LEGEND: Evidence Appraisal of a Single Study
Diagnosis, Assessment
Systematic Review / Meta-Analysis

Cincinnati Children's
changing the outcome together

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:

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 systematic review or meta-analysis valid?*

1.	**Did the overview address a focused clinical question?**	☐ Yes	☐ No	☐ Unknown
2.	**Was the search for relevant studies detailed and exhaustive?**	☐ Yes	☐ No	☐ Unknown
	• Were the selection criteria clearly described?			
	• Was it *unlikely* that important, relevant studies were missed?			
3.	**Was the quality of the included studies appraised?**	☐ Yes	☐ No	☐ Unknown
4.	**Were the methods consistent from study to study?**	☐ Yes	☐ No	☐ Unknown
	• Did the sample include an appropriate variety of patients to whom the diagnostic test will be applied in clinical practice?			
	• Did the clinicians know the participant diagnosis prior to reviewing any test results *(i.e., diagnostic uncertainty)*?			
	• Were the index tests *(e.g., test being studied)* and reference standards *(e.g., gold standard or currently used test)* described?			
	• Were withdrawals from the studies described?			
5.	**Did studies use independent, blind comparisons with reference standard tests** *(without knowledge of the results of the other test)***?**	☐ Yes	☐ No	☐ Unknown
	• Were the reference standards likely to correctly classify the target condition?			
	• Did all studies include verification of diagnosis using a reference standard?			
6.	**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?*

7.	**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
8.	**Were all test results reported, including uninterpretable or intermediate test results?**	☐ Yes	☐ No	☐ Unknown
9.	**What were the main results of the systematic review/meta-analysis?** *(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 results statistically significant?**	☐ Yes	☐ No	☐ Unknown
11.	**Were the results clinically significant?**	☐ Yes	☐ No	☐ Unknown
	• If potential confounders were identified, were they discussed in relationship to the results?			

Comments on Study Reliability:

Applicability   *Can I apply these valid, important study results to my patients?*

12.	**Can the results be applied to my population of interest?**	☐ Yes	☐ No	☐ Unknown
	• Is the diagnostic test feasible in my care setting?			
	• Are the likely benefits worth the potential harm and costs?			
	• Are the patients in this study similar to my population of interest?			
13.	**Are my patient's and family's values and preferences satisfied by the use of this diagnostic test?**	☐ Yes	☐ No	☐ Unknown
14.	**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 Systematic Review**   [**1a**]
☐ **Lesser Quality Systematic Review**   [**1b**]

☐ **Not Valid, Reliable, or Applicable**

Table of Evidence Levels														
	TYPE OF STUDY / STUDY DESIGN													
DOMAIN OF CLINICAL QUESTION	**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

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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. 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.