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SCM



世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM 000*-20**

中医证候诊断标准适用性评价指南

Applicability Evaluation guideline for diagnostic criteria of Chinese
medicine syndromes

征求意见稿

(Committee draft)

世界中医药国际组织标准

International Standard of WFCMS

2020-**-**发布实施

Issued & implemented on ** **, 2020

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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。

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引 言

中医证候诊断标准（以下简称“证候标准”）的规范化、客观化是中医药标准化的基础与核心。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。但证候标准的适用性评价及相关研究尚未引起足够重视，证候标准存在“重制定，轻评价”、应用不足、推广困难等问题。证候标准的临床适用性是影响证候标准推广应用的决定性因素，证候标准建立后从可获得性、可读性、可行性、可接受性等多角度评价证候标准的适用性具有重要意义。目前适用性评价工具主要集中在临床实践指南领域，尚缺乏证候标准的适用性评价指南。因此，亟待制定证候标准适用性评价指南，以甄别临床适用性高的证候标准并推广应用，优化证候标准的制定和更新。

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，借鉴国内外相关适用性评价工具的研制方法与流程，结合证候标准的特点，开展本文件的研制工作。本文件旨在提升证候标准的临床适用性，促进证候标准的推广应用。

中医证候诊断标准适用性评价指南

1 范围

本文件规定了中医证候诊断标准适用性评价的评价原则、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适用性评价时使用。

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

适用性

某一文件在特定范围内（区域、组织、单位等）适合应用的程度，指南适用性即指南推荐意见能够应用于临床实践的程度。

[来源：<https://g-i-n.net/wp-content/uploads/2021/05/ADAPTE-Resource-toolkit-V2.1-March-2010-updated-disclaimer.pdf>]

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 可获得性

- a) 该标准容易获取。

5.2 可读性

5.2.1 结构

- a) 结构完整、合理。
- b) 诊断要点易于识别。
- c) 研制流程清晰明了。

5.2.2 内容

- a) 内容完整、合理。
- b) 适用范围明确。
- c) 诊断要点描述准确。
- d) 语言表达清晰、规范。
- e) 内容一致。
- f) 包括常见的证候分类（如适用）。

5.3 可行性

5.3.1 临床应用特点

- a) 临床应用简便。
- b) 临床应用准确。
- c) 临床应用一致性高。

5.3.2 技术水平

- a) 与本地区医疗水平相适应。
- b) 较其他证候诊断标准更规范。

5.3.3 协调配套性

- a) 与诊疗指南/共识/方案/路径的辨证原则相匹配。

5.3.4 作用

- a) 可提高辨证水平、提升诊疗效果。

5.3.5 应用的促进或障碍因素

- a) 可清楚描述使用人群和环境。
- b) 使用者可以理解该标准内容，具备实施的专业能力。
- c) 使用者需要获得必要的培训。

5.4 可接受性

- a) 标准针对的临床问题与使用者所面临的临床问题的相符程度。

- b) 使用者对标准的认同程度。
- c) 使用者在开展工作时参考标准的意愿程度。

5.5 总体评价

- a) 标准的临床适用性。
- b) 使用者对标准的满意度及整体印象。

6 评分标准

评价标准包括对上述每一个主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，证候标准在该条目适用性越好。具体评分要求参考附录 B。

附录 A
(资料性)
中医证候诊断标准适用性评价清单

领域	条目	说明
1.可获得性		
	a) 容易获取。	评价获取标准的便捷程度。
2.可读性		
2.1 结构	a) 结构完整、合理。	评价标准结构的完整性、合理性。
	b) 诊断要点易于识别。	评价标准的诊断要点是否易于识别，如诊断要点条列清晰等。
	c) 研制流程清晰明了。	评价标准的研制流程是否清晰明了，是否提供完整流程，流程是否清晰。
2.2 内容	a) 内容完整、合理。	评价标准内容的完整性、合理性。
	b) 适用范围明确。	评价标准的适用范围明确，如是否明确目标病种、是否明确目标证候、是否规定证候诊断标准或其特定部分的适用范围等。
	c) 诊断要点描述准确。	评价标准诊断要点是否准确描述，如证候分类是否合理、症状描述是否规范。
	d) 语言表达清晰、规范。	评价标准语言是否表达清晰、规范，是否对相关术语进行规范化处理。
	e) 内容一致。	评价标准内容前后描述是否一致，如证候诊断要素与组合条件之间无矛盾。
	f) 包括常见的证候分类（如适用）。	评价标准是否包含目标病种常见证候的分类。
3.可行性		
3.1 临床应用特点	a) 临床应用简便。	评价标准临床应用的简便性，如参考标准做出诊断是否耗时长、步骤繁琐。
	b) 临床应用准确。	评价标准临床应用的准确性。
	c) 临床应用一致性高。	评价标准临床应用的一致性，如在不同临床环境或不同医师中诊断结果是否一致。
3.2 技术水平	a) 与本地区医疗水平相适应。	评价标准与本地区医疗水平相比的适应性，本地区是否存在应用该标准较为困难的情况，如本地区使用者普遍无法理解标准内容，或辨证后无法进一步施治。
	b) 较其他证候诊断标准更规范。	评价标准与其他标准（或研究成果）相比的优越性、规范性。
3.3 协调配套性	a) 与诊疗指南/共识/方案/路径的辨证原则相匹配。	评价标准与诊疗指南/共识/方案/路径的辨证原则的匹配程度，是否存在较大分歧，内容是否协调互补。
3.4 作用	a) 可提高辨证水平、提升诊疗效果。	评价标准在提高辨证水平、提升诊疗效果方面的作用。
3.5 促进或阻碍因素	a) 可清楚描述使用人群和环境。	评价标准是否明确描述适用人群和使用环境，如供中医医师/中西医结合医师/西医医师使用，供三级甲等医院/三级乙等医院/社区诊疗中心使用。
	b) 使用者可以理解该标准内容，具备实施的专业能力。	评价使用者是否可以理解标准内容，具备实施的专业能力，如专业知识、临床经验等。
	c) 使用者需要获得必要的培训。	评价使用者参考标准时是否需要获得必要的培训。

4.可接受性		
	a) 标准针对的临床问题与使用者所面临的临床问题的相符程度。	评价标准针对的临床问题是否与您所面临的临床问题相符。
	b) 使用者对标准的认同程度。	评价您是否认同该标准，如诊断要点等。
	c) 使用者在开展工作时参考标准的意愿程度。	评价您是否愿意参照标准开展临床工作。
5.总体评价		
	a) 标准的临床适用性。	评价标准的临床适用性。
	b) 使用者对标准的满意度及整体印象。	评价您对标准的满意度及整体印象。

附录 B (资料性)

中医证候诊断标准适用性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%。

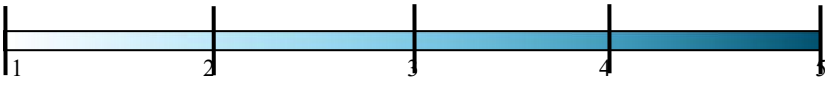
B.2 评分准则

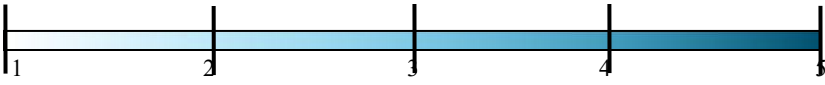
本适用性评价指南评分准则可参考表 B。

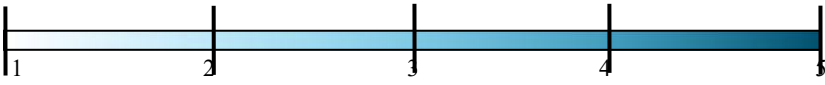
表 B 评分准则

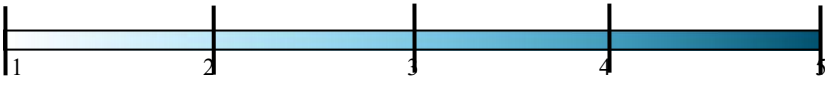
评价领域	评价条目
1.可获得性 (能方便获取该证候标准)	<p>a) 容易获取。</p> <p><input type="checkbox"/> 不容易 <input type="checkbox"/> 不太容易 <input type="checkbox"/> 一般 <input type="checkbox"/> 比较容易 <input type="checkbox"/> 非常容易</p>
2.可读性 (能读懂该证候标准)	<p>2.1 结构</p> <p>a) 结构完整、合理。</p> <p><input type="checkbox"/> 不完整、不合理 <input type="checkbox"/> 不太完整、不太合理 <input type="checkbox"/> 一般 <input type="checkbox"/> 比较完整、合理 <input type="checkbox"/> 非常完整、合理</p> <p>b) 诊断要点易于识别。</p> <p><input type="checkbox"/> 不容易 <input type="checkbox"/> 不太容易 <input type="checkbox"/> 一般 <input type="checkbox"/> 比较容易 <input type="checkbox"/> 非常容易</p> <p>c) 研制流程清晰明了。</p> <p><input type="checkbox"/> 不清晰 <input type="checkbox"/> 不太清晰 <input type="checkbox"/> 一般 <input type="checkbox"/> 比较清晰 <input type="checkbox"/> 非常清晰</p> <p>2.2 内容</p> <p>a) 内容完整、合理。</p> <p><input type="checkbox"/> 不完整、不合理 <input type="checkbox"/> 不太完整、不太合理 <input type="checkbox"/> 一般 <input type="checkbox"/> 比较完整、合理 <input type="checkbox"/> 非常完整、合理</p> <p>b) 适用范围明确。</p>

- 1 2 3 4 5
- ☐ 不明确 ☐ 不太明确 ☐ 一般 ☐ 比较明确 ☐ 非常明确
- c) 诊断要点描述准确。

- 
- ☐ 不准确 ☐ 不太准确 ☐ 一般 ☐ 比较准确 ☐ 非常准确
- d) 语言表达清晰、规范。

- 
- ☐ 不清晰、不规范 ☐ 不太清晰、不太规范 ☐ 一般 ☐ 比较清晰、规范 ☐ 非常清晰、规范
- e) 内容一致。

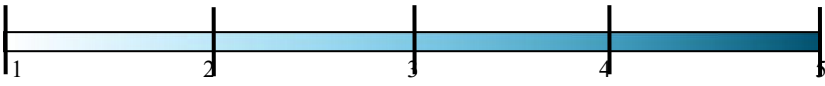
- 
- ☐ 不一致 ☐ 不太一致 ☐ 一般 ☐ 比较一致 ☐ 完全一致
- f) 包括常见的证候分类（如适用）。

- 
- ☐ 不包括 ☐ 不完全包括 ☐ 一般 ☐ 比较包括 ☐ 完全包括

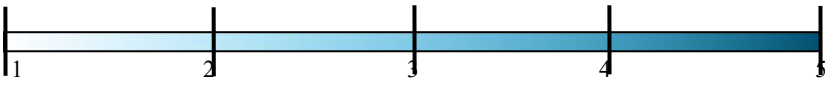
3.可行性 (实施该证候 标准)

3.1 临床应用特点

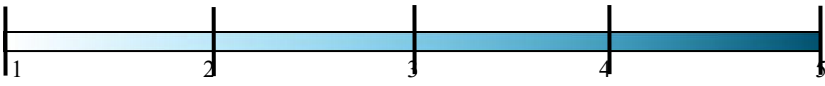
a) 临床应用简便。

- 
- ☐ 不简便 ☐ 不太简便 ☐ 一般 ☐ 比较简便 ☐ 非常简便

b) 临床应用准确。

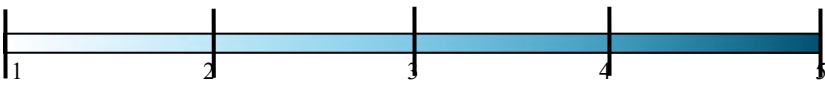
- 
- ☐ 不准确 ☐ 不太准确 ☐ 一般 ☐ 比较准确 ☐ 非常准确

c) 临床应用一致性高。

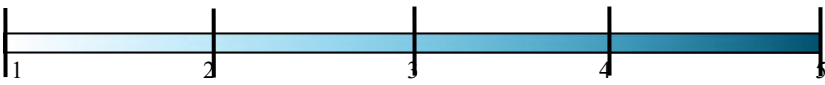
- 
- ☐ 一致性低 ☐ 一致性较低 ☐ 一般 ☐ 一致性较高 ☐ 一致性高

3.2 技术水平

a) 与本地区医疗水平相适应。

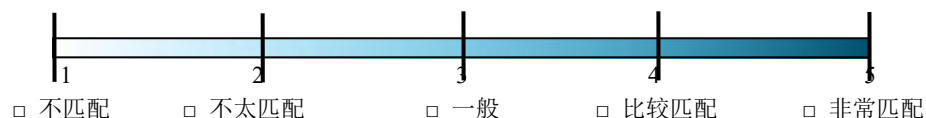
- 
- ☐ 不适应 ☐ 不太适应 ☐ 一般 ☐ 比较适应 ☐ 非常适应

b) 较其他证候诊断标准更规范。

- 
- ☐ 完全落后 ☐ 比较落后 ☐ 一般 ☐ 比较优于 ☐ 完全优于

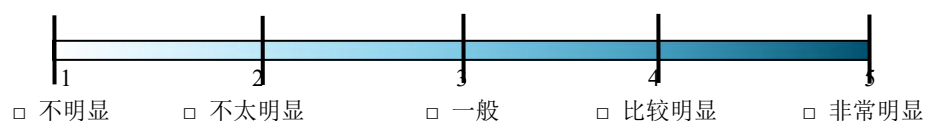
3.3 协调配套性

a) 与诊疗指南/共识/方案/路径的辨证原则相匹配。



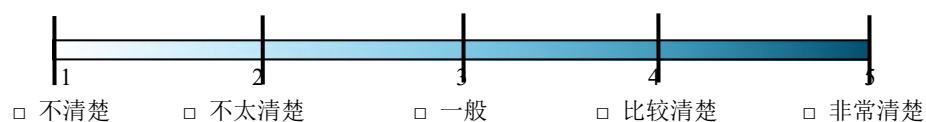
3.4 作用

a) 可提高辨证水平、提升诊疗效果。

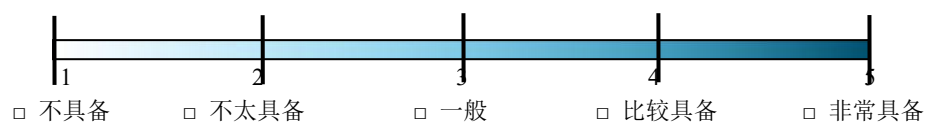


3.5 促进或阻碍因素

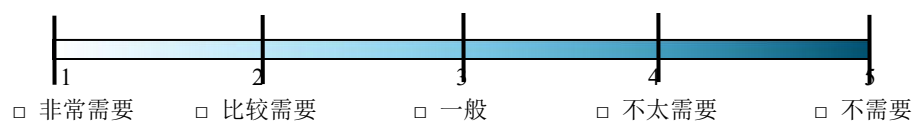
a) 可清楚描述使用人群和环境。



b) 使用者可以理解该标准内容，具备实施的专业能力。

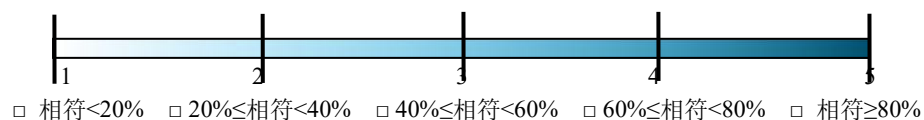


c) 使用者需要获得必要的培训。

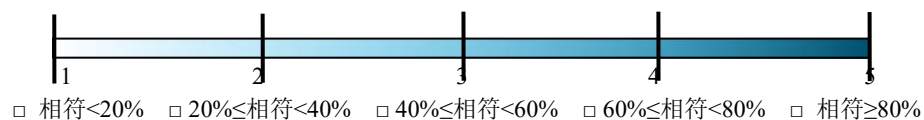


4.可接受性 (同意该标准的 证候诊断内容)

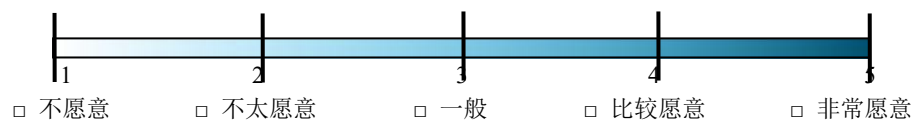
a) 标准针对的临床问题与使用者所面临的临床问题的相符程度。



b) 使用者对标准的认同程度。

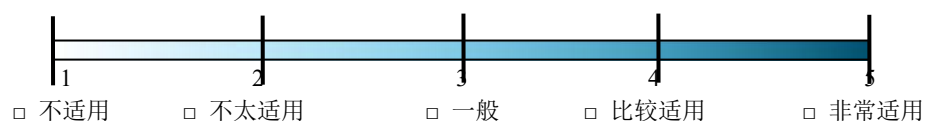


c) 使用者在开展工作时参考标准的意愿程度。

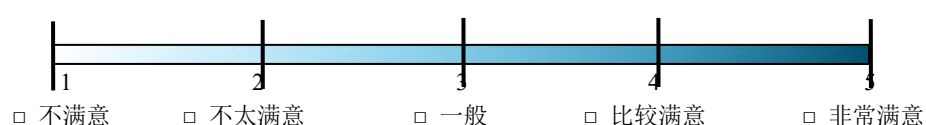


5.总体评价

a) 标准的临床适用性。



b) 使用者对标准的满意度及整体印象。



参考文献

- [1] 张 雯,王洋洋,王 旭,等. 中国中医药指南与共识的科学性、透明性和适用性评价(2022年)[J]. 中国循证医学杂志, 2024,24(08):959-966.
- [2] 谢秀丽,邓静文,周 赫,等. 适用性评价应用于中医诊疗指南的探讨[J]. 时珍国医国药, 2013,24(04):991-992.
- [3] 石雨晴,刁 莎,曾力楠,等. 指南临床适用性评价指标体系的系统评价[J]. 中国循证医学杂志, 2024,24(01):61-68.
- [4] 宇文亚,刘孟宇,赵学尧,等. 中医临床实践指南真实世界适用性评价现状[J]. 中华中医药杂志, 2014,29(4):1098-1101.
- [5] 曾力楠,易秋莎,张 川,等. 制订指南临床适用性评价工具[J]. 中国循证医学杂志, 2020,20(04):466~475.
- [6] 王 强,李幼平,张伯礼,等. 指南临床适用性评价的问题与需求[J]. 中国循证医学杂志, 2020,20(03):249-251.
- [7] 张佳乐,张逸雯,王孟秋,等. 中医证候诊断标准研制现状与思考[J]. 中华中医药杂志, 2024,39(01):33-38.
- [8] 白 雪,刘建平,郭宇博,等. 建立中医药临床实践指南评价体系的思考[J]. 中国中药杂志, 2020,45(07):1596-1599.
- [9] 中华中医药学会肺系病专业委员会/中国民族医药学会肺病分会. 支气管哮喘中医证候诊断标准(2016版)[J]. 中医杂志, 2016,57(22):1978-1980.
- [10] 中华中医药学会肺系病分会/中华中医药学会内科分会/中国民族医药学会肺病分会. 特发性肺纤维化中医证候诊断标准 (2019版)[J]. 中医杂志, 2020,61(18):1653-1656.
- [11] 世界中医药学会联合会,呼吸疾病中医药防治省部共建协同创新中心,河南中医药大学,等. 中医证候诊断标准研制指南[J]. 中国循证医学杂志, 2023,23(09):993-998.
- [12] 张佳乐,张逸雯,王孟秋,等. 中医证候诊断标准研制现状与思考[J]. 中华中医药杂志, 2024,39(01):33-38.

Foreword

Some contents of this document may involve patents. World Federation of Chinese Medicine Societies (WFCMS) shall not be held responsible for identifying any or all such patent rights.

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Introduction

The standardization and objectification of the diagnostic criteria for Chinese medicine (CM) syndromes (hereinafter referred to as “syndrome criteria”) are the foundation and core of the standardization of CM. In recent years, the standardization of CM has developed rapidly, with a significant increase in the number of syndrome criteria published, which has to some extent promoted the research and application of syndrome standardization. However, the evaluation of the applicability of syndrome criteria and related research have not received sufficient attention. There are issues such as “emphasis on formulation but neglect of evaluation”, insufficient application, and difficulties in promotion in the syndrome criteria. The clinical applicability of syndrome criteria is a decisive factor affecting their promotion and application. After the establishment of syndrome criteria, it is of great significance to evaluate their applicability from multiple perspectives such as availability, readability, feasibility, and acceptability. Currently, applicability evaluation tools are mainly concentrated in the field of clinical practice guidelines, and there is still a lack of guidelines for evaluating the applicability of syndrome criteria. Therefore, it is urgent to develop guidelines for evaluating the applicability of syndrome criteria to identify and promote those with high clinical applicability, and to optimize the formulation and updating of syndrome criteria.

This document comprehensively considers health policies, regulations and relevant guiding principles. Based on SCM 70-2022 *Guideline on Establishing Diagnostic Criteria of Chinese Medicine Syndromes* and related syndrome Criteria, it draws on the development methods and processes of relevant applicability evaluation tools at home and abroad, and combines the characteristics of syndrome criteria to carry out the development of this document. This document aims to enhance the clinical applicability of syndrome criteria and promote their popularization and application.

Applicability Evaluation Guideline for Diagnostic Criteria of Chinese Medicine Syndromes

1 Scope

This document stipulates the evaluation principles, evaluation contents and scoring methods for the applicability evaluation of the diagnostic criteria of Chinese medicine syndromes.

This document shall be applicable for professional personnel in various levels of medical and educational institutions and scientific research institutes of Chinese medicine (Integration of Chinese and Western medicine) when evaluating the applicability of syndrome criteria.

2 Normative references

The contents of the following documents, through normative references in the text, constitute essential provisions of this document. For dated references, only the edition corresponding to that date is applicable to this document; for undated references, the latest edition (including all amendments) is applicable to this document.

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

GB/T 16751.2-2021 *Clinical Terminology of Chinese Medicine Part 2: Syndromes*

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

3 Terms and Definitions

The following terms and definitions apply to this document.

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

Applicability

The degree to which a certain document is applicable within a specific scope (region, organization, unit, etc.). The applicability of the guidelines refers to the extent to which the recommended opinions in the guidelines can be applied in clinical practice.

[Source:<https://g-i-n.net/wp-content/uploads/2021/05/ADAPTE-Resource-toolkit-V2.1-March-2010-updated-disclaimer.pdf>]

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 Availability

a) The standard is easily accessible.

5.2 Readability

5.2.1 Structure

a) The structure is complete and reasonable.

b) The diagnostic points are easy to identify.

c) The development process is clear and straightforward.

5.2.2 Content

- a) The content is complete and reasonable.
- b) The scope of application is clear.
- c) Diagnostic points are accurately described.
- d) The language is clear and standardized.
- e) The content is consistent.
- f) Common syndrome classifications (if applicable) are included.

5.3 Feasibility

5.3.1 Clinical Application Characteristics

- a) The clinical application is convenient.
- b) The clinical application is accurate.
- c) The consistency of clinical application is high.

5.3.2 Technical Level

- a) It's adapted with the local medical level.
- b) It's more standardized compared to other syndrome diagnostic criteria.

5.3.3 Coordination and Compatibility

- a) It's matched with the syndrome differential principles of the diagnosis and treatment guidelines, consensus, protocol and pathways.

5.3.4 Function

- a) It can improve the level of syndrome differentiation and enhance the effectiveness of diagnosis and treatment.

5.3.5 Factors Promoting or Hindering Application

- a) It can clearly describe the user population and environment.
- b) The user can understand the content of the criteria and has the professional capability to implement it.
- c) Users need to receive the necessary training.

5.4 Acceptability

- a) The extent to which the clinical issues addressed by the criteria matches the clinical issues faced by the users.
- b) The degree of users' recognition of the standards.
- c) The degree of users' willingness to refer to criteria while carrying out their work.

5.5 Overall Evaluation

- a) The clinical applicability of the criteria.
- b) User's satisfaction with the criteria and overall impression.

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 applicability of the syndrome criteria for that item. Detailed scoring requirements are provided in Appendix B.

Annex A
(Informative)
Checklist of Applicability Evaluation Guideline for Chinese Medicine
Syndrome Diagnostic Criteria

Domain	Item	Explanation
1.Availability		
	a)The criteria are easily accessible.	Evaluate the convenience of obtaining criteria .
2.Readability		
2.1 Structure	a)The structure is complete and reasonable.	Evaluate the completeness and rationality of the structure of the evaluation criteria.
	b)The diagnostic points are easy to identify.	Whether the diagnostic key points of the evaluation criteria are easy to identify, such as whether the diagnostic key points are clearly listed.
	c)The development process is clear and straightforward.	Is the development process of the evaluation criteria clear and straightforward? Does it provide a complete process, and is the process clear?
2.2 Content	a)The content of the criteria is complete and reasonable.	Evaluate the completeness and reasonableness of the content of the criteria.
	b) The scope of application is clear.	The scope of application of the evaluation criteria is clear, e.g. whether the target disease is specified, whether the target syndrome is specified, whether the diagnostic criteria for the syndrome or the scope of application of its specific parts are specified, etc.

	c)Diagnostic points are accurately described.	Evaluate whether the diagnostic points in the criteria are accurately described, whether the syndrome classification is reasonable and whether the symptom descriptions are standardized.
	d)The language is clear and standardized.	Evaluate whether the language of the criteria is expressed clearly and standardly, and whether the relevant terms have been standardized.
	e) The content is consistent.	Evaluate whether the descriptions of the criteria are consistent before and after, with no contradiction between the diagnostic elements of the syndrome and the combination conditions.
	f)Common syndrome classifications (if applicable) are included.	Does the evaluation criteria include the classification of common syndromes of the target disease.
3.Feasibility		
3.1 Clinical application characteristics	a)The clinical application is convenient.	Evaluate the convenience of the clinical application of the criteria, e.g., whether it is time-consuming and cumbersome to make a diagnosis with reference to the criteria.
	b)The clinical application is accurate.	Evaluate the accuracy of the clinical application of the criteria.
	c) The consistency of clinical application is high.	Evaluate the consistency of the clinical application of the criteria, such as the consistency of diagnostic results in different clinical settings or among different physicians.

3.2 Technical Level	a) It's adapted with the local medical level.	The adaptability of the evaluation criteria compared to the local medical level; whether there are difficulties in applying these criteria in the local area, such as local users generally being unable to understand the content of the criteria, or being unable to further implement treatment after differential diagnosis.
	b) It's more standardized compared to other syndrome diagnostic criteria.	The superiority and normativity of the evaluation criteria compared to other criteria (or research results).
3.3 Coordination and Compatibility	a) It's matched with the syndrome differential principles of the diagnosis and treatment guidelines, consensus, protocol and pathways.	The degree of matching between evaluation criteria and syndrome differential principles of diagnostic and treatment guidelines, consensus, protocol and pathways, whether there are significant discrepancies, and whether the content is coordinated and complementary.
3.4 Function	a) It can improve the level of syndrome differentiation and enhance the effectiveness of diagnosis and treatment.	The role of evaluation criteria in improving syndrome differential level and enhancing diagnostic and therapeutic effects.
3.5 Factors Promoting or Hindering Application	a) It can clearly describe the user population and environment.	Whether the evaluation criteria clearly describe the applicable population and usage environment, such as for use by Chinese medicine practitioners/integrated Chinese and Western medicine practitioners/Western medicine practitioners, for use in Class III Grade A hospitals or Class III Grade B hospitals or community medical centers.

	b)The user can understand the content of the criteria and has the professional capability to implement it.	Evaluate whether the user can understand the criteria content and possesses the professional capability for implementation, such as professional knowledge, clinical experience, etc.
	c) Users need to receive the necessary training.	Evaluate whether it is necessary to obtain the required training when using reference criteria.
4.Acceptability		
	a)The extent to which the clinical issues addressed by the criteria matches the clinical issues faced by the users.	Whether the clinical problems addressed by the evaluation criteria match the clinical problems you are facing.
	b)The degree of your recognition of the criteria.	Evaluate whether you agree with the criteria, such as the diagnostic points, etc.
	c)The degree of your willingness to refer to the criteria while carrying out their work.	Evaluate your willingness to work clinically with reference to the criteria.
5.Overall Evaluation		
	a) The clinical applicability of the criteria.	Evaluate the clinical applicability of the criteria.
	b) Your satisfaction with the criteria and overall impression.	Evaluate your satisfaction with the criteria and overall impression.

Annex B
(Informative)
Scoring Methods and Criteria for Applicability Evaluation Guideline for
Chinese Medicine Syndrome Diagnostic Criteria

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

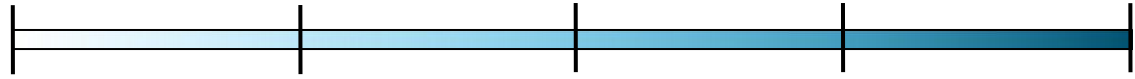
The scoring criteria for this applicability evaluation guideline are referenced in Table B.

Table B Scoring Criteria

Evaluation Domain	Evaluation Items
1. Availability (The syndrome criteria is easily accessible.)	<div>a) The criteria is easily accessible.</div> <div><div><div></div><div></div><div></div><div></div><div></div></div><div>12345</div><div><div>□ Not easy</div><div>□ Not very easy</div><div>□ Neutral</div><div>□ Relatively easy</div><div>□ Very easy</div></div></div>
2. Readability (Being able to understand the syndrome criteria)	<div>2.1 Structure</div> <div>a) The criteria is complete and reasonable.</div> <div><div><div></div><div></div><div></div><div></div><div></div></div><div>12345</div><div><div>□ Incomplete, unreasonable</div><div>□ Not very complete, reasonable</div><div>□ Neutral</div><div>□ Relatively complete, reasonable</div><div>□ Very complete, reasonable</div></div></div> <div>b) The diagnostic points are easy to identify.</div> <div><div><div></div><div></div><div></div><div></div><div></div></div><div>5</div></div>

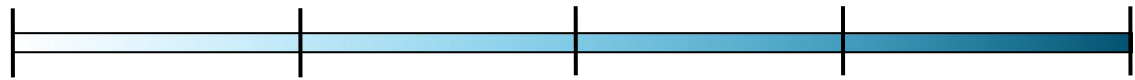
1 2 3 4 5
☐ Not easy ☐ Not very easy ☐ Neutral ☐ Relatively easy ☐ Very easy

c) The development process is clear and straightforward.

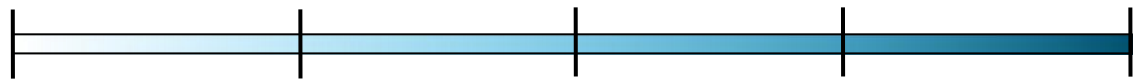

1 2 3 4 5
☐ Unclear ☐ Not very clear ☐ Neutral ☐ Quite clear ☐ Very clear

2.2 Content

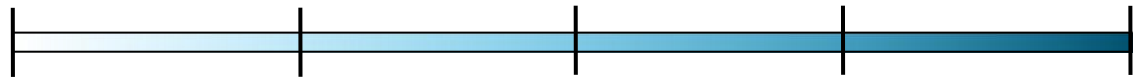
a) The content is complete and reasonable.


1 2 3 4 5
☐ Incomplete, unreasonable ☐ Not very complete, reasonable ☐ Neutral ☐ Relatively complete, reasonable ☐ Very complete, reasonable

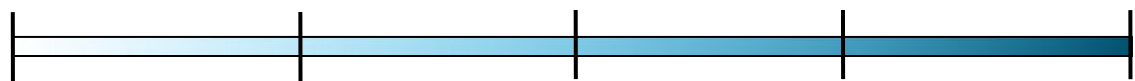
b) The scope of application is clear.


1 2 3 4 5
☐ Unclear ☐ Not very clear ☐ Neutral ☐ Quite clear ☐ Very clear


c) Diagnostic points are accurately described.


1 2 3 4 5
☐ Inaccurate ☐ Not very accurate ☐ Neutral ☐ Quite accurate ☐ Very accurate


d) The language is clear and standardized.


1 2 3 4 5
☐ Unclear, non-standard ☐ Not very clear, standard ☐ Neutral ☐ Relatively clear, standard ☐ Very clear, standard

e) The content is consistent.

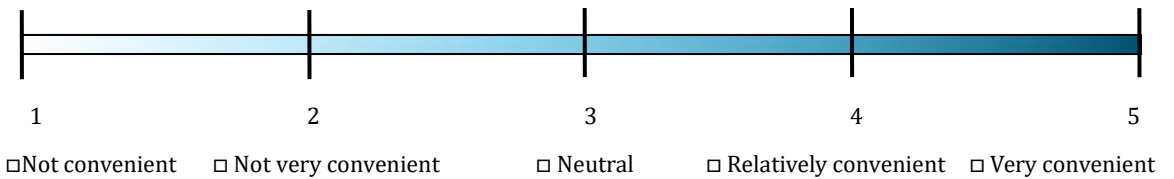

1 2 3 4 5
☐ Inconsistent ☐ Slightly consistent ☐ Neutral ☐ Mostly consistent ☐ Completely consistent

f) Common syndrome classifications (if applicable) are included.

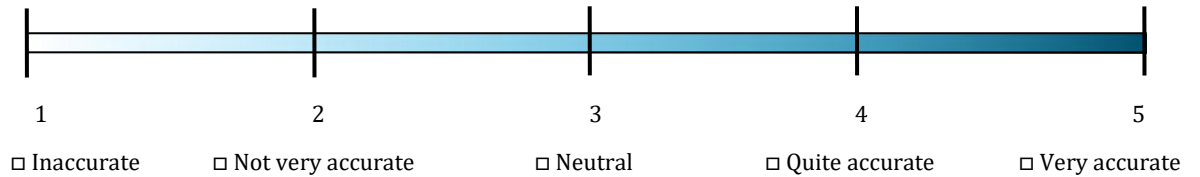

1 2 3 4 5

3.1 Clinical Application Characteristics

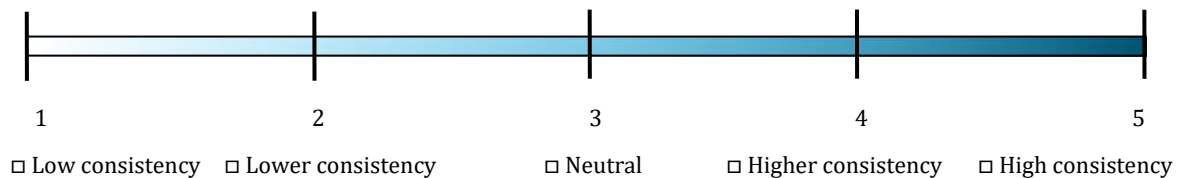
a) The clinical application is convenient.



b) The clinical application is accurate.



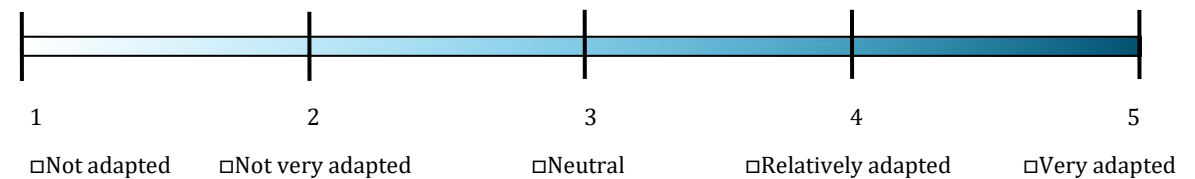
c) The consistency of clinical application is high.



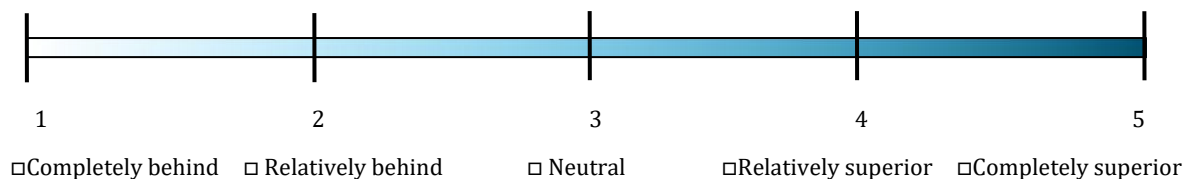
3.2 Technical Level

3. Feasibility
(Implementation
of the criteria
standard)

a) It's adapted with the local medical level.

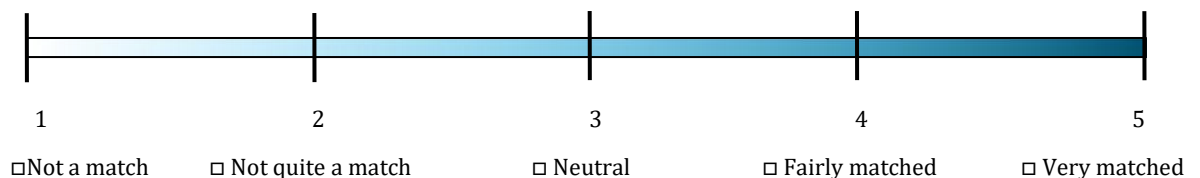


b) It's more standardized compared to other syndrome diagnostic criteria.



3.3 Coordination and Compatibility

a) It's consistent with the syndrome differentiatial principles of the diagnosis and treatment guidelines, consensus, protocol and pathways.



3.4 Function

a) It can improve the level of syndrome differentiation and enhance the effectiveness of diagnosis and treatment.



1 2 3 4 5
☐ Not obvious ☐ Not very obvious ☐ Neutral ☐ Quite obvious ☐ Very obvious

3.5 Factors Promoting or Hindering Application

a) It can clearly describe the user population and environment.

1 2 3 4 5
☐ Unclear ☐ Not very clear ☐ Neutral ☐ Quite clear ☐ Very clear

b) The user can understand the content of the criteria and has the professional capability to implement it.

1 2 3 4 5
☐ Not equipped ☐ Not very equipped ☐ Neutral ☐ Relatively equipped ☐ Very equipped

c) Users need to receive the necessary training.

1 2 3 4 5
☐ Very necessary ☐ Somewhat necessary ☐ Neutral ☐ Not very necessary ☐ Not necessary

a) The extent to which the clinical issues addressed by the criteria matches the clinical issues faced by the users.

1 2 3 4 5
☐ Match <20% ☐ 20%≤Match <40% ☐ 40%≤Match <60% ☐ 60%≤Match <80% ☐ Match≥80%

4. Acceptability (Agree with the syndrome diagnosis content of this criteria)

b) The degree of users' recognition of the standards.

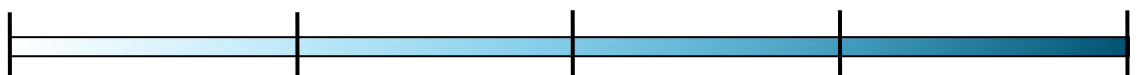
1 2 3 4 5
☐ Match <20% ☐ 20%≤Match <40% ☐ 40%≤Match <60% ☐ 60%≤Match <80% ☐ Match≥80%

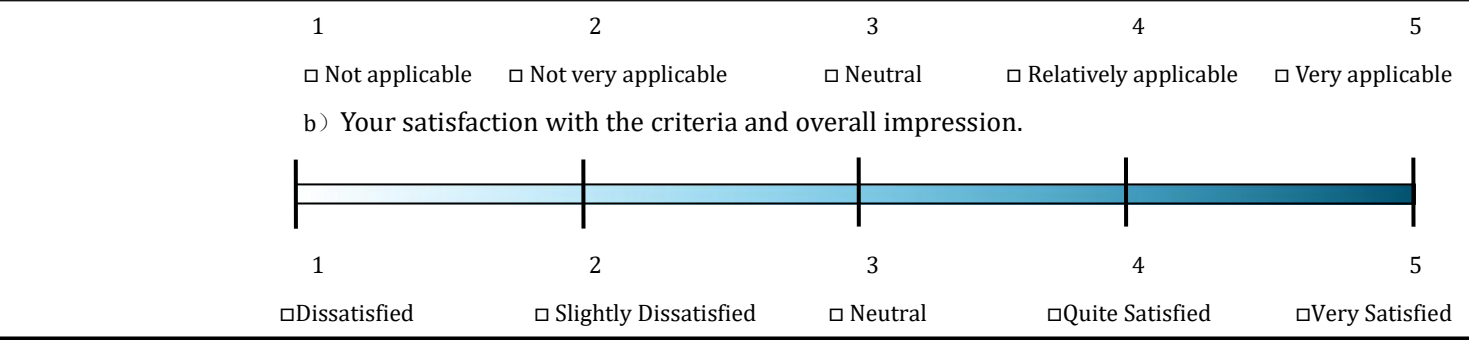
c) The degree of users' willingness to refer to criteria while carrying out their work.

1 2 3 4 5
☐ Unwilling ☐ Not very willing ☐ Neutral ☐ Quite willing ☐ Very willing

5. Overall Evaluation

a) The clinical applicability of the criteria.





Billiography

- [1]Bai Xue, Liu Jianping, Guo Yubo, et al. Suggestions and Interpretation for Quality Evaluation of Clinical Practice Guidelines in Traditional Chinese Medicine[J]. China Journal of Chinese Materia Medica, 2020,45(07):1600-1605.
- [2]Wang Jiyao, Wang Qiang, Wang Xiaoqin, et al. Development and preliminary validation of the evaluation system for clinical practice guidelines in China[J]. Chinese Medical Journal, 2018,98(20):1544-1548.
- [3]Bai Xue, Liu Jianping, Guo Yubo, et al. Thoughts on Establishing an Evaluation System for Clinical Practice Guidelines of Traditional Chinese Medicine[J]. China Journal of Chinese Materia Medica, 2020,45(07):1596-1599.
- [4]Yang Sihong, Chen Keji, Liu Jianping, et al. Key Points and Interpretation of Formulating Recommendations from Evidence in Clinical Practice Guidelines of Traditional Chinese Medicine[J]. Chinese Journal of Integrated Traditional and Western Medicine, 2021,41(04):494-498.
- [5]Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 1: performance, usefulness and areas for improvement[J]. CMAJ, 2010,182(10):1045-1052.
- [6]World Federation of Chinese Medicine Societies, Provincial-Ministerial Co-construction Collaborative Innovation Center for Prevention and Treatment of Respiratory Diseases with Traditional Chinese Medicine, Henan University of Chinese Medicine, et al. Guidelines for the Development of Diagnostic Criteria for Traditional Chinese Medicine Syndromes[J]. Chinese Journal of Evidence-Based Medicine, 2023,23(09):993-998.
- [7]Zhang Jiale, Zhang Yiwen, Wang Mengqiu, et al. Current Status and Thoughts on the Development of Diagnostic Criteria for TCM Syndromes[J]. Chinese Journal of Traditional Chinese Medicine, 2024,39(01):33-38.
- [8]Specialized Committee of Pulmonary Diseases, Chinese Association of Chinese Medicine/ Pulmonary Diseases Branch, Chinese Ethnic Medicine Association. Diagnostic Criteria for TCM Syndromes of Bronchial Asthma (2016 Edition)[J]. Journal of Traditional Chinese Medicine, 2016,57(22):1978-1980.
- [9]Pulmonary Disease Branch of Chinese Association of Traditional Chinese Medicine/Internal Medicine Branch of Chinese Association of Traditional Chinese Medicine/Pulmonary Disease Branch of Chinese Ethnic Medicine Association. Diagnostic Criteria for TCM Syndromes of Idiopathic Pulmonary Fibrosis (2019 Edition)[J]. Journal of Traditional Chinese Medicine, 2020,61(18):1653-1656.
- [10]World Federation of Chinese Medicine Societies, Provincial-Ministerial Co-construction Collaborative Innovation Center for Prevention and Treatment of Respiratory Diseases with Traditional Chinese Medicine, Henan University of Chinese Medicine, et al. Guideline on Establishing Diagnostic Criteria of Chinese Medicine Syndromes[J]. Chinese Journal of

Evidence-Based Medicine, 2023,23(09):993-998.