LEGEND: Evidence Appraisal of a Single Study orvention In

Cincinnati

Unknown

Unknown

Unknown

| Inter | vention Nort Study - Prospective or Retrospective | | changi | ng the outc | | | | |
|----------------------|--|---------------------------------|----------------------|-------------|--|--|--|--|
| Rev Pro | viewer: Today's Date: ject/Topic of your Clinical Question: | Final | Final Evidence Level | | | | | |
| Yea | r: First Author: | Journal: | | | | | | |
| Do th answ • S | ne study aim/purpose/objectives and inclusion/exclusion criteria assist in vering your clinical question? Study Aim/Purpose/Objectives: | □ Yes | 🗆 No | 🗆 Un | | | | |
| • Ir | nclusion Criteria: | | | | | | | |
| • E | xclusion Criteria: | | | | | | | |
| ls a c abov | cohort study congruent with the author's study aim, purpose, or objectives /e? | S □ Yes | 🗆 No | 🗆 Un | | | | |
| Whe If you | n reading the bolded questions, consider the bulleted questions to help answer to u are uncertain of your skills in evidence evaluation, please consult a local evide <u>CCHMC Evidence Experts</u> | the main ques nce expert for | tion. assistanc | ce: | | | | |
| Unfa | miliar terms can be found in the <u>LEGEND Glossary</u> . | | | | | | | |
| val | Are the results of the Cohort Study valid? | | | | | | | |
| 1. | Were the study methods appropriate for the question? Were the study methods clearly described (e.g., setting, sample population)? Were the instruments clearly described? Were the interventions clearly described? | □ Yes | □ No | 🗆 Ur | | | | |
| 2. | Were the participants recruited prospectively with a comparison group? Note: If no comparison group was studied, consider using the Longitudinal Appraisal Form. | □ Yes | □ No | 🗆 Ur | | | | |
| 3. | Were instruments used to measure the outcomes valid and reliable?Were the instruments tested to be valid and reliable? | □ Yes | 🗆 No | 🗆 Ur | | | | |
| 4. | Were all appropriate variables (e.g., potential confounders, exposures, predictors and interventions clearly described? |) 🗆 Yes | □ No | 🗆 Ur | | | | |
| 5. | Were all appropriate outcomes clearly described? | □ Yes | □ No | 🗆 Ur | | | | |
| 6. | Was the follow-up process described and complete? | □ Yes | □ No | 🗆 Ur | | | | |

Unknown • Was the follow-up long enough to fully study the effects of the intervention? • Was there a low rate of attrition? Note: If greater than 20% lost to follow up, bias may be of greater concern. 7. Was there freedom from conflict of interest? □ Yes 🗆 No Unknown • Sponsors, Funding Agency, Investigators

Comments on Study Validity:

| Reliability | | Are these valid study results important? | | | | | | | |
|-------------|---|--|-------|------|-----------|--|--|--|--|
| 8. | Were the statistical ana | ysis methods appropriate? | □ Yes | 🗆 No | 🗆 Unknown | | | | |
| | Were the statistical analys | is methods clearly described? | | | | | | | |
| 9. | Did the study have a su | fficiently large sample size? | 🗆 Yes | 🗆 No | 🗆 Unknown | | | | |
| | Was a power analysis des | cribed? | | | | | | | |
| | • Did the sample size achie | | | | | | | | |
| | Did each subgroup also have | | | | | | | | |
| | | | | | | | | | |

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LEGEND: Evidence Appraisal of a Single Study Intervention Cohort Study – Prospective or Retrospective



10. What were the main results of the study? (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?) |) |
|--|---|
|--|---|

| 11. | Were the results statistically significant? | □ Yes | 🗆 No | 🗆 Unknown |
|-----|---|-------|------|-----------|
| 12. | Were the results clinically significant? | □ Yes | 🗆 No | 🗆 Unknown |
| | • If potential confounders were identified, were they discussed in relationship to the results? | | | |
| 13. | Were adverse events assessed? | □ Yes | 🗆 No | 🗆 Unknown |
| | | | | |

Comments on Study Reliability:

| Applicability | | Can I apply these valid, important study results to my patients? | | | | | | | | |
|---------------|--|--|-------|------|-----------|--|--|--|--|--|
| 14. | Can the results be ap | plied to my population of interest? | □ Yes | 🗆 No | 🗆 Unknown | | | | | |
| | Is the treatment feasibl | e in my care setting? | | | | | | | | |
| | Do the patient outcome | es apply to my population or question of interest? | | | | | | | | |
| | | | | | | | | | | |

Are the likely benefits worth the potential harm and costs?
Are the patients in this study similar to my population of interest?

| 15. | Are my patient's and family's values and preferences satisfied by the | □ Yes | 🗆 No | 🗆 Unknown |
|-----|---|-------|------|-----------|
| | treatment and its consequences? | | | |
| 16. | Would you include this study/article in development of a care | □ Yes | 🗆 No | 🗆 Unknown |
| | recommendation? | | | |

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 Prospective Cohort Study [3a]
- Lesser Quality Prospective Cohort Study [3b]
- Good Quality Retrospective Cohort Study [4a]
- Lesser Quality Retrospective Cohort Study [4b]
- □ Not Valid, Reliable, or Applicable

LEGEND: Evidence Appraisal of a Single Study



Cohort Study – Prospective or Retrospective

| Table of Evidence Levels | | | | | | | | | | | | | | | | | | |
|--|------------------------------------|----------|----------|-------------------|-------------------------|---------------------------|----------------|---|-------------------|--|-------------------------------|---------------------|---|------------|------------------------------|-------------|-----------------------------|--|
| | TYPE OF STUDY / STUDY DESIGN | | | | | | | | | | | | | | | | | |
| 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 Epidemiology Case Series | Quality Improvement (PDSA) | Mixed Methods Study | Decision Analysis Economic Analysis Computer Simulation | Guidelines | Case Reports N-of-1 Studv | 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:

Intervention

 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.

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

5. 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.

6. 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.

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

 Clark, E., Burkett, K., & Stanko-Lopp, D. (2009, Dec). Let Evidence Guide Every New Decision (LEGEND): an evidence evaluation system for pointof-care clinicians and guideline development teams [CCHMC LEGEND development]. J Eval Clin Pract, 15(6), 1054-1060.