Cincinnati Children's

LEGEND: Evidence Appraisal of a Single Study
Prognosis
Cross–Sectional Study

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? ☐ Yes ☐ No ☐ Unknown

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

Is a cross-sectional study congruent with the author's study aim/purpose/objectives above? ☐ Yes ☐ No ☐ Unknown

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
Unfamiliar terms can be found in the LEGEND Glossary: http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf

VALIDITY: ARE THE RESULTS OF THE CROSS–SECTIONAL STUDY VALID OR CREDIBLE?

1. **Are the study methods clearly described and appropriate for the question?** ☐ Yes ☐ No ☐ Unknown
   - Is the setting clearly described and appropriate?
   - Was there a representative sample of patients at a well-defined point in the course of disease?
   - Is the sample population clearly described and sufficient?
   - Were the participants recruited prospectively?

   Comments:

2. **Were all potentially important prognostic factors assessed?** ☐ Yes ☐ No ☐ Unknown
   - Were the patients sufficiently homogeneous with respect to prognostic risk?
   - Are there subgroups in the sample with very different prognosis compared to other subgroups in the study?

   Comments:

Copyright © 2006-2011 Cincinnati Children's Hospital Medical Center; all rights reserved.

3. Were objective and unbiased outcome criteria used? ☐ Yes ☐ No ☐ Unknown

- Were the outcomes quantifiable and precisely measurable?
- Were instruments used to measure the outcomes tested to be valid and reliable?
- Was the assessment of the outcome made independent of knowledge of prognostic factors?

Comments:

4. Were all participants accounted for at the conclusion of the study? ☐ Yes ☐ No ☐ Unknown

- Were withdrawals from the study explained?
- Was the rate of attrition acceptable?

Comments:

5. Was there freedom from conflict of interest? ☐ Yes ☐ No ☐ Unknown

- Sponsor/Funding Agency or Investigators

Comments:

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

6. Were the statistical analysis methods appropriate? ☐ Yes ☐ No ☐ Unknown

- Were the statistical analysis methods clearly described?
- If subgroups in the sample had different prognostic factors *(e.g., demographics, disease specifics, comorbidity)*, was an adjustment made for the differences between groups?
- Does the prognosis change by age?

Comments:

7. Did the study have a sufficiently large sample size? ☐ Yes ☐ No ☐ Unknown

- 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)*?

Comments:

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

- How likely are the outcomes over time?
  - Absolute results *(e.g., 5 year survival rate)* or Relative results *(e.g., risk from prognostic factor)* or Survival Curves *(e.g., cumulative events)*

Copyright © 2006-2011 Cincinnati Children's Hospital Medical Center; all rights reserved.

- What were the measures of statistical uncertainty *(e.g., precision)*?
  (Were the results presented with Confidence Intervals or Standard Deviations?)

9. Were the results statistically significant? ☐ Yes ☐ No ☐ Unknown

Comments:

10. Were the results clinically significant? ☐ Yes ☐ No ☐ Unknown

- If potential confounders were identified, were they discussed in relationship to the results?

Comments:

APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

11. Can the results be applied to my population of interest? ☐ Yes ☐ No ☐ Unknown

- Is the setting of the study applicable to my population of interest?
- Do the patient outcomes apply to my population or question of interest?
- Were the patients in this study similar to my population of interest?

Comments:

12. 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

Comments:

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

Comments:

ADDITIONAL COMMENTS OR CONCLUSIONS ("TAKE-HOME POINTS"):

Copyright © 2006-2011 Cincinnati Children's Hospital Medical Center; all rights reserved.

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 Cross-Sectional Study** (4a)
☐ **Lesser Quality Cross-Sectional Study** (4b)
☐ **Not Valid, Reliable, or Applicable**

TABLE OF EVIDENCE LEVELS							
	TYPE OF STUDY / STUDY DESIGN						
DOMAIN OF CLINICAL QUESTION	Systematic Review Meta–Analysis	Cohort – Prospective	Cohort – Retrospective	Case – Control	Cross – Sectional	Epidemiology Descriptive Case Series	Expert Opinion Case Reports
Prognosis	1a 1b	2a 2b	3a 3b	4a 4b	4a 4b	4a 4b	5a 5b

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

Copyright © 2006-2011 Cincinnati Children's Hospital Medical Center; all rights reserved.