

**EVIDENCE APPRAISAL OF A SINGLE STUDY**

**– TREATMENT / THERAPY: SYSTEMATIC REVIEW / META-ANALYSIS –**

**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 RESULTS OF THE SYSTEMATIC REVIEW / META-ANALYSIS VALID OR CREDIBLE?**

**1. Were the primary studies of high methodologic quality?**  Yes  No  Unknown

*Comments:*

**A.** Did the overview address a focused clinical question?  Yes  No  Unknown

*Comments:*

**B.** Were the criteria used to select articles for inclusion appropriate?  Yes  No  Unknown

*Comments:*

**2. Was the search for relevant studies detailed and exhaustive?**  Yes  No  Unknown

*Comments:*

Is it *unlikely* that important, relevant studies were missed?  Yes  No  Unknown

*Comments:*

**3. Was the validity of the included studies appraised?**  Yes  No  Unknown

*Comments:*

Were assessments of studies reproducible?  Yes  No  Unknown

*Comments:*

**4. Were the methods consistent from study to study?**  Yes  No  Unknown

*Comments:*

**A.** Was the assignment of patients to treatments randomized?  Yes  No  Unknown

*Comments:*

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**B.** Were there clearly identified comparison groups that were similar with respect to important determinants of outcome, other than the one of interest?  Yes  No  Unknown

*Comments:*

**C.** Were the outcomes and exposures measured in the same way in the groups being compared?  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. Did the studies have a sufficiently large sample size?**  Yes  No  Unknown

*Comments:*

**7. What are the main results of the systematic review/meta-analysis?**  
*(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?)*

**8. 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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**9. 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:*

**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:*

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

Comments:

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

Comments:

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

Comments:

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

\* 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 Systematic Review (1a)
  - Lesser Quality Systematic Review (1b)
  - Not Valid, Reliable, or Applicable

**TABLE OF EVIDENCE LEVELS**

DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN								
	Systematic Review	RCT <sup>+</sup>	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 1b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	4a 4b	4a 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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### – TREATMENT / THERAPY: SYSTEMATIC REVIEW / META-ANALYSIS –

#### 2X2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

	<b>Outcome / Disease</b>		Control Event Rate – CER = $c / c+d$	
	Yes	No	Experimental Event Rate – EER = $a / a+b$	
<b>Exposed / Treatment Group</b>	a	b	Relative Risk – RR = $EER / CER$ RR Reduction – RRR = $(CER - EER) / CER = 1-RR$ Odds Ratio – OR = $ad / bc$	
<b>Unexposed / Control Group</b>	c	d	Absolute Risk Reduction – ARR = $CER - EER$ Number Needed to Treat – NNT = $1 / ARR$	
			Degrees of Freedom – df = $n1 + n2 - 2$	$n1 + n2 - 2$ $((n1 - 1)*sd1^2 + (n2 - 1)*sd2^2)$ df
			Pooled Variance – pv =	
			Standard Error – SE = $\sqrt{p \times (1-p) / n} = pv * \sqrt{(1/n_1) + (1/n_2)}$	$\sqrt{p \times (1-p) / n} = pv * \sqrt{(1/n_1) + (1/n_2)}$ # control pts.    # exper. pts. = difference +/- (t * SE)
			Confidence Interval – CI = $\pm 1.96 \sqrt{CER*(1-CER) + EER*(1-EER)}$	

TREATMENT OUTCOMES	Sample Size (N)	Event Rates	Relative Risk (RR)	Odds Ratio (OR)	Confidence Interval (95% CI)	Difference (ARR)	Number Needed to Treat (NNT)	... Harm (NNH)	Other Data Results	p value
<b>Outcome Study 1:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									
<b>Outcome Study 2:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									
<b>Outcome Study 3:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									
<b>Outcome Study 4:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									
<b>Outcome Study 5:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									
<b>Overall Outcome:</b>	N =	CER =								
	n <sub>group 1</sub> =	EER =								
	n <sub>group 2</sub> =									