

Project/Topic of your Clinical Question: _____
 Reviewer: _____ Today's Date: _____ Final Evidence Level: _____
 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
 Comments: _____

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: <http://groups/ce/NewEBC/EBDMHelp.htm>
 Unfamiliar terms can be found in the LEGEND Glossary: <http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf>

VALIDITY: ARE THE RESULTS OF THE RCT OR CCT VALID OR CREDIBLE?

1. Were patients randomly assigned to experimental/exposure and control groups? Yes No Unknown
Note: If the study was not randomized, it should be assigned a level for a CCT.
 Comments: _____

2. Was that randomization conducted appropriately? Yes No Unknown

- Was the randomization concealed from those responsible for recruiting subjects?
- Was the randomization concealed from patients, parents, clinicians, and analysts?

Comments: _____

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
 Comments: _____

4. Aside from the experiment/exposure, were the groups treated equally? Yes No Unknown
 Comments: _____

5. Were all patients who entered the study accounted for at its conclusion? Yes No Unknown

- Were withdrawals from the study explained?
- Was the rate of attrition acceptable?

Comments:

6. Were patients analyzed in the groups to which they were randomized? Yes No Unknown

Comments:

7. Was the study process long enough to fully study effects of the experiment/exposure? Yes No Unknown

Comments:

8. Were instruments used to measure the outcomes valid and reliable? Yes No Unknown

Comments:

9. Was there freedom from conflict of interest? Yes No Unknown

- Sponsor/Funding Agency or Investigators

Comments:

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

10. Did the study have a sufficiently large sample size? Yes No Unknown

- 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)?

Comments:

11. 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?

Comments:

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

Comments:

14. Were the results clinically significant?

Yes No Unknown

- If potential confounders were identified, were they discussed in relationship to the results?

Comments:

15. Were adverse events assessed?

Yes No Unknown

Comments:

APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO MY POPULATION?

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?

Comments:

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

Comments:

18. Would you include this study/article in development of a care recommendation?

Yes No Unknown

Comments:

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**

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	2a	3a	3a	4a	4a	4a	4a	2/3/4	5a	5a	5a	5a	5a	5
	1b	2b	3b	3b	4b	4b	4b	4b	a/b	5b	5b	5b	5b	5b	

⁺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.