### Project/Topic of your Clinical Question:

**Reviewer:**

**Today’s Date:**

**Final Evidence Level:**

**Article Title:**

**Year:**

**First Author:**

**Journal:**

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<table>
<thead>
<tr>
<th><strong>Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question?</strong></th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
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- **Study Aim/Purpose/Objectives:**

- **Inclusion Criteria:**

- **Exclusion Criteria:**

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**Is a QI study design congruent with the author’s study aim/purpose/objectives above?**

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

- **Is the need for the improvement clearly described?**

**Comments:**

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**VALIDITY: ARE THE RESULTS OF THE QUALITY IMPROVEMENT STUDY VALID OR CREDIBLE?**

1. **Was an improvement method clearly identified?**

   - **What was the improvement method?**
     - PDSA
     - CQI
     - Six Sigma
     - FADE
     - TQM
     - Other:

   **Comments:**

2. **Is the need for improvement clearly described?**

   - **Was the current state of the process discussed?**
   - **Was the intended impact of improvement predicted and outlined?**

   **Comments:**

3. **Were the stakeholders and organizational culture clearly described and appropriate?**

   - **Were the stakeholders involved in decisions to make changes?**
     - *e.g., champions, supporters, early adopters, clinicians, care givers, patients, process owners*

   **Comments:**

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**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)
4. Are the study methods clearly described and appropriate for the aim/purpose/objectives?
   - Is the setting clearly described and appropriate (e.g., unit, clinic)?
   - Are the participants (e.g., clinicians, patients, groups) clearly described and appropriate?
   - Is(Are) the improvement intervention(s) clearly described and appropriate?
   - Is the aim specific, measurable, actionable, relevant, time bound (i.e., SMART)?

Comments:

5. Was(Were) the planned improvement intervention(s) (i.e., action plans) described in enough detail to be replicated by others?

Comments:

6. Were the planned improvement interventions based on evidence?
   - Which source(s) of evidence contributed to the choice of specific improvement interventions?
     - Published Research
     - Published QI Reports
     - Key Driver Analysis (local data)
     - Pareto Analysis (local data)
     - Failure Mode and Effects Analysis (analysis of causes of dysfunction)
     - Other:

Comments:

7. Were appropriate baseline data collected and reported for the outcome of interest?
   - Did the baseline data indicate the need for improvement?
   - Were valid and reliable tools used for measurement of the outcomes?

Comments:

8. Was outcome data collection planned and appropriate to evaluate whether the change resulted in an improvement?
   - Was the plan for data collection of improvement intervention measurement clearly described?
   - Were appropriate valid and reliable tools used for measurement of the improvement interventions and outcomes?
   - Was each improvement intervention tested to determine its unique influence? (e.g., turned on and turned off)

Comments:
9. If adaptations/modifications were made to the planned improvement intervention, were they appropriately based on outcome data from small tests of change or pilot studies?
   - Yes
   - No
   - Unknown

   • Were small tests of change or pilot studies conducted with more than one unit, setting, or persons (e.g., cycle, ramping up)?
   • Was the magnitude of testing appropriate prior to implementation of the final improvement intervention?

   Comments:

10. Were modified improvement interventions (i.e., the future state of the process) described in enough detail to be replicated by others?
    - Yes
    - No
    - Unknown

    Comments:

11. Was all outcome data for the improvement intervention(s) collected in the same way as the baseline data?
    - Yes
    - No
    - Unknown

    Comments:

12. Was there freedom from conflict of interest?
    - Yes
    - No
    - Unknown

    • Sponsor/Funding Agency or Investigators
    Comments:

**RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?**

13. Were the statistical analysis methods appropriate?
    - Yes
    - No
    - Unknown

    • What was the unit of analysis (e.g., clinician, clinician group, care area, process, etc.)?
    • What was measured?
    • Were the statistical analysis methods clearly described?
    • If multiple improvement interventions were used, was statistical analysis conducted on each intervention?

    Comments:

14. What are the main results of the study? (e.g., Helpful data: Page #, Table #, Figures, Graphs)

    • Were results of the small tests of change or pilot studies reported?
    • How large was the main improvement intervention effect? (e.g., strength of association between changes in outcomes and planned improvement interventions, decreased variability)
    • What were the measures of statistical uncertainty (e.g., precision)? (Were the results presented with Confidence Intervals or Standard Deviations?)

Comments:
15. Were the results statistically significant?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

16. Were the results clinically significant?  
   - If potential confounders were identified, were they discussed in relationship to the results?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

17. Were the lessons learned discussed?  
   - Were benefits/harms, costs, unexpected results, problems, or failures reported or discussed?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

18. Were the successful improvement interventions implemented with other clinicians or care groups (i.e., spread)?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

19. Were the improvement interventions studied over a period of time long enough to determine sustainability (e.g., long term effects, attrition, institutionalization)?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

**Applicability: Can I apply this Case Report Information?**

20. Can the results be applied to my improvement issue of interest?  
   - Is the improvement intervention exportable to my site?  
     (Are the setting, participants, and variables of interest similar to those at my site?)  
   - Were all patient-important and other appropriate outcomes considered?  
   - Are the likely benefits worth identified burdens, risks of harm, and costs?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

21. Are my patient’s and family’s values and preferences satisfied by the knowledge gained from this study?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown

22. Would you include this study/article in development of a recommendation?  
   Comments:  
   [ ] Yes  [ ] No  [ ] Unknown
### 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 – Quality Improvement Study [4a]
- [ ] Lesser Quality – Quality Improvement Study [4b]
- [ ] Not Valid, Reliable, or Applicable

### Table of Evidence Levels

| Domain of Clinical Question | Systematic Review | Meta-Analysis | RCT | CCT | Qualitative Study | Cohort – Prospective | Cohort – Retrospective | Case Control | Longitudinal (Before/After, Time-Series) | Cross – Sectional | Descriptive Study | Case Series | Quality Improvement | 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 |
|----------------------------|-------------------|---------------|-----|-----|-------------------|----------------------|----------------------|--------------|----------------------------------------|-------------------|-------------------|-------------|-------------------|---------------------|-----------------|-----------------|-------------------|-------------|--------------|---------------|-------------|---------------|-----------------|-----------------|------------------|
| Intervention               |                   |               |     |     |                   |                      |                      |              |                                        |                   |                   |              |                   |                     |                 |                 |                   |              |              |                |              |                |                |
| Treatment, Therapy, Prevention, Harm, Quality Improvement | 1a     | 2a     | 3a   | 4a   | 3a   | 4a   | 4a   | 4a | 4a | 4a | 4a | 4a | 4a | 2/3/4 | 5a | 5b | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a | 5a |

*RCT = Randomized Controlled Trial; CCT = Controlled Clinical Trial

Development for this appraisal form is based on: