EVIDENCE APPRAISAL OF A SINGLE STUDY
– TREATMENT / THERAPY: EPIDEMIOLOGIC/ECOLOGICAL STUDY –

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 sample group clearly described and sufficient? ☐ Yes ☐ No ☐ Unknown
Comments:

B. Is the setting clearly described and appropriate? ☐ 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:

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:

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

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:

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

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:

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:

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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:

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 Epidemiologic Study** (4a)
☐ **Lesser Quality Epidemiologic Study** (4b)
☐ **Not Valid, Reliable, or Applicable**

TABLE OF EVIDENCE LEVELS

DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN								
	Systematic Review **Meta–Analysis**	**RCT** [+]	**Cohort – Prospective**	**Cohort – Retrospective**	**Case – Control**	**Longitudinal** (Before/After, Time Series)	**Cross – Sectional**	**Epidemiology** **Descriptive** **Case Series**	**Expert Opinion** **Case Reports**
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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2X2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

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

TREATMENT OUTCOMES	Sample Size [N]	Event Rates	Relative Risk [RR]	Odds Ratio [OR]	Effect Size	Confidence Interval [95% CI]	Other Data Results	p value
Outcome 1:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							
Outcome 2:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							
Outcome 3:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							
Outcome 4:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							
Outcome 5:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							
Outcome 6:	**N** =	**CER** =						
	$\mathbf{n}_{\text{group 1}}$ =	**EER** =						
	$\mathbf{n}_{\text{group 2}}$ =							