Cincinnati Children's

Project/Topic of your Clinical Question: _____

Reviewer: _____ **Today's Date:** _____ **Final Evidence Level:** _____

Article Title: _____

Year: _____ **First Author:** _____ **Journal:** _____

Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question?   ☐ Yes ☐ No ☐ Unknown

- Study Aim/Purpose/Objectives:

- Inclusion Criteria:

- Exclusion Criteria:

Is a cross-sectional study congruent with the author's study aim/purpose/objectives 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

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VALIDITY: ARE THE RESULTS OF THE CROSS-SECTIONAL STUDY VALID OR CREDIBLE?

1. **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:

2. **Were the study methods appropriate for the question?**   ☐ Yes ☐ No ☐ Unknown
   - Were the data collected at one point in time?
   - Were the study methods clearly described _(e.g., setting, sample population)_?
   - Was the execution of the index test described in sufficient detail to permit replication of the test?
   - Was the execution of the reference standard described in sufficient detail to permit replication of the test?
   Comments:

3. **Were all appropriate variables** *(e.g., potential confounders, predictors)* **clearly described?** ☐ Yes ☐ No ☐ Unknown
   Comments:

4. **Was there an independent, blind comparison with a reference standard?** ☐ Yes ☐ No ☐ Unknown
   - Did all participants receive verification of diagnosis using the same reference standard, regardless of the index test result?
   Comments:

5. **Were the index test and reference standard tested simultaneously or in a short period of time, such that you are reasonably sure that the target condition did not change between tests?** ☐ Yes ☐ No ☐ Unknown
   Comments:

6. **Were all participants 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 THESE VALID STUDY RESULTS IMPORTANT?

8. **Were the statistical analysis methods appropriate?** ☐ Yes ☐ No ☐ Unknown
   - Were the statistical analysis methods clearly described?
   Comments:

9. **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:

10. 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?)

11. 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:

12. 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:

13. Were all test results reported, including uninterpretable or intermediate test results? ☐ Yes ☐ No ☐ Unknown
Comments:

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

14. 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:

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

16. 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 Cross-Sectional Study** [4a]
☐ **Lesser Quality Cross-Sectional Study** [4b]

☐ **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** **1b**	**2a** **2b**	**2a** **2b**	**3a** **3b**	**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.