Improving the Quality of Published Economic Evaluations of Health Technologies Through Better Reporting of the Effectiveness Evidence

(the Case of Single Trials)

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BACKGROUND The growing concern over the cost-effectiveness of health care resulted in an increasing number of economic evaluations of health technologies. Guidelines for the conduct and reporting of analyses have been developed to improve standards, and some journals have published guidelines for authors and reviewers of economic submissions.[1, 2] Furthermore, there are detailed guidelines on reporting the effectiveness evidence in the medical literature.[3, 4]

The quality of an economic evaluation of a health technology can only be as good as the underlying effectiveness analysis. Thus, when single trials are used to obtain the effectiveness evidence, sufficient details should be reported in order to assess their internal and external validity.

OBJECTIVE To investigate the quality of reporting the effectiveness evidence from single trials within economic evaluations of health technologies, and to identify the minimum data set, to be reported in published cost-effectiveness papers.

METHODS The NHS Economic Evaluation Database (NHS EED) is a database of structured critical abstracts of economic evaluations of health care, published after 1994.[5] It is a powerful research tool because of its consistency in reporting a number of features of published economic evaluations.

We analysed the abstracts of economic evaluations, included on the NHS EED, extracting the following details on the effectiveness evidence from single trials:

- Hypothesis/study question
- Dates to which data relate
- Source of effectiveness data
- Study sample – sample size calculation
- Study design
- Analysis of effectiveness

Descriptive statistics were used in reporting the results.

RESULTS As of July 2001, approximately 2500 abstracts of economic evaluations were available on the database. We identified 1515 abstracts (over 60% of all abstracts), which were based on economic evaluations deriving the effectiveness evidence from a single study only. All these abstracts were further analysed.

See Chart 1 for breakdown of abstracts according to year of publication.

Abstracts According to Year of Publication of Original Paper

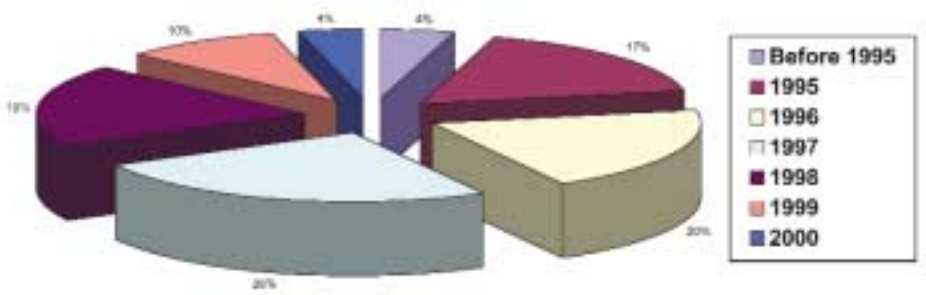
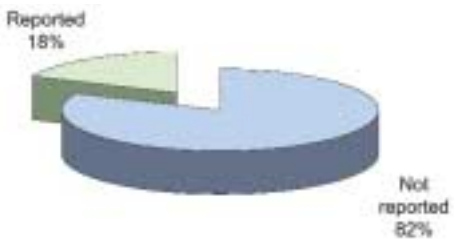


Chart 1.

In 276 (18.2%) of the papers the authors did not report the dates when effectiveness data were collected.

Only 204 (13.5%) studies reported the method of determining the sample size or retrospectively calculated the power of the study. In the remaining of the papers the sample size was not justified and may have been inadequate. (See Chart 2.)

When Were the Effectiveness Data Collected?



How Was Sample Size Determined?

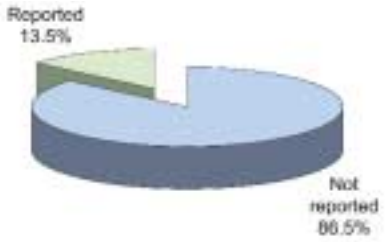


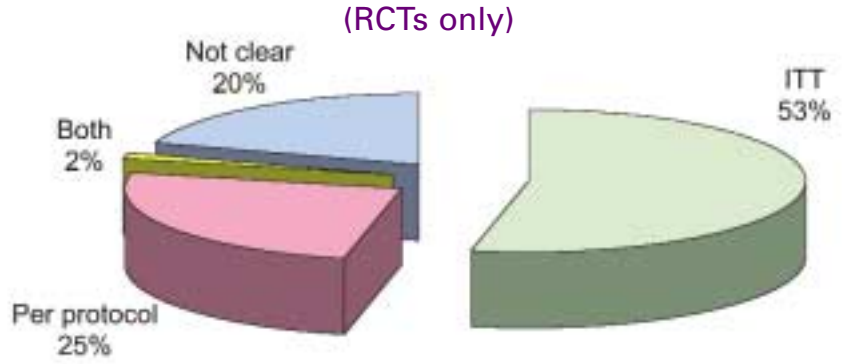
Chart 2.

522 (34.5%) economic evaluations derived the effectiveness evidence from randomised controlled trials (RCTs), the remaining used non-randomised studies (16%), cohort studies (15%), case series (24%), and others.

Within this subgroup the baseline characteristics of the study groups were not reported in 183 (35%) studies. Almost 21% of the studies provided details about the methods of random allocation, and 33.7% used blinding. Intention to treat analysis was adopted in 279 (53.4%) RCTs, while per protocol analysis was used in 131 studies (25.1%). Ten studies compared their results from an intention-to-treat analysis with the results of a per protocol analysis. The type of effectiveness analysis was not reported and it was not possible to identify it in 102 RCTs (20%).

How were the Effectiveness Data Analysed

(RCTs only)



An attempt was made to assess the proportion of studies deriving the effectiveness evidence from previously published trials. At least 8% of studies cited a previously published clinical trial (predominantly an RCT) as the source of underlying effectiveness evidence. This information was not routinely recorded in the abstracts and is, therefore, underestimated.

In cases like these, it is not obvious from the abstracts what exactly was reported by the authors of the economic paper as these abstracts are usually written using both the economic study and the clinical paper. Otherwise it would not be possible to complete the critical commentary and make quality judgements. However, readers may not have easy access to the cited paper and as a result would not be able to assess the overall quality of the economic evaluation.

REPORTING THE EFFECTIVENESS EVIDENCE

Our experience with the NHS EED project shows that economic evaluations report the effectiveness evidence from single studies in three main formats:

A. Cite the reference of a previously published clinical trial without any further details about its design, data collection and analysis;

B. Report briefly the original clinical trial and provide a reference;

C. Report the clinical trial and the cost analysis in a single paper or as two parts of a paper, which allows authors to report both analyses adequately.

The adequate reporting of the trial allows assessment of any limitations which weaken the effectiveness analysis, and thus affect the economic evaluation as a whole.

Submitted papers classified as format A are unacceptable as they only represent one side of the coin ignoring a major part of the economic evaluation. Thus, format A should be replaced with format B. Editors should encourage and allow authors to provide brief description of the clinical trial, including methods (study design, participants, outcomes, sample size, randomizartion, blinding, etc.) and results. In the case of RCTs a flow diagram of subject progress through the phases of the trial can be helpful.[4] Further details to support the peer review process can also be provided. These may not be included in the published version of the paper, but they can be made available for public access via the internet.

The authors should also justify their choice of a previously published clinical study for the source of effectiveness evidence in an economic evaluation, for example:

- Why they did not conduct a systematic review, which is a superior source of effectiveness evidence,

And

- Why this particular study was selected amongst others, available in the literature.

There is a chance that a given study was poorly performed or inappropriate for the economic analysis, while other more suitable (relevant) studies may have been identified, but ignored. Therefore, search results for similar studies in the medical literature should be reported. Otherwise, the reader (and the editor), may not be in the capacity to assess the availability of other relevant trials.

Ideally, economic evaluations should be performed alongside trials, which , amongst others, will give the opportunity to submit a complete paper, reporting both the effectiveness and cost analysis (format C). Again, editors can encourage authors to submit as many details as possible. However, this is not likely to be feasible in mainstream clinical journals, which often have limitations on space. Nevertheless, the availability of some journals on-line opens up better possibilities to provide more details (e.g. on trial design) for those that require it by clicking on a link in the main paper.

Overall, the effectiveness evidence in economic evaluations should be subject (at least) to the same scrutiny, applied by editors and peer reviewers to any other effectiveness study.

CONCLUSIONS Our findings show that basic details are often omitted when reporting effectiveness evidence within an economic evaluation. Routine information, such as dates of the trial and patients' baseline characteristics are often not provided in the paper. Quality assessment of the cost analysis is only meaningful when there is sufficient detail to judge the quality of the underlying effectiveness evidence.

There is room for improvement in the reporting of economic studies and in particular the effectiveness evidence from single trials as a part of the process of ensuring transparency an credibility of cost-effectiveness analyses

A good quality economic evaluation should be carried out lege artis. Reporting of studies, however, is also an art, and failing in it can be just as dangerous.

Acknowledgements:
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References:

1. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. BMJ 1996;313(7052):275-283.
2. Task Force on Principles for Economic Analysis of Health Care Technology. Economic analysis of health care technology. Annals of Internal Medicine 1995;122:61-70.
3. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA 1996;276(8):637-9.
4. Moher D, Schulz KF, Altman D. CONSORT Group (Consolidated Standards of Reporting Trials). The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA 2001;285(15):1987-91.
5. NHS Centre for Reviews and Dissemination. Making cost-effectiveness information accessible: The NHS Economic Evaluation Database. 2nd ed. York: NHS CRD, 2001.

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