

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 treatment 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?
- Were patients, parents, clinicians, and analysts masked to which treatment was being received?

Comments:

3. Were the groups similar at the start of the trial, with respect to known prognostic factors (i.e., demographic and clinical variables)? Yes No Unknown
Comments:

4. Aside from the experimental treatment, were the groups treated equally? Yes No Unknown
Comments:

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

- Was there a low rate of attrition?

Note: If greater than 20% lost to follow up, bias may be of greater concern.

Comments:

6. Were patients accounted for (and analyzed) in the groups to which they were randomized (i.e., intention-to-treat analysis)? Yes No Unknown

Comments:

7. Was the study process long enough to fully study effects of the intervention? 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. What were the main results of the RCT or CCT? (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?)

12. Were the results statistically significant? Yes No Unknown

Comments:

13. Were the results clinically significant? Yes No Unknown

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

*Comments:***14. Were adverse events assessed?** Yes No Unknown*Comments:***APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?****15. Can the results be applied to my population of interest?** Yes No Unknown

- 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?
- Were the patients in this study similar to my population of interest?

*Comments:***16. Are my patient's and family's values and preferences satisfied by the treatment and its consequences?** Yes No Unknown*Comments:***17. 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	Longitudinal (Before/After, Time Series)	Cross – Sectional	Epidemiology Descriptive Case Series	Expert Opinion Case Reports
Intervention									
Treatment, Therapy, Prevention, Harm, Quality Improvement	1a 1b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	4a 4b	4a 4b	5a 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.