Convergent Points
AN EAST-WEST CASE REPORT JOURNAL

For Clinicians: Chinese Herbal Medicine Case Report Guidelines (CHM-CARE)

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Abstract

Chinese herbal medicine (CHM) relies on a complex diagnostic system, materia medica, and herbal formulary. Case reports have long been used in China in CHM, but this tradition is less common in the West, partly due to an absence of case reporting guidelines specific to the discipline. This study, involving practitioner focus groups, content analysis, and a Delphi survey with international experts, aimed to create CHM case report guidelines to help practitioners create structured and comprehensive herbal case reports. The result was the identification of key elements for a CHM case report checklist and guidelines offering robust recommendations tailored to the CHM practitioner.

Keywords: traditional Chinese medicine, Chinese herbal formula, chronic insomnia, case report

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Brigitte Linder has been practicing acupuncture and Chinese herbal medicine for the past 20 years. She immigrated to Australia from Switzerland in 2008 and has been running a national herbal dispensary service in Victoria since then. Brigitte has looked after many patients with various health challenges in her local community. In addition to being a mentor and author, she is also interested in exploring how Traditional East Asian Medicine (TEAM) practitioners can use structured case reports to enhance their practice and increase their publications in Chinese herbal medicine and indexed journals.

Summary

Case reports and case report series (several case reports) capture detailed and comprehensive information about an individual patient receiving a specific healthcare service. If the data in case reports are captured systematically, they provide valuable information, particularly for Traditional East Asian Medicine (TEAM) clinicians. In TEAM, case reports have a long history and continue to play an integral part in expanding clinical skills.

Despite case reports ranking lower on the evidence-based research pyramid, case reports have become more prevalent across many fields of medicine. In 1995, the prestigious Lancet Journal introduced a case report section, and case report publications have experienced a significant resurgence since then. One reason could be that general medicine and psychology may have begun focusing on patients in the late 1990s (Bradbury et al., 2020).

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The Chinese Herbal Medicine Case Report (CHM-CARE) guidelines include a checklist with 61 sub-items across 16 sections to assist TEAM practitioners in generating a structured case report. Each item describes the information that needs to be placed in each section. We created new guidelines because the existing Case Report Guidelines (CARE) (Care Guidelines 2012 - 2014) did not accommodate all the requirements of a complex TEAM modality. One such complexity is that TEAM interventions can hold evolving diagnostic processes; thus, the prescribed herbs might change multiple times during treatment. Also, a detailed section to capture self-care advice routinely given to patients by TEAM practitioners was missing in the CARE guidelines. The higher number of checklist items in the CHM-CARE was to assist inexperienced TEAM practitioners in creating a structured and comprehensive case report.

Putting the patient at centre stage comes naturally to all TEAM clinicians; hence, writing case reports should be simple, too, as long as there is guidance as to what information needs to be provided for a case report to have salient information.

The co-designed CHM-CARE guidelines and checklist came out of a graduate research degree at Western Sydney University in Australia, the goal of which was to inspire more TEAM clinicians to participate in research activities and produce structured case reports.

The CHM-CARE guidelines project

Background: Chinese Herbal Medicine (CHM) is a popular complementary medicine (CM) modality. Previous research has established that randomized controlled trials (RCTs) are suboptimal to investigate complex interventions as the customization of treatment poses a significant challenge in the typical RCT design (Padarini et al., 2020). In addition, TEAM clinicians are reporting considerable barriers in translating RCT results into clinical practice (Armour et al., 2021). Current guidelines such as CARE and Case Report in Chinese Medicine (CARC) (Fu et al., 2016) do not accommodate the practice settings of most Western TEAM practitioners. The CHM-CARE aimed to co-design guidelines for CHM practitioners who operate in private clinics or outpatient settings.

Method: This project used a two-phased, mixed-method approach based on an exploratory sequential design. Focus groups with 18 participants (at least 18 years of age and qualified in CHM at Diploma Level or higher) and registered with a professional association with primary practices in Australia, New Zealand, the UK, or the US were held to investigate essential components

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Dr. Guoyan (Emily) Yang joined NICM Health Research Institute in 2019 and is now a Research Support Program Fellow. Her doctoral research examined the effect of tai chi for cardiovascular disease, which she continues to study, along with performing clinical trials of Chinese herbal medicine and acupuncture as they pertain to cardiovascular disease, cerebrovascular disease, and cognitive impairment. Her goals are to improve prevention, treatment and rehabilitation for people with chronic diseases. Dr. Yang's findings have been widely published in high impact peer-reviewed journals, cited by leading researchers from different countries, and presented at national and international conferences.

OPEN ACCESS
Citation: Linder, Brigitte. (2023). For Clinicians: Chinese Herbal Medicine Case Report Guidelines (CHM-CARE).

and attitudes towards case reports. A Delphi survey was then conducted after the content analysis of Phase One, and current sources of case report guidelines were considered. Fifteen international TEAM experts participated to refine the checklist further. Those experts had 5+ years of clinical TEAM experience with either holding a higher degree, a current academic appointment, previous experience in case report writing and/or publishing or being an editor or contributor to an editorial board of a journal for case TEAM case reports. The consensus for each item was defined as reached at > 70%.

Results: From the 18 focus group participants with a median age of 50.7 years, the content analysis produced 349 codes, which informed a checklist with 98 subitems that were subsequently used in the first round of the Delphi survey. The 15 international panelists rated 37 items below the median of 3. For the second round, 14 experts achieved consensus on 61 items.

Conclusion: Consensus was reached on critical elements of the CHM-CARE checklist and guidelines. To facilitate and enhance the reporting of CHM case reports and encourage the growth of clinician-researchers, we expect that the co-designed case report guidelines will inspire TEAM practitioners to adopt the practice of case report compilation and publication.

Similarities and differences to the Case Report (CARE) guidelines used in biomedicine

The CHM-CARE guidelines were developed with the CARE guidelines in mind. The principal sections are comparable, but the CHM-CARE guidelines have three more sections and a higher number of items. The additional sections were *Advice and precautions*, a separate *References* section, and a *Nomenclature and terminology* section. We anticipated that TEAM clinicians might have less experience with compiling structured case reports for publishing. Consequently, we provided more prompts for the information required in each section of the case report. The main difference to the CARE guidelines is the provision to accommodate TEAM language and the use of various TEAM frameworks.

Case report layout (CHM-CARE checklist)

Topic	Item	Checklist item description	Details and example
Title	1	Include the phrase "case study" or "case report," the TEAM modality, and, if relevant, the biomedical diagnosis.	Case report: The treatment of stroke with Chinese herbal medicine
Abstract	2a	Main lessons learnt	The Abstract should not exceed 250 words and briefly describe items a – e. This information should cover the

Convergent Points, 2(2).
www.convergentpoints.com
Editor: Kathleen Lumiere, Bastyr University, UNITED STATES
Received: September 28, 2023
Accepted: October 11, 2023
Published: October 15, 2023

Data Availability Statement: All relevant data are within the paper and its supporting information files.
Funding: This article received no funding of any type.
Competing interests: The author has declared that no competing interests exist.

	2b	Main diagnoses and therapeutic interventions	background and context of this case. For example, the main takeaway message could be what you learnt from this case and how the unique features help understand a diagnosis, a treatment modality, a rationale, or the outcomes in more detail.
	2c	Main symptoms and important clinical findings	
	2d	Rationale	
	2e	Outcomes	
Keywords	3	Three to five keywords should include the phrase "case report," modality and the biomedical name	Examples of keywords: "case report," "Chinese herbal medicine," "Traditional East Asian herbal medicine," "stroke"
Introduction	4a	An explanation of the case's importance	This section should be concise, be two paragraphs or less long and include items a – c with as many pertinent details as possible. If other researchers are quoted, it must include relevant references.
	4b	A brief description of the pathology, including common presentations and disease progression	
	4c	Information about general incidence/prevalence and aetiology	
Patient information & case presentation	5a	Chief complaint(s)	This section should include items a – h with as many relevant details as possible.
	5b	A brief description of the pathology, including common presentations and disease progression	
	5c	Patient age	
	5d	Sex and/or gender identity	
	5e	Relevant social, economic, and environmental context	
	5f	Allergies and sensitivities if relevant	
	5g	History of the present illness	
	5h	Past medical history (including other interventions and their outcomes)	
Clinical findings & physical examination	6a	Describe the main complaint	This section should include items a – g. All your clinical findings and any insights from your physical examination (channels, abdominal, pulse, etc.) should be reported.
	6b	List all TEAM symptoms and signs	
	6c	Describe the characteristics of the tongue.	
	6d	Describe the characteristics of the pulse.	
	6e	Include the results of radiographic, laboratory, or orthopaedic testing.	
	6f	Describe any other palpatory findings such as channels, abdomen, etc.	
	6g	Include physical observations, including skin, etc.	
Diagnostic assessment	7a	TEAM diagnosis, e.g., Spleen qi deficiency, etc.	This section should give pertinent information on the diagnosis and include the therapeutic intent and the specific framework used. For TEAM diagnoses, details should consist of aetiology and diagnostic rationale, i.e., clinical judgment.
	7b	Biomedical diagnosis, e.g., irritable bowel syndrome, etc.	
	7c	Therapeutic intent, e.g., return of period, ability to	

		walk to work without pain, having daily bowel motions, etc.	
	7d	Theoretical framework, e.g., eight principles theory, five elements, six conformations, three levels, Kampo, etc.	
Therapeutic interventions	8a	Product or formula name	In this section, items a – e should be included for CHM interventions. For additional acupuncture interventions, the point names must be listed. In case of any other interventions used in conjunction with CHM, they must also be noted.
	8b	Single herb ingredients	
	8c	Dosing of the herbs	
	8d	Treatment course	
	8e	Administration of the herbs	
		If acupuncture is used in conjunction with herbal treatment: Point names using WHO terminology, e.g., SP6, etc., should be used	
		If any other therapeutic interventions are used, they should always be reported.	
Follow-up & assessment	9a	Self-assessed clinician outcomes, e.g., periods have become regular, etc.	In this section, items a – f covering follow-up assessments should be listed.
	9b	Follow-up diagnostic or other test results	
	9c	Intervention adherence, e.g., is the patient taking the herbs as prescribed, following the diet and lifestyle advice, etc.	
	9d	Any adverse effects occurring during the treatment course (reporting in this section as opposed to another section)	
	9e	Intervention tolerability, e.g., has the patient complained of bad taste, nausea or similar, etc.	
	9f	Objective clinician outcomes, e.g., Hamilton depression scale (HDS or HAMD), blood tests, etc.	
Advice and precautions	10a	Based on the TEAM framework	In this section, we would like you to report any diet, lifestyle, or other advice given to the patient. Again, they can be within the TEAM or any other framework.
	10b	Based on any other framework	
Discussion	11a	A 'take away' conclusion/lesson in one paragraph	In this section, items a – e should be included.
	11b	Strengths and limitations of your approach in this case	
	11c	The TEAM-relevant rationale for your outcomes and conclusions	
	11d	Significances and difficulties for the diagnosis or treatment in this case	

	11e	How this case might inform practice guidelines	
Patient perspective	12	A patient perspective of 1 - 2 paragraphs (in their own words) should be included.	One to two paragraphs in narrative format should be included from the patient in this section.
References	13	Detailed reference list	This section should include a detailed reference list (for example, if you refer to conclusions discussed elsewhere). If referring to medical literature, details of sources used need to be provided as they acknowledge the work of other authors.
Nomenclature & Terminology	14a	To report the Chinese names (e.g., Bai Zhu) of the herbal ingredients	Please use Chinese pinyin or Kampo names to report the herbal intervention. If available, use biomedical terminology (especially if the patient has a biomedical diagnosis such as stroke). The WHO list containing standard terminology should be used to standardize the language.
	14b	To include biomedical terminology	
	14c	to use AEMA/TEAM language designed in the "WHO international standard terminologies on TCM" list (Choi et al, 2010)	
Patient consent	15	Obtained consent from the patient.	The patient must provide informed consent for the publishing of their case report.
Supplementary material	16	Provide photos, tables, and figures.	Please provide good-quality materials that are relevant to the case report presentation.

Conclusion

The international CHM-CARE guidelines team and the editorial board at Convergent Points urge clinicians to adopt the checklist and guidelines for Chinese herbal medicine (CHM) case reports and publications. In addition to communicating findings of note to fellow practitioners and the broader medical community, and learning a great deal in the process, writing case reports to the CARE-CHM standards contributes to a repository of data that can be beneficially used in synthesis and trend analysis. Secondary data analysis, the process of discovering patterns in large datasets, could be valuable to uncover patterns that may assist our patients and advance practice-based research. At the same time, whilst discussions with TEAM practitioners revealed there is suspicion towards "evidence-based knowledge" (Robinson et al., 2012), and there exists a dichotomy between TEAM clinicians and researchers, compiling and reading structured case reports could be a means to help close that gap and use the strengths of each for the benefit of the whole profession.

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