

LEGEND: Evidence Appraisal of a Single Study

Etiology, Risk Factors, Prevalence

Case-Control Study

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 case-control 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 Case-Control Study valid?

- | | | | |
|--|------------------------------|-----------------------------|----------------------------------|
| 1. Were there clearly defined groups of patients, matched on factors or exposures other than the hypothesized association? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| <ul style="list-style-type: none">• Were cases and controls at similar risk of developing the outcome? | | | |
| 2. Was there a plausible association between exposure and outcome? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| <ul style="list-style-type: none">• Is it clear that the exposure preceded the onset of the outcome?• Does the association make biological sense?• Was the amount of exposure associated with the severity of outcome (i.e., dose-response)? | | | |
| 3. Were treatments/exposures and clinical outcomes measured in the same way in both groups? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 4. Was the assessment of outcomes either objective or blinded to exposure? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 5. Was the interval between exposure of study patients and measurement of outcome long enough to determine the hypothesized association? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 6. Was there freedom from conflict of interest? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| <ul style="list-style-type: none">• Sponsors, Funding Agency, Investigators | | | |

Comments on Study Validity:

Reliability

Are these valid study results important?

- | | | | |
|---|------------------------------|-----------------------------|----------------------------------|
| 7. 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 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 (e.g., at least 6 to 12 participants)? | | | |
| 8. Were the statistical analysis methods appropriate? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| <ul style="list-style-type: none">• Were the statistical analysis methods clearly described?• If subgroups were evaluated, was a statistical adjustment made for the differences? | | | |

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9. **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/correlation between exposure and outcome? (What is the estimate of risk?)
 - **For a Prevalence Study:** What are the rates? (e.g., number per case population, number per control population)
 - What were the measures of statistical uncertainty (e.g., precision)?
(Were the results presented with Confidence Intervals or Standard Deviations?)

10. **Were the results statistically significant?** ☐ Yes ☐ No ☐ Unknown
Note: This question may not be applicable in all prevalence studies.

11. **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?*

12. **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 exposures and outcomes apply to my population or question of interest?
- Were the patients in this study similar to my population of interest?

13. **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

14. **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 Case-Control Study**
☐ **Lesser Quality Case-Control Study**

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

**Etiology /
Risk Factors**

☐ **4a**
☐ **4b**

Prevalence

☐ **2a**
☐ **2b**

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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	5a 5b	5
Prevalence	1a 1b					2a 2b	3a 3b	4a 4b			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:

- 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
- Melnik, B. M. and E. Fineout-Overholt (2005). Evidence-based practice in nursing & healthcare : a guide to best practice. Philadelphia, Lippincott Williams & Wilkins.
- 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.
- Fineout-Overholt, E. and L. Johnston (2005). "Teaching EBP: asking searchable, answerable clinical questions." *Worldviews Evid Based Nurs* 2(3): 157-60.
- 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.
- 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>.
- Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs*, 2(3): 157-60, 2005.
- 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.