



## Establishment of basic principles and methods of acupuncture standardization in traditional Chinese medicine

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### ABSTRACT

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Standardization is the universal language of the world, and standardization of traditional Chinese medicine (TCM) is essential for its communication in China and globally. However, the principles and methods of TCM acupuncture standardization have been unclear and inadequate in the early stages. Based on an investigative approach to understanding the current status, identifying problems, and finding solutions, our team has established basic principles of TCM acupuncture that embody Chinese wisdom, evaluated the international strategic environment systematically, proposed the principle of “importance of harmony and exercise of impartiality”, and established basic working principles. A series of methods for TCM acupuncture standard development and evaluation have been constructed, including general standards for the revision of TCM acupuncture standards, the first TCM acupuncture clinical research management specification, a shared full chain technology platform, a data center, and an evaluation research base for TCM acupuncture clinical research. Evaluation criteria for ancient literature and expert experience, a recommendation method for the “three main and three auxiliaries” TCM guideline for prevention were established, and quantifiable assessment methods of TCM standard applicability were proposed. These findings provide methodological guidance for TCM acupuncture standardization.

## 1 Introduction

Traditional Chinese medicine (TCM) embodies profound philosophical wisdom and thousands of years of

health and wellness concepts and practical experiences of the Chinese nation. Standardization has been integral to the development of TCM throughout history. As it continues to gain popularity worldwide, the demand for

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standardization is increasing. Thanks to the strong support of the Chinese government, significant progress has been made in the standardization of TCM. However, the standardization of acupuncture has faced challenges due to late start, such as unclear principles, inadequate methods, outdated standards, and a lack of skilled professionals. To overcome these challenges, we have integrated the basic principles of standardization, traditional Chinese cultural wisdom, and the unique features of TCM. We followed a closed-loop research model of “principle-method-technique-use”, systematically evaluated the international strategic environment for the standardization of acupuncture [1], and created basic principles that reflect Chinese wisdom [2]. We also developed methods for standard formulation and evaluation that have been applied and promoted in various international, national, and industry/organizational standards [3-6].

## 2 Basic principles of TCM acupuncture standardization research

### 2.1 Research on the development strategy of TCM standardization

Through literature research, in-depth interviews, and surveys, the current status, issues, and trends of TCM standardization were analyzed comprehensively and compared. Four regular features of TCM standardization from an international perspective were summarized [7]: public demand and related systems as the foundation for national standards; legislation as a guarantee for standard development and implementation; registration standards as crucial for international standardization of TCM; and international organizations as key drivers of standardization. These findings provided important references for the formulation of the development strategy of TCM standardization.

Based on the research, guidance documents such as the “Research on the Development Strategy of the Standardization of Traditional Chinese Medicine” “Development Plan of the Standardization of Traditional Chinese Medicine (2006-2010)” “Outline of Medium- and Long-term Development Plan for the Standardization of Traditional Chinese Medicine (2011-2020)”, and “Guidelines on Strengthening Traditional Chinese Medicine Standardization” were issued. The main principles and tasks of TCM standardization work were established, such as comprehensive planning, step-by-step implementation, inheritance and innovation, scientific democracy, practical effectiveness, progressive guidance, domestic focus and international orientation, government leadership, and social participation. In our study, the main tasks of TCM standardization were established to strengthen the construction of the TCM standardization system, the

international standardization and the fundamental work of the TCM standardization.

### 2.2 Research on the standard system of TCM and acupuncture

A TCM standard system with a three-dimensional (3D) structure was established by employing a systematic analysis method [8]. TCM standards within the same scope were integrated to form the system based on their intrinsic connections. The system included basic theory standards, technical standards, management standards, and operational standards of TCM, with basic standards being core, technical standards being critical, management standards being fundamental, and operational standards being essential. The TCM standard system was divided into three dimensions based on the requirements of the national standard system construction: professional (or field), category, and level.

Drawing on the standardization plan for TCM acupuncture and the current state of development within the acupuncture discipline, a comprehensive system was created through the use of system analysis. This system was built around two essential components: a primary structure centered on standard development and a subsidiary structure oriented towards standard implementation. Both of these are driven by the internal relationship laws that govern TCM acupuncture standards. The outcome of this initiative was the development of an overarching framework for the standardization of acupuncture [9]. On this basis, we issued the “Outline of the Standardization Plan for Acupuncture and Moxibustion by China Association of Acupuncture and Moxibustion” and the “11th Five-Year Plan for Acupuncture and Moxibustion Standardization”. These documents were designed to establish the basic system of acupuncture standards, based on the theoretical framework of the discipline, and to promote its practical application and development. As such, they provided an important foundation for the initial design and implementation of TCM acupuncture standardization work.

### 2.3 Research on the basic principles of TCM acupuncture standardization

The relationship between TCM syndrome differentiation and treatment and standardization is highly individualized and general, specific and universal. Therefore, TCM acupuncture standards should reflect both general and traditional Chinese characteristics, advantages, and development laws. Based on the basic principles of standardization, such as simplicity, uniformity, coordination, and optimization, as well as China’s traditional culture and TCM academic characteristics, the principles of “harmony in diversity” [10, 11] and “comprehensive

consideration without comparison” [10, 12] from the *Analects of Confucius* (*Lun Yu*, 《论语》) were proposed, with the idea of being inclusive, full of consideration, and allowing different perspectives to coexist without comparing one against another. The standardization of TCM acupuncture is achieved through unification in diversity by finding commonalities in individual experiences and summarizing common rules to seek harmony. The process values personal experience and characteristics while relying on the experience of multiple doctors as the basis for standardization. The key principles of TCM standardization are centered on the “importance of harmony and exercise of impartiality and recommendation following syndrome differentiation” [2, 10], without being partial in dealing with reliable data from all aspects. The recommendation following syndrome differentiation in the standardization process is based on evidence, which refers to the evidence-based approach in developing TCM standards. This approach involves identifying, combining, and recommending the best possible evidence to find the optimal solution that adheres to the principles of standardization.

#### 2.4 Research on basic work principles of acupuncture standardization

Based on the characteristics of standardization in TCM acupuncture, the team proposed the principle of “four must nots” [10, 13], namely, “no wild conjectures, no arbitrary assertion, no stubbornness, and no arrogance”. The “four must nots” originate from the *Analects of Confucius* and mean the elimination of four kinds of drawbacks: avoiding imagination, avoiding a fixed goal, avoiding stubbornness, and avoiding self-centeredness. This means that the development of TCM acupuncture standards should not be based on subjective inferences, but rather on scientific evidence. Moreover, the standardization process should prioritize important aspects and consider secondary ones later, with no need for reaching every aspect. In addition, TCM acupuncture standards should not be rigid in thinking, and should not consider personal experience as the only aspect of standards. Instead, they should be open to all perspectives and suggestions.

These principles and guidelines provide a theoretical foundation for addressing important relationships between personal experience, national standards, internal standardization, different standards, domestic standards, and international standards, as well as standards, laws, regulations, clinical efficacy, and innovation. This effectively dispels concerns about academic stagnation within the TCM acupuncture industry that standardization might lead to and enhances understanding of the necessity and importance of TCM acupuncture standardization.

### 3 Study on the development and evaluation methods of standards for TCM acupuncture

#### 3.1 Study on general standards for the revision of TCM acupuncture standards

Standards are a basic element that constitutes the core competitiveness of a country and an important technical system that regulates economic and social development. Japan, South Korea, European countries, and the United States have long sought to dominate the development of international standards for traditional medicine through various forms and channels. The Chinese traditional medicine standardization industry lacks awareness and started late, and there is a lack of basic theories and methods for developing TCM standards. Therefore, guided by the national “Guidelines for Standardization Work”, the team first compiled a set of guidelines and writing rules suitable for the standardization of TCM acupuncture work, which provided guidance and methods for the orderly development of its standardization.

#### 3.2 Development of a clinical evaluation system and general technical platform for TCM acupuncture

Targeting the specificity of acupuncture intervention and the differences in clinical research objectives, the team established the first domestic and international “Good Clinical Practice of Acupuncture and Moxibustion Research Management”, namely GCP of Acupuncture and Moxibustion, which have become the standard regulations for the design, implementation, reporting, and management of institutions and personnel related to acupuncture clinical research. This established a complete set of acupuncture clinical evaluation rules and regulations that are both in line with international rules and reflect the characteristics of TCM acupuncture.

The team created a general technical platform for acupuncture clinical research, a data center, and an evaluation research base covering a central random system, a clinical research data management system, a clinical data acquisition management system, and an acupuncture case registration platform. The team established a World Health Organization (WHO)-recognized acupuncture clinical trial registration platform with over 340 registered acupuncture clinical trials, providing data support services for 240 types of TCM acupuncture clinical research projects. The team selected acupuncture advantages such as stress urinary incontinence and constipation to conduct high-quality clinical research. The results were published in international top journals such as *JAMA* [14] and *Annals of Internal Medicine* [15], introducing a series of high-quality acupuncture clinical evidence. In particular, the research results on stress urinary incontinence in women are written into the USA clinical practice guidelines, promoting the development of TCM acupuncture towards the world.

### 3.3 Research on grading standards for evaluation of TCM ancient literature and expert experience

Based on the internationally recognized Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence grading and strength recommendation system and the historical and characteristic development of TCM acupuncture, the team creatively proposed the “three-in-one”<sup>[3]</sup> method for collecting, evaluating, combining, and recommending evidence in the TCM clinical practice guidelines. The “three-in-one” refers to evidence from modern literature, ancient literature, and clinical experience from frontline practitioners. Ancient Chinese medical literature and ancient medical records lack comparison and repetition, and cannot be evaluated solely based on modern evidence. The team innovatively proposed the principles that should be followed when evaluating ancient Chinese medical literature, namely, “the ancient literature has records, the medical experts have passed down, and modern practitioners have applied them”. Based on this, the team proposed evidence grading standards for TCM ancient literature, and established an evidence evaluation method based on the authoritative level and influence of experts. “Combining” refers to combining evidence. Based on ancient Chinese medical literature, graded evidence is established according to GRADE evaluation, and expert experience is included as a characteristic. The team adopted the analytic hierarchy process to combine evidence, determined a score index, and recommended a plan according to the score, thereby supplementing the shortcomings of the modern evidence of TCM acupuncture, while retaining the concept and method of evidence-based medicine and reflecting the features of TCM acupuncture.

### 3.4 Research on the recommendation method of guidelines for TCM preventative treatment

The concept of “treating disease before its onset” as preventative treatment is the advantage and core concept of TCM for serving human health. The National Healthcare Security Project urgently requires the formulation of a batch of industry guidelines and operation standards for “preventative treatment”. The development of the practice guidelines of TCM preventative treatment is the first of its kind. To reflect the characteristics of preventative treatment and differ from disease practice guidelines, the team conducted in-depth research on the concept of preventative treatment and proposed the selection of the “three main and three auxiliaries”<sup>[16]</sup> solution in the recommendation plan, namely, “the eradication of the cause is the main focus, followed by post-illness rehabilitation; active regulation is the main aspect, followed by passive interventions; and physical interventions are the

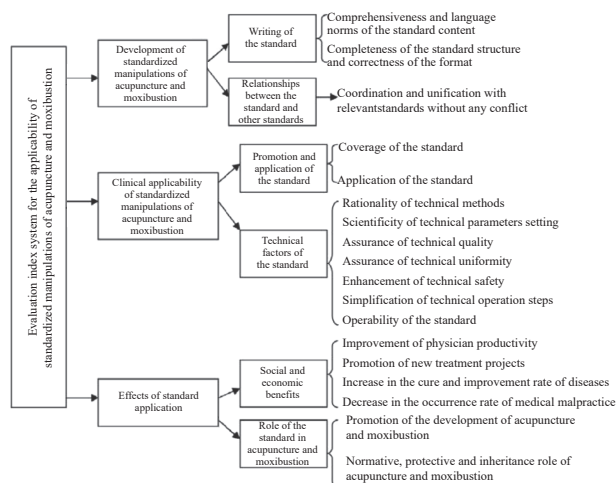
main focus, followed by chemical interventions”. This recommendation method has been applied to 37 projects of the State Administration of Traditional Chinese Medicine’s preventative treatment standard operation and featured therapy group and has been published as the Group Standard of the China Association of Chinese Medicine.

### 3.5 Research on the method for evaluating the applicability of TCM standards

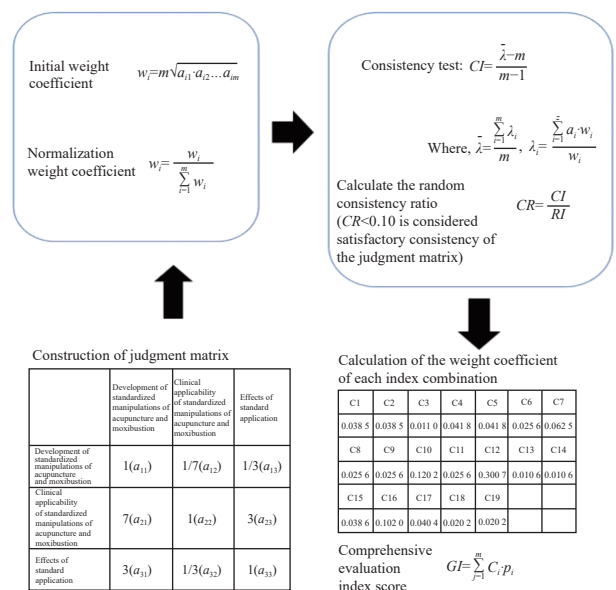
The analytic hierarchy process was first introduced to evaluate the applicability of TCM acupuncture standards, and an indicator system consisting of 21 specific evaluation indicators was established through the exploration of standard development, clinical applicability, and standard function dimensions via the Delphi method and expert workshops (Figure 1)<sup>[6,17]</sup>. In addition, the importance of the indicators at the same level was compared pairwise, and the proportional numerical values of each indicator’s relative importance were obtained by constructing a pairwise comparison judgment matrix. The normalized weight coefficient was calculated according to the formula, and consistency was checked to determine whether the weight coefficient was logical. Finally, the normalized weight coefficients obtained at each level were multiplied to obtain the combination weight coefficients of each indicator, and a comprehensive evaluation score was calculated. Based on this, a method for evaluating the applicability of TCM acupuncture standards was constructed (Figure 2), and it was used to conduct applicability evaluations on TCM acupuncture standards, such as the acupuncture technique operation standard that has already been published. After the combination weight coefficients were established, the comprehensive evaluation score (GI) was used to evaluate the applicability of three national standards for ear acupuncture, three-edged needle, and basic techniques of filiform needle. A survey questionnaire was conducted on the clinical applicability of ear acupuncture, triangular needle, and basic filiform needle. The standardized manipulations project was based on an indicator hierarchy. The results showed that ear acupuncture, triangular needle, and basic techniques of filiform needle had comprehensive applicability scores of 84.02, 83.53, and 86.11, respectively, indicating good clinical applicability. This confirms the scientific feasibility of these methods.

The above method has constructed a closed-loop research paradigm and methodology system for the establishment, development, application, evaluation, and revision of TCM acupuncture standards, which makes the development of TCM acupuncture standards a solid basis while also enhancing the quality and level of standard writing.





**Figure 1** TCM acupuncture standardized manipulations applicability evaluation indicator system



**Figure 2** Analytic hierarchy process establishing comprehensive evaluation index

**4 Conclusion**

In response to the challenges encountered during the initial stage of TCM standardization development, the research team adopted a strategy of investigating the current status, identifying issues, and seeking solutions. After 15 years of exploration and practice, the team established a set of basic principles for TCM acupuncture standardization that embody Chinese wisdom. We evaluated the international strategic environment and proposed the “importance of harmony and exercise of impartiality” as a fundamental principle for TCM acupuncture standardization. We established basic working principles for TCM acupuncture standardization, developed a series of methods for the development and evaluation, and formulated common norms for the revision of TCM acupuncture standards. Besides, we established the first

management standard for TCM acupuncture clinical research, and created a standardized platform for TCM acupuncture clinical research, data center, and evaluation research base. Additionally, we proposed a grading standard for evaluating TCM ancient literature and expert experience, established a recommendation method for TCM preventative treatment guidelines based on “three main and three auxiliaries”, and proposed a quantifiable method for evaluating the applicability of TCM standards based on the analytic hierarchy process. This provides a methodological reference for TCM standardization research.

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**Competing interests**

The authors declare no conflict of interest.

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## 中医针灸标准化基本原理与方法的创建研究

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**【摘要】** 标准是世界通用语言, 中医标准化有助于中医国内外交流。然而中医标准化初期原理不明、方法不足, 团队本着摸清现状、找准问题、寻找对策的研究思路, 创建了彰显中国智慧的中医针灸标准化基本原理, 系统评估了中医针灸标准化国际战略环境, 提出了“贵和执中”的中医针灸标准化基本原理, 确立了中医针灸标准化基本工作原则。构建了中医针灸标准研制与评价系列方法, 制订了中医针灸标准制修订共性规范, 建立了首个中医针灸临床研究管理规范, 创建了全链条中医针灸临床研究共性技术平台、数据中心和评价研究基地, 提出了中医古代文献和专家经验评价分级标准, 确立了“三主三辅”的中医治未病指南方案推荐方法, 建立了可量化的中医标准适用性评价方法。为中医针灸标准化工作顺利开展提供了方法学参考。

**【关键词】** 中医; 针灸; 标准化; 理论; 方法