LEGEND: Evidence Appraisal of a Single Study
Intervention
Quality Improvement (QI) Study

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 QI study design 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 Quality Improvement Study valid or credible?

1. Was an improvement method clearly identified? ☐ Yes ☐ No ☐ Unknown

- What was the improvement method?

☐ PDSA ☐ FADE
☐ CQI ☐ TQM
☐ Six Sigma ☐ Other:

2. Is the need for improvement clearly described? ☐ Yes ☐ No ☐ Unknown

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

3. Were the stakeholders and organizational culture clearly described and appropriate? ☐ Yes ☐ No ☐ Unknown

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

4. Are the study methods clearly described and appropriate for the aim, purpose, or objectives? ☐ Yes ☐ No ☐ Unknown

- 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)*?

5. Was *(Were)* all planned improvement intervention*(s)* *(i.e., action plans)* described in enough detail to be replicated by others? ☐ Yes ☐ No ☐ Unknown

6. Were the planned improvement interventions based on evidence? ☐ Yes ☐ No ☐ Unknown

- 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:

7. Were appropriate baseline data collected and reported for the outcome of interest? ☐ Yes ☐ No ☐ Unknown

- Did the baseline data indicate the need for improvement?
- Were valid and reliable tools used for measurement of the outcomes?

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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 off)*?	☐ **Yes**	☐ **No**	☐ **Unknown**
9.	**If adaptation/modifications were made to the planned improvement intervention, were they appropriately based on outcome data from small tests of change or pilot studies?** • Were small tests of change or pilot studies conducted with more than one unit, setting, or persons *(e.g., turned on and off)*? • Was the magnitude of testing appropriate prior to implementation of the final improvement intervention?	☐ **Yes**	☐ **No**	☐ **Unknown**
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**
11.	**Was all outcome data for the improvement intervention***(s)* **collected in the same way as the baseline data?**	☐ **Yes**	☐ **No**	☐ **Unknown**
12.	**Was there freedom from conflict of interest?** • Sponsors, Funding Agency, Investigators	☐ **Yes**	☐ **No**	☐ **Unknown**

Comments on Study Validity:

Reliability

Are these valid study results important?

13.	**Were the statistical analysis methods appropriate?** • 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?	☐ **Yes**	☐ **No**	☐ **Unknown**
14.	**What were 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?)*			
15.	**Were the results statistically significant?**	☐ **Yes**	☐ **No**	☐ **Unknown**
16.	**Were the results clinically significant?** • If potential confounders were identified, were they discussed in relationship to the results?	☐ **Yes**	☐ **No**	☐ **Unknown**
17.	**Were the lessons learned discussed?** • Were benefits/harms, costs, unexpected results, problems, or failures reported or discussed?	☐ **Yes**	☐ **No**	☐ **Unknown**
18.	**Were the successful improvement interventions implemented with other clinicians or care groups** *(i.e., spread)***?**	☐ **Yes**	☐ **No**	☐ **Unknown**
19.	**Were the improvement interventions studied over a period of time long enough to determine sustainability?**	☐ **Yes**	☐ **No**	☐ **Unknown**

Comments on Study Reliability:

Applicability

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

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?	☐ **Yes**	☐ **No**	☐ **Unknown**

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21.	**Are my patient's and family's values and preferences satisfied by the knowledge gained from this study?**	☐ **Yes**	☐ **No**	☐ **Unknown**
22.	**Would you include this study/article in development of a 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 – Quality Improvement Study** [**4a**]
☐ **Lesser Quality – Quality Improvement Study** [**4b**]
☐ **Not Valid, Reliable, or Applicable**

Table of Evidence Levels

DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN																	
	Systematic Review Meta–Analysis	RCT [+]	CCT [+]	Qualitative Study	Cohort – Prospective	Cohort – Retrospective	Case – Control	Longitudinal *(Before/After, Time Series)*	Cross – Sectional	Descriptive Study Epidemiology Case Series	Quality Improvement *(PDSA)*	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 1b**	**2a 2b**	**3a 3b**	**4a 4b**	**3a 3b**	**4a 4b**	**4a 4b**	**4a 4b**	**4a 4b**	**4a 4b**	**4a 4b**	**2/3/4 a/b**	**5a 5b**	**5a 5b**	**5a 5b**	**5a 5b**	**5a 5b**	**5**

[+] *RCT = Randomized Controlled Trial; CCT = Controlled Clinical Trial*

Development for this appraisal form is based on:

1. Fan, E., Laupacis, A., Pronovost, P.J., et al.: How to use an article about Quality Improvement. *JAMA*, 304(20): 2279-87, 2010.
2. Ogrinc, G., et al: The SQUIRE (Standards for QUality Improvement Reporting Excellence) guidelines for quality improvement reporting: explanation and elaboration. *Qual Saf Health Care,* 17(Suppl I):i13-i32. doi:10.1136/qshc.2008.029058, 2008.
3. 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
4. Melnyk, B. M. and E. Fineout-Overholt (2005). Evidence-based practice in nursing & healthcare : a guide to best practice. Philadelphia, Lippincott Williams & Wilkins.
5. 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.
6. Fineout-Overholt, E. and L. Johnston (2005). "Teaching EBP: asking searchable, answerable clinical questions." Worldviews Evid Based Nurs 2(3): 157-60.
7. 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.
8. 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.
9. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs,* 2(3): 157-60, 2005.
10. 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.