Growth and Quality of the Cost–Utility Literature, 1976–2001

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ABSTRACT

Purpose: Cost-utility analyses (CUAs) have become increasingly popular, although questions persist about their comparability and credibility. Our objectives were to: 1) describe the growth and characteristics of CUAs published in the peer-reviewed literature through 2001; 2) investigate whether CUA quality has improved over time; 3) examine whether quality varies by the experience of journals in publishing CUAs, or the source of external funding for study investigators; and 4) examine changes in practices in US-based studies following recommendations of the US Panel on Cost-Effectiveness in Health and Medicine (USPCEHM). This study updates and expands our previous work, which examined CUAs through 1997.

Methods: We conducted a systematic search of the English-language medical literature for original CUAs published from 1976 through 2001, using Medline and other databases. Each study was audited independently by two trained readers, who recorded the methodological and reporting practices used.

Results: Our review identified 533 original CUAs. Comparing articles published in 1998 to 2001 (n = 305) with those published in 1976 to 1997 (n = 228), studies improved in almost all categories, including: clearly presenting the study perspective (73% vs. 52%, $P < 0.001$); discounting both costs and quality-adjusted life-years (82% vs. 73%, $P = 0.0115$); and reporting incremental cost-utility ratios (69% vs. 46%, $P < 0.001$). The proportion of studies disclosing funding sources did not change (65% vs. 65%, $P = 0.939$). Adherence to recommended practices was greater in more experienced journals, and roughly equal in industry versus non-industry-funded analyses. The data suggest an impact in methodological practices used in US-based CUAs in accordance with recommendations of the USPCEHM.

Conclusions: Adherence to methodological and reporting practices in published CUAs is improving, although many studies still omit basic elements. Medical journals, particularly those with little experience publishing cost-effectiveness analyses, should adopt and enforce standard protocols for conducting and reporting CUAs.

Keywords: cost-effectiveness analysis, cost–utility analysis.

Despite the rapid growth in the number of cost-utility analyses (CUAs) published in the medical literature, studies have shown that many analyses do not adhere to recommended practices for conducting or reporting them [1–3]. In this article we characterize this literature and investigate whether the methodological and reporting practices used in published CUAs have improved over time. Specifically, our objectives were to: 1) describe the growth and characteristics of CUAs published in the peer-reviewed literature through 2001; 2) investigate whether quality of CUAs has improved over time; 3) examine whether quality varies by the experience of journals publishing CUAs, or the source of external funding; and 4) examine changes in practices in US-based studies following recommendations of the US Panel on Cost-Effectiveness in Health and Medicine (USPCEHM).

This study updates a previous analysis, which examined the quality of CUAs from 1976 to 1997 [3,4]. This update more than doubles the previous sample size, and also permits an analysis of the impact of the Panel on Cost-Effectiveness in Health and Medicine, which published its widely cited recommendations in 1996 [5,6].

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Data and Methods

The Harvard School of Public Health (HSPH) Cost-Effectiveness Registry

Researchers at the Center for Risk Analysis at the HSPH have developed a comprehensive registry of cost–utility analyses, which contains detailed information on CUAs published in the health and medical literature from 1976 through 2001. Briefly, we conducted a systematic search for original English-language CUAs using Medline, CancerLit, and NLM Gateway through 2001. We validated our final sample against CUAs listed in the Health Economics Evaluation Database [7], which identified a number of additional studies. The databases were searched for medical subject headings or text keywords "quality-adjusted," "quality-adjusted life-year or QALY," and "cost-utility analysis." We excluded review, editorial, or methodological articles, as well as cost-effectiveness analyses that measured health effects in units other than QALYs, and articles in languages other than English. A final set of 533 articles was judged ultimately to contain original CUAs and became part of the registry. More detail on the search strategy as well as the general development and contents of the registry is provided elsewhere [3,4] and on our Web site, http://www.hsph.harvard.edu/cearegistry.

Each article was scrutinized with the aid of a standard data auditing form to determine its clarity, completeness, and quality. Two readers, all with masters or doctoral degree training in decision analysis and cost-effectiveness analysis, independently read and audited each article and then convened for a consensus audit to resolve discrepancies. Data were collected on a wide variety of elements related to the study sponsorship, intervention and comparators under investigation, and the methods used to estimate and report costs, health effects preference weights, modeling assumptions, and data limitations. We also included a subjective assessment of overall study quality on a Likert-type scale from 1 (low) to 7 (high). The score reflects readers' best judgment about the overall study quality, taking into account the methodological rigor, the clarity of the presentation, and the potential value of the study to decision makers.

Kappa statistics (K) were calculated to measure the interrater reliability for each item before consensus. The overall mean K was 0.67 (95% confidence interval, 0.62–0.72), a rate considered to represent a "good strength of agreement." [8]

Analysis of Data

To describe the growth and characteristics of the published literature, we examined the number of CUAs published each year by source of funding (industry, nonindustry, not reported). We also describe CUAs by country of study, author affiliation, disease category, and prevention level. Quality was measured in two ways: by examining the subjective quality score for each article, and by measuring an article's adherence to specific methodological and reporting practices. Methodological and reporting practices were based on published recommendations [5,6,9]. We examined eight data categories: disclosing funding sources; clearly presenting the study perspective; calculating and reporting incremental ratios; discounting both costs and QALYs; clearly stating the year for cost estimates; performing sensitivity analyses; conducting probabilistic sensitivity analyses; and discussing model validation. The proportion of published CUAs that adhered to each of these recommended practices and the mean quality ratings during 1998 to 2001 were compared with the proportion during 1976 to 1997 (the period covered in our previous data collection effort).

We also compared practices in journals publishing a high-volume ($n > 3$) versus low-volume ($n \leq 3$) of CUAs during the study period. Our volume cutoff of three articles is somewhat arbitrary, although it provides a convenient threshold, dividing the sample roughly in half.

Finally, we compared practices in studies funded by the pharmaceutical and medical device industry with those funded by governments, foundations, or other nonindustry sources.

To explore the impact of the Panel on Cost-Effectiveness in Health and Medicine on US-based studies, we examined three key Panel recommendations: assuming a societal perspective; using a 3% discount rate to adjust future costs and health benefits; and using community-based preference weights as the source of preferences for QALYs. For this analysis, we compared two 3-year time periods, 1993–1995 versus 1998–2000, which correspond to years before and after the Panel recommendations were published in 1996 [10]. We excluded 1996 and 1997, because it is unclear whether authors of studies published in those years would have known about the Panel recommendations when they submitted their articles to journals. We focus on the impact for US-based studies (those conducted primarily by investigators based in the United States with US policy makers in mind), because non-US investigators may have followed guidelines issued in other countries.

Comparisons were made using chi-square and Student's *t* tests. All analyses were performed using Microsoft Excel software. A *P*-value of less than 0.05 was considered significant for all tests.

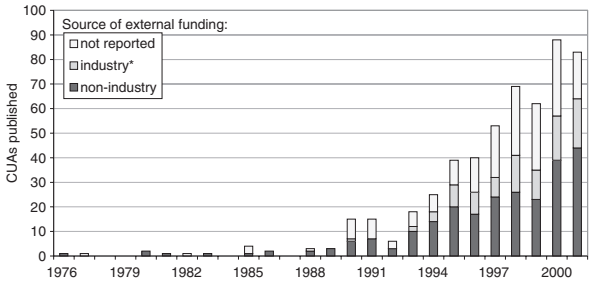
Results

Our review identified 533 original CUAs. The number of published CUAs has increased steadily over time, with somewhat more studies sponsored by the pharmaceutical and device industry in recent years (22% in 1998–2001 vs. 14% in 1976–1997, $P = 0.034$) (Fig. 1).

Most CUAs have pertained to the United States (61%), followed by Canada (8%) and the U.K. (8%) (Table 1). Study investigators have been predominantly university-affiliated (90%). As shown in Table 1, analyses have covered a wide range of disease areas, most frequently covering cardiovascular disease (21%), infectious disease (21%), and cancer (15%). Most CUAs have covered tertiary care (63%), followed by interventions for secondary (22%) and primary prevention (14%).

Numerous journals have published CUAs, most frequently *Annals of Internal Medicine* (n = 29), *Pharmacoeconomics* (n = 28), and the *Journal of the American Medical Association* (n = 26). Some journal's proclivity for publishing CUAs has shifted over time (Table 2). For example, the *New England Journal of Medicine*, which published nine CUAs from 1976 to 1997, published only one in the 1998 to 2001 period; in contrast, the *American Journal of Medicine* published one in the former period and nine in the latter.

Comparing the 1998 to 2001 period (n = 305) with the 1976–1997 period (n = 228), articles improved in: clearly presenting the study perspective (73% vs. 52%, $P < 0.001$); reporting incremental cost-utility ratios (69% vs. 46%, $P < 0.001$); discounting both costs and QALYs (82% vs. 73%, $P = 0.011$); stating the year of currency for cost estimates (82% vs. 68%, $P < 0.001$), performing sensitivity analyses (93% vs. 89%, $P = 0.069$); and conducting probabilistic sensitivity analyses (14%



Source: CUA Registry, Harvard School of Public Health, www.hsph.harvard.edu/cearegistry.

Figure 1 Growth in published cost–utility analyses, 1976–2001. *Industry category includes pharmaceutical and medical device company funded studies.

Table 1 Characteristics of published cost–utility analyses, 1976–2001 (n = 533)

	#	%
By country		
US	323	61%
Canada	43	8%
UK	41	8%
The Netherlands	26	5%
Sweden	21	4%
Australia	18	3%
Other	61	11%
By author affiliation*		
Academic	482	90%
Health-care organization	92	17%
Government	87	16%
Consultant/contract	41	8%
Pharmaceutical industry	36	7%
By disease category		
Cardiovascular	114	21%
Infectious diseases	105	20%
Cancer	81	15%
Endocrine	46	9%
Neuropsychiatric	46	9%
Other	141	27%
By prevention level		
Primary	75	14%
Secondary	115	22%
Tertiary	336	63%

*Category is not mutually exclusive.
Source: CUA Registry, Harvard School of Public Health, http://www.hsph.harvard.edu/cearegistry.

Table 2 Journals ranked by number of published cost–utility analyses

	1976–1997		1998–2001		1976–2001	
Journal	#	rank	#	rank	#	rank
Ann Intern Medicine	11	2	18	2	29	1
Pharmacoeconomics	9	4	19	1	28	2
JAMA	16	1	10	3	26	3
Int J Tech Assess Health Care	9	4	9	4	18	4
Medical Decis Mak	10	3	3	11	13	5
J Clin Oncol	5	8	6	6	11	6
Am J Medicine	1	15	9	4	10	7
Circulation	6	7	4	10	10	7
N Engl J Medicine	9	4	1	17	10	7
J Vasc Surg	3	14	6	6	9	10
AIDS	1	15	6	6	7	11
J General Int Medicine	4	9	3	11	7	11
Radiology	1	15	6	6	7	11
Stroke	4	9	3	11	7	11
Am J Public Health	4	9	2	14	6	16
BMJ	4	9	2	14	6	16
Health Policy	4	9	2	14	6	16

Source: CUA Registry, Harvard School of Public Health, http://www.hsph.harvard.edu/cearegistry.

Table 3 Comparisons of methodological and reporting practices in published cost–utility analyses (CUAs)

	1976–1997 (n = 228)	1998–2001 (n = 305)	Low-volume journals (≤3 CUAs published) N = 233	High-volume journals (>3 CUAs published) N = 300	Industry-sponsored (n = 95)	Non-industry sponsored (n = 438, including nonreported)
Disclosed funding sources	65%	65%	57%†	70%†	–	–
Clearly presented study perspective	52%‡	73%‡	56%‡	70%‡	68%	63%
Calculated and reported incremental ratios	46%‡	69%‡	53%†	63%†	61%	58%
Discounted both costs and QALYs	73%†	82%†	73%†	82%†	82%	78%
Stated year of currency for cost estimates	68%‡	82%‡	70%†	81%†	72%	77%
Sensitivity analyses performed	89%*	93%*	86%‡	95%‡	91%	91%
Probabilistic sensitivity analyses	2%‡	14%‡	6%*	11%*	7%	9%
Discussed model validation/verification	13%	14%	10%†	16%†	11%	14%
Quality score on a scale from 1 (low) to 7 (high): mean (SD)	4.10 (1.33)	4.25 (1.28)	3.74 (1.26)‡	4.53 (1.23)‡	4.33 (1.16)	4.15 (1.33)

*P-value < 0.1; †P-value < 0.05; ‡P-value < 0.001.

vs. 2%, $P < 0.001$) (Table 3). The proportion of studies disclosing funding sources did not change (65% vs. 65%, $P = 0.939$).

Studies published in "high-volume" journals had greater adherence to methodological practices than did studies published in "low-volume" journals in all categories. In contrast, adherence to protocols did not vary by the external funding source (Table 3).

Finally, after publications of the recommendations of the Panel on Cost-Effectiveness in Health and Medicine, most US-based studies used a 3% rather than 5% discount rate (72% in the post-Panel period vs. 2% before the Panel, $P < 0.001$) (Table 4). There was also an increase in the use of community preferences ($P = 0.06$) and societal perspective ($P = 0.04$). There was also a trend toward a 3% discount rate in non-US studies (9% before the Panel and 24% after, $P = 0.048$), although no increase in the use of community preferences or societal perspective.

Table 4 Change in practices in US-based cost–utility analyses (CUAs) following the report of the US Panel on Cost Effectiveness in Health and Medicine*

	Before panel (1993–1995, n = 48)	After panel (1998–2000, n = 137)	*P*
Community preferences	13%	26%	0.06
Discount rate 3%	2%	72%	<0.001
Discount rate 5%	67%	9%	<0.001
Societal perspective†	17%	32%	0.04

*The table includes only US-based CUAs published during the years in question (n = 185). The US Panel on Cost-Effectiveness in Health and Medicine published its report in late 1996.
†Based on readers' assessment.

Discussion

Our review and critique of the cost–utility literature through 2001 reveals a dynamic and growing field. CUAs have been published in a wide array of journals and covered a diverse set of topics.

Our data demonstrate that CUAs are published not only in specialty methods journals such as *Medical Decision Making and International Journal of Technology Assessment in Health Care*, but also in mainstream medical journals such as *Annals of Internal Medicine* and the *Journal of the American Medical Association* (the cross-journal comparisons are somewhat unfair because some journals were unavailable in 1976, e.g., *Pharmacoeconomics* was launched in 1992, but the general point still holds). The trend data also suggest an influence of changes in editorial policies—in particular, the *New England Journal of Medicin*e adopted a policy imposing restrictions for publishing CUAs in its pages in the mid-1990s [11], and has published few CUAs in recent years.

Although numerous studies in the past have raised concerns about the quality of cost-effectiveness analyses [1,2,12–23], our data provide some encouraging new evidence that the methodological rigor of published CUAs is improving. Adherence to key recommended protocols (e.g., clearly stating the study perspective, discounting future costs and health benefits, reporting incremental cost–utility ratios) has increased considerable.

The data also suggest an impact of the Panel on Cost-Effectiveness in Health and Medicine, a trend suggested by smaller studies of the topic [24]. Although the data could reflect natural trends or other factors (e.g., recommendations of other con-

sensus groups) and not have been caused by the Panel, the magnitudes of changes seen, particularly in the use of the 3% discount rate make this seem unlikely.

To be sure, some concern about the credibility and comparability of studies lingers. Although overall adherence to protocols for conducting and reporting CUAs has improved, in absolute terms, there have still been a substantial number of poorer-quality studies published in recent years. Even in the 1998 to 2001 periods, over one-third of analyses did not disclose their sources of funding; 31% did not report incremental ratios; and 27% did not clearly report the perspective of the analysis.

As we found in earlier analyses [3], our data suggest that a journal's lack of experience in publishing CUAs is a key factor in explaining poor adherence to recommended practices. In contrast, we found no evidence that pharmaceutical industry funding was associated with poor practices. These findings suggest the need for improvement in the peer review process, where better quality control among journal editors is warranted, especially among journals with little experience publishing CUAs.

One way to improve matters is for journals to follow existing guidelines and checklists for authors, referees, and editors to improve editorial management and the quality of articles [13,25,26]. Independent task forces have called for the full disclosure of all commercial ties and funding support and whether any restrictions were placed on authors, such as control and access to data, publication rights, and sponsors' right to review [25]. Other groups have published guidelines calling for transparency in reporting study methods, as well as protocols for releasing model software and data for peer review, and making technical reports available [6]. Some medical journals have published checklists for reviewers and editors to follow [2,13].

Continued monitoring of the field is also important [27,28]. Research has shown, for example, that editors and reviewers often fail to adhere to their own guidelines [13].

Formal scoring systems for evaluating the quality of health economic analyses may help in terms of discriminating higher quality studies and providing an aid to journal editors, and perhaps decision makers themselves [29]. But more work on their validation and usefulness is required [30,31]. Observers draw parallels to the success of the CONSORT and QUORUM initiatives to improve the methods and reporting of randomized trials and systematic reviews [32,33]. Rennie and Luft [33] point out that efforts to provide a formal systematic structure in order to reduce selection bias and make studies more transparent revolutionized the reporting of reviews.

Beyond that, editors could insist that authors provide all material on the journal's Web site themselves, as some observers have advocated, so that all assumptions and data can be reviewed, "like the discovery process in lawsuits, whereby each side has access to the underlying data that may be presented." [33,34]Concerns about confidentiality and intellectual property raise challenges, but it is an area worthy of exploration.

There are a number of limitations to note about our analysis. An important one is that our investigation is restricted to CUAs, which comprise only a subset of all economic evaluations—about 8% according to the Health Economics Evaluation Database [7].

A second limitation is that our search strategy was limited to select key words and databases and may have omitted some studies, although a recent study has confirmed that Medline is a superior source for reviews of economic evaluations [35].

Third, other groups of study auditors might score reporting practices differently, although we note that our interrater reliability scores between readers were high. It should be noted that our readers were not blinded to articles' journals and authors, which may have influenced results. We acknowledge the lack of blinding as a potential source of bias, particularly in our subjective assessment scores. We found that blinding presented a formidable challenge: even if journal names and authors had been concealed, our investigators could often identify them, either by the journal's distinctive style, by references in an article to CUA authors' past work, or through readers' previous familiarity with the article itself. In future work, it will be important to consider more carefully ways to blind readers.

Fourth, our comparisons of methodological and reporting practices imply that each item has equal weight in judging quality, when in fact some are likely more important than others; in addition, not all items are necessarily good measures of quality. For example, there continues to be debate about how to best analyze and characterize uncertainty in cost-effectiveness analyses, as well in other matters such as whose preferences should be measured in estimating QALYs [36–38]. In the future, it may be useful to consider ways to provide differential weightings according to the importance of items to an article's overall quality.

Finally and perhaps most importantly, we did not judge the merits of clinical or modeling assumptions

made in analyses, only whether protocols for conducting and reporting them were followed. Ultimately, the quality of an analysis is largely a reflection of whether assumptions are reasonable, not simply whether authors adhered to procedural guidelines for reporting.

Determining the overall reasonableness of assumptions or the usefulness of CUAs for decision makers was beyond the scope of our analysis—and ultimately may require an effort that goes beyond traditional peer review. Even with access to all of the data and models, it required Australian authorities 2 weeks to thoroughly review cost-effectiveness analyses submitted to them by drug companies for reimbursement consideration, for example [39], much more time than any reasonable peer reviewer would spend. In the future, public or private institutions may emerge to vet economic evaluations for decision makers.

In conclusion, we found that both the methodologic and reporting practices in published CUAs have improved over time. It appears that the Panel on Cost-Effectiveness in Health and Medicine had an impact on practices, particularly in the United States. Reassuringly, industry sponsorship does not appear to be associated with poorer methods or reporting. It does appear, however, that journals with little experience publishing CUAs have poorer adherence to good methodologic practices and would benefit from increased editorial scrutiny and adoption of standard protocols for conducting and reporting CUAs.

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