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?  

- Study Aim/Purpose/Objectives:  
- Inclusion Criteria:  
- Exclusion Criteria:  

Is a RCT or CCT congruent with the author’s study aim/purpose/objectives above?  
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](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 RCT OR CCT VALID OR CREDIBLE?

1. Were patients randomly assigned to treatment and control groups?  
   
   **Note:** If the study was not randomized, it should be assigned a level for a CCT.  
   Comments:

2. Was that randomization conducted appropriately?  
   - Was the randomization concealed from those responsible for recruiting subjects?  
   - Were patients, parents, clinicians, and analysts masked to which treatment was being received?  
   Comments:

3. Were the groups similar at the start of the trial, with respect to known prognostic factors (i.e., demographic and clinical variables)?  
   Comments:

4. Aside from the experimental treatment, were the groups treated equally?  
   Comments:
5. Were all patients who entered the trial accounted for at its conclusion?  
   - Was there a low rate of attrition?  
     \[ \text{Note: If greater than 20\% lost to follow up, bias may be of greater concern.} \]  
     \[ \text{Comments:} \]

6. Were patients accounted for (and analyzed) in the groups to which they were randomized (i.e., intention-to-treat analysis)?  
   \[ \text{Comments:} \]

7. Was the study process long enough to fully study effects of the intervention?  
   \[ \text{Comments:} \]

8. Were instruments used to measure the outcomes valid and reliable?  
   \[ \text{Comments:} \]

9. Was there freedom from conflict of interest?  
   - Sponsor/Funding Agency or Investigators  
     \[ \text{Comments:} \]

**Reliability: Are these valid study results important?**

10. Did the study have a sufficiently large sample size?  
    - Was there a power analysis?  
    - 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)?  
     \[ \text{Comments:} \]

11. What were the main results of the RCT or CCT? (e.g., Helpful data: Page #, Table #, Figures, Graphs)  
    - What was the effect size? (How large was the treatment effect?)  
    - What were the measures of statistical uncertainty (e.g., precision)? (Were the results presented with Confidence Intervals or Standard Deviations?)

12. Were the results statistically significant?  
    \[ \text{Comments:} \]
13. Were the results clinically significant?  □ Yes  □ No  □ Unknown
   • If potential confounders were identified, were they discussed in relationship to the results?

Comments:

14. Were adverse events assessed?  □ Yes  □ No  □ Unknown

Comments:

<table>
<thead>
<tr>
<th>APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?</th>
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<tbody>
<tr>
<td>15. Can the results be applied to my population of interest?  □ Yes  □ No  □ Unknown</td>
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</table>
   • Is the treatment feasible in my care setting?
   • Do the patient outcomes apply to my population or question 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:

16. Are my patient’s and family’s values and preferences satisfied by the treatment and its consequences?  □ Yes  □ No  □ Unknown

Comments:

17. Would you include this study/article in development of a care recommendation?  □ Yes  □ No  □ Unknown

Comments:

<table>
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<tr>
<th>ADDITIONAL COMMENTS OR CONCLUSIONS (“TAKE-HOME POINTS”):</th>
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**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 RCT [2a]
- [ ] Lesser Quality RCT [2b]
- [ ] Good Quality CCT [3a]
- [ ] Lesser Quality CCT [3b]
- [ ] Not Valid, Reliable, or Applicable

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### Table of Evidence Levels

<table>
<thead>
<tr>
<th>DOMAIN OF CLINICAL QUESTION</th>
<th>TYPE OF STUDY / STUDY DESIGN</th>
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<tbody>
<tr>
<td></td>
<td>Systematic Review</td>
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<tr>
<td>Intervention</td>
<td>Treatment, Therapy, Prevention, Harm, Quality Improvement</td>
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</tbody>
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*RCT = Randomized Controlled Trial; CCT = Controlled Clinical Trial

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Development for this appraisal form is based on: