

CASE REPORTING GUIDELINES



David Riley

2437 NW Overton Street

Portland, OR 97210

dsriley@integrativemed.org



In God we trust, everyone else has to show data.

THE ROLE OF CASE REPORTS

documenting the care of individual patients

- “Case reports and case series have a high sensitivity for detecting novelty and are a cornerstones of medical progress providing new ideas in medicine.”
- “Good case reporting demands a clear focus to make explicit to the audience why a particular observation is important in the context of existing knowledge.”

Vandenbroucke J. In Defense of Case Reports and Case Series. *Ann Intern Med.* 2001;134:330-334.

Clinical Practice & Evidence-Based Medicine

“Without clinical expertise, practice risks becoming tyrannized by evidence, for even excellent external evidence may be... inappropriate for individual patients.”

Sackett D. Evidence based medicine: what it is and what it isn't. *BMJ* Jan 1996;312;71-72

“High quality evidence doesn't necessarily imply strong recommendations, and strong recommendations can arise from low quality evidence.”

Guyatt G, Oxman A, Schünemann H. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008 April 26;336(7650);924-928

“In theory there is no difference between theory and practice.
In practice there is.”

Yogi Berra

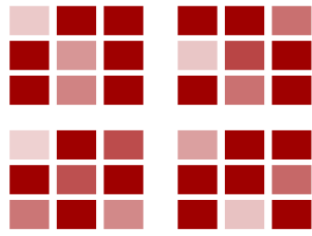
Health Research Reporting Guidelines

- 1962: The FDA required drug and medical device testing for safety and efficacy leading to the rise of controlled clinical trials and the concomitant decline of case reports).
- 1980s: Meta-analysis and Systematic Reviews—Lancet editorial (Richard Peto) on the role of aspirin in recurrent heart attacks.
- 1996: CONSORT Health Research Reporting Guidelines for randomized controlled trials (RCTs)
- 2013: CARE guidelines for case reports

Health Research Reporting Guidelines

- Needs Assessment
- Delphi process
- Consensus Meeting
- Publish Health Research Reporting Guidelines
- Endorsement and Author utilization
- Evaluate Implementation

Moher D, Schulz KF, Simera I, et al. Guidance for developers of health research reporting guidelines. PLoS Med 2010;7:e1000217.

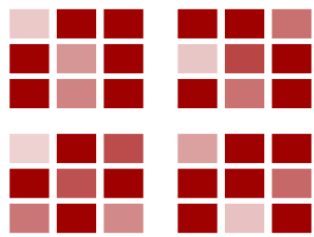


CARE

case report guidelines

The Narrative: A case report tells a story in a narrative format that includes the presenting concerns, clinical findings, diagnoses, interventions, outcomes (including adverse events), and follow-up. The narrative should include a discussion of the rationale for any conclusions and other ‘take-away’ messages.

Section	Item Number	Description
Title	1	The words ‘case report’ should appear in the title along with phenomenon of greatest interest (symptom, diagnosis, test, intervention, etc.)
Keywords	2	The key elements of the case in 2-5 words
Abstract	3	a) Introduction—What does this case add? b) Case Presentation: symptoms, clinical findings, diagnoses, interventions, and outcomes c) Conclusion and ‘take-away’ lessons
Introduction	4	Brief background summary referencing the relevant medical literature
Timeline	5	Depicts important milestones in this case as a table or figure
Patient Information	6	a) Demographic information b) Main symptoms as described by the patient (chief complaint) c) Medical, and family history including lifestyle and genetic information when possible d) Co-morbidities, past interventions and outcomes
Clinical Findings	7	Relevant physical examination findings



CARE

case report guidelines

Section	Item Number	Description
Diagnostic Assessments	8	a) Diagnostic methods, challenges, and reasoning (including other possible diagnoses) b) Prognosis where applicable
Therapeutic Interventions	9	Interventions (pharmacologic, surgical, clinician intervention, preventive, self-care, etc.) <ul style="list-style-type: none"> - Administration of intervention (dosage, frequency, duration, etc.) - Changes in the intervention (with explanations)
Follow-up and Outcomes	10	Summarize the clinical course of all follow-up visits including <ul style="list-style-type: none"> - Clinician assessed outcomes (patient assessment when appropriate) - Important follow-up test results (positive or negative) - Interventional adherence and tolerability (how was this assessed) - Adverse and unanticipated events
Discussion	11	a) Strengths and limitations of the management of this case b) Relevant medical literature c) Rationale for conclusions (assessment of cause and effect) d) The main 'take-away' lessons from this case
Patient Perspective	12	The patient should share his or her perspective or experience when appropriate
Informed Consent	13	Did the patient give informed consent? Please provide if requested

Section	Item	Checklist item description	Reported on Page
Title	1	The words “case report” should be in the title along with what is of greatest interest in this case	_____
Key Words	2	The key elements of this case in 2 to 5 key words	_____
Abstract	3a	Introduction—What is unique about this case? What does it add to the medical literature?	_____
	3b	The main symptoms of the patient and the important clinical findings	_____
	3c	The main diagnoses, therapeutics interventions, and outcomes	_____
	3d	Conclusion—What are the main “take-away” lessons from this case?	_____
Introduction	4	Brief background summary of this case referencing the relevant medical literature	_____
Patient Information	5a	Demographic information (such as age, gender, ethnicity, occupation)	_____
	5b	Main symptoms of the patient (his or her chief complaints)	_____
	5c	Medical, family, and psychosocial history including co-morbidities, and relevant genetic information ..	_____
	5d	Relevant past interventions and their outcomes	_____
Clinical Findings	6	Describe the relevant physical examination (PE) findings.	_____
Timeline	7	Depict important milestones related to your diagnoses and interventions (table or figure)	_____
Diagnostic Assessment	8a	Diagnostic methods (such as PE, laboratory testing, imaging, questionnaires)	_____
	8b	Diagnostic challenges (such as financial, language, or cultural)	_____
	8c	Diagnostic reasoning including other diagnoses considered	_____
	8d	Prognostic characteristics (such as staging in oncology) where applicable	_____
Therapeutic Intervention	9a	Types of intervention (such as pharmacologic, surgical, preventive, self-care)	_____
	9b	Administration of intervention (such as dosage, strength, duration)	_____
	9c	Changes in intervention (with rationale)	_____
Follow-up and Outcomes	10a	Clinician-assessed outcomes and when appropriate patient-assessed outcomes	_____
	10b	Important follow-up test results	_____
	10c	Intervention adherence and tolerability (How was this assessed?)	_____
	10d	Adverse and unanticipated events	_____
Discussion	11a	Discussion of the strengths and limitations in the management of this case	_____
	11b	Discussion of the relevant medical literature	_____
	11c	The rationale for conclusions (including assessment of possible causes)	_____
	11d	The main “take-away” lessons of this case report	_____
Patient Perspective	12	Did the patient share his or her perspective or experience? (Include when appropriate)	_____
Informed Consent	13	Did the patient give informed consent? Please provide if requested	Yes <input type="checkbox"/> No <input type="checkbox"/>

CASE REPORTS

documenting the care of individual patients

Integrative Medicine

Case reports, systematically collected and aggregated can provide “real world” evidence of effectiveness and offer an example of interprofessional collaboration.

Case Reports and the Care Guidelines

- Systematic case reports following the CARE guidelines (created from the CA in case and RE in reports) could:
 - **Provide early signals of effectiveness, harms and cost**
 - **Inform clinical practice and improves clinical reasoning**
 - **Provide feedback on clinical practice guidelines, and**
 - **Generate testable hypotheses for clinical research**

Gagnier J, Kienle G, Altman DG, Moher D, Sox H, Riley DS, and the Care Group. The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development. *Journal of Clinical Epidemiology (JCE)*, 67(1):46-51. Simultaneously published in *BMJ Case Reports*, *Deutsche Ärzteblatt*, *Headache*, *Global Advances in Health and Medicine*, *J. of Dietary Supplements*, and the *J. of Medical Case Reports (BMC)*.