LEGEND: Evidence Appraisal of a Single Study
All Domains
Decision Analysis, Economic Analysis, Computer Simulation

Reviewer: **Today's Date:**   **Final Evidence Level:**

Project/Topic of your Clinical Question:

Article Title:

Year: **First Author:**   **Journal:**

Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question? • Study Aim/Purpose/Objectives: • Target Population:	☐ Yes	☐ No	☐ Unknown
Is a decision analysis, economic analysis, or computer simulation congruent with the author's study aim, purpose, or objectives above?	☐ Yes	☐ No	☐ Unknown

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When reading the bolded questions, consider the bulleted questions to help answer the main question.

If you are uncertain of your skills in evidence evaluation, please consult a local evidence expert for assistance:
- CCHMC Evidence Experts

Unfamiliar terms can be found in the LEGEND Glossary.

Validity   *Are the results of the Decision Analysis or Economic Analysis valid?*

1.	**Was a well-defined question posed?** *Note: An ideal, well-defined question includes Population, Interventions/Comparators, and Outcomes. Economic analysis also includes Cost and Perspectives (e.g., societal, healthcare system, payor, consumer).*	☐ Yes	☐ No	☐ Unknown
2.	**Were all important, realistic strategies included and clearly specified?** • Was the intervention*(s)* or strategy*(ies)* clearly described and appropriate? • Were the comparator*(s) (e.g., competing alternatives, reference case, standard of care)* clearly described and appropriate?	☐ Yes	☐ No	☐ Unknown
3.	**Was there evidence that the intervention/strategy effectiveness had been established?** • What was the evidence level *(i.e., quality level of the evidence)*? Click or tap here to enter text.	☐ Yes	☐ No	☐ Unknown
4.	**Were all important and relevant outcomes considered** *(e.g., clinical, quality of life, harm, disability, death, costs, lost time from work)*? • Was the length of time considered *(analysis time horizon)* long enough to identify all important and relevant outcomes?	☐ Yes	☐ No	☐ Unknown
5.	**Was a model clearly described and appropriate?**	☐ Yes	☐ No	☐ Unknown
6.	**For an economic analysis, do included costs match stated perspective*(s)*?**	☐ Yes	☐ No	☐ Unknown
7.	**Were the outcomes and costs measured using valid and reliable tools?**	☐ Yes	☐ No	☐ Unknown
8.	**In measuring outcomes and costs, were the measures/utilities used valued and appropriate?** *Note: Measures/Utilities include, but are not limited to, ICER (Incremental Cost-Effectiveness Ratio), QALY (Quality-Adjusted Life Years), or DALY (Daily-Adjusted Life Years).* • Were the measures/utilities obtained in an explicit and sensible way from credible sources?	☐ Yes	☐ No	☐ Unknown
9.	**Was an explicit and sensible process used to identify, select, and combine evidence into probabilities?** • Was the potential impact of any uncertainty in the evidence determined *(e.g., Sensitivity Analysis)*?	☐ Yes	☐ No	☐ Unknown
10.	**Was there freedom from conflict of interest?** • Sponsors, Funding Agency, Investigators	☐ Yes	☐ No	☐ Unknown

Comments on Study Validity:

Reliability   *How were Outcomes and Costs Assessed and Compared?*

11.	**Does one strategy result in a clinically important gain for patients?** *If No, is the result a toss-up?* • Were the main assumptions stated and justified?	☐ Yes	☐ No	☐ Unknown

12.	**Could uncertainty in the evidence change the result?**	☐ Yes	☐ No	☐ Unknown
13.	**For an economic analysis, was a comprehensive economic comparison of all important health care strategies conducted?** • Were the main assumptions stated and justified?	☐ Yes	☐ No	☐ Unknown
14.	**What were the main results of the study?** *(e.g., Helpful data: Page #, Table #, Figures, Graphs)* • How large was the main effect *(e.g., clinical outcomes, process outcomes, magnitude of ratios, total cost, cost-effectiveness ratios)*? • Is the model validated by the results? ☐ Yes ☐ No If not, describe how the model was modified, according to the results: 			
15.	**Was an incremental analysis** *(i.e., CE Ratios)* **of the outcomes and costs of alternatives performed** *(i.e., Sensitivity Analysis)***?**	☐ Yes	☐ No	☐ Unknown
16.	**Was appropriate allowance made for uncertainties in the analysis?** • What were the measures of statistical uncertainty *(e.g., precision)*? *(Were the results presented with Confidence Intervals or Standard Deviations?)* 	☐ Yes	☐ No	☐ Unknown
17.	**Were outcomes and costs adjusted for different times at which they occurred, such as discounting?**	☐ Yes	☐ No	☐ Unknown
18.	**Are the estimates of outcomes and costs related to the baseline risk in the treatment population, if relevant?**	☐ Yes	☐ No	☐ Unknown
19.	**Were the results statistically significant?**	☐ Yes	☐ No	☐ Unknown
20.	**Were the results clinically significant?** • If potential confounders were identified, were they discussed in relationship to the results?	☐ Yes	☐ No	☐ Unknown
21.	**Were the conclusions of the evaluation justified by the evidence presented?**	☐ Yes	☐ No	☐ Unknown

Comments on Study Reliability:

Applicability   *Can I apply these valid, important study results to my patients? Is the evaluation usable?*

22.	**Did the presentation and discussion of the results include all or enough of the issues that are of concern to consumers** *(e.g., patient, healthcare system, policy maker, payor)***?**	☐ Yes	☐ No	☐ Unknown
23.	**Can the results be applied to my population of interest?** • Is the intervention feasible in my care setting? • Are the likely benefits worth the potential harm and costs?	☐ Yes	☐ No	☐ Unknown
24.	**Would you include this study/article in development of a recommendation?**	☐ Yes	☐ No	☐ Unknown

Comments on Study Applicability:

Additional Comments or Conclusions *("Take-Home Points")*

Quality Level / Evidence Level

- *Consider each "No" answer and the degree to which this limitation is a threat to the validity of the results, then check the appropriate box to assign the level of quality for this study/article.*
- *Consider an "Unknown" answer to one or more questions as a similar limitation to answering "No," if the information is not available in the article.*

The Evidence Level is:

☐ **Good Quality Decision Analysis, Economic Analysis, or Computer Simulation** **[5a]**
☐ **Lesser Quality Decision Analysis, Economic Analysis, or Computer Simulation** **[5b]**

☐ **Not Valid, Reliable, or Applicable**

	Table of Evidence Levels																			
	TYPE OF STUDY / STUDY DESIGN																			
DOMAIN OF CLINICAL QUESTION	Systematic Review Meta–Analysis	Meta–Synthesis	RCT*	CCT*	Qualitative Study	Psychometric Study	Cohort – Prospective	Cohort – Retrospective	Case – Control	Longitudinal (Before/After, Time Series)	Cross – Sectional	Descriptive Study Epidemiology Case Series	Quality Improvement	Mixed Methods Study	Decision Analysis Economic Analysis Computer Simulation	Guidelines	Case Reports N-of-1 Study	Bench Study	Published Expert Opinion	Local Consensus Published Abstracts
All Domains	1a 1b											4a 4b		2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5

⁺ *RCT = Randomized Controlled Trial; CCT = Controlled Clinical Trial*

Development for this appraisal form is based on:

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2. Drummond, M. F.; Aguiar-Ibanez, R.; and Nixon, J.: Economic evaluation. Singapore Med J, 47(6): 456-61; quiz 462, 2006.
3. Kopec, J. A. et al.: Validation of population-based disease simulation models: a review of concepts and methods. BMC Public Health, 10: 710, 2010.
4. Siegel, J. E.; Weinstein, M. C.; Russell, L. B.; and Gold, M. R.: Recommendations for reporting cost-effectiveness analyses. Panel on Cost-Effectiveness in Health and Medicine. JAMA, 276(16): 1339-41, 1996.
5. Soares, M., and Dumville, J. C.: Critical appraisal of cost-effectiveness and cost-utility studies in health care. Evidence-Based Nursing, 11(4): 99-102, 2008.
6. Weinstein, M. C.; Siegel, J. E.; Gold, M. R.; Kamlet, M. S.; and Russell, L. B.: Recommendations of the Panel on Cost-effectiveness in Health and Medicine. JAMA, 276(15): 1253-8, 1996.
7. Denzen, N. & Lincoln. Y. (2005). The Sage Handbook of Qualitative Research, Sage Publications: Thousand Oaks, California.
8. Freshwater, D. (2004). Deconstructing Evidence Based Practice, Routledge: New York: New York.
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12. Lincoln, Y. & Guba, E. (1985). Naturalistic Inquiry, Sage Publications: Newbury Park, California.
13. Morse, J., Swanson, J., & Kuzal, A. (2001). The Nature of Qualitative Evidence, Sage Publications: Thousand Oaks, California.
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15. Melnyk, B. M. and E. Fineout-Overholt (2005). Evidence-based practice in nursing & healthcare : a guide to best practice. Philadelphia, Lippincott Williams & Wilkins.
16. Lohr, K. N. and T. S. Carey (1999). "Assessing "best evidence": issues in grading the quality of studies for systematic reviews." Joint Commission Journal on Quality Improvement 25(9): 470-9.
17. Jerosch-Herold, C. (2005). "An evidence-based approach to choosing outcome measures: a checklist for the critical appraisal of validity, reliability and responsiveness studies." British Journal of Occupational Therapy 68(8): 347-53.
18. Phillips, et al: Oxford Centre for Evidence-based Medicine Levels of Evidence, 2001. Last accessed Nov 14, 2007 from http://www.cebm.net/index.aspx?o=1025.
19. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs,* 2(3): 157-60, 2005.
20. Clark, E., Burkett, K., & Stanko-Lopp, D. (2009, Dec). Let Evidence Guide Every New Decision (LEGEND): an evidence evaluation system for point-of-care clinicians and guideline development teams [CCHMC LEGEND development]. J Eval Clin Pract, 15(6), 1054-1060.