

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 ⁺	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	1a	2a	3a	4a	3a	4a	4a	4a	4a	4a	4a	2/3/4	5a	5a	5a	5a	5a	5
<i>Treatment, Therapy, Prevention, Harm, Quality Improvement</i>	1b	2b	3b	4b	3b	4b	4b	4b	4b	4b	4b	a/b	5b	5b	5b	5b	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.