefore, we recommend that editorial boards issue and enforce guidelines for standard reporting, including abstracts, of economic evaluations.

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APPENDIX

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