

LEGEND: EVIDENCE APPRAISAL OF A SINGLE STUDY

– **DIAGNOSIS / ASSESSMENT: CONTROLLED CLINICAL TRIAL (CCT)
COHORT (PROSPECTIVE & 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 your clinical question?

Yes No Unknown

• Study Purpose/Objective: _____

• Inclusion Criteria: _____

• Exclusion Criteria: _____

Is a CCT or cohort study congruent with the author's study purpose above?

Yes No Unknown

Comments:

When reading the bolded questions, consider the bulleted questions to help answer the main question.

If you are uncertain of your skills in evidence evaluation, please consult a local evidence expert for assistance:

CCHMC Evidence Experts: <http://groups/ce/NewEBC/EBDMHelp.htm>

Unfamiliar terms can be found in the LEGEND Glossary: <http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf>

VALIDITY: ARE THE RESULTS OF THE CLINICAL TRIAL OR COHORT STUDY VALID OR CREDIBLE?

1. Were data collected prospectively?

Yes No Unknown

Comments:

2. Did the sample include an appropriate variety of patients to whom the index test (e.g., diagnostic test being studied) will be applied in clinical practice?

Yes No Unknown

- Were the selection criteria clearly described?
- Was the reference standard (e.g., gold standard or currently used test) likely to correctly identify the diagnosis in question?
- Did the cohort include both diseased and non-diseased participants?
- Were the clinicians blinded to the participant diagnosis prior to reviewing any test results (i.e., diagnostic uncertainty)?

Comments:

3. Were the patients similar at the start of the trial, with respect to known prognostic factors (demographic and clinical variables)?

Yes No Unknown

Comments:

4. Did patients receive the same reference standard, regardless of the index test?

Yes No Unknown

Comments:

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5. Was the execution of the index test and the reference standard described? Yes No Unknown

- Was the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between tests?

Comments:

6. Were all patients accounted for at the conclusion of the study? Yes No Unknown

- Were withdrawals from the study explained?
- Was the rate of attrition acceptable?

Comments:

7. Was there freedom from conflict of interest? Yes No Unknown

- Sponsor/Funding Agency or Investigators

Comments:

RELIABILITY: ARE THE VALID STUDY RESULTS IMPORTANT?

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

- Was a power analysis described?
- Did the sample size achieve or exceed that resulting from the power analysis?
- Did each subgroup also have sufficient sample size (e.g., at least 6 to 12 participants)?

Comments:

9. What are the main results of the study? (e.g., Helpful data: Page #, Table #, Figures, Graphs)

- What was the effect size?
(e.g., Diagnostic Accuracy – Sensitivity/Specificity, Likelihood Ratios, Limits of Agreement, Patient data to calculate these)
- What were the measures of statistical uncertainty (e.g., precision)?
(Were the results presented with Confidence Intervals or Standard Deviations?)

10. Were the index test results and the reference standard results interpreted independently (without knowledge of the results of the other test, blinded)? Yes No Unknown

Comments:

11. 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:

12. Were all test results reported, including uninterpretable / intermediate test results? Yes No Unknown

Comments:

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

13. Can the results be applied to my population of interest? Yes No Unknown

- Is the diagnostic test feasible in my care setting?
- Is the setting of the study applicable to my population of interest?
- Are the likely benefits worth the potential harm and costs?
- Were the patients in this study similar to my population of interest?

Comments:

14. Are my patient's and family's values and preferences satisfied by the use of the diagnostic test? Yes No Unknown

Comments:

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

Comments:

ADDITIONAL COMMENTS OR CONCLUSIONS (“TAKE-HOME POINTS”): _____

QUALITY LEVEL / EVIDENCE LEVEL

- 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.
- Consider an “Unknown” answer to one or more questions as a similar limitation to answering “No,” if the information is not available in the article

- THE EVIDENCE LEVEL IS:**
- Good Quality CCT / Cohort-Prospective** (2a)
 - Lesser Quality CCT / Cohort-Prospective** (2b)
 - Good Quality Cohort-Retrospective** (3a)
 - Lesser Quality Cohort-Retrospective** (3b)
 - Not Valid, Reliable, or Applicable**

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