

LEGEND: Evidence Appraisal of a Single Study

Etiology, Risk Factors, Incidence

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?

- | | | | |
|--|------------------------------|-----------------------------|----------------------------------|
| 1. At the start of the study, were the participants similar (<i>homogeneous</i>) with respect to known factors of interest (<i>e.g., demographic, exposure, risk, treatment, or etiology</i>)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 2. Were treatments/exposures and clinical outcomes measured in the same way in each group? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 3. Was the assessment of outcomes objective or blinded to factors of interest? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 4. 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 |
| 5. If the study addresses causation, was there a plausible association between exposure and outcome? <ul style="list-style-type: none">Does the association make biological sense?Is it clear that the exposure preceded the onset of the outcome?Was the amount of exposure associated with the severity of outcome (<i>i.e., dose-response</i>)?Was re-exposure associated with the outcome (<i>i.e., challenge or dechallenge-rechallenge</i>)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 6. 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 |
| 7. Was there freedom from conflict of interest? <ul style="list-style-type: none">Sponsors, Funding Agency, Investigators | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |

Comments on Study Validity:

Reliability

Are these valid study results important?

- | | | | |
|---|------------------------------|-----------------------------|----------------------------------|
| 8. Did the study have a sufficiently large sample size? <ul style="list-style-type: none">Was there a power analysis?Did the sample size achieve or exceed that resulting from the power analysis?Did each subgroup also have sufficient sample size (<i>e.g., at least 6 to 12 participants</i>)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
|---|------------------------------|-----------------------------|----------------------------------|

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9. Were the statistical analysis methods appropriate? ☐ Yes ☐ No ☐ Unknown

- Were the statistical analysis methods clearly described?
- If subgroups were evaluated, was a statistical adjustment made for the differences?

10. What were the main results of the study? (e.g., Helpful data: Page #, Table #, Figures, Graphs)

- **For an Etiology Study:** How strong is the association between exposure and outcome?
(What is the correlation or estimate of risk?)
- **For an Incidence Study:** What is the rate?
(e.g., number per population per year or other time period)
- What were the measures of statistical uncertainty (e.g., precision)?
(Were the results presented with Confidence Intervals or Standard Deviations?)

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

Note: This question may not be applicable in all incidence studies.

12. 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?

13. 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?

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

15. 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

Lesser Quality **Prospective** Cohort Study

Good Quality **Retrospective** Cohort Study

Good Quality **Retrospective** Cohort Study

☐ Not Valid, Reliable, or Applicable

Etiology /
Risk Factors

Incidence

☐ 3a

☐ 2a

☐ 3b

☐ 2b

☐ 4a

☐ 3a

☐ 4b

☐ 3b

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Table of Evidence Levels														
DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN													
	Systematic Review Meta-Analysis	RCT +	CCT +	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
Etiology / Risk Factors	1a 1b	2a 2b	3a 3b	3a 3b	4a 4b	4a 4b	4a 4b	4a 4b	2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5
Incidence	1a 1b			2a 2b	3a 3b			4a 4b			5a 5b	5a 5b	5a 5b	5

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

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 [Cincinnati Children's LEGEND development]. *J Eval Clin Pract*, 15(6), 1054-1060.