

EVIDENCE APPRAISAL OF A SINGLE STUDY

– DIAGNOSIS / ASSESSMENT: 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. Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice?

Yes No Unknown

Comments:

A. Were the selection criteria clearly described?

Yes No Unknown

Comments:

B. Is the reference standard likely to correctly classify the target condition?

Yes No Unknown

Comments:

C. Did the clinicians face diagnostic uncertainty?

Yes No Unknown

Comments:

D. Did the cohort include both diseased and non-diseased participants?

Yes No Unknown

Comments:

E. Was data collected prospectively?

Yes No Unknown

Comments:

2. Was there an independent, blind comparison with a reference standard?

Yes No Unknown

Comments:

A. Was the execution of the *index test* described in sufficient detail to permit replication of the test?

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 execution of the *reference standard* described in sufficient detail to permit replication of the test? Yes No Unknown

Comments:

- C.** Did all participants receive verification of diagnosis using a reference standard? Yes No Unknown

Comments:

- D.** Did patients receive the same reference standard regardless of the index test result? Yes No Unknown

Comments:

- E.** Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between tests? Yes No Unknown

Comments:

- 3. Were all patients who entered the trial accounted for at its conclusion?** Yes No Unknown

Comments:

Were withdrawals from the study explained? Yes No Unknown

Comments:

- 4. 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?

- 5. Did the study have a sufficiently large sample size?** Yes No Unknown

Comments:

- 6. 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 #s, Table #s, Figures, Graphs)*

B. How precise were the results? *(Were the results presented with Confidence Intervals?)*

- 7. Were the index test results and the reference standard results interpreted independently** (without knowledge of the results of the other test)? Yes No Unknown

Comments:

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- 8. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?** Yes No Unknown
Comments:
- 9. Were uninterpretable/intermediate test results reported?** 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 diagnostic test feasible in my care setting?** Yes No Unknown
Comments:
- B. Were all patient important outcomes considered?** 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:

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 – next page...*

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TABLE OF EVIDENCE LEVELS								
<i>DOMAIN OF CLINICAL QUESTION</i>	TYPE OF STUDY / STUDY DESIGN							
	Systematic Review Meta-Analysis	CCT ⁺	Psychometric Study	Cohort – Prospective	Cohort – Retrospective	Cross – Sectional	Descriptive Study Case Series	Expert Opinion Case Reports
	1a 1b	2a 2b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	5a 5b
Diagnosis / Assessment	1a 1b	2a 2b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	5a 5b

⁺ 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. 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>.
4. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs*, 2(3): 157-60, 2005.

2X2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

		Disease/Gold Std		Sensitivity = a / a+c
		Positive	Negative	Specificity = d / b+d
Test Result	Positive	a <i>True Positive</i>	b <i>False Positive</i>	Positive Predictive Value – PPV = a / a+b
	Negative	c <i>False Negative</i>	d <i>True Negative</i>	Negative Predictive Value – NPV = c / c+d
	Positive Likelihood Ratio – LR+ = (a/a+c) / (b/b+d) = Sensitivity / (1 – Specificity) Negative Likelihood Ratio – LR– = (b/a+c) / (d/b+d) = (1 – Sensitivity) / Specificity			
Diagnostic Odds Ratio – DOR = ad / bc = LR+ / LR– Test Accuracy = a+d / a+b+c+d Confidence Interval – CI = +/-1.96√CER*(1–CER)+EER*(1–EER) # control pts. # exper. pts.				

DIAGNOSTIC TESTS	Specificity	95% CI*	Sensitivity	95% CI*	PPV	NPV	LR+	95% CI*	LR–	95% CI*	DOR
Test/Symptom 1:											
Test/Symptom 2:											
Test/Symptom 3:											
Test/Symptom 4:											
Test/Symptom 5:											

* CI = Confidence Interval

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