LEGEND: Evidence Appraisal of a Single Study
Intervention
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 the study methods appropriate for the question?** • Were the study methods clearly described *(e.g., setting, sample population)*? • Were cases and controls matched appropriately for confounders or comorbidities? • Were appropriate numbers of control participants matched to the case participants?	☐ Yes	☐ No	☐ Unknown
2.	**Were instruments used to measure the outcomes valid and reliable?** • Were the instruments tested to be valid and reliable?	☐ Yes	☐ No	☐ Unknown
3.	**Were all appropriate variables** *(e.g., potential confounders, exposures, predictors)* **and interventions clearly described?**	☐ Yes	☐ No	☐ Unknown
4.	**Were all appropriate outcomes clearly described?**	☐ Yes	☐ No	☐ Unknown
5.	**Were all participants accounted for at the conclusion of the study?** • Were missing data explained?	☐ Yes	☐ No	☐ Unknown
6.	**Was there freedom from conflict of interest?** • Sponsors, Funding Agency, Investigators	☐ Yes	☐ No	☐ Unknown

Comments on Study Validity:

Reliability

Are these valid study results important?

7.	**Were the statistical analysis methods appropriate?** • Were the statistical analysis methods clearly described?	☐ Yes	☐ No	☐ Unknown
8.	**Did the study have a sufficiently large sample size?** • 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)*?	☐ Yes	☐ No	☐ Unknown
9.	**What were the main results of the study?** *(e.g., Helpful data: Page #, Table #, Figures, Graphs)* • What was the effect size? *(How large was the treatment effect?)* • What were the measures of statistical uncertainty *(e.g., precision)*? *(Were the results presented with Confidence Intervals or Standard Deviations?)*			

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

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?** • Is the treatment feasible in my care setting? • Do the patient outcomes apply to my population or question of interest? • Are the likely benefits worth the potential harm and costs? • Are the patients in this study similar to my population of interest?	☐ **Yes**	☐ **No**	☐ **Unknown**
14.	**Are my patient's and family's values and preferences satisfied by the treatment and its consequences?**	☐ **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 Case-Control Study** [**4a**]
☐ **Lesser Quality Case-Control Study** [**4b**]
☐ **Not Valid, Reliable, or Applicable**

Table of Evidence Levels

DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN																	
	Systematic Review Meta–Analysis	RCT [+]	CCT [+]	Qualitative Study	Cohort – Prospective	Cohort – Retrospective	Case – Control	Longitudinal (Before/After, Time Series)	Cross – Sectional	Descriptive Study Epidemiology Case Series	Quality Improvement (PDSA)	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
Intervention *Treatment, Therapy, Prevention, Harm, Quality Improvement*	1a 1b	2a 2b	3a 3b	4a 4b	3a 3b	4a 4b	4a 4b	4a 4b	4a 4b	4a 4b	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*

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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.