

# LEGEND: Evidence Appraisal of a Single Study

## Diagnosis, Assessment

### Controlled Clinical Trial (CCT) or Cohort Study (Prospective or Retrospective)



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 CCT or cohort 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 Clinical Trial or Cohort Study valid or credible?*

- |    |   |                              |                             |                                  |
|----|---|------------------------------|-----------------------------|----------------------------------|
| 1. | <b>Were the data collected prospectively?</b>   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 2. | <b>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?</b> <ul style="list-style-type: none"><li>• Were the selection criteria clearly described?</li><li>• Was the reference standard (e.g., gold standard or currently used test) likely to correctly identify the diagnosis in question?</li><li>• Did the cohort include both diseased and non-diseased participants?</li><li>• Were the clinicians blinded to the participant diagnosis prior to reviewing any test results (i.e., diagnostic uncertainty)?</li></ul> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 3. | <b>Were the patients similar at the start of the trial, with respect to known prognostic factors (i.e., demographic and clinical variables)?</b>  | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 4. | <b>Did patients receive the same reference standard, regardless of the index test (diagnostic test being studied)?</b>  | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 5. | <b>Was the execution of the index test and the reference standard described?</b> <ul style="list-style-type: none"><li>• Was the time period between reference standard and diagnostic test being studied short enough to be reasonably sure that the target condition did not change between tests?</li></ul>  | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 6. | <b>Were all patients accounted for at the conclusion of the study?</b> <ul style="list-style-type: none"><li>• Were withdrawals from the study explained?</li><li>• Was the rate of attrition acceptable?</li></ul>   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
| 7. | <b>Was there freedom from conflict of interest?</b> <ul style="list-style-type: none"><li>• Sponsors, Funding Agency, Investigators</li></ul>   | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |

Comments on Study Validity:

## Reliability

*Are these valid study results important?*

- |    |   |                              |                             |                                  |
|----|---|------------------------------|-----------------------------|----------------------------------|
| 8. | <b>Did the study have a sufficiently large sample size?</b> <ul style="list-style-type: none"><li>• Was there a power analysis?</li><li>• Did the sample size achieve or exceed that resulting from the power analysis?</li><li>• Did each subgroup also have sufficient sample size (e.g., at least 6 to 12 participants)?</li></ul> | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> Unknown |
|----|---|------------------------------|-----------------------------|----------------------------------|

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9. **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?)

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
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
12. **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?*

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?
  - Are the patients in this study similar to my population of interest?
14. **Are my patient's and family's values and preferences satisfied by the use of the diagnostic test?** ☐ Yes ☐ No ☐ Unknown
15. **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 CCT** [2a]
- ☐ **Lesser Quality CCT** [2b]
- ☐ **Good Quality Cohort – Prospective** [3a]
- ☐ **Lesser Quality Cohort – Prospective** [3b]
- ☐ **Good Quality Cohort – Retrospective** [4a]
- ☐ **Lesser Quality Cohort – Retrospective** [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.