LEGEND Evidence Appraisal of a Single Study
Prognosis
Cross-Sectional Study

Cincinnati Children's
changing the outcome together

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?   ☐ Yes   ☐ No   ☐ Unknown

- Study Aim/Purpose/Objectives:

- Inclusion Criteria:

- Exclusion Criteria:

Is a cross-sectional study 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 Cross-Sectional Study valid or credible?*

1. **Are the study methods clearly described and appropriate for the question?**   ☐ Yes   ☐ No   ☐ Unknown
   - Is the setting clearly described and appropriate?
   - Was there a representative sample of patients at a well-defined point in the course of disease?
   - Is the sample population clearly described and sufficient?
   - Were the participants recruited prospectively?

2. **Were all potentially important prognostic factors assessed?**   ☐ Yes   ☐ No   ☐ Unknown
   - Were the patients sufficiently homogeneous with respect to prognostic risk?
   - Are there subgroups in the sample with very different prognoses compared to other subgroups in the study?

3. **Were objective and unbiased outcome criteria used?**   ☐ Yes   ☐ No   ☐ Unknown
   - Were the outcomes quantifiable and precisely measurable?
   - Were instruments used to measure the outcomes tested to be valid and reliable?
   - Was the assessment of the outcome made independent of knowledge of prognostic factors?

4. **Were all participants accounted for at the conclusion of the study?**   ☐ Yes   ☐ No   ☐ Unknown
   - Were withdrawals from the study explained?
   - Was the rate of attrition acceptable?

5. **Was there freedom from conflict of interest?**   ☐ Yes   ☐ No   ☐ Unknown
   - Sponsors, Funding Agency, Investigators

Comments on Study Validity:

Reliability   *Are these valid study results important?*

6. **Were the statistical analysis methods appropriate?**   ☐ Yes   ☐ No   ☐ Unknown
   - Were the statistical analysis methods clearly described?
   - If subgroups in the sample had different prognostic factors *(e.g., demographics, disease specifics, comorbidity)*, was an adjustment made for the differences between groups?
   - Does the prognosis change by age?

7. **Did the study have a sufficiently large sample size?**   ☐ Yes   ☐ No   ☐ Unknown
   - Was a power analysis described?
   - Did the sample size achieve or exceed that resulting from the power analysis?
   - Did each subgroup also have sufficient sample size *(e.g., at least 6 to 12 participants)*?

8. **What are the main results of the study?** *(e.g., Helpful data: Page #, Table #, Figures, Graphs)*
   - How likely are the outcomes over time?
   Absolute results (e.g., 5-year survival rate) or Relative results (e.g., risk from prognostic factor) or Survival Curves (e.g., cumulative events)
   - What were the measures of statistical uncertainty *(e.g., precision)*?
   (Were the results presented with Confidence Intervals or Standard Deviations?)

9.	**Were the results statistically significant?**	☐ Yes ☐ No ☐ Unknown	
10.	**Were the results clinically significant?**	☐ Yes ☐ No ☐ Unknown	
	• If potential confounders were identified, were they discussed in relationship to the results?		

Comments on Study Reliability:

Applicability   *Can I apply these valid, important study results to my patients?*

11.	**Can the results be applied to my population of interest?**	☐ Yes ☐ No ☐ Unknown	
	• Is the setting of the study applicable to my population of interest?		
	• Do the patient outcomes apply to my population or question of interest?		
	• Were the patients in this study similar to my population of interest?		
12.	**Are my patient's values and preferences satisfied by the knowledge gained from this study** *(such as outcomes considered)*?	☐ Yes ☐ No ☐ Unknown	
13.	**Would you include this study/article in development of a care 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 Cross-Sectional Study**   [**4a**]
☐ **Lesser Quality Cross-Sectional Study**   [**4b**]

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

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Prognosis
Cross-Sectional Study

	TYPE OF STUDY / STUDY DESIGN												
DOMAIN OF CLINICAL QUESTION	Systematic Review Meta–Analysis	Cohort – Prospective	Cohort – Retrospective	Case – Control	Cross – Sectional	Descriptive Study Epidemiology Case Series	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
Prognosis	1a 1b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5

Table of Evidence Levels (above)

Development for this appraisal form is based on:

1. Guyatt, G.; Rennie, D.; Evidence-Based Medicine Working Group.; and American Medical Association.: Users' guides to the medical literature : a manual for evidence-based clinical practice. *Users' guides to the medical literature : a manual for evidence-based clinical practice:* "JAMA & archives journals." Chicago, IL, 2002
2. Melnyk, B. M. and E. Fineout-Overholt (2005). Evidence-based practice in nursing & healthcare : a guide to best practice. Philadelphia, Lippincott Williams & Wilkins.
3. 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.
4. Fineout-Overholt, E. and L. Johnston (2005). "Teaching EBP: asking searchable, answerable clinical questions." Worldviews Evid Based Nurs 2(3): 157-60.
5. 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.
6. 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.
7. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs,* 2(3): 157-60, 2005.
8. 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.