Poster ID: PMC45

# Reviewer's Checklist for Assessing the Quality of Decision Models

**Evelina Zimovetz, Sorrel Wolowacz**

RTI Health Solutions, Manchester, United Kingdom

## BACKGROUND

- The National Institute for Health and Clinical Excellence (NICE) Single Technology Appraisal (STA) process requires submission of a systematic review of existing economic evaluations.
- Critical appraisal of the identified studies is an important component of this review.
- Numerous assessment tools have been devised to critically appraise the quality of decision models.
- None of these accurately reflects the quality criteria specified by the NICE Reference Case published in the updated 2008 *Guide to the Methods of Technology Appraisal*.[1]

## OBJECTIVES

- We aimed to develop a checklist that assesses the quality of decision-analytic models that may be used in the context of STA submissions, and which both reflects the requirements of the NICE Reference Case and incorporates important elements of existing highly regarded tools.

## METHODS

- A systematic review was undertaken to identify existing good practice guidelines and checklists for critical appraisal of health economics studies.

### Search Strategy

- We searched MEDLINE, EconLit, and the Health Economic Evaluation Database (HEED) for published guidelines and checklists and the Internet for relevant grey literature, discussion papers, and conference abstracts.
- We adopted a modified version of the search strategy reported in Philips and colleagues.[2] No searches of HTA Web sites were performed to identify country-specific recommendations for conducting economic evaluations.

### Inclusion Criteria

- We included studies that report general good practice guidelines or/and checklists for assessment of quality and validity of decision models.
- We excluded studies presenting disease-specific good practice guidelines and modelling recommendations, those discussing only certain aspects of methodology, and those specifically developed to assess the methodological quality of economic evaluations alongside clinical trials (e.g., the CHEC-list).
- Included studies were restricted to those published in the English language between 1990 and September 2009.
- Editorial letters and comments were excluded from the review.

## RESULTS

- Electronic searches retrieved 623 publications of which 22 were duplicates.
- By screening the titles and abstracts of 601 papers, 14 were found to be relevant.
- 12 additional relevant studies were identified by hand searches, resulting in a total of 26 papers included in the review.
- Of these, 16 reported general good practice guidelines for conducting health economic modelling studies.[2-17]
- A detailed summary of most of these guidelines can be found in Philips and colleagues.[2] The review identified 14 checklists for conducting and reporting health economic studies (Table 1).

**Table 1. Summaries of Checklists Identified by the Review**

| Checklist | Purpose | Number of Domains/ Items | Scoring System |
|---|---|---|---|
| Centre for Reviews and Dissemination, 2008[18] | Guide the quality assessment of economic evaluations | 36 | No |
| Philips et al., 2004[2] Philips et al., 2006[3] | Provide a broad framework for quality assessment and best practice in decision-analytic modelling for cost-effectiveness analysis | 22/61 | No |
| Drummond et al., 2005[19] | Assess the generalisability of modelling studies | 7 | No |
| Chiou et al., 2003[20] | Appraise the quality of cost-effectiveness studies | 16 | Yes |
| Ungar et al., 2003[21] | Evaluate the quality of health economic studies in children | 14/57 | Yes |
| Soto, 2002[7] | Follow in the design and elaboration of decision analytic modelling | 13/51 | No |
| Sculpher et al., 2000[11] | Provide a framework for quality assessment of decision analytic cost-effectiveness models | 9/35 | No |
| Gerard et al., 2000[22] | Assess the quality of cost-utility analyses | 3/33 | Yes |
| Gonzalez-Perez, 2002[23] | Assess economic evaluations (a scoring system based on Drummond et al., 1996 10-point checklist) | 10 | Yes |
| Wallace et al., 2002[24] | Assess the methodological quality of economic analyses | 20 | Yes |
| Halpern et al., 1998[13] | Evaluate a manuscript describing a health outcomes model | 28 | No |
| Drummond et al., 1997[25] | Critically appraise published economic analyses | 10 | No |
| Drummond et al., 1996[26] | Provide guidelines for authors and peer reviewers of economic submissions to the BMJ | 35 | No |
| Sacristán et al., 1993[27] | Systematically evaluate the quality of pharmacoeconomic studies | 12/40 | No |

BMJ = British Medical Journal.

- The checklist developed by Philips and colleagues (2006)[3] was found to be the most comprehensive.
- The checklist provided by the Centre for Reviews and Dissemination[18] is based on the widely used 35-item BMJ checklist[26] and includes an additional item to cover generalisability issues.
- The checklist by Philips et al. (2006)[3] incorporates the evidence from a systematic review of best practice guidelines and focuses on three dimensions of quality: (1) structure, (2) data, and (3) consistency.
- The "structure" domain incorporates aspects relating to the scope and mathematical structure of the model; the "data" domain includes data identification methods and handling of uncertainty, and "consistency" relates to the overall quality of the model.[3]
- Our checklist adopts similar basic domains as in Philips and colleagues (2006),[3] but incorporates modified criteria for the data domain to provide a more sensitive framework reflecting the most up-to-date requirements of the NICE Reference Case.
- Our checklist introduces an extra domain, "relevance," which examines how relevant the appraised economic study is to the current STA.
- The quality assessment tool presented here is a fairly simple checklist and does not incorporate elements of a quality scoring system.
- Evidence suggests that checklists or descriptive critical assessments are preferred to quality scoring systems.[18, 28]
- Our checklist is designed such that more "yes" responses indicate higher quality on a quick visual examination of the completed checklist.

**Table 2. A Checklist for Assessing the Quality of Decision Models**

| | Questions for Appraisal | Yes/No/NA/ Not Clear | Comments |
|---|---|---|---|
| **Relevance to Current Technology Appraisal** | | | |
| 1. | Is the economic analysis evaluating the intervention under assessment (i.e., appraised drug at a licensed dose)? | | |
| 2. | Is the analysis evaluating any of the comparators relevant to this technology appraisal? | | |
| 3. | Is the model investigating the population relevant to this technology appraisal? | | |
| 4. | Was the analysis performed from a perspective of NHS and PSS? | | |
| 5. | Does it report incremental cost-utility results? | | |
| 6. | Are the results generalisable to the UK setting? | | |
| 7. | Were both costs and benefits discounted at 3.5%? | | |
| **Structure** | | | |
| 8. | Is the research question clearly stated (including intervention, comparators, and perspective)? | | |
| 9. | Does the model structure account for all differences between comparators in events/health states (including adverse events) that have important impact on costs and/or outcomes? | | |
| 10. | Does the time horizon encompass important differences in costs and outcomes (e.g., where survival is affected at differential rates, is a lifetime horizon adopted in the analysis?)? | | |
| 11. | Does the model type (e.g., decision tree, Markov, discrete event simulation) allow accurate estimation of all costs and outcomes (i.e., are there any features in the model design that prevent accurate estimation of costs and outcomes?)? | | |
| **Data: *Clinical Evidence*** | | | |
| 12. | Was a systematic review[a] of clinical evidence undertaken to identify efficacy and safety data relevant to the decision problem? | | |
| 13. | Were at least the following databases searched: MEDLINE, EMBASE, MEDLINE In-Progress, Cochrane Library, NHS EED, and EconLit ? | | |
| 14. | Is the rationale for exclusion of studies from use in the model provided (e.g., inclusion/exclusion criteria applied in the systematic review, exclusion from data synthesis and/or model) and the number excluded reported (e.g., using a flow diagram)? | | |
| 15. | Was each included study critically appraised? | | |
| 16. | Were studies selected for inclusion in the model in accordance with the Methods Guide[b] (e.g., were head-to-head RCTs comparing the interventions with relevant comparators favoured over indirect and non-RCT evidence)? | | |
| 17. | Was all relevant clinical evidence included in the model (e.g., trials reported since the analysis was performed, supplement ary indirect or non-RCT evidence)? | | |
| 18. | Was the key evidence of efficacy and safety appropriately applied in the model (e.g. , was trial randomisation preserved? were differences in outcome measures or heterogeneity in data synthesis adequately accounted for?)? | | |
| 19. | Were intermediate outcome measures linked to final outcomes (such as change in a biomarker to a final outcome)? If so, was the association between intermediate and final outcomes adequately demonstrated? | | |
| 20. | Were any supplementary clinical data used in the model identified via a systematic review and selected values justified (e.g., incidence of long-term events or any other clinical evidence used in the model from sources other than those discussed in Q12)? | | |
| 21. | Where expert opinion was used, were the methods described and justified? | | |
| **Data: *Utility Data*** | | | |
| 22. | Were HRQL data collected directly from patients or from their caregivers? | | |
| 23. | Was the valuation of changes in HRQL based on preferences elicited using a choice-based method in a representative sample of the UK general population? | | |
| 24. | Was HRQL measured using the EQ-5D? | | |
| 25. | Were methods of obtaining EQ-5D values fully described? | | |
| 26. | In the absence of EQ-5D data, were methods of estimating the utility data in accordance with the Methods Guide (e.g., was mapping from other relevant measures adequately validated? was direct utility estimation performed using the time trade-off method?)? | | |
| 27. | Where EQ-5D is considered inappropriate to use, is rationale provided for using an alternative measure? | | |
| 28. | Where utility estimates were obtained from published literature, were these identified via a systematic review and selected values justified? | | |
| **Data: *Resource Use and Cost Data*** | | | |
| 29. | Did the acquisition cost of the intervention and comparators represent the public list price? | | |
| 30. | Were estimates of other unit costs obtained from official published listings? | | |
| 31. | Where resource use or cost estimates were obtained from published literature, were these identified via a systematic review and selected values justified? | | |
| 32. | Were all costs related to the events/health states in the model that were relevant to the perspective of the analysis included? | | |
| 33. | Were costs unrelated to the condition or intervention excluded from the analysis? | | |
| 34. | Did the main analysis include only those costs relating to resources that are under the control of the NHS and PSS? | | |
| 35. | Did the base-case results exclude costs to other central or local government bodies (e.g., non-NHS and non-PSS costs)? | | |
| 36. | If costs that are not reimbursed by the NHS, PSS, or other government bodies (e.g., productivity costs, costs borne by patients) were included, were they reported separately? | | |
| 37. | Was value-added tax excluded (apart from budget-impact calculations)? | | |
| **Data: *Assessment of Uncertainty*** | | | |
| 38. | Was the impact of structural uncertainty on estimates of cost-effectiveness explored by separate analyses of a representativ e range of plausible scenarios? | | |
| 39. | Was uncertainty about the choice of sources for parameter values explored using alternative sources of data or excluding studies that might be less relevant? | | |
| 40. | Was uncertainly associated with precision of estimates of mean parameter values explored via a probabilistic sensitivity analysis? | | |
| 41. | Was the evidence about the extent of correlation between individual parameters reflected in the probabilistic analysis? | | |
| 42. | Were subgroup analyses performed in the economic analyses or justification provided for their omission? | | |
| 43. | If subgroup analyses were performed, was selection of analyses appropriate (e.g., were potential treatment-effect and baseline risk modifiers [such as age, sex, severity of disease] identified? were they prospectively defined? were important subgroups omitted?)? | | |
| **Consistency** | | | |
| 44. | Were measures undertaken to validate and check the model reported? | | |
| 45. | Were model estimates validated by comparison with clinical trial data or other relevant evidence? | | |
| 46. | Were the results compared with those reported previously and any differences explained? | | |

EED = Economic Evaluation Database; HRQL = health-related quality of life; NA = not applicable; NHS = National Health Service; PSS = Personal Social Services; RCT = randomised controlled trial.

[a] A systematic review is one that is conducted according to a previously specified protocol.

[b] Refers to NICE's Guide to the Methods of Technology Appraisal.[1]

## CONCLUSION

- The proposed checklist will provide a useful tool to assess the quality of health economic models and the evidence underpinning them according to the NICE Reference Case and evidence hierarchy, which includes identification of evidence by systematic review, selection and synthesis of outcomes data, and measurement and valuation of health effects.
- The checklist may be used alongside recognised guidelines for critical appraisal of health economics evaluations.

## REFERENCES

1. National Institute for Health and Clinical Excellence (NICE). 2008. Updated Guide to the Methods of Technology Appraisal. 2008. Available at: http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf. Accessed October 8, 2009.
2. Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, et al. Review of guidelines for good practice in decision-analytic modelling in health technology assessment. Health Technology Assessment (Winchester, England) 2004;8:iii-iiv.
3. Philips Z, Bojke L, Sculpher M, Claxton K, Golder S. Good practice guidelines for decision-analytic modelling in health technology assessment: a review and consolidation of quality assessment. Pharmacoeconomics 2006;24:355-71.
4. Goeree R, O'Brien BJ, Blackhouse G. Principles of good modelling practice in healthcare cost-effectiveness studies. Expert Review of Pharmacoeconomics and Outcomes Research 2004;4:189-98.
5. Hay JW. Evaluation and review of pharmacoeconomic models. Expert Opinion on Pharmacotherapy 2004;5:1867-80.
6. Weinstein MC, O'Brien B, Hornberger J, Jackson J, Johannesson M, McCabe C, et al.; ISPOR Task Force on Good Research Practices. Principles of good practice for decision analytic modelling in health-care evaluation: report of the ISPOR Task Force on Good Research Practices–Modelling Studies. Value in Health 2003;6:9-17.
7. Soto J. Health economic evaluations using decision analytic modelling. Principles and practices–utilization of a checklist to their development and appraisal. International Journal of Technology Assessment in Health Care 2002;18:94-111.
8. Weinstein MC, Toy EL, Sandberg EA, Neumann PJ, Evans JS, Kuntz KM, et al. Modeling for health care and other policy decisions: uses, roles, and validity. Value Health 2001;4:348-61.
9. Akehurst R, Anderson P, Brazier J, Brennan A, Briggs A, Buxton M, et al. Decision analytic modelling in the economic evaluation of health technologies. A consensus statement. Consensus Conference on Guidelines on Economic Modelling in Health Technology Assessment. Pharmacoeconomics 2000;17:443-4.
10. McCabe C, Dixon S. Testing the validity of cost-effectiveness models. Pharmacoeconomics 2000;17:501-13.
11. Sculpher M, Fenwick E, Claxton K. Assessing quality in decision analytic cost-effectiveness models. A suggested framework and example of application. Pharmacoeconomics 2000;17:461-77.
12. Ramsey SD, Sullivan SD. Weighing the economic evidence: guidelines for critical assessment of cost-effectiveness analyses. J Am Board Fam Pract 1999;12:477-85.
13. Halpern MT, Luce BR, Brown RE, Geneste B. Health and economic outcomes modeling practices: a suggested framework. Value Health 1998;1:131-47.
14. Nuijten MJ, Pronk MH, Brorens MJ, Hekster YA, Lockefeer JH, de Smet PA, et al. Reporting format for economic evaluation. Part II: Focus on modelling studies. Pharmacoeconomics 1998;14:259-68.
15. Buxton MJ, Drummond MF, Van Hout BA, Prince RL, Sheldon TA, Szucs T, et al. Modelling in economic evaluation: an unavoidable fact of life. Health Economics 1997;6:217-27.
16. Sonnenberg FA, Roberts MS, Tsevat J, Wong JB, Barry M, Kent DL. Toward a peer review process for medical decision analysis models. Medical Care 1994;32:Suppl-64.
17. Habbema JDF, Bossuyt PMM, Dippel DWJ, Marshall S, Hilden J. Analysing clinical decision analyses Statistics in Medicine 1990;9:1229-42.
18. Centre for Reviews and Dissemination. Systematic reviews. CRD's guidance for undertaking reviews in health care. 2008 York: Centre for Reviews and Dissemination. Available at: http://www.york.ac.uk/inst/crd/pdf/Systematic_Reviews.pdf. Accessed October 8, 2009.
19. Drummond M, Manca A, Sculpher M. Increasing the generalizability of economic evaluations: recommendations for the design, analysis, and reporting of studies. Int J Technol Assess Health Care 2005;21:165-71.
20. Chiou CF, Hay JW, Wallace JF, Bloom BS, Neumann PJ, Sullivan SD, et al. Development and validation of a grading system for the quality of cost-effectiveness studies. Med Care 2003;41:32-44.
21. Ungar WJ, Santos MT. The Pediatric Quality Appraisal Questionnaire: an instrument for evaluation of the pediatric health economics literature. Value Health 2003;6:584-94.
22. Gerard K, Seymour J, Smoker I. A tool to improve quality of reporting published economic analyses. Int J Technol Assess Health Care 2000;16:100-10.
23. Gonzalez-Perez JG. Developing a scoring system to quality assess economic evaluations. Eur J Health Econ 2002;3:131-6.
24. Wallace JF, Weingarten SR, Chiou CF, Henning JM, Hohlbauch AA, Richards SS, et al. The limited incorporation of economic analyses in clinical practice guidelines. J Gen Intern Med 2002;17:210-20.
25. Drummond M, O'Brien B, Stoddart G, Torrance G. Methods of economic evaluation of health care programmes. 2nd ed. New York, NY: Oxford University Press Inc; 1997.
26. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. BMJ 1996;313:275-83.
27. Sacristán JA, Soto J, Galende I. Evaluation of pharmacoeconomic studies: utilization of a checklist. Ann Pharmacother 1993;27:1126-33.
28. Thurston SJ, Craig D, Wilson P, Drummond MF. Increasing decision-makers' access to economic evaluations: alternative methods of communicating the information. Int J Technol Assess Health Care 2008;24:151-7.

## CONTACT INFORMATION

**Evelina Zimovetz, MSc**
Health Economist

RTI Health Solutions
Williams House
Manchester Science Park
Lloyd Street North
Manchester M15 6SE

Telephone: +44.161.232.4925
Fax: +44.161.232.3409
E-mail: ezimovetz@rti.org

Presented at: ISPOR 12th Annual European Congress
October 24–27, 2009
Paris, France