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Nixon, J., Stoykova, B., Glanville, J.M. et al. (2000) The UK NHS Economic Evaluation Database: Economic issues in evaluations of health technology. *International Journal of Health Technology Assessment*. pp. 731-742. ISSN: 1471-6348

<https://doi.org/10.1017/S0266462300102016>

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THE U.K. NHS ECONOMIC EVALUATION DATABASE

Economic Issues in Evaluations of Health Technology

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Abstract

Objective: The U.K. NHS Economic Evaluation Database (EED) project is commissioned to identify papers on economic evaluations of health technologies and to disseminate their findings to NHS decision makers by means of structured abstracts that are available through a public database and the Cochrane Library. This paper discusses current issues relating to the economic aspects of producing NHS EED abstracts.

Methods: A review of NHS EED was undertaken between 1994 and 1999 to determine the methodologies adopted and issues that influence the usefulness of economic evaluations. Methods adopted to improve the quality of NHS EED abstracts are also reported.

Results: Eighty-five percent of NHS EED abstracts are cost-effectiveness analyses (CEAs), 9.3% are cost-utility analyses (CUAs), and only 1.4% are cost-benefit analyses (CBAs). Of the total abstracts, 65.9% are based on single studies, 19.5% on reviews, 3.9% on estimates of effectiveness, and 10.7% on combinations of these sources. Models are utilized in 16.7% of CEAs, 60.2% of CUAs, and 20% of CBAs. Analyses of CBA studies reveal a degree of misuse of well-established definitions. NHS EED internal control mechanisms are reported that provide a means of ensuring that abstracts are based on sound academic principles.

Conclusions: Most economic evaluations are conducted by means of CEA, followed by CUA, while CBA accounts for an extreme minority of cases. Single studies form the principal source of effectiveness data, although models are widely used, principally in CUA. The structure of NHS EED abstracts provides decision makers with the principal results and an interpretation of the relative strengths and weaknesses of economic evaluations.

Keywords: Economic evaluation, Health technology, Structured abstract, Database

The U.K. National Health Service (NHS) Economic Evaluation Database (EED) was established in 1995 and is commissioned by the NHS R&D Programme to identify papers

on economic evaluations of health technologies and to disseminate the principal findings to clinicians and decision makers by means of a database of structured abstracts. These are accessible through a public database¹ and now as part of the Cochrane Library (the first edition was the first issue of 2000).

The project encompasses all clinical areas that lend themselves to full economic evaluations in their generic forms of cost-effectiveness, cost-utility, and cost-benefit analyses (CEA, CUA, and CBA, respectively). The database also records bibliographic details of cost studies (including burden of illness studies), methodology studies, and reviews of cost-effectiveness as classified by NHS EED researchers. The rationale to include structured abstracts of full economic evaluations only is that for the purposes of decision making the costs and effects should only be considered with respect to the most appropriate alternatives, thus helping the process of making informed choices.

The increasing awareness of and need for economic evaluations is now well recognized by researchers and health professionals undertaking them (10). However, it is also generally well known that the quality of economic evaluations is a mixed feast, and therefore the value of such studies to decision makers is often questioned. Moreover, researchers adopt a wide range of methodological approaches that may not be familiar to those making decisions concerning competing health technologies.

The type of economic evaluation undertaken may also be a factor in terms of its value to decision makers, depending on the level at which it is being considered—clinician-patient, health authority, or policy maker. For example, at the clinician-patient level cost-consequences studies, a subclassification of CEAs, may be desirable because they leave the health outcomes disaggregated and explicit to the decision maker, with associated costs usually being reported for each. However, in making decisions that affect competing health interventions across a wide range of clinical specializations, a cost-utility (e.g., cost per quality-adjusted life-year [QALY]) approach may be preferable as a common and aggregated benefit measure is utilized, which makes such comparisons possible. In a similar manner, CBAs convert both benefits and costs to monetary units, which can be analyzed independently of other alternatives as either a net cost or a net benefit in their own right.

The decision maker wishing to gather cost-effectiveness evidence in support of competing health technologies, however, is initially faced with a formidable task because the potentially useful material is vast and located within a variety of paper and electronic sources. For example, a MEDLINE search that includes cost-effectiveness-related and relevant clinical keywords may produce hundreds of studies. Further refinement of the search strategy following the reading of retrieved studies may be required to capture all relevant sources required by the researcher. Moreover, the interpretation of such studies may be limited by the reader's knowledge of what constitutes good research in health economics, and the relative strengths and weaknesses of such material may not be immediately obvious to the researcher or decision maker.

In response to these issues, the principal aim of the NHS EED project is to identify as many potential economic evaluations as possible in the literature and filter out the ones that meet well-accepted definitions of what constitutes an economic evaluation (9). Other potentially useful methodology papers, cost studies, and reviews of economic evaluations are stored on the database as bibliographic references for users. After filtering, a structured abstract, recording the principal findings of the study, along with a critical appraisal by health economists working on the project, is produced for those studies that meet the project's inclusion criteria as full economic evaluations.

The aim of this paper is to report the experience of the NHS EED project in achieving its aims and to discuss current economic issues relating to the reporting of economic evaluations and the abstracting process, based on our records to date. The clinical effectiveness issues

most commonly identified in the economic evaluations on the database are the subject of a forthcoming report.

THE 'IDEAL' ECONOMIC EVALUATION

The methods adopted by authors in conducting economic evaluations are many and varied, and reflect the particular study question or hypothesis being examined. As such, there is no one "gold standard," although a number of salient features should be in evidence when conducting economic evaluations. The ideal economic evaluation would:

- Be based on high-quality effectiveness data;
- Conform to stringent economic criteria;
- Be internally valid;
- Be externally valid, i.e., generalizable to other settings/countries.

An ideal economic evaluation would be based on the best available clinical evidence. If these data were to come from a single trial, then a randomized controlled trial (RCT) would probably provide the most reliable data. However, due to ethical considerations, impracticability due to the nature of the interventions being considered, or patient recruitment difficulties, many studies often undertake other forms of trial or reviews of previously completed studies and may incorporate these data into a decision tree and/or Markov model. In the latter case, the review should ideally be from a previously published systematic review, or the authors should undertake their own systematic review of the literature. Additionally, well-recognized techniques for deriving summary statistics (such as meta-analysis for point estimates) should be applied to derive the chosen input parameters.

The economic analysis should conform to well-documented economic criteria, such as Drummond's 35-point checklist (4). Some of these are summarized later in the paper.

The study should also have good internal validity in ensuring that all forms of bias (selection, information, and recall, among others) are addressed and confounding variables are taken into account in the analysis. Cost data should also be derived from reliable sources as dictated by the chosen perspective (i.e., hospital, healthcare system, society, etc.).

The final point here is perhaps the most important consideration of any economic evaluation and concerns the generalizability of the results to other settings or patient domains. The specific issues that influence generalizability are addressed in more detail later in the paper. Before examining these issues in detail, it will be beneficial to outline the method of study identification and study inclusion criteria for NHS EED.

IDENTIFICATION AND INCLUSION CRITERIA

Economic evaluations tend to be published in medical and health policy and planning journals rather than economic journals, so searches are carried out in databases covering those areas. Weekly searches of Current Contents-Clinical Medicine are conducted along with hand searches of a range of journals and gray literature sources. MEDLINE and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) are searched on a monthly basis. Search strategies are continuously being refined to improve the retrieval of relevant studies.

To qualify as a full NHS EED abstract, the study needs to meet the project's inclusion criteria of explicitly examining the costs and benefits (or effectiveness) for a healthcare intervention in comparison with at least one alternative (which is normally standard practice for the setting of the analysis). Papers identified as being cost studies (including burden of

Nixon et al.

illness), methodology papers, or reviews of economic evaluations are also identified by the project's researchers and included in the NHS EED to assist researchers and decision makers in identifying all relevant economic studies related to their area of interest.

These processes are carried out according to guidelines that provide a rigorous framework and academic foundation for the project (9).

NHS EED: SUMMARY OF STATISTICS

The following information provides a summary of key findings from the NHS EED project and is based on all records up to February 2000. As such, it provides a reflection of the types of economic evaluation that are being conducted and reported in the literature. The total records for NHS EED under each category are as follows: 1,718 full abstracts, 1,953 cost studies, 459 reviews, and 649 methodology studies. New records are added each month to the Internet version and every 3 months for the Cochrane Library version.

An analysis of database usage has shown an increase in searches over the past year (1999). In the first 3 months of the year, there was an average of 4,088 searches per month, and this rose to an average of 5,611 searches in the last 3 months of the year. This indicates a growing awareness of the database that may also increase as a result of inclusion in the Cochrane Library. Given that access to the Internet in the NHS is still patchy (J. Droogan, unpublished data, 2000), availability on the Cochrane Library CD-ROM will improve access to those who cannot search the World Wide Web.

Sources of Effectiveness

As indicated earlier, the source of effectiveness data in an economic evaluation can be either a single study, a review of the literature, or an estimate based on the authors' assumptions. Taking this broad overview, 65.9% of papers abstracted were derived from a single effectiveness study, 19.5% were based on a review, and 3.9% were based on estimates of effectiveness. Various permutations of a single study, review, and estimates also exist, the most common being a review plus a model. Grouping all of these together, we have found that 10.7% of abstracts are based on a combination of effectiveness sources. These findings are summarized in Figure 1.

Types of Economic Evaluation

Economic evaluations, as briefly outlined in the introduction, fall under three major categories: CEA, CUA, and CBA. Many studies also utilize effectiveness and cost data within a model (most commonly by means of a decision tree or Markov model). Our records show that the vast majority (85%) of economic evaluations are CEA, 9.3% are CUA, and only 1.4% are CBA (Figure 2). Of the total CEAs, 16.7% employed a model, while 60.2% of CUAs and 20% of CBAs employed a model. The results are consistent with what is done in practice, since CUAs are often based on a literature survey to determine the input parameters

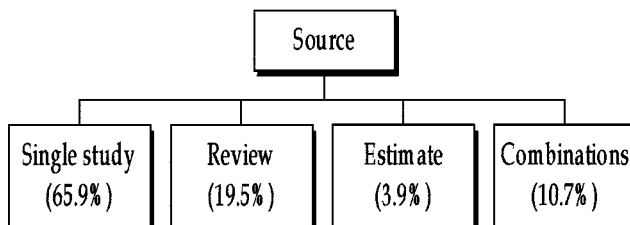


Figure 1. NHS EED: Sources of effectiveness data in economic evaluations.

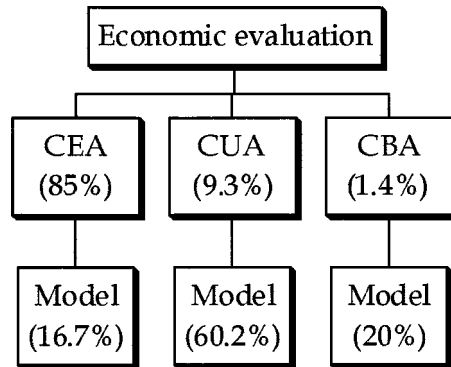


Figure 2. NHS EED: Breakdown of abstracts in the database by type of economic analysis.

for the model being used in the analysis. The model then produces the summary benefit measure as part of its outputs.

Cost-effectiveness Studies. Cost-effective analyses can be divided into three sub-categories. The first involves the use of a single measure of effectiveness in natural units, such as life-years gained or heart attacks avoided, for which a cost can be attributed within a synthesized measure of cost-effectiveness (i.e., \$10,000 per heart attack avoided). NHS EED records show that 55% of CEAs fall under this category.

A second subgroup is the cost-minimization study, which assumes, based on clinical evidence, that the effectiveness of two competing health technologies are equivalent, and as such the analysis is based on cost differences only. Of all CEAs of the NHS EED, 16% are cost-minimization studies.

The third subgroup is the cost-outcomes or cost-consequences CEA, which retains all health outcomes in a disaggregated form. From discussions with users and observations in managing the NHS EED project, this category would appear to be more popular at the clinician-patient level, since clinicians may prefer to know explicitly what the health outcomes associated with an intervention are. On the NHS EED, 29% of all CEAs are cost-consequences studies. These categories are summarized in Figure 3.

CUA. As can be seen from Figure 4, in terms of CUAs the vast majority (76%) of studies employ the quality-adjusted life-year (QALY). As subgroups of QALY, the quality-adjusted

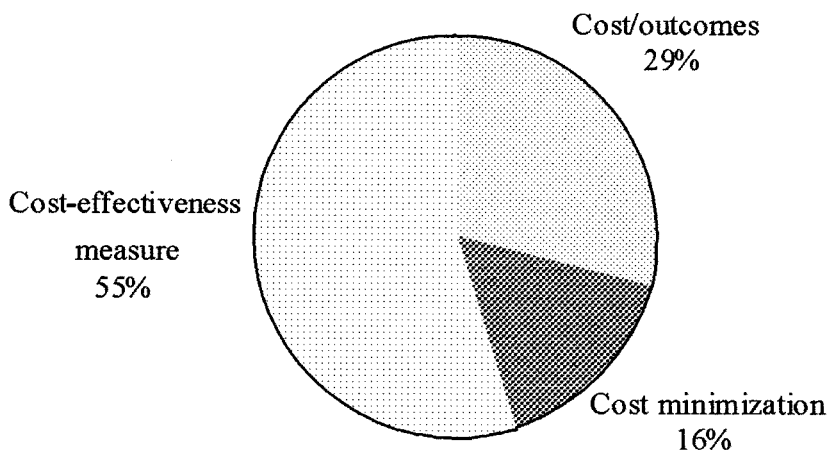


Figure 3. CEA: Use of effectiveness measures.

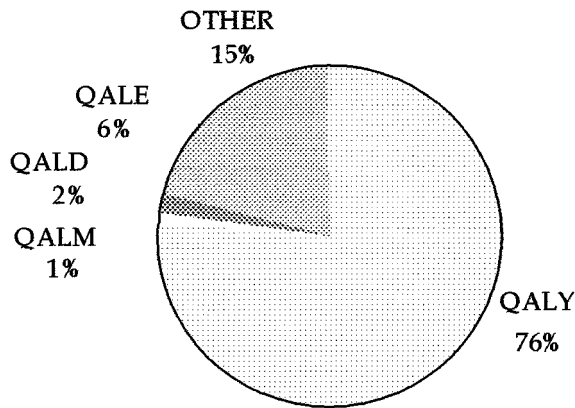


Figure 4. CUA: Measures of benefit (other = authors' estimates).

life-month (QALM) has been used in 1% of studies and the quality-adjusted life-day (QALD) has been used in 2% of studies. An alternative health evaluation system is quality-adjusted life expectancy (QALE), which has been utilized in 6% of studies abstracted by the NHS EED project. Fifteen percent of studies use a variety of other health valuation instruments, which are not listed individually here. It is interesting to note, from a methodologic point of view, that although healthy-years equivalent is put forward by some health economists as being either equivalent or superior to the QALY (c.f. references 1 and 6), the economic evaluations seen in the literature are predominantly based on the QALY.

CBA. One common feature of economic evaluations found in the literature is the misuse of common, well-accepted classifications. This especially relates to CUAs, as authors tend to use the term “benefits” in a general way to reflect (improved) health outcomes. However, in CBA there is a requirement to convert both costs and benefits to monetary terms and determine the net present value as the difference in value between costs and benefits (5). If the result is negative, the intervention should not be adopted. All interventions with a positive net present value can be considered for provision and should be ranked in order to determine the optimal choice. An alternative approach is the use of the benefits-to-costs ratio in which the highest ratio is deemed to be the preferred option (2). Although CBA is considered by many to be potentially the most powerful and versatile form of economic evaluation, its value is limited by the methods used to translate benefits to monetary values.

Two common approaches to the conversion of health outcomes to monetary terms are willingness to pay (WTP) and the human capital approach (HCA) (8). The former involves asking individuals how much they are willing to pay (from their surplus income) to avoid risk, with an example study being Ghosh et al. (7), or by use of surveys in which individuals are asked about their willingness to pay for benefits, as illustrated in a study by the Office of Health Economics (11). In HCA, the value of a human life is determined by the present value of future earnings, which gives rise to arguments concerning the value of livelihoods rather than lives (among other criticisms, it is clearly ageist by putting those who are retired at a disadvantage, for example).

Our records show that of all CBAs held on the database, 15% used WTP, 30% used HCA, and 55% used other approaches (Figure 5). A typical example of other approaches would be the monetary costs to a funding authority (such as a government or health service) of a screening program versus the monetary costs of no screening for the same condition. Neither WTP nor HCA are applied, but the authors, arguably with good reasons, tend

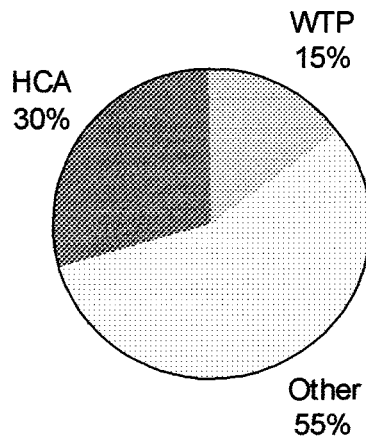


Figure 5. CBA: Valuing healthcare benefits.

to regard and classify this form of analysis as CBA, since both options are presented in monetary terms and do address the health outcomes of both alternatives. The methodologic approach being adopted is that of “avoided costs” with the use of benefit-to-cost ratios or net benefits (in monetary terms). It has proved difficult in some instances to interpret these as cost-effectiveness studies, and the original classification of CBA (by the author) has been retained.

This issue clearly invites clarification in the methodology of economic evaluation and the way in which other CBAs, such as those described above, are to be classified. Further research in the area of misuse of terminology in the economic evaluation literature is to be undertaken by NHS EED project staff in the near future.

ECONOMIC ISSUES ADDRESSED BY NHS EED ABSTRACTS

NHS EED abstracts aim to provide a detailed description of the methods of economic analysis used by authors in reporting the results of their studies. Although it is beyond the scope of this paper to describe the NHS EED abstracting process in detail (see reference 9 for full details), the following points constitute the principal economic areas addressed.

Choice of Comparator (Alternative Interventions)

A major point of focus is the alternative health technologies under consideration. In the reporting of the abstract, the aim is to confirm that the intervention is being compared with a credible (usually traditional) comparator and that justification by the authors for their choice is given. This is an important issue because the costs and effectiveness/benefits of the intervention should be judged against usual practice. The choice of comparator in relation to the setting is, however, taken into consideration in the commentary.

Clear Perspective

The abstracts also report the perspective adopted in the economic analysis, such as that of the hospital, the third-party payer, or society. This is especially relevant because it may reflect the healthcare system of the host country (for example, many studies from the United States adopt a third-party payer perspective, whereas in the United Kingdom an NHS or societal perspective may be a preferred option). Of principal relevance, the chosen perspective will dictate the combination of costs that “should” be reported by the authors. For example, if a societal perspective is chosen, the author should include all direct medical and nonmedical

Nixon et al.

costs as well as indirect costs such as travel and productivity costs due to loss of earnings for the patient and other informal carers. The abstracts therefore inform the reader concerning what reporting would be appropriate for the stated perspective and whether relevant costs were included.

Summary Benefit Measure Used/Necessary?

The abstracts provide the clinical outcomes of the analysis undertaken in studies being reported and, where appropriate, the measure of benefit used and how it was derived. However, many cost-effectiveness studies do not include a single unit of effectiveness (or benefit), and in this case the abstract reports the analysis performed (i.e., cost consequences or cost minimization).

Direct/Indirect Costs and Their Sources

Direct costs, as well as indirect costs, are reported and differentiated between in the abstracts. The latter will be relevant where the authors undertake analysis from a societal perspective. The source of cost data is a key point considered and reported within the abstracts. Typically, these data come from hospital records, official reports or tariffs, the literature, or pharmacies.

Data Collection: Prospective/Retrospective?

An important issue in economic evaluations is that of the perspective adopted in collecting cost data. Prospective costing alongside a clinical trial would be considered superior to retrospective analysis or literature-based data due to the problems of recall bias and variability in the ways costs are recorded. NHS EED abstracts also comment on the use of charges when these are reported rather than costs. This is because charges do not reflect opportunity costs, and the generalizability of the results is weakened in reporting charges because the profit margin used in formulating charges is not revealed by authors of papers.

Results Tested for Uncertainty

A key issue in terms of the reliability of results concerns how variability in the data is dealt with. For single trials the normal approach would be to apply some form of statistical analysis to the results and provide confidence intervals and/or *p* values. In the case of modeled solutions, where data are normally derived from the literature and/or estimates, sensitivity analyses are often applied to test the robustness of the results. NHS EED abstracts report on these aspects concerning the economic analysis as well as the clinical evidence.

Discounting Where Appropriate (>2 Years)

Discounting of both benefits and costs may be appropriate for periods of analysis that go beyond 1 year (strictly speaking, beyond 2 years). The abstracts provide details as applied by the study and comment on the appropriateness (or otherwise) of adopting discounting. Although discounting of costs is not generally a contentious issue in economic evaluations, the application of discounting to benefits is a matter of some debate (12). For example, in the study cited by Torgeson and Raftery (12), the undiscounted and discounted cost-effectiveness (CE) ratios are compared for hormone replacement therapy (for 10 years) and vitamin D and calcium (also for 10 years) in the prevention of hip fractures. The undiscounted (benefits) CE ratio favors the use of hormone replacement therapy, while the discounted (benefits) CE ratio favors vitamin D and calcium. This is a useful illustration to show that the use or avoidance of discounting can have an impact on the magnitude as well as the direction of any decision. NHS EED abstracts therefore aim at informing

the user regarding the approach adopted by authors of economic evaluations in relation to discounting of both costs and benefits such that their potential impact can be determined by the reader.

Incremental Analysis (or Average CE Ratios)

In terms of calculating CE ratios, it is well recognized that incremental ratios are superior to average ratios because they reflect the additional costs that are necessary to obtain the additional benefits (3). This form of analysis is required when the intervention is both more effective in delivering extra benefits and more costly. Average CE ratios tend to mislead the decision maker because an intervention that has low costs and low effectiveness may produce a lower CE ratio compared with a more costly and more effective alternative. What the decision maker would rather know is how much the extra benefits will cost if the most effective intervention is selected.

Incremental analysis also allows dominated strategies (those that are more costly and less effective than alternatives) to be eliminated. NHS EED abstracts report the way in which the analysis was conducted according to these considerations.

Dates

Dates to which the resources and prices refer, where given, are reported. This is an important issue for those wishing to replicate or generalize the results of economic evaluations to other settings or time periods. Economic evaluations that do not report price years, therefore, are criticized accordingly.

Separate Reporting of Costs and Quantities

NHS EED abstracts also indicate whether costs and quantities were reported separately by the authors. When the cost and resource data are presented in this manner, the generalizability of the results is enhanced, since local costs only need be applied to verify the results, assuming the clinical effectiveness data are not also affected by the settings being considered.

Validity (Internal and External)

Finally, the internal validity (good study design, elimination of bias and confounders, appropriate sample size, and group comparability, among other factors) and external validity (generalizability) of the results are commented upon, based mostly on what is reported in the papers themselves but also on the judgment of the NHS EED abstractors and research fellows, who check all abstracts for quality.

NHS EED: KEY RESPONSES

The principal areas that need to be addressed in the production of structured and critical abstracts of economic evaluations relate to both the quality of reporting and the methodologies adopted by authors in presenting their findings, and the quality and usefulness of the structured (in this case NHS EED) abstracts reporting them. Experience indicates that authors use a myriad of methodologic approaches in their studies, and therefore it is important for projects such as NHS EED to have a strong academic foundation and mechanisms that allow those involved in the production of abstracts to be kept abreast of existing and new methodologic developments.

To this end and to ensure greater consistency in the way in which abstracts are compiled, a number of measures have been introduced. These include an enhancement of the initial training package for NHS EED-commissioned abstractors with the inclusion of educational

elements as well as training in the process of compiling abstracts, the details of which are included in the reference manual for the NHS EED project (9). Each commissioned abstractor also has a nominated project research fellow to act as a personal supervisor and adviser. A quarterly newsletter is also compiled containing useful feedback on technical and general issues, which is sent out to all personnel working on the project.

A key strategy adopted by the project team is to put mechanisms in place that ensure the consistency of NHS EED abstracts in terms of definitions, classifications, and interpretations of what is being reported. To this end, a Quality Assurance Group has recently been introduced, which is staffed by health economists and medically trained methodologists working on the NHS EED project. The principal aim of the Quality Assurance Group, in conjunction with the project's management team, is to provide a forum for the discussion of methodologic issues surrounding economic evaluations, and hence to act as a vehicle for providing feedback to the commissioned abstractors who actually compile the abstracts. Theoretical issues and areas of uncertainty that emerge from the process of compiling abstracts are therefore addressed in a consistent and reliable manner. Improved ongoing training and seminars, in addition to the initial training outlined earlier, have also been key in improving both the quantity and quality of abstracts being loaded each month onto the database.

NHS EED abstracts contain a commentary field that addresses four key areas concerning the paper upon which the abstract is produced. First, the commentary indicates whether the chosen *comparator* for the intervention under consideration appeared to be a credible one (normally the traditional or established intervention). Second, it comments upon the *validity of the estimate of benefit* (or effectiveness in the case of no unitary benefit measure being reported). In this respect the commentary will indicate whether appropriate study design was employed and relevant statistical analyses undertaken on the estimates of effectiveness/benefit. Third, the *validity of the estimate of costs* is considered with relevant comments being made, and based on what was reported throughout the structured abstract. Finally, a heading for *other issues* is available, which includes comments that highlight other key areas of the study, such as the generalizability of the results to other settings and whether the author(s) undertook comparisons with similar studies to compare/validate their results. The comments made under this heading are based on the methods and results reported throughout the abstract in terms of their influence on these factors.

As an adjunct to the NHS Centre for Reviews and Dissemination commentary, the *implications* of the study are recorded in a separate field by the abstractor to indicate how future treatment policies or additional research may be relevant in light of the findings of the study being reported. This is specifically aimed at providing the decision maker with information concerning the likely impact of the study being reported.

DISCUSSION AND CONCLUSIONS

The principal aim of the NHS EED project is to provide a decision-making tool to the NHS and others concerning the cost-effectiveness of competing healthcare interventions. To ensure this service will continue to improve, a number of research initiatives are currently under way. These include statistical analyses of the database in terms of effectiveness (clinical) data and issues surrounding the quality of effectiveness data used in economic evaluations, the classifications and use of health measurement instruments employed in economic evaluations, trend analyses in these areas, the potential for development of a quality scoring system for economic evaluations, and research into the usage of NHS EED by those within the NHS and elsewhere, as appropriate. Presentations at relevant health technology assessment conferences have been given and are planned for the future, along

with suitable article submissions to high-quality journals. The aim of these initiatives is to disseminate and market the NHS EED to a wider audience both within and outside the NHS. To enhance the availability of the NHS EED and encourage its wider use, it has now been included in the Cochrane Library as an additional point of access over and above the project's Internet web site. Inclusion in the Cochrane Library will also ensure that a closer link is established with those concerned with clinical effectiveness issues by providing high-quality cost-effectiveness information for the competing interventions decision makers are considering.

The number of abstracts on the NHS EED is expanding each month, and usage increased significantly during 1999. The database is being continuously improved in terms of both quantity and quality through a comprehensive range of mechanisms aimed at achieving consistency, comprehensiveness, and reliability in the way abstracts are written. NHS EED is therefore a valuable tool for decision makers concerned with the cost-effectiveness of competing health technologies and a constantly developing window on the standard of published economic evaluations.

POLICY IMPLICATIONS

The importance of gaining access to information on cost-effectiveness as well as clinical effectiveness in the decision-making process is now well established. This is exemplified by the work of the newly formed National Institute of Clinical Excellence (NICE) in England and Wales, which now commissions reviews of health technologies in specific clinical areas and issues guidelines to the NHS regarding clinical practice. These reviews explicitly require an assessment of cost-effectiveness information. Consequently, organizations such as NICE are raising the profile of the application of economic evaluations. It is helpful for those involved at the policy level to be able to access sources such as NHS EED, which provides critical assessments of all types of economic evaluations. The NHS EED can also be considered as a research vehicle that may be able to contribute to developing the quality and usefulness of future economic evaluations, because of its focus on those elements that constitute a well-conducted economic evaluation.

NOTE

¹ The NHS EED can be accessed free of charge through the Internet at <http://nhscrd.york.ac.uk/welcome.html>.

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Nixon et al.

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