APPLYING EVIDENCE-BASED METHODS IN PSYCHIATRY

JOURNAL CLUB: HOW TO READ & CRITIQUE ARTICLES

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SECTION 1
WHAT IS EBM?
According to the most widely quoted definition, EBM is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”

It can also be described as:

- the use of *mathematical estimates*
  - of the *risk of benefit and harm*
  - derived from *high-quality research*
  - on *population samples*

- *to inform clinical decision-making in the diagnosis, investigation, or management of individual patients.*”

EBM involves a paradigm shift

Traditional Paradigm
• Individual clinical experience provides the basis for practice.
• Authority is in proportion to individual experience.

Evidence-Based Paradigm
• Clinicians should guide practice on the basis of replicated studies

The Evidence-Based Paradigm

• Clinicians should use information from systematic, unbiased, and reproducible studies to guide their practice.

• Understanding pathophysiology is necessary but not sufficient.

• Understanding certain rules of evidence is necessary to evaluate and apply medical findings to clinical practice.
Duke University, Introduction to Evidence-Based Practice Tutorial
http://guides.mclibrary.duke.edu/c.php?g=158201&p=1036002
Evidence-Based Medicine Steps

1. Convert problem into an answerable question.
2. Find the best evidence.
3. Critically appraise the evidence for its validity and usefulness.
4. Implement into your practice.
5. Evaluate performance and repeat process, if necessary.

Anatomy of a good clinical question

**PICO** helps determine key components of a well-focused question:

- **P** - Patient/Problem/Population: What is the key problem?
- **I** - Intervention: What treatment or tests are you considering?
- **C** - Comparison: Which alternative treatment or tests are being considered (if any)?
- **O** - Outcome: What is the desired outcome to promote or avoid?
## PICO COMPONENTS

<table>
<thead>
<tr>
<th><strong>Patient/Population/Problem/Program:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Most important characteristics of the patient (primary problem, disease, or co-existing conditions). Sometimes the sex, age or race of a patient might be relevant to the diagnosis or treatment of a disease.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Intervention, prognostic factor, or exposure:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Which main intervention, prognostic factor, or exposure are you considering? What do you want to do for the patient? Prescribe a drug? Order a test? Order surgery? What factor may influence the prognosis of the patient? Age? Co-existing conditions? Has the patient been exposed to something? Asbestos? Cigarette smoke?</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th><strong>Comparison Intervention (If applicable):</strong></th>
</tr>
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<tbody>
<tr>
<td>What is the main alternative being considered to compare with the intervention (placebo, standard therapy, no treatment, gold standard). Your clinical question does not always need a comparison.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Outcome:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>What you hope to accomplish, measure, improve, or affect? Relieve or eliminate the symptoms? Reduce the number of adverse events? Improve function or test scores?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Type of Question:</strong> Etiology, Diagnosis, Therapy, Prognosis, Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Study:</strong> Randomized Controlled Trial, Cohort Study, Longitudinal Study, etc.</td>
</tr>
</tbody>
</table>

Two added components include:
<table>
<thead>
<tr>
<th>Most common type of questions</th>
<th>Type of study/Search Strategy</th>
</tr>
</thead>
</table>
| **Diagnosis**<br>How to select and interpret diagnostic tests | Prospective, blind comparison to a gold standard  
(Search terms: sensitivity and specificity, diagnostic use) |
<p>| <strong>Therapy</strong>&lt;br&gt;How to select treatments that do more good than harm and that are worth the efforts and cost of using them | Randomized Controlled Trial (RCT), Cohort Study, Case Control Study, Case Series |
| <strong>Prognosis</strong>&lt;br&gt;How to estimate the patients likely clinical course over time and anticipate likely complications | Cohort Study, Case Control, Case Series (Search terms: Mortality, Prognosis, Course, Prediction) |
| <strong>Harm/Etiology</strong>&lt;br&gt;How to identify causes for disease | RCT, Cohort Study, Case Control, Case Series |</p>
<table>
<thead>
<tr>
<th>Most common type of questions</th>
<th>Type of study/Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>RCT, Cohort Study, Case Control, Case Series</td>
</tr>
<tr>
<td>Clinical Exam</td>
<td>Prospective, blind comparison to gold standard</td>
</tr>
<tr>
<td>Cost Benefit</td>
<td>Economic Analysis</td>
</tr>
</tbody>
</table>
As you move up the pyramid, the study designs are more rigorous and allow for less bias.
How does EBM relate to Journal Club?

The term “journal club” traditionally refers to a gathering of physicians for the critical review of current medical literature and discussion regarding the clinical application of the results.

PubMed search on journal club & residency training
Results: 62 articles in the last 5 years.
PubMed Search on journal club & psychiatry residency training:
Only 12 results in the entire database...
And only 1 article in the last 5 years.
I think it is time for YOU to publish!
Some of the articles’ conclusions...

• Journal clubs can provide a suitable environment for solving health system problems.

• In an evidence-based journal club, one should try to find appropriate solutions and answers for actual clinical problems and questions instead of searching for one’s favorite topic among the titles of articles.

• Moving toward evidence-based journal clubs seems like an appropriate measure to reach the goals set by this educational tool.

How to practice EBM?

Step 1. Convert problem into an answerable question

For a 28-year-old pregnant Anglo-American woman with bipolar disorder, is lithium better than lamotrigine for reducing the occurrence of depression?
Use PICO to create a search strategy

<table>
<thead>
<tr>
<th>PICO</th>
<th>Clinical Question</th>
<th>Search Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient/Problem</td>
<td>Bipolar Disorder AND Pregnancy</td>
<td>bipolar disorder AND (pregnancy OR pregnant)</td>
</tr>
<tr>
<td>Intervention</td>
<td>Lithium</td>
<td>Lithium Carbonate OR Lithobid</td>
</tr>
<tr>
<td>Comparison</td>
<td>Lamotrigine</td>
<td>Lamotrigine OR Lamictal</td>
</tr>
<tr>
<td>Outcome</td>
<td>Reduce depression</td>
<td>Depression OR depressive OR depressed</td>
</tr>
<tr>
<td>Type of Question</td>
<td>Therapy</td>
<td></td>
</tr>
<tr>
<td>Type of Study</td>
<td>RCT</td>
<td></td>
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</tbody>
</table>

bipolar disorder AND (pregnancy OR pregnant) AND (lithium carbonate OR Lithobid) AND (lamotrigine OR lamictal)
Step 2. Find the best evidence by searching the literature...Use PubMed Clinical Queries
Enter your query using Boolean Operators (AND, OR, NOT)

PubMed Clinical Queries

Results of searches on this page are limited to specific clinical research areas. For comprehensive searches, use PubMed directly.

bipolar disorder AND (pregnancy OR pregnant) AND (lithium carbonate OR Lithobid) AND (lamotrigine OR lamictal)

Clinical Study Categories

Systematic Reviews

Medical Genetics

This column displays citations filtered to a specific clinical study category and scope. These search filters were developed by Haynes RB et al. See more filter information.

This column displays citations for systematic reviews, meta-analyses, reviews of clinical trials, evidence-based medicine, consensus development conferences, and guidelines. See more filter information.

This column displays citations pertaining to topics in medical genetics. See more filter information.
Scrandis DA.

Mood stabilisers and pregnancy outcomes - a review.
Costoloni O, Pierantozzi E, Goracci A, Bolognesi S, Fagiolini A.

Mood stabilizers in pregnancy: a systematic review.

Is lithium a real teratogen? What can we conclude from the prospective versus retrospective studies? A review.
Yacobi S, Ornuy A.

Women are not the same as men: specific clinical issues for female patients with bipolar disorder.
Curtis V.
Mood stabilizers in pregnancy: a systematic review.

Galbally M1, Roberts M, Buist A. Perinatal Psychotropic Review Group.

1. Collaborators (7)
2. Author information
   1. Mercy Hospital for Women, Heidelberg, Victoria, Australia. MGalbally@mercy.com.au

Abstract

OBJECTIVE: To undertake a systematic review of the effects of exposure to mood stabilizer medication in pregnancy, evaluating teratogenicity and other outcomes for mother and child. This was one of three concurrent systematic reviews of psychotropic medication exposure in pregnancy.

METHOD: A systematic search was carried out of electronic databases, reference books and other sources for original research studies which examined the effects of commonly used mood stabilizers (sodium valproate, carbamazepine, lamotrigine and lithium carbonate) on pregnancy outcomes. These included malformations, pregnancy complications, neonatal complications and longer term developmental outcomes for children exposed.

RESULTS: All mood stabilizers were found to be associated with a risk of malformation and perinatal complications. Studies which examined longer term neurodevelopmental outcomes found poorer outcomes for those children exposed to sodium valproate or polytherapy in pregnancy than for other individual AEDs. The data available for longer term child outcomes with lithium exposure is too limited to draw any conclusions.

CONCLUSIONS: This review found that exposure in pregnancy to all four commonly used mood stabilizers may be teratogenic, and is associated with increased rates of pregnancy and neonatal complications. There was also more limited information that sodium valproate may be associated with poorer longer term child developmental outcomes. These findings must be balanced with the risk of relapse and poor pregnancy and child outcomes with untreated maternal bipolar disorder. The information obtained from these reviews of psychotropic medications will assist clinicians in managing women with mental illness in pregnancy.

PMID: 21034180 DOI: 10.3109/00048674.2010.506637

[Indexed for MEDLINE] Similar articles

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Step 3. Critically appraise the evidence for its validity and usefulness
Elements of a research article

- Abstract
- Introduction
- Methods
- Results
- Discussion
Abstract

Structured vs. Unstructured

• Structured:
  – Rationale/Objectives
  – Method or Design
  – Results
  – Conclusions

• Unstructured: Simple narrative synopsis

Evaluating the Abstract:

• Is the topic important?
• Is it worth knowing about?
• What is the purpose of the study?
• If results are statistically significant, are they also clinically significant?
Introduction

• Orients reader to the general area of the study.
• Reviews previous relevant studies.
• Identifies a need for additional information.
• Establishes a reason for the study.
• States specific research questions.

Evaluating the Introduction:
• What research has already been done?
• Will the current study contribute to the research literature?
Methods

• Explains how the study was done.

• **Participants:** Who was involved, how were they recruited, and why are they the correct group for the study?

• **Procedure:** What was done, when, and how?

• **Data analysis:** What analyses were planned, and why?

Evaluating the Methods:

• Is the correct study design used?

• Are inclusion and exclusion criteria explicitly stated?

• Do criteria affect the applicability of conclusions?

• Are statistical methods stated?

• Are they appropriate? In a clinical trial, how are subjects recruited?

• How are subjects assigned to study groups?

• Is there a control group?

• Is the study blinded?
Results

• Explains what was found.

• Describes participants on relevant variables, such as age, gender, and language or cultural group.

• States findings of planned data analyses.

• Explains why other analyses were done, if they were.

Evaluating the Results Section:

• Do the reported findings answer the research question?

• Are actual values (e.g., means and standard deviations) reported?

• Were groups similar on baseline measures?
Discussion/Conclusion

• Recaps the results, placing them in the context of the introduction.
• Explains similarities and differences between current and previous findings.
• Expands on the importance of current findings.
• Suggests directions for future research.
More Evaluation Questions

• There are three basic questions that need to be answered for every type of study:
  – Are the results of the study valid?
  – What are the results?
  – Will the results help in caring for my patient?
Are the results valid?

1. Were the patients randomized?
2. Was group allocation concealed?
3. Were patients in the study groups similar with respect to known prognostic variables?
4. To what extent was the study blinded?
5. Was follow-up complete?
6. Were patients analyzed in the groups to which they were first allocated?
7. Was the trial stopped early?
What are the results?

1. How large was the treatment effect?
2. What was the relative risk reduction?
3. What was the absolute risk reduction?
4. How precise was the estimate of the treatment effect?
5. What were the confidence intervals?
How can I apply the results to patient care?

1. Were the study patients similar to my population of interest?
2. Were all clinically important outcomes considered?
3. Are the likely treatment benefits worth the potential harm and costs?
Systematic Reviews and Meta-Analysis

• Systematic reviews provide a rational basis for comparing similar studies

• They use uniform criteria for choosing studies and deciding which studies to include

• They may include a meta-analysis, a quantitative method for comparing results across multiple studies

• SR Databases: Cochrane, JBI, PubMed SR filter
Meta-Analysis

• Meta-analyses usually begin with a systematic search for all relevant references
• Studies may be included or excluded based on specific criteria, such as the use of randomization or adequate control
• The effect of interventions across studies is converted to a common metric, often termed “effect size”
• Statistical analyses can be performed on these data, allowing comparisons of results across multiple studies
Journal Club Formats & Charts

1. Neurology Journal Club
2. University of Pittsburgh Critical Care Medicine Fellows format (PowerPoint slide presentation)
3. Joanna Briggs Evidence Based Database Journal Club Tool
4. McMaster EBCP Workshop/Duke University Medical Center Critical Review Form for Therapy Study
Outline for Neurology Journal Club Submissions:

• **Background and significance**
  – What is already known on the subject?
  – How does this study add to the available literature?

• **Hypothesis and design**
  – What is the research question?
  – Is this question relevant?
  – Is the hypothesis reasonable?
  – What type of study was performed (e.g., randomized controlled, retrospective cohort, case control, or meta-analysis)?
  – Is the type of study performed feasible to test the hypothesis?
• Methods
  – What methods were used?
  – Why were these methods chosen?
  – What population was studied?
  – What was the intervention or exposure?
  – What was the control?

• Results
  – What are the results?
  – Are the results valid?

• Interpretation
  – Discuss the strengths and weaknesses.
  – Do the results support the conclusions?
  – Does this study change clinical practice?
<table>
<thead>
<tr>
<th>Journal Club Critique Section</th>
<th>What to include</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background</td>
<td>Why is this an important clinical question?</td>
</tr>
<tr>
<td></td>
<td>Show key studies to date in this area.</td>
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<tr>
<td></td>
<td>Key relevant mechanistic or pathophysiologic issues.</td>
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<tr>
<td>Hypothesis or objectives of</td>
<td></td>
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<tr>
<td>the article of interest</td>
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<tr>
<td>Methods</td>
<td>Entry criteria</td>
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<td></td>
<td>Inclusion criteria</td>
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<tr>
<td></td>
<td>Exclusion criteria</td>
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<tr>
<td></td>
<td>Study protocol and intervention, if available</td>
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<tr>
<td></td>
<td>Primary and secondary endpoints</td>
</tr>
<tr>
<td></td>
<td>Statistical analyses</td>
</tr>
<tr>
<td>Results</td>
<td>Flow of study participants (CONSORT DIAGRAM)</td>
</tr>
<tr>
<td></td>
<td>Baseline characteristics of patients enrolled in the study</td>
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<tr>
<td></td>
<td>Main results (show key Tables and Figures)</td>
</tr>
<tr>
<td>Conclusions</td>
<td>Strengths of the study</td>
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<td></td>
<td>Limitations of the study</td>
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<td></td>
<td>General Discussion Points</td>
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<td></td>
<td>Other issues of interest</td>
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</table>

University of Pittsburgh Critical Care Medicine Fellows @ [https://www.ccm.pitt.edu/instructions-fellows](https://www.ccm.pitt.edu/instructions-fellows)
Consort Diagram

http://gforge.se/2012/05/creating-nice-flow-diagrams/
Welcome to the club Carmen

New Session

Session Details
- Opened: Jul 20, 2017
- By: Carmen Bou-Clark
- Original Publication: [Open Publication](#)
- Journal Article Report: Report cannot be opened until appraisal completed

Session Name
- Psychiatry Journal Club

Find a Publication
- Search for a paper in JBI ConNECT+, PubMed or Cvd
- Copy and paste the publication URL into the box below
- Enter the URL of the publication

Or browse for a paper on your computer and upload a PDF of the paper

Update Session
<table>
<thead>
<tr>
<th><strong>Author/s</strong></th>
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<tbody>
<tr>
<td>Wesseloo, Richard Liu, Xiaojin; Clark, Crystal T.; Kushner, Steven A.; Munk-Olsen, Trine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Study / Review Title</strong></th>
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<tbody>
<tr>
<td>Risk of postpartum episodes in women with bipolar disorder after lamotrigine or lithium use during pregnancy: A population-based cohort study.</td>
</tr>
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</table>

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<tr>
<th><strong>Year</strong></th>
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<tr>
<td>2017</td>
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<table>
<thead>
<tr>
<th><strong>Journal</strong></th>
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<tbody>
<tr>
<td>Journal of Affective Disorders</td>
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<tr>
<th><strong>Volume</strong></th>
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<td>218</td>
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<tbody>
<tr>
<td>394-397</td>
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<table>
<thead>
<tr>
<th><strong>Study Design</strong></th>
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<tbody>
<tr>
<td>Risk</td>
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<table>
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<tr>
<th><strong>Risk Study</strong></th>
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<tbody>
<tr>
<td>Cohort</td>
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* Required

Save  Reset Form
# Checklist for appraisal of Risk

**STUDY DESIGN**

| 1. The choice of study method is appropriate. | Yes | No | Unclear | N/A |
| 2. The population studied is appropriate. | Yes | No | Unclear | N/A |
| 3. The comparison group used was appropriate. | Yes | No | Unclear | N/A |
| 4. A type 1 and/or 2 error and bias has been considered. | Yes | No | Unclear | N/A |
| 5. All possible effect explanations are acknowledged. | Yes | No | Unclear | N/A |
| 6. The outcomes are objectively measured. | Yes | No | Unclear | N/A |
| 7. The duration of follow-up was adequate. | Yes | No | Unclear | N/A |
| 8. The effect was sufficiently long term. | Yes | No | Unclear | N/A |
| 9. The dropout rate was not significant. | Yes | No | Unclear | N/A |
| 10. The rate of patient follow up was adequate. | Yes | No | Unclear | N/A |

In reflecting upon my critical appraisal I believe that this paper is of good quality.
Journal Article Report

Phase 1

Participants: A total of 114 women between the ages of 32 and 34 years old, taking either lamotrigine or lithium during their pregnancy.

Exposure: Lamotrigine or lithium use during pregnancy.

Outcome: Severe psychiatric relapse/recurrence, defined as any psychiatric admission for mental disorders (ICD-10 codes F00-F99) within three months postpartum.

<table>
<thead>
<tr>
<th>Yes</th>
<th>13</th>
</tr>
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<tbody>
<tr>
<td>No</td>
<td>101</td>
</tr>
</tbody>
</table>

Sample Size: 114

CI: 0.22-3.14

Chi Square
4 Conclusion - Risk

**Authors Conclusions**

State the conclusions that are most relevant to your clinical question, regardless of whether you agree with the authors or not. This information should be in the "Conclusions" section of the article.

**Your Conclusions**

Quality of the Paper

**Domains of appraisal most significant for the study**

Describe which critical appraisal questions were most relevant to the study design, and whether the paper scored well for those questions.
Appropriateness of authors interpretation of results

Congruency with Actual Findings

STATE WHETHER THE AUTHORS’ CONCLUSIONS WERE APPROPRIATE AND CORRECT BASED ON THE RESULTS DATA THEY PRESENTED.

Applicability of the Paper

For local practice

DESCRIBE THE POTENTIAL IMPLICATIONS FOR CLINICAL PRACTICE IN YOUR CONTEXT. INCLUDE ANY POTENTIAL BARRIERS, AND HOW THOSE CAN BE MANAGED IN ORDER TO USE THESE FINDINGS IN PRACTICE.
Describe if the findings have any possible implications for your organization. If possible, suggest which policies might be impacted, whether at ward/unit level or beyond.

List some key learning outcomes for your group based on the critical appraisal of, or the results and implications of this paper.
### Critical Review Form for Therapy Study

<table>
<thead>
<tr>
<th>Users' Guide</th>
<th>Article</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Are the Results Valid?</strong></td>
<td></td>
</tr>
<tr>
<td>Did experimental and control groups begin the study with a similar prognosis?</td>
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<tr>
<td>Were patients randomized?</td>
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<tr>
<td>Was randomization concealed?</td>
<td></td>
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<tr>
<td>Were patients analyzed in the groups to which they were randomized?</td>
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<tr>
<td>Were patients in the treatment and control groups similar with respect to known prognostic factors?</td>
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<tr>
<td><strong>Did experimental and control groups retain a similar prognosis after the study started?</strong></td>
<td></td>
</tr>
<tr>
<td>Were 5 important groups (patients, caregivers, collectors of outcome data, adjudicators of outcome, data analysts) aware of group allocation?</td>
<td></td>
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<tr>
<td>Aside from the experimental intervention, were groups treated equally?</td>
<td></td>
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<tr>
<td>Was follow-up complete?</td>
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<tr>
<td><strong>What are the Results?</strong></td>
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<tr>
<td>How large was the treatment effect?</td>
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<td>How can I apply the results to my patient care?</td>
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<td>Were the study patients similar to my patient?</td>
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<td>Were all patient-important outcomes considered?</td>
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<tr>
<td>Are the likely benefits worth the potential harms and costs?</td>
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</tbody>
</table>

From McMaster EBCP Workshop/Duke University Medical Center

Additional Checklists in *How to Read a Paper*

Visit Calder Library’s homepage http://calder.med.miami.edu
Coming soon! The Journal Club presentation slides will be on this guide!
To learn more:

https://scholarlyrepository.miami.edu/
Thank you for your attention!

Questions/Comments?

Contact me at:

Carmen Bou-Crick
205-243-1967

cbou@Miami.edu

Evaluation form http://tinyurl.com/CalderClassEval