

REGULATION AND GUIDELINE

Consensus-Based Recommendations for Case Report in Chinese Medicine (CARC)*

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ABSTRACT Case reports are valuable clinical evidence in traditional Chinese medicine (TCM). However, the general reporting quality is suboptimal. A working group comprising 20 members was set up to develop systematic recommendations on case report in Chinese medicine (CARC). The working group (CARC group) developed a primary checklist based on reviewing the general reporting quality of case reports in TCM and thorough internal discussion. Two-round consensus process had been carried out among clinical experts, evidence-based medicine methodologists, medical journal editors and clinical practitioners with designated questionnaire embedded with the primary checklist. In total, 118 participants from 17 provinces of China and Korea completed the questionnaires. Their feedback was analyzed and discussed by the CARC group. The checklist was amended accordingly, and the final version, comprising 16-item, is presented here. Under the framework of CARC recommendations, the reporting quality of case reports in TCM can be improved.

KEYWORDS case report, Chinese medicine, reporting recommendations

Traditional Chinese medicine (TCM) has a long history of more than 2,000 years. Its theory is established and being completed by long-term clinical practice. Case report is a delicate and irreplaceable reporting form to record the diagnosis, therapeutic principle, remedy, treatment effect and prognosis of vivid practical case. It fully manifests the TCM theory implied and the points of views of practitioners on the basis of their own knowledge, which makes deep impression to the readers. Therefore, case report with the role of inheritance and exchange clinical experience is an important component for the development of TCM theory. Many TCM writings are collections of case reports, such as *Classified Case Records of Celebrated Physicians* (Ming Yi Lei An)⁽¹⁾ and *Case Records as a Guide to Clinical Practice* (Lin Zheng Zhi Nan Yi An)⁽²⁾ or are enclosed with several case reports as examples, such as *Augmented Compendium of Materia Medica* (Zeng Guang Ben Cao Gang Mu)⁽³⁾ and *Treatise on Cold Damage and Miscellaneous Disease* (Shang Han Za Bing Lun)⁽⁴⁾.

Today, as in the past, case reports are valuable clinical evidence in TCM, and case reporting is one of the most popular types of articles published in medical journals. However, the general reporting quality is suboptimal. We systematically reviewed 1,858 case reports, covering 3,417 cases, in 13 core Chinese

medical journals from 2006 to 2010. There were large variations in content and format. Less than 50% of them used terms like "case report" or "medical record" to identify the nature of the study. Reporting was commonly incomplete with regard to interventions, including dosages of medications and each ingredient, quality control, and treatment protocols. Only 70% of reports described the treatment rationale in the parts of "discussion" or "comment". Less than 40% had made recommendations or take-away

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messages, which could inform and/or improve future clinical practice. Other findings will be reported in a separate article in details. As these records represent valuable human experiences,⁽⁵⁾ computer technology, machine learning technology, information technology, knowledge discovery technology and data mining technology which enables rapid, thorough searching are now widely used in the field of TCM. However, to succeed, precise, accurate and complete reporting of case records is necessary.

Standardized and concise reporting recommendation can help to improve the quality of publications by promoting transparent, complete and accurate reporting.⁽⁶⁾ Although there are some studies which have made suggestions on writing and publication of case reports on TCM,⁽⁷⁻⁹⁾ none have developed these recommendations into a consensus process or a checklist. Nor has any authoritative body, including medical journal editorial review board, produced such a checklist of recommendations. Therefore, adherence to the suggestions is relatively low, and the quality of case reporting does not improve. For this current study, recommendations on case report in Chinese medicine (CARC) were developed by two rounds of an email-based survey among TCM clinical experts, methodology experts, medical journal editors and clinical practitioners. These recommendations are both consistent with similar guidelines for adverse-event case reports⁽¹⁰⁾ and case report for conventional medicine,⁽¹¹⁾ but tailor-made for general case reporting in TCM.

Research Design

The design of the study consisted of four development phases, namely: (1) preparation of a questionnaire based on checklist items generated from a literature review on the reporting quality of case reports in TCM by the CARC group, (2) selection of expert participants, (3) two rounds of email survey, and (4) finalization of the CARC recommendations. A flowchart of the study design is presented in Figure 1.

Preparation of Questionnaire

Firstly, the CARC group conducted a systematic review for more than 1,800 case reports in 13 core Chinese medical journals from 2006 to 2010 to analyze the case reporting situation in Chinese medicine. The results will be published in a separated paper. An internal meeting was then held to frame

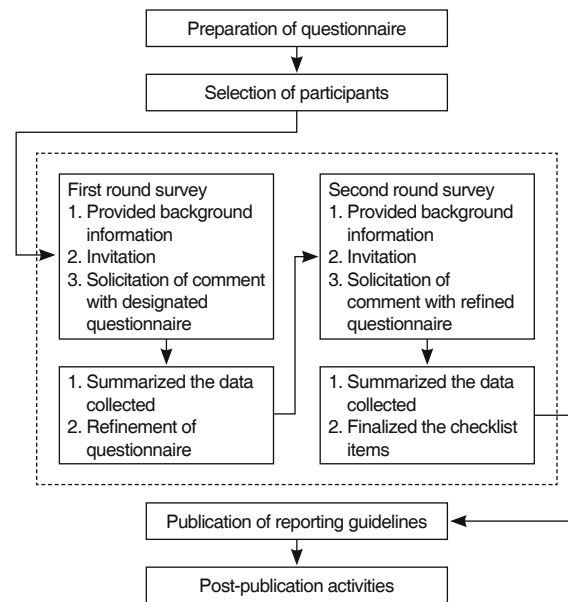


Figure 1. Flowchart of the Study Design

the domains and generate items which should be included in a good TCM case report with reference to the clinical case reporting guideline for conventional medicine⁽¹¹⁾ and consolidated standards for reporting trials of TCM.⁽¹²⁾ The checklist comprised 14 domains, namely: Chinese summary (title, abstract, key words), English summary (title, abstract, key words), background, patient's personal information, clinical findings, diagnosis, treatment strategy, therapeutic effectiveness assessment, follow-up, advices and precautions, discussion/comment, acknowledgements, references, and tables/figures. Items of chief complaint, medical history, symptoms and signs collected by TCM diagnostic methods, tongue and pulse characteristics, and details of intervention were categorized as essential. Other items were listed with options of "necessary/less necessary/unnecessary", or choices for participants to categorize. Each item was grouped and presented according to the domains they represented. There was space for comments and/or suggestions on any aspect of each item.

Selection of Participants

Multidisciplinary participants, including clinical experts, evidence-based medicine methodologists, medical journal editors and clinical practitioners, were invited to complete the questionnaire. For the first round survey, a small group of participants who had senior professional title and with at least 20 years of clinical or editorial experience was invited. The questionnaire was refined according to the comment

and feedback collected. After that, a bigger group of participants including front line clinical practitioners were invited to take the second-round survey.

Consensus Process

Potential participants from all over the China, including Hong Kong and Taiwan, were emailed with a research handbook and a questionnaire to solicit their participation. The background, objectives, methods and workflow of the survey and the key members of the CARC group were thoroughly explained together with a cover letter. Participants were requested to complete the questionnaire and send back the comments and suggestions within two weeks. In the meanwhile, remainder phone calls were made to all participants to reply the questionnaires on time.

Finalization of CARC Recommendations

A database was established recording experts' basic information (e.g. field of professional, years of working experience and professional title), choices, comments and suggestions for each question and the whole survey. Items on the checklist were retained or removed based on the overall replies plus CARC group discussion. If fewer than 50% of the returned questionnaires listed an item as "necessary", the CARC group discussed and ultimately decided whether to retain or delete the item. The consensus-based recommendation checklist was finalized.

Characteristics of Participants

In the first round of the survey, 31 replies were received in response to 34 invitations. After carefully analyzing the feedback and modifying some controversial items, we emailed the revised questionnaire to 144 experts for the second round survey. Of these, 87 valid replies were received within the predetermined period. In total, 118 participants completed the survey and their feedbacks were analyzed.

Except one from Korea, all participants came from 17 provinces and regions of China, including Hong Kong and Taiwan. The majority of participants were male (71.2% of male vs. 28.8% of female), and 87.3% were with senior professional title. They had worked in their professional fields from 3 to 54 years. Among them, 76 participants (64.4%) had more than 20 years' experience. Ninety-four out of 118 participants (79.7%) were TCM clinical experts

in different fields, 14 (11.9%) were evidence-based methodologists and 3 (2.5%) were editors of medical journals. The characteristics of the 118 participants are described in Table 1.

Table 1. Background of Included 118 Participants

Characteristics	Case (%)
Gender	
Female/male	34/84 (28.8/71.2)
Working experience (Years)	
≤10	16 (13.6)
10–20	24 (20.3)
20–30	59 (50.0)
>30	17 (14.4)
Missing data	2 (1.7)
Professional field	
Clinical medicine	94 (79.7)
Chinese medicine	49
Acupuncture/moxibustion/massage	24
Chinese and Western integrative medicine	21
Methodology	14 (11.9)
Editor of medical journal	3 (2.5)
Others	5 (4.2)
Missing data	2 (1.7)
Professional title	
Senior	103 (87.3)
Middle level	5 (4.2)
Primary	9 (7.6)
missing data	1 (0.9)
Geographical distribution	
China	
Northern	37 (31.4)
Northeast	2 (1.7)
Southeast	34 (28.8)
South-central	12 (10.2)
Southwest	4 (3.4)
Taiwan and Hong Kong	28 (23.7)
Korea	1 (0.9)

Items to Be Included in TCM Case Reports

The CARC group analyzed each checklist item with the feedback and comments collected. The group discussed at length the format of abstract (Item 2 in Table 2). There were 65.3% of experts agreed that a TCM case report should include an abstract; however, only 22.9% agreed that the abstract needed to have a structured format according to "objective", "methods", "results" and "conclusion". When we went

through their comments in detail, some of them did agree to have a well-organized abstract to report the characteristics of TCM case report, but without any specific recommendations. Therefore, we reworded the item referring to the abstract, and specified that the abstract should have a structured format that included main symptoms of patients, differentiation of disease and TCM pattern, treatment, outcome assessment, treatment outcomes, and highlights.

Another controversial item was Item 5b which concerned obtaining consent from patients or their guardians prior to publication. Personal confidentiality has attracted attention in recent years, and consensus on securing patients' confidentiality was reached in the International Committee of Medical Journal Editors (ICMJE) Conference in 1991.⁽¹³⁾ As personal data is easily exposed in a case report, more and more international journals now require written consent from the patients or their guardians before publishing case reports.⁽¹⁴⁾ The situation is different in China. We found that patient consent was not required for publishing a case report in any medical journal in China today. Although less than 50% (44.9%) of participants picked this item as "necessary" in the consensus survey, because of its importance in international medical journal, we retained this item in the finalized reporting recommendations.

For outcome assessment (Item 10), there are currently no universal criteria to evaluate the therapeutic effect of TCM. Even though we provided the choices of (1) TCM symptoms and signs, (2) modern examination findings, (3) TCM symptoms and signs plus modern examination findings, and (4) others, many experts pointed out that there were too many forms of outcome measures depending on the target disease and the type of intervention to fit this format. Given the diversity outcome measures, a standardized reporting format seemed impractical. Therefore, we only recommended the use of widely recognized gold standard assessment criteria, if applicable, or self designated criteria with explanation in details.

Other less necessary controversial items, such as differential diagnosis of conventional medicine, batch number of Chinese proprietary medicine, and source of materia medica used in the herbal decoction, were classified as "selective content" in

a case report. The author of the report could include or not include this information at his/her discretion. For the quality control of interventions, although this is crucial factor affecting treatment efficacy, several experts expressed the opinion that it was difficult for a clinical practitioner to provide this kind of information in routine clinical practice. Hence, these items were reserved for further discussion and determination in the future.

Reporting TCM Interventions in Case Report

From the feedback collected from two-round consensus survey and reference with the reporting standards on randomized controlled trials of Chinese herbal medicine (CHM),⁽¹²⁾ acupuncture⁽¹⁵⁾ and moxibustion,⁽¹⁶⁾ the reporting details of these three most common TCM interventions in Item 9 of the CARC recommendations were listed. Other traditional interventions, such as therapeutic massage (Tuina), scraping and herbal fumigation and steaming, have also been used in clinical practice. However, further studies should be implemented before developing individual reporting recommendations of these interventions. Therefore, only some general key information, such as procedure, treatment courses and number of treatment sessions, was recommended to report in case report. When the CARC recommendations are updated as appropriate in future, specific reporting items of each TCM intervention will be supplemented.

Finalization of Reporting Recommendations for Case Report on TCM

The finalized reporting recommendations comprise 16-item checklist in 14 domains. They provide a framework by which the needs for completeness and transparency for publication of case reports on TCM can be satisfied. The details are shown in the following Table 2.

Discussion

A case report is a narrative describing an intervention and its outcome in one patient.⁽¹⁷⁾ It is less important than randomized controlled trial, prospective comparative study, cohort study and case-control study, which represents the lowest level of published clinical evidence in evidence-based medicine.⁽¹⁸⁾ However, this study design targeting one or a small group of patients is particularly suitable for TCM because TCM emphasizes individualized

Table 2. The Reporting Recommendations Checklist

Item name	No.	Brief description
Title	1	a. The words "case report" or similar terms (e.g. "medical record" and "case study") should appear in the title b. The number of cases/patients included if for case series
Abstract	2	Briefly describe the characteristics of the reporting cases, and state the discussion and comment may arise-Can reference to a structured format [e.g. main symptoms of patients, differentiation of disease and TCM pattern, treatment, outcome assessment, treatment outcomes, and highlights of this case]
Keywords	3	The key elements of this case in 3–5 words (e.g. case report, name of disease, name of TCM pattern, treatment remedy)
English summary	4	The title, abstract and keywords in English
Introduction	5	a. Why choose this case to report? b. The informed consent obtained from patients or their guardians
Patient information	6	a. List out patient's appellation (use the surname instead of using the word "patient" or represent with the inpatient/outpatient number), gender, age, date of consultation, as well as the 24 solar terms if related to the case b. Recommend to report the patient's height/weight/marital status/occupation/source (name of hospital, inpatient / outpatient case), and the qualification of practitioner who treat and report the case
Clinical findings	7	Describe the main complaint, present and other medical history, TCM symptoms and signs, characteristics on tongue and pulse. Other optional items include allergies, social life history, family / inheritance history
Diagnosis	8	a. For case diagnosed by TCM - Must report the differentiation of TCM pattern. Diagnostic criteria (rationale) can be presented by citing related literatures b. For case diagnosed by conventional medicine - Report examination finding and diagnosis of conventional medicine; - Diagnostic criteria (rationale) can be presented by citing related literatures - Can report the differential diagnosis on conventional medicine, if applicable c. For case diagnosed by both TCM and conventional medicine - Report the contents 8a and 8b simultaneously
Treatment	9	a. The therapeutic principle of TCM b. Chinese herbal intervention - For Chinese proprietary medicine, must report the product name, dosing, administration and treatment course, and also report the name of manufacturer and lot number. Recommend to report the quality control standard, if applicable - For self-prepared herbal intervention, must report the composition, dose of each ingredient, manufacturing procedure (e.g. brewing), dosing, administration, treatment course, and also report the place of cultivation, preparation method, and quality control standards, if applicable c. Acupuncture intervention - Must report the names (or location if no standard name) of points used (uni/bilateral), operating procedure (e.g. insertion angle, stimulation), needle retention time, and treatment sessions (frequencies). Recommend to report the rationale of point selected, needle type (diameter, length or material), and depth of insertion (based on a specified unit of measurement or on a particular tissue level). - For electroacupuncture, the model of device, the stimulus intensity, frequency, and wave form should also be reported d. Moxibustion intervention - Must report the names (or location if no standard name) of points used (uni/bilateral), materials used, procedure and technique for moxibustion, treatment sessions (frequency). Recommend to report the rationale of points selected, quality of the material used, number of moxibustion units - For electromoxibustion, the model of device, and the stimulus intensity and frequency should also be reported e. For integrated treatment including the interventions above, please reference to Item 9b, 9c and 9d individually f. For integrated treatment not including the interventions above, must report the procedure and treatment courses/sessions in details g. Must report the precautions of each single intervention
Outcome assessment	10	Using widely recognized gold standard assessment criteria, if applicable or self-designated criteria with explanation in details
Follow-up	11	a. During the treatment period, the changes of treatment remedies with underlying rationale b. Follow-up visit with date and consequent, if applicable
Advices and precautions	12	The advices and precautions on diet, emotions and living
Discussion / comment	13	Specify the significances and difficulties for the diagnosis or treatment of this case; highlight the strengths and characteristics, elaborate the rationale of prescription, and the take away message from this case
Acknowledgement	14	Acknowledge anyone who contributed towards this case
References	15	The literatures are relevant to this case (unlimited with exact number of references)
Figures / Tables	16	The figures and tables are relevant to this case (unlimited with exact number)

treatment. Even patients diagnosed with the same disease (Western criteria) and/or TCM pattern may

receive different treatment. Furthermore, different TCM practitioners are likely to prescribe different

prescriptions in term of ingredients and dosages for the same patient. Therefore, the readers cannot just copy the intervention from a TCM case report to re-apply in clinical practice directly. Instead, the significance of a TCM case report is the "take-away" message as to how the patient was diagnosed and why a particular intervention was prescribed.

Case reporting has played an important role in the development of TCM theory over centuries. However, the incompleteness of reporting in the past impedes the collection, compilation and analysis of case reports today. In this current study, we try to establish a comprehensive set of recommendations for reporting of TCM cases by thorough consultation with clinical experts, methodologists, medical journal editors and clinical practitioners. For the post-publication activities, we will present the CARC recommendations in international conferences and workshops and publish its Chinese translation in local medical journal for better dissemination, encourage endorsement from medical journals, and support adherence from authors and peer reviewers for better implementation.⁽⁶⁾ Furthermore, we will also seek feedback and criticism from all stakeholders, and update the recommendations and the checklist as appropriate.

The development of current reporting recommendations had several possible limitations. First, we did not offer open-ended questions in the first-round survey in order to enhance the efficiency of consensus process. This might have missed some opportunities to gather ideas from the experts. However, participants could make suggestions as each survey question was followed with a remarks column where the participants could express their own comments and ideas. Second, the representativeness of participants made a great impact on the survey results. The participants of the present study were mainly composed of clinical experts, while only three medical journal editors responded to the survey. As the support from the editors is important to achieve endorsement from medical journals, the feedback and comments from them were very valuable. Third, more than 70% of participants came from Hong Kong, Beijing, Shanghai or Tianjin. The feedbacks collected might not be able to generalize to experts in other regions. Further consensus survey can be done for experts from central and western regions.

Standardization can promote the development of TCM. By retaining the principles of scientific, diversity and practicability, the proposed reporting recommendations not only can illustrate the specialties on TCM, but also can introduce itemization commonly used in modern health research. Under the framework of CARC recommendations which satisfies the need for precision, completeness and transparency, the general quality of case report in TCM can be elevated into a higher level.

Conflict of Interests

The authors declare that they have no competing interests.

Author Contributions

Bian ZX, Shang HC, Zhang BL and Wang YY formed the CARC group. Fu SF, Zhang L, Bian ZX and Shang HC prepared and distributed the questionnaires. Fu SF, Zhang L, Cheng CW, Kun W and Lin J summarized the feedback and comments. Fu SF, Cheng CW, Bian ZX, Shang HC and the CARC group finalized the recommendations. Fu SF, Cheng CW, Zhong LL and Bian ZX wrote the manuscript. All authors have read and approved the final version of the manuscript.

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