GUIDELINE

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Guideline on Establishing Diagnostic Criteria for Chinese Medicine Syndromes

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Abstract

Aim: To formulate the guideline for the development of diagnostic criteria for Chinese medicine syndromes, which can contribute to standardization of development of Chinese medicine syndrome diagnostic standards.

Methods: We embark into account on the development of Guideline on Establishing Diagnostic Criteria for Chinese Medicine Syndromes through Delphi method with reference to the existing technical system of diagnostic criteria for Chinese medicine syndromes and relevant criteria.

Results: Our guideline specifies principles, methods, and procedures for the formulation of diagnostic criteria for Chinese medicine syndromes.

Conclusions: It is a comprehensive and systematic evidence-based guideline, and we hope this guideline can be applied as a reference in developing diagnostic criteria for Chinese medicine syndromes in other disciplines. It is also applicable to the formulation of diagnostic criteria for relevant clinical, educational, and scientific research by hospitals, institutes, and academies.

KEYWORDS
Chinese medicine syndromes, diagnostic criteria, guideline

1 | INTRODUCTION

Standardization plays a fundamental, global, and strategic role in the development of Chinese medicine. The establishment of diagnostic criteria for Chinese medicine syndromes paves the way for the standardization of Chinese medicine diagnosis and treatment. In recent years, scholars have constantly put forward research ideas and methods of diagnostic criteria for Chinese medicine syndromes,[1–9] and established diagnostic criteria for certain diseases, which has promoted the research and application. However, the unclearness of ideas and methods, the immaturity of key technologies and the lack of specifications have restricted the establishment, popularization, and

application of syndrome diagnostic criteria. Therefore, it is urgent to formulate guidelines for the development of diagnostic criteria for Chinese medicine syndromes, which can contribute to standardization of development of Chinese medicine syndrome diagnostic standards.

This document defers to health policies and regulations, relevant guiding principles and the existing research on syndrome diagnostic standards,[6–9] and embarks into account the development of Guideline on Establishing Diagnostic Criteria for Chinese Medicine Syndromes[10–23] through Delphi method with reference to the existing technical system of diagnostic criteria for Chinese medicine syndromes and relevant criteria. It defines the ideas, methods, and key procedures for the standardization of the development of Chinese medicine syndrome diagnostic criteria. The criteria are formed on the basis of literature research, with clinical epidemiological investigation as the ground, the establishment of index system as the core, multivariate statistics and data mining as the support, and experts' opinions as the references. It includes five key procedures of syndrome classification and characteristics, determination of common syndromes, division of primary and secondary symptoms, basis, and form of establishing diagnostic criteria, and verification of diagnostic criteria. The purpose is to provide guidance for the development of diagnostic criteria for Chinese medicine syndromes, so as to improve the accuracy, authority and representativeness of the criteria, and further facilitate the application of syndrome diagnostic criteria in clinical and basic research.

2 | METHODS AND PROCEDURES OF THE FORMULATION OF DIAGNOSTIC CRITERIA FOR CHINESE MEDICINE SYNDROMES

2.1 | Preparation

2.1.1 | Defining research purpose

Define the model and target groups of the diagnostic criteria.

2.1.2 | Organizing research team

Guidance team
The guidance team responsible for the whole process and major decision-making are constituted by high-level experts in the field.

Expert team
The expert team responsible for promoting the project and providing instruction are formed by experts in Chinese and Western medicine, evidence-based medicine, epidemiology, and statistics, who have above intermediate professional and technical titles and over 10 years of work experience.

Working team
The working team is responsible for daily research tasks, meeting arrangements, and work coordination.

2.2 | Literature study

2.2.1 | Purpose

Count and screen the disease syndromes and corresponding symptom items, and be combined with the first round of expert consultation (see Section 2.3 for the contents and methods of the expert questionnaire) to formulate the clinical questionnaire, with the aim of providing the basis for the clinical survey.

2.2.2 | Key points

Developing retrieval strategy
Select the databases and build the search formulation. The Chinese Databases include CNKI, Wanfang Data, CBM, VIP, the English databases include PubMed, The Cochrane Library, Embase, Web of Science. According to research needs, other databases can be supplemented.

Literature selection
Set the inclusion and exclusion criteria for the literature and standardize the evaluation and selection methods of the literature.

Information extraction
Extract contents about syndromes and four diagnostic methods from the included literature and establish a literature database accordingly.

Terminology standardization
Standardize the terminology of Chinese medicine syndromes and symptoms with the same connotation but different expressions according to relevant terminology standardization documents.[24–30]

Statistical analysis
Apply comprehensive statistical analysis and necessary data mining techniques to explore the distribution rules and characteristics of common syndromes and corresponding symptoms.

2.3 | Expert consultation

2.3.1 | Purpose

It is recommended to conduct two or more rounds of consultations by questionnaires. The main purpose of the first round of consultation is to provide basis for the formulation of clinical questionnaires by preliminarily screening syndromes and corresponding symptom items. The following round(s) is to identify common syndromes and corresponding primary and secondary symptoms according to the clinical survey.

2.3.2 | Key points

Questionnaire format
A semiopen-ended questionnaire format is appropriate.

Questionnaire distribution

The questionnaire can be delivered in person, in paper form by mail, or in electronic form through professional websites, mobile apps, email, etc.

Selection of experts

Experts shall be selected based on the principles of representativeness, authority, and regionality. The selected experts shall (1) have senior professional and technical titles; (2) have high academic influence and are representative in the field of Chinese medicine or Chinese and Western integrative medicine, with over 10 years of work experience; (3) have been engaged in relevant researches; (4) come from different places.

Statistical analysis

Analyze experts' positive level (positive coefficient), consensus level of opinions (mean score, full score ratio), coordination level of opinions (variation coefficient, expert coordination coefficient), and authority level.

2.4 | Clinical survey

2.4.1 | Purpose

Collect clinical information through clinical survey to explore the distribution of common syndromes and corresponding primary and secondary symptoms with the methods of statistical analysis and data mining.

2.4.2 | Key points

Formulating questionnaire

Formulate a draft questionnaire based on the literature study and the first round of expert consultation. Conduct a clinical pilot survey to check whether the format of the draft questionnaire is reasonable and whether there is any ambiguity in the items and then improve the draft questionnaire accordingly to form a formal one. The questionnaire shall include patient's general condition, previous health condition, Western medicine diagnosis, Chinese medicine syndromes and symptoms, and necessary laboratory indicators. The definition, specification, and quantitative or semiquantitative grading of symptoms need to be clear.

Calculating sample size

Design the sample size for clinical survey, which is generally 5–10 times of the number of the variables.

Determining survey method

Cross-sectional survey can be adopted. It is recommended to select the hospitals in different regions and different levels with research conditions, and the patients who are willing to share feelings to ensure efficient communication.

Defining target group

Define the diagnostic criteria of Western medicine and the reference criteria of Chinese medicine syndrome differentiation and the inclusion and exclusion criteria of patient.

Quality control

(a) Establish a four-level quality management system of self-inspection, inspection, monitoring, and audit. (b) Unified training and corresponding assessment are required for all personnel before the survey. The training process and assessment results shall be recorded.

Statistical analysis

Use statistical analysis (such as statistical description, factor analysis, cluster analysis, binary logistic regression) and data mining (such as neural network, latent structure) to identify the classification of common syndromes and corresponding primary and secondary symptoms and to reveal the relationship between common syndromes and corresponding symptom(s).

2.5 | Establishment of diagnostic criteria

Establish the diagnostic criteria for syndromes in an appropriate form based on the above research, evaluation of experts, and the discussion of the expert working team.

2.6 | Verification process

2.6.1 | Purpose

To verify the clinical diagnostic efficacy of the established diagnostic criteria.

2.6.2 | Key points

Survey method

Prospective clinical survey shall be adopted. Set up reference group and trial group to evaluate the authenticity and clinical value of the draft diagnostic criteria.

Scope of survey

Define the diagnostic criteria of Western medicine, the reference criteria of Chinese medicine syndrome differentiation; and the inclusion and exclusion criteria of patients. The reference group uses syndrome differentiation from experts, while the trial group uses syndrome differentiation according to the draft criteria

Calculating sample size

It is recommended to estimate the sample size with the formula of $n = u_a^2 \times p(1-p)/\delta^2$ (generally, $\alpha = 0.05$, $\delta = 0.1$, i.e., $u_a = 1.96$, and the sensitivity of the diagnostic test is estimated as 80%).[31]

TABLE 1 Indicators of verifying syndrome diagnostic criteria.

Indicators	Formula	Explanation
Sensitivity	$\frac{TP}{TP+FN}$	The ability that someone with certain syndrome can be diagnosed with that syndrome
Specificity	$\frac{TN}{FP+TN}$	The ability that someone without certain syndrome cannot be diagnosed with that syndrome
Accuracy	$\frac{TP+TN}{TP+FN+FP+TN}$	The degree that the diagnostic result of syndrome verification coincides with the result of experts' differentiation
PPV	$\frac{TP}{TP+FP}$	The proportion of patients diagnosed with certain syndrome and without certain syndrome after the verification of that syndrome.
NPV	$\frac{TN}{FN+TN}$	
+LR	$\frac{TN/(TP+FN)}{FP/(FP+TN)}$	The percentage ratio of the number of patients with certain syndrome (e.g., positive or negative) to that of the patients not diagnosed with that syndrome but with that result of syndrome after the verification
−LR	$\frac{FN/(TP+FN)}{TN/(FP+TN)}$	
Area under the ROC curve	–	Combine the sensitivity and specificity by curve to reveal the accuracy

Note: ① Abbreviations: FP, False positive rate; TP, True positive rate; FN, False negative rate; TN, True negative rate.
② The bigger the sensitivity, specificity, accuracy and prediction value, the higher the accuracy of diagnostic criteria.
③ +LR ≥ 10 and −LR ≤ 0.10 indicate the higher diagnostic value of the verification.
④ The value of area under the ROC curve is usually between 0.5 and 1. and Value < 0.7 indicates lower diagnostic value. Value between 0.7 and 0.9 indicates middle diagnostic value. Value > 0.9 indicates higher diagnostic value.

Formulating questionnaire for clinical verification

Formulate the questionnaire for Chinese medicine syndrome diagnosis in accordance with the draft diagnostic criteria for common syndromes. The questionnaire shall include options for syndrome diagnosis and symptoms (tongue and pulse).

Statistical analysis

It is recommended to adopt indicators such as sensitivity, specificity, accuracy, positive and negative predictive values, positive and negative likelihood ratios, and area under the ROC curve (Table 1) to assess the clinical diagnostic efficacy of the diagnostic criteria.

2.7 | The flow chart for the formulation of diagnostic criteria for Chinese medicine syndromes

Establish an expert team to clarify the research model. Develop a clinical questionnaire based on literature research combined with the first round of expert consultation; conduct systematic clinical investigation and research, and formulate syndrome diagnosis standards based on the second round of expert consultation; verify the preliminarily formed diagnostic criteria for syndromes; finally, the diagnostic criteria for syndromes are formed. The five key links: syndrome classification and characteristics, determine nation of common syndromes, division of primary and secondary symptoms, basis and form of standard establishment, and verification of standards. The specific development process is shown in Figure 1.

3 | KEY CONTENT IN THE DEVELOPMENT PROCESS

Determination of common syndromes, identification of primary and secondary symptoms, and presentation of diagnostic criteria are key elements in the process of establishing diagnostic criteria for syndromes.
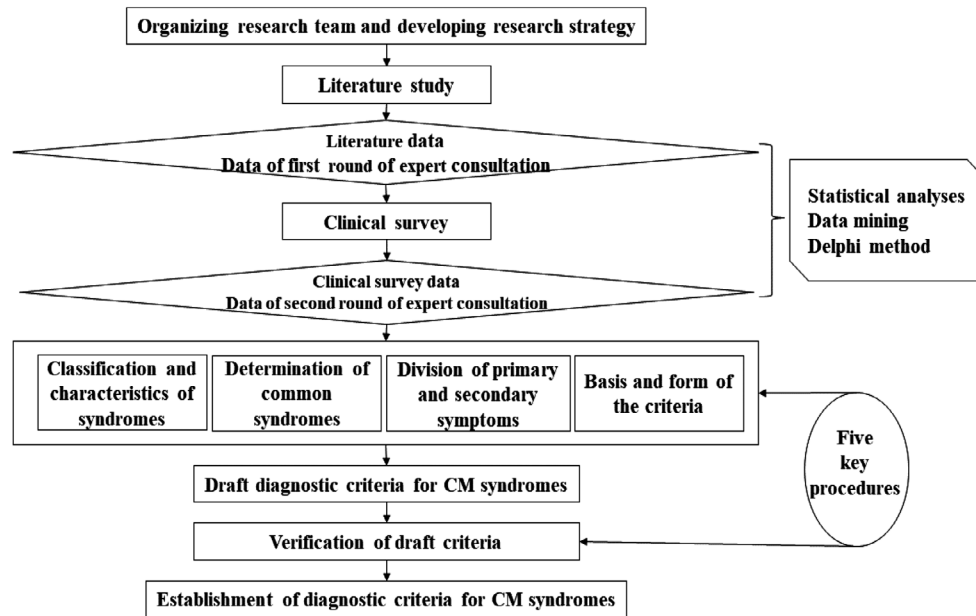
3.1 | Determination of common syndromes

3.1.1 | Identification principles

During the formulation of diagnostic criteria for syndromes, the identification of common syndromes shall comply with the following principles: Authenticity: it shall truly reflect the pathogenesis and the law of the whole course of disease; Representativeness: the common syndromes identified shall have a high clinical incidence; Practicability: the syndrome diagnostic criteria formulated shall be feasible and popularized.

3.1.2 | Identification methods

The identification decision methods for common syndromes include statistical methods, data mining, and Delphi method. The recommendation opinions are shown in Table 2. Identification method: a syndrome can be determined as common syndrome if it shares the same result among three methods. If a syndrome shares the same result in two methods, the experts and clinical practices will determine whether it is a common syndrome or not. See Sections 2.3 and 2.4 for specific processes. Note: The determination of common syndromes is only for the diagnosis and classification of syndromes of one disease under the mode of disease and syndrome combination. For subhealth condition or multiple diseases, the formulation of diagnostic criteria for single syndrome is only for reference. Common syndromes can appear alone or be in combination with several other syndromes. The distribution and characteristics of concurrent syndromes shall be clarified in clinical practices.

FIGURE 1 Formulation process of diagnostic criteria for Chinese medicine syndromes.

TABLE 2 Common methods for determining common syndrome.

Key process	Key common technology		Recommendation parameter	Condition
Decision methods for common syndrome	1. Statistical methods	① Descriptive statistics	Frequency ≥ 10%	Combination of two methods
		② Cluster analysis	Between-class similarity coefficient	
	2. Data mining	① Neutral network	Valid percent value and clustering coefficient product	Either ① or ②
		② Concealed structure	Threshold	
	3. Delphi method		Mean ≥ 4.00 and coefficient of variation < 20%	Must have

Note: ① Statistical methods and data mining methods for reference are common recommendations but not limitations.
② Due to the different characteristics of diseases and syndrome, some parameters for statistical methods and data mining methods need to be adjusted accordingly.

3.2 | Identification of primary and secondary symptoms

The identification methods for primary and secondary symptom include statistical methods, data mining, and Delphi method. The recommendation opinions are shown in Table 3. Identification method: ① A symptom can be determined as a primary symptom if it shares the same result among three methods. If a symptom shares the same result in two methods, the experts and clinical practices will determine whether it is a primary symptom. ② A symptom can be determined as a secondary symptom if it shares the same result among three methods. When a symptom shares same results in one or two methods, the experts and clinical practitioners will determine whether it is a secondary symptom. See Sections 2.3 and 2.4 for specific processes.

3.3 | Presentation of diagnostic criteria

After determining common syndromes and corresponding primary and secondary symptoms, the presentation of diagnostic criteria for syndromes shall adopt the combination of diagnostic conditions or the measurement (score) diagnostic method. ① Combination of diagnostic conditions method: it includes two methods. One is to establish the diagnosis basis of syndromes according to the combination of symptom(s) and its contributing degree to the syndrome diagnoses (recommendation opinions shown in Table 4), and by combining the experts' group discussion. Refer to the examples syndrome of phlegm-heat obstructing lung and spleen-lung qi deficiency in Traditional Chinese Medicine Diagnostic Standard for Chronic Obstructive Pulmonary Diseases (2011)[13] (shown in Table 5). The other is to establish

TABLE 3 Common methods for determining primary and secondary symptoms.

Key process	Key common technology		Recommendation parameter	Condition
Decision methods for primary and secondary symptoms	1. Statistical methods	① Descriptive statistics	Primary symptoms: frequency ≥ 50% Secondary symptoms: 30% ≤ frequency < 50%	Based on ①, combining one of ② to ⑤
		② Factor analysis	Primary symptoms: Load factor ≥ 0.5 Secondary symptoms: 0.3 ≤ load factor < 0.5	
		③ Principal component analysis	Contributing rate	
		④ Logistic regression	Primary symptoms: OR value ≥ 3 Secondary symptoms: 1 ≤ OR value < 3	
		⑤ Structural equation	Load factor	
	2. Data mining	① Neutral network	Primary symptoms: 0.5 ≤ Wij < 1 Secondary symptoms: 0.3 ≤ Wij < 0.5	Either ① or ②
		② Concealed structure	Threshold	
	3. Delphi method		Primary symptoms: mean ≥ 4.00 and coefficient of variation < 20% Secondary symptoms: mean ≥ 3.00 and coefficient of variation < 30%	Must have

Note: ① Statistical methods and data mining methods for reference are common recommendation but not limitation.
② Due to the different characteristics of diseases and syndrome, some parameters for statistical methods and data mining methods need to be adjusted accordingly.

TABLE 4 Common methods for establishing syndrome diagnostic criterion basis.

Key process	Key common technology		Recommendation parameter	Condition
Establishment basis for syndrome diagnostic criterion	1. Data mining	Association rule	Support ≥ 80%, confidence ≥ 10%, lift> 1	Combination of two methods
		Bayesian network	Conditional probability ≥ 0.5	
	2. Experts discussion		Consensus > 70%	Must have

Note: ① Statistical methods and data mining methods for reference are common recommendation but not limitation.
② Due to the different characteristics of diseases and syndrome, some parameters for statistical methods and data mining methods need to be adjusted accordingly.

TABLE 5 Combination method of diagnostic conditions exemplified by syndrome of phlegm-heat obstructing lung and spleen-lung Qi deficiency in COPD.

Syndrome	Diagnostic condition	Diagnostic criteria
Syndrome of phlegm-heat obstructing lung	① Coughing, gasping or shortness of breath ② Large amount of phlegm, color yellow or white, sticky or stagnant ③ Fever or thirst and fond of cold drinks ④ Constipation ⑤ Red tongue, yellow or greasy tongue fur, pulse rapid or slippery	① and ②, plus two of ③ to ⑤
Syndrome of spleen-lung Qi deficiency	① Coughing, gasping or shortness of breath; worsen after movement ② Fatigue, weakness or spontaneous sweating; worsen after movement ③ Aversion to wind, easily catch cold ④ Anorexia ⑤ Stomach, epigastric or abdominal distension, or loose stool ⑥ Tongue plump, tongue fur thin and white or white and greasy, pulse deep, or thready	Two of ① to ③, plus two of ④ to ⑥

TABLE 6 Combination method of diagnostic conditions exemplified by internal retention of damp-heat in viral hepatitis.

Syndrome	Internal retention of damp-heat
Manifestation	Anorexia, vomiting, nausea, dislike greasy food, right hypochondriac pain, bitter taste, dry mouth, fatigue, weakness, epigastric or abdominal distension, malaise, loose or greasy stool, yellow or red urine, skin and eyes yellowish, fever, red tongue, yellow or greasy tongue fur, pulse rapid or slippery.
Primary symptoms Secondary symptoms	① Anorexia, vomiting, or nausea; ② right hypochondriac pain; ③ red tongue, yellow or greasy tongue fur ① Fatigue, weakness or epigastric or abdominal distension; ② bitter taste and dry mouth, ③ pulse rapid, slippery, or stringy
Criterion	① The syndrome can be diagnosed if all the primary symptoms are satisfied, ② The syndrome can be diagnosed if two primary symptoms and two secondary symptoms are satisfied.

TABLE 7 Quantitative diagnostic method exemplified by coronary heart disease in blood stasis syndrome.

Types of indicator	Contents of indicator	Indicator grading
Primary indicator	1. Chest pain site fixed	10
	2. Tongue purplish or dark	10
	3. Ecchymosis or petechia on tongue	10
	4. At least one branch of coronary artery shows stenosis ≥75% in coronary angiography	9
	5. Coronary arterial thrombus or mural thrombus in the heart chamber are shown on ultrasonic contrast	8
Secondary indicator	1. Chest pain, worsen at night	6
	2. Mouth, lips, or gum purplish dark	7
	3. Sublingual varices, or purplish dark	7
	4. At least one branch of coronary artery shows stenosis ≥ 50%, but <75% in coronary angiography	6
	5. Activated partial thromboplastin time (APTT) or prothrombin time (PT) shortened	5
Assistant indicator	1. Complexion darkish	2
	2. Pulse hesitant	4
	3. Coronary angiography or computed tomography angiography (CTA) show obvious signs of calcification or diffuse lesions in blood vessels	3
	4. Fibrinogen rises	3

Note: (1) According to the diagnostic criterion of coronary heart disease, scientific researches should meet the requirement: at least one branch of coronary artery shows stenosis ≥ 50%. (2) Blood stasis syndrome can be diagnosed if the score of coronary heart disease in blood stasis syndrome is or more than 19. The score can also be used to assess the degree of coronary heart disease in blood stasis syndrome. (3) Diagnosis of coronary heart disease in blood stasis syndrome should contain primary indicators and at least one macro indicator in secondary indicators. Physical and chemical indicators solely cannot be used for diagnosis.

the diagnostic criterion according to identification methods for the combination of primary and secondary symptoms, and by combining the experts' group discussion. Refer to the example syndrome internal retention of damp-heat in the standards of traditional Chinese medicine syndrome differentiation for viral hepatitis[6] (shown in Table 6). ② Quantitative diagnostic method: Grading the contributing degree of the symptoms to the syndromes, and add the weight of all the symptoms. The criterion is satisfied if cumulative scores reach the threshold. Refer to the example Diagnostic Standard for Coronary Heart Disease in Blood Stasis syndrome[8] (shown in Table 7) and the standards of syndrome differentiation for apoplexy.[23]

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