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A TOOL TO IMPROVE QUALITY OF REPORTING PUBLISHED ECONOMIC ANALYSES

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Abstract

Objectives: To test the feasibility of obtaining a baseline level of quality of reporting for cost-utility analysis (CUA) studies using the *British Medical Journal* economic submissions checklist, test interrater reliability of this tool, and discuss its longer term implications.
Methods: CUA studies in peer-reviewed English language journals in 1996, assessed using the *British Medical Journal* checklist, a quality index, and interrater reliability correlations.
Results: Forty-three CUA studies were assessed, with 23 checklist items acceptable and 10 items inadequate. Lowest quality scores were reported in specialist medical journals. Proportional agreement between assessors was over 80%.
Conclusions: The *British Medical Journal* checklist is a feasible tool to collect baseline information on the quality of reporting in journals other than the *British Medical Journal*. Editors of specialist medical journals are in greatest need of economic guidance. If handled carefully, they might consider adopting the *British Medical Journal* checklist.

Keywords: Cost-utility analysis, Economic evaluation, guidelines, Reporting standards, Research in practice

There is heightened awareness in healthcare systems around the world that governments and other agencies called upon to fund health care need to find ways of using scarce healthcare resources more efficiently. Part of the solution lies in selecting knowledge-based evidence to identify systematically effective interventions and to

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understand their likely resource consequences. As such it is increasingly likely that economic evaluation will be seen as a useful conceptual framework and viable management tool to support this effort.

Over the past two decades the use of economic principles and evidence to support health policy has grown substantially (16;24). Indeed, in some countries it has become a more integrated part of policy making (4;6), and more emphasis is now placed on the need for evidence-based health policy (5). Hutton (12) has pointed out that growth in use of economic evaluation technology need not be synonymous with its maturity. He suggests questions may need to be addressed concerning how current application can be further developed to a point where it is used routinely by healthcare decision makers. Reporting of economic evaluations is a surrogate indicator of the impact and value such analyses can have (25), and therefore guidelines concerning the review and presentation of published studies is a component in advancing this technology. Hutton concluded "economists should continue to be concerned about the quality of the economic studies to which clinicians and managers are exposed, and their ability to distinguish the reliable results from the questionable and useless" (12).

Medical journals have been a major publication outlet for the dissemination of the growing economic evaluation literature. However, in parallel with this expansion, concern has continued over its quality (9). There is a substantial body of evidence that recognizes there are variations in a number of aspects of quality, indicating that while some studies are considered to be of good quality, there are others that fall far too short (1;2;8;9;17;20;21;26;27). Areas for improvement suggested by these reviews cover both issues of methodological content and reporting and pervade the spectrum of types of economic evaluation (i.e., cost-benefit, cost-utility, cost-consequence, cost-effectiveness, and cost-minimization analyses).

The health economics community, governments, and other agencies have responded to these quality issues with the development and growth in economic evaluation guidelines and checklists. Guidance for particular uses has emerged; for example, industry submission to health policy-making processes (4;11) is different from academic requirements for economic evaluation databases (19;22). However, incorporation of guidelines within the peer-review process of the medical literature as a means of improving quality has lagged behind. Recent evidence has shown no medical journal editors have criteria or guidelines in place for peer reviews of economic studies (13).

An assessment of economic submissions made to the *British Medical Journal* (*BMJ*) during 1994 further highlighted the need for specific guidelines (14) and resulted in the journal seeking to raise its own standards by publishing guidelines for editors, reviewers, and authors (7). Shortly after this initiative was implemented, an evaluation demonstrated no improvement in the quality of submitted or published manuscripts, but the guidance helped to streamline the review process (15). However, given the early stage of this evaluation, it would seem overly pessimistic to rule out longer term change for the better. We believe the *BMJ* initiative is to be commended. Furthermore, we believe there could be wider benefits of using a set of consistent guidelines. Thus, systematic promotion of a form of the *BMJ* guidelines could benefit editors, authors, reviewers, and readers of other medical journals, the Cochrane Collaboration initiatives, healthcare policy makers and decision makers, and the wider health economics community.

Our pilot investigation had three objectives. These were: a) to measure a baseline level of quality for cost-utility studies using a reproducible tool; b) to test interrater reliability of this tool; and c) to discuss the longer term feasibility of

using the tool to improve the clarity and quality of reporting of economic evaluation studies in the peer-review process.

METHODS

The study was designed to assess one type of economic evaluation, cost-utility analysis (CUA). This type was selected because it has grown in popularity as it provides a focus on measuring quality of life as well as quantity of life. Limiting the unit of analysis to one type of economic evaluation also has the advantage that it homogenizes application of the checklist. As the size of CUA literature published in any single year to date remains relatively small, the population of CUAs was identified for this investigation.

Searches

A CUA was defined as reporting primary data in the form of a "cost per healthy-year ratio," e.g., cost per quality-adjusted life-year (QALY), written in the English language, and published in a peer-reviewed journal in 1996. Potential studies were identified by two specialist economic evaluation databases: the NHS Economic Evaluation Database (19) and the Office of Health Economics Health Economic Evaluation Database (22), as well as on-line searches of EconLit, EMBASE, MEDLINE, PsychLit, and Social Sciences Index. The keywords used were *cost-benefit analysis; cost* and *utility; cost per QALY; cost-utility analysis; cost-effectiveness analysis;* and *economic evaluation*. Building on the specialism of the two economic evaluation databases rendered blinding for authors' names in the selection of CUA studies unnecessary. The team culled potential studies by reading each abstract and discussing ambiguous cases.

The *BMJ* Checklist

Some minimal adjustment of the referee's and author's checklist was necessary because of the specific focus on CUA. This resulted in the original checklist being reduced and refined from 35 to 33 items, but the adjustment did not influence results. The mapping of *BMJ* checklist items to the amended version used is shown in Table 1.

To assess the competence of reporting for each item, three response categories were used and values assigned: "not carried out" = 0; "partially carried out" = 1; and "fully carried out" = 2. A response of "not applicable" was recorded if a particular item was not relevant to the study being assessed (e.g., if an analysis was conducted over a 12-month or shorter time frame, discounting was not required).

These numeric responses could represent ordinal data making it possible to calculate a quality index to summarize each CUA. The developers of the *BMJ* checklist do not suggest a scoring system. However, rolling information into a single index was appealing in this context because it provided the opportunity to conduct analyses by single classification. The index calculated was the sum of responses for 28 of the 33 amended items, giving equal weight to each item. The excluded items were 14, 19, 25, 26, and 35b in Table 1. In this particular population, these emerged as being of little relevance. What may be useful in the future would be to find out whether there was a core set of items on which health economics experts could agree. If so, a sensitive weighting of items would be possible. The index constructed ranged from a minimum of 0 to a maximum of 56 points. Although interpretation of scores is subjective, the index depicts a meaningful ordered continuum of quality based on the assumptions described.

Table 1. Mapping of *BMJ* Checklist Items to Study items

BMJ items	Study items (No difference between items is denoted by "same")
Study design	
1. The research question is stated.	1. Same
2. The economic importance of the research question is stated.	2. Same
3. The viewpoint(s) of the analysis are clearly stated and justified.	3a. The viewpoint for the analysis is clearly stated. 3b. The viewpoint for the analysis is clearly justified.
4. The rationale for choosing the alternative programs or interventions compared is stated.	4. Same
5. The alternatives being compared are clearly described.	5. The alternative interventions are described in sufficient detail to assess the relevance of other settings.
6. The form of economic evaluation used is stated.	6. Not applicable
7. The choice of form of economic evaluation is justified in relation to the questions addressed.	7. A justification is given for why cost utility analysis is chosen in relation to the question being addressed.
Data collection	
8. The source(s) of effectiveness estimates used are stated.	8. Details of effectiveness data are provided.
9. Details of the design and results of effectiveness study are given (if based on a single study).	
10. Details of the methods of synthesis or meta-analysis of estimates are given (if based on an overview of studies).	
11. The primary outcome measure for the economic evaluation is clearly stated.	11. Same
12. Methods to value health states and other benefits are stated.	12. Same
13. Details of the subjects from whom valuations were obtained are given.	13. Same
14. Productivity changes (if included are reported separately).	14. If changes in productivity (indirect benefits) are included, they are reported separately and their relevance to the study question is discussed.
15. The relevance of productivity changes to the study question are discussed.	
16. Quantities of resources are reported separately from their unit costs.	16. Same

(*Continued*)

Table 1. (*Continued*)

BMJ items	Study items (No difference between items is denoted by "same")
17. Methods for the estimation of quantities and unit costs are described.	17a. Methods for the estimation of quantities are given. 17b. Methods for the estimation of quantities for unit costs are given.
18. Currency and price data are recorded.	18a. The currency is recorded. 18b. The price data is recorded.
19. Details of currency of price adjustments for inflation or currency conversion are given.	19. Same
20. Details of any model used are given.	20. Same
21. The choice of model used and the key parameters on which it is based are justified.	21. Same
Analysis and interpretation of results	
22. Time horizon of costs and benefits is stated.	22. Same
23. The discount rate(s) is stated.	23. Same
24. The choice of rate(s) is justified.	24. Same
25. An explanation is given if costs or benefits are not discounted.	25. Same
26. Details of statistical tests and confidence intervals are given for stochastic data.	26. Same
27. The approach to sensitivity analysis is given.	27. Same
28. The choice of variables for sensitivity analysis is justified.	28. Same
29. The range over which the variables are varied are stated.	29. Same
30. Relevant alternatives are compared.	30. An incremental analysis is reported, comparing the relevant alternatives.
31. Incremental analysis is reported.	
32. Major outcomes are presented in a dissaggregated as well as aggregated form.	32. Same
33. The answer to the study question is given.	33. The answer to the original study question is given; any conclusions follow clearly from the data reported.
34. Conclusions follow from the data reported.	
35. Conclusions are accompanied by the appropriate caveats.	35a. Limitations of the study discussed. 35b. Comparisons with other healthcare interventions are made when methods and settings are similar.

Journal Type

Journals were categorized under "specialist medical" (focusing on a main disease or specialty area); "general medical" (covering all aspects of medicine, surgery, and health care); and "nonmedical" (a variety of health economics, health policy, and health service management journals).

Assessors and Application of the Guidelines

Assessors were health economists from the Centre for Health Economics Research and Evaluation (CHERE) at the University of Sydney. Experience levels varied in health economics generally and in economic evaluation in particular. The most experienced had 15 years of experience in both; the least experienced, 1 year. Studies were independently assessed by a minimum of two of these assessors.

Data Sets, Analysis, and Criteria to Judge Quality and Reliability

Descriptive statistics report quality of individual items and the quality index. As no single assessor reviewed all studies, the population was assessed by compiling the 25 assessments made by the senior assessor with a random selection of 18 studies, with nine each assessed by the other two assessors. Interrater reliability was tested constructing two sets of assessments (one comprising 20 CUAs, the other 18 CUAs) involving the most experienced assessor paired with the others. Proportional agreement between raters measured reliability.

Quality of reporting on individual items was judged by examining the proportion of relevant studies reporting particular responses. Good quality was judged if a cut-off of more than 50% of relevant CUAs reported a response "fully carried out." Items were judged poor quality if at least 50% of relevant studies reported a response of either "not carried out" or "partially carried out."

Quality of individual CUAs was assessed by the quality index. Although arbitrary, it seemed inherently reasonable that a CUA was considered "high quality" if it scored at least 40 of a maximum 56 points (i.e., $\geqslant 70\%$ of the maximum score). Conversely, a score below 30 (or less than approximately 50% of maximum points) indicated "poor quality" and therefore scope for considerable improvement. Mid-range scores (i.e., 30–39 points) also indicated potential for improvement.

RESULTS

Forty-three peer-reviewed, published CUAs were identified (see reference 9 for references of studies included). These were published largely in the medical literature using 26 different specialist medical journals, three general medical journals and five nonmedical journals.

Table 2 reports that there were 10 checklist items (30.3%) judged poorly reported. Twenty-three items, not reported in the table, were rated acceptable quality, since more than 50% of studies had fully carried reporting of each item.

In view of space constraints imposed on authors, it is important to distinguish which, if any, items might be considered relatively more important in reflecting the essential elements of CUA. It was our view that eight items in Table 2 were essential, and thus their poor reporting standard was of concern. In particular, 34 studies (81%) did not adequately justify the viewpoint of their analyses; 22 studies (51%) had either not carried out, or only partially carried out, reporting of how QALYs were obtained; 23 studies (54%) inadequately reported the source of QALY valuations; 25 studies (58%) failed to report adequately methods for estimating resource

Table 2. *BMJ* Items Indicating Poor Quality of Reporting for CUAs

BMJ item (Item number corresponds to study item)	Not carried out, % studies	Partially carried out, % studies	No. of studies[a]
3b. The viewpoint of the analysis is justified.	74%	7%	42
16. Quantities of resources are reported separately from unit costs.	81%	5%	43
24. The choice of discount rate is justified.	79%	6%	34
25. An explanation is given if costs and benefits are not discounted.	88%	13%	8
35b. Comparisons with other healthcare interventions are made when study methods and settings are similar.	74%	15%	27
12. If health benefits (QALYs) have been valued, details are given of methods used.	21%	30%	43
13. Details of the subjects from whom valuations were obtained are given.	35%	19%	43
17a. Methods for estimatioin of resource quantities are given.	44%	14%	43
28. The choice of variables for sensitivity analysis is justified.	21%	51%	39
29. The range over which the variables are varied are stated.	34%	40%	38

[a] N = 43 − (missing values + studies where items are not applicable).

Table 3. Quality Scores for CUAs Overall and by Journal Type

Quality score	Journals: Specialist medical	Journals: General medical	Journals: Nonmedical	Total (%)
50–56	0	0	0	0 (0.0)
45–49	3	2	4	9 (20.9)
40–44	7	1	1	9 (20.9)
35–39	9	1	1	11 (25.6)
30–34	5	2	2	9 (20.9)
24–28	3	0	0	3 (6.9)
<24	2	0	0	2 (4.6)
Total, %	29 (67.4)	6 (13.9)	8 (18.6)	43 (99.8)

quantities; 37 studies (86%) failed to report quantities of resources separately from price data; 28 studies (72%) did not justify choice of variables included in sensitivity analyses; and 28 studies (74%) did not justify ranges over which variables were varied. Of the studies that made comparisons with other healthcare interventions, 80% did so without demonstrating a close similarity in study methods and settings.

Table 3 reports the overall quality scores. Interestingly, no studies achieved a maximum score; the highest reached was 49. Eighteen studies (41.8%) were rated high quality, five studies (11.5%) were poor quality, and 20 studies (46.5%) rated in the mid-range. These data indicate 25 studies (58.0%) in need of improved reporting standards.

Although the numbers are small for nonspecialist medical journals, analysis by journal type highlights a *potential* source of poor quality. The majority of studies published in specialist medical journals (29 studies, or 67.4%) were likely to be of poorer quality. Five CUAs (17.2%) scored less than 30, and 14 studies (48.3%) scored between 30 and 39 points. This compared with 0% and 50%, respectively, of CUAs published in general medical journals, and 0% and 37.5% for nonmedical journal studies. Five of 8 studies (62.5%) published in nonmedical journals, 3 of 6 studies (50%) in general medical journals, and 10 of 29 (34.5%) in specialist medical journals were considered good quality.

Table 4 shows the extent of proportional agreement between two sets of assessors. For 23 items in set 1 and 22 items in set 2, there was over 80% agreement between assessor pairs. This suggests a high probability that different pairs of assessors categorized responses on the *BMJ* checklist consistently.

Table 4. Proportional Agreement Scores on *BMJ* Items, With Two Sets of Assessors

Proportional agreement	Set 1 (20 CUAs): No. of *BMJ* items (%)	Set 2 (18 CUAs): No. of *BMJ* items (%)
100%	6 (21.4)	5 (17.9)
91–99%	9 (32.1)	8 (28.6)
81–90%	8 (28.6)	9 (32.1)
< 80%	5 (17.9)	6 (21.4)
Total *BMJ* items	28	28

DISCUSSION

Information generated from CUA studies has great potential to inform health policy. Otherwise, why would there be such concern voiced by prominent health economists about the current state of play of health economic evaluation (3;18;23)? Our results reinforce those of similar investigations that there continues to be important variation in the quality of reporting of CUAs. By implication this raises questions about the quality of some analyses. It would seem some fundamental components of the general economic evaluation methodology are not being reported clearly enough or often not at all, thus severely limiting readers' ability to understand the full relevance of results. Systematic, transparent, and regular assessment of publications and scrutiny of peer-review processes in dominant publication outlets are needed if standards of reporting are to improve. The *BMJ* guidelines offer an opportunity to adhere to a comprehensive minimum set of items, which if promoted widely, could serve to form the basis of consistent measurement over time and across different types of economic evaluation.

We have demonstrated that the *BMJ* guidelines for economic submissions can be adapted for wider use, collecting baseline information on the quality of reporting of CUAs. In addition, when different assessors were used to apply the checklist results, they were found to be reproducible to an acceptable level of reliability. We would expect many factors besides the *BMJ* checklist would contribute to a rise in reporting standards; however, by being in the public domain, this tool's adoption by other journals could be beneficial. This appears to be particularly relevant for the review processes of specialist medical journals.

A recent review of CUA studies has shown an important shift toward specialist peer-reviewed medical journals publishing CUAs over the past decade (9). Although we are unable to draw strong conclusions because of the limited number of journals involved in this study, there appears to be a greater likelihood of poorer standards being reported in specialist medical journals, according to our interpretation of the criteria. This would suggest to us the need for closer examination of editorial policy for economic submissions and review processes in these journals. While some explanation for poor reporting may lie with constraints imposed by editors, a balance between these constraints and sufficient clarity in reporting needs to be struck. When editors of these specialist medical journals were contacted, they informed us that health economists were often used as reviewers but were not supplied with guidance on reporting standards. As a result, the use of health economists as reviewers did not guarantee quality reporting.

Our findings therefore have direct relevance to the potential for the *BMJ* checklist in the future. The checklist could be helpful to the editors of specialist medical journals, who collectively contribute a relatively large number of CUAs to the economic evaluation literature but individually publish few. While these editors may be keen to raise the standards of the economic analyses, it seems unlikely (and inefficient) for them to invest in developing economic guidelines separately. More plausible and practical would be to promote the existing *BMJ* checklist, along with suggestions as to how this might be adapted to suit particular journals.

Given that editors usually use at least two reviewers, it was reassuring that we were able to show reliability between pairs of assessors with a broad range of health economics expertise. At the same time we recognize that it would be desirable to extend this test of reliability beyond the CHERE organization. Of course, this research would further benefit from work testing the validity of the *BMJ* tool to allay concerns that the assessors could be biased in their reporting.

There were some further caveats to note about this study. First, care is needed in interpreting the value judgments used when applying the checklist. It can be argued that the response categories are insufficient to reflect true quality of reporting. It is possible, for example, that a "fully carried out" checklist item can also be a wrongly carried out item if an inappropriate method or procedure was used. However, in this particular study we are confident this problem was minimized. Care was taken to ensure methods or procedures applied to "fully carried out" items were correct or appropriate. But if the checklist is to be used more widely, there may be further guidance needed to address this issue. Raising standards in methodological rigor has been tackled (10), but the jury is still out on the influence of specific guidelines until such time as appropriate evaluation data become available.

Second, the *BMJ* checklist was adapted so it could focus solely on CUAs. However, in doing this we did not detract from the meaning of the original checklist, as it is possible to track back to the original checklist. Third, the quality index was based on ordered data and therefore is to be interpreted only as relative ordinal data. While certain assumptions underlie the construction of this index, they are explicitly stated so that they can be reassessed and reapplied if other value judgments are considered more appropriate.

Finally, the choice of response category was limited. This could lead to less reliability between different assessors without clear instructions of their meaning. Part of the strength of our approach was to provide the two junior assessors with appropriate training to mitigate this effect.

The ultimate aim of the *BMJ* guidelines is to improve the quality of economic evaluation published by the *British Medical Journal* without being unduly restrictive. The data presented in this paper have shown it is feasible to extend the use of the tool to provide an important baseline for charting changes over time with respect to the quality of reporting of cost-utility studies in medical and nonmedical peer-reviewed literature. If it can be shown that reporting quality rises through evaluations such as that planned by the *BMJ* working party, and thus the benefits of the *BMJ* working party's efforts can be spread longer term, potentially to a number of stakeholders, including editors, authors, reviewers, and readers of other journals, as well as the wider health economics and health policy communities. Although the jury is still out on the value of health economic evaluation guidelines, at this stage the *BMJ* checklist ought to be seen as a move in the right direction for promoting evidence-based policy making.

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