

LEGEND: Evidence Appraisal of a Single Study

All Domains

Case Report*



Reviewer:

Today's Date:

Final Evidence Level:

Project/Topic of your Clinical Question:

Article Title:

Year:

First Author:

Journal:

** Note: Although an N-of-1 or single subject study is best evidence for that individual patient, a published report of an N-of-1 or single subject study is a case report.*

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 case report 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](#).

Basic Elements of a Case Report

1.	Does the case report fit into one of the categories expected? <i>Check the category that applies:</i> <ul style="list-style-type: none"><input type="checkbox"/> New associations or variations in disease processes<input type="checkbox"/> Innovative approaches/interventions for treatment in disease processes<input type="checkbox"/> Findings that shed light on the possible pathogenesis of a disease or an adverse event<input type="checkbox"/> Presentations, diagnoses, or management of new and emerging diseases<input type="checkbox"/> Unreported or unusual side effects or adverse interactions involving medications or treatment<input type="checkbox"/> Unexpected or unusual presentations of a disease<input type="checkbox"/> Unexpected association between diseases and symptoms<input type="checkbox"/> Unexpected event in the course of observing or treating a patient<input type="checkbox"/> Does not fit one of the categories expected for case reports	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
2.	Does the case report include a background of the issue on which the case report focuses?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
3.	Does the case report include an up-to-date review of the previous cases in the field?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
4.	Does the case report include details relevant to the case? <i>Check the details that apply for each patient or for all patients (if >1 patient reported):</i> <ul style="list-style-type: none"><input type="checkbox"/> A description of the patient's demographic information<input type="checkbox"/> Any relevant medical history of the patient or their family<input type="checkbox"/> The patient's signs and symptoms<input type="checkbox"/> Any tests that were carried out<input type="checkbox"/> A description of pertinent details (e.g., disorder, medication, interventions/treatments, adverse events)<input type="checkbox"/> The outcome of the case	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.	Is the importance of the case explained? <ul style="list-style-type: none">• What will be learned from the case report?• How will the case report advance our clinical knowledge?• Other?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

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6. Was there freedom from conflict of interest?

☐ Yes ☐ No ☐ Unknown

- Sponsors, Funding Agency, Investigators

Comments:

Applicability

Can I apply this Case Report Information?

7. Can the results be applied to my population of interest?

☐ Yes ☐ No ☐ Unknown

- Is the setting of the case(s) applicable to my population of interest?
- Do the patient outcomes apply to my population or question of interest?
- Was the patient (or were the patients) in this report similar to my population of interest?

8. Are my patient's and family's values and preferences satisfied by the knowledge gained from this report (such as outcomes considered)?

☐ Yes ☐ No ☐ Unknown

9. Would you include this report 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 Case Report [5a]
☐ Lesser Quality Case Report [5b]
☐ Not Valid, Reliable, or Applicable

Adjust the level, if the domain of your clinical question is different than the domain of the study's clinical question.
(See the entire Table of Evidence Levels or consult a local evidence expert for assistance.)

Final Evidence Level:

Rationale for adjustment:

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 Epidemiology Case Series	Quality Improvement	Mixed Methods Study	Decision Analysis Economic Analysis Computer Simulation	Guidelines	Case Reports N-of-1 Study	Bench Study
All Domains	1a 1b											4a 4b		2/3/4 a/b	5a 5b	5a 5b	5a 5b	5a 5b

* 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. 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.
5. 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.
6. <http://www.jmedicalcasereports.com/jmedicalcasereports/about/submissions>