REPORTING GUIDELINES

The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development

CARE 指引： 基于共识制定临床病例报告指引

Las pautas CARE: Desarrollo basado en el consenso de pautas para informes de casos clínicos

Joel J. Gagnier, ND, MSc, PhD, *United States*; Gunver Kienle, Dr med, *Germany*; Douglas G. Altman, DSc, *United Kingdom*; David Moher, PhD, *Canada*; Harold Sox, MD, *United States*; David Riley, MD, *United States*; and the CARE Group*

Author Affiliations
Department of Orthopedic Surgery, University of Michigan, Department of Epidemiology, School of Public Health, University of Michigan, Ann Arbor (Dr Gagnier); Institute for Applied Epistemology and Medical Methodology, University of Witten/Herdecke, Freiburg, Germany (Dr Kienle); Centre for Statistics in Medicine, University of Oxford, United Kingdom (Dr Altman); Ottawa Hospital Research Institute, Department of Epidemiology and Community Medicine, University of Ottawa, Ontario, Canada (Dr Moher); The Dartmouth Institute and Geisel School of Medicine at Dartmouth, Hanover, New Hampshire (Dr Sox); editor-in-chief, *Global Advances in Health and Medicine*, Portland, Oregon (Dr Riley).

Correspondence
David Riley, MD
driley@gahmllc.com

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ABSTRACT

Background: A case report is a narrative that describes, for medical, scientific, or educational purposes, a medical problem experienced by one or more patients. Case reports written without guidance from reporting standards are insufficiently rigorous to guide clinical practice or to inform clinical study design.

Primary Objective: Develop, disseminate, and implement systematic reporting guidelines for case reports.

Methods: We used a three-phase consensus process consisting of (1) premeeting literature review and interviews to generate items for the reporting guidelines, (2) a face-to-face consensus meeting to draft the reporting guidelines, and (3) postmeeting feedback, review, and pilot testing, followed by finalization of the case report guidelines.

Results: This consensus process involved 27 participants and resulted in a 13-item checklist—a reporting guideline for case reports. The primary items of the checklist are title, key words, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective, and informed consent.

Conclusions: We believe the implementation of the CARE (CAse REport) guidelines by medical journals will improve the completeness and transparency of published case reports and that the systematic aggregation of information from case reports will inform clinical study design, provide early signals of effectiveness and harms, and improve healthcare delivery.

抽象

背景：病例报告是一种出于医疗、科学或教育目的，而对一名或多名患者所遇到的医疗问题进行描述的记叙文。在无报告标准指导的情况下编写的案例报告是不够严谨的，无法指导临床实践或报告临床研究设计。主要目标：制定、传播和推行适用于病例报告的系统性报告指引。方法：我们采用的是一个由三个阶段组成的共识形成过程，其中包括 (1) 在会议之前审核文字材料并进行口头审查，以生成适用于报告指引的条目，(2) 召开面对面的共识会议，起草报告指引，和 (3) 在会议之后进行反馈、审核和试点测试，然后完成病例报告指引。结果：此共识形成过程涉及 27 名参与者并产生了一个包含 13 个条目的清单－案例报告的报告指引。该清单的主要条目有标题、关键字、摘要、简介、患者信息、临床发现、时间表、诊断评估、治疗干预、随访和结果、讨论、患者观点和知情同意书。

SINOPSIS

Antecedentes: Un informe de caso es una narración que describe, con un objetivo médico, científico o educativo, un problema médico experimentado por uno o más pacientes. Los informes de caso redactados sin la orientación de normas de elaboración de informes no son suficientemente rigurosos para guiar la práctica clínica ni para servir de base en el diseño de los estudios clínicos.

Objetivo principal: Desarrollar, difundir e implementar pautas sistemáticas de elaboración de informes para los informes de caso.

Métodos: Hemos utilizado un proceso de consenso de tres fases consistente en (1) antes de la reunión, revisión de la bibliografía y entrevistas para crear elementos para las pautas de elaboración de informes, (2) reunión de consenso en persona para elaborar un borrador de las pautas de elaboración de informes, y (3) después de la reunión, recogida de opiniones, revisión y pruebas piloto, y, a continuación, redacción definitiva de las pautas de elaboración de informes.

Resultados: En este proceso de consenso intervinieron 27 participantes y dio como resultado una lista de comprobación de 13 elementos—una guía para la elaboración de informes aplicable a los informes de caso. Los principales elementos de la lista de comprobación son el título, las palabras clave, el resumen, la introducción, la información al paciente, los hallazgos clínicos, el calendario, la evaluación diagnóstica, las intervenciones terapéuticas, el seguimiento y los resultados, la discusión, la perspectiva del paciente y el consentimiento informado.

Conclusiones: Creemos que la implementación de las pautas CARE (de CAse REport o informe de caso) por las revistas médicas mejorará la exhaustividad y transparencia de los informes de caso publicados, y que la agregación sistemática de los datos procedentes de informes de caso servirá de base para el diseño de los estudios clínicos, proporcionará las primeras señales de efectividad y daños, y mejorará la prestación de servicios médicos.

*For a complete list of members of the CARE Group, see the author contributions at the end of this article.

INTRODUCTION

A case report is a detailed narrative that describes, for medical, scientific, or educational purposes, a medical problem experienced by one or several patients.

Case reports present clinical observations customarily collected in healthcare delivery settings. They have proved helpful in the identification of adverse and beneficial effects, the recognition of new diseases, unusual forms of common diseases, and the presentation of rare diseases.[1] For example, our understanding of the relationship between thalidomide and congenital abnormalities[2] and the use of propranolol for the treatment of infantile hemangiomas began with case reports.[3] Case reports may generate hypotheses for future clinical studies, prove useful in the evaluation of global convergences of systems-oriented approaches, and guide the individualization and personalization of treatments in clinical practice.[4,5] Furthermore, case reports offer a structure for case-based learning in healthcare education and may facilitate the comparison of healthcare education and delivery across cultures.

Case reports are common and account for a growing number of articles in medical journals[6]; however their quality is uneven.[7,8] For example, one study evaluated 1316 case reports from four peer-reviewed emergency-medicine journals and found that more than half failed to provide information related to the primary treatment that would have increased transparency and replication.[9] Written without the benefit of reporting guidelines, case reports often are insufficiently rigorous to be aggregated for data analysis, inform research design, or guide clinical practice[7,9]

Reporting guidelines exist for a variety of study designs including randomized controlled trials (Consolidated Standards of Reporting Trials, or CONSORT),[10] observational studies (Strengthening the Reporting of Observational studies in Epidemiology, or STROBE),[11] and systematic reviews and meta-analyses (Preferred Reporting Items for Systematic Reviews and Meta-Analyses, or PRISMA).[12] Empirical evidence suggests that a journal's adoption of the CONSORT statement as a guide to authors is associated with an increase in the completeness of published randomized trials.[13] Guidelines have been developed for adverse-event case reports[14]; however, general reporting guidelines for case reports do not exist. Our primary objective was to develop reporting guidelines for case reports through a consensus-based process.

METHODS

Research Design

We followed the Guidance for Developers of Health Research Reporting Guidelines[15] and developed a three-phase consensus process.[16] This consisted of (1) a premeeting literature review followed by interviews to generate items for a case report checklist, (2) a face-to-face consensus meeting for drafting a reporting guideline, and (3) postmeeting feedback and pilot testing followed by finalization of the case report guidelines.

Participants

We contacted 28 individuals who fulfilled at least one of four criteria[17-19]: (1) publication of articles related to case reports; (2) publication of a manual, handbook, or method guidelines related to case reports; (3) publication of a systematic review of methods or reporting related to case reports; and (4) publication of other reporting guidelines for clinical research.

Consensus Process

Phase 1: Four of the authors, the steering committee (JG, GK, DM, and DR), searched the literature for publications on the role of case reports, recommendations for their publication, and surveys on reporting quality. A letter was sent to 28 potential participants explaining the purpose of the meeting and details of the consensus technique and requesting their participation in generating specific recommendations for case reporting. Twenty-seven people agreed to participate and were scheduled for a telephone interview and sent a selection of key articles on case reports. During the telephone interview, participants were asked (1) what information was required to be included in case-reporting guidelines, (2) the rationale for their suggestions, and (3) for references that supported their reasoning.

Three of the authors (JG, GK, and DR) grouped the recommendations from the literature search and interviews by theme together with their rationale, references, and operational definitions. No quantitative scoring was done.

Phase 2: The face-to-face consensus meeting at the University of Michigan in Ann Arbor (October 2012) included 18 participants from Phase 1, one research assistant, and two student observers. The meeting began with a review of the blinded recommendations elicited during the Phase 1 interviews in whole group and small group sessions. On the second day, open discussion of each potential item continued, during which clarifications, opinions, justifications, operational definitions, and new ideas were expressed. By the end of the second day, the group had agreed upon a set of preliminary reporting recommendations.

Phase 3: The draft checklist was refined by the steering committee and sent for two rounds of review to the complete group (Phase 1 and Phase 2 participants). The finalized reporting guidelines incorporated the feedback from the entire group.

RESULTS

The CAse REport (CARE) guidelines checklist is structured to correspond with key components of a case report and capture useful clinical information (including "meaningful use" information mandated by some insurance plans).

The checklist begins with a statement that describes the narrative of a case report. The meeting CARE group felt that a case report should tell a story using prose that has a consistent style across all sections, including the rationale for any conclusions and takeaway messages.

We recommend a timeline (item 7) in the form of a table or figure that gives the specific dates and times of important components of the case. This might include family and past medical history, genetic information, current symptoms, diagnostic test results, interventions, and events that occurred during follow-up. The timeline should show how the key events of the case unfolded.

We created separate checklist items for diagnostic assessments (item 8) and therapeutic interventions (item 9) with the recognition that both items often will be relevant in a case report.

The group discussed at length whether to include the patient's perspective on his or her experience. In the end, we advocated for patient-reported outcomes (item 10) and experiences (item 12) whenever possible. There was also discussion about the need for guidelines for patient-reported outcomes of their care. In a similar vein, a recent extension of the CONSORT statement was published for patient-reported outcomes in randomized trials: CONSORT-PRO.[20]

Finally, we included an item on informed consent (item 13). We believe that authors have an ethical duty to obtain informed consent from the patient to publish patient information in a case report. Consent becomes informed when the patient or a relative reads the case report and approves its contents. If the patient cannot give consent and attempts to find a relative to give proxy consent have failed, the authors should seek permission to publish from an institutional committee. There may be other circumstances where an ethics committee or institutional review board (IRB) approval may be necessary. The CARE guidelines are shown in the Table.

DISCUSSION

This 13-item checklist provides a framework to satisfy the need for completeness and transparency for published case reports. We attempted to strike a balance between adequate detail and the concise writing that is one of the appealing characteristics of a case report. Our consensus process resulted in a set of essential items for authors to consider when submitting a case report for publication.

While case reports have long been an important source of new ideas and information in medicine,[21] it appears that case reports are likely to begin to play a role in the discovery of what works and for whom. BioMed Central launched the *Journal of Medical Case Reports* in 2007[22] and its Cases Database in 2012 with more than 11 000 published case reports from 50 medical journals. In 6 months, it has grown to more than 26 000 case reports from 212 medical journals.[23] The CARE guidelines checklist is part of a growing effort to improve the reporting of case reports.

There is substantial empirical evidence that reporting guidelines improve the completeness of published scientific reports.[eg, 13,24,25] A recent Cochrane review examining the influence of journal endorsement of the CONSORT statement on reporting included 53 publications assessing 16 604 randomized controlled trials and found that CONSORT-endorsing journals consistently have better overall reporting.[13] However, the potential impact of the CONSORT statement and related reporting guidelines has not been fully realized. A study examining the instructions to peer reviewers of 116 health research journals found that only 41 (35%) provided online instructions to peer reviewers. Of those, only 19 (46%) mentioned or referred to reporting guidelines as a useful resource.[26] In response, the authors provide several recommendations for editors to improve the peer review of submitted manuscripts, suggesting that journals have a responsibility to support peer reviewers.[26]

The developers of reporting guidelines have a responsibility to plan a dissemination and implementation strategy that supports guidelines utilization.[15] Our efforts have several components:

1. The CARE guidelines will be presented at international conferences and workshops including the Peer Review and Biomedical Publication Congress in Chicago on September 10, 2013.
2. This article will be published simultaneously in multiple medical journals and outreach to the 212 journals depositing case reports into the BioMed Central Case Report Database.
3. We will develop a more detailed explanation and elaboration article to outline the rationale for each item and include empirical evidence and examples of good reporting from published case reports.
4. The CARE guidelines are being pilot tested, and preliminary results support the guidelines as currently written (personal communication with Helmut Kiene, Dr med; Erica Oberg, ND, MPH; Bill Manahan, MD). Guidelines extensions for specialties are being developed.
5. The CARE guidelines and related documents will be available on a dedicated website (www.CARE-statement.org), the EQUATOR Network website (www.equator-network.org), and translated into multiple languages.
6. Authors, journal editors, peer reviewers, and the wider medical community are encouraged to use the CARE checklist and provide feedback that can be incorporated into regular updates of the CARE guidelines.
7. We will conduct and support research into the impact of the CARE guidelines on the reporting of case reports.

LIMITATIONS

The CARE guidelines and their development have several possible limitations. First, these guidelines were developed through a consensus method and thus represent the opinions of the participants. However, consensus was easily reached during our meeting, we referred to the empirical evidence where available,

Table The CARE 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 any takeaway messages.

ITEM NAME	ITEM NO.	BRIEF DESCRIPTION
Title	1	The words *case report* (or *case study*) should appear in the title along with phenomenon of greatest interest (eg, symptom, diagnosis, test, intervention)
Keywords	2	The key elements of this case in 2 to 5 words
Abstract	3	Introduction—What does this case add? Case Presentation: Main symptoms of the patient Main clinical findings Main diagnoses and interventions Main outcomes Conclusion—What were the main takeaway lessons from this case?
Introduction	4	Brief background summary of this case referencing the relevant medical literature
Patient Information	5	Demographic information (eg, age, gender, ethnicity, occupation) Main symptoms of the patient (his or her chief complaints) Medical, family, and psychosocial history—including diet, lifestyle, and genetic information whenever possible and details about relevant comorbidities including past interventions and their outcomes
Clinical Findings	6	Describe the relevant physical examination (PE) findings
Timeline	7	Depict important dates and times in this case (table or figure)
Diagnostic Assessment	8	Diagnostic methods (eg, PE, laboratory testing, imaging, questionnaires) Diagnostic challenges (eg, financial, language/cultural) Diagnostic reasoning including other diagnoses considered Prognostic characteristics (eg, staging) where applicable
Therapeutic Intervention	9	Types of intervention (eg, pharmacologic, surgical, preventive, self-care) Administration of intervention (eg, dosage, strength, duration) Changes in intervention (with rationale)
Follow-up and Outcomes	10	Summarize the clinical course of all follow-up visits, including • Clinician- and patient-assessed outcomes • Important follow-up test results (positive or negative) • Intervention adherence and tolerability (and how this was assessed) • Adverse and unanticipated events
Discussion	11	Strengths and limitations of the management of this case Relevant medical literature Rationale for conclusions (including assessments of cause and effect) Main takeaway lessons of this case report
Patient Perspective	12	The patient should share his or her perspective or experience whenever possible
Informed Consent	13	Did the patient give informed consent? Please provide if requested

and we received feedback from a wide selection of individuals, beyond those involved in our consensus meeting. Second, we recognize that causality determinations are a challenge for case reports even when following reporting guidelines.[27,28] The CARE guidelines emphasize information quality independent of causality assessments. Different specialties, practitioners, and patients are likely to require extensions of the CARE guidelines with specialty specific information. We welcome discussions with groups interested in using the CARE guidelines as the basis for their specific reporting needs.

Though not mentioned in our guidelines, medical journals often require authors to address three issues: (a) potential competing interests, (b) de-identification of patient-related data, and (c) ethics committee or IRB approval if obtained or necessary.

CONCLUSIONS

Anticipating a long future for case reports, we have provided guidance in the form of reporting standards for use by healthcare stakeholders around the world. The growth of case reports in an era in which clinical trials and systematic reviews dominate the tables of content of medical journals indicates that case reports have value, particularly with the increasing importance of individualized care. Unlike randomized controlled trials, case reports are individual reports related to the care of individual patients where the sample size is one. When systematically collected and combined into larger datasets, they can be analyzed, enhancing the early discovery of effectiveness and harms.

We anticipate that the analysis of systematically aggregated information from patient encounters (now mandated by some insurance plans) will provide scalable, data-driven insights into what works for which patients in real time, facilitating comparisons across medical systems and cultures. Practitioners will soon be able to provide—and in some cases they are required to provide—patients with information from their encounters. This will transform how we think about "evidence" and revolutionize its creation, diffusion, and use—opening new opportunity landscapes. When it becomes clear how new data contributes to evidence, the stewardship needed to produce high-quality data will be more rewarding and our attitude toward "observation" will shift. The CARE guidelines provide a framework to satisfy the need for precision, completeness, and transparency.

AUTHOR CONTRIBUTIONS

JG, GK, DGA, DM, HS, and DR met the ICMJE criteria for authorship. JG and DR wrote the first draft of the article. DGA, JG, GK, DM, DR, and HS critically reviewed and edited drafts. The entire CARE group participated in parts or all of the guidelines development process and contributed to the editing and revision of the CARE guidelines and this article.

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The CARE Group

1. Alyshia Allaire, BS, Portland, Oregon, United States
2. Douglas G. Altman, DSc, Centre for Statistics in Medicine, University of Oxford, United Kingdom
3. Jeffrey Aronson, MB, ChB, MA Dphil, FRCP, FB, PharmacolS, University of Oxford, United Kingdom
4. James Carpenter, MD, Department of Orthopaedic Surgery, University of Michigan, Ann Arbor, United States
5. Joel Gagnier, ND, MSc, PhD, Departments of Orthopaedic Surgery and Epidemiology, University of Michigan, Ann Arbor, United States
6. Patrick Hanaway, MD, Director of Medical Education, Institute for Functional Medicine, Asheville, North Carolina, United States
7. Carolyn Hayes, PhD, RN, NEA-BC, Dana-Farber Brigham and Women's Cancer Center, Boston, Massachusetts, United States
8. David Jones, MD, President, Institute for Functional Medicine, Ashland, Oregon, United States
9. Marietta Kaszkin-Bettag, PhD, University of Frankfurt, Pharmalex GmbH, Mannheim, Germany
10. Michael Kidd, AM, Editor-in-Chief, *Journal of Medical Case Reports*, Faculty of Health Sciences, Flinders University, Adelaide, Australia
11. Helmut Kiene, Dr med, Editor, *Global Advances in Health and Medicine*®, Institute for Applied Epistemology and Research Methodology, University of Witten/Herdecke, Freiburg, Germany
12. Gunver Kienle, Dr med, Editor, *Global Advances in Health and Medicine*®, Institute for Applied Epistemology and Research Methodology, University of Witten/Herdecke, Freiburg, Germany
13. Ben Kligler, MD, MPH, Co-Editor-in-Chief, *Explore*, Beth Israel Medicine Center, New York, New York, United States
14. Lori Knutson, RN, BSN, HN-BC, Integrative Healthcare Solutions, Minneapolis, Minnesota, United States
15. Christian Koch, Dr med habil, PhD, FACP, FACE, Deputy Editor, *Journal of Medical Case Reports*, University of Mississippi, Jackson, Mississippi, United States
16. Karen Milgate, MPP, Independent Health Policy Consultant, Washington, DC, United States
17. Michele Mittelman, RN, MPH, Editor, *Global Advances in Health and Medicine*®, Dover, Massachusetts, United States
18. David Moher, PhD, Ottawa Hospital Research Institute; Department of Epidemiology and Community Medicine, University of Ottawa, Ontario Canada
19. Hanna Oltean, MPH, University of Michigan, Ann Arbor, United States
20. Greg Plotnikoff, MD, MTS, FACP, Editor, *Global Advances in Health and Medicine*®, Allina Center for Healthcare Innovations and the Penny George Institute for Health and Healing, Minneapolis, Minnesota, United States

21. Richard Alan Rison, MD, FAANEM, Deputy Editor, *Journal of Medical Case Reports*, Section Editor, *BMC Research Notes*, PIH Health Hospital, Whittier, University of Southern California, Los Angeles, California, United States
22. David Riley MD, Editor-in-Chief, *Global Advances in Health and Medicine*®, Portland, Oregon, United States
23. Anil Sethi, MS, Johns Hopkins School of Medicine – Information architecture and IT, Palo Alto, California, United States
24. Larissa Shamseer, MSc, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada
25. Richard Smith, MB, ChB, MSc, United Healthcare Chronic Disease Initiative, London, United Kingdom
26. Harold Sox, MD, The Dartmouth Institute and Geisel School of Medicine, Hanover, New Hampshire, United States
27. Peter Tugwell, MD, FRCP, University of Ottawa, Ottawa, Ontario, Canada

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