

**EVIDENCE APPRAISAL OF A SINGLE STUDY**

**– TREATMENT / THERAPY: LONGITUDINAL STUDIES (BEFORE/AFTER, TIME SERIES) –**

**Project / Topic of your Clinical Question:** \_\_\_\_\_

**Reviewer:** \_\_\_\_\_ **Today's Date (mm/dd/yy):** \_\_\_\_\_ **Final Evidence Level:** \_\_\_\_\_

**Article Title:** \_\_\_\_\_

**Year:** \_\_\_\_\_ **First Author:** \_\_\_\_\_ **Journal:** \_\_\_\_\_

**Do the study purpose/objectives and inclusion/exclusion criteria assist in answering the clinical question?**

Yes  No  Unknown

*Comments:*

**A.** What is the study purpose/objective? \_\_\_\_\_

**B.** What are the Inclusion Criteria? \_\_\_\_\_

**C.** What are the Exclusion Criteria? \_\_\_\_\_

\* **Bolded** questions represent the key criteria for each section.

\* *Lettered questions (A., B., ...) provide additional information to better answer the bolded questions.*

**VALIDITY: ARE THE STUDY RESULTS VALID OR CREDIBLE?**

**1. Is the study purpose clearly stated? (e.g., aim, hypothesis, or objective)**  Yes  No  Unknown

*Comments:*

**2. Are the study methods clearly described and appropriate for the question?**  Yes  No  Unknown

*Comments:*

**A.** Is the setting clearly described and appropriate?  Yes  No  Unknown

*Comments:*

**B.** Is the sample population clearly described and sufficient?  Yes  No  Unknown

*Comments:*

**C.** Does the sample population adequately represent the population of interest?  Yes  No  Unknown

*Comments:*

**D.** Were data collected at two points in time (before/after study; pretest/posttest)?  Yes  No  Unknown

Or were data collected at three or more points in time (time series study)?  Yes  No  Unknown

*Comments:*

**3. Were instruments used to measure the outcomes tested to be valid and reliable?**  Yes  No  Unknown

*Comments:*

**A.** Are the variables and interventions clearly described and appropriate?  Yes  No  Unknown

*Comments:*

**B.** Are the outcome measures clearly described and appropriate?  Yes  No  Unknown

*Comments:*

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- 4. Was the follow up process described and complete?**  Yes  No  Unknown  
*Comments:*
- A.** Were all patients who entered the study accounted for at its conclusion?  Yes  No  Unknown  
*Comments:*
- B.** Was the follow up described and complete with a low rate of attrition?  Yes  No  Unknown  
*Comments:*
- C.** Was the follow up long enough to fully study the effects of the intervention?  Yes  No  Unknown  
*Comments:*
- 5. Was there freedom from conflict of interest?**  Yes  No  Unknown  
*Comments:*
- A.** Was there freedom from conflict of interest in the sponsor/funding agency?  Yes  No  Unknown  
*Comments:*
- B.** Was there freedom from conflict of interest in the investigators?  Yes  No  Unknown  
*Comments:*

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### RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

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- 6. Were the statistical analysis methods clearly described and appropriate?**  Yes  No  Unknown  
*Comments:*
- 7. Did the study have a sufficiently large sample size?**  Yes  No  Unknown  
*Comments:*
- 8. What are the main results of the study?**  
*(Enter or calculate results in the appropriate fields in the tables below. Point estimates? Effect Size? How large was the treatment effect?)*  
\* A table is also available for calculation or presentation of study results on the last page of this form.
- A.** What are the main tables or graphs of results in the article? *(Page #, Table #, Figures, Graphs)*
- B.** How precise were the results? *(Were the results presented with Confidence Intervals?)*

- 9. Were any adverse events clearly described?**  Yes  No  Unknown  
*Comments:*

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### APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

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- 10. Can the results be applied to my population of interest?**  Yes  No  Unknown  
*Comments:*
- A.** Is the treatment feasible in my care setting?  Yes  No  Unknown  
*Comments:*

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**B.** Were all patient important outcomes considered? (Are substitute endpoints valid?)  Yes  No  Unknown

Comments:

**C.** Are the likely benefits worth the potential harm and costs?  Yes  No  Unknown

Comments:

**D.** Were the patients in this study similar to my population of interest?  Yes  No  Unknown

Comments:

**11. Are your patient's values and preferences satisfied by the treatment and its consequences?**  Yes  No  Unknown

Comments:

**12. Would you include this study/article in development of a recommendation?**  Yes  No  Unknown

Comments:

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**Additional Comments or Notes:** \_\_\_\_\_

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\* 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.

**THE EVIDENCE LEVEL IS:**  **Good Quality Longitudinal Study** (4a)  
 **Lesser Quality Longitudinal Study** (4b)  
 **Not Valid, Reliable, or Applicable**

| TABLE OF EVIDENCE LEVELS    |                              |          |                      |                        |                |  |                   |                                      |                             |
|-----------------------------|------------------------------|----------|----------------------|------------------------|----------------|--|-------------------|--------------------------------------|-----------------------------|
| DOMAIN OF CLINICAL QUESTION | TYPE OF STUDY / STUDY DESIGN |          |                      |                        |                |  |                   |                                      |                             |
|                             | Systematic Review            | RCT +    | Cohort – Prospective | Cohort – Retrospective | Case – Control | Longitudinal (Before/After, Time Series) | Cross – Sectional | Epidemiology Descriptive Case Series | Expert Opinion Case Reports |
|                             | Meta-Analysis                |          |                      |                        |                |  |                   |                                      |                             |
| Treatment / Therapy         | 1a<br>1b                     | 2a<br>2b | 3a<br>3b             | 4a<br>4b               | 4a<br>4b       | 4a<br>4b                                 | 4a<br>4b          | 4a<br>4b                             | 5                           |

+ RCT = Randomized Controlled 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.

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2X2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

|                        |                          |           |   |
|------------------------|--------------------------|-----------|---|
|                        | <b>Outcome / Disease</b> |           | Control Event Rate – CER = $c / c+d$  |
|                        | <b>Yes</b>               | <b>No</b> | Experimental Event Rate – EER = $a / a+b$   |
| <b>Exposed Group</b>   | <b>a</b>                 | <b>b</b>  | Relative Risk – RR = $EER / CER$<br>RR Reduction – RRR = $(CER - EER) / CER = 1-RR$<br>Odds Ratio – OR = $ad / bc$                    |
| <b>Unexposed Group</b> | <b>c</b>                 | <b>d</b>  | Confidence Interval – CI = $\pm 1.96 \sqrt{\frac{CER*(1-CER)}{\# \text{ control pts.}} + \frac{EER*(1-EER)}{\# \text{ exper. pts.}}}$ |

| TREATMENT OUTCOMES | Sample Size [N]        | Event Rates | Relative Risk [RR] | Effect Size | Confidence Interval [95% CI] | Other Data Results | p value |
|--------------------|------------------------|-------------|--------------------|-------------|------------------------------|--------------------|---------|
| <b>Outcome 1:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |
| <b>Outcome 2:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |
| <b>Outcome 3:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |
| <b>Outcome 4:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |
| <b>Outcome 5:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |
| <b>Outcome 6:</b>  | N =                    | CER =       |                    |             |                              |                    |         |
|                    | n <sub>group 1</sub> = | EER =       |                    |             |                              |                    |         |
|                    | n <sub>group 2</sub> = |             |                    |             |                              |                    |         |