LEGEND: Evidence Appraisal of a Single Study

All Domains

Descriptive Study, Epidemiologic Study, Case Series

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 descriptive, epidemiologic, or case series study 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 study valid?

1.	**Were study methods appropriate for the question?** • Were the study methods clearly described? *(e.g., setting, sample population, instruments, intervention, etc.)*	☐ Yes	☐ No	☐ Unknown
2.	**Were valid and reliable instruments/methods used to measure the outcomes?** • Was evidence provided to support the validity and reliability?	☐ Yes	☐ No	☐ Unknown
3.	**Were all appropriate variables** *(e.g., potential confounders, exposures, predictors)* **clearly described?**	☐ Yes	☐ No	☐ Unknown
4.	**Were all appropriate outcomes clearly described?**	☐ Yes	☐ No	☐ Unknown
5.	**Were all participants accounted for at the conclusion of the study?** • Were withdrawals from the study explained? • Was the rate of attrition acceptable?	☐ Yes	☐ No	☐ Unknown
6.	**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?

7.	**Were the statistical analysis methods clearly described and appropriate?**	☐ Yes	☐ No	☐ Unknown
8.	**Did the study have a sufficiently large sample size?** • Was there a sufficient response rate? • Was a power analysis described? • 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)*?	☐ Yes	☐ No	☐ Unknown
9.	**What were the main results of the study?** *(e.g., Helpful data: Page #, Table #, Figures, Graphs)* • What were the measures of statistical uncertainty *(e.g., precision)*? *(Were the results presented with Confidence Intervals or Standard Deviations?)*			

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10.	**Were the results statistically significant?**	☐ **Yes**	☐ **No**	☐ **Unknown**
11.	**Were the results clinically significant?**	☐ **Yes**	☐ **No**	☐ **Unknown**
12.	**Were any adverse events, safety concerns, or risks/benefits appropriately described?**	☐ **Yes**	☐ **No**	☐ **Unknown**

Comments on Study Reliability:

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

13.	**Can the results be applied to my population of interest?** • 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?	☐ **Yes**	☐ **No**	☐ **Unknown**
14.	**Are my patient's and family's values and preferences satisfied by the knowledge gained from this study** *(such as outcomes considered)***?**	☐ **Yes**	☐ **No**	☐ **Unknown**
13.	**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 Descriptive/Epidemiologic Study** [**4a**]
☐ **Lesser Quality Descriptive/Epidemiologic Study** [**4b**]
☐ **Not Valid, Reliable, or Applicable**

Table of Evidence Levels

DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN																			
	Systematic Review Meta–Analysis	Meta-Synthesis	RCT*	CCT*	Qualitative Study	Psychometric Study	Cohort – Prospective	Cohort – Retrospective	Case – Control	Longitudinal (Before/After, Time Series)	Cross – Sectional	Descriptive Study Epidemiologic 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
All Domains	**1a 1b**											**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

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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. 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.
5. 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.
6. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs,* 2(3): 157-60, 2005.
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.