Cincinnati Children's

LEGEND: Evidence Appraisal of a Single Study
Etiology, Risk Factors, Incidence
Cohort Study (Prospective or Retrospective)

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 cohort 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 COHORT STUDY VALID OR CREDIBLE?

1. **At the start of the study, were the participants similar** *(homogeneous)* **with respect to known factors of interest** *(e.g., demographic, exposure, risk, treatment, or etiology)***?** ☐ Yes ☐ No ☐ Unknown

   Comments:

2. **Were treatments/exposures and clinical outcomes measured in the same way in each group?** ☐ Yes ☐ No ☐ Unknown

   Comments:

3. **Was the assessment of outcomes objective or blinded to factors of interest?** ☐ Yes ☐ No ☐ Unknown

   Comments:

4. **Were participants followed long enough for outcomes to occur?** ☐ Yes ☐ No ☐ Unknown
   - Was the follow-up process clearly described?
   - Was the follow-up process complete?

   Comments:

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5. If the study addresses causation, was there a plausible association between exposure and outcome? ☐ **Yes** ☐ **No** ☐ **Unknown**

- Does the association make biological sense?
- Is it clear that the exposure preceded the onset of the outcome?
- Was the amount of exposure associated with the severity of outcome *(i.e., dose-response)*?
- Was re-exposure associated with the outcome *(i.e., challenge or dechallenge–rechallenge)*?

Comments:

6. 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:

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

- Sponsor/Funding Agency or Investigators

Comments:

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

8. 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:

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

- Were the statistical analysis methods clearly described?
- If subgroups were evaluated, was a statistical adjustment made for the differences?

Comments:

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

- ***Etiology:*** How strong is the association between exposure and outcome?
  (What is the correlation or estimate of risk?)

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- ***Incidence:*** What is the rate?
  (e.g., number per population per year or other time period)

- 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**

Note: *This question may not be applicable in all incidence studies.*

Comments:

12. 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?

13. 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:

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**

Comments:

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

Comments:

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

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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:		Etiology / Risk Factors	Incidence
	☐ **Good Quality *Prospective* Cohort Study**	(2a)	(3a)
	☐ **Lesser Quality *Prospective* Cohort Study**	(2b)	(3b)
	☐ **Good Quality *Retrospective* Cohort Study**	(3a)	(4b)
	☐ **Lesser Quality *Retrospective* Cohort Study**	(3b)	(4b)
	☐ **Not Valid, Reliable, or Applicable**		

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

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

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.

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