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SCM

世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM 000*-20**

中医证候诊断标准质量评价指南

Quality evaluation guideline for diagnostic criteria of Chinese medicine syndromes

世界中联国际组织标准

International Standard of WFCMS

2020–**–**发布实施

Issued & implemented on ** **, 2020

目　次

前　言

本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

主要起草单位：河南中医药大学、河南中医药大学第一附属医院。

参与起草单位：北京大学、北京中医药大学、北京中医药大学东直门医院、中国中医科学院、中国中医科学院西苑医院、首都医科大学附属北京中医医院、广州中医药大学第一附属医院、广东省中医院、天津中医药大学、天津中医药大学第一附属医院、兰州大学、四川大学华西医院、成都中医药大学附属医院、香港浸会大学、英国利物浦热带医学院、加拿大阿尔伯塔省卫生厅数据分析中心、澳大利亚中医药学会。

指导专家委员会：王永炎、张伯礼、孙塑伦。

主要起草人：李建生、谢洋、王佳佳、雷斯媛、袁月。

参与起草人及审阅专家　（以姓氏笔画为序）：

中国：于长禾、王天芳、王晓辉、史楠楠、吕爱平（中国香港）、杜亮、李博、吴大嵘、杨小波、杨克虎、刘建平、刘孟宇、刘新灿、张声生、张明妍、张俊华、陈薇、陈耀龙、费宇彤、侯政昆、胡思源、唐健元、高蕊、葛龙、廖星。

美国：孙凤。

英国：陈涛。

加拿大：陈冠民。

澳大利亚：郑建华、韦国庆。

本文件起草程序遵守了世界中医药学会联合会发布的SCM 1.1-2021《标准化工作导则 第1部分：标准制定与发布》。

引　言

中医证候诊断标准（以下简称“证候标准”）是中医药标准化的主体之一。客观、科学的证候标准是提高中医诊治水平的关键，也是提供高级别中医药临床疗效证据的有力保障。近年来，中医药标准化工作发展迅速，证候标准发布数量呈快速增长态势，一定程度上推动了证候标准化研究及应用。但证候标准在临床实践中存在应用不足、推广困难等问题，可能与“证候标准”自身存在着研制方法不规范、方法学质量参差不齐等有关。质量评价是指评估单个研究在设计、制定、结果分析整个过程中可能出现各种偏倚的程度，质量评价工具则是依据这些可能出现的偏倚的各个方面，提出共性问题，形成指南条目清单。目前质量评价工具主要集中在临床实践指南领域，尚缺乏证候标准的质量评价指南。因此，亟待制定证候标准质量评价指南，对证候标准的方法学质量进行合理评价，以提升证候标准质量，使其更好应用于临床，提高中医临床疗效。

本文件综合考虑卫生政策法规和相关指导原则，以 SCM 70-2022《中医证候诊断标准研制指南》及相关证候标准为基础，借鉴国内外相关质量评价工具的研制方法与流程，结合证候标准特点，开展本文件研制工作。本文件旨在帮助减少/规避证候标准研制过程中技术与方法学偏倚，为证候标准研制过程的科学化、规范化提供参考。

中医证候诊断标准质量评价指南

1 范围

本文件规定了中医证候诊断标准质量评价的评价原则、评价内容、评分方法等内容。

本文件适用于各级中医（中西医结合）医疗、教学机构及科研院所专业人员进行证候标准质量评价时使用。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 20348-2006　　中医基础理论术语

GB/T 16751.2-2021　中医临床诊疗术语 第 2 部分：证候

GB/T 15657-2021　　中医病证分类与代码

3 术语和定义

下列术语和定义适用于本文件。

3.1

证候

证的外候，即疾病过程中一定阶段的病位、病因、病性、病势及机体抗病能力的强弱等本质有机联系的反应状态，表现为临床可被观察到的症状等。

[来源：ISBN 7-03-015154-2，04.548]

3.2

质量评价

指评估单个研究在设计、制定、结果分析整个过程中可能出现各种偏倚的程度。

[来源：https://training.cochrane.org/resource/grade-handbook]

4 评价原则与流程

4.1 评价原则

评价应坚持科学性、客观性和公正性，确保评价过程基于真实数据和事实，避免主观偏见的干扰，保证评价结果的可追溯性。

4.2 评价流程

评价流程包括确定目标证候标准、结合评价工具对证候标准全面评分、形成评价报告。

5 评价内容与要求

5.1 目的和范围

a）明确描述目的。

b）明确描述适用人群。

c）明确描述使用者。

5.2 参与人员

a）制定组由多学科人员组成，职责明确。

b）报告起草人和起草单位。

c）报告发布单位。

5.3 研制流程

5.3.1 文献研究

a）描述文献研究目的。

b）描述文献检索策略。

c）描述文献筛选过程。

d）描述信息提取过程。

e）描述术语规范过程。

f）明确统计分析方法。

5.3.2 专家咨询

a）描述专家咨询目的。

b）描述专家遴选条件。

c）描述问卷内容。

d）明确统计分析方法。

5.3.3 临床调查

a）描述调查目的。

b）界定调查人群。

c）描述调查方法。

d）描述临床调查表制定过程及内容。

e）描述样本量估算方法。

f）明确统计分析方法。

5.3.4 标准建立

a）报告标准建立的依据。

b）采用适宜的形式呈现标准。

5.3.5 标准验证

a）描述验证目的。

a）界定调查人群。

c）描述调查方法。

b）描述验证调查表制定过程及内容。

e）描述样本量估算方法。

f）明确统计分析方法。

5.4 其他

a）引用并标注参考文献。

b）报告资金支持情况。

c）报告利益冲突情况。

d）报告定期更新计划。

6 评分标准

评价标准包括对上述每一个条目的评价及其具体细节的评价。评价标准阐明了条目可用定义的分值，采用 5 级李克特评分，即 1-5 分，分值越高，证候标准在该条目质量越高。具体评分要求参考附录 B。

附录 A

（资料性）

中医证候诊断标准质量评价清单

领域	条目	说明
1.目的和范围		
	a）明确描述目的。	评价标准是否明确描述目的。
	b）明确描述适用人群。	评价标准是否明确描述适用人群，如患者特征。
	c）明确描述使用者。	评价标准是否明确描述使用者，如医生、科研人员等。
2.参与人员		
	a）制定组由多学科人员组成，职责明确。	评价制定组是否由多学科人员组成，如中西医临床、循证医学、流行病学、统计学等，职责是否明确。
	b）报告起草人和起草单位。	评价标准是否报告起草人和起草单位。
	c）报告发布单位。	评价标准是否报告发布单位。
3.研制流程		
3.1 文献研究	a）描述文献研究目的。	评价标准是否描述文献研究目的。
	b）描述文献检索策略。	评价标准是否描述文献检索策略，如检索数据库、检索时间等。
	c）描述文献筛选过程。	评价标准是否描述文献筛选过程，如纳入与排除标准、筛选方法等。
	d）描述信息提取过程。	评价标准是否描述信息提取过程，如提取纳入文献的证候及四诊信息等。
	e）描述术语规范过程。	评价标准是否描述术语规范过程。
	f）明确统计分析方法。	评价标准是否描述统计分析方法，如描述性统计、聚类分析、隐结构等。
3.2 专家咨询	a）描述专家咨询目的。	评价标准是否描述专家咨询目的。
	b）描述专家遴选条件。	评价标准是否描述专家遴选条件，如职称、从事专业、从业时间等。
	c）描述问卷内容。	评价标准是否描述问卷内容。
	d）明确统计分析方法。	评价标准是否描述统计分析方法，如评价标准是否描述采用哪些指标统计专家问卷结果，如使用均数、变异系数等。
3.3 临床调查	a）描述调查目的。	评价标准是否描述临床调查目的。
	b）界定调查人群。	评价标准是否界定调查人群，如明确西医诊断标准等。
	c）描述调查方法。	评价标准是否描述调查方法，如采用横断面调查等。

	d）描述临床调查表制定过程及内容。	评价标准是否描述临床调查表制定过程及内容。
	e）描述样本量估算方法。	评价标准是否描述样本量估算方法。
	f）明确统计分析方法。	评价标准是否描述统计分析方法，如描述性统计、聚类分析、Logistic 回归分析等。
3.4 标准建立	a）报告标准建立的依据。	评价标准是否报告标准建立的依据。
	b）采用适宜的形式呈现标准。	评价标准是否采用适宜的形式呈现标准，如诊断条件组合法、积分计量诊断法等。
3.5 标准验证	a）描述验证目的。	评价标准是否描述验证目的。
	b）界定调查人群。	评价标准是否界定调查人群，如明确西医诊断标准等。
	c）描述调查方法。	评价标准是否描述调查方法，如采用前瞻性临床调查等。
	d）描述验证调查表制定过程及内容。	评价标准是否描述验证调查表制定过程及内容。
	e）描述样本量估算方法。	评价标准是否描述样本量估算方法。
	g）明确统计分析方法。	评价标准是否描述统计分析方法，如采用哪些指标统计验证结果，如灵敏度、特异度、ROC 曲线下面积等。
4.其他		
	a）引用并标注参考文献。	评价标准是否引用并标注参考文献。
	b）报告资金支持情况。	评价标准是否报告资金支持情况。
	c）报告利益冲突情况。	评价标准是否报告利益冲突情况。
	d）报告定期更新计划。	评价标准是否报告定期更新计划。

附录 B

（资料性）

中医证候诊断标准质量评价计分方法与评分准则

B.1 计分方法

B.1.1 某领域标准化得分计算方法

领域标准化得分（%）=（所有评价者该领域评价分数之和−该领域最小可能获取分数）/（该领域最大可能获取分数−该领域最小可能获取分数）×100%。

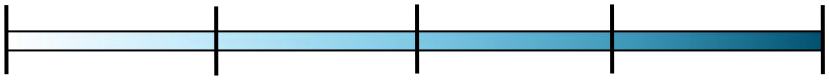
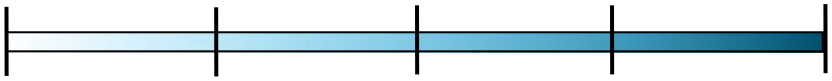
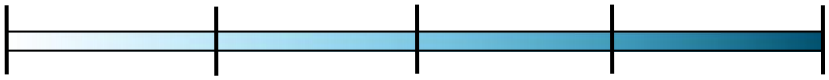
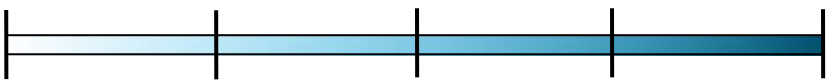
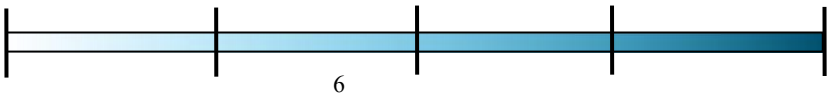
B.1.2 总体标准化得分计算方法

总体标准化得分（%）=（所有评价者总体评价分数之和−总体评价最小可能获取分数）/（总体评价最大可能获取分数−总体评价最小可能获取分数）×100%。

B.2 评分准则

本质量评价指南评分准则参考表 B。

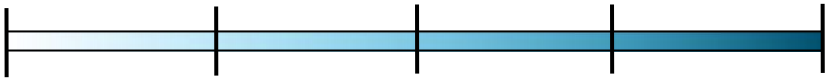
表 B 评分准则

评价领域	评价条目
1.目的和范围	a）明确描述目的。  1 2 3 4 5 □ 不明确 □ 不太明确 □ 一般 □ 比较明确 □ 非常明确 b）明确描述适用人群。  1 2 3 4 5 □ 不明确 □ 不太明确 □ 一般 □ 比较明确 □ 非常明确 c）明确描述使用者。  1 2 3 4 5 □ 不明确 □ 不太明确 □ 一般 □ 比较明确 □ 非常明确
2.可读性	a）制定组由多学科人员组成，职责明确。  1 2 3 4 5 □ 不明确 □ 不太明确 □ 一般 □ 比较明确 □ 非常明确 b）报告起草人和起草单位。 

1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

c）报告发布单位。

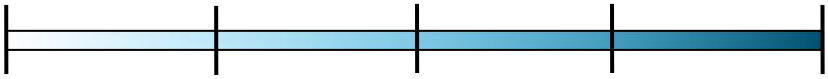


1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

3.研制流程　3.1 文献研究

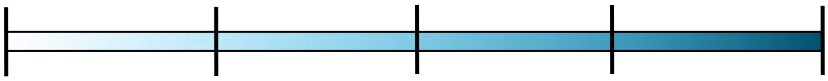
a）描述文献研究目的。



1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

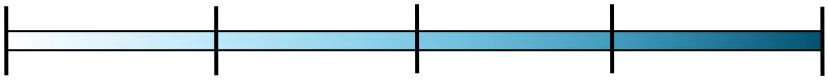
b）描述文献检索策略。



1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

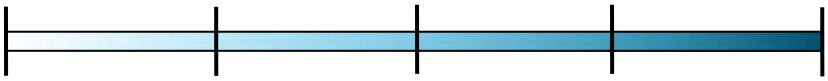
c）描述文献筛选过程。



1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

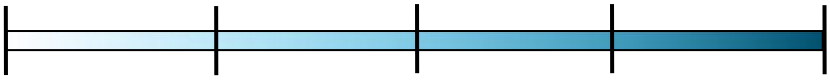
d）描述信息提取过程。



1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

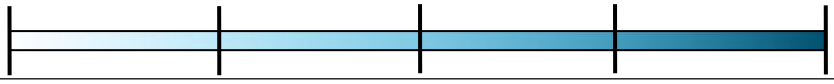
e）描述术语规范过程。



1　　2　　3　　4　　5

□ 不详细　□ 不太详细　□ 一般　□ 比较详细　□ 非常详细

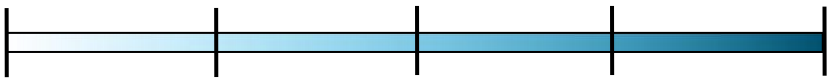
f）明确统计分析方法。



1 2 3 4 5

□ 不明确 □ 不太明确 □ 一般 □ 比较明确 □ 非常明确 3.2 专家咨询

a）描述专家咨询目的。



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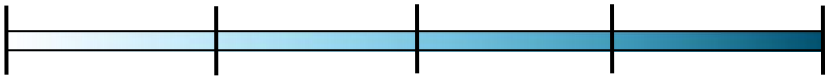
b）描述专家遴选条件。



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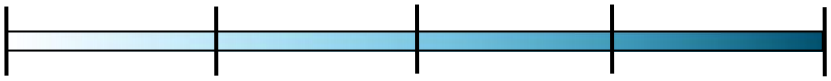
c）描述问卷内容。



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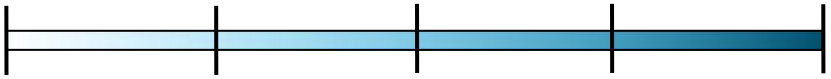
d）明确统计分析方法。



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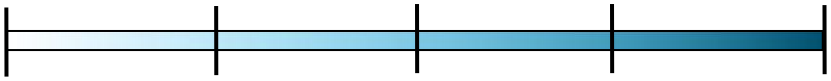
3.3 临床调查

a）描述临床调查目的。



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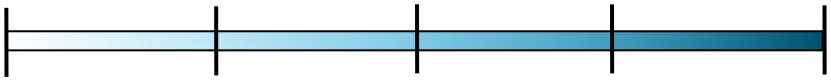
b）界定调查人群。



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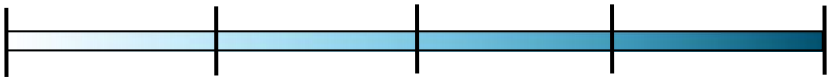
c）描述调查方法。



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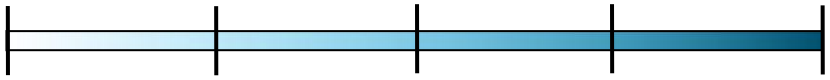
d）描述临床调查表制定过程及内容。



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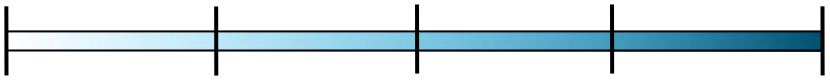
e）描述样本量估算方法。



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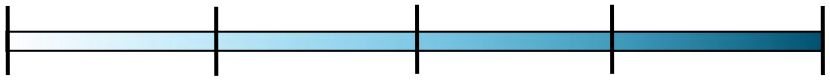
f）明确统计分析方法。



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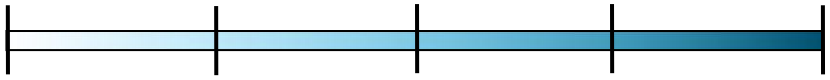
□ 不明确　□ 不太明确　□ 一般　□ 比较明确　□ 非常明确 3.4 标准建立

a）描述验证目的。



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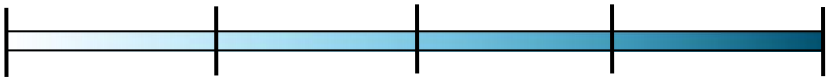
b）界定调查人群。



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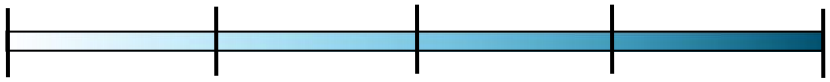
c）描述调查方法。



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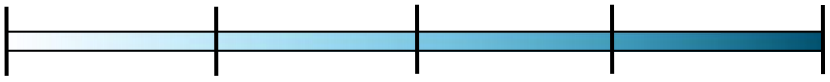
d）描述验证调查表制定过程及内容。



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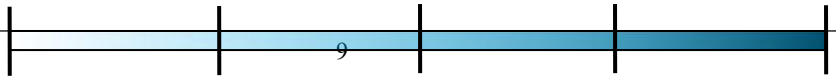
e）描述样本量估算方法。



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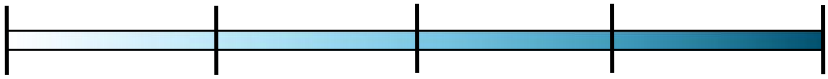
f）明确统计分析方法。



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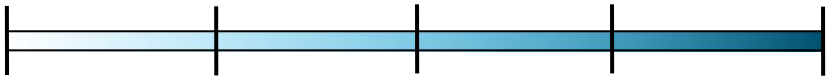
4.其他

a）引用并标注参考文献。



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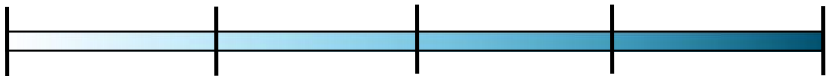
b）报告资金支持情况。



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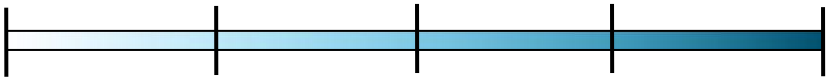

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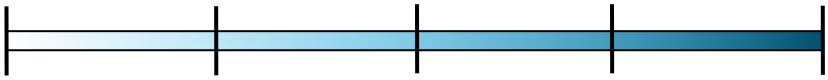
d）报告定期更新计划。



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Foreword

Attention is drawn to the possibility that some of the elements of this criteria may be the subject of patent rights. World Federation of Chinese Medicine Societies (WFCMS) shall not be held responsible for identifying any or all such patent rights.

Main Drafting Units: Henan University of Chinese Medicine, The First Affiliated Hospital of Henan University of Chinese Medicine

Drafting Units Participated: Beijing University of Chinese Medicine, Dongzhimen Hospital of Beijing University of Chinese Medicine, China Academy of Chinese Medical Sciences, Xiyuan Hospital of China Academy of Chinese Medical Sciences, Beijing Hospital of Chinese Medicine Affiliated to Capital Medical University, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangdong Provincial Hospital of Chinese Medicine, Tianjin University of Chinese Medicine, The First Affiliated Hospital of Tianjin University of Chinese Medicine, Lanzhou University, West China Hospital of Sichuan University, The Affiliated Hospital of Chengdu University of Chinese Medicine, Hong Kong Baptist University, Peking University, Liverpool School of Tropical Medicine, Alberta Health Services Data Analytics Centre, Chinese Medicine Association of Australia.

Advisory Expert Committee:: Wang Yongyan, Zhang Boli, Sun Sulun.

Main Drafters: Li Jiansheng, Xie Yang, Wang Jiajia, Lei Siyuan, Yuan Yue.

Experts Participated (sort by surname phonetic alphabet): Yu Changhe, Wang Tianfang, Wang Xiaohui, Shi Nannan, Lv Aiping(Hong Kong, China), Du Liang, Li Bo, Wu Darong, Yang Xiaobo, Yang Kehu, Liu Jianping, Liu Mengyu, Liu Xincan, Zhang Shengsheng, Zhang Mingyan, Zhang Junhua, Chen Wei, Chen Yaolong, Fei Yutong, Hou Zhengkun, Hu Siyuan, Tang Jianyuan, Gao Rui, Ge Long, Liao Xing.

America: Sun Feng.

England: Chen Tao.

Canada: Chen Guanmin.

Australia: Zheng Jianhua, Wei Guoqing.

The drafting procedure of this document complies with SCM 1.1-2021 *Working Standardization Guidelines Part 1: Regulations for Formulation and Publication of Criteria* issued by the WFCMS.

Introduction

Diagnostic criteria of Chinese medicine (CM) syndromes (hereinafter referred to as “syndrome criteria”) are a major component of CM standardization. Objective and scientific syndrome criteria are key to improving CM diagnosis and treatment, as well as providing high-level evidence for clinical efficacy. In recent years, CM standardization has developed rapidly, with a significant increase in the number of published syndrome criteria, which has promoted research and application in this field. However, challenges such as insufficient clinical application and difficulties in promotion persist, possibly due to issues like non-standardized development methods and uneven methodological quality. Quality evaluation refers to assessing the degree of potential bias in the design, development, and analysis of individual studies. Quality evaluation tools identify common issues and form guideline checklists. Currently, such tools are primarily focused on clinical practice guidelines, with a lack of quality evaluation guidelines for syndrome criteria. Therefore, there is an urgent need to develop quality evaluation guidelines for syndrome criteria to improve their methodological quality, enhance clinical application and elevate CM clinical efficacy.

This document considers health policies, regulations and relevant guidelines, builds upon SCM 70-2022 *Guideline on Establishing Diagnostic Criteria of Chinese Medicine Syndromes* and related criteria, and incorporates the development methods and procedures of domestic and international quality evaluation tools. It aims to reduce or avoid technical and methodological biases in the development of syndrome criteria and provide a scientific and standardized reference for the process.

Quality Evaluation Guideline for Diagnostic Criteria of Chinese Medicine Syndromes

1 Scope

This document specifies the evaluation principles, content and scoring methods for the quality evaluation of CM syndrome diagnostic criteria.

This document is applicable to professionals from CM (integrated Chinese and Western medicine) medical, educational, and research institutions for evaluating the quality of syndrome criteria.

2 Normative References

The following documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition (including any amendments) applies.

GB/T 20348-2006 *Basic Theory Terminology of Chinese Medicine*

GB16751.2-2021 *Clinic Terminology of Chinese Medical Diagnosis and Treatment—Part 2: Syndromes/Patterns*

GB/T 15657-2021 *Classification and Codes of Diseases and Syndromes in Chinese Medicine*

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

3.1

Syndrome

The external manifestation of the interaction of disease location, etiology, disease nature, disease trend and disease resistance at a certain stage of the disease, which is manifested as clinically observable symptoms.

[Source: ISBN 7-03-015154-2, 04.548]

3.2

Quality Evaluation

The assessment of the degree of potential bias in the design, development, and analysis of individual studies.

[Source: https://training.cochrane.org/resource/grade-handbook]

4 Evaluation Principles and Process

4.1 Evaluation Principles

The evaluation should adhere to scientificity, objectivity and fairness, ensuring the process is based on authentic data and facts, free from subjective bias, and guaranteeing the traceability of evaluation results.

4.2 Evaluation Process

The evaluation process includes: determining the target syndrome criteria, conducting a comprehensive scoring of the syndrome criteria using evaluation tools, and formulating an evaluation report.

5 Evaluation Content and Requirements

5.1 Purpose and Scope

a) Clearly describe the purpose.
b) Clearly describe the applicable population.
c) Clearly describe the intended users.

5.2 Participants

a) The development team should consist of multidisciplinary members with clearly defined roles.
b) Report the drafters and drafting units.
c) Report the issuing organization.

5.3 Development Process

5.3.1 Literature Research

a) Describe the purpose of literature research.
b) Describe the literature search strategy.
c) Describe the literature screening process.
d) Describe the data extraction process.
e) Describe the terminology standardization process.
f) Specify the statistical analysis methods.

5.3.2 Expert Consultation

a) Describe the purpose of expert consultation.
b) Describe the expert selection criteria.

c) Describe the questionnaire content.
d) Specify the statistical analysis methods.

5.3.3 Clinical Investigation

a) Describe the purpose of the investigation.
b) Define the target population.
c) Describe the investigation methods.
d) Describe the development process and content of the clinical investigation form.
e) Describe the sample size estimation method.
f) Specify the statistical analysis methods.

5.3.4 Criteria establishment

a) Report the basis for criteria establishment.
b) Present the criteria in an appropriate format.

5.3.5 Criteria Validation

a) Describe the purpose of validation.
b) Define the target population.
c) Describe the validation methods.
d) Describe the development process and content of the validation form.
e) Describe the sample size estimation method.
f) Specify the statistical analysis methods.

5.4 Others

a) Cite and reference relevant literature.
b) Report funding support.
c) Report conflicts of interest.
d) Report the plan for periodic updates.

6 Scoring Criteria

The evaluation criteria include assessments for each of the above items and their specific details. The scoring system uses a 5-point Likert scale (1-5), where higher scores indicate better quality of the syndrome criteria for that item. Detailed scoring requirements are provided in Appendix B.

Annex A

(Informative)

Checklist of Quality Evaluation Guideline for Diagnostic Criteria of Chinese Medicine Syndromes

Domain	Item	Explanation
1. Purpose and Scope		
	a) Clearly describe the purpose.	Evaluate whether the criteria clearly describe the purpose.
	b) Clearly describe the applicable population.	Evaluate whether the criteria clearly describe the applicable population (e.g., patient characteristics).
	c) Clearly describe the intended users.	Evaluate whether the criteria clearly describe the intended users (e.g., clinicians, researchers).
2. Participants		
	a) The development team consists of multidisciplinary members with clearly defined roles.	Evaluate whether the team includes members from multiple disciplines (e.g., clinical CM/WM, evidence-based medicine, epidemiology, statistics) and whether roles are clearly defined.
	b) Report the drafters and drafting units.	Evaluate whether the criteria report the drafters and drafting units.
	c) Report the issuing organization.	Evaluate whether the criteria report the issuing organization.
3. Development Process		
3.1 Literature Research	a) Describe the purpose of literature research.	Evaluate whether the criteria describe the purpose of literature research.
	b) Describe the literature search strategy.	Evaluate whether the criteria describe the search strategy (e.g., databases, time frame).
	c) Describe the literature screening process.	Evaluate whether the criteria describe the screening process (e.g., inclusion/exclusion criteria, screening methods).
	d) Describe the data extraction process.	Evaluate whether the criteria describe the data extraction process (e.g., extraction of syndrome and diagnostic information).

	e) Describe the terminology standardization process.	Evaluate whether the criteria describe the terminology standardization process.
	f) Specify the statistical analysis methods.	Evaluate whether the criteria specify statistical methods (e.g., descriptive statistics, cluster analysis, latent structure analysis).
3.2 Expert Consultation	a) Describe the purpose of expert consultation.	Evaluate whether the criteria describe the purpose of expert consultation.
	b) Describe the expert selection criteria.	Evaluate whether the criteria describe expert selection criteria (e.g., professional title, field of expertise, years of experience).
	c) Describe the questionnaire content.	Evaluate whether the criteria describe the questionnaire content.
	d) Specify the statistical analysis methods.	Evaluate whether the criteria specify statistical methods for analyzing expert questionnaire results (e.g., mean, coefficient of variation).
3.3 Clinical Investigation	a) Describe the purpose of the clinical investigation.	Evaluate whether the criteria describe the purpose of the clinical investigation.
	b) Define the target population.	Evaluate whether the criteria define the target population (e.g., clear diagnostic criteria for Western medicine).
	c) Describe the investigation methods.	Evaluate whether the criteria describe the investigation methods (e.g., cross-sectional study).
	d) Describe the development process and content of the clinical investigation form.	Evaluate whether the criteria describe the development process and content of the clinical investigation form.
	e) Describe the sample size estimation method.	Evaluate whether the criteria describe the sample size estimation method.
	f) Specify the statistical analysis methods.	Evaluate whether the criteria specify statistical methods (e.g., descriptive statistics, cluster analysis, logistic regression).
3.4 Criteria Establishment	a) Report the basis for criteria establishment.	Evaluate whether the criteria report the basis for criteria establishment.

	b) Present the criteria in an appropriate format.	Evaluate whether the criteria present the criteria in an appropriate format (e.g., diagnostic condition combination, scoring-based diagnostic methods).
3.5 Criteria Validation	a) Describe the purpose of validation.	Evaluate whether the criteria describe the purpose of validation.
	b) Define the target population.	Evaluate whether the criteria define the target population (e.g., clear diagnostic criteria for Western medicine).
	c) Describe the validation methods.	Evaluate whether the criteria describe the validation methods (e.g., prospective clinical investigation).
	d) Describe the development process and content of the validation form.	Evaluate whether the criteria describe the development process and content of the validation form.
	e) Describe the sample size estimation method.	Evaluate whether the criteria describe the sample size estimation method.
	g) Specify the statistical analysis methods.	Evaluate whether the criteria specify statistical methods for validation results (e.g., sensitivity, specificity, AUC-ROC).
4. Others		
	a) Cite and reference relevant literature.	Evaluate whether the criteria cite and reference relevant literature.
	b) Report funding support.	Evaluate whether the criteria report funding support.
	c) Report conflicts of interest.	Evaluate whether the criteria report conflicts of interest.
	d) Report the plan for periodic updates.	Evaluate whether the criteria report the plan for periodic updates.

Annex B
(Informative)
Scoring Methods and Criteria for Quality Evaluation Guideline for Diagnostic Criteria of Chinese Medicine Syndromes

B.1 Scoring Methods

B.1.1 Domain Standardized Score Calculation Method

Domain Standardized Score (%) = (Sum of all evaluators' scores for the domain − Minimum possible score for the domain)/(Maximum possible score for the domain − Minimum possible score for the domain)×100%.

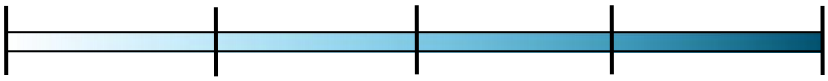
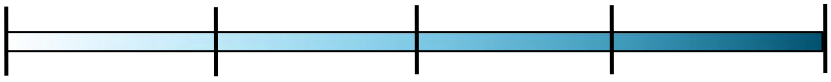
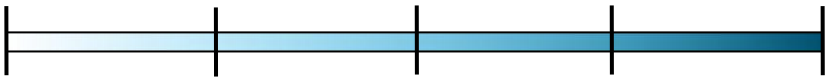
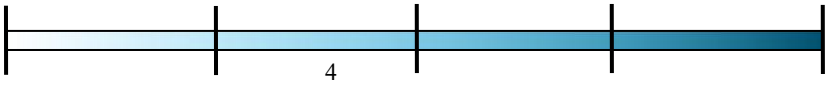
B.1.2 Overall Standardized Score Calculation Method

Overall Standardized Score (%) = (Sum of all evaluators' overall scores−Minimum possible overall score) /(Maximum possible overall score−Minimum possible overall score)×100%.

B.2 Scoring Criteria

The scoring criteria for this quality evaluation guideline are referenced in Table B.

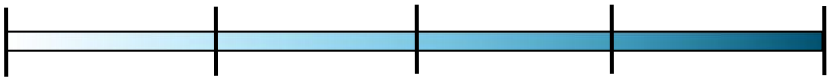
Table B Scoring Criteria

Evaluation Domain	Evaluation Items
1. Purpose and Scope	a) Clearly describe the purpose.  1 2 3 4 5 □ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete b) Clearly describe the applicable population.  1 2 3 4 5 □ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete c) Clearly describe the intended users.  1 2 3 4 5 □ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete
2. Readability	a) The development team consists of multidisciplinary members with clearly defined roles. 

1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

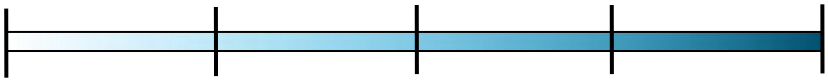
b) Report the drafters and drafting units.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

c) Report the issuing organization.

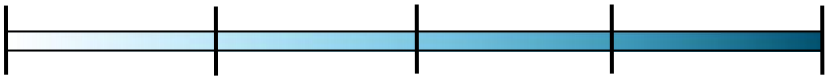


1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

3. Development Process	3.1 Literature Research

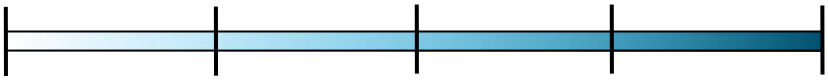
a) Describe the purpose of literature research.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

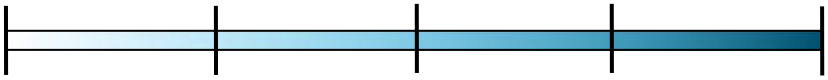
b) Describe the literature search strategy.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

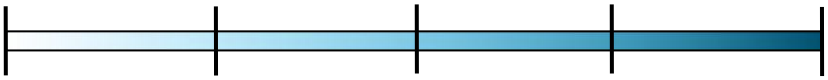
c) Describe the literature screening process.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

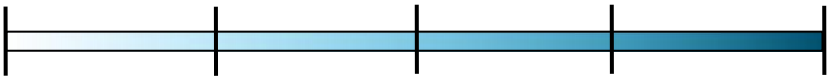
d) Describe the data extraction process.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

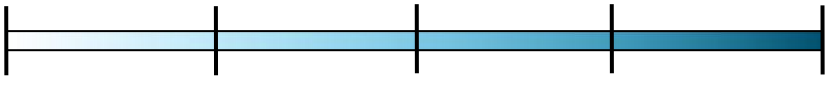
e) Describe the terminology standardization process.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

f) Specify the statistical analysis methods.

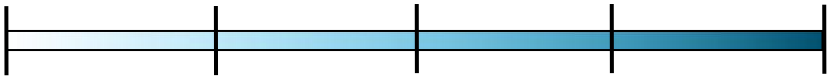


1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

3.2 Expert Consultation

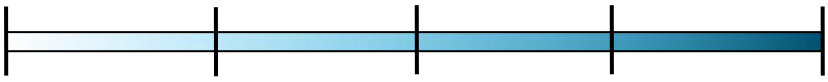
a) Describe the purpose of expert consultation.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

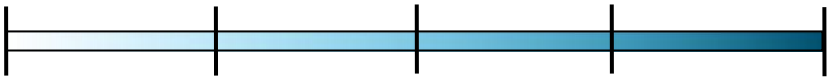
b) Describe the expert selection criteria.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

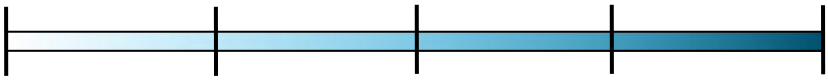
c) Describe the questionnaire content.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

d) Specify the statistical analysis methods.

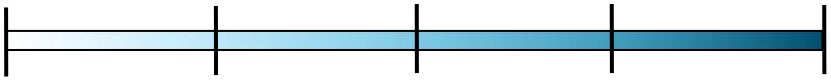


1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

3.3 Clinical Investigation

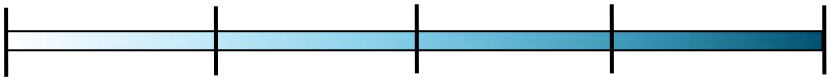
a) Describe the purpose of the clinical investigation.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

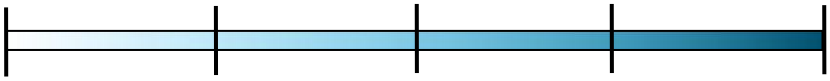
b) Define the target population.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

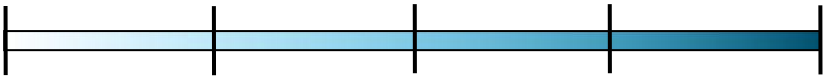
c) Describe the investigation methods.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

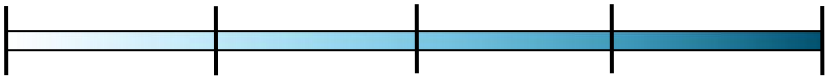
d) Describe the development process and content of the clinical investigation form.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

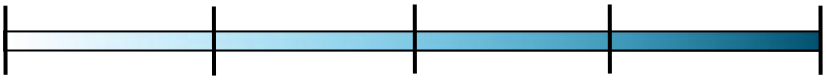
e) Describe the sample size estimation method.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

f) Specify the statistical analysis methods.

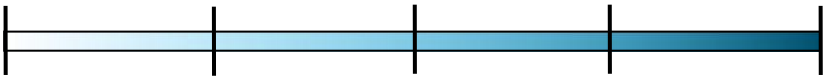


1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

3.4 criteria establishment

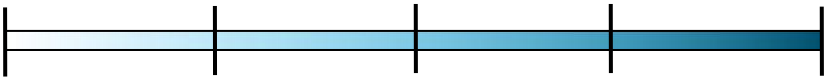
a) Describe the purpose of validation.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

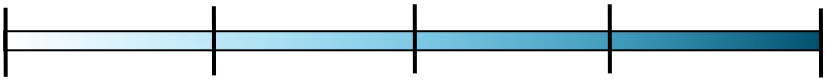
b) Define the target population.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

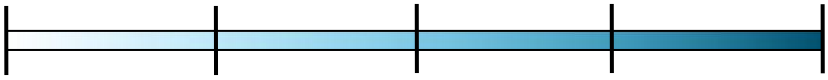
c) Describe the validation methods.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

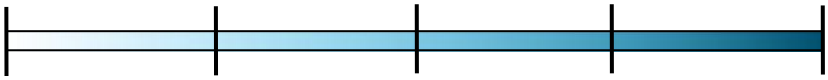
d) Describe the development process and content of the validation form.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

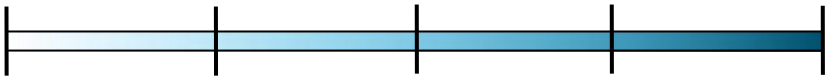
e) Describe the sample size estimation method.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

f) Specify the statistical analysis methods.

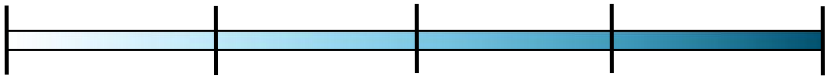


1 2 3 4 5

☐ Unclear ☐ Slightly unclear ☐ Neutral ☐ Fairly clear ☐ Very clear

4. Others

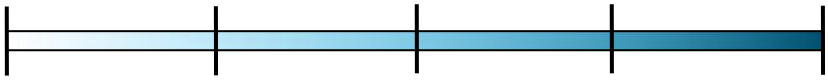
a) Cite and reference relevant literature.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

b) Report funding support.



1 2 3 4 5

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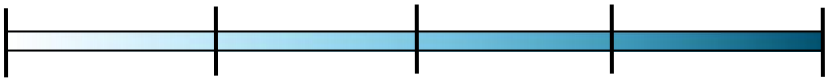
c) Report conflicts of interest.



1 2 3 4 5

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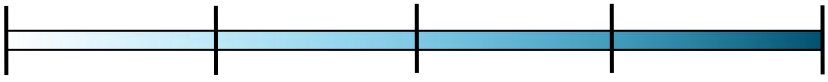
d) Report the plan for periodic updates.



1 2 3 4 5

□ Incomplete □ Slightly incomplete □ Neutral □ Fairly complete □ Very complete

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[1] Bai X, Liu JP, Guo YB, et al. Suggestions and interpretation for quality evaluation of clinical practice guidelines in Chinese medicine [J]. China Journal of Chinese Materia Medica, 2020,45(07):1600-1605. Very complete

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