LEGEND: Evidence Appraisal of a Single Study
Etiology, Risk Factors
Randomized Controlled Trial *(RCT)* or Controlled Clinical Trial *(CCT)*

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 RCT or CCT congruent with the author's study aim/purpose/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 RCT or CCT valid?*

1.	**Were patients randomly assigned to experimental/exposure and control groups?** ***Note:*** *If the study was not randomized, it should be assigned a level for a CCT.*	☐ Yes	☐ No	☐ Unknown
2.	**Was that randomization conducted appropriately?** • Was the randomization concealed from those responsible for recruiting subjects? • Was the randomization concealed from patients, parents, clinicians, and analysts?	☐ Yes	☐ No	☐ Unknown
3.	**At the start of the study, were the participants similar** *(homogeneous)* **with respect to known factors of interest** *(e.g., demographic, exposure, risk, treatment, or etiology)***?**	☐ Yes	☐ No	☐ Unknown
4.	**Aside from the experiment/exposure, were the groups treated equally?**	☐ Yes	☐ No	☐ Unknown
5.	**Were all patients who entered the study accounted for at its conclusion?** • Were withdrawals from the study explained? • Was the rate of attrition acceptable?	☐ Yes	☐ No	☐ Unknown
6.	**Were patients analyzed in the groups to which they were randomized?**	☐ Yes	☐ No	☐ Unknown
7.	**Was the study process long enough to fully study effects of the experiment/exposure?**	☐ Yes	☐ No	☐ Unknown
8.	**Were instruments used to measure the outcomes valid and reliable?**	☐ Yes	☐ No	☐ Unknown
9.	**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?*

10.	**Did the study have a sufficiently large sample size?** • 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)*?	☐ Yes	☐ No	☐ Unknown
11.	**Were the statistical analysis methods appropriate?** • Were the statistical analysis methods clearly described? • If subgroups were evaluated, was a statistical adjustment made for the differences?	☐ Yes	☐ No	☐ Unknown

12.	**What were the main results of the RCT or CCT?** *(e.g., Helpful data: Page #, Table #, Figures, Graphs)*			

- How strong is the association between experiment/exposure and outcome? *(What is the correlation or estimate of risk?)*
- What were the measures of statistical uncertainty *(e.g., precision)*?
  (Were the results presented with Confidence Intervals or Standard Deviations?)
- What was the effect size? *(How large was the effect of the experiment/exposure?)*

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?			
15.	**Were adverse events assessed?**	☐ Yes	☐ No	☐ Unknown

Comments on Study Reliability:

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

16.	**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?			
17.	**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
18.	**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 RCT**   [**2a**]
☐ **Lesser Quality RCT**   [**2b**]

☐ **Good Quality CCT**   [**3a**]
☐ **Lesser Quality CCT**   [**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	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

[+] *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 [CCHMC LEGEND development]. J Eval Clin Pract, 15(6), 1054-1060.