

LEGEND: Evidence Appraisal of a Single Study

Diagnosis, Assessment

Cross-Sectional Study



Reviewer:

Today's Date:

Final Evidence Level:

Project/Topic of your Clinical Question:

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, or objectives above?

☐ Yes ☐ No ☐ Unknown

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](#)

Unfamiliar terms can be found in the [LEGEND Glossary](#).

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 to 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)?

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?

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

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?

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

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?

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

- Sponsors, Funding Agency, Investigators

Comments on Study Validity:

Reliability

Are these valid study results important?

8. **Were the statistical analysis methods appropriate?** ☐ Yes ☐ No ☐ Unknown

- Were the statistical analysis methods clearly described?

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9. Did the study have a sufficiently large sample size? ☐ Yes ☐ No ☐ Unknown
- Was the 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)?

10. What were 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, blinded)? ☐ Yes ☐ No ☐ Unknown
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
13. Were all test results reported, including uninterpretable or intermediate test results? ☐ Yes ☐ No ☐ Unknown

Comments on Study Reliability:

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?
 - Are the patients in this study similar to my population of interest?
15. Are my patient's and family's values and preferences satisfied by the use of the diagnostic test? ☐ Yes ☐ No ☐ Unknown
16. Would you include this study/article in development of a care recommendation? ☐ Yes ☐ No ☐ Unknown

Comments on Study Applicability:

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

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Table of Evidence Levels														
DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN													
	Systematic Review Meta-Analysis	CCT *	Psychometric Study	Cohort – Prospective	Cohort – Retrospective	Cross – Sectional	Descriptive Study Epidemiology Case Series	Mixed Methods Study	Decision Analysis Economic Analysis Computer Simulation	Guidelines	Case Reports N-of-1 Study	Bench Study	Published Expert Opinion	Local Consensus Published Abstracts
Diagnosis / Assessment	1a 1b	2a 2b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b	5a 5b	5

* 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. 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.
8. Clark, E., Burkett, K., & Stanko-Lopp, D. (2009, Dec). Let Evidence Guide Every New Decision (LEGEND): an evidence evaluation system for point-of-care clinicians and guideline development teams [CCHMC LEGEND development]. *J Eval Clin Pract*, 15(6), 1054-1060.