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Original Article

CaReL Guidelines: A Consensus-Based Guidelines on Case Reports and Literature Review (CaReL)

Sakshi Prasad[1], Mahmoud Nassar[2], Ahmed Y. Azzam[3], Francisco García-Muro-San José[4], Mahnaz Jamee[5], Rim Kasem Ali Sliman[6], Giuseppe Evola[7], Ayman M. Mustafa[8], Hiwa O. Abdullah[8], Berun A. Abdalla[8], Shvan H. Mohammed[9], Fahmi H. Kakamad[10*], Abdulwahid M. Salih[10], Nicola Tartaglia[11], Giovanna Pavone[11], Giuliano D'Onghia[12], Silviu Daniel Preda[13], Sofia Maraki[14], Ivona Butorac Ahel[15], Carlo Pietro Campobasso[16], Jacek K. Szymański[17], Andrea Bottari[18], Laura Fortuna[19], Stefano Giuseppe Caraffi[20], Ilaria Mormile[21], Gaetano Riemma[22], Emmanuel Roilides[23], Serena Xodo[24], Nives Pecina-Slaus[25], Matteo Paganini[26], Giacomo Brisca[27], Giorgia Perniola[28], Matteo Frigerio[29], Rok Civljak[30], Salvatore Sardo[31], Marco Colizzi[32], Luminita Iliuta[33], Eric Chun-Pu Chu[34], Tummidi Santosh[35], Ahmed El Shamarka[36], Hossam Tharwat Ali[37], Reşat Özaras[38], Alparslan Dilsiz[39], Baha'eddin A. Muhsen[40], Maysa Al-Hussaini[41], Ricardo Grillo[42], G.V. Oliveira[43], Neil H. Riordan[44], Ishag Adam[45], Abdulqadir J. Nashwan[46], Nima Rezaei[47], Rasoul Goli[48], Abhigan Babu Shrestha[49], Sajina Shrestha[50], Jairo Corchuelo-Ojeda[51], Imen Ben Ismail[52], Umaharan Thamotharampillai[53]

1. *Bronxcare Health System, New York City, USA*
2. *Endocrine fellow PGY4, Department of Medicine, Division of Endocrinology, Diabetes and Metabolism, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, New York, USA*
3. *Montefiore-Einstein Cerebrovascular Research Lab, Albert Einstein College of Medicine, USA*
4. *Department of Physiotherapy, Faculty of Medicine, University San Pablo-CEU, Urbanización Montepríncipe, Boadilla del Monte, Spain*
5. *Pediatric Nephrology Research Center, Research Institute for Children's Health, Shahid Beheshti University of Medical Sciences, Tehran, Iran*
6. *Department of Pediatrics, Carmel Medical Center, Carmel Hospital, 7 Michal St., Haifa, Israel*
7. *Department of Surgery, Division of Surgery, "Garibaldi" Hospital, Catania, Italy*
8. *Smart Health Tower, Madam Mitterrand Street, Sulaymaniyah, Kurdistan, Iraq*
9. *Kscien Organization for Scientific Research (Middle East Office), Hamid Street, Sulaymaniyah, Kurdistan, Iraq*
10. *College of Medicine, University of Sulaimani, Madam Mitterrand Street, Sulaymaniyah, Kurdistan, Iraq.*
11. *Department of Medical and Surgical Sciences - University of Foggia, Foggia, Italy*
12. *Department of Surgery, Sapienza University of Rome, Rome, Italy*
13. *University of Medicine and Pharmacy of Craiova, Department of Surgery, Craiova, Romania*
14. *Department of Clinical Microbiology and Microbial Pathogenesis, University Hospital of Heraklion, Crete, Greece*
15. *Department of Pediatrics, Clinical Hospital Center Rijeka, Rijeka, Croatia*
16. *Department of Experimental Medicine, University of Campania "Luigi Vanvitelli", via Luciano Armanni, Naples, Italy*
17. *Department of Obstetrics and Gynecology, Centre of Postgraduate Medical Education, Warsaw, Poland*
18. *UOC Chirurgia Generale e d'urgenza, Ospedale Valdarno, Arezzo, Italy*
19. *Department of Clinical and Experimental Medicine, University of Florence, AOU Careggi, Largo Brambilla, Florence, Italy*
20. *Medical Genetics Unit, Azienda USL-IRCCS di Reggio Emilia, Reggio Emilia, Italy*
21. *Department of Translational Medical Sciences, University of Naples Federico II, Naples, Italy*
22. *Department of Woman, Child and General and Specialized Surgery, University of Campania "Luigi Vanvitelli", Naples, Italy*
23. *Infectious Diseases Unit, 3rd Dept Paediatrics, School of Medicine, Faculty of Health Sciences, Aristotle University and Hippokration General Hospital, Thessaloniki, Greece*
24. *Clinic of Obstetrics and Gynecology, Santa Maria della Misericordia hospital, Udine, Azienda Sanitaria Universitaria Friuli Centrale,, Udine, Italy*
25. *School of Medicine University of Zagreb, Department of Biology, Salata, Zagreb, Croatia*
26. *Department of Biomedical Sciences, University of Padova, Padova, Italy*
27. *Division of Neonatal and Pediatric Critical Care and Semi-Intensive Care, IRCCS Istituto Giannina Gaslini, Genoa, Italy*

28. *Department of Maternal and Child Health and Urological Sciences, Sapienza University of Rome, Rome, Italy*
29. *Gynecology Department, Fondazione IRCCS San Gerardo dei Tintori, Monza, Italy*
30. *University Hospital for Infectious Diseases 'Dr. Fran Mihaljevic' Zagreb, Croatia*
31. *Department of Medical Sciences and Public Health, University of Cagliari, Monserrato, Italy*
32. *Unit of Psychiatry, Department of Medicine (DMED), University of Udine, Italy*
33. *Medical Informatics and Biostatistics Department, University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania*
34. *New York Chiropractic and Physiotherapy Centre, EC Healthcare, 41/F Langham Place Office Tower, 8 Argyle Street, Kowloon, Hong Kong*
35. *Department of Pathology & Lab Medicine, All India Institute of Medical Sciences (AIIMS), Kalyani, West Bengal, India*
36. *General Surgery Department, Main University Hospital, Alexandria University, Alexandria, Egypt*
37. *Qena Faculty of Medicine, South Valley University, Qena, Egypt*
38. *İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine, Department of Infectious Diseases and Clinical Microbiology, İstanbul, Turkey*
39. *Department of Periodontology, Faculty of Dentistry, Atatürk University, Erzurum, Turkey*
40. *Neurosurgery Unit, Department of Surgery, Islamic Hospital, Amman, Jordan*
41. *Pathology, King Hussein Cancer Centre (KHCC), Amman, Jordan*
42. *Department of Oral and Maxillofacial Surgery, Faculdade Patos de Minas, Brasília, Brazil*
43. *Medical Sciences University of Minas Gerais (FCMMG), Belo Horizonte, Brazil*
44. *MediStem Panama Inc., Panama City, Panama*
45. *Department of Obstetrics and Gynecology, College of Medicine, Qassim University, Buraydah, Saudi Arabia*
46. *Nursing & Midwifery Research Department (NMRD), Hamad Medical Corporation, Doha, Qatar*
47. *Research Center for Immunodeficiencies, Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran*
48. *Department of Medical-surgical Nursing, School of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran*
49. *M Abdur Rahim Medical College, Dinajpur, Bangladesh*
50. *KIST Medical College Teaching Hospital, Imadol, Patan, Nepal*
51. *Community Department, School of Dentistry, Universidad del Valle, Cali, Colombia*
52. *Department of General Surgery, Traumatology and Severe Burns Center, University of Tunis El Manar, Ben Arous, Tunisia*
53. *Department of Psychiatry, University of Jaffna, Jaffna, Sri Lanka*

[*] ***Corresponding author***: fahmi.hussein@univsul.edu.iq *(F.H. Kakamad). Doctor City, Building 11, Apartment 50, Zip code: 46001, Sulaymaniyah, Iraq*

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Abstract

Introduction

Clinical case reports enrich medical literature by presenting rare medical issues. However, case reports that do not adhere to a standard template often lack rigor and limit their usefulness in clinical guidance. Several guidelines for reporting case reports have been structured, while further improvements are still required. The current guideline (CaReL) aims to enhance the comprehensiveness of case reports by integrating a detailed literature review.

Methods

In total, 56 researchers were selected based on specific publication criteria for structuring the guidelines. The guideline development was based on a two-step consensus process, including a literature review and survey distribution. Responses underwent scrutiny to ensure reliability and validity. Content validity was assessed, with revisions made to achieve a content validity index exceeding 0.78. The guideline's feasibility and effectiveness were evaluated by pilot testing, with feedback incorporated for finalization, ensuring the robustness and practicality of the guideline.

Results

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The CaReL guidelines can improve the quality of case reports through a comprehensive checklist with an increased emphasis on literature review. In addition to traditional sections with their subsections discussed in previous guidelines, the checklist also focuses on literature review in the abstract and discussion.

Conclusion

The CaReL guidelines offer a comprehensive structure for documenting case reports. They highlight the importance of incorporating a literature review to better introduce medical issues to readers and scholars and embedding reported cases into the current scientific state of the art. Implementing these guidelines can promote knowledge sharing and improve patient care.

1. Introduction

Clinical case reports have been vital in the medical literature [1]. The earliest recorded instance dates back to an ancient Egyptian papyrus from the 16th to the 17th dynasty, detailing the treatment of a dislocated jawbone [2]. From the time of Hippocrates in the 5th century BC to Galen in the 2nd century AD, physicians have used case reports to share intriguing cases they encountered with their peers [2]. Sir William Osler, often called the father of modern medicine, emphasized the importance of documenting and publishing unusual cases by physicians, stating that such communications are always valuable [3]. The Journal of Medical Case Reports, the first peer-reviewed journal exclusively dedicated to case reports, was launched in January 2007 [4]. In 2009, MEDLINE contained over one million case reports, growing by 40,000 annually [5].

A case, derived from the Latin word "casus," refers to an event or occurrence. While some view the patient or individual as the case, strictly speaking, the disease or clinical phenomenon under consideration constitutes the case. A case report, therefore, provides a comprehensive account of the experience of a single patient, detailing the specifics of the patient's condition or medical situation [2]. Case reports typically showcase clinical observations gathered in healthcare delivery settings. They have been instrumental in identifying both adverse and beneficial effects of drugs, recognizing new diseases, uncovering unusual presentations of common diseases, and shedding light on rare diseases [6]. They have the potential to spark hypotheses for future clinical investigations, aid in assessing global convergences of systems-oriented approaches, and assist in tailoring treatments to individual patients in clinical settings [7]. For instance, the initial clinical presentations of acquired immunodeficiency syndrome (AIDS) were documented in case reports. Additionally, in 1981, a single case report led to the hypothesis that oral contraceptives raise the risk of venous thromboembolic disease. Among 51 articles compiled by the Journal of the American Medical Association in 1985, five (10%) were case reports [5]. Penicillin, ether, and insulin were introduced through case reports or series [8].

When not adhering to established reporting guidelines, case reports frequently lack the rigor necessary for their inclusion in aggregated data analyses or serving as guides in clinical practice [5]. Several reporting guidelines exist in the genuine literature [9] for different study designs. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) for systematic reviews and meta-analyses [10], STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies [11], CONSORT (Consolidated Standards of Reporting Trials) for randomized controlled trials [12]. Several guidelines for reporting case reports have been structured, while further improvements are still required [13-15]. The current study aims to introduce a consensus-based guideline named CaReL (Case Report and Literature Review) to enhance the rigor and comprehensiveness of case reports by integrating a detailed literature review.

2. Methods

2.1 Study design and population

The study population comprised 56 researchers (among 90 invited scholars) identified based on specific criteria related to their publication history in case reports, manuals, systematic reviews, or other reporting guidelines for clinical research. The convenience sampling method was used to select participants for the study. The responses were collected through a survey distributed via Google Forms, with participants being recruited via invitations sent to their emails.

2.2 Sample size determination

The sample size was determined using G*power statistical software version 3.1.9.4, employing a sign test with two tails, an effect size of 0.3, an alpha error probability of 0.05, and a statistical power of 0.95. The software calculated a minimum sample size requirement of 32 participants. Consequently, 56 participants were recruited for the current study.

2.3 Guideline development

2.3.1 Literature review and survey

The study followed the Guidance for Developers of Health Research Reporting Guidelines and underwent a two-step consensus process [16]. Initially, a literature review on Google Scholar using the keywords “guideline OR guidelines AND “case report” OR “case reports” was

conducted to understand the importance of case reports, existing publication guidelines, and reporting quality assessments. This review generated a survey with six suggested modifications to the original CARE guidelines and nine optional answers to explain why the guideline was being made, how the agreement was being reached, and to collect feedback and ideas (Table 1) [14].

2.3.2 Survey distribution and response collection

Following the survey distribution, participants could supplement their responses by offering additional recommendations. Among the 90 invited scholars, 56 consented to participate in the study and engaged in and committed to the research endeavor. The responses gathered underwent meticulous scrutiny to ensure their reliability and validity.

2.3.3 Measurement of content validity index (CVI)

The CVI was determined by the proportion of experts who agreed upon the questions, divided by the total number of experts. The survey initially featured nine options and was subsequently condensed into three distinct categories. These categories comprised: firstly, "Agree," consolidating responses such as "slightly agree," "moderately agree," "agree," and "strongly agree"; secondly, "Undecided"; and thirdly, "Disagree," combining responses spanning from "slightly disagree" to "strongly disagree.". Scores ranged from 0 to 1. A CVI of 0.79 or higher indicates item relevance, while 0.70 to 0.78 suggests the need for revisions. Conversely, values below 0.70 suggest potential elimination. For studies with over five experts, an acceptable CVI is set at 0.78 [17]. Since most of the suggestions have been checked for validity and reliability before [14], the CVI was performed for only six suggestions in this study. Items with a CVI lower than 0.78 underwent revision, resulting in all items achieving a CVI exceeding 0.78.

3. Results

Initially, four out of the six (66.7%) suggestions demonstrated a strong validity with a CVI exceeding 0.78. However, the remaining two suggestions (33.3%) did not meet this threshold, requiring revision. After adjustments, these items attained a CVI above 0.78 and were included in the finalized guidelines (Supplementary 1). The checklist comprised ten main sections and ten minor subsections. Under the title section (Item 1), it was specified that titles should include the term "case report" along with the literature review and the primary focus of the study. The abstract (Item 2), which consists of four main subsections, crafts an informative summary of the case report's significance. It was recommended to emphasize the contribution to existing knowledge or clinical practice through a literature review related to the case. Additionally, keywords (Item 3) were expanded to 4 to 6 words. Within the introduction (Item 4), authors were instructed to provide background information on the case, its

Table 1: The survey questions to collect expert opinions.

No.	Question content	Options							
1	Adjusting the title containing only "Case Report" to include "Case Report and Literature Review".	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree
2	Expanding the number of keywords from 2-5 to 4-6.	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree
3	Modifying the subheadings in the abstract from "Introduction, Case presentation, Conclusion" to "Introduction, Case presentation, Literature review, Conclusion." Within the literature review section, a brief discussion on the significance of relevant literature about the case will be included.	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree
4	Introducing a "Review Table" within the discussion section, summarizing the key findings of the most significant published papers.	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree
5	Incorporating a paragraph at the end of the discussion section before the conclusion to highlight any missing important data and investigations "Limitations paragraph."	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree
6	Name the guideline "CaReL Guidelines" (Case Report and Literature review).	Strongly Disagree	Moderately Disagree	Slightly Disagree	Undecided	Slightly Agree	Moderately Agree	Agree	Strongly Agree

Table 2: Expert-based assessment of the guidelines and content validity index scores.

Experts	Q1	Q2	Q3	Q4	Q5	Q6
1	D	D	D	D	D	D
2	A	A	A	A	A	A
3	A	A	A	A	A	A
4	A	A	A	A	A	A
5	A	A	A	A	A	A
6	A	A	A	A	A	A
7	A	A	A	A	A	A
8	A	A	A	A	A	A
9	A	A	A	A	A	A
10	A	D	A	A	A	U
11	A	A	A	A	A	D
12	D	A	A	A	A	A
13	A	A	A	A	A	A
14	D	D	D	D	D	D
15	D	U	D	D	D	D
16	A	A	A	A	U	D
17	A	U	A	A	U	D
18	D	D	D	D	D	D
19	A	A	A	A	A	A
20	A	D	A	A	A	A
21	A	A	A	A	A	A
22	A	A	A	A	U	A
23	A	D	A	A	A	A
24	A	A	A	A	A	A
25	A	A	A	A	A	A
26	A	A	A	A	A	A
27	A	A	A	A	A	A
28	A	A	A	A	A	A
29	A	A	A	A	A	A
30	A	A	A	A	A	A
31	A	A	A	A	A	A
32	A	A	A	A	A	A
33	A	A	A	A	A	A
34	A	A	A	A	A	U
35	A	U	A	A	A	A
36	A	A	D	A	A	A
37	A	A	A	A	A	A
38	A	A	A	A	A	A
39	A	A	A	D	A	D
40	A	A	A	A	A	A
41	A	A	A	A	A	A
42	A	A	A	A	A	A
43	A	A	A	A	A	A
44	A	A	A	A	A	A
45	A	U	A	A	A	A
46	A	A	A	A	A	A
47	D	D	D	D	D	D
48	A	A	A	A	A	A
49	D	A	D	D	A	D
50	A	D	A	A	A	A
51	A	A	A	A	A	A
52	A	A	A	D	A	A
53	A	A	A	A	A	A
54	A	A	A	A	A	A
55	A	A	A	A	A	A
56	A	A	A	A	A	A
CVI	0.89	0.80	0.89	0.88	0.86	0.80

A: Agree, D: Disagree, U: Undecided, CVI: content validity index

significance in the broader medical context, and the objectives of reporting the case. In the case presentation section (Items 5a–5f), a timeline of significant events, details of the diagnostic approach, therapeutic interventions, and follow-up outcomes of the case have been focused on. This comprehensive overview aimed to understand the patient's condition from presentation to management and outcome. In the discussion section (Item 6), authors were prompted to critically analyze the case, aligning it with pertinent medical literature. This included dissecting the reasoning behind drawn conclusions, assessing causality, and effect relationships. Furthermore, they were encouraged to underscore the primary message gleaned from the case and introduce a review table outlining pivotal findings from notable publications. It was suggested that the final paragraph be integrated into the discussion section preceding the conclusion to spotlight any pertinent data or investigations that might have been overlooked as limitations of the report. Furthermore, these guidelines outline the inclusion of both patient perspective and informed consent as essential components. The guidelines are detailed in (Table 2).

4. Discussion

The CaReL guidelines encompass ten main sections and ten minor subsections, addressing critical aspects of the case report and literature review documentation. From the title section, emphasizing the inclusion of "case report" and the “literature review” component, to the discussion section, urging critical analysis aligned with medical literature, CaReL offers a comprehensive framework to meet the need for completeness and transparency in published case reports and brief literature reviews. Efforts were undertaken to achieve an equilibrium between providing sufficient details and maintaining the concise and appealing writing style typically found in case reports. Through the consensus process, a set of essential items was identified for authors to consider when submitting a case report for publication.

Many reports on health research fail to provide clear explanations for their methods and findings. Insufficient details about the research questions, procedures, and analyses can confuse readers. Studies in biomedical literature show varying quality and notable deficiencies in reporting methods and results [18]. To address this issue, the scientific community requires strong collaborations among journal editors, peer reviewers, authors, readers, and other stakeholders [19]. Research reporting guidelines aim to enhance the transparency and quality of research reports. Notably, there has been a significant rise in reporting guidelines, with over 300 guidelines cited by the Equator network [18].

Studies indicated that employing reporting guidelines, such as CONSORT, enhances the quality of scientific papers. For example, a Cochrane review revealed that journals endorsing CONSORT consistently exhibit improved reporting standards [11]. Nevertheless, not all journals maximize the use of these guidelines, with only a minority providing online instructions to peer reviewers and fewer still mentioning reporting guidelines. To remedy this, authors suggest that editors support peer reviewers by offering explicit instructions that include references to reporting guidelines [20].

Literature review plays a crucial role in case reports, often determining the acceptance or rejection of borderline cases. For rare cases, a thorough literature review and a prepared table are recommended additions to the manuscript in the current guidelines. This approach to promoting the CaReL guidelines includes several strategies: encouraging the implementation of the guidelines by medical journals in publishing case reports, extensions for medical specialties, accessibility through dedicated websites, promoting community engagement and feedback, and ongoing research on guideline impact.

The CaReL guideline, despite enhancing case report documentation, has several limitations. The development process involved a small sample of 56 researchers, potentially introducing selection bias. Limited pilot testing and subjective survey responses may affect the guideline's consistency. Additionally, the focus on pre-validated suggestions might exclude other relevant elements. Adoption could face resistance due to varying editorial policies and resource constraints. Regular updates are essential to maintain the guideline's relevance. Its applicability to all case reports, particularly in specialized fields, may be limited, requiring further adaptations. Addressing these limitations through broader engagement and continuous improvement is crucial for maximizing the guideline's impact.

5. Conclusion

The CaReL guideline offers a comprehensive structure for documenting case reports. It highlights the importance of incorporating a literature review to better introduce medical issues to readers and scholars and align it with pertinent medical literature. Implementing this guideline can promote knowledge sharing and improve patient care.

Declarations

Conflicts of interest: The author(s) have no conflicts of interest to disclose.

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