

EVIDENCE APPRAISAL OF A SINGLE STUDY

– TREATMENT / THERAPY: COHORT STUDY (PROSPECTIVE AND RETROSPECTIVE)* –

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. Were the participants recruited prospectively? Yes No Unknown

Comments:

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

Comments:

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

Comments:

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

Comments:

6. 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:

* May include Pilot Studies or Case Series, if study follows cohort with fair or better sample size (>40 participants)

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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:

7. 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?

8. Were the statistical analysis methods clearly described and appropriate? Yes No Unknown

Comments:

9. Did the study have a sufficiently large sample size? Yes No Unknown

Comments:

10. 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?)*

11. Were any adverse events clearly described? Yes No Unknown

Comments:

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

12. 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:

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

Comments:

14. 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 Prospective Cohort Study (3a)
 - Lesser Quality Prospective Cohort Study (3b)
 - Good Quality Retrospective Cohort Study (4a)
 - Lesser Quality Retrospective Cohort 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 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		Control Event Rate – CER = $c / c+d$
	Yes	No	Experimental Event Rate – EER = $a / a+b$
Exposed Group	a	b	Relative Risk – RR = EER / CER RR Reduction – RRR = $(CER - EER) / CER = 1-RR$ Odds Ratio – OR = ad / bc
Unexposed Group	c	d	Confidence Interval – CI = $\pm 1.96 \sqrt{\frac{CER*(1-CER)+EER*(1-EER)}{\# \text{ control pts. } \# \text{ exper. pts.}}}$

TREATMENT OUTCOMES	Sample Size [N]	Event Rates	Incidence Rate	Relative Risk	Odds Ratio	Effect Size	Confidence Interval [95% CI]	p value
Outcome 1:	N =	CER =						
	n _{group 1} =	EER =						
	n _{group 2} =							
Outcome 2:	N =	CER =						
	n _{group 1} =	EER =						
	n _{group 2} =							
Outcome 3:	N =	CER =						
	n _{group 1} =	EER =						
	n _{group 2} =							
Outcome 4:	N =	CER =						
	n _{group 1} =	EER =						
	n _{group 2} =							
Outcome 5:	N =	CER =						
	n _{group 1} =	EER =						
	n _{group 2} =							

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