

LEGEND Evidence Appraisal of a Single Study

Prognosis

Cohort Study – Prospective or Retrospective



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 cohort study congruent with the author's study aim, purpose, or objectives above?

☐ Yes ☐ No ☐ Unknown

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 Cohort Study valid or credible?

1.	Were data collected prospectively?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
2.	Was the study sample representative of patients with the disease in question?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
3.	Were all participants at the same well-defined point in the course of the disease?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
4.	At the start of the study, were the participants similar with respect to known prognostic factors (e.g., demographic and clinical variables)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.	Were all potentially important prognostic factors assessed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
6.	Were the outcomes quantifiable and precisely measurable? <ul style="list-style-type: none">Were instruments used to measure the outcomes valid and reliable?Was the assessment of the outcome made independent of knowledge of prognostic factors?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
7.	Were participants followed long enough for outcomes to occur? <ul style="list-style-type: none">Was the follow-up process clearly described?Was the follow-up process complete?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
8.	Were all participants accounted for at the conclusion of the study? <ul style="list-style-type: none">Were withdrawals from the study explained?Was the rate of attrition acceptable?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
9.	Was there freedom from conflict of interest?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

Comments on Study Validity:

Reliability

Are these valid study results important?

10.	Did the study have a sufficiently large sample size?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
	<ul style="list-style-type: none">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)?			

11. 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?
- Was an adjustment made for changes that occur as the patient ages, if any?

12. 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?)

13. Were the results statistically significant? ☐ Yes ☐ No ☐ Unknown

14. 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?

15. 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?

16. Are my patient's values and preferences satisfied by the knowledge gained from this study (such as outcomes considered)? ☐ Yes ☐ No ☐ Unknown

17. 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 Prospective Cohort Study [2a]
- ☐ Lesser Quality Prospective Cohort Study [2b]
- ☐ Good Quality Retrospective Cohort Study [3a]
- ☐ Lesser Quality Retrospective Cohort Study [3b]
- ☐ Not Valid, Reliable, or Applicable

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Table of Evidence Levels													
DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN												
	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

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.