### Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question?

- **Study Aim/Purpose/Objectives:**
  - Yes
  - No
  - Unknown

- **Inclusion Criteria:**
  - Yes
  - No
  - Unknown

- **Exclusion Criteria:**
  - 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:** [http://groups/ce/NewEBC/EBDMHelp.htm](http://groups/ce/NewEBC/EBDMHelp.htm)
- **Unfamiliar terms can be found in the LEGEND Glossary:** [http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf](http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf)

### VALIDITY: ARE THE RESULTS OF THE SYSTEMATIC REVIEW / META-ANALYSIS VALID OR CREDIBLE?

#### 1. Did the overview address a focused clinical question?

- **Comments:**

- **Yes**
- **No**
- **Unknown**

#### 2. Was the search for relevant studies detailed and exhaustive?

- **Were the selection criteria clearly described?**
- **Was it unlikely that important, relevant studies were missed?**

- **Comments:**

- **Yes**
- **No**
- **Unknown**

#### 3. Was the quality of the included studies appraised?

- **Comments:**

- **Yes**
- **No**
- **Unknown**

#### 4. Were the methods consistent from study to study?

- **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?**

- **Comments:**

- **Yes**
- **No**
- **Unknown**
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?
   Comments:
   • Did all studies include verification of diagnosis using a reference standard?

6. Was there freedom from conflict of interest?
   ☐ Yes ☐ No ☐ Unknown
   • Sponsor/Funding Agency or Investigators
   Comments:

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
   Comments:

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

11. Were the results clinically significant?
    ☐ Yes ☐ No ☐ Unknown
    • If potential confounders were identified, were they discussed in relationship to the results?
    Comments:
APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

12. Can the results be applied to my population of interest?  
   • Is the diagnostic test feasible in my care setting?  
   • Are the likely benefits worth the potential harm and costs?  
   • Were the patients in this study similar to my population of interest?  
   □ Yes  □ No  □ Unknown  
   Comments:  

13. Are my patient’s and family’s values and preferences satisfied by the use of the diagnostic test?  
   □ Yes  □ No  □ Unknown  
   Comments:  

14. 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 Systematic Review  [1a]
- [ ] Lesser Quality Systematic Review  [1b]
- [ ] Not Valid, Reliable, or Applicable

### Table of Evidence Levels

<table>
<thead>
<tr>
<th>TYPE OF STUDY / STUDY DESIGN</th>
<th>DOMAIN OF CLINICAL QUESTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic Review</td>
<td>Diagnosis / Assessment</td>
</tr>
<tr>
<td>Meta-Analysis</td>
<td>1a</td>
</tr>
<tr>
<td>Psychometric Study</td>
<td>2a</td>
</tr>
<tr>
<td>Cohort – Prospective</td>
<td>3a</td>
</tr>
<tr>
<td>Cohort – Retrospective</td>
<td>4a</td>
</tr>
<tr>
<td>Descriptive Study</td>
<td>2/3/4</td>
</tr>
<tr>
<td>Epidemiology Case Series</td>
<td>2/3/4</td>
</tr>
<tr>
<td>Mixed Methods Study</td>
<td>1a</td>
</tr>
<tr>
<td>Decision Analysis</td>
<td>Case Reports</td>
</tr>
<tr>
<td>Economic Analysis</td>
<td>N-of-1 Study</td>
</tr>
<tr>
<td>Computer Simulation</td>
<td>Bench Study</td>
</tr>
<tr>
<td>Guidelines</td>
<td>Published Literature</td>
</tr>
<tr>
<td>Case Reports</td>
<td>Published Abstracts</td>
</tr>
<tr>
<td>N-of-1 Study</td>
<td>Local Consensus</td>
</tr>
<tr>
<td>Bench Study</td>
<td>Published Abstracts</td>
</tr>
<tr>
<td>Published Literature</td>
<td>Published Abstracts</td>
</tr>
<tr>
<td>Local Consensus</td>
<td>Published Abstracts</td>
</tr>
</tbody>
</table>

* *CCT = Controlled Clinical Trial*

Development for this appraisal form is based on: