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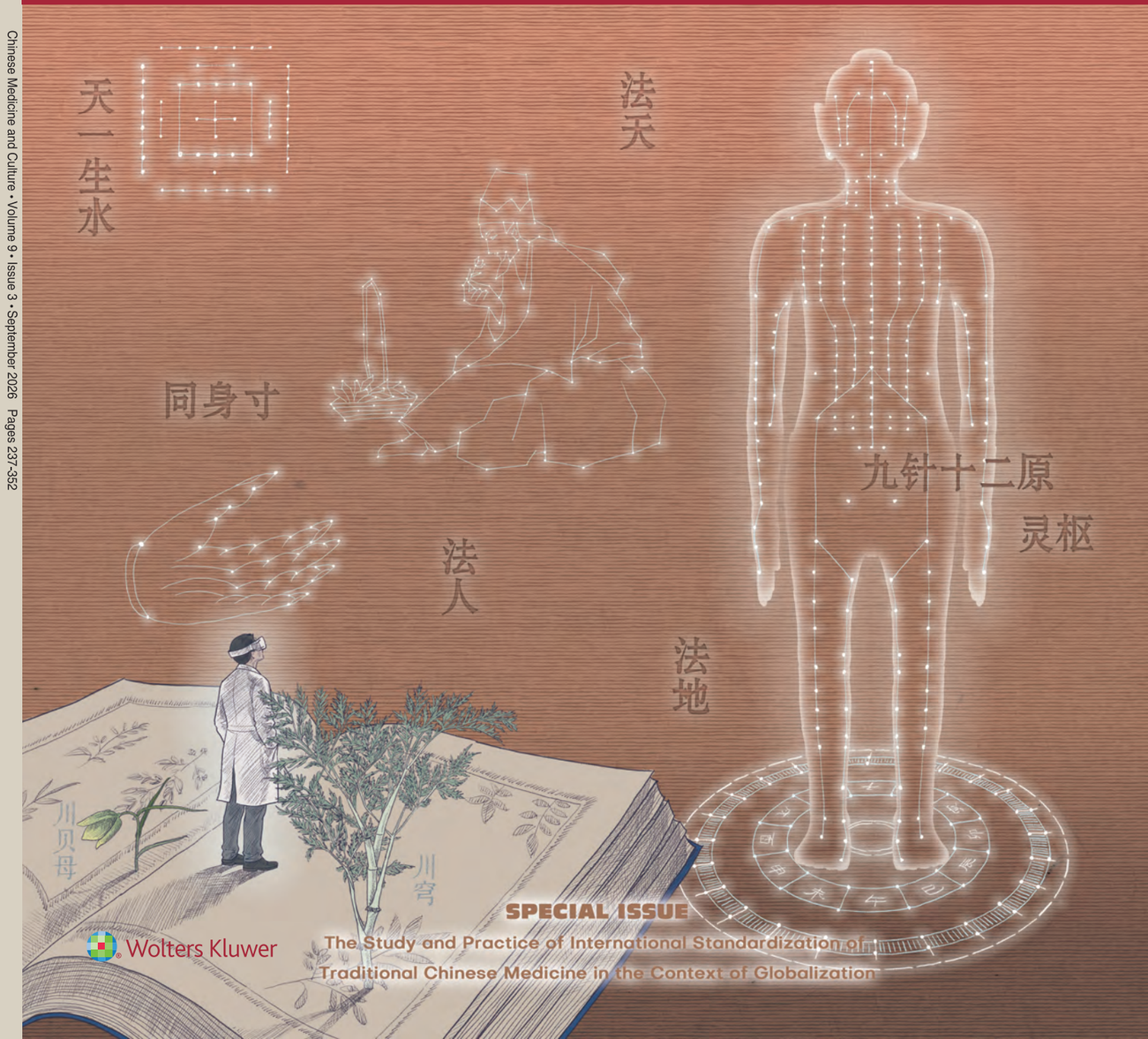
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SPECIAL ISSUE
The Study and Practice of International Standardization of Traditional Chinese Medicine in the Context of Globalization

Chinese Medicine and Culture

中医药文化（英文）

Special Issue: The Study and Practice of International Standardization of Traditional Chinese Medicine in the Context of Globalization

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Shen Yuandong is an internationally recognized leader in the internationalization and standardization of traditional Chinese medicine (TCM). He currently serves as chair of ISO/TC 249, chair of the “Shanghai Standard” Evaluation Committee, and director of the Shanghai Technical Committee for TCM Standardization. A former consultant on traditional medicine to the World Health Organization, he led the Chinese expert group for the WHO ICD-11 ICTM project and has made significant contributions to the global development and international standardization of TCM.

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About this Issue

Standards are the achievements of human civilization’s progress. As a global “universal language”, standards support industrial development, promote technological innovation, and regulate social governance. They play a crucial role in facilitating trade and promoting global connectivity, serving as an important technical foundation for global governance and economic cooperation. Currently, TCM is accelerating its modernization and internationalization. Developing TCM standards is not only a key technical step to breaking trade barriers and obtaining international recognition, but also a core element in advancing the internationalization of TCM. This special issue focuses on the “International Standardization of Traditional Chinese Medicine”, aiming to publish the latest academic research achievements in the field of international standards of TCM and explore the practice and innovation of TCM standards in the context of globalization.

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Chinese Medicine and Culture is an interdisciplinary academic journal focusing on the study of Chinese medicine. It aims to promote communication and dialogue between researchers in the natural sciences and humanities of Chinese medicine. The objectives are to build an interactive platform for interdisciplinary research on Chinese medicine and to comprehensively reflect the high-level and latest research results of Chinese medicine in the fields of medical science research, cultural exchange and historical heritage conservation.

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Editorial

CHINESE 中医药文化(英文版)
MEDICINE AND CULTURE

OPEN

Upholding Fundamentals and Embracing Innovation: Historical Wisdom and Contemporary Practice in TCM Standardization

守正创新：中医药标准化的历史智慧与当代创新

SHEN Yuandong (沈远东)[1,2,✉]

The international standardization of traditional Chinese medicine (TCM) has never been a purely technical exercise. It is simultaneously a historical negotiation, a scientific challenge, and a cultural translation. As TCM expands beyond its Chinese origins into global markets and clinical settings, the urgency of how to measure, describe, and validate its practices has never been greater. Yet standardization—while essential for safety, quality, and mutual recognition—risks flattening the very diversity that makes TCM a living, adaptive medical tradition. How can we develop standards that are scientific enough for international acceptance yet flexible enough to accommodate unique and evolving TCM? This special issue, "The Study and Practice of International Standardization of Traditional Chinese Medicine in the Context of Globalization", brings together 10 original contributions that address this question from historical, technological, policy, and cultural perspectives.

We open with a historical contribution that reviews the remarkable achievements and accumulated wisdom of acupuncture standardization during China's Northern Song Dynasty, providing direct inspiration for modern TCM standardization. Cheng Han (程晗), Xu Kun (徐坤), and Sang Zhen (桑珍) examine how the court under Emperor Renzong (宋仁宗) produced bronze figures, illustrated classics, and the proportional *Cun* (寸) measurement method. Their analysis reveals that effective standardization does not merely codify texts; it requires physical carriers, institutional closed loops, and a deliberate balance between uniformity and individual variation. This historical paradigm, the authors argue, distills ancient expertise to illuminate contemporary pathways.

Transitioning from classical to contemporary practice, Liang Ning (梁宁), Yan Lijiao (晏利姣), Zhang Xuefei (张雪飞), and Shi Nannan (史楠楠) explore the development of scenario-oriented clinical practice guidelines. Recognizing that conventional "one-size-fits-all" guidelines often fail in real-world settings, they propose differentiated strategies for public health emergencies (rapid and living guidelines) and for Chinese patent medicine applications. Their emphasis on scenario-specific evidence synthesis, dynamic updating, and implementable recommendations offers a pragmatic path forward. Complementing this, the *Clinical Diagnosis and Treatment Guidelines for Spinal Tendon off Position and Bone Malalignment (2026 Edition)*, developed by a multidisciplinary expert group led by Professor Zhan Hongsheng (詹红生) and grounded in Shi's Traumatology (石氏伤科)—a renowned medical lineage from Shanghai—represents the fruitful convergence of this prestigious local heritage with modern standardization. Relevant standardized outcomes of this work were included in the national standard in 2023.

The convergence of artificial intelligence (AI) and big data with TCM constitutes perhaps the most transformative—and contested—frontier. Two articles address this theme from complementary angles. Chen Huangyan (陈黄炎) and Linda LD Zhong (钟丽丹) provide a comprehensive overview of AI applications spanning diagnosis, herbal medicine, acupuncture and *Tui Na* (推拿), and clinical research. They identify persistent challenges: data heterogeneity, model explainability, regulatory gaps, and the complexity of multi-component interventions. In a more conceptual contribution, You Fei (尤飞) and Shao Qiongyan (邵琼琰) propose a "Knowledge–Data Dual-Driven Paradigm" for TCM modernization. Rather than treating AI as a replacement for traditional epistemology, they argue for a hybrid architecture that combines

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large-scale knowledge graphs and TCM-specific large language models with digitized *Si Zhen* (四诊 four diagnostic methods) data. Their vision of "computational intelligence amplifying empirical wisdom" offers a principled way to preserve theoretical grounding while embracing objectivity.

Case studies of specific medicinal substances bring abstraction down to earth. Hou Kai (侯凯), Jiang Shunyuan (蒋舜媛), Wang Mei (王梅), and their colleagues trace the trajectory of Chinese herbal medicine *Chuan Xiong* (川芎 Rhizoma Ligustici Chuanxiong) from Sichuan to global markets. They document how divergent pharmacopoeia standards led to a sharp decline in exports, and how iterative scientific negotiations eventually produced an ISO standard that reconciles local cultivation heritage with international quality parameters. This is a rare, detailed account of how trade disputes can be resolved through evidence-based harmonization. In a different vein, Sun Hongbing (孙洪兵), Tang Yina (汤依娜), Zeng Rui (曾锐), and Yang Huijie (杨慧捷) examine Chinese herbal medicine *He Zi* (诃子 Fructus Chebulae and T. chebula var. tomentella fruit), a medicinal plant that traveled the Silk Roads, acquiring distinct functional profiles in different traditional medicines. Using a comparative medical anthropology framework and quantitative pharmacopoeial analysis, they develop a "dissemination–interpretation–standardization" model that illuminates how cultural meaning and chemical markers co-evolve across regions. Beyond material substances, linguistic precision is paramount in international standardization. Xu Gaonan (徐高楠) addresses the enduring challenge of TCM core term translation, moving beyond lexical gap arguments to identify failures in cultural transmission, cognitive mapping, and functional adaptation. Her Cultural-Cognitive-Functional Triad Model and dynamic three-layer standardization pathway offer a sophisticated alternative to static glossaries. By linking theoretical rigor to empirical case studies from *Huang Di Nei Jing* (《黄帝内经》*The Yellow Emperor's Inner Classic*) and *Shang Han Lun* (《伤寒论》*Treatise on Cold Damage*), Xu demonstrates that terminology work is not a peripheral task but a core component of global integration.

Finally, international perspectives are essential to any discussion of global standards. Christopher Zaslawski, Zhao Hong (赵宏), and Chen Huan (陈欢) survey the four major organizations driving TCM and acupuncture standardization worldwide, categorizing their outputs and highlighting the potential impact of AI on future standard development. A perspective from an Australian expert in TCM standardization with acupuncture knowledge is provided, showing how national contexts shape and are shaped by global frameworks. Huang Yiran (黄奕然), Zhu Gerui (朱哿瑞), and Li Jing (李静) then undertake a comparative analysis of the WHO and ISO approaches—one foundationally public-welfare oriented, the other market-driven. Their macro–meso–micro framework reveals overlaps and gaps, particularly in terminology and Chinese materia medica standards, and calls for enhanced coordination mechanisms. Both articles underscore that standardization is not a zero-sum game but a terrain of overlapping authorities that requires deliberate governance.

Collectively, these 10 articles converge on several cross-cutting insights. First, standardization is far more than technical—it is always also historical, institutional, and cultural. Second, the tension between uniformity and diversity is not a failing but a feature of living medical systems, and managing it requires layered approaches. Third, global standards gain legitimacy not only through scientific rigor but also through participatory processes that include local knowledge holders, as the *Chuan Xiong* case vividly shows. Fourth, AI and big data are not magic bullets; their value depends on careful integration with existing epistemic frameworks and on solving data interoperability and explainability challenges.

We thank all authors for their sincere contributions, the peer reviewers for their constructive insights, and the editorial team for their patience and professionalism. It is our hope that this special issue will serve not as a final word but as a catalyst for further interdisciplinary dialogue—between historians and computer scientists, clinicians and policymakers, and across the diverse cultural worlds that TCM continues to inhabit.

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Author contributions

SHEN Yuandong wrote and reviewed the article.

Declaration of generative AI and AI-assisted technologies in the writing process

The author declares that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

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Feature Article

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A Historical Model Informing the Future: Acupuncture Standardization in the Northern Song Dynasty

以史为鉴：北宋时期的针灸标准化

CHENG Han (程晗)[1], XU Kun (徐坤)[1], SANG Zhen (桑珍)[2,3,✉]

Abstract

This study takes the acupuncture standardization movement in the early Northern Song dynasty as its research object, focusing on the landmark achievements led by Wang Weiyi (王惟一) during the reign of Emperor Renzong, namely *Tong Ren Shu Xue Zhen Jiu Tu Jing* (《铜人腧穴针灸图经》*Illustrated Classic of Acupoints on the Bronze Figure*), *Zhen Jiu Tong Ren* (针灸铜人 Acupuncture Bronze Figure), the Proportional Body-cun Acupoint Locating Method, and the associated institutional measures. By employing historical document analysis and standardization theory, it systematically examines the core components, operational mechanisms, and institutional design of the movement. The findings reveal groundbreaking advancements across multiple dimensions: at the technical level, the official adoption of the Proportional Body-cun Method balanced measurement uniformity with individual patient variation; at the carrier level, the "paper–stone–bronze" trinity presentation transformed abstract acupuncture knowledge into tangible, verifiable physical standards; at the institutional level, a closed-loop management system of "formulation–teaching–assessment–feedback" ensured effective implementation and dynamic revision of standards. This historical paradigm suggests that contemporary traditional Chinese medicine standardization should balance group uniformity with individual differences, adopt diverse and complementary carriers, and be supported by an institutional closed loop, rather than remaining merely at the level of textual formulation.

Keywords: Acupuncture; Standardization; *Zhen Jiu Tong Ren* (针灸铜人 Acupuncture Bronze Figure); *Tong Ren Shu Xue Zhen Jiu Tu Jing* (《铜人腧穴针灸图经》*Illustrated Classic of Acupoints on the Bronze Figure*); Traditional Chinese medicine (TCM); Northern Song dynasty

1 Introduction

Standardization is a pivotal hallmark of a discipline's evolution from empirical accumulation to a mature body of knowledge. Within traditional Chinese medicine (TCM), the awareness of standardization dates back to antiquity—from *Huang Di Nei Jing* (《黄帝内经》*The Yellow Emperor's Inner Classic*), which established the theoretical framework of meridians and acupoints, to *Shang Han Za Bing Lun* (《伤寒杂病论》*Treatise on Cold Damage and Miscellaneous Diseases*), which constructed the diagnostic paradigm of *Liu Jing Bian Zheng* (六经辨证 pattern differentiation of six meridians). Throughout history, physicians have consistently advanced academic development through processes of collation and unification. However, the first truly systematic standardization initiative driven by state power took place during the Tiansheng era of the Northern Song dynasty, under the direction of the imperial physician Wang Weiyi (王惟一). This endeavor was not merely the promulgation of a single authoritative text; it comprised the compilation of *Tong Ren Shu Xue Zhen Jiu Tu Jing* (《铜人腧穴针灸图经》*Illustrated Classic of Acupoints on the Bronze Figure*) as the textual standard, the casting of the *Tian Sheng Tong Ren* (天圣铜人 Tiansheng Acupuncture Bronze Figure) as the tangible model, and the engraving of the acupoint charts on stone steles as public media. Together, these three elements formed an integrated "text-artifact-inscription" standard system, deeply embedded within the rigid institutional framework of the

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Imperial Medical Academy's pedagogy and practitioner examinations. This initiative not only resolved the chaotic divergence of acupoint theories and the loss of classical texts that had prevailed since the late Tang dynasty, but also established a pioneering precedent for state-promulgated national acupuncture standards enforced through institutional authority.

The material and institutional conditions for this landmark endeavor had been steadily cultivated since the founding of the Northern Song dynasty in 960 AD. The robust growth of agriculture, handicrafts, and commerce, along with a thriving bronze manufacturing industry, provided the material basis for the bronze acupuncture figure.[1] Movable-type printing enabled the mass printing of *Tong Ren Shu Xue Zhen Jiu Tu Jing*. The Northern Song government placed great emphasis on medicine, established institutions such as *Han Lin Yi Guan Yuan* (翰林医官院 Imperial Medical Academy) and *Jiao Zheng Yi Shu Ju* (校正医书局 Medical Literature Collating Bureau). Through the systematic editorial work of the *Jiao Zheng Yi Shu Ju*, foundational acupuncture classics were rigorously collated and standardized as official teaching materials, thereby laying a solid and reliable academic groundwork for subsequent developments in TCM.[2]

Over a millennium later, Chinese acupuncture is navigating a critical transition from traditional knowledge to a modern scientific discipline. Although contemporary acupuncture standardization has seen substantial quantitative growth, it is still trapped in structural dilemmas, including systemic fragmentation, weak enforcement mechanisms, an insufficient evidence base, diminished international discursive power, delayed digital integration, and a shortage of interdisciplinary talents. The crux of these challenges lies in the unresolved tension between the operational logic of modern standardization and the inherent characteristics of acupuncture theory and practice. In retrospect, the Northern Song standardization movement should not be regarded as a mere object of antiquarian appreciation; rather, it must be examined as a comprehensive and sophisticated socio-institutional practice. It prompts us to investigate how, in the absence of modern information technology, it achieved the profound internalization of standards and cross-cultural transmission through a closed-loop design of state coordination, material authority, and educational institution. It provides methodological insights that go beyond mere textual revision for resolving the current impasse.

2 The standardization of acupuncture before the Northern Song dynasty

Prior to the Northern Song dynasty, China lacked authoritative national standards for acupuncture, leaving practitioners plagued by ambiguity regarding the precise location of acupoints on the human body. From the perspective of standardization, such confusion can be elaborated with the following explanations:

2.1 Absence of basic standards: confused acupoint locations

In clinical treatment, the accuracy of acupoint location has a direct effect on the clinical efficacy of acupuncture treatment. Before the Northern Song dynasty, the Chinese people had already created several monumental works on acupuncture techniques, such as *Huang Di Nei Jing*, *Huang Di Ming Tang Jing* (《黄帝明堂经》*The Ming Tang Classic of the Yellow Emperor*), and *Zhen Jiu Jia Yi Jing* (《针灸甲乙经》*The Systematic Classic of Acupuncture and Moxibustion*). The release of *Huang Di Nei Jing* marked the point at which the theoretical framework of acupuncture and moxibustion formally took shape.[3] *Huang Di Ming Tang Jing* is the earliest monograph on acupoint knowledge in China,[4] while *Zhen Jiu Jia Yi Jing* is the earliest comprehensive classic on the knowledge of acupuncture and moxibustion still preserved in China.[5] However, despite the authoritative status of these texts, such as *Huang Di Ming Tang Jing* and *Zhen Jiu Jia Yi Jing*, they were merely "practical protocols", rather than official standards. Therefore, in the folk community, different medical schools and practitioners maintained their own viewpoints in real practice. There lacked clear and unified national official standards on acupoint location for clinical use. The difficulty in standardizing the location of acupuncture points and establishing unified criteria stems primarily from two factors. First, the numerous measurement methods used to locate acupoints often diverged significantly, resulting in considerable errors. Second, the units of the measurement scales for locating acupoints varied across different dynasties in ancient China.

Throughout history, a multitude of empirical measurement methods evolved for acupoint location; however, these fragmented techniques were prone to a significant margin of error. During the Jin dynasty (266 AD–420 AD), many medical practitioners tended to locate acupoints with scaled rulers. As it goes in *Zhou Hou Bei Ji Fang* (《肘后备急方》 *Emergency Formulas to Keep up One's Sleeve*), "when practicing moxibustion treatment at Juque (CV14), locate the acupoint at a distance of one cun below the tip of the *Xin Yan* point, measuring with a scaled ruler (次灸巨阙，在心厌尖尖四下一寸，以赤度之)".[6] In this description, "measuring with a scaled ruler" means measuring the distance of the acupoint with a scaled ruler.[6] As such ruler-based measurement methods were widely applied in real practice, people came to notice that such methods were not convenient for measuring body parts with complex curves. Subsequently, new measurement methods with ropes and bamboo sticks were introduced. Ropes replaced rulers to measure the distance of the acupoints around lips and breasts, and the locations of acupoints were determined by

folding the measurement rope. The measurement unit "cun" used in acupoint location, however, varied across different dynasties in ancient China. Moreover, ropes could be flexible when measuring acupoint location. As a result, significant errors in acupoint location emerged in clinical practice. To handle those problems, another measurement tool, bamboo sticks, were introduced to replace ropes in locating acupoints.[7]

As more measurement tools were introduced in acupuncture clinic applications, medical practitioners gradually recognized the limitations of rigid, static measurement frameworks, such as the complicated measuring process, inaccurate acupoint locations, and ultimately poor clinical efficacy. Acupuncture points are recognized as a three-dimensional structure in consideration of their external distribution on the body surface, and their locations change with the patient's body position. Furthermore, patients vary greatly in body size. Take Wenliu (L15) as an instance. According to *Huang Di Ming Tang Jing*, Wenliu is located "five-cun behind the wrist of a slim person, but six-cun behind the wrist of a strong person (在腕后少士五寸，大士六寸)". It demonstrates the differences of individual patients in acupoint location. Measuring acupoint locations with the fixed measurement unit "cun" was no longer proper for clinical application.[7]

Measurement unit is a fundamental criterion for acupoint location. However, over a long period in ancient China, there had been no consensus on the ideal measurement unit for acupoint location. To locate a given acupoint, different acupuncture classics would give different measurement solutions. The concept of locating acupoints by the proportions and lengths of the patient's bones was firstly introduced in *Huang Di Nei Jing* as early as thousands of years ago. However, it was not practiced until the Sui and Tang dynasties. *Huang Di Nei Jing Ling Shu Gu Du* (《黄帝内经·灵枢·骨度》 *The Yellow Emperor's Inner Classic: The Spiritual Pivot: The Measurement of the Bones*) noted that human figures of different heights can be divided into 75 equal parts taking the average height of a medium-built person (7 chi and 5 cun) as the standard. In this system, "one cun" represents one seventy-fifth of the standard height. Sun Simiao (孙思邈), a renowned Chinese physician of the Tang dynasty, stated in his classic work, *Qian Jin Yao Fang* (《千金要方》 *Important Formulas Worth a Thousand Gold Pieces*), that "According to *Huang Di Ming Tang Jing*, the height of a normal person should be seven chi six cun and four fen (根据《黄帝明堂经》正经人是七尺六寸四分之身)". Therefore, in *Huang Di Ming Tang Jing*, "one cun" should represent 1/76.4 of a person's height (Fig. 1). Both *Huang Di Nei Jing Ling Shu Gu Du* and *Huang Di Ming Tang Jing* defined that the distance from episternum to navel should be eight cun. But as for the distance "from the point below the knee to the lateral malleolus", *Huang Di Nei Jing Ling Shu Gu Du* stated that it should be one chi and six cun, while *Huang Di Ming Tang Jing* claimed that it should be one chi and seven cun.[7] *Huang Di Nei Jing* was not created by a single author nor over a short period, but the chapter "*Gu Du*" was written by a single author over a short period. Moreover, the acupoints described in



Figure 1 The "*Gu Du*" description in *Qian Jin Yao Fang* (《千金要方》 *Important Formulas Worth a Thousand Gold Pieces*) (source with permission from: https://www.ding-xiu.com/ancientbook/portal/readPage/26779EF5B65B47DA84FB855CD8A521E4/1/index.do?heightWord=%25E5%258D%2583%25E9%2587%2591%25E8%25A6%2581%25E6%2596%25B9)

Huang Di Ming Tang Jing were not discovered simultaneously or not by a single medical practitioner. Therefore, different measurement methods and units were adopted for different acupoints. *Huang Di Ming Tang Jing*, one of the "practical protocols" widely referred and adopted by numerous medical practitioners in ancient China for many years, fails to establish a fundamental standard on the measurement methods and units for acupoint location. This inevitably gives rise to significant differences in acupoint positioning between ancient and modern medical practitioners, leading to inconsistent clinical treatment efficacies.

2.2 Carrier constraints: garbled and lost texts

Standardized carriers for written records play a fundamental role in developing and promoting standards. To some extent, they could even determine the limits of the development and promotion of standards. Over the past thousands of years, Chinese people kept upgrading information recording mediums, from tortoise shells and bamboo/wood scripts to silk fabrics, and then replacing bamboo/wood scripts with paper sheets in the later period of the Northern and Southern Dynasties. From then on, the medium of written records achieved a qualitative breakthrough. Literature on acupuncture standards also evolved through various ill-defined stages and eventually opened a new era in the Song dynasty. In ancient times, bamboo and wood scripts were heavy and cumbersome, while silk fabrics were expensive. The copying, transportation and preservation of ancient texts were very difficult, as such materials were prone to insect damage, breakage, and deterioration. Consequently, ancient Chinese acupuncture classics could only circulate within an extremely limited circle. It is fair to say that before the popularization of papermaking technology, relevant medical knowledge was monopolized by the upper class. Moreover, the compilation and interpretation of acupuncture theories were largely concentrated in the hands of medical families that transmitted their expertise through generations. In those years, acupuncture literature saw an unstandardized state of "family inheritance and teacher transmission" and "inconsistent saying of various medical schools". The widespread adoption of paper-making technique laid a physical foundation for the systematic compilation of acupuncture literature.

Before the widespread adoption of printing technique, the classic works on acupuncture were mostly copied by hand. It was almost inevitable to find errors, omissions or copying mistakes in those manually copied versions. The text of *Ling Shu* (《灵枢》*The Spiritual Pivot*) often varied significantly in different regions when it was copied by different medical practitioners. In clinical acupuncture and moxibustion practice, once there is an error in acupoint location, that will directly affect clinical application or even lead to clinical malpractice.

The chaotic state of the literature of acupuncture standards is not only the consequence of the underdeveloped technology of the ancient time, but also a result of the changes of dynasties, frequent wars and turmoil. The ancient Chinese medical literature also suffered from systematic destruction. *Huang Di Ming Tang Jing*, one of the "practical protocols" of acupuncture in ancient China, was lost due to warfare in the late Tang dynasty. As a result, the medical practitioners in the later dynasties could not refer to this important reference for acupoint location. In the early period of the Northern Song dynasty, less than one-tenth of the ancient TCM classics could survive the continuous warfare. Moreover, the recording about acupoint location varied significantly among different copies circulated among the ordinary people. A lack of unified standards left medical practitioners at a loss and triggered frequent occurrence of medical malpractice. Under such circumstances, the rulers of the Northern Song dynasty attached unprecedented importance to formulating acupuncture standards.

2.3 Institutional void: disorderly adoption

In the era preceding the Northern Song dynasty, the medical system of China was virtually integrated into the administrative system, and medical education was interwined with government institutions, without any dedicated medical administration authorities. Medical education intertwined with government institutions under the feudal rules would lead to concentration of medical resources in the ruling class as well as a superior central medical facility and inferior local medical resources.[8] The teaching and assessment systems of the *Tai Yi Shu* (太医署 The Bureau of Imperial Doctors) were inevitably biased towards the diseases affecting the royal officials and families. For the epidemics, parasitic diseases and endemic diseases that plagued ordinary people, imperial medical authorities paid little attention to them and lacked the incentive to conduct relevant research. As a result, there were no standardized governance measures for folk medical activities nor a universal and unified implementation standard for medical techniques. Ultimately, the technical gap between the central and local governments, as well as between the official and the folk medical practitioners was widening.

There was no systematic assessment framework applied to medical students nor any certification and recruitment framework applied to medical practitioners. During the Tang dynasty, the imperial court established "Acupuncture Division (针科)" under the *Tai Yi Shu*, and appointed *Zhen Jiu Jia Yi Jing* and two other classic medical works by Sun Simiao, *Qian Jin Yao Fang* and *Qian Jin Yi Fang* (《千金翼方》*Supplement to "Important Formulas Worth a Thousand Gold Pieces"*), as official textbooks for medical students. In addition, the imperial court implemented an examination system to evaluate medical officers and award medical students with different titles

based on their academic performance, such as Physician (technical practitioner 医师), Medical Supervisor (junior administrative officer for clinical affairs 医正), and Erudite of Medicine (instructor of medical classics 医博士).[9] A medical practitioner could obtain the "ultimate certification" for his medical skills when he passed the assessment and was awarded an official position by the imperial court. However, such an assessment system actually blocked the formal pathway for physicians to pursue further study and career promotion, as there were no applicable standard systems for training, assessing, and certifying physicians. Moreover, in real practice, it was hard to objectively evaluate the "therapeutic effect" of the treatment provided by the medical physician serving the influential officials or nobles.

Over the long history of ancient China, before the Northern Song dynasty, few governments attempted to regulate and standardize acupoint locations, thus no official standards on acupoint location had been formulated and implemented. Acupoints location plays a fundamental role in the standardization of acupuncture knowledge. Without the revision and promotion initiatives by the government, the basic standards on acupuncture elements, such as measurement units, acupoint locating methods, and naming of acupoints, would not take shape. In addition, various versions of "practical protocols" would inevitably lead to confusion in adoption of standards. Further, it would be difficult to establish an objective evaluation system for the therapeutic effect of acupuncture treatment in clinical application, as there was no corresponding supervision and punishment mechanisms for reference.

The confusion and absence of basic standards and management standards led to an awkward situation where medical education lacked a unified standard, clinical practice was difficult to evaluate, academic exchanges were hindered, and industry supervision was absent. Both TCM and acupuncture techniques would fall into another dilemma if those problems could not be solved from the perspective of standardization.

3 Core achievement in acupuncture standardization during the Northern Song dynasty

The frequent occurrence of clinical errors in acupuncture, resulting from the absence of unified standards and the chaotic divergence of acupoint theories, drew widespread attention from both the imperial court and the common people of the Northern Song dynasty. In order to correct the urgent situation where "Transmitting through the mind is inferior to clear visual comprehension; recording in text is less effective than demonstrating with physical models (传心岂如会目，著辞不若案形)", the government of the Northern Song dynasty sped up its pace to formulate acupuncture standards.[10]



Figure 2 Portrait of Wang Weiyi (source with permission from: https://zyywh.hactcm.edu.cn/info/1004/1396.htm)

In the fourth year of Tiansheng (天圣四年, 1026 AD), under the guiding principle of "rectifying errors and benefiting the people (思革其谬，永济于民)", the imperial court assigned Wang Weiyi (Fig. 2), Imperial Medical Attendant, to undertake the compilation of *Tong Ren Shu Xue Zhen Jiu Tu Jing*. This seminal work set a definitive benchmark for rectifying long-standing malpractices in acupuncture. It established uniform regulations, specified the precise locations of meridians and acupoints, and eliminated long-standing errors and fallacies in this discipline. As such, it ushered in an era of robust, systematic progress in acupuncture standardization during the Northern Song dynasty. The publication of *Tong Ren Shu Xue Zhen Jiu Tu Jing* stands as a landmark achievement in the history of acupuncture standardization.

3.1 The adaptive localization criterion: official codification of the Proportional Body-cun Measurement Method

Within this comprehensive reform, the text did not merely codify *Tong Shen Cun Qu Xue Fa* (同身寸取穴法 The Proportional Body-cun Acupoint Locating Method), but formally elevated it to an official state standard, complete with detailed operational protocols. The Proportional Body-cun Acupoint Locating Method, also known as Finger-cun Measurement (指寸定位法), is an acupoint locating technique based on the lengths of the patient's own fingers. This measurement technique

was first systematically proposed by Sun Simiao in his classic *Qian Jin Yao Fang*, which can be roughly divided into three types: Middle Finger-cun Measurement (中指同身寸法), Thumb-cun Measurement (拇指同身寸法), and Four-finger-cun Measurement (Finger Breadth Measurement) (横指同身寸法、一夫法).[11] In Middle Finger-cun Measurement, the distance between the two crests of the middle joint of the patient's middle finger is considered as one cun; in Thumb-cun Measurement, the width of the patient's thumb joint is considered as one cun; while in Finger Breadth Measurement, the width of the patient's four fingers when they are extended and closed together is considered as three cun.

Wang Weiyi not only adopted the Proportional Body-cun Acupoint Locating Method, but also specified and described "the Middle Finger-cun Measurement". He believed that it should be used as the core measurement for acupoint location when he compiled *Tong Ren Shu Xue Zhen Jiu Tu Jing* (Fig. 3). In addition, he combined the *Gu Du* Measurement Method (骨度分寸法) with the Proportional Body-cun Acupoint Locating Method systematically, established an overall framework for acupoint location by *Gu Du*, and precisely determined the position of acupoints in a local part of human body by the Proportional Body-cun Acupoint Locating Method.

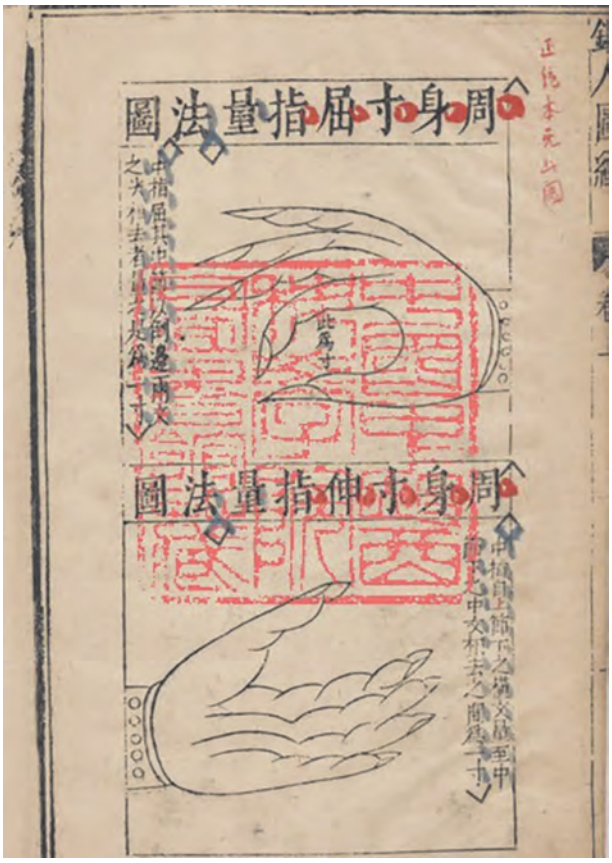


Figure 3 The Body-cun Acupoint Locating Method in *Tong Ren Shu Xue Zhen Jiu Tu Jing* (《铜人腧穴针灸图经》*Illustrated Classic of Acupoints on the Bronze Figure*) (source with permission from: https://gydc-v4.cintcm.cn/#/bookDetail?book=941370)

This significant breakthrough not only put an end to the chaos of acupoint measurement in the previous era, but also provided official measurement standards for acupoint location.

The Proportional Body-cun Acupoint Method epitomizes a harmonious synthesis between the principle of standardized uniformity and the recognition of individual anatomical variations in clinical practice. The principle of unification is one of the fundamental principles for standardization as well as the cornerstone for standard formulation.[12] Considering the highly sophisticated structure of human body, medical standards should take the different physical conditions of individual patients into account. It is also a challenge to be addressed in the process of formulating medical standards. In traditional Chinese medical applications, the method *Bian Zheng Lun Zhi* (辨证论治 treatment based on pattern differentiation) places greater emphasis on the individuality and uniqueness of individual patients. Therefore, TCM standards would need to balance uniformity and individual differences. The Proportional Body-cun Acupoint Locating Method not only adheres to the principle of uniformity, but also fully takes the differences of acupoint locations on individual patients into account. It perfectly embodies the method of *Bian Zheng Lun Zhi* held in TCM.

As an individual "self-adaptive" and flexible approach to acupoint location, the Proportional Body-cun Acupoint Locating Method serves as a verification method for the established norms. Any standard that cannot be verified by a specific validation method is inherently flawed, while the Proportional Body-cun Acupoint Locating Method ingeniously avoids such defects. When a medical practitioner applies the Proportional Body-cun Acupoint Locating Method to a patient and the patient receives the treatment by such method, both sides are actually openly verifying and confirming the locations of acupoints. Such immediate two-way feedback mechanism is incomparable to any other external measuring approaches, as it transformed the standard-learning process into a dynamic and interactive verification process and also seamlessly integrated the "definition" and "verification" mechanisms for acupuncture standards. Therefore, it further enriched and enhanced the essence of acupuncture standards.

3.2 Modular and systematic thinking in standardization: the systematic construction of acupuncture theory

Standardized modules and systematic thinking lie in the center of modern standardization theory. These two elements complement each other and jointly transform complex parts into a manageable and scalable organic whole.[13] Both *Tong Ren Shu Xue Zhen Jiu Tu Jing* and the acupuncture bronze figure defined each acupoint as a standardized information module, containing name, meridian affiliation, precise location, indications, and

needling/moxibustion methods, enabling independent and precise description, learning, and evaluation.

Tong Ren Shu Xue Zhen Jiu Tu Jing comprises three volumes and documents 354 acupoints (or 657 when counting bilateral points separately).[10] Each acupoint entry follows a consistent structure:

- Meridian affinity (归经): Explicit assignment to a specific meridian, e.g., "Lung Meridian of Hand Taiyin" or "Stomach Meridian of Foot Yangming", establishing a standard relationship between acupoints and meridians.
- Location (定位): Precise coordinates using bone-proportion measurement and the Proportional Body-cun Method, e.g., "one cun and five fen behind the wrist, between two tendons".
- Indications (主治): A systematic list of treatable diseases and symptoms, e.g., "treats febrile diseases with anhidrosis, chest and rib pain, cough with upward qi counterflow".
- Needling and moxibustion methods (刺灸法): Standardized parameters including depth of the needle, number of moxa cones, and contraindications, e.g., "needle three fen, moxa three cones".
- Compatibility examples (配伍示例): Common acupoint combinations for clinical reference.

For example, the entry for Zusanli (ST36) in *Tong Ren Shu Xue Zhen Jiu Tu Jing* reads: "Zusanli, three cun below the knee, between the two tendons on the lateral side of the tibia, where the Foot-Yangming Stomach Meridian enters. Indications: cold in the stomach, fullness and distension in the chest and abdomen, insufficiency of stomach qi, aversion to the smell of food, borborygmus and abdominal pain, and indigestion. Moxa three cones, needle five fen (足三里，在膝下三寸，胫外廉两筋间，足阳明脉所入也。治胃中寒，心腹胀满，胃气不足，闻食臭，肠鸣腹痛，食不化。可灸三壮，针入五分)". This complete knowledge unit integrates location, meridian affiliation, indications, and operation methods.

The bronze figure further materializes this modular thinking. Cast at approximately 175 cm (the height of an adult male), its front and back parts can be opened to reveal internal organ models, and limb joints can be disassembled—demonstrating an anatomical module. Each acupoint hole on the surface serves as a spatial coordinate module, integrating location, meridian attribute, and a physical interface for needle insertion. The engraved meridian lines on the surface form a network connection module, linking individual acupoint modules into a coherent system. The "wax sealing and water filling" mechanism constitutes an interactive assessment module, providing objective feedback on needling accuracy (Fig. 4).

In summary, *Tong Ren Shu Xue Zhen Jiu Tu Jing* and acupuncture bronze figure transform complex acupuncture knowledge into a manageable, teachable, and verifiable organic system, exemplifying the systematic governance framework that underpins successful standardization.



Figure 4 A replica of the acupuncture bronze figure from the Ming dynasty (1368–1644) in Shanghai Museum of Traditional Chinese Medicine (source with permission from: taken by the authors)

3.3 The three-dimensional standardization model: a systematic breakthrough in presenting acupuncture standards

In the fourth year of Tiansheng, *Tong Ren Shu Xue Zhen Jiu Tu Jing* was completed as the text of the fundamental standard on acupuncture (Fig. 5). In the following year (1027 AD), the Northern Song government decreed that the entire text of *Tong Ren Shu Xue Zhen Jiu Tu Jing* be engraved onto stone steles and erected in *Zhen Jiu Tu Shi Bi Tang* (针灸图石壁堂 Hall of the Stone Wall of Acupuncture Illustrations) at the Ren Ji Palace in Grand Xiangguo Temple (大相国寺仁济殿) (Fig. 6). In the same year, Wang Weiyi cast an acupuncture bronze figure (针灸铜人) according to the edict from the government, which was later known as "Tiansheng Bronze Figure". Thus, a multi-carrier system for acupuncture standards (that is, using paper, stone inscriptions, and bronze) was established in a three-dimensional presentation format.

Under the promotion of the Northern Song government, *Tong Ren Shu Xue Zhen Jiu Tu Jing* was printed and published by the Imperial Academy of the Northern Song dynasty as an official textbook and a mandatory



Figure 5 The title page of *Tong Ren Shu Xue Zhen Jiu Tu Jing* (《铜人腧穴针灸图经》 *The Illustrated Classic of Acupoints on Bronze Figure*) (source with permission from: https://gydc-v4.cintcm.cn/#/bookDetail?book=941370)



Figure 6 The rubbings of the stone steles inscribed with *Xin Zhu Tong Ren Shu Xue Zhen Jiu Tu Jing* (《新铸铜人腧穴针灸图经》 *The Illustrated Classic of Acupoints on Newly Cast Bronze Figure*) in Shanghai Museum of Traditional Chinese Medicine (source with permission from: taken by the authors)

educational source for acupuncture meridians across the country. This was the first instance in Chinese history in which an ancient medical classic was systematically compiled by the government. It is not only an authoritative classic of TCM, but also a unified national standard for TCM popularized by woodblock printing. The adoption of stone steles as the carrier of TCM standards marks a breakthrough, rendering the canonical norms enduring and immune to tampering. Stone tablets can not only resist natural erosion by wind and rain, but also avoid textual errors in the process of reproduction. Wang Weiyi cast two acupuncture bronze figures upon the imperial edict of the emperor, of which one figure was placed in the Imperial Medical Academy for both education and examination, and the other one was placed in Grand Xiangguo Temple for public visit. Such multi-carrier system for acupuncture standards not only effectively popularized and disseminated acupuncture knowledge nationwide at that time, but also facilitated the preservation of acupuncture standards and knowledge as well as the legacy of Chinese culture.

The acupuncture bronze figure is not merely a pedagogical model, but also the first physical carrier for the acupoint location standards issued by the government in history of China and even in the history of the world. It transformed the abstract and variable theories of acupuncture to a precise, stable and authoritative physical model. The acupuncture bronze figure, cast with multiple tiny holes serving as the standard spatial coordinates of acupoints, provided a standardized reference for all acupuncture medical practitioners. Moreover, it enables mutual verification between the three-dimensional and two-dimensional acupuncture standard systems, and closely connects all components of the former. From the perspective of standardization instrument, the Tiansheng Bronze Figure cast in the Northern Song dynasty marked a revolutionary transformation in medical knowledge and standards from ambiguous representation to precise demonstration, from dispersed schools of medical practice to a unified standard system, and from subjective determination to objective location.

The three-dimensional presentation method of acupuncture standards, that is, by using paper, stone tablets, and bronze, not only highlights the diversity of the standard carriers, but also constitutes a collection of multi-dimensional standards. First, *Tong Ren Shu Xue Zhen Jiu Tu Jing* constituted the theoretical core and laid a textual foundation for the entire system, as it primarily served as a written standard and defined the "standard on acupuncture terminology". Then, the stone inscriptions of the classic served as the acupuncture standard represented by stone tablet, marking a crucial step in elevating "the variable written text" to "a permanent norm" combining the openness of "terminology standard" and the authority of "normative standard". Finally, the Tiansheng Bronze Figure was cast as a three-dimensional bronze standard in the center of the entire standardization system. The acupuncture bronze figure primarily plays a role in defining the "normative standard" and directly presenting the precise locations, depths, and interrelationships of acupoints in a single physical figure. Moreover, the assessment method for acupuncture techniques represents a set of extremely strict, unified, and practical standards, that is, "sealing the acupoints with yellow wax and filling the interior with water (黄蜡封穴，内蓄以水)" and "water flowing out upon accurate needling (针入水出)".[13] In this way, the assessment standard on acupuncture techniques was transformed from medical practitioners' subjective experience to an objective and quantifiable physical phenomenon.

3.4 The institutional safeguard mechanism: constructing a framework for acupuncture standard implementation

The significant implications of the acupuncture standardization movement of the Northern Song dynasty are not limited to *Tong Ren Shu Xue Zhen Jiu Tu Jing* and the Tiansheng Bronze Figure. More importantly, it transformed the static standards into a dynamic and executable assessment mechanism through institutional reform and design. The acupuncture standardization movement provided a solid institutional support for the promotion and application of acupuncture standards by reforming the medical education system and establishing the standardized assessment mechanism.

Acupuncture standards had been promoted nationwide through reforms of the medical education system in the Northern Song dynasty. The toughest challenge blocking the standardization process lies in how to convert theoretical knowledge into a common understanding and practical guidelines applicable for all medical practitioners. To tackle this bottleneck, the government of the Northern Song dynasty took a series of reform measures to integrate new standards deeply into its official medical education system by establishing the Imperial Medical Bureau, separating medical education from government institutions, establishing Acupuncture Department, promulgating *Tong Ren Shu Xue Zhen Jiu Tu Jing* as the mandatory textbook on acupuncture, using bronze figures as teaching aids. In this way, the government of the Northern Song dynasty gave an effective answer to the question of "How to make standards widely known and accepted in the society?" and promoted the professionalization and standardization of acupuncture education.[14]

The establishment of a standardized assessment mechanism ensures the real application of acupuncture standards. The ultimate vitality of a standard lies in application. Standards, no matter how perfect they could be, will be left unused if there are no effective application scenarios for people to practice. The most revolutionary measure of the Northern Song government in the acupuncture standardization movement lies in its direct adoption of the acupuncture bronze figure as a tool to assess medical practitioners' acupuncture skills, and the establishment of an objective and quantifiable evaluation mechanism closely aligned with acupuncture standards. The assessment principle of "pinpricking the acupoints with an acupuncture needle and extracting water out from the bronze figure" should be the gist of the entire assessment system, as assessment results could be evaluated with a physical phenomenon, some subjective factors (such as personal preferences of examiners and academic biases) could be eliminated, and the assessment process could be promoted in a more fair and impartial way. Further, the assessment principle, that is, "pinpricking the acupoints with an acupuncture needle and extracting water out from the bronze figure", emphasized the extreme importance of precise needling techniques and thus upgraded the assessment of theoretical knowledge to a rigorous test of practical skills. Ultimately, a management process integrating "teaching, learning, and assessment" had been seamlessly cemented with the three steps of acupuncture standardization, namely, "promulgating standards, promoting standards by teaching, and assessing application performance", so as to form a closed-loop management system ensuring the smooth implementation and evaluation of acupuncture standards.

4 Implications for contemporary acupuncture standardization in TCM

At present, following decades of systematic development, acupuncture standards have progressively extended across multiple tiers, encompassing international, national, industry, local, and group levels. As of August 2024, a total of 346 acupuncture-related standards are in effect, comprising 63 international standards, 40 national standards, 6 industry standards, 43 local standards, and 194 group standards.[15]

Each tier of standards exhibits its own distinctive orientation, and standards issued by different bodies

vary according to their respective scopes of application. International standards largely focus on acupuncture instruments and devices, prioritizing the facilitation of international trade safety and product mutual recognition. However, they remain notably weak in fundamental theory and technical operation standards, presenting a pattern best characterized as "emphasizing artifacts over techniques". National standards constitute the core backbone of the system, demonstrating the greatest completeness in areas such as acupoint nomenclature and location, technical operation specifications, and foundational terminology. They command the highest level of authority and general applicability. Industry standards are specifically responsible for the quality supervision and market access of acupuncture medical devices, forming a functional complementarity with national standards in the domains of "devices" and "techniques". Local standards focus on region-specific acupuncture and moxibustion techniques as well as ethnic medical technologies, serving as crucial vehicles for the standardized transmission of local acupuncture schools and traditions. Group standards, meanwhile, are distinguished by their sheer volume, rapid responsiveness, and vibrant innovation. They have filled numerous gaps in evidence-based clinical guidelines, real-world research methodologies, and various specialized subfields. The five tiers of standards possess their own emphases and complement one another; nevertheless, they also exhibit structural issues such as overlapping and duplicated content, uneven quality, and insufficient coordination. How to propel acupuncture standardization from a phase of "quantitative accumulation" toward a phase of "qualitative advancement" remains a question that warrants profound reflection.

Although the Northern Song acupuncture standardization movement lies nearly a millennium in the past, the sophistication of its institutional design and the originality of its methodological insights nonetheless offer a cross-temporal intellectual resource for resolving the structural predicaments confronting contemporary acupuncture standardization.

4.1 Balancing uniformity and individualization: reconciliation of group consistency and personalized conditions in TCM standard formulation

The deep-seated tension between the demand for uniformity inherent in standardization and the individualized tradition of *Bian Zheng Lun Zhi* constitutes a unique dilemma that has confronted the standardization of TCM from its very inception—a dilemma for which no fully satisfactory resolution has yet been found. At the root of this predicament lies a structural collision between two philosophical paradigms. The evaluative framework of modern medicine is grounded in the logic of aggregate evidence, reproducibility, and rigorously controlled trials. It has established an entire edifice of standardization centered upon "scientific evidence". TCM, by contrast, takes the dynamic assessment of each patient's constitutional and pathophysiological state as its fundamental orientation, emphasizing flexible adjustment according to individual, temporal, and geographical particularities. The collision of these two modes of thought has rendered the integration of TCM standardization into the discursive system of modern medicine a persistently arduous endeavor.

Faced with this cross-temporal challenge, the Northern Song acupuncture standardization movement offered a paradigm of resolution imbued with profound methodological wisdom. The Proportional Body-cun Acupoint Location Method, established and promulgated in *Tong Ren Shu Xue Zhen Jiu Tu Jing*, not only unified the fundamental rules of acupoint localization collectively, but also inherently preserved an adaptive space that accommodates individual variation in body size and morphology. This standard system achieved an exquisite equilibrium between "collective uniformity" and "individual particularity", standing as an exemplary model in the global history of medical standardization for its capacity to reconcile normativity with flexibility. In stark contrast, among all TCM standards developed to date, not a single one has attained the conceptual sophistication of the Proportional Body-cun in simultaneously addressing both individual adaptability and group consistency. It is in this respect that the enduring, trans-historical significance of the Song standardization movement resides.

Within a contemporary social context dominated by modern medicine, the fundamental question confronting the endeavor of TCM standardization is this: How can standardization better facilitate the advancement of TCM and render its underlying logic and core values more clearly intelligible? The answer, perhaps, lies not in the continued emulation of modern medicine's evaluative paradigms, but rather in the construction of a novel evidence system and evaluative methodology—one that both embodies the distinctive academic character of *Bian Zheng Lun Zhi* and remains comprehensible and acceptable to modern science. This is an urgent task facing all those engaged in TCM standardization. The approaching wave of artificial intelligence—with its capacity to decipher individualized diagnostic and therapeutic patterns through deep learning and to construct dynamic chains of evidence from real-world data—may well furnish an unprecedented technological pathway toward resolving this century-spanning conundrum. The methodological principle illuminated by the Song-era *tong shen cun* method—"preserving elasticity within uniformity"—may yet resonate across the millennium with the personalized standardization technologies of the age of artificial intelligence, producing a profound intellectual consonance across the ages.

4.2 Systematic implementation: advancing the earnest execution of established TCM standards

The fundamental purpose of standards lies in establishing consensus, unifying action, enhancing efficiency, and ensuring safety and quality. If standards remain confined to textual promulgation without being translated into practice, they will ultimately amount to nothing more than empty words. Although contemporary acupuncture standards have taken shape within a multi-tiered collaborative framework, they are pervasively beset by implementation dilemmas—namely "emphasis on formulation at the expense of dissemination", "promulgation without feedback mechanisms", "divergence between standards and clinical practice", and the absence of a unified management and enforcement mechanism. The full lifecycle management chain of standards frequently terminates abruptly at the stage of "issuance", rendering implementation at the "last mile" particularly arduous.

In contrast, the Northern Song acupuncture standardization movement offers a historical paradigm of how a standard system can be systematically advanced and substantively grounded in practice. The Song architects of this movement keenly understood that the implementation of standards is by no means reducible to a singular act of authoritative promulgation; rather, it constitutes a full lifecycle management system encompassing dissemination and training, pilot demonstrations, information feedback, and effectiveness evaluation. *Tong Ren Shu Xue Zhen Jiu Tu Jing* was widely distributed to prefectures and counties via woodblock printing. It ensured that practitioners and students alike could "see, comprehend, and retain" its contents. The acupuncture bronze figure served both as a tangible teaching aid and an examination instrument. It provided immediate information feedback through its assessment mechanism. Sealed with wax on the exterior and filled with water within, a correct needle insertion would yield an instantaneous visual and tactile confirmation. The incorporation of bronze-figure examinations into the physician selection protocols of the Imperial Medical Academy subjected the implementation outcomes of the standard to institutionalized verification and evaluation. The textual standard of *Tong Ren Shu Xue Zhen Jiu Tu Jing*, the material embodiment of the bronze figure, the clinical practice of acupuncture, and the evaluative validation of the examination system formed an interlocking, progressively advancing chain, constituting a standardized practical closed loop capable of self-verification and dynamic optimization.

A clearly defined application scenario constitutes the critical prerequisite for the successful implementation of any standard. At the very inception of standard formulation, the intended application scenario must be delineated with precision, and the standard's content granularity, presentational form, and supporting instruments must be designed accordingly. The Song conversion of the prescriptive provisions of *Tong Ren Shu Xue Zhen Jiu Tu Jing* into the acupoint orifices on the surface of the bronze figure was precisely such a mediation of medium and a calibration of instrumentality, grounded in the core application scenario of "pedagogy and examination". Standards divorced from specific application scenarios are no more than castles in the air; only by embedding standards within authentic institutional contexts and operational procedures and establishing a closed-loop, full-lifecycle management mechanism can standardization advance from text to practice, and from conception to efficacy.

Furthermore, current acupuncture standards, once promulgated, generally suffer from a dearth of effectiveness evaluation research and corresponding evaluative indicator systems. The updating of standards lags considerably, and their timeliness is demonstrably insufficient. The prevailing inclination to "emphasize formulation while neglecting evaluation" impedes the continuous optimization and iterative refinement of standards. To surmount this predicament, it is imperative to institute a system of periodic review and effectiveness evaluation for acupuncture standards, incorporating core indicators—such as clinical applicability, user satisfaction, and implementation costs—into the evaluative framework, and to fully leverage real-world data and adverse event monitoring systems to furnish an empirical foundation for standard revision. Only by constructing a full lifecycle management closed loop—"formulation—dissemination—implementation—evaluation—revision"—can acupuncture standards sustain their vitality and substantive efficacy amidst dynamic evolution.

4.3 Cultural dissemination and promotion: facilitating TCM culture export via a refined standard system

First, the acupuncture standardization movement of the Northern Song dynasty did transform Chinese acupuncture techniques from a medical discipline full of regional variations to a well-structured "national brand", visually intuitive and easy to teach and disseminate. It is a culmination in the history of TCM as well as a good model in disseminating scientific and cultural influence of Chinese civilization to East Asia. During the reign of Emperor Song Huizong of the Song dynasty (宋徽宗时期 1103 AD), the Goryeo King Ruizong (高丽睿宗王) specifically dispatched his Imperial Envoy Huang Zongmao (黄宗懋) to request the Northern Song court granting them an acupuncture bronze figure, and Emperor Song Huizong consented.[16] This historical evidence clearly demonstrates that the Northern Song dynasty exported standardized acupuncture techniques to neighboring states as a "national gift". The acupuncture standards disseminated by the Northern Song dynasty were formally adopted by Goryeo as its national medical standard. With well-structured standards, a "common language"

free of ambiguous interpretations was established in the dissemination of TCM knowledge and acupuncture techniques to other nations. In particular, the acupuncture bronze figure functioned as a practical teaching aid for foreign medical scholars. It allowed them to intuitively and accurately master the core framework of acupuncture merely by observing and touching the bronze figure, and by imitating acupuncture techniques from the Northern Song dynasty. This approach freed scholars from full reliance on the complex textual interpretations of such professional knowledge written in Chinese. Second, the well-structured acupuncture standards built in the Northern Song dynasty ensure "high fidelity" replication of the whole knowledge system of acupuncture techniques. The standardized acupuncture knowledge was replicated into printed literature in large quantities at a lower cost thanks to the advancement of the printing techniques and the official endorsement in the Northern Song dynasty. In this way, the errors, omissions, additions or deletions that might occur during the transmission of acupuncture techniques by hand-copied manuscripts could be eliminated at the root. The importing countries, on the other hand, would no longer study the fragmented or even distorted acupuncture theories and techniques from ancient China through second-hand dissemination. Instead, they could study acupuncture theories and techniques in a closed-loop system which was completely consistent with the one adopted by the Imperial Medical Bureau of the Northern Song dynasty.

It is the unified acupoint location and meridian theories exported from the Northern Song dynasty and served as a "standard model" for acupuncture study that the medical experts of ancient Japan and Korea were able to make fruitful innovation in line with the specific physical conditions of local patients, the local climate conditions as well as their own clinical experience on the solid foundation of such "standard model". For instance, ancient Japanese medical experts developed the "tube-assisted needle-inserting method (针管法)". Ancient Korean medical experts concluded their unique understandings about acupoints in "Oriental Sixiang medicine (四象医学)" based on their intensive study of the standardized acupuncture theories and techniques exported from the Northern Song dynasty.

The profound value of the acupuncture standardization movement in the Northern Song dynasty lies not only in accomplishing the qualitative transformation of acupuncture from a "regionally diverse discipline" to a "systematic national brand" but also in pioneering a successful paradigm for the standardized dissemination of TCM culture. This historical practice of "establishing standards first, promoting dissemination thereafter, and embracing localized innovation" has profoundly confirmed that standardization serves as the core pillar of cultural export. Only by building a rigorous and unified knowledge system can traditional medicine preserve its core essence in cross-regional dissemination; only by providing intuitive and tangible practical carriers can cultural and cognitive barriers be reduced to achieve in-depth recognition; only by reserving space for localized innovation can foreign knowledge integrate with local practices, coexist harmoniously, and radiate new vitality.

5 Conclusion

The acupuncture standardization movement of the Northern Song dynasty stands as a milestone systematic project in the history of ancient Chinese medicine, whose wisdom remains profoundly relevant across millennia. This movement solved the core problem of acupoint location through the adoption of the "proportional body-cun measurement method". It realized the integration of standard uniformity and individual adaptability. It promoted carrier innovation with the trinity model of "paper, stone inscriptions, and bronze", turning abstract medical knowledge into a verifiable and transmissible standardized system. In addition, it built a closed-loop management system of "formulation-popularization-practice-optimization" relying on the education, assessment and dynamic revision mechanisms of the Imperial Medical Bureau, which endowed these standards with lasting vitality and practical effectiveness.

This historical paradigm reveals that TCM standardization is far more than mere technical unification. Rather, it is a complex project integrating knowledge organization, technical materialization, institutional support, and cultural dissemination. Faced with the dual challenges of digitalization and globalization, contemporary TCM standardization must be rooted in its inherent characteristics, striking a balance between uniformity and individuality, tradition and modernity. It should leverage technological tools such as artificial intelligence and big data to construct a modern standardized system that aligns with international norms while embodying the essence of TCM, guides clinical practice, and drives innovation.

Only in this way can TCM, a treasure of Chinese civilization, truly go global under the scientific auspices of standardization and contribute lasting and profound value to human health. To draw on historical insights, absorb ancient wisdom, and forge a path for TCM standardization that upholds core principles, embraces innovation and bridges theories with clinical practice—these constitute the defining mission of contemporary scholars.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

SANG Zhen provided the core ideas and offered invaluable guidance throughout the development of this article. CHENG Han collected relevant research literature, wrote framework construction and content writing of the article. XU Kun was responsible for revising language expression and format modification of the article. All authors agreed to publish the contents.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, the authors employed DeepSeek for language refinement and grammar checking after translating the manuscript into English. The authors carefully reviewed and revised the manuscript and assume full responsibility for the final version of the paper.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Zhao MZ. *A Study of TCM Education on the Influence of Science and Technology in Song Dynasty* (宋代科技对中医教育影响的研究) [dissertation]. Hohhot: Inner Mongolia Normal University; 2008. Chinese.
[2] Xiong HL. *A Study on Chinese Medical Education in Song Dynasty* (宋代医学教育研究) [dissertation]. Hangzhou: Zhejiang University; 2008. Chinese.
[3] Shen XY. *Meridians and Acupoints* (经络腧穴学). Beijing: China Press of Chinese Medicine; 2002. p. 2–3. Chinese.
[4] Huang LX, Wang XT. *Compilation and Editing of the Ming Tang Classic of the Yellow Emperor* (黄帝明堂经辑校). Beijing: China Medical Science and Technology Press; 1987. p.7. Chinese.
[5] Wang XD, Zheng QY, Li XN. A horizontal exploration of acupuncture and moxibustion: academic history and ancient literature (针灸史学精要与文献述要). *Chinese Medical Culture*. 2025;20(1):1–12. Chinese.
[6] Ge H. *Emergency Formulas to Keep up One's Sleeve* (肘后备急方). Beijing: The People's Health Press; 1956. Chinese.
[7] Huang LX. *The Historical Development of Acupuncture* (中国针灸学术史大纲). Beijing: Huaxia Publishing House; 2001. p. 489–492. Chinese.
[8] Gao EZ, Li HL, Wen ZL. Analysis of the evolution, characteristics, and contemporary implications of ancient medical systems in China (中国古代医事制度的演变规律、特点分析及当代启示). *Health Law*. 2024;32(6):1–6,73. Chinese.
[9] Zhou YM. The medical system and medical education in the Tang dynasty (唐代的医事制度与医学教育). *Ancient Medical Literature and Knowledge*. 1991;(1):2. Chinese.
[10] Wang WY. *Annotated Edition of the Newly Published Illustrated Classic of Acupuncture Points on the Bronze Figure* (新刊补注铜人腧穴针灸图经校注). Zhengzhou: Henan Science and Technology Press; 2015. p. 1–10. Chinese.
[11] Ma X, Tang JG, Yang Y, et al. Differences between the Middle Finger-cun Measurement and the *Gu Du* (腧穴定位方法中指寸法与骨度分寸法的差异). *Tianjin Journal of Traditional Chinese Medicine*. 2009;26(5):385–387. Chinese.
[12] Mai LB. *Standardizology: Science Theory of Standardization* (标准化学：标准化的科学理论). Beijing: Science Press; 2017. p. 25–28. Chinese.
[13] Wang ZP. *Essential Works of Renowned Physicians of the Republican Era: A Treatise on the Origins and Development of Chinese Medicine* (民国名医著作精华：中国医学源流论). Fuzhou: Fujian Science and Technology Press; 2015. p. 65. Chinese.
[14] Lyu HA. A brief analysis of medical education in the Song dynasty (浅析宋代的医学教育). *Journal of Science and Education (Second Half Edition)*. 2007;(18):18–19. Chinese.
[15] Zhong ZY, Gao B, Xie YF, et al. Current status and development suggestions for acupuncture standards (针灸标准现状及发展建议). *Chinese Acupuncture and Moxibustion*. 2025;45(11):1650–1660. Chinese.
[16] Tuo T. *History of the Song Dynasty* (宋史). Changchun: Jilin People's Publishing House; 1995. Chinese.

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Feature Article

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Developing Scenario-oriented Clinical Practice Guidelines for Traditional Chinese Medicine

中医药临床实践指南制定的多元场景探索

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Abstract

Clinical practice guidelines for traditional Chinese medicine (TCM) are important for standardizing practice and supporting evidence-informed decision-making, but their applicability and real-world use remain limited. As clinical needs vary across settings, conventional guideline development approaches are insufficient. This article explores the development of TCM clinical practice guidelines in varied scenarios, focusing on rapid and living guidelines in public health emergencies and clinical application guidelines in medicine use scenarios, particularly for Chinese patent medicines (CPMs). It summarizes the current situation, highlights key methodological challenges and proposes scenario-specific strategies, including rapid evidence synthesis, dynamic updating, conflict-of-interest management, and clearer, more implementable recommendations. A scenario-oriented approach may improve the rigor, responsiveness, and applicability of TCM guidelines, thereby promoting the translation of evidence into practice and the high-quality development of TCM healthcare.

Keywords: Clinical practice guidelines (CPGs); Traditional Chinese medicine (TCM); Chinese patent medicines (CPMs)

1 Introduction

Clinical practice guidelines for traditional Chinese medicine (TCM) play a critical role in regulating TCM-related health care practices and supporting clinical decision-making, serving as an important tool for translating standardized knowledge into clinical practice. TCM standardization could be traced back to the 1980s, when early exploratory work began, and Chinese scholars actively participated in the development of traditional medicine guidelines within the World Health Organization (WHO) Western Pacific Region.[1] Over the past three decades, the number of guidelines published in China has increased rapidly, with more than 200 TCM guidelines and consensus statements issued between 2010 and 2020.[2,3] With the introduction of evidence-based medicine (EBM), evidence-based guideline development has become a major trend, emphasizing the integration of the best available evidence, clinical expertise, and patient values.[4] Despite these advances, the methodological quality and real-world utilization of TCM guidelines remain suboptimal. In particular, limited applicability, insufficient operational detail, and low utilization have become major barriers to the translation of guideline recommendations into clinical action. A survey on the awareness and use of guidelines among TCM physicians found that 85% of 4,495 respondents were familiar with the publication and recommendations of guidelines in their specialties, yet only 50% actually adhered to and used them; notably, approximately 52% of physicians with less than five years of work experience reported that they had never referred to or used such guidelines.[5] These challenges indicate that methodological rigor alone is insufficient, and guidelines must be actionable, adaptable, and responsive to clinical needs.

Importantly, these problems are not uniform across all settings, as the characteristics, evidence base, and technical requirements of guideline development vary substantially depending on the intended use scenario. In public health emergencies, for instance, guideline development must balance between methodological rigor and the urgent need for rapid formulation and continuous updating of recommendations. In contrast, in medicine use scenario, especially for Chinese patent medicines (CPMs), guidelines must address the complexity of

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selecting appropriate medications and provide clear, implementable guidance for rational use.

Recognizing these differences, there is a pressing need to develop approaches tailored to varied scenarios in TCM guideline development. This article therefore explores the development of TCM clinical practice guidelines in varied scenarios, focusing on rapid and living guidelines in public health emergencies and clinical application guidelines in medicine use scenarios, with the aim of summarizing current progress, identifying methodological challenges, and proposing key strategies for improvement.

2 Rapid and living guidelines in public health emergency scenario

Clinical practice guidelines typically require two years to develop and are updated every 2–3 years, or even every 4–5 years.[6,7] However, in the context of public health emergencies, such as emerging infectious diseases (e.g. COVID-19) or natural disasters (e.g. earthquakes), these conventional timelines for guideline development and updating are insufficient to support rapid, high-quality clinical decision-making and to ensure the timeliness of recommendations.[8] Rapid guidelines are developed within a shortened timeframe in response to public health emergencies or other urgent needs.[7] To give global leadership and timely guidance, WHO usually develops a rapid guideline within 1 to 3 months, following the basic steps of guideline development with certain modifications to accelerate the progress.[9,10] To keep pace with the growing volume and rapid emergence of new evidence, living guidelines have emerged, which rely on continuous evidence surveillance and the timely incorporation of new findings through living systematic reviews.[11] Based on the two key features of guideline development, namely, "rapid development" and "dynamic updating", our team was among the first to propose the concept of rapid and living guidelines in TCM.[12]

2.1 Overview of rapid and living guidelines in TCM

A previous review identified eight rapid and living TCM guidelines as of June 2023. They were all developed in China and focused on the diagnosis and treatment of COVID-19.[8] Five were explicitly titled as "rapid advice guideline" or "living evidence-based guideline", while the other three clearly stated that they followed rapid or living guideline methodologies, such as the WHO rapid advice guideline development method. Common measures used to shorten TCM guideline development timelines included defining clinical questions through expert consultations, discussions, or literature reviews instead of time-consuming clinical surveys,[13–15] conducting rapid reviews rather than full systematic reviews,[16] and forming a small, focused guideline development team.[16,17]

In public health emergencies, evidence accumulates rapidly and evolves continuously. Early TCM recommendations often rely on indirect and experiential evidence, owing to the scarcity of disease-specific research. As evidence matures, the evidence body gradually shifts toward direct, research-based evidence, typically progressing from observational studies to interventional trials.[12] The TCM evidence base is inherently multi-sourced, encompassing classical literature, expert-validated cases, and modern clinical studies. To accommodate these features, rapid and living TCM guidelines should systematically retrieve both direct and indirect evidence using rapid review method, integrate research- and experience-based evidence while prioritizing higher-level evidence and recognizing complementary value of classical texts and expert experience, and dynamically update both evidence and recommendations through living systematic reviews.

2.2 Methodological challenges and key strategies

2.2.1 Development steps and key requirements during the preparation stage

The preparation stage is a critical initial phase of developing rapid and living TCM guidelines, as it determines whether a rapid-living approach is warranted and establishes an efficient foundation for subsequent process. Generally, initiation of a rapid and living guideline is justified when the following criteria are met: the public health emergency is urgent or high-risk; timely and applicable high-quality TCM guidelines are not available; and unresolved clinical questions require immediate guidance with continuously emerging evidence.[18] To ensure rapid yet rigorous development, a small and elite multidisciplinary team is recommended, with streamlined management, simplified conflicts-of-interest (COI) procedures, and flexible communication methods such as virtual meetings.

Clinical questions should be formulated using the PICO (population, intervention, comparison, and outcome) framework, following the principle of being important and concise. "Important" refers to prioritizing the most urgent and clinically relevant issues, particularly those for which TCM interventions may offer advantages, while "concise" emphasizes limiting the number of questions (typically ≤3) and focusing on key effectiveness and safety outcomes. The formulation of clinical questions should also reflect TCM characteristics, such as pattern differentiation and stage-specific treatment strategies. Unlike conventional guidelines, clinical questions in rapid and living TCM guidelines require dynamic updating. For example, during the COVID-19 pandemic, early questions focused on reducing respiratory symptoms and mortality, while later shifted toward post-recovery management, reflecting evolving clinical needs.

2.2.2 Rapid evidence collection, integration, and recommendation

Given the frequent lack of high-quality direct evidence in emergency settings, both direct and indirect evidence

should be systematically integrated, following a direct-evidence-first principle, with indirect evidence used as necessary supplementation.[19] Guided by the TCM theory of "treating different diseases with the same method", indirect evidence can be identified based on similarity in pathogenesis, transmission characteristics, and clinical manifestations, with consideration of disease stage and severity. For example, during the COVID-19 pandemic, evidence from SARS and symptom-based analogies was used to inform TCM interventions when direct evidence was limited.

To enhance efficiency, evidence retrieval and screening should be conducted within a predefined scope, with explicit restrictions on databases, timeframes, language, and eligibility criteria. Priority is given to higher-level evidence, while taking study design (e.g., randomized versus non-randomized trials) and methodological quality (e.g., risk of bias) into account. In recent years, a growing suite of artificial intelligence (AI)-based tools and frameworks—including transformer-based large language models for automated screening and data extraction, active-learning engines and dedicated platforms have been developed to rapidly identify, prioritize, and synthesize relevant evidence, substantially reducing screening burden and supporting near real-time evidence synthesis.[20,21] After evidence synthesis, the body of evidence for each clinical question should be initially graded using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach, considering standard upgrading factors (i.e. large magnitude of effect, dose–response relationship, negative bias) and downgrading factors (i.e. risk of bias, inconsistency, indirectness, imprecision, publication bias).[22] In TCM, this grading may be further refined by incorporating experiential evidence and its consistency with research findings, with predefined adjustment rules specified in Figure 1 as an example, when multisource evidence is available. However, this evidence grading based on TCM characteristics is only applicable within a highly restricted scope, that is during the very early stage of emergencies when direct research evidence is scarce with more experiential evidence, and must be rigorously validated using real-world data before broader application.

2.2.3 Evidence monitoring and dynamic updating

Dynamic updating should focus on high-priority clinical questions where new evidence is expected and likely to change existing recommendations. Updating is particularly warranted for recommendations based on low-certainty or indirect evidence, or those with uncertainty in specific populations or risk of bias, and may also include the incorporation of newly emerging clinical questions.[6] The frequency of evidence monitoring should be determined by the urgency of updating recommendations, the rate at which new evidence emerges, and the availability of resources. In general, monitoring should occur at least every three months, but for high-priority topics with rapidly evolving evidence, more frequent monitoring (e.g., weekly or even daily) may be required based on specific PICO questions. Beyond the emerging published clinical studies, the monitoring of evidence should also encompass newly issued or updated guidelines and relevant policies, changes in disease epidemiology, and real-world implementation of recommendations including effectiveness and safety data, patient values and preferences, and evolving clinical needs.

Based on evidence monitoring, different updating actions may be undertaken, including revising clinical questions, updating the evidence and recommendations, or withdrawing the guideline (Fig. 2). Clinical questions should be dynamically reprioritized, downgraded when

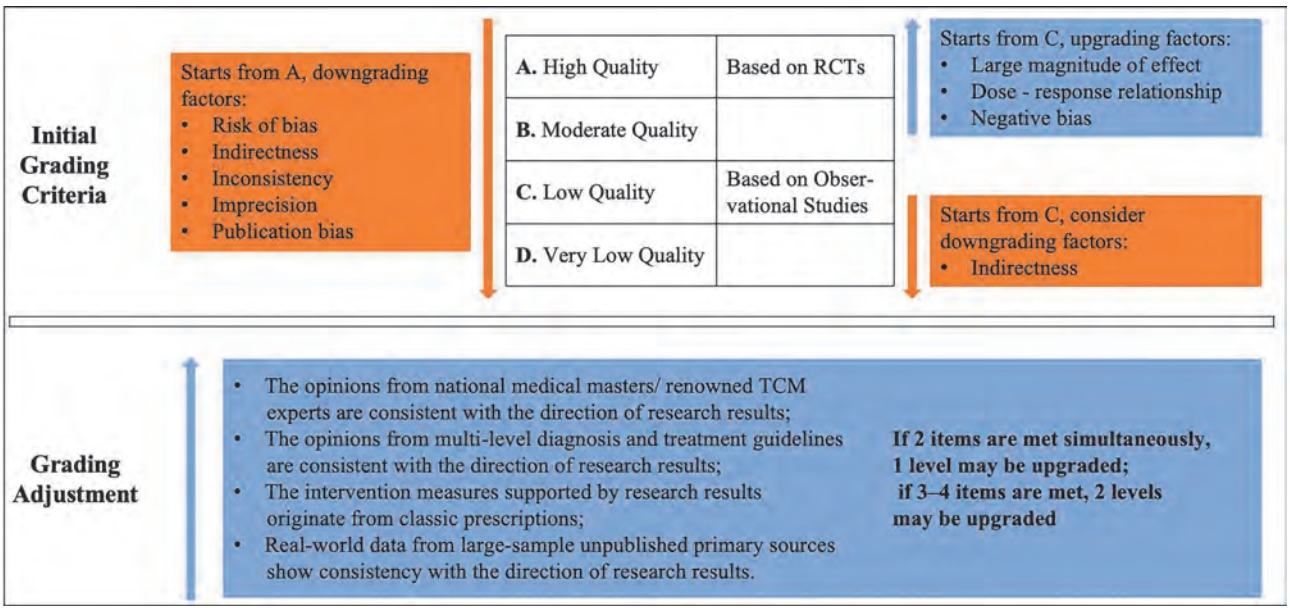


Figure 1 Framework for evidence grading (source with permission from: self-developed by the team, picture made by the authors)

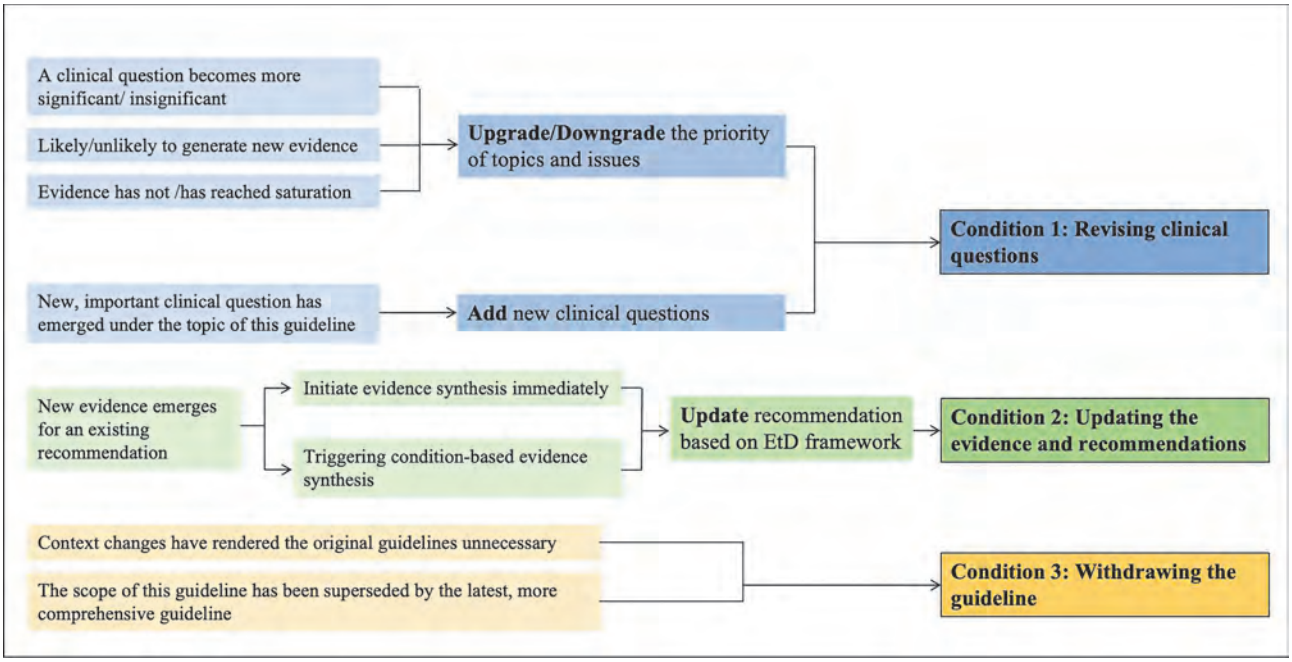


Figure 2 Roadmap of updating TCM rapid and living guidelines (source with permission from: self-developed by the team, picture made by the authors)

no longer clinically important, unlikely to generate new evidence, or when evidence has reached saturation; conversely, they should be upgraded when new evidence may alter existing recommendations. In addition to the clinical questions already addressed by the guideline, newly identified important clinical questions should be incorporated into the guideline when they arise. Updating of evidence and recommendations may be conducted either immediately for high-priority topics or according to predefined triggering conditions, thereby balancing timeliness with resource constraints. The triggering conditions may include the volume of newly available evidence, its precision and certainty, and whether the estimated effect reaches the threshold for a minimal clinically important difference.[23] Guideline withdrawal may be considered when the clinical context changes substantially or when more comprehensive or up-to-date guidance becomes available.

To support high-frequency evidence monitoring and dynamic updating, AI technologies including natural language processing (NLP) and large language models (LLMs) can be leveraged to automate evidence pre-screening, data extraction, and preliminary synthesis, thereby accelerating the identification of relevant evidence. By incorporating AI-assisted workflows, the proposed updating strategy can achieve sustainable operability in real-world practice, ensuring guideline recommendations remain timely, responsive, and evidence-informed.

3 Clinical application guidelines in medicine use scenario

In clinical practice, a single disease is often associated with multiple therapeutic options, making it difficult for clinicians to determine the most appropriate treatment. This issue is particularly prominent in the context of CPMs. Currently, more than 10,000 CPMs have been approved by national regulatory authorities, with 268 included in *National Essential Medicines List* (2018 Edition) (《国家基本药物目录（2018年版）》) and 1,311 covered by the latest national medical insurance catalogue (2021).[24] Along with their widespread use, reports of irrational prescribing have increased, especially given that over 70% of CPMs are prescribed by Western medicine practitioners, many of whom lack specialized training in TCM. This challenge highlights the necessity of clinical application guidelines in medicine use scenario, which support decision-making by identifying the most effective medicines, providing graded recommendations, and offering tailored guidance according to indications, disease stages, or patient subgroups. Broadly defined as evidence-based recommendations for the rational use of CPMs, these guidelines serve two primary functions: guiding how to select the most appropriate medication among multiple options and guiding how to use it effectively in clinical practice.

3.1 Overview of CPM guidelines

Current CPM clinical practice guidelines can be broadly categorized into two models, including disease/syndrome-oriented and medicine-oriented guidelines. The former focus on specific clinical conditions, select and compare multiple CPMs, and often provide stage- or subtype-specific recommendations, while the latter center on a single or a class of CPMs, summarize evidence for their use across one or multiple indications, and emphasize standardized application.

As of July 31, 2023, a total of 140 CPM guidelines had been published, including 51 disease/syndrome-oriented and 89 medicine-oriented guidelines. Overall, although CPM guidelines are increasingly available, their methodological rigor and reporting quality remain insufficient when assessed using AGREE II (Appraisal of Guidelines for Research & Evaluation II) instrument and the RIGHT (Reporting Items for Practice Guidelines in Healthcare) checklist.[25–27] Medicine-oriented guidelines resemble an extension of medicine monographs, providing comprehensive evidence for individual products but lacking comparative information across alternative options, thereby offering limited support for optimal medicine selection in a given disease or syndrome. In contrast, disease/syndrome-oriented guidelines are more aligned with clinical decision-making; however, their utility is often constrained by insufficient evidence grading, unclear recommendation strength, and particularly inadequate guidance on practical use, and as a result, even when appropriate CPMs are selected, suboptimal use in practice may compromise therapeutic effectiveness.[27]

3.2 Methodological challenges and key strategies

3.2.1 Management of conflict of interest

CPMs have dual attributes as both therapeutic agents and commercial products, increasing the risk of COIs in guideline development. Moreover, as guideline recommendations are increasingly used as an important basis for medicine evaluation and market access decisions, pharmaceutical stakeholders are more likely to be involved in guideline development, further intensifying the potential for COIs. Without clear and transparent COI management, the credibility and impartiality of recommendations may be compromised.

COIs should be identified comprehensively, including both financial interests (e.g., consultancy fees, funding, stock ownership) and non-financial interests (e.g., prior involvement in clinical studies of the target CPM or authorship of related publications).[9] Identification should rely not only on self-reported disclosure by guideline members, but also on independent verification to ensure completeness; this may include reviewing publicly available information, such as participation in industry-sponsored activities, publications, or research projects funded by pharmaceutical companies.[28] After identification, a structured COI management process should be implemented, including collection, assessment, updating, and reporting. All guideline members should complete standardized disclosure forms, and an independent committee should evaluate the relevance and potential impact of identified COIs. Given the absence of universal thresholds, assessment criteria (e.g., timeframe and financial magnitude) may be adapted from established frameworks. Based on severity, COIs may be managed at three levels including no restriction, restricted participation (e.g., exclusion from specific discussions), and full exclusion from decision-making.

3.2.2 Clear positioning of CPM advantages and efficacy evaluation

Current CPM guidelines often fail to adequately identify and synthesize the advantageous scenarios, target populations, and outcome measures of CPMs, which may contribute to inappropriate clinical use. A key reason lies in the insufficiently structured formulation of clinical questions, which directly determines subsequent evidence retrieval and efficacy evaluation. To better capture the unique strengths of CPMs, the conventional PICO framework can be extended to a DSCO framework, that is comprising drug (D), specific disease stage (S), comparison (C), and specific outcome (O), to guide the construction of clinical questions.[29] For example, in a stable angina guideline with CPM, a DSCO-based clinical question could be: "Does Danshen injection (D), used as an adjunct to standard antianginal therapy during the chronic stable stage (S), reduce the frequency of angina episodes (O) compared with standard therapy alone (C)?" This approach emphasizes the principle of "specific stage, specific medicine, and specific outcome", thereby facilitating more precise identification of where and how CPMs demonstrate clinical advantages.

Evidence retrieval for CPM guidelines should adopt a multi-source approach, integrating evidence from systematic reviews, clinical studies, and where appropriate, traditional medical literature. However, given that a single disease may involve numerous available CPMs, indiscriminate comprehensive retrieval and evaluation of all candidate drugs may be neither efficient nor methodologically necessary. A prior scoping phase is therefore recommended to predefine eligible interventions before full evidence synthesis, and this process should be guided by explicit, transparent, and reproducible criteria. For example, eligible CPMs may be required to have at least one randomized controlled trial with an adequate sample size (e.g., >100 participants) reporting clinically relevant outcomes, or to be supported by expert consensus with a predefined agreement threshold (e.g., ≥80%). Such a strategy balances comprehensiveness and feasibility, ensuring that subsequent evidence retrieval and appraisal are focused on clinically meaningful interventions while maintaining transparency and credibility in guideline development.

3.2.3 Evidence retrieval and reporting for rational CPM use

To address the current limitations of CPM guidelines in providing actionable medication guidance, evidence retrieval should go beyond efficacy and systematically incorporate comprehensive information on rational drug use. This includes detailed evidence on dosage and administration (e.g., medication route, frequency, timing,

and duration), criteria for initiation and discontinuation of the CPMs, interactions between CPMs and Western medicines, safety profiles (e.g., adverse reactions, contraindications, precautions), as well as economic considerations.

From the perspective of implementation science, clinical practice guidelines should not only be evidence-based but also interpretable, actionable, and feasible in real-world clinical settings.[30] Accordingly, CPM guideline recommendations should explicitly present structured and context-sensitive and implementable medication-use information to facilitate translation into practice, particularly among non-TCM practitioners. In this context, *Clinical Practice Guideline Reporting Checklist for Chinese Patent Medicines V1.0* was developed through literature research, brainstorming, clinical surveys, and expert consensus to enhance reporting quality and standardize clinical application.[31] Within this checklist, the "recommendation details" domain contains 10 themes and 29 items, including indications for use, route of administration, dosage frequency and duration, combination therapy, dietary compatibility, discontinuation criteria, adverse reactions, contraindications, usage notes, and reference considerations. Key elements of guideline reporting should align with these items, presenting clearly implementable recommendations on CPMs. Furthermore, user-friendly tools such as checklists, tables, or digital decision-support aids can be integrated to enhance clarity and adoption.[30,32]

4 Conclusion

The development of TCM clinical practice guidelines in varied scenarios is not merely a methodological refinement, but a necessary pathway for advancing the modernization, standardization, and high-quality development of TCM. As clinical contexts become increasingly complex and diversified, a one-size-fits-all approach to guideline development can no longer adequately support the demands of decision-making in real-world practice. Instead, the guideline development method must evolve toward a more scenario-oriented model that is sensitive to differences in clinical urgency, evidence generation, intervention characteristics, and implementation needs.

From this perspective, the exploration of rapid and living guidelines in public health emergencies, together with clinical application guidelines in medicine use scenarios, reflects a broader shift in TCM guideline development, that is from producing static technical documents to constructing dynamic, implementable, and context-responsive tools that support healthcare governance and clinical practice. This shift is essential not only for improving the scientific credibility and practical utility of guidelines, but also for strengthening the capacity of TCM to respond to major public health challenges, guide rational medicine use, and better serve patient-centered care.

In the future, TCM guideline development should place greater emphasis on scenario-specific methodological standards, multidisciplinary collaboration, transparent governance, continuous evidence updating, and implementation-oriented recommendation design. Only by integrating methodological rigor with contextual adaptability and practical applicability can TCM guidelines truly fulfill their role in bridging evidence and practice. In this way, guideline development in varied scenarios will become an important foundation for enhancing the quality, safety, consistency, and international influence of TCM health care. Additionally, insights from TCM guideline development, combined with the similar evidence characteristics of other traditional medicine systems, may offer a transferable framework for evidence-based, context-responsive guideline practices beyond TCM.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

LIANG Ning and SHI Nannan designed this paper and drafted the manuscript. YAN Lijiao contributed to the methodological analysis related to the rapid and living guidelines part, and modified the paper. ZHANG Xuefei contributed to the methodological analysis related to Chinese patent medicine part, made figures, and modified the paper.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Wang YP, Wang YY. Analysis of the development course of traditional Chinese medicine standardization and recommendations on future work. *Guidelines and Standards of Chinese Medicine*. 2023;1(1):1–8.

[2] Yang N, Chen YL. Evaluation of Chinese clinical practice guidelines published in medical journals in 2019. *Medical Journal of Peking Union Medical College Hospital*. 2021;12(3):407–410.

[3] Shi XQ, Li HY, Zhou J, et al. Grading criteria of evidence quality and recommendation strength in traditional Chinese medicine/integrated traditional Chinese and Western medicine clinical practice guidelines and expert consensus (中医/中西医结合临床实践指南与专家共识中证据质量评价与推荐意见的应用现状分析). *Journal of Traditional Chinese Medicine*. 2023;64(6):581–586. Chinese.

[4] Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. *Clinical Practice Guidelines We Can Trust*. Washington, D.C.: National Academies Press; 2011.

[5] Liu M, Zhang C, Zha Q, et al. A national survey of Chinese medicine doctors and clinical practice guidelines in China. *BMC Complementary and Alternative Medicine*. 2017;17(1):451.

[6] Vernooij RW, Sanabria AJ, Solà I, et al. Guidance for updating clinical practice guidelines: a systematic review of methodological handbooks. *Implementation Science*. 2014;9(1):3.

[7] Kowalski SC, Morgan RL, Falavigna M, et al. Development of rapid guidelines: 1. systematic survey of current practices and methods. *Health Research Policy and Systems*. 2018;16(1):61.

[8] Yan LJ, Liang N, Hu ZT, et al. Methodology for developing rapid and living guidelines of traditional Chinese medicine (RALIG-TCM) (part 1): concept and current practice (中医药快速动态指南制定方法（一）：快速动态指南的定义及其在中医药领域的制定现状). *Journal of Traditional Chinese Medicine*. 2024;65(3):269–274. Chinese.

[9] World Health Organization. *WHO Handbook for Guideline Development (2nd Edition)*. Geneva: WHO Press; 2015.

[10] Morgan RL, Florez I, Falavigna M, et al. Development of rapid guidelines: 3. GIN-McMaster Guideline Development Checklist extension for rapid recommendations. *Health Research Policy and Systems*. 2018;16(1):63.

[11] Cheyne S, Fraile Navarro D, Hill K, et al. Methods for living guidelines: early guidance based on practical experience. Paper 1: introduction. *Journal of Clinical Epidemiology*. 2023;155:84–96.

[12] Liang N, Chen YX, Li HZ, et al. Reflections on development of rapid and living evidence-based Chinese medicine guidelines for coronavirus disease 2019 (新型冠状病毒肺炎疫情下快速动态化制订循证中医指南的思考). *Chinese Journal of Integrated Traditional and Western Medicine*. 2022;42(2):218–222. Chinese.

[13] Li JS, Zhang HL. Expert consensus on rehabilitation of Chinese medicine for COVID-19 (first edition) (新型冠状病毒肺炎中医康复专家共识（第一版）). *Acta Chinese Medicine*. 2020;35(4):681–688. Chinese.

[14] Liang N, Ma YF, Wang JY, et al. Traditional Chinese medicine guidelines for coronavirus disease 2019. *Journal of Traditional Chinese Medicine*. 2020;40(6):891–896.

[15] Collaborative Group for COVID-19, Institute of Basic Clinical Medicine, China Academy of Chinese Medical Sciences, and COVID-19 Prevention and Control Research Group, Zhongnan Hospital of Wuhan University. A clinical diagnosis & treatment rapid advice guideline for integrating Chinese and Western medicine of COVID-19 (新型冠状病毒肺炎（COVID-19）中西医结合临床诊疗快速建议指南). *Chinese Research Hospitals*. 2020;7(2):51–64. Chinese.

[16] Jin YH, Cai L, Cheng ZS, et al. A rapid advice guideline for the diagnosis and treatment of 2019 novel coronavirus (2019-nCoV) infected pneumonia (standard version). *Military Medical Research*. 2020;7(1):4.

[17] Liang N, Li H, Wang J, et al. Development of rapid advice guidelines for the treatment of coronavirus disease 2019 with traditional Chinese medicine. *The American Journal of Chinese Medicine*. 2020;48(7):1511–1521.

[18] Cheyne S, Fraile Navarro D, Buttery AK, et al. Methods for living guidelines: early guidance based on practical experience. Paper 3: selecting and prioritizing questions for living guidelines. *Journal of Clinical Epidemiology*. 2023;155:73–83.

[19] Zhang Q, Wang Q, Hou LY, et al. An introduction to the development methods and cases of living guidelines (动态指南制订方法及案例介绍). *Chinese Journal of Evidence-Based Medicine*. 2021;21(4):491–496. Chinese.

[20] Li Y, Huang Z, Luan Z, et al. Efficient evidence selection for systematic reviews in traditional Chinese medicine. *BMC Medical Research Methodology*. 2025;25(1):1–11.

[21] Li Y, Luan Z, Liu Y, et al. Automated information extraction model enhancing traditional Chinese medicine RCT evidence extraction (Evi-BERT): algorithm development and validation. *Frontiers in Artificial Intelligence*. 2024;7:1454945.

[22] Cuello-Garcia CA, Santesso N, Morgan RL, et al. GRADE guidance 24 optimizing the integration of randomized and non-randomized studies of interventions in evidence syntheses and health guidelines. *Journal of Clinical Epidemiology*. 2022;142:200–208.

[23] Alonso-Coello P, Schünemann HJ, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: introduction. *BMJ*. 2016;353:i2016.

[24] Gu ZR, Ge B, Zheng XL, et al. Status, problems and recommendations of building of guidelines for clinical application of Chinese patent medicines in China (我国中成药临床应用指南类建设的现状、问题与建议). *Chinese Journal of Information on Traditional Chinese Medicine*. 2023;30(4):6–11. Chinese.

[25] Brouwers MC, Kerkvliet K, Spithoff K, AGREE Next Steps Consortium. The AGREE reporting checklist: a tool to improve reporting of clinical practice guidelines. *BMJ*. 2016;352:i1152.

[26] Chen Y, Yang K, Marušić A, et al. A reporting tool for practice guidelines in health care: the RIGHT statement. *Annals of Internal Medicine*. 2017;166(2):128–132.

[27] Zhang FQ, Hu ZT, Zhang YJ, et al. Methodology for the development of clinical practice guidelines for Chinese patent medicine (part 8): quality evaluation with AGREE Ⅱ and RIGHT (中成药临床实践指南制定方法（八）——基于AGREE Ⅱ和RIGHT的中成药临床实践指南质量评价). *Journal of Traditional Chinese Medicine*. 2024;65(2):185–201. Chinese.

[28] Zhao MJ, Jin YH, Zhang J, et al. Methodology for clinical practice guidelines: declaration and management of conflicts of interest (临床实践指南制定方法：利益冲突的声明和管理). *Chinese Journal of Evidence-Bases Cardiovascular Medicine*. 2018;10(5):513–517. Chinese.

[29] Li H, Chen YL, Wei D, et al. Methods for developing and revising clinical practice guidelines in traditional Chinese medicine/integrated traditional and Western medicine: building clinical questions (中医[中西医结合]临床实践指南制修订方法：临床问题的构建). *China Journal of Traditional Chinese Medicine and Pharmacy*. 2016;31(6):2202–2205. Chinese.

[30] Jones LK, Sturm AC, Gionfriddo MR. Translating guidelines into practice via implementation science: an update in lipidology. *Current Opinion in Lipidology*. 2022;33(6):336–341.

[31] Zhang YJ, Zhang FQ, Yan LJ, et al. Methodology for the development of clinical practice guidelines for Chinese patent medicine (part 7): introduction and interpretation of the guideline reporting checklist (中成药临床实践指南制定方法[七]：指南报告清单及其解读). *Journal of Traditional Chinese Medicine*. 2024;65(2):178–184. Chinese.

[32] Zhang J, Xue X, Liang S, et al. Implementation science promotes clinical practice of guidelines: a scoping review. *BMC Health Services Research*. 2025;25(1):1431.

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Feature Article

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MEDICINE AND CULTURE

OPEN

Clinical Diagnosis and Treatment Guideline for Spinal Tendon off Position and Bone Misalignment (2026 Edition)

脊柱筋出槽骨错缝临床诊疗指南 (2026年版)

Standardization Project Expert Group for *Clinical Diagnosis and Treatment Guideline for Spinal Tendon off Position and Bone Misalignment* (《脊柱筋出槽骨错缝临床诊疗指南》标准化项目专家组); Editorial Office of *The Journal of Traditional Chinese Orthopedics and Traumatology* (《中医正骨》编辑部); ZHAN Hongsheng (詹红生)[1,✉]

1 Introduction

As a globally standardized language for disease classification, the International Classification of Diseases (ICD) underpins the exchange and mutual recognition among different medical systems. In May 2019, the 72nd World Health Assembly adopted ICD-11, which for the first time includes a traditional medicine chapter. This chapter establishes a disease and pattern classification system rooted in traditional Chinese medicine (TCM) while also accommodating traditional Japanese and Korean medicine, marking the official integration of traditional medicine into the internationally mainstream disease classification framework. Consequently, TCM's unique disease concepts, pattern names, and diagnostic therapeutic logic have gained internationally applicable codes and discursive authority. In November 2020, the National Health Commission and the National Administration of Traditional Chinese Medicine of China released revised editions of *Classification and Codes of Diseases and Patterns of Traditional Chinese Medicine* (《中医病证分类与代码》) and *Clinic Terminology of Traditional Chinese Medical Diagnosis and Treatment* (《中医临床诊疗术语》), which are aligned with the ICD-11 traditional medicine chapter. Among the newly added disease and pattern terms are "tendon off position (筋出槽)" and "bone misalignment (骨错缝)" of the spine.

The concept of "tendon off position and bone misalignment" of the spine is a distinctive theoretical construct in TCM orthopedics and traumatology. It is based on the understanding of dynamic imbalance of the tendons and bones. It constitutes the core treatment target for interventions such as manipulation and acupuncture.[1] However, due to the longstanding lack of unified diagnostic and treatment standards and the difficulty in matching TCM disease names with Western biomedical diagnoses, clinical practice has been plagued by considerable variations in diagnosis and treatment, poor reproducibility of therapeutic effects, leading to obstacles to international exchange.[2] To address these issues, under the standardization project of the China Association of Chinese Medicine and following the principle of "evidence-based, consensus-assisted, and experience-informed", a four-year effort has led to the completion of *Clinical Diagnosis and Treatment Guideline for Spinal Tendon off Position and Bone Misalignment (2026 Edition)* (hereafter referred to as the Guideline). The Guideline was developed under the leadership of Professor Zhan Hongsheng (詹红生) from Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, with the involvement of experts in TCM orthopedics, Western orthopedics, integrated traditional Chinese and Western orthopedics, *Tui Na* (推拿 Chinese massage), and methodology. This work fills a gap in the field. The release of the Guideline will promote the integration of TCM and Western medicine and further standardize, systematize, and internationalize TCM orthopedic diagnosis and treatment as well as spinal manipulative medicine.

* This article is an authorized English translation of the Chinese clinical guideline entitled "脊柱筋出槽骨错缝临床诊疗指南", originally published in *The Journal of Traditional Chinese Orthopedics and Traumatology* (《中医正骨》), Issue 2, in 2026.

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2 Terms and definitions

Tendon off position: A condition characterized by localized pain, restricted movement, hypertonia, nodules, ropiness, and tenderness. It typically occurs when indirect or chronic external force impact damages the structure, function and position of the tendons.[3]

Bone misalignment: A condition characterized by localized pain, restricted movement, and palpable enhancement of ROM (range of motion) end feel, decreased relaxation, and tenderness. It typically occurs when indirect or chronic force causes the bones/joints to subluxate.[3]

3 Corresponding Western medical disease names

Spinal tendon off position and bone misalignment involve a total of 28 Western medical conditions, including: cervicogenic headache, acute torticollis, cervical disc herniation, cervical spinal stenosis, atlantoaxial joint displacement, cervical spondylosis, atlantoaxial subluxation, atlantoaxial joint misalignment, cervical radiculopathy, cervical vertigo, neck pain, mechanical neck pain, non-specific neck pain, adolescent idiopathic scoliosis, thoracic facet joint dysfunction, acute lumbar sprain, low back pain, lumbodorsal pain, lumbar disc herniation, lumbar spinal stenosis, lumbar spondylolisthesis, lumbar muscle strain, third lumbar transverse process syndrome, sacroiliac joint sprain, sacroiliac joint dysfunction, spinal joint synovial entrapment, fibromyalgia syndrome, fasciitis. Tendon off position and bone misalignment can occur at different stages of the above diseases.

4 Diagnosis

4.1 Medical history

History of prolonged poor posture, desk work, prolonged sitting or standing, exposure to cold, sprain, or other acute spinal injuries or chronic strain.

4.2 Symptoms

Pain, discomfort, and functional impairment involving one or more regions, including the cervical-occipital junction, cervical spine, thoracic spine, lumbar spine, sacrococcygeal region, and/or sacroiliac joints. Manifestations include stiffness, aching distension, a sensation of tightness or restriction, and/or numbness, which may be accompanied by signs of nerve irritation.

4.3 Physical examination

4.3.1 Specialized palpation

Static palpation assesses the alignment of the spinous processes and articular processes, and the presence of tenderness, nodules, cord-like masses, and other positive reactions in paraspinal muscles. Dynamic palpation evaluates the end-feel and mobility of a given motion unit to assess the degree of dysfunction as the joint reaches its passive limit of motion.[4]

4.3.2 Specialized physical examination

Select appropriate specialized physical examinations according to affected spinal regions. For the cervical spine, tests may include the brachial plexus traction test and intervertebral foramen compression test; for the lumbar spine, tests may include the straight leg raise and its augmentation test, and the femoral nerve traction test. Also assess spinal range of motion, sensory and motor function, deep tendon reflexes, and pathological reflexes.

4.4 Imaging examination

Use imaging techniques such as plain X-ray and CT scan to measure the degree and direction of vertebral displacement, joint space changes, and alterations in physiological curvature. Simultaneously combine with specialized palpation to determine the corresponding segments of tendon off position and bone misalignment, providing a reference for selecting manipulative therapy. Currently, there is a lack of high-quality evidence-based medical evidence regarding objective imaging criteria for "degree of misalignment" for spinal bone misalignment, and no consensus was reached during the Guideline development process. Therefore, imaging findings are only used as a reference for diagnosis.

4.5 Differential diagnosis

When clinically diagnosing spinal tendon off position and bone misalignment, differentiation should be made from conditions such as fracture, dislocation, vascular malformation, symptomatic vertebral hemangioma, primary or secondary bone tumors, and intraspinal tumors.

4.6 Diagnostic criteria

4.6.1 Diagnostic criteria for spinal tendon off position[5]

① Sudden or recurrent paraspinal muscle pain within the past 1 month;
② Static palpation reveals nodules, cord-like masses, tender points, accompanied by signs of increased muscle tension;
③ History of acute paraspinal muscle strain or prolonged poor posture;
④ Limited active and passive range of spinal motion;
⑤ Exclusion of bone misalignment, spinal trauma, dislocation, tumor, tuberculosis.

Diagnosis can be made if criteria ① and ② are met, along with any one of criteria ③, ④, or ⑤.

4.6.2 Diagnostic criteria for spinal bone misalignment[6]

① Sudden or recurrent paraspinal muscle pain within the past 1 month;
② Static palpation reveals nodules, cord-like masses, increased muscle tension with tenderness; dynamic palpation reveals enhanced end-feel and decreased mobility at the corresponding site;
③ Plain X-ray or CT three-dimensional reconstruction reveals vertebral displacement, spinous process deviation, abnormal joint space changes, altered physiological curvature, consistent with clinical manifestations;
④ History of acute sprain, chronic strain, or prolonged poor posture;
⑤ Pain and discomfort manifest as a sensation of blockage or stiffness, often provoked or aggravated by specific movements or postures;
⑥ Limited active and passive range of spinal motion;
⑦ Exclusion of trauma, dislocation, tumor, tuberculosis, etc.

Diagnosis can be made if criteria ①, ②, and ③ are all met, along with any one of criteria ④, ⑤, ⑥, or ⑦.

See Figure 1 for the diagnostic flowchart for spinal tendon off position and bone misalignment.

4.7 Staging

4.7.1 Acute stage

Moderate or severe paraspinal pain within the past 1 month, or sudden severe pain or progressively worsening pain that does not relieve with rest, possibly accompanied by limited movement, claudication, significant nocturnal pain, or sleep disturbance.

4.7.2 Subacute stage

Mild or moderate paraspinal pain persisting for more than 1 month, with paroxysmal exacerbation of pain during strenuous activity, prolonged sitting, or prolonged standing, alleviated by supine rest, accompanied by sensations of blockage, stiffness, soreness, etc.

4.7.3 Chronic stage

Mild paraspinal pain persisting for more than 3 months, with fluctuating intensity, aggravated by passive movement or specific angles, relieved by rest, pain does not affect sleep.

5 Treatment

5.1 Treatment principles

On the premise of excluding contraindications to manipulative therapy and presence of clear surgical indications, manipulative therapy is the primary treatment. This may be selectively combined with fluctuating intensity. The pain is aggravated by passive movement or specific postural angles and relieved by rest, without disturbing sleep.

5.2 Treatment of spinal tendon off position

5.2.1 Recommendation 1

For patients with acute, subacute, and chronic spinal tendon off position presenting with localized pain and limited activity, the use of soft tissue manipulation alone provides immediate relief of localized pain and short-term improvement in spinal function and range of

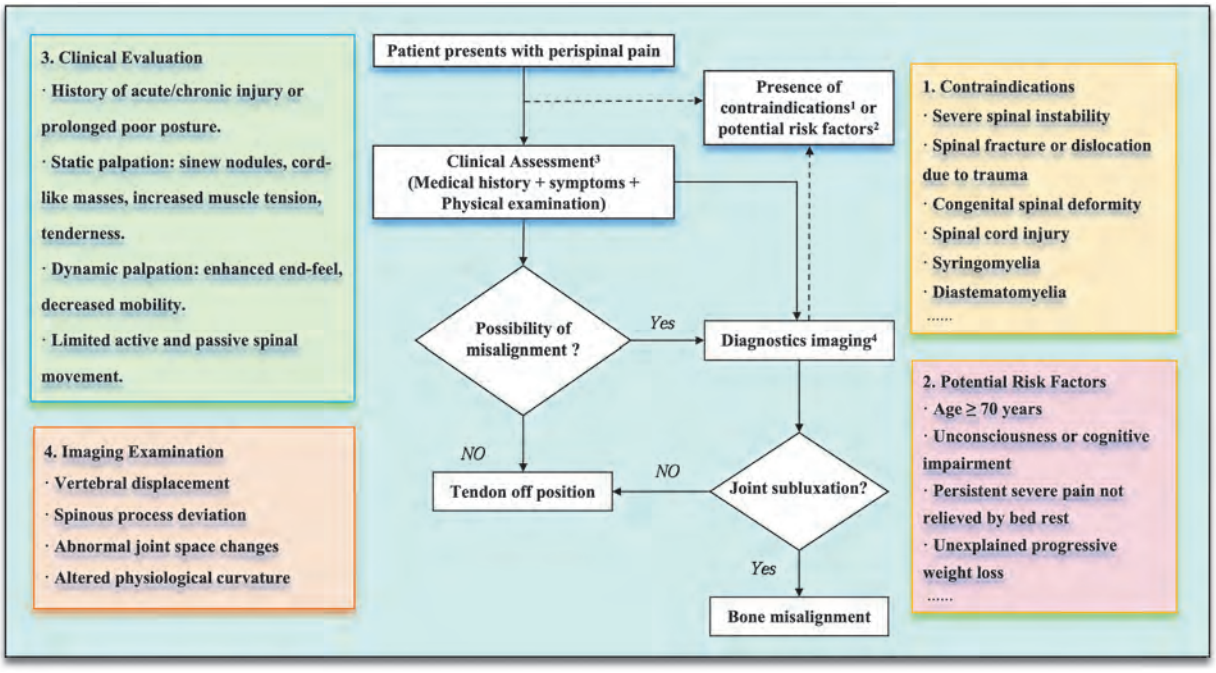


Figure 1 Diagnostic flowchart for spinal tendon off position and bone misalignment (source with permission from: picture made by the authors)

motion compared to sham control. Soft tissue manipulation is recommended 2–3 times per week, 5–15 minutes per session, for 2–4 weeks.[7–15] (Evidence Level: B; Recommendation Strength: Strong)

5.2.2 Recommendation 2

For patients with spinal tendon off position in the acute stage presenting with severe pain, palpable nodules, and significant tenderness, the use of Ashi point acupuncture alone provides immediate pain relief, reduces local tenderness, improves long-term functional status, and increases forward flexion and extension range of spinal motion compared with sham control. In clinical application, after palpation to identify the location, size, and nature of the nodule, perform local acupuncture at the nodule. Lifting-thrusting or twirling techniques may be used, or no manipulation; needles may be left in place for 30–90 seconds or not retained. Transient local muscle twitching may occur during needling.[16–23] (Evidence Level: B; Recommendation Strength: Strong)

5.2.3 Recommendation 3

For patients with chronic spinal tendon off position with moderate pain, supervised and regular exercise therapy can reduce pain in the short term (Evidence Level: B), improve spinal function (Evidence Level: C), restore spinal mobility (Evidence Level: B), improve quality of life with long-term practice (Evidence Level: C), and improve mental well-being (Evidence Level: D). Exercise therapy should be monitored by a professional physician, who should develop weekly or monthly training plans based on the patient's specific condition and provide regular supervision and guidance via phone, text, etc. A 5–10 minute warm-up and cool-down should be performed before and after exercise therapy. The duration depends on the specific exercise, typically 1–3 times per week for 6–12 weeks.[14,24–31] Commonly used exercise therapies include Tai Chi, Pilates, *Qi Gong* (气功 qi therapy), Yoga, and core stability training. (Recommendation Strength: Strong)

5.2.4 Recommendation 4

For patients with spinal tendon off position, soft tissue manipulation is recommended. Compared with other manual techniques, soft tissue manipulation can immediately relieve local pain (Evidence Level: D), improve cervical function (Evidence Level: C), and increase cervical forward flexion (Evidence Level: D) and extension range of motion (Evidence Level: C). In specific operation, the physician may apply pressing and kneading techniques at the nodules, alternately using plucking and kneading techniques for local release when touching deeper muscle bellies. Perform each technique 3–5 times per site, repeating 3–5 times;[7,32–39] it can be combined with passive movements such as rotation and stretching to enhance efficacy. Treatment frequency is recommended as 1–2 times per week, 15–30 minutes per session, for 2–4 weeks. Compared with simple empirical point selection, targeted soft tissue release techniques at the nodules are more effective; no significant correlation exists between different soft tissue manipulation techniques and clinical outcomes. Physicians may flexibly choose appropriate techniques based on clinical presentation and personal practice habits (Consensus opinion). (Recommendation Strength: Weak)

5.2.5 Recommendation 5

For patients with acute stage spinal tendon off position with moderate pain, Ashi point acupuncture is recommended. Compared with meridian based acupuncture, the use of Ashi point acupuncture alone provides better pain relief in the medium and long term (Evidence Level: B) and improves spinal motor function (Evidence Level: C); if the patient has nodules, combining with local soft tissue manipulation can further enhance analgesic effects (Evidence Level: C). The acupuncture site should be the palpable deep nodule, aiming for *De Qi* (得气 getting qi) sensation (soreness, numbness, distension, pain, or radiating sensation). Needles are retained for 30 minutes, once daily[40] or every other day[41], for 1–2 weeks.[40–49] For patients with pain lasting more than six months accompanied by muscle tension and stiffness, soft tissue plucking manipulation combined with Ashi point acupuncture can be used to improve muscle spasm and restore spinal mobility.[42] Additionally, for patients with cold-dampness obstruction pattern, warm-needling acupuncture may be added to warm yang and disperse coldness, improving accompanying symptoms such as cold pain in the lumbus and legs, cold hands and feet, lethargy, and reluctance to speak.[43] (Recommendation Strength: Weak)

5.2.6 Recommendation 6

For patients with chronic spinal tendon off position with moderate pain and a disease course exceeding one year, acupuncture combined with exercise therapy is recommended. Compared with acupuncture alone, this combined approach more effectively relieves local pain in the short term (Evidence Level: B), enhances and maintains dynamic and static muscular endurance of the lumbus (Evidence Level: C), and improves lumbar function and stability (Evidence Level: B). Acupuncture and moxibustion to muscle regions can be combined with exercise therapy. Treatment frequency is once daily, with 5 days as one course, a 2-day interval between courses, for a total of 4 courses. Apply moxibustion to muscle regions until the patient feels comfortable warmth and local skin redness, lasting 30 minutes each time;[50] channel sinew acupuncture aims for *De Qi* sensation (soreness, numbness, distension, pain) at the nodule, with needles retained

for 30 minutes[51]. Short-term acupuncture at nodules helps release local adhesion, while long-term combination with exercise therapy helps maintain the efficacy. Following inpatient acupuncture treatment, physicians may select appropriate exercise therapy methods based on individual patient's conditions and treatment preferences. (Recommendation Strength: Strong)

5.3 Treatment of spinal bone misalignment

5.3.1 Recommendation 7

For patients with bone misalignment, the addition of bone-setting manipulation to soft tissue manipulation provides short-term relief of local pain and improvement in spinal function compared with sham control. Bone-setting manipulation is recommended 1–3 times per week for 3–4 weeks.[51,52] (Evidence Level: B; Recommendation Strength: Strong)

5.3.2 Recommendation 8

For patients with cervical or lumbar bone misalignment, osteopathic manipulation is recommended for treatment. Compared with conventional treatment, bone-setting manipulation can effectively alleviate local pain (Evidence Level: C), improve lumbar function (Evidence Level: C), and significantly increase the angle of straight leg raise (Evidence Level: B) as well as the angle of cervical and lumbar forward flexion (Evidence Level : B). During implementation, it is advised to first perform a precise assessment of the target segment using dynamic and static palpation techniques for "qualitative, localized, and directional" evaluation, ensuring that clinical manifestations and signs are consistent with imaging findings. Treatment frequency: once every 1–3 days; course: 2–4 weeks. Optional bone-setting manipulation techniques include: targeted rotation-reduction maneuver with traction,[53] rotation-lifting manipulation,[54–56] stepwise oblique-pulling manipulation,[56] royal court bone-setting manipulation,[57] spinal fine-adjustment manipulation,[58] sinew-dredging and realignment manipulation,[59] Shi's orthopedic bone-setting manipulation.[60–62] (Recommendation Strength: Strong)

5.3.3 Recommendation 9

For patients with chronic spinal bone misalignment (disease course 6–12 months) presenting with moderate to severe pain and palpable nodules, the addition of local acupuncture (e.g., Fu's subcutaneous needling, electroacupuncture) to soft tissue and bone-setting manipulation is more effective in relieving local pain and improving clinical outcomes compared to bone-setting manipulation alone; compared to acupuncture alone, it is more effective in relieving local pain, improving cervical function, and enhancing clinical outcomes. Manipulative therapy and acupuncture may be administered three times weekly for two weeks, or once daily for one week; the clinical co-treatment process should focus on managing local nodules.[63–72] (Evidence Level: B; Recommendation Strength: Weak)

5.4 Contraindications and potential risk factors for manipulative therapy

See Table 1 for contraindications and potential risk factors for manipulative therapy for spinal tendon off position and bone misalignment.

6 Prevention and aftercare

Prevention of spinal tendon off position and bone misalignment should prioritize cultivating healthy lifestyles, with appropriate exercise therapy integrated throughout. When necessary, manipulative therapy, acupuncture, and medication may be applied to restore the harmonious state of "bone straightening and tendons softening, qi and blood flowing smoothly (骨正筋柔，气血以流)".

For patients with obvious pain in the acute stage, vigorous spinal activity should be avoided. After symptoms subside following manipulative therapy and acupuncture, adaptive training should be performed promptly to resume normal activity. For patients in the subacute and chronic stages, suitable exercise modalities should be selected according to individual circumstances, and exercise prescriptions should be developed under medical guidance, with regular and disciplined use of exercise therapy. Additionally, exposure to cold, excessive load bearing, poor posture, and acute or chronic injury should be avoided.

7 Outcome and safety evaluation

For evaluating the clinical efficacy and safety of interventions for spinal tendon off position and bone misalignment, previous literature has involved outcome measures in nine domains: pain, physical function, physical signs, quality of life, TCM pattern/symptom, muscle status, imaging findings, biochemical indicators, and safety. It is recommended to define primary and secondary outcome measures and necessary time points based on the intervention and disease type.

8 Development notes

8.1 Evidence quality grading

The GRADE method was used to grade evidence quality (Table 2).

8.2 Recommendation strength grading

The Nominal Group Technique was used. Based on evidence quality grading, factors such as balance of benefits and harms, patient values and preferences,

Table 1 Contraindications and potential risk factors for manipulative therapy for spinal tendon off position and bone misalignment

Absolute Contraindications	Relative Contraindications	Potential Risk Factors
Severe spinal instability	Age > 80 years old	Age ≥ 70 years old
Traumatic spinal fracture or dislocation	Body temperature > 37.5°C	Altered consciousness or cognitive impairment
Congenital spinal malformation	BMI < 12 kg·m^{-2}	Persistent severe pain not relieved by bed rest
Ossification of posterior longitudinal ligament	Intractable nocturnal pain	Unexplained progressive weight loss
Spinal cord injury	Presence of potential fracture risk	Gait dysfunction
Syringomyelia	Severe malnutrition	Hyperreflexia
Diastematomyelia	Emaciation and fatigue	Positive pathological reflexes
Spinal or soft tissue mass	Muscle atrophy	Positive spinal percussion pain
Spinal tuberculosis	Decreased muscle strength	Subcutaneous hemorrhage
Spinal infection	Progressive decline of muscle strength	Skin ecchymosis
Basilar invagination	Decreased appetite	Elevated erythrocyte sedimentation rate (ESR)
Chiari malformation	Post-spinal surgery	
Pathological vertebral fracture	Long-term corticosteroid therapy	
Cauda equina	Psychiatric disorder	
Urinary retention or urinary incontinence	Past medical history of cancer	
Fecal incontinence	Inflammatory or systemic disease	
Saddle area numbness	Cervical spondylotic myelopathy (CSM)	
Skin ulceration	Osteoporosis	

Notes: Hyperreflexia indicates upper motor neuron injury, often seen in stroke, spinal cord compression/injury, multiple sclerosis, etc. Positive pathological reflexes indicate pyramidal tract damage, often seen in cerebrovascular disease, spinal cord lesions, demyelinating diseases, etc. Elevated ESR indicates acute or chronic inflammation, infection, tissue damage, autoimmune disease, tumor, or anemia.

Table 2 Evidence quality grading method for the Guideline

Grade	Description
A (High)	Very confident that the true effect lies close to the estimate
B (Moderate)	Moderately confident in the estimate; the true effect is likely to be close to the estimate, but there is a possibility that it is substantially different
C (Low)	Limited confidence in the estimate; the true effect may be substantially different from the estimate
D (Very Low)	Very little confidence in the estimate; the true effect is likely to be substantially different from the estimate

resource use, safety, and patient acceptability were comprehensively considered to vote on recommendations. Recommendation direction is divided into "for" or "against", and recommendation strength into two levels: "strong" and "weak".

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

ZHAN Hongsheng drafted the manuscript. The guideline working group participated in data analysis. The guideline expert group participated in research design.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Hua HY, Guo GX, Chen DK, et al. Treatment differentiation thoughts on chronic tendon-bone lesions based on Shi's traumatology tendon-bone theory (基于石氏伤科筋骨理论探讨慢性筋骨病损的辨治思路). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2024;36(2):65–67. Chinese.
[2] Li ZY, Xu CC, Lu JH, et al. Methodological quality evaluation of clinical practice guidelines and expert consensus for chronic cervical and lumbar tendon-bone lesions (颈腰椎慢性筋骨病损临床实践指南和专家共识的方法学质量评价). *New Medical Knowledge*. 2023;33(3):209–219. Chinese.
[3] National Technical Committee for Standardization of Traditional Chinese Medicine. Clinical terminology of traditional Chinese medicine—part 1: diseases (中医临床诊疗术语 第1部分：疾病). 2021. Available from: https://openstd.samr.gov.cn/bzgk/std/showGb?type=online&hcno=7377FB06FF43DC321BB6A4BF7DAA7F39&request_locale=zh. [Accessed on June 22 2026]. Chinese.
[4] Du GQ, Shen ZB, Li ZY, et al. Value and manipulation methods of palpation in clinical assessment of spinal tendon displacement and bone malalignment disorders (脊柱筋出槽、骨错缝疾病临床评估中触诊的价值和操作方法). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2024;36(2):55–59. Chinese.

[5] Project Group of Clinical Guidelines for Spinal Tendon Displacement and Bone Malalignment. Construction of expert consensus on diagnostic criteria for spinal tendon displacement based on Delphi method (基于德尔菲法构建《脊柱筋出槽疾病诊断标准》专家共识). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2023;35(3):1–5,24. Chinese.
[6] Project Group of *Clinical Guidelines for Spinal Tendon Displacement and Bone Malalignment*. Construction of expert consensus on diagnostic criteria for spinal bone malalignment based on Delphi method (基于德尔菲法构建《脊柱骨错缝疾病诊断标准》专家共识). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2023;35(7):1–5. Chinese.
[7] Buttagat V, Muenpan K, Wiriyasakunphan W, et al. A comparative study of Thai massage and muscle energy technique for chronic neck pain: a single-blinded randomized clinical trial. *Journal of Bodywork and Movement Therapies*. 2021;27:647–653.
[8] Buyukturan B, Sas S, Kararti C, et al. The effects of combined sternocleidomastoid muscle stretching and massage on pain, disability, endurance, kinesiophobia, and range of motion in individuals with chronic neck pain: a randomized, single-blind study. *Musculoskeletal Science and Practice*. 2021;55:102417.
[9] Copurgensli C, Gur G, Tunay VB. A comparison of the effects of Mulligan's mobilization and Kinesio taping on pain, range of motion, muscle strength, and neck disability in patients with cervical spondylosis: a randomized controlled study. *Journal of Back and Musculoskeletal Rehabilitation*. 2016;30(1):1–12.
[10] Gonzalez-Rueda V, Lopez-de-Celis C, Bueno-Gracia E, et al. Short- and mid-term effects of adding upper cervical manual therapy to a conventional physical therapy program in patients with chronic mechanical neck pain. Randomized controlled clinical trial. *Clinical Rehabilitation*. 2021;35(3):378–389.
[11] Malo-Urriés M, Tricás-Moreno JM, Estébanez-de-Miguel E, et al. Immediate effects of upper cervical translatoric mobilization on cervical mobility and pressure pain threshold in patients with cervicogenic headache: a randomized controlled trial. *Journal of Manipulative and Physiological Therapeutics*. 2017;40(9):649–658.
[12] Nguyen C, Boutron I, Zegarra-Parodi R, et al. Effect of osteopathic manipulative treatment vs sham treatment on activity limitations in patients with nonspecific subacute and chronic low back pain: a randomized clinical trial. *JAMA Internal Medicine*. 2021;181(5):620–630.
[13] Pach D, Piper M, Lotz F, et al. Effectiveness and cost-effectiveness of Tuina for chronic neck pain: a randomized controlled trial comparing Tuina with a no-intervention waiting list. *Journal of Alternative and Complementary Medicine*. 2018;24(3):231–237.
[14] Skillgate E, Pico-Espinosa OJ, Cote P, et al. Effectiveness of deep tissue massage therapy, and supervised strengthening and stretching exercises for subacute or persistent disabling neck pain. The Stockholm Neck (STONE) randomized controlled trial. *Musculoskeletal Science and Practice*. 2020;45:102070.
[15] Walker BF, Hebert JJ, Stomski NJ, et al. Short-term usual chiropractic care for spinal pain: a randomized controlled trial. *Spine*. 2013;38(24):2071–2078.
[16] Gallego-Sendarrubias GM, Rodríguez-Sanz D, Calvo-Lobo C, et al. Efficacy of dry needling as an adjunct to manual therapy for patients with chronic mechanical neck pain: a randomized clinical trial. *Acupuncture in Medicine*. 2020;38(4):244–254.
[17] Gallego-Sendarrubias GM, Voogt L, Arias-Buría JL, et al. Can patient expectations modulate the short-term effects of dry needling on sensitivity outcomes in patients with mechanical neck pain? A randomized clinical trial. *Pain Medicine*. 2022;23(5):965–976.
[18] Sánchez-Infante J, Bravo-Sánchez A, Jiménez F, et al. Effects of dry needling on mechanical and contractile properties of the upper trapezius with latent myofascial trigger points: a randomized controlled trial. *Musculoskeletal Science and Practice*. 2021;56:102456.
[19] Valera-Calero JA, Sánchez-Jorge S, Buffet-García J, et al. Changes in stiffness at active myofascial trigger points of the upper trapezius after dry needling in patients with chronic neck pain: a randomized controlled trial. *Acupuncture in Medicine*. 2023;41(3):121–129.
[20] Stieven FF, Ferreira GE, de Araújo FX, et al. Immediate effects of dry needling and myofascial release on local and widespread pressure pain threshold in individuals with active upper trapezius trigger points: a randomized clinical trial. *Journal of Manipulative and Physiological Therapeutics*. 2021;44(2):95–102.
[21] Mousavi-Khatir SR, Fernández-de-las-Peñas C, Saadat P, et al. The effect of adding dry needling to physical therapy in the treatment of cervicogenic headache: a randomized controlled trial. *Pain Medicine*. 2022;23(3):579–589.
[22] Tekin L, Akarsu S, Durmuş O, et al. The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial. *Clinical Rheumatology*. 2013;32(3):309–315.
[23] Gattie E, Cleland JA, Pandya J, et al. Dry needling adds no benefit to the treatment of neck pain: a sham-controlled randomized clinical trial with 1-year follow-up. *Journal of Orthopaedic & Sports Physical Therapy*. 2021;51(1):37–45.
[24] Brämberg EB, Bergström G, Jensen I, et al. Effects of yoga, strength training and advice on back pain: a randomized controlled trial. *BMC Musculoskeletal Disorders*. 2017;18(1):132.
[25] Sihawong R, Janwantanakul P, Jiamjarasrangsí W. Effects of an exercise programme on preventing neck pain among office workers: a 12-month cluster-randomized controlled trial. *Occupational and Environmental Medicine*. 2014;71(1):63–67.
[26] Akkan H, Gelecek N. The effect of stabilization exercise training on pain and functional status in patients with cervical radiculopathy. *Journal of Back and Musculoskeletal Rehabilitation*. 2018;31(2):247–252.
[27] Lauche R, Stumpe C, Fehr J, et al. The effects of Tai Chi and neck exercises in the treatment of chronic nonspecific neck pain: a randomized controlled trial. *The Journal of Pain*. 2016;17(9):1013–1027.
[28] Rendant D, Pach D, Lüdtke R, et al. Qigong versus exercise versus no therapy for patients with chronic neck pain: a randomized controlled trial. *Spine*. 2011;36(6):419–427.
[29] Sahiner Picak G, Yesilyaprak SS. Effects of clinical Pilates exercises in patients with chronic nonspecific neck pain: a randomized clinical trial. *Irish Journal of Medical Science*. 2023;192(3):1205–1214.
[30] von Trott P, Wiedemann AM, Lüdtke R, et al. Qigong and exercise therapy for elderly patients with chronic neck pain (QIBANE): a randomized controlled study. *The Journal of Pain*. 2009;10(5):501–508.
[31] Yildirim P, Gultekin A. The effect of a stretch and strength-based yoga exercise program on patients with neuropathic pain due to lumbar disc herniation. *Spine*. 2022;47(10):711–719.
[32] Alansari SM, Youssef EF, Shanb AA. Efficacy of manual therapy on psychological status and pain in patients with neck pain. A randomized clinical trial. *Saudi Medical Journal*. 2021;42(1):82–89.
[33] Jeong ED, Kim CY, Kim NH, et al. Immediate effects of static and proprioceptive neuromuscular facilitation stretching of hamstring muscles on straight leg raise, craniovertebral angle, and cervical spine range of motion in neck pain patients with hamstring tightness: a prospective randomized controlled trial. *Journal of Back and Musculoskeletal Rehabilitation*. 2022;35(2):429–438.
[34] Khan ZK, Ahmed SI, Baig AAM, et al. Effect of post-isometric relaxation versus myofascial release therapy on pain, functional disability, ROM and QoL in the management of non-specific neck pain: a randomized controlled trial. *BMC Musculoskeletal Disorders*. 2022;23(1):567.
[35] Paanalahti K, Holm LW, Nordin M, et al. Three combinations of manual therapy techniques within naprapathy in the treatment of neck and/or back pain: a randomized controlled trial. *BMC Musculoskeletal Disorders*. 2016;17:176.
[36] Phadke A, Bedekar N, Shyam A, et al. Effect of muscle energy technique and static stretching on pain and functional disability in patients with mechanical neck pain: a randomized controlled trial. *Hong Kong Physiotherapy Journal*. 2016;35:5–11.
[37] Reid SA, Callister R, Katekar MG, et al. Effects of cervical spine manual therapy on range of motion, head repositioning, and balance in participants with cervicogenic dizziness: a randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*. 2014;95(9):1603–1612.
[38] Li B, Li JX, Zhang ZW, et al. Clinical observation on Shi's tendon-regulating manipulation for lumbar disc herniation combined with gluteal tendon nodules (师氏理筋法治疗腰椎间盘突出症合并臀部筋结病变的疗效观察). *Journal of Beijing University of Traditional Chinese Medicine*. 2016;35(10):934–937. Chinese.
[39] Tang HL, Huang X, Nong ZS, et al. Clinical observation of Zhuang meridian tendon massage in treating lumbodorsal myofasciitis

(壮医经筋推拿治疗腰背肌筋膜炎疗效观察). *Journal of Guangxi University of Chinese Medicine*. 2019;22(4):45–48. Chinese.
[40] Lin XX, Liu JD, Dong BQ, et al. A multicenter randomized controlled trial on meridian-tendon acupuncture for non-specific low back pain (经筋刺法治疗非特异性腰痛的多中心随机对照研究). *China Journal of Traditional Chinese Medicine*. 2021;36(10):6230–6233. Chinese.
[41] Zhang SN, Xu P, Bi J, et al. Randomized controlled study of meridian-tendon acupuncture for low back pain (经筋刺法治疗下腰痛的随机对照研究). *Modern Journal of Integrated Traditional Chinese and Western Medicine*. 2021;30(25):2773–2776. Chinese.
[42] Lu GB, Shi WQ, Liu HZ, et al. Clinical observation on combined clustered acupuncture and meridian plucking manipulation for lumbar disc herniation (齐刺法结合循经弹拨法治疗腰椎间盘突出症的疗效观察). *Chinese Journal of Traditional Medical Emergency*. 2019;28(2):308–310. Chinese.
[43] Chen ZH, Zheng QK, Chen SJ, et al. Warm acupuncture combined with three-step seven-method massage for chronic non-specific low back pain of yang deficiency cold-damp obstruction pattern: a randomized controlled trial (温针灸联合三步七法推拿治疗阳虚寒湿痹阻型慢性非特异性腰痛: 随机对照试验). *Chinese Acupuncture & Moxibustion*. 2022;42(5):505–510. Chinese.
[44] Li FL, Ben DY. Randomized controlled study on acupuncture at spinal articular process and transverse process for third lumbar transverse process syndrome (针刺脊椎关节突关节及横突为主治疗第3腰椎横突综合征: 随机对照研究). *Chinese Acupuncture & Moxibustion*. 2017;37(8):810–813. Chinese.
[45] Qi HY, Huang Q, Zhang L, et al. Clinical observation of rapid filiform acupuncture for third lumbar transverse process syndrome (毫针速刺法治疗第三腰椎横突综合征的疗效观察). *Acta Chinese Medicine*. 2019;37(12):2947–2950,3094. Chinese.
[46] Ran WJ, Yu Y. Acupuncture at tendon lesion foci for lumbodorsal myofasciitis (针刺结筋病灶点治疗腰背肌筋膜炎). *Acta Chinese Medicine*. 2019;34(11):2454–2458. Chinese.
[47] Wang CM, Wang YW, Chu JM, et al. Efficacy comparison between superficial oblique acupuncture and perpendicular acupuncture at myofascial trigger points for cervical spondylosis of cervical type (平刺和直刺肌筋膜触发点治疗颈型颈椎病疗效比较). *Shanghai Journal of Acupuncture and Moxibustion*. 2016;35(6):710–712. Chinese.
[48] Zhang JF, Wu YC, Mi YQ. Clinical observation on treating myofascial pain syndrome with pain point as acupoint (“以痛为腧”治疗肌筋膜疼痛综合征疗效观察). *Chinese Acupuncture & Moxibustion*. 2009;29(9):717–720. Chinese.
[49] Tao L, Ren HY. Observation on efficacy, quality of life and cervical hemodynamics of warm acupuncture combined with massage in patients with cervicogenic headache (温针灸联合推拿对颈源性头痛患者疗效、生存质量及颈部血流动力学的影响观察). *Sichuan Journal of Traditional Chinese Medicine*. 2019;37(3):179–181. Chinese.
[50] Cao SQ, Dong BQ, Lin XX, et al. Effects of meridian-tendon moxibustion combined with core stabilization training on pain, function and muscle endurance in patients with chronic non-specific low back pain (经筋灸法联合核心稳定训练对慢性非特异性下腰痛疼痛、功能及肌耐力的影响). *Acta Chinese Medicine*. 2019;37(4):911–914. Chinese.
[51] Zhang Y, Dong BQ, Lin XX, et al. Randomized controlled study of meridian-tendon acupuncture combined with Pilates training for chronic non-specific low back pain (经筋刺法配合普拉提训练治疗慢性非特异性腰痛的随机对照研究). *Journal of Shanghai University of Traditional Chinese Medicine*. 2018;32(3):50–55. Chinese.
[52] Voulgarakis P, Iakovidis P, Lytras D, et al. Effects of joint mobilization versus acupuncture on pain and functional ability in people with chronic neck pain: a randomized controlled trial of comparative effectiveness. *Journal of Acupuncture and Meridian Studies*. 2021;14(6):231–237.
[53] Liu CZ, Yang LX. Clinical efficacy of targeted traction and rotation reduction manipulation for cervical radiculopathy (定位牵旋复位法治疗神经根型颈椎病的临床疗效). *Guangxi Medical Journal*. 2021;43(17):2130–2132,2137. Chinese.
[54] Wang Q, Zhu LG, Gao JH, et al. Clinical observation on rotary lifting manipulation for cervical radiculopathy (旋提手法治疗神经根型颈椎病的疗效观察). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2009;21(6):9–11. Chinese.
[55] Wei X, Gao JH, Zhu LG, et al. Clinical observation on rotary lifting manipulation improving cervical range of motion in vertebral artery type cervical spondylosis (旋提手法改善椎动脉型颈椎病颈椎活动度的临床观察). *China Journal of Traditional Chinese Medicine*. 2012;27(4):900–904. Chinese.
[56] Zhu LG, Yang BW, Zhan JW, et al. Improvement effect and safety of rotary lifting manipulation on vertigo in patients with vertebral artery type cervical spondylosis (旋提手法对椎动脉型颈椎病患者眩晕症状的改善作用及安全性). *Journal of Beijing University of Traditional Chinese Medicine*. 2019;38(7):695–697. Chinese.
[57] Zhang J, Han L, Wang P, et al. Clinical observation on stepwise oblique pulling manipulation for lumbar disc herniation (分步斜扳手法治疗腰椎间盘突出症的临床疗效观察). *China Journal of Orthopaedics and Traumatology*. 2010;23(2):84–86. Chinese.
[58] Qi QX, Liu H, Zhen PC, et al. Effects of court-style bone-setting manipulation on quality of life in patients with lumbar disc herniation of blood stasis and qi stagnation pattern (宫廷正骨手法对血瘀气滞型腰椎间盘突出症患者生活质量影响). *Journal of Liaoning University of Traditional Chinese Medicine*. 2020;22(1):186–189. Chinese.
[59] Zhou N, Fang M, Zhu QG, et al. Biomechanical evaluation of lumbodorsal muscles after spinal fine-tuning manipulation for lumbar disc herniation (脊柱微调手法治疗腰椎间盘突出症的腰背肌生物力学性能评价). *Chinese Journal of Rehabilitation Medicine*. 2012;27(2):115–119. Chinese.
[60] Li R, Zhang ZJ, Zhang SM, et al. Clinical observation of tendon-soothing and bone-reduction manipulation on 65 patients with cervicogenic vertigo caused by atlantoaxial joint malalignment (疏筋整复手法治疗寰枢关节错缝所致颈性眩晕65例临床观察). *Journal of Traditional Chinese Medicine*. 2022;63(5):450–454. Chinese.
[61] Wang LD, Ding KH, Lu B, et al. A multicenter randomized controlled trial on Shi's traumatology bone-setting manipulation for lumbar disc herniation (施氏伤科整骨手法治疗腰椎间盘突出症多中心随机对照研究). *Henan Traditional Chinese Medicine*. 2020;40(10):1594–1597. Chinese.
[62] Liu GM, Yang JY, Ji W, et al. Clinical study on syndrome differentiation treatment of lumbar disc herniation with Shi's traumatology bone-setting manipulation (施氏伤科整骨手法辨证施治腰椎间盘突出症临床研究). *Journal of Cervicodynia and Lumbodynia*. 2016;37(4):290–293. Chinese.
[63] Wang X, Zhan HS, Zhang MC, et al. Clinical observation on Shi's manipulation for cervical radiculopathy (石氏手法治疗神经根型颈椎病的疗效观察). *Chinese Journal of Traditional Medical Traumatology & Orthopedics*. 2015;27(4):12–14,20. Chinese.
[64] Wu LQ, Liu SL, Li TJ, et al. Effects of combined acupoint acupuncture and spinal manipulation on cervical blood flow velocity, cervical function, pain mediators and plasma endothelin in patients with cervical radiculopathy (组穴针刺配合整脊手法对神经根型颈椎病患者颈部血流速度、颈椎功能、疼痛介质及血浆内皮素影响). *Journal of Liaoning University of Traditional Chinese Medicine*. 2021;23(10):160–164. Chinese.
[65] Chen ZL, Zhang JW, Tan ZC, et al. Clinical efficacy observation of spinal manipulation combined with floating acupuncture for degenerative lumbar spondylolisthesis (整脊手法联合浮针疗法治疗退行性腰椎滑脱症临床疗效观察). *Journal of Guangzhou University of Traditional Chinese Medicine*. 2019;36(6):843–846. Chinese.
[66] Huang LY, Chen M, Chen XH. Rehabilitation efficacy observation of Qihuang needle combined with meridian-tendon theory massage in patients with lumbar disc herniation (岐黄针结合经筋理论、推拿用于腰椎间盘突出症患者治疗中的康复效果观察). *Clinical Journal of Chinese Medicine*. 2021;13(19):64–67. Chinese.
[67] He JT, Zhou XP. Clinical observation on Long's manipulation combined with acupuncture for cervical radiculopathy (龙氏手法结合针刺治疗神经根型颈椎病的临床观察). *New Chinese Medicine*. 2006;(12):53–54. Chinese.
[68] Li JT, Qi Y. Clinical observation on massage combined with acupuncture for lumbar disc herniation of blood stasis pattern (推拿联合针灸治疗血瘀型腰椎间盘突出症的临床疗效观察). *World Journal of Traditional Chinese Medicine*. 2020;15(6):920–924. Chinese.
[69] Tang Y, Li XP, Zhang JZ. Intervention effect of TCM syndrome differentiation massage combined with acupuncture on cervical

radiculopathy (中医辨证推拿法联合针刺对神经根型颈椎病的干预效果). *Sichuan Journal of Traditional Chinese Medicine*. 2019;37(5):187–190. Chinese.
[70] Wang B, Wang XK, Li YF, et al. Lumbosacral bone-setting manipulation for lumbar disc herniation combined with sacroiliac joint disorder (腰骶部正骨手法治疗腰椎间盘突出症合并骶髂关节紊乱). *Jilin Journal of Traditional Chinese Medicine*. 2022;42(1):107–110. Chinese.
[71] Zhang JT, Sun ZY, Chen CM, et al. Spinal fixed-point rotational reduction combined with floating acupuncture for lumbar disc herniation (脊柱定点旋转复位法配合浮针疗法治疗腰椎间盘突出症). *Acta Chinese Medicine*. 2019;34(8):1774–1777. Chinese.
[72] Zhang QH, Shi B, Wang CA, et al. Clinical study of three-dimensional balanced spinal manipulation combined with acupuncture for cervical radiculopathy (三维平衡正脊手法配合针刺治疗神经根型颈椎病临床研究). *Shandong Journal of Traditional Chinese Medicine*. 2021;40(1):65–70. Chinese.

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Special Topic: AI & Big Data for
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The Role of Artificial Intelligence and Big Data in the Standardization and Internationalization of Traditional Chinese Medicine

人工智能与大数据在中医药标准化与国际化中的作用

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Abstract

Traditional Chinese medicine (TCM) faces longstanding challenges in standardization and internationalization due to the subjective nature of pattern differentiation, variability in clinical practice, and limited integration with modern evidence-based medical systems. Recent advances in artificial intelligence (AI) and big data offer promising solutions to transform TCM into a more objective, quantifiable, and scientifically interpretable healthcare system. This paper reviews current applications of AI and big data in TCM, including diagnosis, Chinese herbal medicine, acupuncture and *Tui Na* (推拿), and clinical research, examining key technologies (machine learning, computer vision, robotics, network pharmacology) in data standardization, therapeutic optimization, evidence generation, and international translation. In diagnosis, AI-assisted systems demonstrate promising performance in tongue, facial, pulse, voice, and symptom analysis, improving the objectivity and reproducibility of pattern differentiation. In Chinese herbal medicine, AI facilitates quality control, active compound discovery, herb–medicine interaction prediction, and mechanistic analysis through network pharmacology and multi-omics integration. Robotic and AI-assisted acupuncture and *Tui Na* systems improve procedural precision, consistency, and safety while supporting standardized education and training. In clinical research, AI enhances patient recruitment, remote monitoring, data management, adverse event detection, and evidence generation through the integration of electronic health records, wearable technologies, and knowledge graphs. Despite these advances, challenges remain, including limited standardized datasets, privacy and ethical concerns, insufficient model explainability, regulatory uncertainty, and the complexity of multi-component TCM interventions. Nevertheless, AI and big data hold substantial potential to modernize and internationalize TCM by transforming traditionally experience-based practices into reproducible and evidence-supported systems. Through standardized data acquisition, explainable models, multimodal data integration, and alignment with international frameworks, AI may serve as a critical bridge between TCM and modern healthcare systems.

Keywords: Artificial intelligence; Big data; Traditional Chinese medicine; Standardization; Diagnostic method; Acupuncture; Herbal medicine; *Tui Na* (推拿)

1 Introduction

Traditional Chinese medicine (TCM) has a rich history of practice that stretches back over two millennia, originating from Chinese philosophy to build a medical system with unique diagnostic and therapeutic methodologies, and plays an important role in disease diagnosis, treatment and prevention.[1] Rooted in ancient Chinese philosophy, TCM encompasses unique theoretical frameworks such as yin-yang (阴阳) balance, qi (气), *Wu Xing* (五行 five elements), and pattern differentiation (辨证), which guide therapeutic approaches including Chinese herbal medicine, acupuncture, moxibustion, and *Tui Na* (推拿). Diagnostic practice in TCM is traditionally based on the four diagnostic methods of inspection, auscultation and olfaction, inquiry, and palpation, through which physicians evaluate the overall functional state of the body rather than isolated pathological findings. In recognition of its growing global influence, TCM

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was incorporated into the World Health Organization (WHO) International Classification of Diseases 11th Revision (ICD-11) in 2019, reflecting its significance within contemporary healthcare systems.[2]

Despite the long-standing history and effectiveness of TCM in disease management, TCM continues to face major challenges in standardization and internationalization. Many aspects of TCM diagnosis and treatment rely heavily on practitioner experience and subjective interpretation, resulting in considerable variability between physicians and institutions. In addition, the abstract and holistic nature of TCM theories makes it difficult to quantify and evaluate using modern biomedical standards. Variability in terminology, pattern classification, herbal quality control, and treatment procedures further limits reproducibility and interoperability across healthcare systems. The interpretation and translation of ancient Chinese medical texts also present barriers to international communication and education, as classical terminology often lacks direct equivalence in modern biomedical language.[3] Collectively, these challenges hinder the generation of high-quality evidence, reduce global regulatory acceptance, and limit broader integration of TCM into evidence-based healthcare systems.

Recent advances in artificial intelligence (AI) and big data technologies have created new opportunities to address these limitations and modernize TCM practice. AI technologies, including machine learning (ML), deep learning (DL), computer vision, natural language processing (NLP), robotics, and knowledge graphs, possess powerful capabilities for pattern recognition, data mining, prediction, and decision support.[4,5] Together with the increasing availability of electronic health records, wearable devices, multimodal imaging, and large-scale clinical datasets, AI enables the transformation of traditionally qualitative TCM observations into structured, quantifiable, and analysable data. Advanced computational models can assist in pattern differentiation, tongue and pulse analysis, herbal mechanism prediction, clinical trial optimization, and knowledge extraction from classical medical literature. Furthermore, standardized databases, interoperable terminology systems, and explainable AI frameworks may improve diagnostic consistency, therapeutic reproducibility, evidence generation, and cross-cultural translation of TCM concepts into internationally understandable biomedical language. Hence, it would be beneficial if these known capabilities of AI technologies could be progressively integrated into TCM practice to address longstanding gaps in standardization, reproducibility, and internationalization.

A coherent pathway for advancing the standardization and internationalization of TCM through AI can be conceptualized as a four-layer framework encompassing data standardization, diagnostic standardization, evidence generation, and international translation. At the foundational level, data standardization involves the harmonization of heterogeneous TCM data, such as symptoms, tongue and pulse features, and pattern classifications, into interoperable formats using standardized terminologies and ontologies. This enables cross-institutional aggregation and processing by AI. Building upon this, diagnostic standardization leverages AI algorithms to reduce inter-physician variability by transforming pattern differentiation that has been traditionally subjective into reproducible, data-driven processes. The third layer, evidence generation, utilizes standardized datasets and advanced analytics to produce and optimize high-quality clinical evidence, including real-world data analyses and optimized clinical trials, which are essential for validating TCM interventions within evidence-based frameworks. Finally, international translation represents the integration of these validated, standardized outputs into global healthcare systems through alignment with international regulatory requirements, multilingual knowledge graph representation, and culturally adaptable clinical models. Collectively, this framework positions AI not merely as a technical tool, but as a translational bridge that systematically converts traditional experiential knowledge into structured, verifiable, quantifiable and globally interpretable medical evidence.

Therefore, this review aims to summarize the current applications of AI and big data technologies in TCM across major domains, including diagnosis, Chinese herbal medicine, acupuncture and *Tui Na*, and clinical research. In addition, this review discusses how AI contributes to data standardization, diagnostic and therapeutic standardization, evidence generation, and international translation of TCM. Finally, the review highlights current limitations, ethical and regulatory considerations, and future directions for integrating AI-assisted TCM into modern evidence-based and precision-oriented healthcare systems.

2 AI-assisted applications in TCM

2.1 Diagnosis

The four pillars of inspection, auscultation and olfaction, inquiry, and palpation, are at the heart of TCM diagnosis. For centuries, these methods relied on and varied across individual practitioners without methods for quantification and standardization. Such diagnostic methods based on individual judgement are increasingly unrecognized according to the standards of mainstream evidence-based medicine. Therefore, instruments need to be implemented to help physicians quantify diagnostic methods to ensure that every physician utilizes the same criteria for diagnosis and not personal judgment. This would help in the internationalization of TCM as visible distinction in pattern differentiation, and the use of instruments to provide objective analysis would aid in the understanding, acceptance and adoption of TCM. Below, we will introduce the four pillars of diagnostic methods in TCM, their AI-related applications, and how these could be quantified and standardized.

2.1.1 Inspection

The first core pillar of TCM diagnosis is inspection, which aims to analyze a patient's condition through observing abnormalities in the patient's appearance, posture, movement, tongue, and discharge.[6] Many diseases exhibit specific features on both the face and tongue, which aid in the diagnosis of disease and pattern by physicians.[7] However, such a diagnosis method is highly based on personal judgement, which requires vast experience with different patients to make an accurate diagnosis. This highlights the need to shift from subjective physician judgment to objective AI analysis, hence lowering the barrier to entry into TCM diagnosis. Most current research on AI-assisted inspection mainly focuses on facial and tongue diagnosis. Facial diagnosis is mainly based on color, luster, expression, and shape. According to the TCM theory of *Wu Xing*, a person's diseased facial color can be divided into five colors: blue, red, yellow, white, and black.[8] A recent study by Lin et al. used Dlib to fit 68 face landmarks to segment regions of interest (ROI), from which statistical characteristics of color histograms in facial color and texture features, lip color features were extracted to build classification models using k-nearest neighbors (KNN), support vector machine (SVM) and back propagation neural network (BPNN).[9] The study achieved a facial complexion classification accuracy rate of 91.03% using BPNN, after combining facial color, texture and lip color features together. The addition of facial texture and lip color as complementary indicators enhances the accuracy of complexion classification.[10,11]

Researchers also use AI with facial diagnosis to investigate TCM constitution and disease diagnosis, aside from merely distinguishing facial complexion. The patient's constitution will be a factor affecting personalized treatment by TCM physicians.[12] Thus, Xu et al. designed a model for identifying TCM constitutions using heat-suppression valve (HSV) color space and improved local binary patterns (LBP) algorithm to extract bodily features such as facial complexion and body shape.[13] They developed a TCM constitution identification model using random forest (RF) algorithm, achieving accuracy, precision and F1 score of 0.842, 0.868 and 0.790 in identifying TCM constitutions. Facial complexion can also aid in disease diagnosis as disharmony of internal organs reflects on facial complexion, and some diseases have clinical evidence of cutaneous manifestations.[14,15] Zhang et al. proposed a Multi-Feature Learning with Centroid Matrix (MFLCM) method that could differentiate healthy people, diabetes mellitus, fatty liver, and chronic renal failure using facial complexion data with F1 scores of 92.59%, 83.35%, 82.84%, and 85.46%, respectively.[16] AI-assisted facial diagnosis demonstrates potential for constitution and disease screening while improving diagnostic consistency across practitioners.

The tongue is connected to internal organs via meridians, where different parts of the tongue represent the conditions of specific organs. Changes in organ functions will reflect on the appearance of the tongue, coating, and sublingual veins, which is an effective, immediate and non-invasive way to diagnose diseases. However, tongue diagnosis is highly subjective and relies on experiential knowledge, which limits credibility and popularization. Factors pertaining to physical or environmental factors, such as lighting, may also cause imprecise results of tongue diagnosis. Therefore, there is a need for objectification and quantification of tongue diagnosis using AI. As the acquisition of tongue images inevitably results in background noise of other human features, such as the lips, the tongue will need to be accurately and reliably segmented for minimal interference from background noise.[17] Most studies use convolutional neural networks (CNN) for tongue segmentation to obtain the best segmentation results.[18,19] A physician observes the tongue appearance during tongue diagnosis, which includes the tongue body, coating and sublingual veins. Identification, classification and recognition of visual features on the tongue is the general process of how ML and DL classify different tongue diagnoses.[20,21]

Tongue body in tongue diagnosis comprises tongue color and tongue form. Tongue color can be classified into light white, light red, red, sharp red, dark, and edge sharp, and current AI has difficulty distinguishing light white, dark, and light red colors. AI research investigating tongue form mainly focuses on cracks, prickles, texture, and tooth marks.[22–25] Tongue cracks have great significance in TCM diagnosis of spleen and stomach function and are difficult to extract as they are small and complex. Yan et al. proposed using a self-developed annotation tool, Crack-Tongue, and a segmentation-based deep-learning (SBDL) model to recognize tongue cracks, reaching a classification accuracy and sensitivity of 95.2% and 100%, respectively.[25] A pricked tongue manifests as dots, thorns or petechiae protruding from the tongue, which has pathological significance in diagnosing the location and degree of "heatiness" in the body. One study designed a spotted tongue recognition model that comprises multiscale feature map generation using DCNN, region proposal searching, and target region recognition.[26] Using a 2000-sample dataset, the recognition model achieved accuracy, sensitivity, and specificity of 84.30%, 88.20%, and 94.19%, respectively. Tongue texture is classified as tender and tough tongues, with the tender tongue having a delicate texture representing deficiency, and the tough tongue having a rough texture representing the presence of disease. Using image inpainting and ResNet101 residual network, Yan et al. proposed a novel tongue texture classification method that classified tender and tough tongues with an overall accuracy of 91.0%.[24] Tooth-marked tongues are caused by compression of the enlarged tongue on adjacent teeth, often related to spleen deficiency, cold dampness, phlegm and blood stasis in TCM theory. Wang et al. developed a model using ResNet34 architecture and a

dataset consisting of 1548 tongue images, which had an accuracy of 90.50% classifying tooth-marked tongues using raw tongue images.[22] Quantification of cracks, prickles, texture, and tooth marks may provide additional objective indicators for pattern differentiation, which means a higher degree of standardization, as these tongue features can be quantified using AI computation.

Tongue coating in TCM tongue diagnosis refers to the layer of coating on the tongue body surface, in which the color, location, shape and texture reflect the state of the internal organs. It is a reliable and sensitive indicator for pathological changes in the body, reflecting health status and disease progression. Xu et al. proposed a multi-task joint learning method, which is a fusion of U-Net and discriminative filter learning (DFL) to perform tongue segmentation and tongue coating classification simultaneously.[27] The study classified six categories of tongue coating, namely mirror-approximated, normal (thin-white), white-greasy, yellow-greasy, yellow, and grey-black, and achieved an F1-score of 93.02%, higher than other traditional and neural network methods. The TCM treatment decision process heavily depends on the patient's constitution,[12] and more information that can be considered from tongue diagnosis provides a basis for TCM constitution classification.

Sublingual veins are a pair of veins located on the underside of the tongue, lying on both sides of the lingual frenulum. These veins are connected to the inner viscera and reflect the health status of the body, as well as the status of diseases, especially those closely related to blood stasis.[28,29] Many studies have employed AI to diagnose diseases based on tongue images, including colorectal cancer, gastric cancer, lung cancer, diabetes mellitus, nonalcoholic fatty liver disease (NAFLD), and Sjögren's syndrome.[30–35] It is thus possible to make early diagnosis of diseases and their severity[36] with the employment of AI-assisted tongue diagnosis, and fusion with other indicators such as examination biomarkers to enhance model prediction accuracy. Portable tongue diagnosis systems can even assess health status of users according to their tongue images and give healthy lifestyle suggestions.[37]

2.1.2 Auscultation and olfaction

The second core pillar of TCM diagnosis is auscultation and olfaction. Auscultation is an important diagnostic method in TCM that analyzes a patient's vocal changes, such as voice, breathing, coughing, yawning, sighing, sneezing, etc., to diagnose various illnesses. The various areas that AI can be integrated with voice information for listening include physique identification, disease and pattern diagnosis. Auscultation in TCM has been summarized into the phoneme theory of five viscera, which states that the functions of five viscera correspond to five phonemes of *Jue* (角), *Zhi* (徵), *Gong* (宫), *Shang* (商) and *Yu* (羽). Chen et al. used a "Voice Collecting System of TCM" to collect voice samples from patients with liver, heart, spleen, lung, and kidney diseases, and from normal people.[38] The study showed that sample entropy values in multiple frequencies were statistically significantly different in each group sampled.

Another study by Yan et al. analyzed voice signals collected from healthy, qi-deficient, and yin-deficient participants using wavelet packet transform (WPT) and sample entropy (SampEn) technologies.[39] They found that SampEn values were higher in healthy samples as compared to qi-deficient and yin-deficient samples, and qi-deficient samples were lower than yin-deficient samples in frequency bands of 0–4 kHz in 1–5 levels. Similarly, Lai et al. were able to identify qi-deficient and balanced constitutions with 81.5% classification accuracy rate using ResNet34 model.[40] Auscultation diagnosis of various constitutions is not without a research basis, as a study by Huang et al. using voice information from 274 subjects found that yang-deficiency, yin-deficiency, qi-deficiency, blood-stasis, and qi-depression constitutions had negative correlations with acoustic intensity, while pitch-related indices had positive correlations with yang-deficiency, yin-deficiency, qi-deficiency, and blood-stasis constitutions.[41] These could assist clinical physicians in the localization of diseases in the viscera and pattern differentiation using voice analyzing technology and AI.

Olfaction in TCM is mainly used to detect scents emitted by the patient to aid in diagnosis. However, AI integration with the TCM olfaction diagnostic method is limited due to technical difficulties in obtaining olfactory diagnosis data, while in Western medicine, more attempts have been made. Fu et al. proposed an artificial intelligent olfactory (AIO) system to diagnose Parkinson's disease (PD) through analyzing the odor profile of skin sebum.[42] PD patients were distinguished from healthy controls (HC) based on the volatile organic compound (VOC) peaks in the chromatograms of sebum samples using ML algorithms such as RF, KNN, AdaBoost (AB), and Naïve Bayes (NB). The study was able to identify significantly different VOC peaks in PD patients corresponding to octanal, hexyl acetate, and perillic aldehyde, with classification accuracy reaching 70.8%. Another study by Cao et al. even developed a portable AIO system that combines a surface acoustic wave (SAW) sensor along with gas injection and pre-concentration, chromatographic separation, and sensor detection modules of the AIO system.[43] They were able to differentiate PD from HC using VOC peaks from patient sebum with a sensitivity of 83.33% and a specificity of 84.00%. These present a new diagnosis method for PD that is low-cost, non-invasive, fast, and can be self-administered. Research on both auscultation and olfaction diagnosis methods is limited and still in the preliminary phase, which can only be used as a reference indicator along with other diagnostic methods.

2.1.3 Inquiry

The third core pillar of TCM diagnosis is inquiry, which involves asking patients detailed questions about their symptoms, medical history, demographics and lifestyle habits. This allows the physician to gain a more comprehensive understanding of the patient's condition. TCM inquiry diagnostic method mainly encompasses the "Ten Brief Inquiries" created by Zhang Jingyue (张景岳), with additional information from modern medical records, such as past medical history and allergy history for pattern diagnosis.[44] However, data cleaning of TCM medical records for AI analysis has proved to be tedious as many medical records may not contain "Ten Brief Inquiries" entirely, and recording of symptoms may not be according to textbook standards, as these symptoms are subjective to the patient's description. TCM pattern differentiation is mainly done by the physician's theoretical knowledge and clinical experience, which is subject to each physician's understanding and is becoming a bottleneck to the development of TCM diagnosis standardization.[45] Much research has been carried out in recent years on the standardization and digitalization of pattern differentiation.[46,47] However, less has been done for the development of an AI-assisted diagnosis model for both diseases and patterns, with most existing research limited to a single disease application.[48,49] The huge challenge for AI to perform both disease and pattern diagnosis prediction is that the relationship between diseases and patterns is many-to-many instead of one-to-one.[50] The lack of standardization of TCM pattern data collection and the protection of patient record privacy are barriers that prevent the formation of a large standard data set for AI training.[51]

Deep neural networks (DNN) are a hot topic in AI in recent years due to their powerful learning and representation capabilities. However, the construction of the learning model requires extensive and high-quality sample data for training, which restricts the application of DNN in TCM diagnosis. A multi-label deep forest (MLDF) model based on an improved multi-label ReliefF feature selection algorithm (ML-PRDF) was proposed by Gong et al. to overcome the above mentioned problems faced during AI integration into TCM.[52] ML-PRDF algorithm was able to solve multi-label pattern differentiation tasks using small-scale and non-standardized kidney and stomach disease data sets with optimal performance in all aspects, including hamming loss, coverage, ranking loss and average precision. This is highly relevant in modern TCM clinical practice, with many patients having multiple diseases and patterns. Zhang et al. were the first to successfully develop an AI-assisted diagnostic system capable of diagnosing 187 diseases and 466 patterns with system-level accuracy of 80.5%, 91.6%, 94.2% for top 1, top 3, and top 5 scores, respectively.[53] The study used 22,984 electronic health records from Guang'anmen Hospital of the China Academy of Chinese Medical Sciences to be used for supervised training of a bidirectional long short-term memory network with a conditional random forest, CNN for text processing, and an integrated learning model network. These efforts may provide deeper insights into predicting disease progression in addition to disease and syndrome diagnosis, offering tailored advice on lifestyle habit changes for disease preventive care. This could potentially enhance patients' quality of life significantly and reduce the risk of disease relapse.

2.1.4 Palpation

The last core pillar of TCM diagnosis is palpation, which aims to evaluate and classify the patient's pulse into four main elements of pulse depth, pulse rate, pulse shape and pulse strength, making 28 single-pulse types in total.[54] However, a real patient's pulse is often a combination of several single-pulse types to make a compound pulse that is difficult to identify using AI due to the presence of more pulse information.[55] Pulse diagnosis is highly subjective, with individual physicians having their own interpretation of pulse reading depending on experience; even the same physician may make different interpretations of similar pulses taken under different circumstances.[54,56] Therefore, it is of utmost importance to objectify pulse diagnosis for more standardized clinical application, and this could be made possible with the emergence of AI.

The fundamental steps in implementing AI with pulse diagnosis are the collection and processing of pulse signals, signal analysis, pulse condition recognition, and disease diagnosis. Pulse signals are collected by placing a pressure sensor array on the skin of the radial artery, simulating a physician's pulse-taking process at the Cun, Guan, and Chi (寸关尺) regions at the wrist.[57] The sensor needs to be highly fitting, highly sensitive, highly consistent, unaffected by temperature or humidity, and have a wide sensing range to detect dynamic and static pressure of the pulse. The pulse signal contains a lot of information that can reflect a person's condition, which needs to be preprocessed, such as denoising, filtering and normalization to ensure data quality before pulse features can be extracted.[58,59]

Some useful pulse features that can be extracted include shape, frequency, amplitude, time, and more features extracted would give AI more information to classify different pulses. Pulse pattern recognition is the crucial aspect of TCM pulse diagnosis in differentiating patterns. Current ML and DL technology can recognize common pulse patterns but may face difficulty detecting more complex compound pulses.[56,60] Huang et al. have thus proposed a novel high-dimensional pulse classification method that could extract 71 pulse features from time, spatial, and frequency domains.[61] The 71 pulse features were extracted from waveform shape, power spectral density (PSD), gamma density function,

Hilbert-Huang transform (HHT), approximate entropy (ApEn), wavelet transform (WT), and wavelet packet transform (WPT), all used to create a single high-dimensional feature vector. An artificial neural network (ANN) showed that Principal Component Analysis (PCA) accounted for 95% of the total variance, achieving an accuracy rate of 98.2% in classifying 10 different pulse types. To standardize TCM pulse diagnosis using AI technology, it is crucial to develop accurate pulse-measuring devices and standardize pulse features used in pulse classification.

Pulse diagnosis using AI technology does not merely replicate TCM pulse categories, but can also be correlated to biomedical conditions, such as type 2 diabetes, fatty liver disease, lung cancer, coronary heart disease and atrial fibrillation.[62–66] Hao et al. demonstrated that there were significant differences in several pulse wave parameters between type 2 diabetes patients and healthy people.[63] The study applied SVM with linear kernel (SVM-Linear) and SVM with 3-degree polynomial kernel (SVM-Poly) and achieved a prediction accuracy of 96.35% in diagnosing type 2 diabetes. Cao et al. designed a pulse signal acquisition system and used fast Fourier transform (FFT) for data processing, building a CNN-based identity model.[66] The study further tested patient data using multiple layers of CNN, and found that six convolutional layers achieved the highest recognition rate of 93.23%, similar to an atrial fibrillation model built using electrocardiography (ECG) data.[67] These results indicate that pulse diagnosis in TCM, as a non-invasive diagnostic method, may help in the early detection and monitoring of biomedical conditions. However, this technology requires further research for validation and optimization to enhance its application value in clinical practice.

Overall, the AI-assisted transformation of the four diagnostic methods of TCM should be understood as a progressive pathway from data standardization to diagnostic standardization, then to evidence generation, and finally to international translation. First, inspection, auscultation–olfaction, inquiry, and palpation, all generate heterogeneous diagnostic data, including facial and tongue images, pulse waveforms, voice signals, odor-related volatile organic compounds, and textual symptom records; therefore, standardized data acquisition protocols, annotation criteria, terminology systems, and quality-control procedures are essential to reduce variability caused by instruments, environments, physicians, and patients. Second, once high-quality data is available, AI models can convert traditionally experience-based judgments into measurable diagnostic indicators, such as quantified tongue coating features, pulse parameters, acoustic biomarkers, or structured symptom patterns, thereby improving the consistency and reproducibility of pattern differentiation across practitioners and institutions. Third, AI enables large-scale correlation between TCM diagnostic features and biomedical outcomes, disease progression, treatment response, and prognosis, which can help generate clinically verifiable evidence and bridge the gap between TCM theory and evidence-based medicine. Finally, by transforming abstract concepts such as complexion, tongue manifestation, pulse condition, qi deficiency, blood stasis, or organ disharmony into standardized, interpretable, and clinically validated digital indicators, AI can facilitate international understanding, acceptance, and application of TCM. In this sense, AI does not merely modernize individual diagnostic techniques but provides a systematic framework through which TCM diagnosis can become more objective, reproducible, evidence-supported, and translatable across different medical systems.

2.2 Chinese herbal medicine

Previously, TCM formulas of several or more ingredients were developed based on the medicinal value of herbs and empirical observation, with formulations passed down through ancient texts.[68] AI is now able to decode these complex systems and discover new herbal pairs, similar to how Xia et al. discovered potential COVID-19 therapies using association rules to find herbal pairs.[69]

The "single-target-single-medicine" model in modern medicine is common, but now faces many limitations in the treatment of complex diseases. Attention has now been given to the "multi-target-multi-component" therapeutic model to solve these complex diseases, in which TCM has accumulated a wealth of experience using herbal formulations to target multiple aspects of diseases over thousands of years.[70] However, unclear therapeutic principles and target point directivity of complex chemical composition in TCM formulas are the main reasons as to why they are not internationally accepted as valid medicines to treat diseases. Through the use of AI and network science algorithms, the evaluation of disease-specific herbal formula effectiveness is possible based on various evaluation indicators, helping researchers to identify new disease-specific targets and components.[70] Protein-protein interaction (PPI) networks, Gene Ontology (GO) and Kyoto Encyclopedia of Genes and Genomes (KEGG) can be used to assess the biological functions of herbal formulas according to their ingredients and corresponding targets for various diseases, which can evaluate the effectiveness of herbal formulas. These provide scientific evidence for the use of herbal formulas in the treatment of diseases, and are able to propose the herb pairs to better target specific diseases, which allows for easier use of herbal medicine internationally.

Quality consistency of TCM herbs has a great influence on their efficacy, as variation in chemical composition is affected by botanical species, anatomical parts, harvest time, cultivating region, and processing techniques.[71] Validation of herb authenticity, efficacy and safety to support usage in clinical settings has yet to be sufficient

in meeting worldwide criteria, affecting the reliability of TCM herbal formulas. Fingerprinting is a characterization technique using multi-dimensional and multi-informational fingerprints developed from chromatographic methods, spectroscopic methods, and capillary electrophoresis.[72] These large data matrices of fingerprints will then undergo pattern recognition technologies in chemometrics to evaluate the quality, safety and efficacy of TCM herbs, contributing to the internationalization of TCM.

Aside from quality, herb toxicity is a huge concern to consumers and physicians alike. The Chinese Medicine Regulatory Office (CMRO) of the Department of Health in Hong Kong has constantly reported herbs with excess aflatoxins and toxic alkaloids, which may lead to detrimental health consequences such as liver damage or even death.[73] Furthermore, the efficacy or toxicity of herbs is also produced through synergistic effects of multi-ingredients, on multi-targets, and via multi-pathways, all in one herbal decoction.[74] Yang et al. proposed a dual graph attention network (DGAT) to learn the molecular representation features of herbal constituents and identify key functional groups, thus predicting medicine-medicine interactions in TCM herbal formulas.[75] As herbal decoctions contain multiple active components and diverse biological activities, predicting medicine-herb interactions (DHIs) provides a challenge.[76] Pharmacodynamic and pharmacokinetic profiles may even vary between different batches of the same herb, which increases the complexity of analyzing DHIs through both pharmacodynamic and pharmacokinetic mechanisms at primary and secondary targets.[77] AI can integrate large and diverse datasets, including cheminformatics data, genomic data, and pharmacological pathways, to reveal underlying relationships between active components in herbs and medicine metabolism enzymes.[78,79] AI models can even include datasets comprising clinical information and demographics of patients to provide potential DHIs adjusted to suit patient characteristics, aligning with precision medicine.[80] Therefore, AI systems can flag potential risks when TCM is combined with Western medication, a growing concern as integrative medicine becomes more common.

The integration of AI into TCM herbal medicine research facilitates data standardization by integrating heterogeneous datasets, including herbal fingerprints, phytochemical profiles, genomic information, pharmacological pathways, protein-protein interaction networks, and clinical data into interoperable and machine-readable databases, thereby improving consistency in herb identification, quality assessment, and safety evaluation. Through chemometric analysis, network pharmacology, and deep learning algorithms, AI further contributes to therapeutic standardization by objectively characterizing active compounds, herb pairs, synergistic interactions, toxicological risks, and disease-specific molecular targets, reducing variability caused by differences in cultivation, processing, and formulation practices. In terms of evidence generation, AI-driven analyses provide mechanistic insights into the multi-component, multi-target, and multi-pathway actions of herbal formulas, bridging traditional empirical knowledge with modern systems biology and precision medicine frameworks. Predictive modeling of medicine-herb and herb-herb interactions, coupled with integration of patient demographic and clinical data, also enhances safety surveillance and supports individualized treatment strategies. Finally, these developments promote the international translation of TCM by expressing herbal medicine mechanisms in modern biomedical, pharmacological, and computational language that can be scientifically validated and more readily accepted within global healthcare and regulatory systems. AI-assisted quality control, toxicity prediction, and mechanism-based evaluation may therefore facilitate the development of internationally recognized standards for TCM herbal products, while future research integrating multi-omics technologies, explainable AI, digital pharmacology, and global regulatory harmonization may further accelerate the transformation of TCM herbal medicine into a more evidence-based, precision-guided, and internationally integrated therapeutic system.

2.3 Acupuncture and *Tui Na*

Beyond herbal medicine, alternative clinical therapies that require strength and precision, such as acupuncture and *Tui Na*, also require standardization. Although TCM students learn acupuncture and *Tui Na* during the school curriculum and receive guidance from experts during internships, there is still a difference in standard between amateurs and experts, which will affect the treatment outcome for such alternative clinical therapies. In order for TCM students to acquire clinical competency and standardize with experts, AI can be integrated into acupuncture education with the development of a vision-based needling training system by Luu et al.[81] The developed system, based on a phantom model, quantified three needle manipulation parameters, which are needle insertion length, angle and speed. Using the system for novice acupuncture training, the study showed that students in the technology-aided training group achieved their best performance faster than the traditional training approach. Students could review their movements and compare them against those of experts according to the needle manipulation parameters. These quantifiable parameters will allow acupuncture manipulation to be taught more effectively and standardized, and students can understand how to achieve clinical competency. This helps to bridge the standard difference between amateurs and experts.

Recent advancements in robotics present new opportunities in robot-assisted acupuncture treatment. Acupuncture therapy can be dangerous if an inaccurate location or

depth of acupoints is used, which may cause serious adverse events, and even death. The key steps of acupuncture therapy include acupoint localization, needle insertion, acupoint stimulation, and acupoint prescription. While needle insertion and acupoint prescription can be standardized in clinical practice, when faced with different patients, localization of acupoints may be plagued with errors due to differences in physique, and physicians may have different stimulation techniques. Prolonged administration of acupuncture therapy also results in fatigue, which may affect the accuracy of acupoint localization and stimulation as well. Such are the difficulties in standardizing acupuncture therapy, which hinders the acceptance and adoption internationally, as treatment outcomes will vary when acupoint localization and stimulation are inaccurate. To address this, engineers at Shanghai Jiao Tong University successfully developed an acupuncture robot utilizing a hand-eye-force coordination strategy capable of locating acupoints with remarkable precision of deviation less than 1.5 mm, adjusting needle depth and force with errors under half a millimeter.[82] In trials, the robot not only replicated but often surpassed the consistency of human practitioners, offering more consistent and reproducible treatments. However, there may be an imminent danger of over-reliance on robots for acupuncture therapy, as safety will always be a patient concern regarding invasive techniques, and we are still a far cry from reaching safe full-automation without human guidance.

A company based in Singapore, AiTREAT, Pte Ltd., developed an AI-powered electronic massage robot that delivers *Tui Na* therapy known as Expert Manipulative Massage Automation (EMMA). As *Tui Na* therapy is highly labor-intensive, quality of treatment may not be consistent throughout the day, and treatments provided by different *Tui Na* therapists are not standardized, EMMA is able to fill the gap by providing precise, consistent, low-cost, and customizable *Tui Na* therapies.[83] Using sensors, 3D vision technology, and DL algorithms, EMMA can easily identify muscle stiffness and standardize acupoint locations, designing treatment plans personalized to each individual's body proportions, with all patients receiving identical and precise treatments of equal strength that can be adjusted according to preference and independent of therapists. A feasibility trial found that all participants were satisfied with the EMMA treatment experience, which was pleasurable, akin to human touch.[84] Consumer acceptability for such robots as alternatives to *Tui Na* therapists can thus further encourage healthcare institutions to incorporate them into their system. By embedding traditional practices in robotic or AI systems, TCM therapies become more standardized and reproducible, improving the safety and acceptability of *Tui Na* therapy in global healthcare systems worldwide. EMMA has been provided to various research institutions internationally, such as Mayo Clinic Rochester in the United States and Suzhou Industrial Park in China, and further research will raise the acceptability and internationalization of *Tui Na* therapy using robots.

Taken together, AI-assisted acupuncture and *Tui Na* demonstrate how TCM clinical therapies can be advanced through the four layers of standardization and internationalization. At the level of data standardization, vision-based systems, sensors, force detectors, motion tracking, and robotic platforms can convert traditionally experience-dependent therapeutic procedures into measurable parameters, including needle insertion depth, angle, speed, acupoint deviation, stimulation force, massage pressure, body proportions, and muscle stiffness. At the level of therapeutic standardization, these quantified parameters allow trainees, practitioners, and robotic systems to benchmark their performance against expert-level manipulation, thereby reducing variability between amateurs and experts, minimizing practitioner fatigue-related errors, and improving the reproducibility and safety of acupuncture and *Tui Na* interventions. At the level of evidence generation, standardized operational data can be linked with clinical outcomes, adverse events, patient comfort, and treatment efficacy, providing a more objective basis for evaluating whether specific needling or manipulation parameters produce reliable therapeutic benefits. Finally, at the level of international translation, AI and robotic systems can transform acupuncture and *Tui Na* from techniques that are often perceived as subjective, skill-dependent, and difficult to regulate into transparent, measurable, repeatable, and safety-controlled interventions. This transformation may improve global confidence in TCM therapies and facilitate their integration into international healthcare systems, while still requiring appropriate human supervision, ethical regulation, and clinical validation to avoid unsafe over-reliance on automation.

2.4 Clinical research

Clinical trials represent the gold standard for medical validation of safety and effectiveness, but TCM trials have long faced obstacles. Slow patient recruitment, non-adherence, high dropout rates, unforeseen side effects, and contradictory data contribute to the failure of most clinical trials. Patient recruitment is a huge investment of time and effort that can only be materialized via the successful completion of a clinical trial by the patient. Therefore, it is imperative that patients do not drop out and adhere to the trial procedures, ensuring that all required data points are collected reliably.[85] AI can rapidly identify patient subgroups likely to respond favorably to clinical interventions or where a certain illness is most common, speeding up the process of discovering suitable patients. For example, researchers at New York's Mount Sinai Medical Centre classified patients with type 2 diabetes into three categories according to the topological data analysis (TDA) of their electronic

health records (EHR) and genetic data.[86] After a target population has been identified, AI can be used to assist the recruitment process by streamlining and cutting down on unnecessary checks.

Patient engagement is enhanced through AI-powered voice assistants for routine monitoring tasks, such as sending notifications of upcoming appointments to patients, facilitating more effective communication between various study sites, and monitoring patient adherence by keeping track of their daily activities. AI can assist in data collection and management by utilizing digital health technologies such as smart wearable devices and speech recognition technology for remote monitoring of patient conditions.[87] This improves the safety oversight of patients, allowing prompt actions to be taken during life-threatening situations. Integration of AI into patient monitoring in the form of an AI chatbot could also relieve patients' concerns about their symptoms. A cross-sectional study evaluated the preference, quality and empathy of physician and chatbot responses to random questions drawn from a public social media forum, by a team of licensed healthcare professionals.[88] The evaluators preferred chatbot responses in 78.6% of evaluations, with chatbot responses being rated significantly higher quality than physician responses, and physician responses were 41% less empathetic than chatbot responses. As clinical study teams often draft pre-prepared replies in response to messages, incorporating AI chatbots could lessen their workload, saving time for more complex tasks instead. The fast, high-quality and empathetic responses by AI chatbots might potentially improve patient outcomes, affecting adherence to medication and medical appointments.[89]

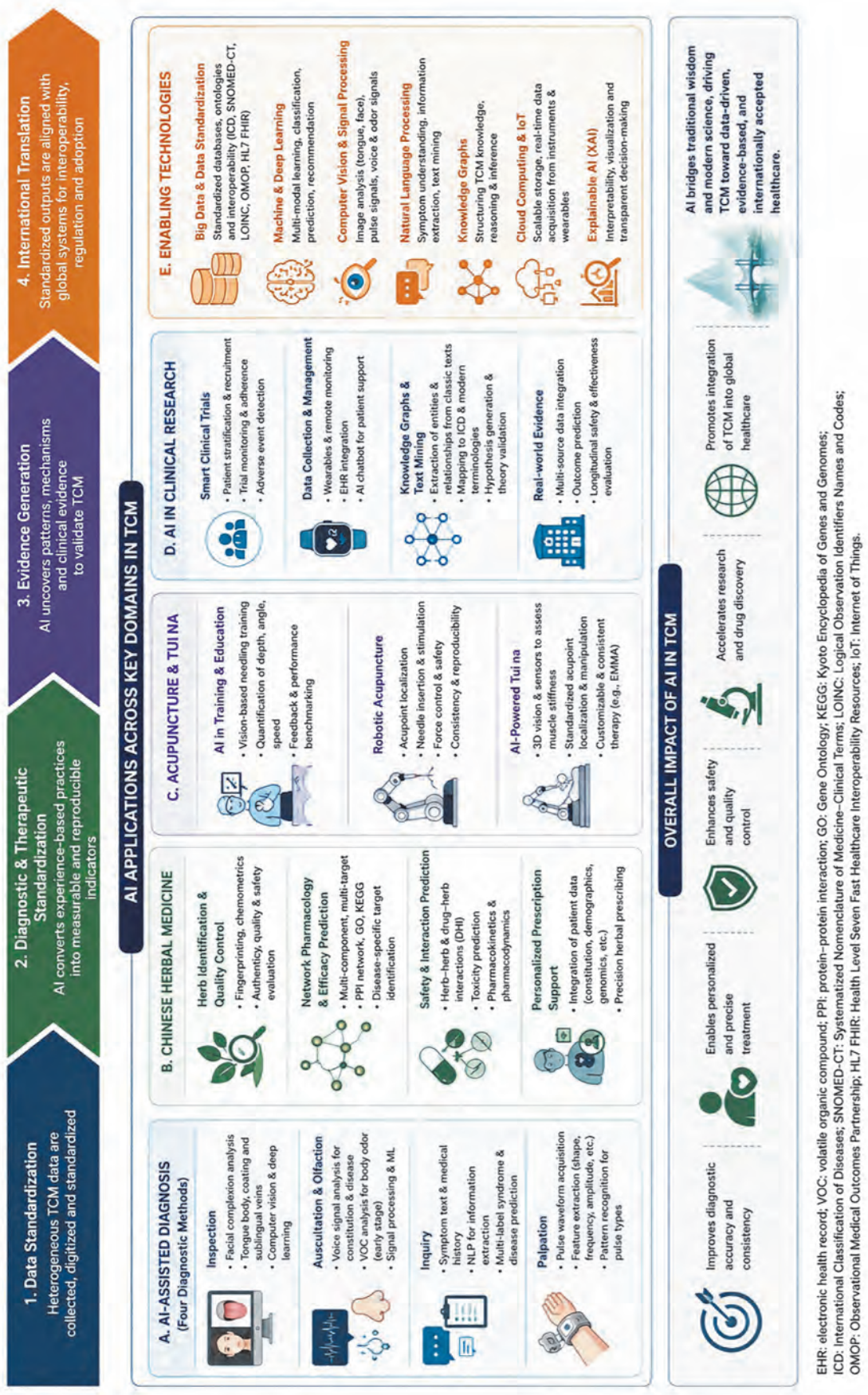
Most of TCM knowledge and theories stem from ancient Chinese medicine classics, of which the most prominent classics include *Huang Di Nei Jing* (《黄帝内经》*The Yellow Emperor's Inner Classic*), *Shang Han Lun* (《伤寒论》*Treatise on Cold Damage*), *Jin Gui Yao Lue* (《金匮要略》*Essentials from the Golden Cabinet*), and *Wen Bing Tiao Bian* (《温病条辨》*Systematic Differentiation of Warm Diseases*). Experience from past physicians provides us with insights into how to treat various diseases, which is important to our understanding of diseases from the TCM perspective. Research on these ancient texts is a difficult task due to the difference in language expression, TCM concepts are not explicitly stated and need to be inferred, and different terms or herbs may mean the same thing when analyzing texts from different eras. Thus, standardizing how terms in the texts are interpreted and translated is critical, so that ancient TCM knowledge can be associated with current medical knowledge and interoperable data standards, such as ICD, for integration with Western medicine systems. A knowledge graph (KG) is a knowledge network that describes objectively existing entities and their relationships, which is key to structuring TCM theories between entities used in ancient texts, for ease of AI analysis. Li et al. designed a KG for *Shang Han Lun* that covers the extraction of concepts, entities, and relationships of diseases, patterns, symptoms, methods and formulas in the text.[90] Using KGs, AI systems can model relationships within TCM knowledge structures and can thus perform reasoning to analyze patterns and predict diagnoses or treatments based on the knowledge. This enables multilingual mapping to bridge TCM and Western medicine, and AI analysis helps to validate TCM theories, facilitating the adoption of TCM internationally.

Overall, AI can strengthen the clinical validation and knowledge translation of TCM by enabling the integration of heterogeneous data sources to support data standardization. This includes electronic health records, genetic information, wearable-device outputs, patient-reported outcomes, chatbot interactions, clinical trial records, and ancient medical texts, while knowledge graphs can structure TCM concepts such as diseases, patterns, symptoms, formulas, herbs, and therapeutic principles into machine-readable formats. For diagnostic and procedural standardization, AI can support more consistent patient stratification, eligibility screening, adherence monitoring, adverse-event detection, and interpretation of classical TCM terminology, thereby reducing variability in trial execution and knowledge interpretation. With regards to evidence generation, AI-assisted recruitment, remote monitoring, real-time safety assessment, and large-scale data analysis can improve trial efficiency, data completeness, patient retention, and the reliability of efficacy and safety evaluation, while knowledge graphs can help generate testable hypotheses from traditional theories. Finally, AI can link TCM concepts with modern biomedical vocabularies, clinical endpoints, and interoperable standards such as ICD, making TCM theories and interventions more understandable, comparable, and acceptable within global evidence-based medical systems to facilitate international translation. Thus, AI not only improves the operational quality of TCM clinical trials but also provides a structured bridge between classical knowledge, modern clinical evidence, and international medical communication (Fig. 1).

3 Discussion

3.1 Data quality and privacy challenges

Despite its promise, the integration of AI and big data into TCM is not without hurdles, particularly in relation to data quality, AI technology, and clinical application. High-quality data is essential for optimal AI performance. Due to the unique diagnostic process of TCM, the collection of objective and standardized data requires the assistance of specialized instruments, such as tools for recording facial, tongue, and pulse data. However, collecting and processing auscultation and olfaction data for AI analysis remains challenging, as technologies for detecting odors are still at an early stage. Symptom



EHR: electronic health record; VOC: volatile organic compound; PPI: protein–protein interaction; GO: Gene Ontology; KEGG: Kyoto Encyclopedia of Genes and Genomes; ICD: International Classification of Diseases; SNOMED-CT: Systematized Nomenclature of Medicine–Clinical Terms; LOINC: Logical Observation Identifiers Names and Codes; OMOP: Observational Medical Outcomes Partnership; HL7 FHIR: Health Level Seven Fast Healthcare Interoperability Resources; IoT: Internet of Things.

Figure 1 Summary of current AI applications in TCM (source with permission from: picture made by the authors)

recording requires unified and standardized vocabulary, as physicians from different regions may use different terms to describe the same pattern, which can contribute to more consistent data. Limited consultation time for diagnosing every patient during clinical practice further makes it hard for physicians to collect comprehensive inquiry data, which may affect the diagnostic outcome, leading to variability in data labeling. This could be addressed by human-computer interaction for preliminary diagnosis, which will require an extensive AI algorithm to simulate the natural diagnostic process across diverse diseases.

Aside from high-quality data, data quantity is essential to increase the accuracy of ML and DL models. However, publicly available TCM datasets for model training remain scarce, which impedes the development of AI applications. Establishing standardized electronic health record databases specifically for TCM clinical and research purposes requires careful consideration of patient privacy and ethical issues. Because big data often involves access to sensitive patient information, inadequate safeguards leading to misuse or data leakage could undermine public trust. Therefore, robust data protection frameworks should be prioritized for data sharing, which demands the coordinated efforts of physicians, patients, institutions, and government agencies. Datasets used for AI model training should also be anonymized to protect patient privacy, decrypting any personally identifiable information.

3.2 AI model design and explainability

Integration of AI is also highly dependent on model design and optimization. TCM diagnosis is often a multilabel task because patients may present with symptoms corresponding to multiple patterns under different disease categories. Therefore, AI algorithms should be designed to perform multi-label classification and process complex symptoms from multiple modalities. TCM treatment is highly individualized, in which the same disease may require different treatments depending on different constitutional types, demographics, environments and seasons. AI models, therefore, need to incorporate these contextual factors to predict suitable herbal formulas or therapeutic strategies. At the same time, stronger integration with modern medical diagnostics, such as biomedical tests and medical imaging, may help establish new relationships between TCM patterns, TCM diagnostics, and modern biomedical evidence. This may potentially enhance the reliability and acceptance of non-invasive diagnostic methods in clinical practice for early detection and prevention. AI models often operate as "black boxes", producing results without clearly explaining their reasoning process. This problem is particularly important in TCM, which relies on abstract concepts such as yin-yang, qi, and *Wu Xing*. A lack of transparency may hinder both clinical trust and international acceptance of TCM. To support clinical adoption, AI systems should not only generate diagnostic or therapeutic recommendations but also explain them in understandable ways. For example, decision-path visualization tools and explainable AI frameworks may help clinicians understand how specific symptoms, biomarkers, or diagnostic features contribute to pattern differentiation and treatment selection.

3.3 AI-enabled standardization of TCM diagnosis and treatment

AI has the potential to become a critical bridge between TCM and modern evidence-based healthcare systems by addressing longstanding challenges related to subjectivity, reproducibility, mechanistic ambiguity, and regulatory acceptance. AI enables data standardization by converting traditionally qualitative TCM observations into structured, quantifiable, and interoperable digital datasets. Tongue images, facial complexion, pulse waveforms, voice characteristics, symptom descriptions, herbal fingerprints, and treatment manipulation parameters can all be transformed into machine-readable formats using computer vision, wearable sensors, natural language processing, and multimodal data fusion technologies. The establishment of standardized ontologies and mappings between TCM terminology and internationally recognized systems such as ICD, Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CTs), Logical Observation Identifiers Names and Codes (LOINCs) etc., allows TCM data to become interoperable with mainstream biomedical databases and hospital information systems. This interoperability is fundamental for multicenter collaboration, regulatory review, and integration into global healthcare infrastructures.

AI can support diagnostic and therapeutic standardization by reducing dependence on practitioner experience and minimizing inter-observer variability. Machine learning and deep learning models can quantify diagnostic indicators such as tongue morphology, pulse characteristics, patterns, and acupuncture manipulation parameters using reproducible computational criteria. Robotic acupuncture systems, AI-assisted *Tui Na* devices, and intelligent decision-support systems further improve procedural consistency and safety. Importantly, explainable AI (XAI) frameworks may enhance transparency by demonstrating how specific diagnostic features, biomarkers, or symptom clusters contribute to pattern differentiation and treatment recommendations. Such explainability is particularly important for regulatory agencies and clinicians who require interpretable evidence before adopting AI-assisted TCM technologies into practice. Future systems should incorporate human-in-the-loop architectures to preserve physician oversight and individualized treatment principles while ensuring reproducibility and safety.

3.4 Evidence generation and clinical validation

AI strengthens evidence generation, which remains one of the largest barriers to global acceptance of TCM. AI-assisted clinical trial platforms can improve patient stratification, optimize recruitment, predict treatment responsiveness, monitor adherence, and identify adverse events in real time using wearable devices and digital health technologies. By integrating TCM diagnostic features with molecular biomarkers, imaging data, metabolomics, microbiomics, and electronic health records, AI enables systems-level investigation of therapeutic mechanisms and treatment outcomes. Network pharmacology and knowledge graph technologies further allow researchers to model the multi-component, multi-target mechanisms of herbal formulas in ways compatible with modern pharmacology and systems biology. Real-world evidence platforms powered by AI can additionally generate longitudinal outcome data beyond conventional randomized controlled trials (RCTs), supporting comparative effectiveness research and post-market surveillance. Together, these approaches help reposition TCM from an experience-based practice toward a data-driven and evidence-supported precision medicine framework.

3.5 Regulatory alignment and global translation

For global clinical adoption, AI-assisted TCM technologies must align with existing international regulatory and approval pathways. Depending on the intended use, these technologies may fall under medical devices, software as a medical device (SaMD), digital therapeutic, diagnostic support system, or pharmaceutical regulatory categories. In the United States, approval pathways may involve the Food and Drug Administration (FDA), particularly through frameworks for AI/ML-enabled medical devices and digital health technologies. In Europe, compliance with Medical Device Regulation (MDR), CE marking requirements, General Data Protection Regulation (GDPR), and AI Act provisions will be essential. In China, regulation may involve the National Medical Products Administration (NMPA), while other regions such as Singapore, Japan, and Australia maintain their own digital health and AI governance frameworks. Key compliance strategies include implementation of Good Clinical Practice (GCP), Good Machine Learning Practice (GMLP), transparent algorithm validation, cybersecurity protections, privacy-preserving data governance, bias mitigation, continuous post-market monitoring, and external multicenter validation across ethnically and geographically diverse populations. Regulatory acceptance will depend heavily on reproducibility, explainability, clinical utility, and demonstration of safety under real-world conditions.

To facilitate translation into globally acceptable healthcare solutions, a practical roadmap for AI-assisted TCM development should involve several progressive stages. The first stage is infrastructure development, including standardized multimodal TCM databases, international terminology harmonization, and interoperable digital platforms. The second stage involves algorithm development and technical validation through multicenter datasets, explainable AI models, and benchmarking against expert consensus and biomedical standards. The third stage focuses on clinical validation using prospective trials, pragmatic real-world studies, and integration of digital biomarkers and patient-reported outcomes. The fourth stage involves regulatory alignment through early engagement with regulatory agencies, adoption of international technical standards, and implementation of quality management systems. The fifth stage is healthcare integration, where AI-assisted TCM tools are embedded into hospital information systems, telemedicine platforms, wearable health ecosystems, and integrative medicine workflows. Finally, continuous post-market learning systems should be established to monitor safety, effectiveness, and algorithm drift while enabling adaptive improvements.

Ultimately, AI functions as a bridge for the internationalization of TCM by translating traditional concepts into computational, physiological, and biomedical language that can be objectively measured, scientifically validated, and globally communicated. Through quantification, mechanistic modeling, and standardized clinical evaluation, AI reduces skepticism surrounding subjectivity and variability in TCM practice. At the same time, AI preserves the holistic and individualized characteristics of TCM by enabling analysis of complex multidimensional patient data beyond reductionist single-target approaches. As AI technologies mature alongside digital health ecosystems, wearable biosensors, robotics, and multi-omics medicine, TCM may increasingly evolve into a globally integrated, precision-oriented, and evidence-driven healthcare system that complements contemporary biomedical practice rather than existing outside it.

4 Conclusion

In conclusion, the integration of artificial intelligence and big data into TCM represents a transformative opportunity to advance the modernization, clinical interpretation, and international communication of TCM while preserving its holistic, individualized, and context-dependent therapeutic philosophy. Across diagnosis, herbal medicine, acupuncture, *Tui Na*, and clinical research, AI has demonstrated strong potential to support the organization of traditionally experience-based knowledge into more structured, quantifiable, reproducible, and evidence-informed frameworks. Through the interconnected layers of data standardization, diagnostic and therapeutic support, evidence generation, and international translation, AI may provide a systematic bridge between classical TCM knowledge and modern biomedical science, digital health technologies, and global healthcare systems.

Nevertheless, challenges related to data quality, ethical governance, explainability, regulatory compliance, algorithmic bias, cultural interpretation, and the preservation of individualized treatment principles must be carefully addressed before widespread adoption can occur. It is also necessary to reflect on whether standardization, as a modern scientific and technical tool, is sufficient to measure all dimensions of TCM knowledge. TCM is not only a collection of diagnostic indicators and therapeutic procedures, but also a distinctive knowledge system shaped by holistic reasoning, pattern differentiation, contextual judgment, practitioner experience, and individualized therapeutic decision-making. Therefore, AI-assisted standardization should not be understood as a process of reducing TCM to fixed categories or uniform protocols. Rather, it should serve as a supportive framework that enhances communication, comparison, and evidence generation while respecting the internal logic, interpretive flexibility, subjectivity, and individualization that are central to TCM practice.

Looking forward, the development of AI-assisted TCM should move beyond a one-way translation of TCM into modern biomedical language. More interdisciplinary research is needed to promote a creative and reciprocal dialogue between TCM and modern medical discourse. Such dialogue may allow modern technologies to provide new tools for observing, interpreting, and validating TCM, while TCM may also contribute alternative perspectives on complexity, individuality, systems thinking, and patient-centred care. Future studies should therefore emphasize diverse and high-quality datasets, explainable and human-centred AI systems, integration with multi-omics and wearable technologies, and adaptive regulatory frameworks that respect both scientific rigor and the unique epistemological characteristics of TCM. Through continued collaboration among TCM practitioners, clinicians, engineers, data scientists, humanistic scholars, policymakers, and regulatory authorities, AI-assisted TCM may evolve into a more transparent, evidence-supported, and globally communicable field, while fully preserving the theoretical richness, subjectivity, and individualized nature of traditional healing systems.

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Ethical approval

This study does not contain any studies with human, or animal subjects performed by any of the authors.

Author contributions

CHEN Huangyan participated in the writing of the paper. Linda LD Zhong participated in the paper design.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT to improve language clarity and readability, and used an AI-assisted image generation tool to create illustrative artwork for the graphical presentation of the study. After using these tools, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Conflicts of interest

Linda LD Zhong is a Youth Editorial Board member of *Chinese Medicine and Culture*. The article was subject to the journal's standard procedures, with peer review handled independently of this Youth Editorial Board member and her research group.

References

[1] Tang JL, Liu BY, Ma KW. Traditional Chinese medicine. *Lancet*. 2008;372:1938–1940.
[2] Lam WC, Lyu A, Bian Z. ICD-11: impact on traditional Chinese medicine and world healthcare systems. *Pharmaceutical Medicine*. 2019;33(5):373–377.
[3] Chu XL, Sun BZ, Huang QC, Peng SP, Zhou YY, Zhang Y. Quantitative knowledge presentation models of traditional Chinese medicine (TCM): a review. *Artificial Intelligence in Medicine*. 2020;103:101810.
[4] Jordan MI, Mitchell TM. Machine learning: trends, perspectives, and prospects. *Science*. 2015;349(6245):255–260.
[5] Esteva A, Robicquet A, Ramsundar B, et al. A guide to deep learning in healthcare. *Nature Medicine*. 2019;25(1):24–29.
[6] Dong JC. The relationship between traditional Chinese medicine and modern medicine. *Evidence-Based Complementary and Alternative Medicine*. 2013;2013(1):153148.
[7] Jones AL. The influence of shape and colour cue classes on facial health perception. *Evolution and Human Behavior*. 2018;39(1):19–29.
[8] Lu LM, Chen X, Xu JT. Determination methods for inspection of the complexion in traditional Chinese medicine: a review (中医面部色诊测定方法述评). *Journal of Chinese Integrative Medicine*. 2009;7(8):701–705. Chinese.
[9] Lin Y, Wang B. Facial complexion recognition of traditional Chinese medicine based on computer vision. Paper presented at: 2020 5th International Conference on Computational Intelligence and Applications (ICCIA); June 19–21 2020; Beijing, China.
[10] Zhou R, Li FF, Wang YQ, Zheng XY, Zhao RW, Li GZ. Application of PCA and LDA methods on gloss recognition research in TCM complexion inspection. Paper presented at: 2010 IEEE International Conference on Bioinformatics and Biomedicine Workshops (BIBMW); December 18–21 2010; Hong Kong, China.
[11] Li FF, Zhao CB, Xia Z, Wang YQ, Zhou XB, Li GZ. Computer-assisted lip diagnosis on traditional Chinese medicine using multi-class support vector machines. *BMC Complementary and Alternative Medicine*. 2012;12(1):127.
[12] Wong W, Lam CLK, Wong VT, Yang ZM, Ziea ETC, Kwan AKL. Validation of the constitution in Chinese medicine questionnaire: does the traditional Chinese medicine concept of body constitution exist? *Evidence-Based Complementary and Alternative Medicine*. 2013;2013(1):481491.
[13] Xu AY, Wang TS, Yang T, et al. Constitution identification model in traditional Chinese medicine based on multiple features. *Digital Chinese Medicine*. 2024;7(2):108–119.
[14] Re DE, Rule NO. About face: new directions for the physician's general survey. *Current Directions in Psychological Science*. 2016;25(1):65–69.

[15] Lima AL, Illing T, Schliemann S, Elsner P. Cutaneous manifestations of diabetes mellitus: a review. *American Journal of Clinical Dermatology*. 2017;18(4):541–553.
[16] Zhang NN, Jiang ZX, Li M, Zhang D. A novel multi-feature learning model for disease diagnosis using face skin images. *Computers in Biology and Medicine*. 2024;168:107837.
[17] Tania MH, Lwin K, Hossain MA. Advances in automated tongue diagnosis techniques. *Integrative Medicine Research*. 2019;8(1):42–56.
[18] Zhou CG, Fan HY, Li ZY. Tonguenet: accurate localization and segmentation for tongue images using deep neural networks. *IEEE Access*. 2019;7:148779–148789.
[19] Huang XD, Zhang H, Zhuo L, Li XS, Zhang J. TISNet-enhanced fully convolutional network with encoder-decoder structure for tongue image segmentation in traditional Chinese medicine. *Computational and Mathematical Methods in Medicine*. 2020;2020(1):6029258.
[20] Song C, Wang B, Xu JT. Classifying tongue images using deep transfer learning. Paper presented at: 2020 5th International Conference on Computational Intelligence and Applications (ICCIA); June 19–21 2020; Beijing, China.
[21] Wang YL, Shi XM, Li L, Efferth T, Shang D. The impact of artificial intelligence on traditional Chinese medicine. *The American Journal of Chinese Medicine*. 2021;49(06):1297–1314.
[22] Wang X, Liu JW, Wu CY, et al. Artificial intelligence in tongue diagnosis: using deep convolutional neural network for recognizing unhealthy tongue with tooth-mark. *Computational and Structural Biotechnology Journal*. 2020;18:973–980.
[23] Wang XZ, Luo SY, Tian GH, Rao XR, He B, Sun FC. Deep learning based tongue prickles detection in traditional Chinese medicine. *Evidence-based Complementary and Alternative Medicine*. 2022;2022:5899975.
[24] Yan JJ, Chen BC, Guo R, et al. Tongue image texture classification based on image inpainting and convolutional neural network. *Computational and Mathematical Methods in Medicine*. 2022;2022(1):6066640.
[25] Yan JJ, Cai JX, Xu Z, et al. Tongue crack recognition using segmentation based deep learning. *Scientific Reports*. 2023;13:511.
[26] Peng CD, Wang L, Jiang DM, Yang N, Chen R, Dong CW. Establishing and validating a spotted tongue recognition and extraction model based on multiscale convolutional neural network. *Digital Chinese Medicine*. 2022;5(1):49–58.
[27] Xu Q, Zeng Y, Tang WJ, et al. Multi-task joint learning model for segmenting and classifying tongue images using a deep neural network. *IEEE Journal of Biomedical and Health Informatics*. 2020;24(9):2481–2489.
[28] Takeichi M, Sato T. Computerized color analysis of "xue yu" (blood stasis) in the sublingual vein using a new technology. *The American Journal of Chinese Medicine*. 1997;25(2):213–219.
[29] Chiu CC, Lan CY, Chang YH. Objective assessment of blood stasis using computerized inspection of sublingual veins. *Computer Methods and Programs in Biomedicine*. 2002;69(1):1–12.
[30] Jiang T, Guo XJ, Tu LP, et al. Application of computer tongue image analysis technology in the diagnosis of NAFLD. *Computers in Biology and Medicine*. 2021;135:104622.
[31] Noguchi K, Saito I, Namiki T, Yoshimura Y, Nakaguchi T. Reliability of non-contact tongue diagnosis for Sjögren's syndrome using machine learning method. *Scientific Reports*. 2023;13(1):1334.
[32] Shi YL, Guo DD, Chun Y, et al. A lung cancer risk warning model based on tongue images. *Frontiers in Physiology*. 2023;14:1154294.
[33] Yuan L, Yang L, Zhang SC, et al. Development of a tongue image-based machine learning tool for the diagnosis of gastric cancer: a prospective multicentre clinical cohort study. *eClinicalMedicine*. 2023;57.
[34] Zhang NN, Jiang ZX, Li JX, Zhang D. Multiple color representation and fusion for diabetes mellitus diagnosis based on back tongue images. *Computers in Biology and Medicine*. 2023;155:106652.
[35] Liu F, Su D, Shi X, et al. Cross-population tongue image features and tongue coating microbiome changes in the evolution of colorectal cancer. *Frontiers in Microbiology*. 2025;16:1442732.
[36] Wang X, Wang XR, Lou YN, et al. Constructing tongue coating recognition model using deep transfer learning to assist syndrome diagnosis and its potential in noninvasive ethnopharmacological evaluation. *Journal of Ethnopharmacology*. 2022;285:114905.
[37] Zhuang QB, Gan SZ, Zhang LY. Human-computer interaction based health diagnostics using ResNet34 for tongue image classification. *Computer Methods and Programs in Biomedicine*. 2022;226:107096.
[38] Chen CF, Wang YQ, Guo R, et al. Analysis of 903 voice signals of patients with five organs illness and normal persons in traditional Chinese medicine auscultation. Paper presented at: 2010 IEEE International Conference on Bioinformatics and Biomedicine Workshops (BIBMW); December 18–21 2010; Hong Kong, China.
[39] Yan JJ, Wang YQ, Guo R, et al. Nonlinear analysis of auscultation signals in TCM using the combination of wavelet packet transform and sample entropy. *Evidence-Based Complementary and Alternative Medicine*. 2012;2012(1):247012.
[40] Lai T, Guan YT, Men SY, Shang HC, Zhang HL. ResNet for recognition of qi-deficiency constitution and balanced constitution based on voice. *Frontiers in Psychology*. 2022;13:1043955.
[41] Huang CJ, Lin HJ, Liao WL, Ceurvels W, Su SY. Diagnosis of traditional Chinese medicine constitution by integrating indices of tongue, acoustic sound, and pulse. *European Journal of Integrative Medicine*. 2019;27:114–120.
[42] Fu W, Xu LX, Yu QW, et al. Artificial intelligent olfactory system for the diagnosis of Parkinson's disease. *ACS Omega*. 2022;7(5):4001–4010.
[43] Cao YN, Jiang LN, Zhang JX, et al. A fast and non-invasive artificial intelligence olfactory-like system that aids diagnosis of Parkinson's disease. *European Journal of Neurology*. 2023;31(3):e16167.
[44] Li MH, Wen GH, Zhong JH, Yang P. Personalized intelligent syndrome differentiation guided by TCM consultation philosophy. *Journal of Healthcare Engineering*. 2022;2022(1):6553017.
[45] Song YJ, Zhao B, Jia J, et al. A review on different kinds of artificial intelligence solutions in TCM syndrome differentiation application. *Evidence-Based Complementary and Alternative Medicine*. 2021;2021(1):6654545.
[46] Fan BC, Li YH, Wen GH, et al. Personalized body constitution inquiry based on machine learning. *Journal of Healthcare Engineering*. 2020;2020(1):8834465.
[47] Xia SJ, Zhang J, Du GD, et al. A microcosmic syndrome differentiation model for metabolic syndrome with multilabel learning. *Evidence-Based Complementary and Alternative Medicine*. 2020;2020(1):9081641.
[48] Pang HX, Wei SK, Zhao YF, et al. Effective attention-based network for syndrome differentiation of AIDS. *BMC Medical Informatics and Decision Making*. 2020;20(1):264.
[49] Xie JG, Li Y, Wang N, Xin L, Fang YY, Liu J. Feature selection and syndrome classification for rheumatoid arthritis patients with traditional Chinese medicine treatment. *European Journal of Integrative Medicine*. 2020;34:101059.
[50] Zhou L, Li GG, Zhou YM, et al. Traditional Chinese medicine (TCM) diagnosis model building based on multi-label classification. *MATEC Web of Conferences*. 2018;232(8):02026.
[51] Zhang XH, Shi QL, Wang B, et al. Review of machine learning algorithms in traditional Chinese medicine. *Computer Science*. 2018;45(11A):32–36.
[52] Gong LJ, Jiang JD, Chen SQ, Qi MM. A syndrome differentiation model of TCM based on multi-label deep forest using biomedical text mining. *Frontiers in Genetics*. 2023;14:1272016.
[53] Zhang H, Ni WD, Li J, Zhang JJ. Artificial intelligence–based traditional Chinese medicine assistive diagnostic system: validation study. *JMIR Medical Informatics*. 2020;8(6):e17608.
[54] Yan JJ, Cai XL, Chen SY, Guo R, Yan HX, Wang YQ. Ensemble learning-based pulse signal recognition: classification model development study. *JMIR Medical Informatics*. 2021;9(10):e28039.
[55] Xu LS, Meng MQH, Wang KQ, Lu W, Li NM. Pulse images recognition using fuzzy neural network. *Expert Systems with Applications*. 2009;36(2):3805–3811.
[56] Leung YLA, Guan BH, Chen S, et al. Artificial intelligence meets traditional Chinese medicine: a bridge to opening the magic box of sphygmopalpation for pulse pattern recognition. *Digital Chinese Medicine*. 2021;4(1):1–8.
[57] Chen S, Ji Z, Wu HY, Xu YC. A non-invasive continuous blood pressure estimation approach based on machine learning. *Sensors*. 2019;19(11):2585.

[58] Wu HK, Ko YS, Lin YS, Wu HT, Tsai TH, Chang HH. The correlation between pulse diagnosis and constitution identification in traditional Chinese medicine. *Complementary Therapies in Medicine*. 2017;30:107–112.
[59] Wang X, Wu GR, Zhang XK, et al. Traditional Chinese medicine (TCM)-inspired fully printed soft pressure sensor array with self-adaptive pressurization for highly reliable individualized long-term pulse diagnostics. *Advanced Materials*. 2025;37(1): 2410312.
[60] E QY. Pulse signal analysis based on deep learning network. *BioMed Research International*. 2022;2022(1):6256126.
[61] Huang CH, Wang YM, Smith S. Using high-dimensional features for high-accuracy pulse diagnosis. *Mathematical Biosciences and Engineering*. 2020;17(6):6775–6790.
[62] Cui J, Song LC. Wrist pulse diagnosis of stable coronary heart disease based on acoustics waveforms. *Computer Methods and Programs in Biomedicine*. 2022;214:106550.
[63] Hao YM, Cheng F, Pham M, et al. A noninvasive, economical, and instant-result method to diagnose and monitor type 2 diabetes using pulse wave: case-control study. *JMIR mHealth and uHealth*. 2019;7(4):e11959.
[64] Zhang ZC, Zhang Y, Yao LN, Song HB, Kos A. A sensor-based wrist pulse signal processing and lung cancer recognition. *Journal of Biomedical Informatics*. 2018;79:107–116.
[65] Wang NY, Yu YH, Huang DW, et al. Pulse diagnosis signals analysis of fatty liver disease and cirrhosis patients by using machine learning. *The Scientific World Journal*. 2015;2015(1):859192.
[66] Cao YJ, Li P, Zhu YR, et al. Artificial intelligence-enabled novel atrial fibrillation diagnosis system using 3D pulse perception flexible pressure sensor array. *ACS Sensors*. 2025;10(1):272–282.
[67] Sun L, Wang YK, He JY, Li HY, Peng DD, Wang YL. A stacked LSTM for atrial fibrillation prediction based on multivariate ECGs. *Health Information Science and Systems*. 2020;8(1): 19.
[68] Chen YB, Tong XF, Ren J, Yu CQ, Cui YL. Current research trends in traditional Chinese medicine formula: a bibliometric review from 2000 to 2016. *Evidence-Based Complementary and Alternative Medicine*. 2019;2019(1):3961395.
[69] Xia SJ, Zhong ZF, Gao BZ, et al. The important herbal pair for the treatment of COVID-19 and its possible mechanisms. *Chinese Medicine*. 2021;16(1):25.
[70] Niu QK, Li HT, Tong L, et al. TCMFP: a novel herbal formula prediction method based on network target's score integrated with semi-supervised learning genetic algorithms. *Briefings in Bioinformatics*. 2023;24(3):bbad102.
[71] Cheng TF, Jia YR, Zuo Z, et al. Quality assessment of traditional Chinese medicine herb couple by high-performance liquid chromatography and mass spectrometry combined with chemometrics. *Journal of Separation Science*. 2016;39(7):1223–1231.
[72] Liu XY, Jiang WW, Su M, et al. Quality evaluation of traditional Chinese medicines based on fingerprinting. *Journal of Separation Science*. 2020;43(1):6–17.
[73] Ngai HL, Shaw PC. Advancing global herbal medicine: enhancing herb quality through innovative strategies explored in Hong Kong — an international hub. *Phytomedicine Plus*. 2025;5(1): 100727.
[74] Hussin AH. Adverse effects of herbs and drug-herbal interactions. *Malaysian Journal of Pharmacy (MJP)*. 2002;1(2):39–44.
[75] Yang B, Song D, Li YD, Wang JL. Drug-drug interaction prediction of traditional Chinese medicine based on graph attention networks. *Scientific Reports*. 2025;15(1):18635.
[76] Brantley SJ, Argikar AA, Lin YS, Nagar S, Paine MF. Herb-drug interactions: challenges and opportunities for improved predictions. *Drug Metabolism and Disposition*. 2014;42(3):301–317.
[77] Spanakis M, Tzamali E, Tzedakis G, et al. Artificial intelligence models and tools for the assessment of drug-herb interactions. *Pharmaceuticals (Basel)*. 2025;18(3):282.
[78] Chen SQ, Li TC, Yang LN, et al. Artificial intelligence-driven prediction of multiple drug interactions. *Briefings in Bioinformatics*. 2022;23(6):bbac427.
[79] Sonaji P, Subramanian L, Rajesh M. Artificial intelligence-driven drug interaction prediction. *World Journal of Biology Pharmacy and Health Sciences*. 2024;17(2):297–305.
[80] Abdelhalim H, Berber A, Lodi M, et al. Artificial intelligence, healthcare, clinical genomics, and pharmacogenomics approaches in precision medicine. *Frontiers in Genetics*. 2022;13:929736.
[81] Luu TH, Cao HL, Pham DD, Tran LTC, Verstraten T. Development and validation of a vision-based needling training system for acupuncture on a phantom model. *Journal of Acupuncture Research*. 2023;40(1):44–52.
[82] Su JB, Zhu YC, Zhu MD. Hand-eye-force coordination of acupuncture robot. *IEEE Access*. 2019;7:82154–82161.
[83] Si W, Srivastava G, Zhang YZ, Jiang L. Green internet of things application of a medical massage robot with system interruption. *IEEE Access*. 2019;7:127066–127077.
[84] Yang J, Croghan IT, Fokken SC, et al. Satisfaction and feasibility evaluation of an Electronic Massager—Expert Manipulative Massage Automation (EMMA): a pilot study. *Journal of Primary Care & Community Health*. 2023;14:21501319231199010.
[85] Harrer S, Shah P, Antony B, Hu J. Artificial intelligence for clinical trial design. *Trends in Pharmacological Sciences*. 2019; 40(8):577–591.
[86] Li L, Cheng WY, Glicksberg BS, et al. Identification of type 2 diabetes subgroups through topological analysis of patient similarity. *Science Translational Medicine*. 2015;7(311):311ra174.
[87] Weissler EH, Naumann T, Andersson T, et al. The role of machine learning in clinical research: transforming the future of evidence generation. *Trials*. 2021;22(1):537.
[88] Ayers JW, Poliak A, Dredze M, et al. Comparing physician and artificial intelligence chatbot responses to patient questions posted to a public social media forum. *JAMA Internal Medicine*. 2023;183(6):589–596.
[89] Rotenstein LS, Holmgren AJ, Healey MJ, et al. Association between electronic health record time and quality of care metrics in primary care. *JAMA Network Open*. 2022;5(10):e2237086.
[90] Liu DB, Wei CF, Xia SS, Yan JF. Construction and application of knowledge graph of *Treatise on Febrile Diseases*. *Digital Chinese Medicine*. 2022;5(4):394–405.

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Special Topic: AI & Big Data for TCM Standardization & Globalization

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From Empirical Wisdom to Computational Intelligence: A Knowledge-Data Dual-Driven Paradigm for Modernizing Traditional Chinese Medicine

从经验智慧到计算智能：知识–数据双驱动下的中医药现代化

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Abstract

The integration of artificial intelligence (AI) with traditional Chinese medicine (TCM) presents a unique epistemological challenge posed by the tension between TCM's holistic, experiential paradigm and AI's data-driven logic. This paper introduces and defends a "Knowledge-Data Dual-Driven" paradigm as a foundational framework for the authentic modernization of TCM. The paradigm involves two synergistic pathways: first, formalizing implicit TCM wisdom into explicit, computable structures using large-scale knowledge graphs (KGs) and TCM-specific large language models (LLMs); second, objectifying diagnostic information by digitizing the "four diagnostic methods" to construct a multimodal "TCM Phenomics". The integration of these pillars via hybrid AI architectures (e.g., KG-grounded LLMs) aims to create next-generation intelligent diagnostic systems that are accurate, interpretable, and theoretically grounded. However, critical challenges persist, including data heterogeneity, model interpretability, and clinical integration bottlenecks. Overcoming these challenges requires steadfast interdisciplinary collaboration to develop human-centered AI that augments, rather than replaces, clinical decision-making. The ultimate vision lies in leveraging computational intelligence to amplify TCM's empirical wisdom, enabling more precise, personalized, and scientifically grounded healthcare within an integrative framework.

Keywords: Data-driven; Traditional Chinese medicine (TCM); Artificial intelligence; Vertical large language model; Knowledge graph; Modernization

1 Introduction

Traditional Chinese medicine (TCM), with its millennia of clinical wisdom rooted in holistic philosophy and pattern differentiation (辨证), constitutes a unique and indispensable medical system. Its diagnostic and therapeutic frameworks are fundamentally experiential, relying on the practitioner's synthesis of multi-dimensional information from the "four diagnostic methods (inspection, auscultation and olfaction, inquiry, and palpation)". This knowledge is often implicit, context-dependent, and encoded in classical texts and case narratives.

The advent of artificial intelligence (AI), particularly data-intensive paradigms like machine learning and large language models (LLMs), presents a transformative opportunity to make TCM diagnostic processes more quantitative and objective. LLMs also offer potential for systematizing fragmented, experience-dependent TCM knowledge.

However, this integration is fraught with a profound epistemological challenge. The core tension lies between TCM's holistic, symbolic, and individualized paradigm and AI's data-driven, computational, and generalizable logic.[1] Key bottlenecks include three major aspects. First, knowledge formalization: TCM's unique terminology, complex diagnostic patterns, and polysemy of concepts

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(e.g., herb names) resist straightforward digitization and computational modeling. Second, data objectification: the subjective, qualitative nature of diagnostic information (e.g., tongue appearance, pulse patterns) and the lack of unified collection standards hinder the creation of large-scale, high-quality, multimodal datasets necessary for robust AI training. Third, model generalization and safety: LLMs pre-trained on general or Western medical corpora lack domain-specific understanding of TCM and may generate inaccurate or even harmful outputs (e.g., incorrect herb combinations) when applied directly, due to "hallucinations" and reasoning limitations.

1.1 Existing research paradigms: knowledge-driven vs. data-driven approaches

To address these fundamental bottlenecks, prior research has primarily bifurcated into two distinct, often non-converging pathways. The first is a "knowledge-driven" approach focused on the formalization and computation of TCM wisdom. This approach is exemplified by the construction of large-scale TCM knowledge graphs (KGs) and domain ontologies, as well as the development of rule-based expert systems.[2] These endeavors have laid a crucial foundation for the digital preservation and standardization of TCM theory, ensuring theoretical consistency in intelligent applications. However, this path often grapples with "knowledge silos": its construction is heavily expert-dependent and costly to update, resulting in largely static knowledge systems that struggle to adapt to complex, dynamic clinical realities and lack the capacity for continuous learning from real-world data[3]—a limitation that a truly integrated, dual-driven paradigm is uniquely positioned to overcome.

In parallel, the "data-driven" approach quantifies TCM diagnostic information by utilizing computer vision and signal processing techniques, such as deep learning and wavelet analysis, to extract objective features from tongue images and pulse signals.[4] Furthermore, it integrates multi-omics technologies, including genomics and metabolomics, to explore molecular-level biomarkers associated with TCM patterns, thereby connecting traditional diagnostics with modern biological evidence.[5]

This pathway has contributed to diagnostic objectification and precision, demonstrating considerable potential for discovering novel patterns from large-scale datasets. However, a primary limitation lies in the "black-box" nature of prevalent deep learning models: the lack of interpretability hinders tracing model outputs back to the theoretical principles of "treatment based on pattern differentiation" in TCM, creating a disconnect from core TCM doctrines.[6] Moreover, practical challenges such as heterogeneous data quality (e.g., variations in imaging devices and lighting conditions) and inconsistent annotation standards across different practitioners and institutions significantly impede model generalizability and clinical applicability—precisely the challenges that a systematically constructed, multimodal "TCM Phenomics" framework, a concept formalized by Duan et al.[7], seeks to address. In this context, domain-specific vertical models tailored for TCM have emerged as a prominent trend. Yet, for these models to be clinically reliable, they inherently require a paradigm that seamlessly integrates formalized knowledge and real-world data—a gap that the knowledge-data dual-driven paradigm proposed in this paper is designed to fill.

1.2 Hybrid attempts and the persistent gap

Recognizing the limitations of either paradigm in isolation, recent research has increasingly pursued hybrid models that combine data-driven techniques with structured domain knowledge. Common strategies include using TCM pattern labels as additional predictive features or embedding KGs as retrievable databases to inform model decisions.[8] However, many current implementations remain at a level of superficial complementarity. For instance, TCM KGs are frequently used merely as static corpora for retrieval-augmented generation (RAG), providing post-hoc evidence for LLM-generated diagnoses without actively constraining the reasoning process.[9] Conversely, data-driven pattern discoveries from multimodal learning are rarely formalized back into the knowledge graph to iteratively refine its ontological relationships and causal chains.[10] This lack of deep, bidirectional synergy prevents the formation of a closed-loop system where knowledge and data continuously inform and enhance each other.

Consequently, without such organic fusion, existing systems struggle to simultaneously fulfill the tripartite core requirements for next-generation intelligent diagnosis: high accuracy (leveraging data patterns), clear interpretability (grounded in explicit knowledge), and robust theoretical coherence with established medical doctrines (e.g., TCM pattern differentiation theory). Truly integrated frameworks would require mechanisms for dynamic knowledge orchestration and iterative knowledge-data alignment to overcome these limitations.

1.3 The Knowledge–Data Dual-Driven paradigm: a path forward

Consequently, the direct application of generic AI models to TCM is insufficient; a paradigm shift is required. This review proposes the "Knowledge-Data Dual-Driven" paradigm as the essential path forward. It seeks to transcend the current dichotomy by synergistically advancing two foundational pillars: Pathway I formalizes implicit TCM wisdom into explicit, computable knowledge structures (e.g., dynamic knowledge graphs, domain-specialized LLMs). Pathway II objectifies multimodal diagnostic

information to construct a "TCM Phenomics"—a high-dimensional, quantitative representation of clinical phenotypes grounded in TCM theory.[5] The ultimate goal is the deep integration of these pillars into next-generation, hybrid AI architectures that are accurate, interpretable, and clinically actionable.

While hybrid AI frameworks integrating symbolic and statistical approaches have been established in fields like biomedical informatics,[11] the novelty of the proposed paradigm lies in its design, which is tailored to the unique epistemological challenges of TCM. Unlike generic frameworks where domain knowledge often plays a supplementary role, this paradigm establishes a dynamic, bidirectional dialogue between codified TCM theory and multimodal clinical data. Its distinctive value is demonstrated in its direct address of three core TCM-specific challenges. First, the ontological primacy of holistic pattern differentiation, which necessitates the knowledge pillar's providing the essential framework for generating and interpreting phenotypic data. Second, the imperative for bidirectional translation between the continuous, narrative-based reasoning of TCM practice and the discrete, computational logic of AI systems. Third, the direct mitigation of characteristic TCM bottlenecks, including terminological ambiguity, the subjective nature of diagnostic methods, and the complex logic of herbal formula composition. Thus, this paradigm constitutes a domain-specific blueprint for bridging the fundamental epistemological gap in TCM modernization.

This paper will systematically review progress and challenges along these two pathways, analyze strategies for their integration, and discuss critical future directions, thereby charting a course for the intelligent and authentic modernization of TCM.

2 Pathway I: formalizing TCM knowledge—from texts to computable structures

The first pillar of the dual-driven paradigm addresses the critical challenge of transforming TCM's vast, implicit, and often unstructured empirical wisdom into explicit, structured, and computable knowledge representations. This pathway is essential for creating a machine-readable foundation that preserves the theoretical integrity and complex relational logic inherent in TCM systems.

2.1 Constructing large-scale TCM knowledge graphs

A primary strategy for knowledge formalization is the construction of comprehensive, multi-relational TCM KGs. KGs provide a semantic network that explicitly defines entities (e.g., herbs, symptoms, patterns, diseases, prescriptions) and their interrelationships (e.g., "treats", "is contraindicated with", "belongs to the meridian of"), thereby structuring the fragmented knowledge scattered across classical texts and clinical records.[12] This structured representation enhances the connectivity between TCM knowledge resources and uncovers latent connections, moving beyond simple text retrieval techniques to enable complex reasoning.

Recent research demonstrates significant progress in this area. For instance, the OpenTCM system extracted over 3.73 million classical Chinese characters from 68 gynecological books to construct a KG comprising more than 48,000 entities and 152,000 interrelationships.[13] This KG spans key TCM concepts, including ingredients, diseases, symptoms, and treatments. The construction process leveraged customized prompts and LLMs (e.g., DeepSeek, Kimi) to ensure high-fidelity semantic extraction from archaic texts, highlighting a synergistic approach where LLMs aid KG construction.[1] Similarly, other efforts have focused on building KGs from electronic health records (EHRs) for specific diseases like hepatitis B, while others aim to create integrated, multi-dimensional KGs to support broader multi-task applications.[12] These KGs serve as a structured, queryable backbone for intelligent systems, supporting tasks like herb-pair recommendation and clinical decision support by modeling the intricate "multi-component, multi-target, multi-pathway" relationship network of TCM.

2.2 Specialized large language models for TCM

While general-purpose LLMs have shown prowess in broad medical QA, their direct application to TCM is limited by a lack of domain-specific understanding, leading to inaccuracies and "hallucinations" when generating prescriptions or interpreting classical terminology. Consequently, developing TCM-specialized LLMs has become a crucial research direction. These models are pre-trained and/or fine-tuned on extensive, curated TCM corpora to internalize the domain's unique linguistic patterns, theoretical frameworks, and factual knowledge.

Several TCM-specialized models exemplify this trend, each adopting distinct strategies that reflect trade-offs between architectural complexity, data utilization, and clinical applicability. BianCang employs a two-stage knowledge injection and instruction fine-tuning approach on a diverse corpus (e.g., *Pharmacopoeia of the People's Republic of China*, TCM classics, clinical records, and KGs), prioritizing holistic clinical reasoning.[14] Tianyi, a 7.6B-parameter model trained on a similarly comprehensive collection, emphasizes integration of classical and modern data for broad diagnostic coverage.[15] In contrast, TCM-GPT-7B represents a lightweight, pre-trained-only option, suitable for scenarios requiring efficient specialization with limited resources.[16] Other models, such as Qibo and MedChatZH, further illustrate this landscape of diverse methodologies.[17]

The development of these specialized models addresses several core challenges: the lack of Chinese-language TCM knowledge during general pre-training, the unique

linguistic structure of classical texts, and the fragmented nature of modern clinical data. By leveraging domain-specific pre-training, they achieve superior performance on TCM tasks compared to general models. However, challenges remain, including the high cost of fine-tuning, ensuring reasoning depth and interpretability, and mitigating safety risks like generating harmful herb combinations.

To elucidate their relative merits and trade-offs, we propose an analysis framework centered on four key dimensions: architectural paradigm, data foundation, core strength, and principal limitation. These dimensions are critical for assessing a model's suitability for specific clinical or research tasks. A synthesis based on this framework is presented in Table 1.

The comparative analysis in Table 1 reveals a fundamental trade-off in current TCM LLM development: a tension between deep, holistic clinical reasoning (as exemplified by comprehensively pre-trained models like BianCang and Tianyi) and guaranteed factual accuracy and safety (as achieved by retrieval-augmented architectures like OpenTCM via knowledge graph grounding). The former risks "black-box" decisions and safety issues, while the latter may sacrifice the flexible, context-sensitive reasoning vital for novel clinical scenarios. This underscores that no single architecture has yet optimally synthesized both capabilities.

This analysis clarifies that the limitations of either approach necessitate their integration, thereby establishing a mutually reinforcing cycle central to the proposed dual-driven paradigm: domain-specialized LLMs can automate the construction and updating of KGs from unstructured corpora, while KGs in turn provide the structured framework to ground, constrain, and explain LLM outputs, thereby enhancing reliability, safety, and interpretability. This synergy is not merely technical; it represents an epistemological step towards realizing the dynamic, bidirectional dialogue between knowledge and data, essential for transforming TCM's implicit wisdom into an explicit, computable knowledge system.

Therefore, the synergistic cycle between LLMs and KGs is envisioned to mature into a formalized, computable knowledge system. This system must ultimately converge with the objective, data-driven stream generated by "TCM Phenomics" (Pathway II). The synthesis of these two forces—structured knowledge reasoning and high-dimensional phenotypic data—epitomizes the proposed dual-driven paradigm. This paradigm aims to resolve the unique epistemological and practical challenges central to TCM modernization by creating a dynamic framework where empirical wisdom and empirical evidence continuously inform and validate each other.

3 Pathway II: objectifying diagnostic information—toward TCM phenomics

The second pillar of the dual-driven paradigm addresses the core challenge of translating the traditionally subjective, experience-dependent diagnostic process of TCM into objective, quantifiable, and multimodal data. This pathway aims to construct a data-driven, high-dimensional representation of the patient state—termed TCM Phenomics—by digitally capturing and integrating information from the four diagnostic methods. This concept represents a specialized application of the phenomics paradigm, with a focus distinct from its general counterpart. While general phenomics seeks high-throughput measurement of traits to link genotype to disease, TCM Phenomics is fundamentally anchored in TCM theory, focusing on the holistic, dynamic "*Zheng Hou* (证候 pattern)" as its core clinical phenotype. Its primary objective is the systematic quantification of the macro-scale, multimodal signatures that constitute a *Zheng Hou*—precisely the data derived from the four diagnostic methods—thereby creating a bridge between TCM's diagnostic framework and modern data science.[18,19] This transformation is fundamental for enabling data-intensive AI analysis and moving TCM diagnostics from artisanal practice toward evidence-based science.

Table 1 Comparative analysis of representative TCM-specialized large language models

Model (Representative)	Core Technical Paradigm	Primary Training Data	Key Strengths	Principal Limitations	Indicative Application
BianCang[14], Tianyi[15]	Comprehensive, pre-training, fine-tuning	Integrated corpora (classics, modern texts, clinical records, KGs)	Holistic clinical reasoning; broad knowledge coverage	High resource cost; "black-box" reasoning; safety risks remain	End-to-end diagnostic simulation; comprehensive QA
TCM-GPT-7B[16]	lightweight, specialization (e.g., with LoRA)	Curated TCM textual corpus	Efficient deployment; lower computational barrier	Constrained reasoning depth; limited generalization	Focused task support (e.g., formula lookup)
OpenTCM (GraphRAG)	Knowledge-grounded, retrieval (RAG)	TCM Classics + Structured Knowledge Graph (KG)	High factual accuracy; mitigated hallucinations; improved safety	Reasoning flexibility may be reduced in novel scenarios	Safety-critical consultation; patient education
General purpose LLM (e.g., GPT-4)	Zero/Few-Shot, inference	General corpus (minimal TCM data)	Powerful baseline reasoning; strong on structured tasks	Lacks internalized TCM theory; prone to domain-specific hallucination	Benchmarking; exploring general model capabilities

Note: KG = Knowledge Graph; QA = Question Answering; RAG = Retrieval-Augmented Generation; GraphRAG = Graph-based Retrieval-Augmented Generation; LoRA = Low-Rank Adaptation.

3.1 Multimodal digital capture of the four diagnostic methods

The four diagnostic methods represent a quintessential yet historically subjective multimodal diagnostic process in TCM, where reliance on physician perception has led to inter-practitioner variability and hindered standardization. However, the advent of AI-powered sensors and algorithms is revolutionizing this domain by enabling the objective, digital capture and quantification of these diagnostic modalities.

Substantial progress has been made in digitizing and quantifying TCM diagnostic data. For inspection, computer vision algorithms extract quantifiable features from tongue and facial images for pattern differentiation. Self-supervised learning strategies automate feature extraction and reduce manual annotation burdens.[20] Furthermore, specialized deep learning frameworks have achieved accurate tongue feature classification and pattern differentiation across clinical cohorts.[6] The field is advancing toward standardization and integration, including end-to-end prescription generation from tongue features. A pivotal frontier is multimodal data fusion, where deep learning integrates data from all four diagnostic methods to emulate holistic diagnostic reasoning. Contemporary methods combine self-supervised learning with TCM-informed data augmentation to enhance model generalizability.[21]

Research in auscultation and olfaction is advancing the quantification of traditional diagnostic cues. For sound analysis, voiceprint recognition techniques, often based on Transformers, extract features from coughs and vocal tones.[22] Deep neural networks also analyze respiratory sounds with high diagnostic accuracy for conditions like diabetes.[23] For odor profiling, electronic nose systems combined with machine learning characterize volatile organic compounds (VOCs), enabling reproducible odor analysis,[24] multi-sensor arrays capture chemical signatures and, with ML algorithms, construct pattern libraries for TCM differentiation.[2] A key trend is multimodal integration of these signals with other examination data via deep learning/LLM frameworks to emulate holistic TCM reasoning. Persistent challenges remain in achieving high-fidelity sensing, and developing interpretable models for complex pulse patterns. Addressing these challenges requires advanced sensing technologies, deep learning methods such as 1D-CNN, specialized datasets, and portable monitoring devices.[25] Ultimately, rigorous clinical validation remains essential for clinical utility.

LLMs are deployed to standardize inquiry by generating systematic questions and structuring patient narratives, minimizing information loss. This has spurred specialized TCM LLMs (e.g., BianCang, Lingdan,[26] ShenNong-TCM[27]) fine-tuned on domain corpora for enhanced diagnostic support. To improve factual accuracy and reasoning reliability, frameworks increasingly integrate Chain-of-Thought (CoT), RAG, and KGs. Recent advances refine clinical reasoning through two-stage training, dialectical thinking simulation, and hybrid retrieval-instruction optimization to mitigate hallucinations.[28] Evaluation rigor is increasing via dynamic benchmarks (e.g., TCM-Eval) and self-iterative training, fostering model-data co-evolution.[29] Complex reasoning is further advanced by reinforcement learning and GraphRAG for interpretable clinical support.[13] Despite rapid progress, consensus emphasizes that rigorous validation with extensive real-world data remains essential for clinical utility and safety.

Palpation is digitally quantified via multi-sensor pulse analyzers that capture radial pulse waveforms, thereby translating tactile sensations into reproducible digital data.[30] Hardware advancements—such as flexible sensor arrays and wearable setups—enable high-fidelity, continuous monitoring at key positions (Cun [寸], Guan [关], Chi [尺]).[30] On the software side, deep learning models leverage these signals to classify complex pulse waveforms with high accuracy for disease diagnosis. Beyond analysis, frontier research employs generative AI to synthesize pulse data, mitigating dataset scarcity. A prominent shift is multimodal integration, combining pulse features with other examination data to construct comprehensive digital profiles for personalized diagnosis. Concurrent efforts on standardized benchmarks and interpretable AI are crucial for clinical translation. Key advances in digitalizing the four diagnostic methods are summarized in Table 2.

The integration of data from these multimodal sensors with deep learning algorithms facilitates the objective quantification of traditional diagnostic indicators, moving beyond isolated measurements. However, the digitization of individual modalities is insufficient. Advanced multimodal data fusion is essential for accurately modelling the patient's holistic condition and performing pattern differentiation, as signals from any single diagnostic method provide an incomplete picture. Therefore, the intelligent integration of complementary information from all four examinations, rather than their isolated digitalization, constitutes a defining trend and core challenge in the development of authentic TCM intelligent diagnostic systems.

3.2 Building TCM-oriented big data infrastructures

The systematic digital capture of the four diagnostic methods generates vast, heterogeneous, and high-dimensional datasets, forming the empirical bedrock of TCM Phenomics. However, constructing robust, TCM-oriented big data infrastructures to manage and utilize this data presents significant challenges that must be addressed to fuel AI-driven advancements.

A primary challenge is data quality and standardization. TCM data is characterized by multi-source heterogeneity, inconsistent formats, incompleteness, and a large proportion of unstructured content (e.g., classical texts, clinical

Table 2 AI-enhanced digitalization of the four diagnostic methods: advances, challenges, and clinical readiness

Diagnostic Method	Digital Object & Core AI Methods	Representative Advances & Techniques	Current Key Challenges	Status of Clinical Validation & Standardization
Inspection	Tongue/facial images; computer vision (CNN, self-supervised learning)	• High-precision tongue segmentation and feature classification[6] • End-to-end prescription generation from tongue features[6] • Self-supervised learning for automated feature extraction[20] • TCM-informed data augmentation to enhance model generalization[21]	• Standardization of image acquisition (lighting, positioning, environment) • Fine-grained quantification of complex features (e.g., coating texture, color nuances)	• Numerous retrospective studies available • Transitioning toward prospective multi-center validation • Urgent need for unified equipment and feature annotation standards
Auscultation & olfaction	Cough/voice sounds; audio processing (Transformer); body odor VOCs; electronic nose with ML	• Voiceprint analysis for disease detection (e.g., diabetes)[23] • ML-enhanced electronic nose for syndrome pattern profiling[2] • Multi-sensor arrays for capturing chemical signatures[24]	• Scarcity of high-fidelity, portable sensors • Lack of large-scale, clinically annotated datasets • Limited interpretability of models for complex odor–syndrome associations	• Early exploratory phase • Studies predominantly small-scale • Clinical utility requires rigorous validation
Inquiry	Patient complaints and dialogues; large language models (LLMs)	• Specialized TCM LLMs (e.g., BianCang, Lingdan, ShenNong-TCM)[14,26,27] • Enhanced reasoning via Chain-of-Thought, RAG, and knowledge graphs[28] • Dynamic evaluation benchmarks (e.g., TCM-Eval)[29] • Hallucination mitigation through optimized training strategies[28]	• Faithful integration of TCM logical reasoning into LLM architectures • Hallucinations and factual errors in generated content • Validation in real-world, multi-turn diagnostic dialogues	• Evaluation often limited to simulated or benchmark dialogues • Insufficient validation for real-world clinical decision support • Safety and reliability benchmarks still under development
Palpation	Radial pulse waveforms; multi-sensor pulse analyzers; deep learning	• High-fidelity wearable pulse monitoring devices • Deep learning for pulse waveform classification and disease prediction[30] • Generative AI (e.g., GANs, diffusion models) for synthetic pulse data augmentation	• Standardization of sensor placement and acquisition protocols • Digital translation of subjective tactile sensations (“finger-feel”) • Lack of interpretable models linking pulse features to pathophysiology	• Promising clinical correlations reported • Absence of unified pulse classification standards • Interpretable AI models urgently needed for clinical trust

Note: This table synthesizes representative advances; RAG = Retrieval-Augmented Generation; KG = Knowledge Graph; VOCs = Volatile Organic Compounds; TCM = Traditional Chinese Medicine.

narratives), which complicates integration and deep analysis. Furthermore, the absence of unified collection standards for diagnostic instruments leads to inconsistent data acquisition, further limiting holistic research.[31] Therefore, a foundational priority is to establish standardized systems and normalized databases containing the basic concepts of TCM. This involves developing automated feature extraction protocols, standardized imaging procedures, and machine learning algorithms that can identify consistent diagnostic patterns across multiple practices.

Furthermore, the acquisition of high-quality, annotated TCM data itself is a major bottleneck, requiring deep domain expertise, sustained clinical data collection, and extensive manual annotation, which are resource-intensive. The data encompasses not only modern clinical records but also classical literature, expert treatises, and pharmacological data, all requiring meticulous digitization and structuring.

To overcome these hurdles, future infrastructures must focus on four key areas: 1) Unified Data Protocols, including the development and adoption of community-wide standards for data collection (e.g., for tongue imaging, pulse signal acquisition) to ensure interoperability and reproducibility. 2) Multimodal Data Warehouses, including centralized or federated repositories that can store and link diverse data types—text (clinical notes, classics), images (tongue, face), signals (pulse, voice), and omics data—under a common patient or pattern identifier. 3) Advanced Data Processing Pipelines, leveraging AI technologies such as natural language processing (NLP) and computer vision to automatically extract, clean, structure, and annotate unstructured and semi-structured data at scale, thereby transforming raw data into a machine-readable format suitable for complex AI modeling. 4) Ethical and Secure Frameworks, implementing robust governance for data privacy, security, and ethical use, especially when dealing with sensitive patient health information.

The successful construction of such infrastructures is not merely a technical undertaking but an interdisciplinary imperative. It requires close collaboration between TCM clinicians, data scientists, biomedical engineers, and ethicists. Only with high-quality, standardized, and multimodal big data can the full potential of AI be unleashed to map microscopic omics data onto macroscopic TCM phenotypic traits, thereby constructing the evidence networks that are central to the TCM Phenomics vision.[22]

4 Envisioning TCM AI diagnostic models under the Knowledge-Data Dual-Driven paradigm

The ultimate goal of the Knowledge-Data Dual-Driven paradigm is the synthesis of formalized TCM knowledge (Pathway I) and objectified diagnostic data (Pathway II) into next-generation intelligent diagnostic systems. These systems aim to overcome the limitations of single-modality or single-algorithm approaches by leveraging hybrid AI architectures that synergistically combine the strengths of symbolic reasoning, data-driven learning, and human expertise. Concurrently, the evaluation of such systems must evolve beyond simplistic accuracy metrics to encompass dimensions of safety, interpretability, clinical utility, and alignment with TCM's holistic theoretical principles.

4.1 Hybrid AI architectures

The inherent complexity of TCM—encompassing symbolic theory, high-dimensional multimodal data, and experience-based clinical reasoning—necessitates AI architectures that are equally sophisticated and integrative. Pure data-driven models often struggle with the symbolic logic and causal relationships underpinning TCM pattern differentiation, while purely rule-based systems lack the adaptability to handle the variability and nuance of real-world clinical data. Therefore, the frontier of intelligent TCM diagnostics lies in the development of hybrid AI architectures that strategically combine multiple AI paradigms.

A prominent design is the integration of KGs with LLMs. KGs provide a structured, explicit representation of TCM entities (e.g., herbs, symptoms, patterns, meridians) and their relationships, offering a reliable source of factual knowledge and enabling logical inference.[32] LLMs, on the other hand, excel at processing unstructured text, understanding natural language queries, and generating fluent explanations. By augmenting LLMs with KG-retrieved evidence through techniques like RAG, systems can ground their responses in verified knowledge, significantly reducing hallucinations and improving diagnostic reliability. This hybrid approach, as exemplified by systems like OpenTCM, allows the model to leverage both the broad parametric knowledge of the LLM and the precise, structured knowledge of the KG for more accurate and traceable reasoning.

Another critical hybrid paradigm combines data-driven deep learning with interpretable, rule-based or symbolic reasoning modules. For instance, an AI model for TCM can start with pattern elements, use rule integration as a path variable, and symptom scores from guidelines as weights. It then forms recommended prescriptions through a multi-step process involving symptom combination, disease identification, pattern derivation, and formula generation.[33] This architecture embeds TCM's theoretical logic (rules) into a computational framework that can be refined with clinical data. Furthermore, hybrid methodologies that combine interpretable prior rules with deep learning models, utilizing layered credibility fusion systems, have been proposed for clinical decision support in TCM holistic differentiation diagnosis.[9] This ensures that the system's outputs are not only accurate but also interpretable and aligned with established TCM principles.

These hybrid architectures may also incorporate multi-model ensembles, where specialized models for tongue image analysis, pulse signal classification, and clinical text understanding work in concert, with a meta-model or fusion mechanism integrating their outputs for a comprehensive diagnosis. The overarching goal is to create systems that are greater than the sum of their parts: capable of deep pattern recognition from data while remaining grounded in and explicable through the rich symbolic framework of TCM theory.

4.2 Evaluation beyond accuracy

While predictive accuracy remains a fundamental metric, it is insufficient for evaluating intelligent TCM diagnostic systems intended for clinical support or knowledge dissemination. The unique characteristics of TCM and the high-stakes nature of medical AI demand a more comprehensive, multi-dimensional evaluation framework.

First, safety and ethical alignment are paramount. LLMs applied to TCM pose unique safety risks, such as generating harmful herb combinations or overlooking critical contraindications, which are not adequately addressed by general medical safety benchmarks. Therefore, evaluation must include rigorous testing for pharmacological safety, adherence to TCM contraindication principles (e.g., "*Shi Ba Fan* [十八反 eighteen incompatibilities]", "*Shi Jiu Wei* [十九畏 nineteen incompatibilities]"), and the avoidance of recommendations that conflict with established biomedical knowledge.

Second, interpretability and theoretical consistency are crucial for gaining the trust of TCM practitioners. The system's diagnostic reasoning should be transparent and traceable back to TCM theoretical constructs (e.g., yin-yang [阴阳], *Wu Xing* [五行 five elements], *Zang Xiang* theory [藏象学说 visceral manifestation theory]). Evaluations should assess not just what the system concludes, but how it arrives at that conclusion, ensuring its logic aligns with TCM's holistic and dialectical reasoning. Benchmarks like TCM-3CEval, which evaluates models across conceptual understanding, clinical reasoning, and safety/ethics, represent a step in this direction.

Third, clinical utility and human-AI collaboration must be evaluated. This involves assessing how the system performs in real-world, multi-turn diagnostic dialogues, its ability to handle ambiguous or incomplete patient information, and its role in augmenting rather

than replacing clinician judgment. The system should facilitate a collaborative process where it provides evidence-based suggestions that the practitioner can review, modify, and integrate into their final decision. Metrics here may include user satisfaction (from both practitioners and patients), time-to-decision efficiency, and the system's ability to explain its recommendations in clinically meaningful terms.

Finally, evaluation must consider robustness and generalizability across diverse patient populations, disease types, and schools of TCM thought. Systems should be tested on out-of-distribution data to ensure they do not exhibit catastrophic failure when faced with novel or rare presentations. The development of high-quality, multi-dimensional benchmarks that include not only textbook Q&A but also complex case simulations, multimodal diagnostic challenges, and ethical dilemmas is essential for driving the field toward clinically reliable and theoretically sound intelligent TCM systems.

5 Critical challenges and future directions

The journey towards fully realized, intelligent TCM systems, while promising, is fraught with significant hurdles that stem from the intrinsic complexity of TCM itself and the nascent state of its integration with advanced AI. Successfully navigating this path requires a clear-eyed assessment of the core bottlenecks, a steadfast commitment to interdisciplinary collaboration, and a guiding vision that places human clinicians and patients at the center of technological development.

5.1 Core bottlenecks

Several persistent and interconnected challenges currently constrain the development and deployment of robust AI systems for TCM.

First, data quality, standardization, and heterogeneity remain foundational obstacles. TCM data are characterized by multi-source heterogeneity, inconsistent formats, incompleteness, and a high proportion of unstructured content (e.g., classical texts, clinical narratives). The data collected by four diagnostic methods are highly subjective, with over 70% being unstructured, and lack unified collection standards, leading to inconsistent data acquisition.[34] This fragmentation severely hampers the construction of large-scale, high-quality datasets necessary for training reliable models. Furthermore, there is a scarcity of high-quality, integrative datasets that bridge TCM and modern biomedical knowledge.

Second, the inherent complexity of TCM theory and practice poses a unique modeling challenge. TCM's emphasis on holistic treatment, systemic balance, and pattern-based reasoning (pattern differentiation) is fundamentally different from the reductionist, disease-centric paradigm of Western medicine. AI systems must be sophisticated enough to comprehend and interpret these nuances, including the intricate interactions between herbal compounds and their effects on the human body. Translating abstract concepts like "qi imbalance (气机失调)" or "liver yang rising (肝阳上亢)" into computable, mechanistic models that can interface with molecular pathway data is a profound epistemological and technical challenge.

Third, significant gaps exist in model interpretability, reasoning depth, and safety. Many AI models, especially pure data-driven or LLM-based approaches, operate as "black boxes", generating answers without transparent, traceable reasoning back to TCM theoretical constructs.[9] This lack of interpretability erodes clinician trust and limits clinical utility. Furthermore, models may exhibit "hallucinations", generating plausible but incorrect or even unsafe recommendations, such as harmful herb combinations or overlooking critical contraindications like the "*Shi Ba Fan*" and "*Shi Jiu Wei*".[35] Existing safety benchmarks are inadequate for TCM's nuanced protocols.

Finally, ethical considerations and integration into clinical workflows are critical yet under-addressed bottlenecks. Issues of patient data privacy, informed consent for using AI-processed clinical data, and the transparency of AI algorithms need resolution for broader acceptance. Moreover, simply achieving high accuracy on a benchmark is insufficient; systems must be designed for seamless integration into real-world clinical practice, supporting rather than disrupting the practitioner's workflow and decision-making process.

5.2 Interdisciplinary imperatives

Overcoming these bottlenecks is not a task for AI or TCM specialists alone; it demands deep, sustained interdisciplinary collaboration. The future of intelligent TCM hinges on the synergy between TCM clinicians and theorists, data scientists, AI engineers, bioinformaticians, ethicists, and Western medical researchers.

A primary imperative is the co-development of domain-adapted AI methodologies and benchmarks. AI researchers must work hand-in-hand with TCM experts to develop models that are not just trained on TCM data but are architecturally aligned with TCM's logic. This includes creating hybrid models that combine the pattern recognition power of deep learning with explicit, interpretable symbolic rules derived from TCM theory. Similarly, the development of comprehensive, multi-dimensional evaluation benchmarks like TCM-3CEval—which assesses conceptual understanding, clinical reasoning, and safety/ethics—is essential and requires joint expertise.

Furthermore, advancing TCM phenomics and multi-omics integration is a quintessentially interdisciplinary endeavor. It requires biologists and bioinformaticians to generate and analyze genomic, proteomic, and metabolomic data, while TCM researchers provide the clinical

and theoretical framework to link these molecular signatures to macroscopic TCM patterns and phenotypes. This collaboration is key to objectifying TCM diagnostics and uncovering the material basis of its effects.

Finally, establishing data standards and shared infrastructures necessitates consensus across institutions, schools of TCM thought, and technical domains. Creating federated learning frameworks to build cross-institutional databases while protecting privacy, and developing unified ontologies and annotation protocols for TCM concepts, are large-scale projects that can only succeed through coordinated, interdisciplinary effort.

5.3 Toward human-centered intelligent TCM

The ultimate goal of integrating AI into TCM is not to replace the practitioner but to augment human expertise, making TCM care more precise, accessible, and evidence-based. Future systems must be designed with a human-centered AI philosophy.

This means developing AI as a collaborative clinical decision support system (CDSS). The AI should act as an intelligent assistant, providing data-driven insights, differential diagnosis suggestions, or literature-supported treatment options that the clinician can review, modify, and integrate into their holistic assessment. The system must enhance, not replace, the crucial practitioner-patient relationship and the clinician's experiential judgment.

Key to this collaboration is enhanced interpretability and interactive explainability. Systems should not only output a diagnosis or prescription but also provide the reasoning chain—which symptoms led to which pattern elements, which classical texts or case records support the conclusion, and what potential alternatives or cautions exist. Visualizations of rule activation or knowledge graph traversals can make the AI's "thought process" more accessible.

Looking ahead, the vision extends beyond diagnosis to personalized, predictive, and preventive care. By integrating longitudinal patient data, genetic information, and lifestyle factors with TCM constitutional theory, AI could help model disease progression and suggest personalized preventive regimens. Furthermore, AI can play a vital role in TCM education and knowledge dissemination, creating interactive tutoring systems for students and providing the public with reliable, AI-vetted TCM health information.

In conclusion, the path forward requires balancing innovation with rigor. It calls for building AI that is deeply respectful of TCM's theoretical integrity, rigorously evaluated for safety and efficacy, seamlessly integrated into human-centric workflows, and developed through genuine partnership across disciplines. The promise is not just "intelligent TCM", but augmented TCM—where millennia of empirical wisdom are powerfully amplified by computational intelligence, leading to more effective, personalized, and scientifically grounded healthcare.

6 Conclusion

The modernization of TCM stands at a pivotal crossroads, where its ancient empirical wisdom must converge with the rigorous demands of contemporary evidence-based science and technological innovation. This review has articulated and defended a Knowledge–Data Dual-Driven paradigm as the foundational framework for this essential transition. This paradigm does not seek to replace the holistic and dialectical core of TCM theory but aims to build computational bridges that translate its principles into actionable, verifiable, and scalable intelligent systems.

The first pathway, Formalizing TCM Knowledge, addresses the challenge of encoding millennia of implicit, textual, and experiential knowledge into explicit, computable structures. The construction of large-scale, multi-relational KGs, such as TCMSSD[36] and those built for specific applications like OpenTCM or case retrieval,[37] provides the essential semantic backbone. Concurrently, the emergence of specialized LLMs—ranging from general-purpose TCM models like Tianyi and Qibo[38] to task-specific systems like TCM-GPT for prescription generation and BianQue for multi-turn health dialogue[39]—demonstrates the power of deep learning to internalize and perform reasoning upon this structured and unstructured knowledge. These models are moving beyond mere pattern matching to engage in dialectical reasoning and differential exclusion, as seen in frameworks like DiagX-DT[28].

The second, complementary pathway, Objectifying Diagnostic Information, tackles the historical subjectivity of the four diagnostic methods by transforming them into quantifiable, multimodal digital phenotypes. Significant progress has been made in digitizing tongue diagnosis, with deep learning models achieving high accuracy in identifying features like teeth-marked tongue[40] and prickly tongue[41], and even linking tongue images to specific conditions like gastric cancer[42] or CKD[43]. Similarly, pulse diagnosis is being revolutionized by wearable, high-sensitivity sensor arrays[44] and AI models that analyze waveform data for disease prediction.[45] The aggregation of such multimodal data—images, waveforms, textual symptoms—forms the "TCM-Oriented Big Data" necessary for building robust, data-driven models.

The true potential of Intelligent TCM[46] is unlocked at the integration point of these two pathways. Next-generation systems are increasingly built on hybrid AI architectures that synergistically combine the strengths of KGs and LLMs, as exemplified by KG2TRAG-enhanced models for lung cancer Q&A and TCM-KLLaMA for prescription generation. Furthermore, evaluation is maturing beyond simple accuracy metrics. Comprehensive, domain-specific benchmarks like

TCMBench,[47] TCM-3CEval, and MTCMB now assess models across dimensions of core knowledge, classical text comprehension, clinical reasoning, and safety, providing a more holistic view of a system's readiness for clinical application, and establishing a critical threshold for translational validation.

However, this journey is fraught with critical challenges. Core bottlenecks persist, including data scarcity, heterogeneity, and a lack of standardized, high-quality multimodal datasets. Model adaptability remains an issue, as systems trained on narrow tasks often fail to generalize to the complex, holistic reasoning required in real-world TCM practice. Significant methodological and evaluation gaps exist, with many models lacking rigorous clinical validation and transparent reasoning processes. Perhaps most critically, the integration of AI into TCM raises profound ethical and privacy dilemmas, particularly concerning the handling of culturally sensitive health information.

Addressing these challenges demands interdisciplinary approaches. Close collaboration among TCM practitioners, data scientists, clinical researchers, and ethicists is essential. Future research must focus on creating larger, ethically sourced, and well-annotated multimodal datasets. AI architectures need to evolve towards greater interpretability and the ability to incorporate causal and dialectical reasoning explicitly. Evaluation frameworks must become more dynamic, clinically grounded, and capable of assessing the longitudinal impact of AI-assisted decisions on patient outcomes.

Ultimately, the goal is to advance toward human-centered intelligent TCM. The technology should not aim to automate physicians but to augment their expertise. The ideal system acts as a computational stethoscope—translating subtle phenotypic signals into interpretable clinical insights—thereby operationalizing the vision of "TCM Phenomics", which seeks to establish a closed-loop framework linking syndrome, phenotype, mechanism, and intervention.

In conclusion, the Knowledge–Data Dual-Driven paradigm offers a coherent and productive roadmap for TCM modernization. By systematically formalizing its theoretical corpus and objectively digitizing its diagnostic practices, and then intelligently fusing these streams through advanced AI, TCM can transcend its historical limitations without sacrificing its unique strengths. The convergence of TCM's holistic philosophy with the analytical power of computational intelligence holds the promise of a more robust, personalized, and globally accessible model of medicine, contributing uniquely to the future of integrative and precision healthcare.

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This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

YOU Fei conducted the investigation and drafted the original manuscript. SHAO Qiongyan was responsible for conceptualization, original draft writing, as well as manuscript review and editing.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

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References

[1] Yip HF, Li Z, Zhang L, Lyu A. Large language models in integrative medicine: progress, challenges, and opportunities. *Journal of Evidence-Based Medicine*. 2025;18(2):e70031.
[2] Sun Y. Research on the application of artificial intelligence technology in modern traditional Chinese medicine assisted consultation and dialectic. *Health, Medicine and Therapeutics*. 2025;1(1):35–53.
[3] Zhang FW, Hu J, Sun YZ. Underwater fish image recognition based on knowledge graphs and semi-supervised learning feature enhancement. *Scientific Reports*. 2025;15(1):45245.
[4] Tian ZK, Wang DJ, Sun X, et al. Current status and trends of artificial intelligence research on the four traditional Chinese medicine diagnostic methods: a scientometric study. *Annals of Translational Medicine*. 2023;11(3):145.
[5] Xu M, Shao XY, Guo DG, et al. Phenomics of traditional Chinese medicine 2.0: the integration with digital medicine. *Digital Chinese Medicine*. 2025;8(3):282–299.
[6] Yin L, Xue XY, Pan SS, et al. Artificial intelligence in traditional Chinese medicine: systematic insights from data mining, large language models, and multimodal fusion. *Acta Materia Medica*. 2025;4(4):674–697.
[7] Wang XQ, Du X, Cao Q, et al. Interpretation and application of terms related to phenomics of traditional Chinese medicine (中医药表型组学相关术语释义与应用). *Journal of Nanjing University of Traditional Chinese Medicine*. 2023;39(3):210–220. Chinese.
[8] Li HT, Xia CM, Hou YJ, et al. TCMRD-KG: innovative design and development of rheumatology knowledge graph in ancient Chinese literature assisted by large language models. *Frontiers in Pharmacology*. 2025;16:1535596.
[9] Chen Z, Zhang D, Nie PF, et al. Developing the artificial intelligence method and system for "multiple diseases holistic differentiation" in traditional Chinese medicine and its interpretability to clinical decision. *Journal of Evidence-Based Medicine*. 2025;18(2):e70016.
[10] Dong X, Zhao WY, Li FF, et al. Semantic repurposing model for traditional Chinese ancient formulas based on a knowledge graph. *Digital Discovery*. 2026;5(1):317–331.
[11] Zhang Q, Zhou JH, Zhang B. Computational traditional Chinese medicine diagnosis: a literature survey. *Computers in Biology and Medicine*. 2021;133:104358.
[12] Long JJ, Niu JH, Wang HP, et al. RTGN: robust traditional Chinese medicine graph networks for patient similarity learning. *IEEE Journal of Biomedical and Health Informatics*. 2024;29(3):2185–2198.

[13] He JL, Guo YQ, Lam LK, et al. OpenTCM: a graphRAG-empowered LLM-based system for traditional Chinese medicine knowledge retrieval and diagnosis. *arXiv preprint arXiv: 250420118*. 2025.
[14] Wei SB, Peng XP, Wang YF, et al. Biancang: a traditional chinese medicine large language model. *IEEE Journal of Biomedical and Health Informatics*. 2025:1–12.
[15] Liu Z, Yang T, Wang J, et al. Tianyi: a traditional Chinese medicine all-rounder language model and its real-world clinical practice. *Information Fusion*. 2025:103663.
[16] Yang GX, Liu XH, Shi JY, et al. TCM-GPT: efficient pre-training of large language models for domain adaptation in traditional Chinese medicine. *Computer Methods and Programs in Biomedicine Update*. 2024;6:100158.
[17] Zhou CF, Gong QY, Zhan WD, et al. TCMLCM: an intelligent question-answering model for traditional Chinese medicine lung cancer based on the KG2TRAG method. *Digital Chinese Medicine*. 2025;8(1):36–45.
[18] Yan DY, Zheng QG, Chang K, et al. Artificial intelligence in traditional Chinese medicine: from systems biological mechanism discovery, real-world clinical evidence inference to personalized clinical decision support. *Chinese Journal of Natural Medicines*. 2025;23(11):1310–1328.
[19] Zhang MJ, Wen GH, Yang P, et al. Multi-label body constitution recognition via HWmixer-MLP for facial and tongue images. *Expert Systems with Applications*. 2025;269:126383.
[20] Liu Q, Xu D D, Yang P, et al. The contrastive learning method in tongue image representation learning and its significance in intelligent diagnosis. *Health Information Science and Systems*. 2025;13(1):51.
[21] Yan YD, Li CX, Huang Y, et al. TCDiff: triplex cascaded diffusion for high-fidelity multimodal EHRs generation with incomplete clinical data. *arXiv preprint arXiv:250801615*. 2025.
[22] Liu GC, Long X, Peng QH, et al. Advances and prospects of the integration of multi-omics and artificial intelligence in traditional Chinese medicine research. *Digital Chinese Medicine*. 2025;8(3):300–312.
[23] Sui D, Zhang L, Yang F. Data-driven based four examinations in TCM: a survey. *Digital Chinese Medicine*. 2022;5(4):377–385.
[24] Li MY, Zhu JQ, Liu XN, et al. Application and research progress on artificial intelligence in the quality of traditional Chinese medicine. *Front Pharmacol*. 2025;16:1687681.
[25] Lu LK, Lu TS, Tian CY, et al. AI: bridging ancient wisdom and modern innovation in traditional Chinese medicine. *JMIR Medical Informatics*. 2024;12:e58491.
[26] Hua R, Dong X, Wei Y, et al. Lingdan: enhancing encoding of traditional Chinese medicine knowledge for clinical reasoning tasks with large language models. *Journal of the American Medical Informatics Association*. 2024;31(9):2019–2029.
[27] Anonymous. ShenNong-TCM: a traditional Chinese medicine large language model. 2023. Available from: https://github.com/michael-wzhu/ShenNong-TCM-LLM. [Accessed on March 15 2026].
[28] Nie GX, Zhou YL, Xu DY, et al. DiagX-DT: diagnostic exclusion reasoning with dialectical thinking for traditional Chinese medicine in large language models. *Journal of King Saud University Computer and Information Sciences*. 2025;37(5):1–11.
[29] Cheng ZH, Lu YH, Ye HQ, et al. TCM-Eval: an expert-level dynamic and extensible benchmark for traditional Chinese medicine. *arXiv preprint arXiv:251107148*. 2025.
[30] Liu TZ, Gou GY, Gao FP, et al. Multichannel flexible pulse perception array for intelligent disease diagnosis system. *ACS Nano*. 2023;17(6):5673–5685.
[31] Xu JT, Jiang T, Liu S. Research status and prospect of tongue image diagnosis analysis based on machine learning. *Digital Chinese Medicine*. 2024;7(1):3–12.
[32] Zhuang Y, Yu LK, Jiang N, et al. TCM-KLLaMA: intelligent generation model for traditional Chinese medicine prescriptions based on knowledge graph and large language model. *Computers in Biology and Medicine*. 2025;189:109887.
[33] Wang J, Duan L, Li HZ, Liu J, Chen H. Construction of an artificial intelligence traditional Chinese medicine diagnosis and treatment model based on syndrome elements and small-sample data. *Engineering*. 2022;8:29–32.
[34] Meng XL, Lang YJ, Li XF, et al. Progress in the application of AI in the standardization of traditional Chinese medicine: a review based on machine learning and deep learning. *Pharmacological Research-Modern Chinese Medicine*. 2025;16:100639.
[35] Kong SF, Yang XR, Wei YY, et al. MTCMB: a multi-task benchmark framework for evaluating LLMs on knowledge, reasoning, and safety in traditional Chinese medicine. *arXiv preprint arXiv:250601252*. 2025.
[36] Huang L, Wang Q, Duan QC, et al. TCMSSD: a comprehensive database focused on syndrome standardization. *Phytomedicine: International Journal of Phytotherapy and Phytopharmacology*. 2024;128:155486.
[37] Duan YC, Zhou QQ, Li Y, et al. Research on a traditional Chinese medicine case-based question-answering system integrating large language models and knowledge graphs. *Frontiers in Medicine*. 2025;11:1512329.
[38] Zhang HY, Wang X, Meng ZP, et al. Qibo: a large language model for traditional Chinese medicine. *arXiv preprint arXiv:240316056*. 2024.
[39] Chen YR, Wang ZY, Xing XF, et al. BianQue: balancing the questioning and suggestion ability of health LLMs with multi-turn health conversations polished by ChatGPT. *arXiv preprint arXiv:231015896*. 2023.
[40] Wang X, Liu JW, Wu CY, et al. Artificial intelligence in tongue diagnosis: using deep convolutional neural network for recognizing unhealthy tongue with tooth-mark. *Computational and Structural Biotechnology Journal*. 2020;18:973–980.
[41] Peng CD, Wang L, Jiang DM, et al. Establishing and validating a spotted tongue recognition and extraction model based on multiscale convolutional neural network. *Digital Chinese Medicine*. 2022;5(1):49–58.
[42] Yuan L, Yang L, Zhang SC, et al. Development of a tongue image-based machine learning tool for the diagnosis of gastric cancer: a prospective multicentre clinical cohort study. *EClinicalMedicine*. 2023;57:101834.
[43] Chung CJ, Wu CH, Hu WL, et al. Tongue diagnosis index of chronic kidney disease. *Biomedical Journal*. 2023;46(1):170–178.
[44] Zhao YL, Sun QX, Mei SX, et al. Wearable multichannel-active pressurized pulse sensing platform. *Microsystems & Nanoengineering*. 2024;10:77.
[45] Yeh WC, Kuo CY, Chen JM, et al. Pioneering data processing for convolutional neural networks to enhance the diagnostic accuracy of traditional Chinese medicine pulse diagnosis for diabetes. *Bioengineering (Basel)*. 2024;11(6):561.
[46] Tian GH, Qian K, Li XY, et al. Can a holistic view facilitate the development of intelligent traditional Chinese medicine? A survey. *IEEE Transactions on Computational Social Systems*. 2023;10(2):700–713.
[47] Yue WJ, Wang XL, Zhu W, et al. TCMbench: a comprehensive benchmark for evaluating large language models in traditional chinese medicine. *arXiv preprint arXiv:240601126*. 2024.

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Original Article

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From Sichuan to the World: ISO Standards in Quality Control and International Trade of Chinese Herbal Medicine *Chuan Xiong*

从四川走向世界：川芎中药材质量控制和国际贸易中的ISO标准

HOU Kai (侯凯)[1], JIANG Shunyuan (蒋舜媛)[2,3,✉], WANG Mei (王梅)[4,5,✉]

Abstract

This study examines *Chuan Xiong* (川芎 Rhizoma Ligustici Chuanxiong), a traditional Chinese medicinal herb cultivated in Sichuan Province, China. By systematically investigating its botanical origin, cultivation history, and international trade dynamics, the study identifies a sharp decline in global exports—once peaking at approximately 10,000 tons—and evaluates the impact of divergent pharmacopoeial standards, particularly the 2017 requirements of the *European Pharmacopoeia*, on trade performance. Through a historical literature review and a comparative analysis of pharmacopoeial standards across different countries and regions, the research confirms the Sichuan-specific origin and cultivation heritage of *Chuan Xiong*, and reveals inconsistencies in key quality control parameters, including botanical identification, macroscopic characteristics, moisture limits, and bioactive constituents. Through iterative negotiations and scientific consultations among relevant stakeholders, an international consensus was achieved, resulting in the development of a harmonized, evidence-based quality framework, which was subsequently adopted as an ISO standard under ISO/TC 249. This internationally aligned standard addresses previous discrepancies in both parameter selection and specification limits, more accurately reflecting the distinctive quality profile of *Chuan Xiong*. The establishment of this ISO standard provides a scientifically robust and globally recognized basis for quality control, and is expected to support the recovery of exports and facilitate the integration of *Chuan Xiong* into international markets. Ultimately, this initiative provides a replicable model for the global harmonization of quality standards for traditional medicinal botanicals.

Keywords: *Chuan Xiong* (川芎 Rhizoma Ligustici Chuanxiong); Chinese herbal medicine; Quality control; International standards; International trade; International Organization for Standardization (ISO)

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1 Introduction

Rhizoma Ligustici Chuanxiong, known as *Chuan Xiong* (川芎) in Chinese and Sichuan lovage in English, is the dried rhizome of Ligusticum Chuanxiong Hort., belonging to the Apiaceae family.[1] The rhizome is irregularly nodular and fist-shaped, measuring 2–7 cm in diameter. Its surface is brown to dark brown, coarse, and wrinkled, with numerous parallel protuberances at the nodes. The apex bears a concave, rounded stem scar, while the base and nodes are marked by many small tuberculate rootlet scars. The cut surface is greyish yellow to yellowish white, scattered with yellowish-brown oil cavities and a wavy cambium ring (Fig. 1). It emits a characteristic strong aroma, with a slightly numbing initial taste followed by a faintly sweet aftertaste. To sum up, *Chuan Xiong* holds a prestigious position in traditional Chinese medicine (TCM) and has been widely used as a core herb in clinical practice for centuries, renowned for its efficacy in promoting blood circulation, dispelling wind, and alleviating pain.[2] It is an indispensable component

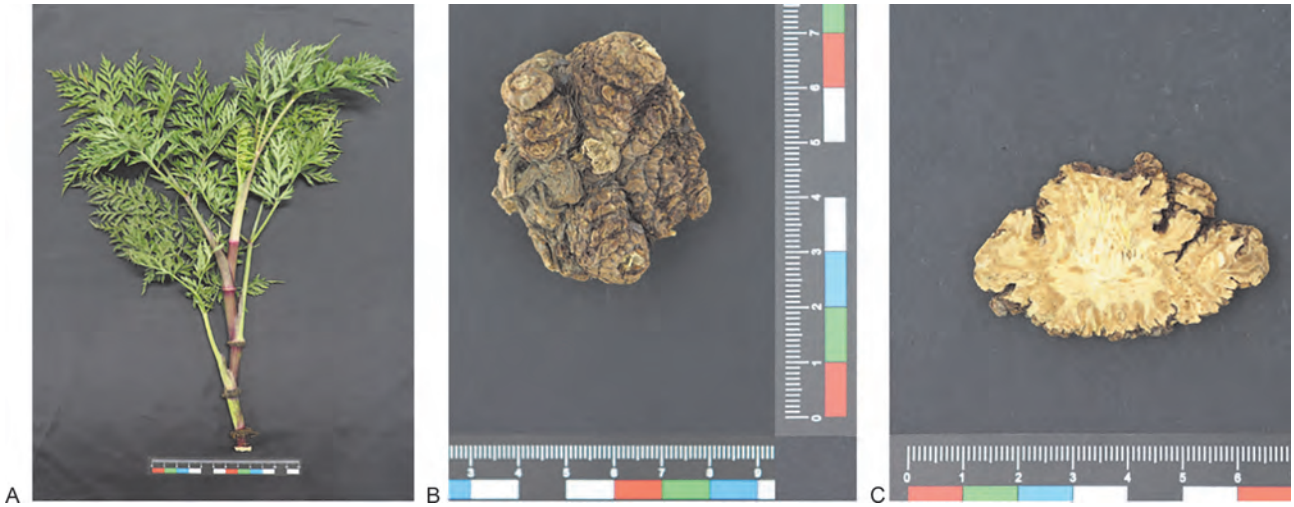


Figure 1 *Chuan Xiong* (川芎 Rhizoma Ligustici Chuanxiong): A Aerial parts of the *Chuan Xiong* plant; B Crude medicine (rhizome) of *Chuan Xiong*; C Sliced crude medicine of *Chuan Xiong* (source with permission from: Sichuan Agricultural University)

of numerous classical TCM formulas. According to statistics, the 2020 edition of the *Pharmacopoeia of the People's Republic of China (Volume I)* contains 1,607 Chinese medicinal patent formulas, among which 246 formulas—including single-ingredient and compound formulas—contain *Chuan Xiong*, accounting for 15.3%.[3] Several proprietary and classical formulas utilize this ingredient, including *Su Xiao Jiu Xin Wan* (速效救心丸 Rapid-Acting Angina-Relieving Pill), *Nao De Sheng Pian* (脑得生片 Cerebral Revitalizing Tablets), and *Si Wu Tang* (四物汤 Four Substances Decoction). In 2002, *Chuan Xiong* was included, along with 114 other medicinal materials such as ginseng, gastrodia, eucommia, and turmeric, in *The Catalogue of Raw Materials for Health Food* (Document No. [2002] 51 issued by the Ministry of Health of the People's Republic of China), and has been regulated as a specific food ingredient. As the geo-authentic origin of this herb, Sichuan Province (四川省) is the core geo-authentic producing area worldwide, accounting for over 80% of the national output.[4] The unique microclimate and cultivation traditions are integral to the distinctive quality of *Chuan Xiong*.

Historically, *Chuan Xiong* has maintained a substantial presence in the international market, with annual exports peaking at approximately 10,000 tons—many of which were destined for the global traditional medicine and herbal product sectors. However, this trade has recently faced challenges due to increasingly stringent and sometimes inconsistent international quality standards. Therefore, it is imperative to systematically review the historical and industrial context of *Chuan Xiong*. The development and implementation of an International Organization for Standardization (ISO) international standard represent a crucial strategic step toward harmonizing these standards, enhancing product quality control, and ultimately fostering the sustainable development and global expansion of the *Chuan Xiong* industry.

The comparative analysis was carried out using a structured multi-step approach, integrating official trade statistics with a detailed examination of the ISO standard development process. Trade data were sourced from the Ministry of Commerce of the People's Republic of China. The ISO standard development process was systematically examined via a review of official protocols, with a focus on consensus building, technical committee deliberations, and public consultation. Crucially, the formulation of these standards is predicated on a foundation that synthesizes traditional knowledge with contemporary practice, rigorously supported by data from scientific testing and statistical analysis. This methodology provides a comprehensive view of both the economic landscape and the regulatory framework governing the standard.

2 Naming in history and geo-authentic origin changes of *Chuan Xiong*

2.1 Nomenclature: historical records of the names of *Chuan Xiong* in ancient medical texts

Chuan Xiong, also known as *Xiong Qiong* (芎藭), was first mentioned in *Shan Hai Jing* (《山海经》*The Classic of Mountains and Seas*): "Further north for a hundred li lies Mount Xiu. Its summit yields jade and dark green jasper. The trees are mostly junipers, and the plants are abundant in *Shao Yao* (芍药 Peony) and *Xiong Qiong* (又北百里，曰绣山，其上有玉、青碧，其木多桫，其草多芍药、芎藭)". *Chuan Xiong* was first documented as a medicinal herb in *Shen Nong Ben Cao Jing* (《神农本草经》*Shen Nong's Classic of the Materia Medica*), which was compiled during the Qin and Han dynasties (221 BC–220 AD).

Interestingly, the National Palace Museum in Taipei, China, houses *Chun Xi Mi Ge Xu Tie* (《淳熙秘阁续帖》*Continued Calligraphy Model Compendium of the*

Chunxi Era), which includes Sun Simiao's (孙思邈) *Su Mi Tie* (《粟米帖》*Millet Calligraphy*) (Fig. 2). This work mentions *Chuan Xiong* and is now the only extant calligraphic work by Sun Simiao, the renowned "King of Medicine (药王)" in Chinese history.

The name *Chuan Xiong* first emerged in *Xian Shou Li Shang Xu Duan Mi Fang* (《仙授理伤续断秘方》*Secret Formulary Bestowed by Immortals for Treating Injuries and Mending Fractures*) during the Sui and Tang dynasties (581–907 AD), which stated: "White medicinal powder, ... *Chuan Xiong* (half jin, soaked in hot water seven times) (白药末，……川芎（半斤，汤泡七次）)". By the Jin dynasty (1115–1234 AD), Zhang Yuansu (张元素), in his work *Yi Xue Qi Yuan* (《医学启源》*Origin of Medicine*), abandoned the name *Xiong Qiong* and adopted *Chuan Xiong* for both prescriptions and medicinal descriptions (Fig. 3). *Fang Feng Tong Sheng San* (防风通圣散 Ledebouriella Sage-inspired Powder), the first formula in this work to include *Chuan Xiong*, represents one of the earliest recorded uses of the herb under the name "*Chuan Xiong*". This work is thus recognized as the first herbal text to formally establish *Chuan Xiong* as the standard common name, a designation that gradually replaced the earlier term *Xiong Qiong* in subsequent literature.

2.2 Production regions: historical shifts in the origins of *Chuan Xiong* and the geo-authenticity of Sichuan *Chuan Xiong*

The character Chuan (川) in *Chuan Xiong* refers specifically to Sichuan Province, indicating that this variety of *Xiong Qiong* originates from this region and is distinguished by its geo-authentic quality. This naming

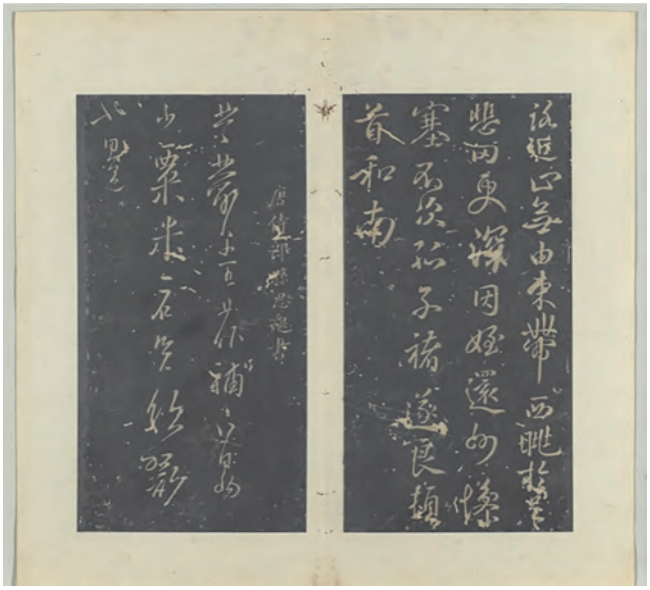


Figure 2 Transcription of Sun Simiao's *Millet Calligraphy*, contained within *Chun Xi Mi Ge Xu Tie* (唐·《淳熙秘阁续帖》*Continued Calligraphy Model Compendium of the Chunxi Era*) (Source with permission from: https://www.sftj.com/sfzitie/128099eloa/)



Figure 3 *Yi Xue Qi Yuan* (《医学启源》*Origin of Medicine*) (source with permission from: https://www.shidianguji.com/)

convention is not unique to *Chuan Xiong*, but is widely applied to a range of renowned authentic Chinese medicinal materials produced in Sichuan, such as *Chuan Bei Mu* (川贝母 Bulbus Fritillariae Cirrhosae), *Chuan Wu* (川乌 Aconiti Radix), *Chuan Mu Tong* (川木通 Caulis Clematidis Armandii), *Chuan Mu Xiang* (川木香 Radix Vladimiriae), *Chuan She Gan* (川射干 Rhizoma Iridis Tectori), and *Chuan Lian Zi* (川楝子 Fructus Toosendan). In each case, the prefix "Chuan" signifies not only geographical origin but also an established reputation for superior quality shaped by Sichuan's unique ecological conditions. This prominence is further reflected in the well-known saying, "No formula is complete without Sichuan medicinal herbs (无川药不成方)", which underscores the indispensable role that Sichuan-origin materia medica has historically played in the formulation and efficacy of traditional Chinese herbal formulas. Beyond a simple expression of regional pride, this phrase encapsulates a broader recognition of the centrality of Sichuan's medicinal resources within the knowledge system and practice of TCM.

Historical records from various materia medica texts indicate that the production areas of *Chuan Xiong* have shifted multiple times. *Shen Nong Ben Cao Jing* merely recorded that it "grows in mountain valleys". During the Wei and Jin dynasties (220–420 AD), the Wugong (武功) and Zhongnan (终南) areas in Shaanxi Province (陕西省) were explicitly identified as the primary producing regions.

A significant transition occurred during the Northern and Southern dynasties (420–589 AD). Following the Yongjia Upheaval (永嘉之乱), a major wave of southward population migration, Liyang (历阳) in Anhui

Province (安徽省) emerged as the principal production area. It was during this period that the earliest records of *Chuan Xiong* cultivation appeared. Based on textual research, Shan Feng (单锋) and colleagues proposed that *Ma Xian Xiong Qiong* (马衔芎藭) produced in Liyang during the Liang dynasty (502–557 AD) was most likely a cultivated product, suggesting that the cultivation history of this herb can be traced back more than 1,500 years.[5]

Following reunification under the Tang dynasty (618–907 AD), the authentic production area shifted to Qinzhou prefecture (秦州, modern-day Tianshui area [天水地区], Gansu Province [甘肃省]), where cultivated *Chuan Xiong* was used as tribute to the imperial court. It was also during this period that the name "*Chuan Xiong*" began to appear in medical formularies. *Xin Xiu Ben Cao* (《新修本草》 *Newly Revised Materia Medica*), published in 659 AD in the Tang dynasty, provides the earliest pharmacopoeial record of *Chuan Xiong* cultivation, stating: "(*Xiong Qiong*) is presently produced in Qinzhou. Cultivated specimens exhibit large, heavy, and compact rhizomes with abundant oily moisture, whereas those collected from mountainous regions are slender and thin ([芎藭]今出秦州，其人间种者，形块大，重实，多脂润，山中采者瘦细)". This passage not only documents the practice of cultivation but also offers a comparative description of the characteristics of cultivated versus wild-harvested specimens.

By the Song dynasty, the Sichuan region had been officially recognized as the genuine producing area of *Chuan Xiong*, and the name *Chuan Xiong* gradually became the standard appellation, even though the herb was also produced in Shaanxi, Gansu, and the Jiangdong area (eastern Jiangsu Province) at that time.[6] In the Northern Song dynasty, Tang Shenwei's (唐慎微) *Zheng Lei Ben Cao* (《证类本草》 *Materia Medica Arranged According to Pattern*) cited *Tu Jing Ben Cao* (《图经本草》 *Illustrated Classic of Materia Medica*) in its assessment of *Chuan Xiong* quality, emphasizing that "the product from the Shuchuan region (present-day Sichuan) is superior". The text further noted: "This herb is now commonly found in the mountains of Guanshan, Shuchuan, and Jiangdong, but that produced in Shuchuan is regarded as the finest (今关陕、蜀川、江东山中多有之，而以蜀川者为胜)" (Fig. 4). Su Shi (苏轼), a renowned poet of the Song dynasty, made two explicit records of picking and consuming *Chuan Xiong* shoots. In the poem "Eleventh set of poems on grasses and trees in the garden, in response to Ziyou, no. 8 (《和子由记园中草木十一首其八》)": "*Xiong Qiong* grows in the Shu Roads (in the Jian Nan region), *Bai Zhi* (白芷 Radix Angelicae Dahuricae) comes from the South of the Lower Yangtze.... Before it flowers and bears fruit, it can fill the baskets (芎藭生蜀道，白芷来江南。……及其未花实，可以资筐篮)".

In the Northern Song dynasty (960–1127 AD), Song Qi's (宋祁) *Yi Bu Fang Wu Lue Ji* (《益部方物略记》 *Record of the Things in the Yi Region*) described

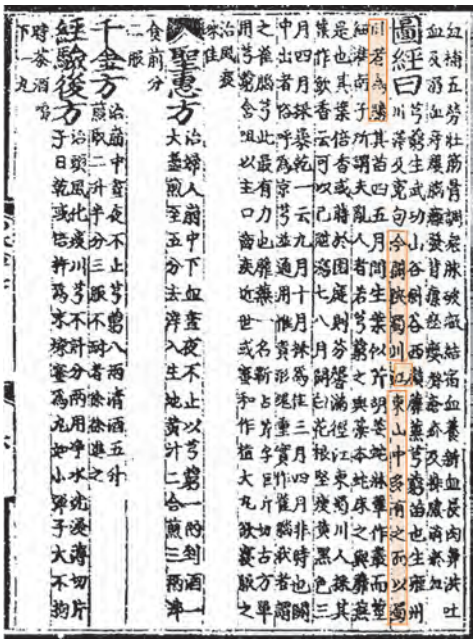


Figure 4 *Zheng Lei Ben Cao* (《证类本草》*Materia Medica Arranged According to Pattern*) (source with permission from: https://www.shidianguji.com/)

widespread cultivation of *Chuan Xiong* in the Chengdu (成都) area (Fig. 5): "It is found everywhere in Shu (蜀中处处有之)"; "At the Chengdu Medicinal Market on the ninth day of the ninth lunar month, *Chuan Xiong* and *Da Huang* (大黄 Radix et Rhizoma Rhei) are piled like mountains, their fragrance overflowing the lanes (成都九月九日药市，芎与大黄如积，香溢于里)"; "People often planted it in gardens and enclosures... The climate in

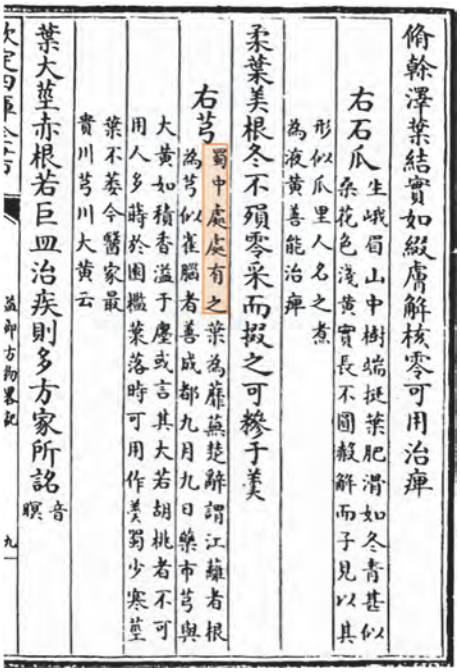


Figure 5 *Yi Bu Fang Wu Lue Ji* (《益部方物略记》*Record of the Things in the Yi Region*) by Song Qi, Northern Song dynasty, 1057 AD (source with permission from: https://www.shidianguji.com/)

Sichuan is not too cold so the stems and leaves of *Chuan Xiong* do not wither. Nowadays, physicians value *Chuan Xiong* and Sichuan *Da Huang* the most highly (人多莳于园槛……蜀少寒，茎叶不萎，今医家最贵川芎、川大黄)". To the best of our knowledge, this is one of the earliest discovered records documenting the large-scale cultivation of *Chuan Xiong* in Sichuan.

After the Ming dynasty, following multiple southward population migrations and increased economic development in southern China, Jiangxi (江西) and Zhejiang (浙江) saw widespread cultivation of *Chuan Xiong*. Varieties began to be distinguished by their producing areas, such as *Chuan Xiong* (川芎, Sichuan), *Jing Xiong* (京芎, Beijing), *Fu Xiong* (抚芎, Jiangxi), and *Tai Xiong* (台芎, Shandong). Among them, Sichuan-produced *Chuan Xiong* was still regarded as the genuine medicinal material of the highest quality.[7]

During the Qing dynasty (1644–1912 AD), new producing areas emerged, including *Xi Xiong* (西芎, Shaanxi), *Guang Xiong* (广芎, Guangxi), and *Nan Xiong* (南芎, Guangdong). In the late Qing dynasty, *Fu Xiong* (Jiangxi) once became mainstream in Jiangsu and Zhejiang. *Qian Long Guan Xian Zhi* (《乾隆灌县志》 *Qianlong Reign Edition of the Guan County Gazetteer*) from the Qing dynasty recorded the medicinal products of Guan County (灌县, present-day Dujiangyan, 都江堰), listing *Chuan Xiong* as the top product (Fig. 6).

By the Republican era (1912–1949 AD), Sichuan reaffirmed its status as the genuine producing area, with products from Dujiangyan (都江堰) being particularly prized, while other varieties gradually became more regionalized. "Throughout history, rhizomes resembling sparrow-brain shape, heavy in quality, white in color, with a pungent aroma and sweet taste, have been considered of superior quality (历代川芎均以根如雀脑者为佳，且以大块而重、色白不油、嚼之辛甘者良)".[8]

It is now widely accepted within the academic community that since the Song dynasty, Sichuan has been recognized as the genuine producing area of *Chuan Xiong*, and the botanical origin, both historical and contemporary, remains consistent, identified as Rhizoma Chuanxiong.[9]

3 Historical cultivation and trade of *Chuan Xiong*

In 1177 AD, Fan Chengda (范成大), a scholar of the Southern Song dynasty (1127–1279 AD), wrote the diary-style travelogue *Wu Chuan Lu* (《吴船录》 *Record of a Boat Journey to Wu*) during his eastward boat voyage back to Lin'an (临安, present-day Hangzhou [杭州]) after serving as the Pacification Commissioner of Sichuan. The text records, "In Qing Cheng Mountains of Sichuan, there is a flat area called Fu Rong Ping, where Daoist priests grow *Chuan Xiong* (于四川青城山，有夷坦曰芙蓉坪，道人于彼种芎)", indicating that artificial

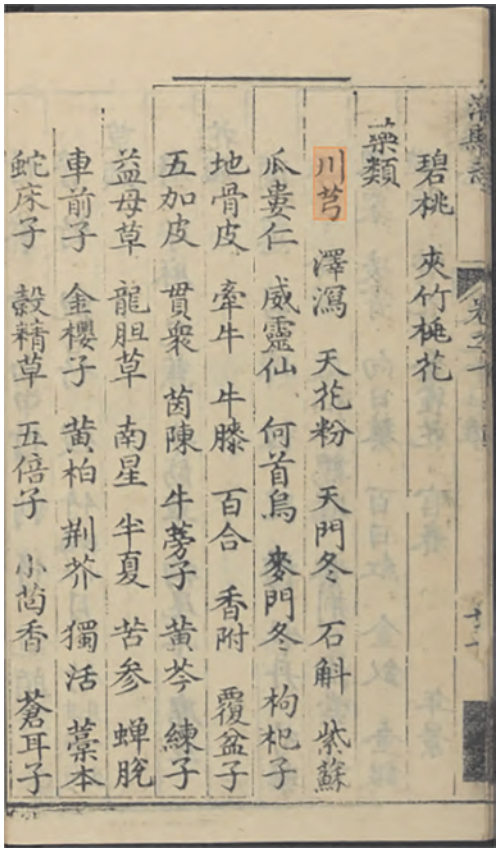


Figure 6 *Qian Long Guan Xian Zhi* (《乾隆灌县志》 *Qian Long Reign Edition of the Guan County Gazetteer*) (source with permission from: https://www.shidianguji.com/)

cultivation of *Chuan Xiong* was already quite common (Fig. 7).

In the mid-to-late Ming dynasty (1368–1644 AD), Li Shizhen (李时珍) provided a clear description of the

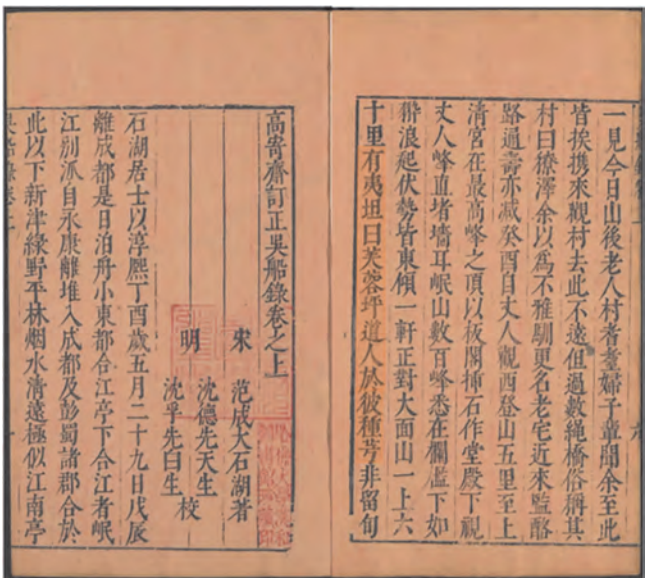


Figure 7 A passage from the Song dynasty edition of *Wu Chuan Lu* (《吴船录》) by Fan Chengda, held at Harvard University (source with permission from: https://www.shidianguji.com/)

cultivation methods of *Chuan Xiong* in Sichuan. His *Ben Cao Gang Mu* (《本草纲目》*The Grand Compendium of Materia Medica*) recorded: "In the land of Shu, the climate is not too cold, so people often cultivate *Chuan Xiong*. Even in deep autumn, the stems and leaves of *Chuan Xiong* do not wither. After the Qingming Festival (early April), sprouts grow from the perennial roots; the branches are divided and buried horizontally, then each node takes root (蜀地少寒，人多栽莳，深秋茎叶亦不萎也。清明后宿根生苗，分其枝横埋之，则节节生根)" (Fig. 8). Here, "the sprouts from the perennial roots" refers to the above-ground stems of *Chuan Xiong* herb (locally called "*Ling Zi* [苓子]"). Burying its branches (the above-ground stems) horizontally allows each node (stem node) to take root. These detailed characteristics align with the modern *Ling Zi* cultivation method: "during planting, the *Ling Zi* is first laid flat and pressed into the soil to ensure close contact with the earth (栽时先将苓子平放，按入土中，使与土紧密接触)". This description is consistent with the cultivation methods still used in the current authentic producing regions.[10]

As a renowned Sichuan-native medicinal herb, *Chuan Xiong* has been a cornerstone of regional trade and exports for centuries. Its commercial history, dating back to the Tang dynasty, reflects Sichuan's pivotal role in global herbal medicine networks.

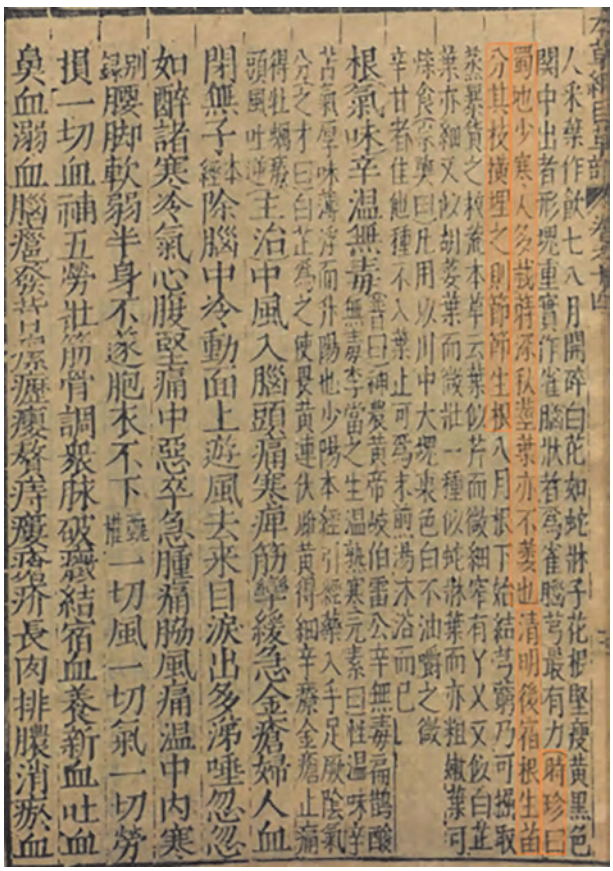


Figure 8 Record of *Chuan Xiong* cultivation in *Ben Cao Gang Mu* (《本草纲目》*The Grand Compendium of Materia Medica*) by Li Shizhen, Ming dynasty (source with permission from: https://www.shidianguji.com/)

During the Tang dynasty, Chengdu emerged as a central hub for *Chuan Xiong* trade. The *Yu Ju Guan* (玉局观 Jade Bureau Temple) in Chengdu hosted one of the earliest recorded medicinal markets, where *Chuan Xiong* was traded alongside other precious herbs like *Niu Huang* (牛黄 Calculus Bovis) and *She Xiang* (麝香 Moschus). Although initially an annual event held on the ninth day of the ninth lunar month, the market expanded significantly by the Song dynasty, becoming a large-scale comprehensive fair that integrated medicine trading with entertainment and cultural activities (Fig. 9). Merchants from distant regions, including ethnic minority areas and even foreign countries like Persia, gathered to trade rare and exotic herbs, with *Chuan Xiong* being a key commodity. Historical records provide enduring evidence of Chengdu's vibrant medicine market from the Song dynasty onward. According to the Song dynasty text *Jin Xiu Wan Hua Gu* (《锦绣万花谷》 *Broidered Valley of Myriad Flowers*), "aromatic medicines are sold on official streets monthly, known as the Medicine Market (月鬻香药于官街，号药市)". By the Ming dynasty, *Shu Zhong Guang Ji* (《蜀中广记》*Extensive Records of the Sichuan Region*) offered a more elaborate depiction: "On the ninth day of the ninth lunar month, the Medicine Market at *Yu Ju Guan* hosts a banquet for Surveillance officials and guests gathered at the former old Xuan Zhao Hall. Evening drinks are held at Five Gate, lasting three days. The government sets up tents and temporary shelters for the events, and some claim to have had vague encounters with immortals (九月九日，玉局观药市，宴监司宾僚于旧宣诏堂。晚饮于五门，凡三日。官为幕帘棚屋，以事游观。或云有恍惚遇仙者)". The Qing dynasty text *Shu Gu* (《蜀故》*Ancient Records of Shu*) affirmed the market's prominence, noting that "among Chengdu's twelve specialized markets, the Medicine Market at *Yu Ju Guan* was the most prosperous (成都十二市，成都药市以玉局观为最盛)". Further corroboration comes from another Qing source, *Du Shu Ji Shu Lue* (《读书纪数略》*Summary of Reading and Numerical Records*), which cites temple inscriptions stating that Chengdu maintained three principal markets—the Silkworm Market, the Medicine Market, and the Seven Treasures Market—with one market established approximately every four *li* (里, an ancient unit of distance equivalent to about 2 km) (庙记：凡四里当一市，成都三市：蚕市、药市、七宝市). Together, these accounts trace the evolution of Chengdu's medicine market from a monthly commercial event to an institutionalized and celebrated fixture of urban life.

By the Republican era (1912–1949 AD), Sichuan's medicinal logistics network had become well-developed. Key logistics centers included Chengdu, Chongqing (重庆), Wanxian (万县), Guanxian (灌县), Yibin (宜宾), Zhongba (中坝), and Hechuan (合川). Before the War of

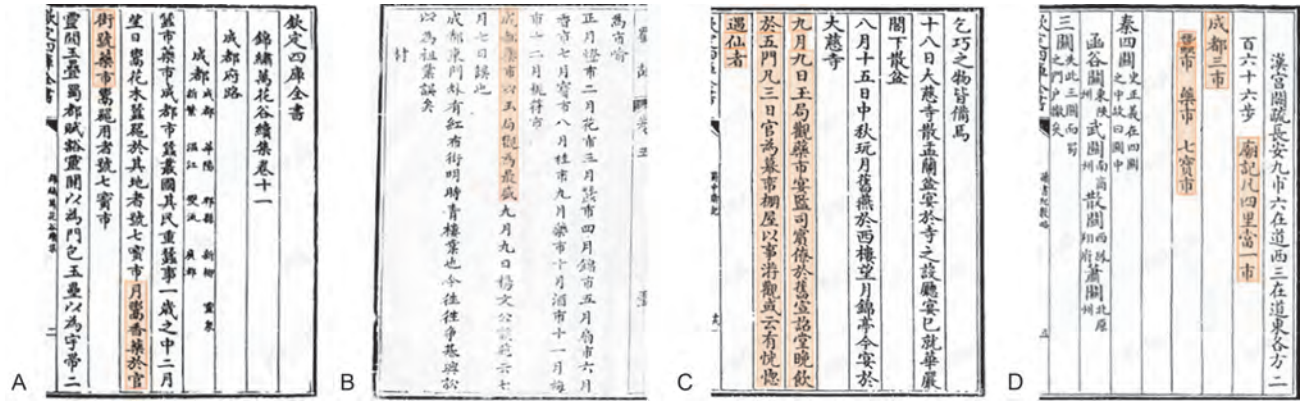


Figure 9 Historical records of the Chengdu medicine market: A *Jin Xiu Wan Hua Gu* (《锦绣万花谷》 *Broidered Valley of Myriad Flowers*), Song dynasty; B *Shu Gu* (《蜀故》 *Ancient Records of Shu*), Qing dynasty; C *Shu Zhong Guang Ji* (《蜀中广记》 *Extensive Records of the Sichuan Region*), Ming dynasty; D *Du Shu Ji Shu Lue* (《读书纪数略》 *Summary of Reading and Numerical Records*), Qing dynasty (source with permission from: https://www.shidianguji.com/)

Resistance Against Japanese Aggression (1937–1945 AD), herbs from western Hubei (湖北), eastern and southeastern Sichuan were shipped via Wanxian (万县) along the Yangtze River (长江) for export, while those from Qinghai (青海), Gansu (甘肃), Guizhou (贵州), Yunnan (云南), and other parts of Sichuan were exported through Chongqing. Although specific export figures for *Chuan Xiong* during this period are not fully detailed in the available sources, the robust logistics network suggests substantial trade volumes. A 1938 survey by the Sichuan Provincial Government Construction Department highlighted Guanxian as a critical production and distribution center for *Chuan Xiong*, underscoring its importance. According to *Shi Shi Xin Bao* (《时事新报》 *The Current Affairs New Journal*), dated October 22, 1946, a report documented that due to the impact of the war, the export volume of *Chuan Xiong* had decreased to less than 20% of its pre-war level, with an annual export volume of 500 tons (Fig. 10).


時事新報
川藥外銷不振
出口數量不及戰前十分之二
交通阻塞
產量減少
綜上所述
國展

Figure 10 *Shi Shi Xin Bao* (《时事新报》 *The Current Affairs New Journal*) (source with permission from: https://www.eastview.com/)

4 Dilemmas in the internationalization of *Chuan Xiong* and breakthroughs in standardization

Chuan Xiong holds a significant position in the history of international exchange of traditional medicines.[11] Its spread, particularly between China and Japan, serves as a remarkable example of the transnational flow of medicinal knowledge and materia medica. Recorded history shows that *Chuan Xiong* was first introduced to Japan during the Tang dynasty (618–907 AD) and became an integral component of Kampo medicine (Japanese traditional medicine derived from TCM). For centuries thereafter, Japan relied on imports of this prized rhizome from China to meet its domestic demand. This changed during the Edo period (1603–1868 AD), when the herb was successfully cultivated in Japan, marking a crucial step towards its local adoption and sustained use.

In Japan, *Chuan Xiong* is not a minor herb but a fundamental pillar of numerous classic Kampo formulas. It is extensively and frequently used, especially as a key ingredient in gynecological remedies. Prominent examples include Toki-shakuyaku-san (当帰芍薬散 Angelica-peony Powder), which is used for menstrual disorders and anemia, and Shimotsu-to (四物湯 Four Substance Decoction), a fundamental blood-tonifying formula. Its application extends beyond gynecology. It is a crucial component of Shichimotsu-koka-to (七物降下湯 Seven-herb Decoction for Lowering Qi) for hypertension and arteriosclerosis, Sansohnin-to (酸枣仁湯 Sour Jujube Seed Decoction) for insomnia, and Senkyu-chacho-san (川芎茶調散 Chuan Xiong Tea-Regulating Powder) for various types of headaches, particularly those caused by wind-cold. This widespread integration, as noted by researchers like Ōbayashi Keiun (大林惠运) at the Japan Easy Food Research Institute, underscores its perceived efficacy and indispensable role within the Kampo system.[12] *Mi Wu* (蘼芜), the aerial part (leaf and stem) of *Chuan Xiong*, possesses significant but underutilized edible value. Beyond its well-documented medicinal uses,

it has been consumed as a traditional food in China for nearly a millennium. Research confirms its rich nutrient profile and safety, positioning it as a promising, sustainable food resource worthy of further development and industrialization.[13]

The worldwide use of *Chuan Xiong* has evolved through historical shifts in production regions, primarily consolidating in the Sichuan Basin. The formation of its authentic producing areas reflects centuries of ecological adaptation and selection.[14,15] Continuous optimization of cultivation practices, including standardized planting, precise harvesting, and integrated pest management, aligns closely with modern ISO international standards.

In modern times, Sichuan's *Chuan Xiong* production has concentrated in Pengzhou (彭州), particularly in Aoping Town (敖平镇), which supplies approximately 70% of China's total output and is regarded as the genuine producing area. Nationally, Sichuan accounts for about 90% of China's *Chuan Xiong* production. Export data reveal significant fluctuations: exports peaked in 2014 at 9,160.4 tons, representing nearly half of the annual production. However, by 2017, exports plummeted to 4,642.6 tons and further dropped to 2,652.8 tons in 2018 (Fig. 11). This decline was largely attributed to stringent international quality standards, particularly the 2017 edition of *European Pharmacopoeia* requirement limiting moisture content to 8%, which conflicted with China's domestic standard of 12% (Table 1).

Table 1 clearly reveals significant disparities in the quality control standards for *Chuan Xiong* across major global pharmacopoeias. The British pharmacopoeia and European pharmacopoeia emphasize essential oil content (≥3.5 mL/kg) and low moisture (≤8.0%), while the Chinese pharmacopoeia uniquely specifies ferulic acid content (≥0.10%) and permits a higher moisture limit (≤12.0%). In contrast, the Korean pharmacopoeia imposes the strictest requirement for acid-insoluble ash (≤1.0%). This fragmented and inconsistent system exposes a core issue in the international trade of TCM herbs: the lack of unified standards. Therefore, establishing a harmonized international standard is both crucial and urgent.

To address these challenges, collaborative efforts led by Sichuan Agricultural University and local governments

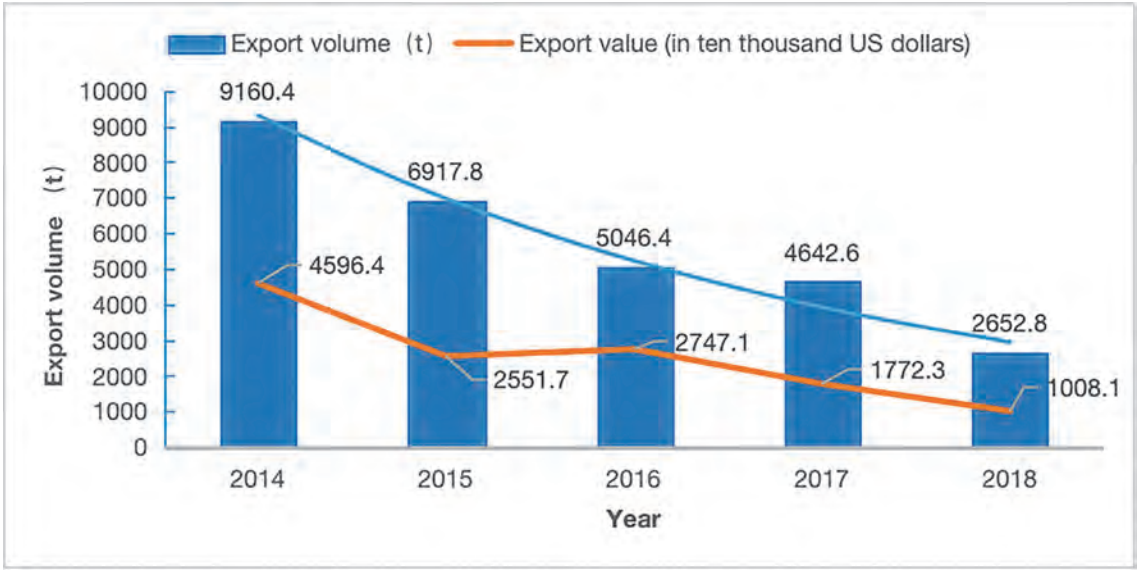


Figure 11 Export data of *Chuan Xiong* (source with permission from: Ministry of Commerce of the People's Republic of China)

Table 1 Specification limits for *Chuan Xiong* in different pharmacopoeias[3,16–21]

Pharmacopoeia	Ferulic Acid	Essential Oil	Loss on Drying/Water	Total Ash	Acid-insoluble Ash
British Pharmacopoeia (2020)	_	≥3.5 mL/kg	≤8.0%	≤6.0%	≤2.0%
Chinese Pharmacopoeia (2020)	≥0.10%	_	≤12.0%	≤6.0%	≤2.0%
(China) Hong Kong Chinese Materia Medica Standards	≥0.47%*	–	≤15.0%	≤6.0%	≤2.0%
European Pharmacopoeia (10.0)	_	≥3.5 mL/kg	≤8.0%	≤6.0%	≤2.0%
Korean Pharmacopoeia (12th Ed.)	_	_	_	≤6.0%	≤1.0%
Thai Herbal Pharmacopoeia (2021)	–	–	≤12.0%	≤6.0%	≤2.0%
Japanese Pharmacopoeia (17th Ed.)	–	–	–	≤6.0%	≤1.0%

Note: Trans-ferulic acid (CAS: 537-98-4) is used as ferulic acid in the monograph of *Chuan Xiong*, *Chinese Pharmacopoeia*. while Z-ligustilide is used as a content indicator in *Hong Kong Chinese Materia Medica Standards*.

resulted in the development of the *Chuan Xiong* ISO International Standard in 2024.[22] The promulgation and implementation of this standard (ISO 8071) (Fig. 12) have not only standardized the cultivation, processing, and quality control systems of *Chuan Xiong*, but have also played a pivotal role in advancing its modernization and internationalization. By establishing unified technical specifications across key stages—including germplasm selection, ecological cultivation, harvesting practices, and post-harvest processing—the standard ensures the consistency, safety, and traceability of medicinal materials.

Particularly for plantations located at the foot of snow-capped mountains, where distinctive climatic and ecological conditions foster the development of high-quality geo-authentic herbs, ISO 8071 provides a scientific framework that integrates traditional knowledge with modern quality management systems, thereby enhancing the stability and reliability of production (Fig. 13). At the same time, the standard strengthens the global credibility and market competitiveness of *Chuan Xiong* by aligning its quality benchmarks with international norms. Comprising 12 stringent indicators consistent with global pharmacopoeial standards, ISO 8071 has also contributed to the revitalization of exports. In 2025, ISO-certified *Chuan Xiong* slices achieved a 40% increase in export unit price and entered multiple international markets, including Germany, Japan, South Korea, and Vietnam, with export values from Aoping Town alone exceeding 50 million Yuan.[23]


ISO

International Standard

ISO 8071

Traditional Chinese medicine — *Ligusticum chuanxiong* rhizome

First edition 2024-03

Médecine traditionnelle chinoise — Rhizome de livèche du Sichuan (Ligusticum chuanxiong)

Reference number ISO 8071:2024(en)

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Figure 12 Cover of ISO 8071:2024, Traditional Chinese medicine—*Ligusticum Chuanxiong* rhizome (source with permission: ISO 8071: 2024, © ISO 2024)

In the future, this base, irrigated by alpine snowmelt water, will further uphold the traditional "medicinal herb–rice–medicinal herb" upland–paddy rotation ecological cultivation model. This system not only improves the multiple cropping index and biodiversity (including beneficial microbial communities), but also mitigates pest and disease pressures, improves soil structure, and enhances nutrient cycling—ultimately enabling the production of more high-quality *Chuan Xiong* products to benefit global health.

The establishment of a unified international standard is a pivotal driver behind the resurgence of *Chuan Xiong* in global trade, addressing several interconnected challenges:

First, eliminating technical barriers to trade. Inconsistent pharmacopeial standards function as *de facto* technical trade barriers. Producers face complex compliance burdens when navigating multiple, often conflicting regulations on key parameters. A single, harmonized ISO standard streamlines the export process, ensures fair market access, and facilitates the smooth global circulation of *Chuan Xiong*, directly enabling its market revival.

Second, guaranteeing consistent quality and efficacy. Disparities in critical quality markers—such as moisture content (affecting stability) and bioactive compound limits (determining efficacy)—create uncertainty regarding the safety and therapeutic value of products



Figure 13 China *Chuan Xiong* Industrial Demonstration Park at the foot of the snow-capped mountains (source with permission: People's Government of Aoping Town)

from different sources. A unified standard establishes a robust, science-based benchmark for stable, consistent, and efficacious quality. This guarantees reliable clinical outcomes for end-users and builds essential trust among manufacturers and practitioners, which is fundamental for sustaining the herb's commercial recovery.

Third, advancing the modernization and global integration of TCM. The adoption of an internationally recognized standard is a strategic imperative for TCM. By fostering scientific consensus on quality, it moves TCM beyond regional paradigms into the mainstream of global healthcare. This harmonization promotes evidence-based use, accelerates related research, and enhances the international credibility and acceptance of TCM. Ultimately, the ISO standard for *Chuan Xiong* is more than a technical document; it is a cornerstone for the future globalization of the entire sector.

This standard provides a framework for quality control, traceability, and sustainable production, bridging traditional knowledge with contemporary scientific rigor. The integration suggests that traditional medicinal systems can enhance their global relevance through standardization without compromising their unique heritage. This synergy offers a model for preserving botanical authenticity while meeting international market expectations, emphasizing that cultural legacy and modern compliance can be mutually reinforcing.

5 Conclusion

Looking ahead, the international outlook for *Chuan Xiong* is promising.

Firstly, international standards should be advanced. The ongoing development and implementation of international quality standards, such as those developed by ISO/TC 249, are paramount. These standards will ensure consistent quality, safety, and efficacy of *Chuan Xiong* in the global market, building international trust and facilitating smoother trade by eliminating technical barriers.

Secondly, scientific research should be strengthened. Modern scientific research is expected to continue validating its pharmacological mechanisms and expanding its evidence-based applications. This will further bridge the gap between traditional use and modern medicine, potentially leading to its integration into broader healthcare contexts beyond traditional systems.

Finally, global demand for natural products should be leveraged. As global interest in natural products and holistic approaches to health continues to grow, particularly for chronic conditions like those it traditionally addresses, the demand for well-standardized and scientifically supported herbs like *Chuan Xiong* is likely to increase. We aim to focus our efforts on the following areas in the future: conducting in-depth case studies on the impact of ISO certification on small-scale growers; establishing a national database for TCM product standards; and developing targeted training programs for producers to align traditional practices with modern regulatory requirements.

With its deep historical roots, combined with modern scientific validation and quality control, *Chuan Xiong* is well-positioned for a promising future as a globally recognized medicinal herb.

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Ethical approval

This study does not contain any studies with human or animal studies performed by any of the authors.

Author contributions

HOU Kai, JIANG Shunyuan and WANG Mei conducted literature research, designed the overall historiographic framework, synthesized the narrative, drafted the original manuscript, performed the final cross-check of references and reviewed the final manuscript. WANG Mei and JIANG Shunyuan checked historical materials, provided historical insights, and critically revised the manuscript.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Chen ZJ, Zhang C, Gao F, et al. A systematic review on the rhizome of *Ligusticum chuanxiong* Hort. (*Chuan Xiong*). *Food and Chemical Toxicology*. 2018;119:309–325.

[2] Liu J, Lei ZW, Wang ZC, et al. Ethnobotanical usages, phytochemistry, pharmacology, and quality control of Chuanxiong Rhizoma: a review. *Journal of Ethnopharmacology*. 2025;337:118902.

[3] China Pharmacopoeia Commission. *Pharmacopoeia of the People's Republic of China* (中华人民共和国药典). Beijing: Chinese Medicines and Technology Press; 2020. Chinese.

[4] Zheng YQ, Zeng JX, Lin JX, et al. Herbal textual research on Chuanxiong Rhizoma in Chinese classical prescriptions (经典名方中川芎的本草考证). *China Journal of Chinese Materia Medica*. 2021;46(16):4293–4299. Chinese.

[5] Shan F, Hao JD. Herbal textual research on origin and development of Chuanxiong (川芎（芎藭）的本草源流考). *China Journal of Chinese Materia Medica*. 2011;36(16):2306–2310. Chinese.

[6] Li Q, He PY, Zhang DK, et al. Current situation and development strategy of Chuanxiong Rhizoma industry (川芎产业现状与发展策略分析). *Chinese Traditional and Herbal Drugs*. 2024;55(8):2771–2783. Chinese.

[7] Liu Y, Jia MR. Historical textual research on the varieties and producing areas of Chuanxiong Rhizoma (川芎品种、产地的历史考证). *Journal of Chinese Medicinal Materials*. 2001;5:364–367. Chinese.

[8] Song PS, Ma X, Zhang BC, et al. Herbal textual research and historical evolution of Ligustici Rhizoma (芎藭（川芎）的本草考证及历史演变). *China Journal of Chinese Materia Medica*. 2000;7:50–52. Chinese.

[9] Wang YH, Zhao JC, Jin Y, et al. Herbal textual research on Chuanxiong Rhizoma in famous classical formulas (经典名方中川芎的本草考证). *Chinese Journal of Experimental Traditional Medical Formulae*. 2022;28(10):262–274. Chinese.

[10] Shi Z, Ni L, Yu S, et al. Research on cultivation of Ligusticum Chuanxiong "Lingzi" from the perspectiveof historical geography (历史地理学视域下川芎"苓子"栽培法本草考证). *Asia-Pacific Traditional Medicine*. 2024;20(7):186–191. Chinese.

[11] Chen L, Peng C, Liu YP, Chen HP, Xiang CB. Discussion on forming pattern of Dao-di Herbs Ligusticum chuanxiong (川芎道地药材形成模式的探讨). Chengdu: Proceedings of the 3rd International Conference on Modernization of Traditional Chinese Medicine. 2010:71–75. Chinese.

[12] Ōbayashi K. Research and application of Ligusticum Chuanxiong in Japan (川芎在日本的研究和应用). Available from: http://toujyou.com/ekisyoku/ronbun/han005.pdf [Accessed on March 30 2026]. Chinese.

[13] Zou JP, Wang JY, Hou K, et al. An underutilized food "Miwu": diet history, nutritional evaluations, and countermeasures for industrial development. *Foods*. 2023;12(7):1385.

[14] Peng GZ, Peng J, Xiong ZQ. Ecological adaptability division of *Ligusticum chuanxiong hort*. in Sichuan Basin (四川道地中药材川芎气候生态适应性区划). *Chinese Journal of Agrometeorology*. 2007;28(2):178–182. Chinese.

[15] Yin L, Peng Y, Liu R, et al. Research on the correlation between ecological environment elements of producing area and quality of traditional Chinese medicine (产地生态环境要素与中药品质相关性研究). *Pharmacy and Clinics of Chinese Materia Medica*. 2012;3(6):9–14. Chinese.

[16] British Pharmacopoeia Commission. *British Pharmacopoeia*. London: The Department of Health; 2019.

[17] European Pharmacopoeia Committee. *European Pharmacopoeia (10th Edition)*. Strasbourg: European Directorate for the Quality of Medicines & Health Care; 2019.

[18] Ministry of Food and Drug Safety. *The Korean Pharmacopoeia (12th Edition)*. Chungcheong Buk-do: The Ministry of Food and Drug Safety; 2019.

[19] Department of Medical Sciences, Ministry of Public Health. *The Thai Herbal Pharmacopoeia*. Nonthaburi: Ministry of Public Health; 2021.

[20] Hong Kong Chinese Materia Medica Standards (HKCMMS) Office. *Hong Kong Chinese Materia Medica Standards (Volume 2)*. Hong Kong: Department of Health; 2008.

[21] Japanese Pharmacopoeia Committee. *Japanese Pharmacopoeia 17th Edition*. Tokyo: Ministry of Health, Labour and Welfare; 2016.

[22] Anonymous. ISO 8071: 2024, Traditional Chinese medicine—*Ligusticum chuanxiong* rhizome. Geneva: ISO; 2024.

[23] Tianfu Media Consortium. CNY 50 million in exports! Chuanxiong decoction pieces from Pengzhou, Chengdu gain huge popularity overseas (5000万出口额！成都彭州的川芎饮片火到了国外). Available from: https://sichuan.scol.com.cn/tfrm/202505/83049300.html. [Accessed on March 30 2026]. Chinese.

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Original Article

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MEDICINE AND CULTURE

OPEN

Research on the Cross-regional Dissemination and Evolution of Quality Standards of Chinese Herbal Medicine *He Zi*

诃子质量标准的跨区域传播与演变研究

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Abstract

As a pivotal medicinal plant integrated within Asian traditional medical knowledge networks, *He Zi* (诃子 Chebula Fructus) has achieved cross-regional dissemination via the overland and maritime Silk Roads, establishing a bidirectional network for pharmaceutical cultural exchange. This study examines the historical circulation, localization, and standardization of *He Zi* across Asian traditional medical knowledge networks, with particular attention to its textual records, clinical interpretations, and modern quality standards in China and related regions. Methodologically, we transition from a descriptive approach to a transparent research design, utilizing primary sources—including *Charaka Samhita* (《遮罗迦本集》*Charaka's Compendium of Medicine*), *Jing Zhu Ben Cao* (《晶珠本草》*Crystal Materia Medica*), and *Xin Xiu Ben Cao* (《新修本草》*Newly Revised Materia Medica*)—alongside a quantitative comparative analysis of modern pharmacopoeial standards. The research explores the distinct developmental trajectories of *He Zi*: its multi-stage role in Ayurvedic rejuvenation (*Rasayana*, 强壮延年法), the "Three Humors" balance doctrine (三因平衡理论, i.e., the harmony of Loong [隆], Tripa [赤巴], and Baekan [培根]) in Chinese Xizang medicine, and the sophisticated functional differentiation in TCM, characterized by astringing the lung and large intestine (敛肺涩肠). The findings indicate that the functional differentiation of *He Zi* fundamentally reflects the cultural construction of medicinal resources, while a critical phytochemical evaluation demonstrates how traditional quality markers, such as "six-ridged" preference ("六棱"者品质佳), correlate with specific secondary metabolite profiles. The constructed "dissemination–interpretation–standardization" model offers empirical insights and standardized approaches for facilitating mutual learning and quality recognition of traditional medicines under the Belt and Road Initiative.

Keywords: *He Zi* (诃子 Chebula Fructus); Cross-regional dissemination; Traditional medical systems; Quality standards; Medical anthropology

1 Introduction

He Zi (诃子 Chebula Fructus), the fruit of *Terminalia chebula* Retz. or its variety *T. chebula* Retz. var. tomentella Kurt. (Fam. *Combretaceae*), is a foundational botanical medicine in Asian therapeutics, historically venerated as the "king of medicines" (万药之王).[1] This reputation facilitated its early dissemination across China, where it became a core constituent of the classic Triphala formulation (三果宝, comprising *Phyllanthus Emblica*, *He Zi*, and *T. bellirica*), driven by nascent trade networks and cross-cultural exchanges.[2–4] Although early historical annals often traced the plant's origin to Persia, primary medical texts—most notably the Tang dynasty *Xin Xiu Ben Cao* (《新修本草》*Newly Revised Materia Medica*)—more accurately localized its production to Jiaozhou (交州, present-day northern Vietnam and southern China) and Aizhou (爱州, present-day Thanh Hóa Province, Vietnam).[5] *Si Sheng Ben Cao* (《四声本草》*Materia Medica in Four Tones*) is a lost pharmacopoeia. Fragmentary passages of the text survive in citations introduced by the phrase "Your servant Yu Xi

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and others respectfully note Xiao Bing (臣禹锡等谨按萧炳)", which are embedded in *Zhen Lei Ben Cao Chong Xiu Zheng He Jing Shi Zheng Lei Bei Ji Ben Cao* (《证类本草重修政和经史证类备急本草》*Revised Zhenghe's Classified Materia Medica for Emergency*), by contrast, identified Persia as a pivotal maritime trading hub rather than a botanical origin, a distinction that nuanced the herb's historical geography.[6] Regardless of these textual ambiguities, *He Zi*'s clinical applications within traditional Chinese medicine (TCM) encompass—not only the clinical framework of "astringing the lung and large intestine (敛肺涩肠)" but also a sophisticated system of bidirectional regulation in which the raw fruit "clears the lung and benefits the qi (生用：清金行气)" and the processed form "warms the stomach and stabilizes the intestines (炮制：温胃固肠)"—a therapeutic versatility that was concurrently echoed in the ethnomedical practices and through the principle of Three Humors Balance (三因平衡理论, the harmonization of Loong, Tripa, and Baekan).[2,7] *He Zi* exemplifies the dynamic localization of cross-regional medicinal resources. Its dissemination routes and functional differentiation offer valuable insights into the transmission patterns of traditional medical knowledge.

Yet existing studies remain largely confined to either descriptive textual verification or pharmacological analysis conducted within isolated medical systems, with limited methodological transparency in text selection, quantitative differentiation of pharmacopoeial standards, and the phytochemical congruence between traditional quality markers and modern metabolic profiles. To bridge this gap, the present study adopts a transparent medical-anthropology framework. Rather than treating medicinal plants merely as traded commodities, this framework conceptualizes them as dynamic vectors of cultural, cosmological, and physiological beliefs, focusing on how a single botanical resource is continuously interpreted and reconstructed across borders.

Guided by this approach, we systematically examined primary classical texts spanning multiple medical traditions, including *Charaka Samhita* (《遮罗迦本集》*Charaka's Compendium of Medicine*),[8] the Ming dynasty *Ben Cao Gang Mu* (《本草纲目》*The Grand Compendium of Materia Medica*),[9] and the *Xizang Jing Zhu Ben Cao* (《晶珠本草》*Crystal Materia Medica*).[10] Through a comparative analysis of medical theories—Ayurvedic six-taste theory (阿育吠陀"六味"理论), Chinese Xizang three-humor doctrine (藏医"三因"学说), and TCM properties theory (药性理论)—coupled with a critical quantitative assessment of current pharmacopoeial standards, including the Chinese Pharmacopoeia (ChP), the Indian Pharmacopoeia (IP), and the United States Pharmacopeia (USP), this research employs multidimensional methods to assess quality indicators. It addresses three core questions: the pathways and mechanisms underpinning *He Zi*'s cross-regional dissemination through interconnected land-sea networks; the patterns of efficacy differentiation and knowledge reconstruction across different medical systems; and the evolutionary trajectory of quality standards from traditional morphological identification (such as the preference for "six-ridged" fruits, 六棱者品质佳) to contemporary scientific quantification based on secondary metabolite concentration. By constructing a methodologically rigorous "dissemination–interpretation–standardization" analytical framework, this study offers both historical perspective and empirical support for promoting cultural mutual learning and quality recognition in traditional medicine under the Belt and Road Initiative.

2 Cross-regional dissemination of *He Zi* from the perspective of historical geography

2.1 Origins and diffusion pathways

The dissemination routes of *He Zi* are reconstructed through a systematic methodology that integrates a critical synthesis of primary medical literature with current archaeological and phytochemical evidence, spanning the overland Silk Road, the Maritime Silk Road, and the Zhangzhung Ancient Trail (象雄古道) (Fig. 1). Historically recorded and circulated across South Asia, Southeast Asia, and southern China, *He Zi* served as a pharmaceutical vector across Ayurvedic, Chinese, and Mongolian medical systems.

First, the overland Silk Road (black dashed line) facilitated the initial westward and northward radiation of *He Zi* from South Asia and Southeast Asia, as well as southern China. It extended through Central Asia—with Samarkand serving as a pivotal logistics hub—to the Persian plateau (labeled "Shiraz"). Methodologically, this study distinguishes between botanical centers of origin and commercial distribution hubs. Crucially, while early historical annals like *Zhou Shu* (《周书》*History of the Zhou Dynasty*)[11] and *Wei Shu* (《魏书》*History of the Wei Dynasty*)[12] record *He Zi* as a tribute from Persian envoys, this identifies Persia primarily as a high-value trade intermediary rather than the botanical center of origin. The 4th-century Bower Manuscript unearthed in Kucha, Xinjiang, provides early evidence of this overland transmission through its inclusion of Haritakī-based mythological and medical narratives. Dunhuang manuscripts (敦煌文献，又名敦煌遗书、敦煌文书、敦煌写本)[13] further substantiate this intermediary trade and integration: scroll P.3644 documents merchant shops trading the herb, while medical texts like P.2662V and P.3378V contain numerous prescriptions, reflecting the integration of Western Regions (西域) materia medica into local practice. The transliteration of Sanskrit Harītakī via Persian Halīla into Chinese He-li-le (诃黎勒) further marks this linguistic-cultural trajectory. In Central China, Zhang Zhongjing's (张仲景) *Jin Gui Yao Lue* (《金匮要略》*Essentials from the Golden Cabinet*)[14]

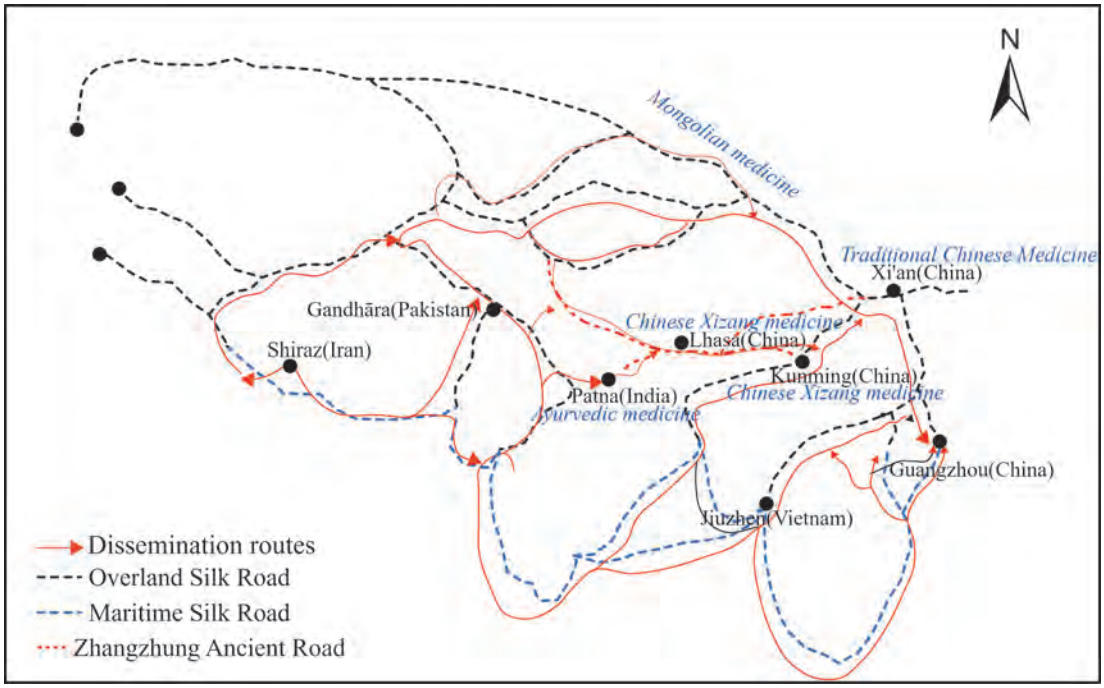


Figure 1 Historical dissemination routes of *He Zi* (source with permission from: picture made by the authors)

provided the earliest medical record of its use in "He-li-le San (诃黎勒散)" qi-related dysentery (气痢). Contrary to the common scholarly misconception that *Xin Xiu Ben Cao* claimed Persian origin, the text explicitly localizes its production to Jiaozhou and Aizhou. This indicates that by the 7th century, the species had achieved successful ecological adaptation and domestic cultivation in the Lingnan (岭南, present-day Guangdong, Guangxi, and Hainan provinces, China, 今中国广东、广西及海南省) region, marginalizing its reliance on long-distance overland imports.

Second, the Maritime Silk Road (blue dashed line) linked the Indian Coromandel Coast directly to the South China Sea trade network. Ji Han's (嵇含) *Nan Fang Cao Mu Zhuang* (《南方草木状》*Plants of the Southern Regions*, c. 304 CE)[15] noted its presence in Jiuzhen commandery (九真郡, present-day Thanh Hóa Province, Vietnam, 现今的越南清化省), evidencing early maritime influx prior to the Tang dynasty. By the Tang and Song periods, Guangzhou (广州, marked as a major port) emerged as the primary distribution center. *Hai Yao Ben Cao* [《海药本草》*Materia Medica from the (Southern) Seaboard Area*]—a primary source emphasizing extrinsic medicines transported via sea—stated that "grows in the various countries of the Southern Sea (生南海诸国)", a geographic designation that encompassed the coastal regions of present-day Guangdong and Guangxi as well as the broader Nanyang (Southeast Asian) archipelago.[16] While the millennium-old tree at Guangxiao Temple (光孝寺, Temple of Bright Filial Piety, located at Yuexiu district, Guangzhou, Guangdong Province, China) remains extant physical evidence of this maritime introduction and subsequent localization. Song dynasty records in *Ling Wai Dai Da* (《岭外代答》*Representative Answers from the Region beyond the Mountains*)[17] confirm that merchant ships transported bulk quantities to Fujian and Zhejiang, reflecting a transition from exotic tribute to a standardized commodity driven by the economic prosperity of maritime trade.

Historical records suggest that plateau trade and medical exchange corridors also contributed to the circulation and reinterpretation of *He Zi* in Chinese Xizang medicine. Rather than indicating a single linear route of transmission, these records reflect complex interactions among materia medica, clinical experience, and local theoretical frameworks. Formulas in *Yue Wang Yao Zhen* (《月王药诊》*The Somaraza: The King of 'Moon's Diagnosis and Therapeutics*)[18]—which predate many Central Chinese medical records—suggest a possible circulation through plateau exchange networks recorded in historical medical texts. In Chinese Xizang medicine, *He Zi* was elevated to the "King of Medicines", and its theoretical framework in *Si Bu Yi Dian* (《四部医典》*The Four Medical Tantras*)[19] developed localized interpretations that show textual and therapeutic parallels with Triphala-related traditions. This lineage subsequently influenced Mongolian medicine, as evidenced in *Jin Guang Zhu Shi Ji* (《金光注释集》*Collection of Golden Light Commentaries*), where it is revered as the "King of Antidotes".[20]

This study systematically reconstructs the three major historical dissemination networks of *He Zi* across the Eurasian continent, each with distinct characteristics and impacts. Serving as the earliest transmission route, the Overland Silk Road centered on Central Asian hubs like Samarkand, with Persia acting as a key intermediary

for high-value trade; originating from the South Asia, Southeast Asia, and southern China, *He Zi* gradually spread to China's Central Plains, and by the 7th century AD, successful cultivation in the Lingnan region significantly reduced reliance on long-distance overland imports, marking its integration into TCM systems. In contrast, the Maritime Silk Road formed a direct sea route linking South Asia and Southeast Asia to China's South Sea trade network, which flourished during the Tang and Song dynasties with Guangzhou as its central hub, where *He Zi* transitioned from an "exotic tribute" reserved for imperial courts to a standardized bulk commodity traded in specialized medicinal markets, reflecting the growing commercialization of maritime trade and expanding demand for medicinal herbs across Asia. Operating independently of the Silk Road, the Zhangzhung Ancient Trail functioned as a high-altitude corridor connecting the Indus River Valley to the Xizang Plateau; introduced from Gandhara (modern northern Pakistan and eastern Afghanistan) to the Zhangzhung Kingdom, *He Zi* was elevated to the "King of Medicines" in Chinese Xizang medicine, absorbing the classical Triphala-related traditions while developing unique therapeutic applications that later influenced Mongolian medical traditions, contributing to the development of plateau medical knowledge within Chinese Xizang medicine. In summary, these three routes not only facilitated the physical exchange of plant resources but also catalyzed the cross-cultural fusion of medical knowledge, with each network adapting to regional ecological, economic, and cultural contexts to result in diverse therapeutic traditions that continue to influence healthcare practices across the Pan-Asian region today.

The cross-regional success of *He Zi* was driven by a synergy of ecological adaptation, phytochemical versatility, and cultural reconstruction. Its broad-spectrum efficacy—initially focused on "balancing Doshas (调和三因)" and "rejuvenation and detoxification (延寿与排毒)" in Ayurveda—was refined in TCM into a sophisticated bidirectional regulation theory. This encompasses not only "astringing the lung and intestine (敛肺涩肠)" to address chronic leakage, but also the nuanced clinical application of "bitter descending lung qi and sour astringing intestinal incontinence (苦降肺气、酸敛肠滑)", with efficacy significantly altered by processing (炮制). The professionalization of quality standards, such as the "six-ridged (六棱者良)" morphological preference first detailed in *Nan Fang Cao Mu Zhuang* and institutionalized in *Lei Gong Pao Zhi Lun* (《雷公炮炙论》*Master Lei's Discourse on Medicinal Processing*),[21] demonstrates an early empirical recognition of phytochemical congruence, as modern analysis confirms that such morphological traits correlate with higher concentrations of secondary metabolites (tannins). In summary, *He Zi* represents more than a traded good; it is an embodiment of theoretical integration and the sharing of natural resources across Eurasian civilizations.

2.2 Localization and formation of production areas in China

The spatio-temporal evolution of the *He Zi* medicinal region reflects a dynamic synergy between ecological

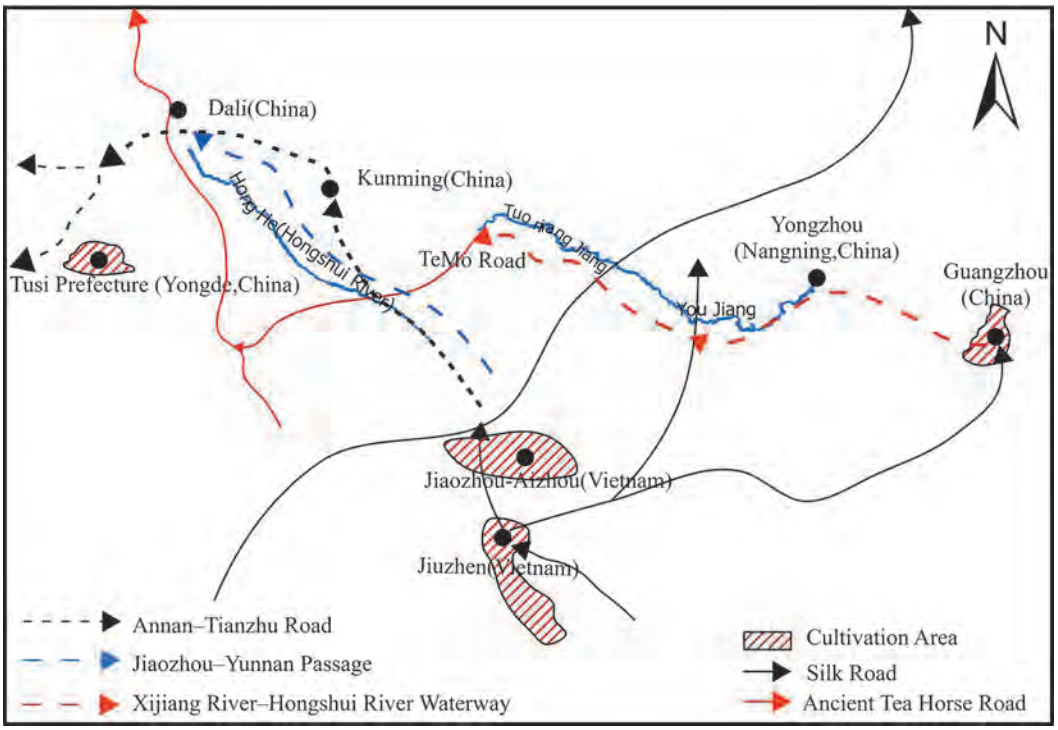


Figure 2 Historical localization and formation of *He Zi* production areas in China (source with permission from: picture made by the authors)

colonization and human civilization (Fig. 2). Historically, its biogeographical center of gravity shifted westward from northern Vietnam to the Lingnan region and ultimately to Yunnan Province (云南省), a trajectory driven by environmental adaptation and the escalating demands of cross-cultural medical networks.

Early records trace this acclimatization phase: *Nan Fang Cao Mu Zhuang* (Jin dynasty) documented its origin in Jiuzhen commandery, marking the pharmaceutical entry point into the Sinitic sphere. By the Tang dynasty, *Xin Xiu Ben Cao* documented a significant northward expansion to Jiaozhou and Aizhou, evidencing a transition from sporadic border trade to systematic localized cultivation. Chen Cangqi's *Ben Cao Shi Yi* (《本草拾遗》*Supplement to "The Grand Compendium of Materia Medica"*)[22] further noted its proliferation in Lingnan region, indicating that the species had established a foothold via the Jiaozhou–Guangzhou overland corridor and maritime trade routes.

The dissemination within the Tang dynasty's Lingnan Circuit (岭南道, present-day Fujian, Guangdong, and Hainan provinces, the Hong Kong and Macao Special Administrative Regions, the majority of the Guangxi Zhuang Autonomous Region, southeastern Yunnan province, and northern Vietnam) operated through an amphibious "land–sea dual-track" infrastructure. External input was facilitated by the overland Jiaozhou–Lingnan corridor, supported by strategic trade routes described in *Yuan He Jun Xian Tu Zhi* (《元和郡县图志》*Maps and Gazetteer of the Prefectures and Counties in the Yuanhe Period*).[23] Concurrently, the maritime Guangzhou–South China Sea artery allowed Persian and Arab merchants to import *He Zi* as a bulk commodity. *Xin Tang Shu Di Li Zhi* (《新唐书·地理志》*New History of the Tang Dynasty: Geography*)[24] records that "myriad Brahmin, Persian, and Kunlun ships (江中有婆罗门、波斯、昆仑等舶，不知其数)" arrived in Guangzhou, with *He Zi* being a foundational species within this "Aromatic Road". Guangzhou's *Fan Fang* (广州蕃坊, the foreign quarter of Guangzhou during the Tang and Song dynasties) hosted specialized medicinal bazaars that served as critical nodes for domestic redistribution. The profound influence of Persian pharmaceutical culture in this trade network is further corroborated by texts like *Tang Guo Shi Bu* (《唐国史补》*Supplement to the History of the Tang Dynasty*),[25] which recorded the popularization of Persian-style medicinal wines such as "*San Le Jiang* (三勒浆, brewed with *He Zi*)".

Internal diffusion relied on intricate hydro-geographic networks extending toward the southwest. The Xijiang–Hongshui River System (西江–红水河水系) served as the primary logistics artery; *Yuan He Jun Xian Zhi* underscores this by noting that vessel traffic on the Xijiang rivaled that of the Qinhuai River (秦淮河) , facilitating a seamless pharmaceutical link from Guangzhou through Duanzhou (端州, present-day Zhaoqing, 今广东省肇庆市) and Yongzhou (邕州, present-day Nanning, 今南宁市) to the Yunnan frontier. Overland diffusion followed the Yongzhou–Yunnan Post Road and the cross-border Jiaozhou–Yunnan–India Passage (安南通天竺道, a historical overland corridor linking Tonkin, Yunnan, and the Indian subcontinent). The latter, described in *Xin Tang Shu Di Li Zhi* as traversing the Red River Valley, was strategically rebranded as the "Qingmuxiang Mountain Road [青木香山路, a historical overland corridor driven by trade in traditional Qingmuxiang (Aristolochia root)]", highlighting its specialized role in the global spice trade.

Archaeological evidence, including Tang-era post road vestiges in Hekou and Pingbian, aligns precisely with the official itineraries recorded in *Xin Tang Shu Di Li Zhi*.[24] Furthermore, the account of the eminent monk Wukong (释悟空) returning to *Chang'an* (长安, the legendary imperial capital of the Han and Tang dynasties, present-day Xi'an City, 西安市) in 789 AD via the Uighur Road (回鹘道, a pivotal overland trade route connecting the Western Regions and China's Central Plains) confirms the functional integration between these southern conduits and the broader Western Regions transportation matrix.[26]

By the Song dynasty, *Ben Cao Tu Jing* (《本草图经》*Illustrated Classic of Materia Medica*) formally recognized Guangzhou as the preeminent production and distribution hub.[27] The final westward migration of the core production zone was completed during the Qing dynasty, as documented in *Dian Hai Yu Heng Zhi* (《滇海虞衡志》*Records of the Superintendent of Mountains and Rivers in Yunnan*).[28] This shift to the Nujiang River basin (怒江流域) was dictated by ecological imperatives—specifically the subtropical microclimates and acidic lithology—which provided optimal conditions for the accumulation of secondary metabolites. The integration of *He Zi* into Xizang Triphala formulations generated sustained high-volume demand, while the Tea-Horse Road (茶马古道) infrastructure enabled efficient regional distribution, eventually marginalizing overseas imports.

This evolution illustrates how medicinal plant distributions are emergent properties of ecological suitability, cultural integration, and economic networks. This holistic spatio-temporal framework remains a critical reference for contemporary resource zoning, conservation of the "King of Medicines", and the standardization of traditional medicine under the Belt and Road Initiative.

3 Temporal and spatial evolution of the medicinal properties and clinical applications of *He Zi*

Adopting a comparative approach within the framework of medical anthropology, this study analyzes how the cultural exchanges along the Silk Road transformed *He Zi* from an Ayurvedic "universal panacea" into a specialized pharmaceutical agent within localized systems.

By synthesizing primary records from *Charaka Samhita*, *Xin Xiu Ben Cao*, and *Jing Zhu Ben Cao*, we observe a progressive pattern of "theoretical gene retention → clinical experience adaptation → philosophical framework integration".

The evolution within TCM represents a sophisticated move beyond simple astringency. While modern textbooks often reduce its function to "astringing the lung and intestine", early primary sources like the Tang dynasty *Xin Xiu Ben Cao* emphasize its role in digestive regulation, specifically "treating cold qi, heart and abdominal distension, and eliminating stagnant food (主冷气心腹胀满，下宿物)". This indicates that the initial TCM absorption preserved the Ayurvedic focus on digestion and detoxification. Further expansions in clinical application are evident across dynasties; for instance, the Five Dynasties text *Hai Yao Ben Cao* proposed its use in ophthalmology for treating eye pain and dimness (肉炙治眼涩痛), while the Song dynasty *Ben Cao Tu Jing* documented its efficacy in treating phlegm-cough and soothing the throat. A hallmark of TCM's creative transformation is the clinical principle of *Sheng Shu Yi Yong* (生熟异用, the differential therapeutic efficacy between raw and prepared herbs). As later codified in *Ben Cao Qiu Zhen* (《本草求真》*Seeking Accuracy in the Materia Medica*), raw *He Zi* (*Sheng Yong*, 生用) was utilized for clearing the lung and moving the qi (清肺行气), whereas roasted *He Zi* (*Pao Zhi*, 炮制) was specialized for warming the stomach and stabilizing the intestines (温胃涩肠).[29] This bidirectional regulation—using the same resource to either promote qi descent (顺气下行) or stop incontinence (固涩滑脱)—represents a unique TCM innovation that refined the broad Ayurvedic rejuvenation therapy into a precise, state-dependent clinical tool.

In contrast, the Chinese Xizang medicine achieved a deep integration through its "balance of Three Humors" theory, utilizing the "five elements" philosophy to interpret the plant's diverse qualities. The 8th-century *Si Bu Yi Dian* asserted that "*He Zi* possesses five tastes, transforming to sweet after digestion (诃子具五味，消化后变甘)", a theory that inherited Ayurvedic rejuvenation concepts while innovatively developing the "post-digestive taste transformation (Zhu-wa, 转化味)" as a mechanism for systemic harmonization. The site-specific application recorded in *Jing Zhu Ben Cao*—in which the peel, pulp, and kernel target bone, muscle, and marrow respectively—represents a refined development of "morphology-efficacy correspondence". Furthermore, Mongolian medicine, influenced by this lineage, adapted the herb to the cold steppe environment, emphasizing its warm nature for "regulating the Three Roots [*Hii* (赫依), *Shira* (希日), *Badgan* (巴达干); 调节三根]" and prioritizing its detoxification role, as systematically detailed in the 19th-century *Meng Yao Zheng Dian* (《蒙药正典》*Classic Canon of Mongolian Materia Medica*).[30]

The modern era marks a transition from empirical identification to scientific quantification. A critical comparative analysis of current pharmacopoeial standards reveals cultural divergence in quality evaluation: while the Ayurvedic Pharmacopoeia of India (API) prioritizes water-soluble and alcohol-soluble extracts (reflecting traditional decoction and oil-based preparations). This phytochemical congruence supports the traditional preference for "six-ridged and thick-fleshed (六路肉厚)" fruits; modern metabolic profiling demonstrates that these morphological traits correlate with significantly higher concentrations of tannins and secondary metabolites. Concurrently, genomic and microbiomic studies have provided empirical evidence for Xizang "taste transformation", identifying how gut microbiota convert high-molecular-weight chebulagic acid into bioavailable gallic acid.

In summary, the evolution of *He Zi*'s medicinal properties is a dynamic process of knowledge reconstruction. It transitioned from the external therapeutic traditions emphasizing "rejuvenation and purification" to TCM's sophisticated "bidirectional regulation" and Chinese Xizang medicine's "systemic harmonization". This evolutionary trajectory—grounded in primary textual analysis and validated by modern quantitative data—stands as an exemplary model of how medicinal resources are culturally constructed and scientifically verified across Silk Road civilizations, embodying the principle of "one medicine, multiple effects, shared across civilizations".

4 Evolution and contemporary challenges of the quality standard of *He Zi*

4.1 Formation of traditional empirical criteria

Applying a cross-cultural medical anthropology lens, the traditional quality evaluation system for *He Zi* can be deconstructed as a three-stage evolutionary model: "morphological identification (性状鉴别) → trade-based validation → *Dao Di* (道地 geo-authentic) certification" (道地认证). This system transitioned from rudimentary sensory assessment to a sophisticated "morphology-origin-characteristics" paradigm.

The first stage established morphological indicators as proxies for botanical authenticity and chemical competent. The Liu Song dynasty text *Lei Gong Pao Zhi Lun* institutionalized the "six-ridged" fruit as the gold standard for authenticity, explicitly stating: "When applying this herb, do not use adulterants (such as Pili-le, Anli-le, etc.). Authentic Heli-le possesses exactly six ridges; those with more or fewer ridges are all considered adulterants (凡使，勿用毗梨勒、庵梨勒、榔精勒、杂路勒。若诃黎勒，文只有六路。或多或少，并是杂路勒)". From a phytochemical perspective, this traditional focus on longitudinal ridges is not merely arbitrary; modern studies suggest that the number and prominence of these ridges often correlate with fruit maturity and the concentration of secondary metabolites, such as chebulic acid and

tannins. This anatomical classification finds parallel recognition in Indian Ayurvedic medicine, which similarly classifies varieties based on shape and crease counts (such as the 5-creased Abhaya or 3-creased Chetaki), marking a cross-civilizational consensus on morphological evaluation.

The second stage involved distinguishing trade routes from botanical origins, a point of frequent historical ambiguity. The Tang dynasty text *Xin Xiu Ben Cao* established early trade-based quality marks, noting that "those coming on Persian ships with six ridges, black color, and thick flesh are superior (波斯舶上来者，六路黑色，肉厚者良)". It is crucial to clarify that this identified a trade-based quality mark rather than a botanical origin. Later, the Song dynasty *Ben Cao Tu Jing* further refined sensory evaluation by emphasizing "black color and thick flesh" and recorded the earliest association between geographical localization and quality: "Now found everywhere in Lingnan, with Guangzhou being the most abundant". The specific preference for "wind-dropped seeds (随风子)"—unripe fruits collected early—demonstrates an empirical understanding of functional differentiation, as these smaller fruits were traditionally favored for specific acute conditions, contrasting with the "thick-fleshed" mature fruits used for chronic deficiency.

The third stage was defined by the westward shift of the *Dao Di* center toward the Yunnan-Guizhou Plateau. *Dian Hai Yu Heng Zhi* documented that *He Zi* production had become concentrated in Cheli (modern Xishuangbanna, 西双版纳), noting that the species was "found everywhere in southern Yunnan". This shift was dictated by ecological specificity; the acidic soils and high-altitude microclimates of the Nujiang River basin provided an optimal environment for the accumulation of bioactive components, eventually marginalizing the earlier Lingnan and imported varieties.

By constructing a closed-loop system of "identification → processing differentiation → clinical validation", traditional practitioners achieved reproducible therapeutic outcomes. The classical text *Ben Cao Qiu Zhen* further elucidated this by linking quality to processing (*Pao Zhi*), stating: "raw used to clear the Lung, roasted to stabilize the intestines (生清肺行气，熟温胃固肠)". Ultimately, this traditional model—integrating ridge count for authenticity, *Dao Di* region (道地药材产区, geo-authentic producing area) for component accumulation, and "thick flesh" for maturity—serves as a historical transitional paradigm for modern scientific standardization, bridging the gap between empirical guidance and quantitative verification.

4.2 Establishment and challenges of modern scientific standards

Following the transparent comparative framework established in our methodology, Table 1 provides a quantitative and critical cross-evaluation of the quality standards for *He Zi* among the ChP 2025, Korean Pharmacopoeia (KP 2026), Indian Pharmacopoeia (IP 2026), Japanese Standards for Non-Pharmacopoeial Crude Drugs (Non-JPS 2022), USP-NF 2026, and Hong Kong Chinese Materia Medica Standards (HKCMMS). This comparative analysis reveals that the divergence in regulatory requirements is not merely administrative but deeply rooted in competing medical ontologies and localized clinical priorities.

Regarding botanical origin, ChP 2025,[31] KP 2026,[32] and HKCMMS[33] recognize both the original species and the var. *tomentella*, reflecting the historical localization and resource availability in East Asia. In contrast, IP 2022[34] and USP-NF 2026[35] restrict the source to the nominate species, prioritizing botanical purity over regional adaptation. While the medicinal part is consistently defined as the "dried ripe fruit", the methodologies for assessing its potency vary significantly, reflecting a transition from "extract-based" to "marker-based" standardization.

A critical interpretation of the "Assay" and "Extractives" sections highlights these distinct regulatory logics. Only the HKCMMS imposes a rigorous quantitative threshold for gallic acid via HPLC, targeting specific tannins as proxies for efficacy. Conversely, the IP 2026 and HKCMMS set the most stringent dual-solvent extractive limits (Table 1), a requirement that aligns with the Ayurvedic and traditional practice of utilizing concentrated aqueous or alcoholic decoctions. This ensures a high yield of total polyphenols, even in the absence of single-marker quantification. Physical purity standards—specifically ash and moisture—further illustrate regional risk management strategies. The USP-NF 2026 imposes the most rigorous moisture control (limit: 8%), a phytochemical imperative designed to prevent the hydrolytic degradation of hydrolyzable tannins (such as chebulagic acid) during global transport. Meanwhile, the pronounced emphasis on total ash and acid-insoluble ash limits in Asian pharmacopoeias (ChP, KP, IP, HKCMMS) reflects a traditional concern with "soil contamination" and the authenticity of the "*Dao Di*" mineral profile.

Safety parameters, including heavy metals and pesticide residues, reveal a tiered approach to risk. The KP 2026 and HKCMMS provide the most granular limits for heavy metals and sulfur dioxide (Table 1), reflecting the high regulatory scrutiny in export-oriented markets. The ChP 2025 has significantly modernized its pesticide residue and aflatoxin protocols, moving toward a "zero-tolerance" risk assessment model that aligns with international food and medicine safety norms.

In conclusion, these pharmacopoeial discrepancies represent "islands of regulation" that present substantial technical barriers to the global trade of the "King of Medicines". International harmonization must move beyond descriptive alignment toward a phytochemical congruence that respects cultural adaptability. Therefore, developing ISO international standards that reconcile

Table 1 National and regional quality requirements of *He Zi*

Test Indicators		ChP 2025	KP 2026	IP2026	HKCMMS	USP-NF 2026	Non-JPS2022[36]
Plant origin		Terminalia chebula Retz./Terminalia chebula Retz, var. tomentella Kurt.	Terminalia chebula Retz./Terminalia chebula Retz, var. tomentella Kurt.	Terminalia chebula Retz.	Terminalia chebula Retz./Terminalia chebula Retz, var. tomentella Kurt.	Terminalia chebula Retz.	Terminalia chebula Retz.
Medicinal part		Dried ripe fruit					
Identification	Macroscopic	√	√	√	√	√	√
	Microscopic	√	√	√	√	√	√
	TLC	√	/	√	√	√	√
Assay (%)		/	/	/	≥1.2 gallic acid (HPLC)	/	/
Extractives (%)		≥30 (water)	≥35.0 (diluted ethanol)	≥35.0 (diluted ethanol); ≥50.0 (water)	≥46.0 (diluted ethanol); ≥44.0 (water)	≥40.0 (diluted ethanol)	≥30 (diluted ethanol)
Total ash (%)		≤5.0	≤5.0	≤6.0	≤5.0	≤15.0	≤5.0
Ash insoluble in hydrochloric acid (%)		/	/	≤3.0	≤1.5	≤5.0	/
Moisture (%)		≤13.0	≤12.0[a]	≤12.0[a]	≤13.0[a]	≤8.0[a]	≤14.0[a]
Foreign matter (%)		/	≤2.0	≤2.0	≤1.0	1.0	/
Heavy metals	Pb	√	≤5 ppm	√	≤5 mg/kg	√	/
	As	√	≤3 ppm	√	≤3 mg/kg	√	/
	Cd	√	≤0.3 ppm	√	≤0.3 mg/kg	√	/
	Hg	√	≤0.2 ppm	√	≤0.2 mg/kg	√	/
Residual pesticides	Total DDT, mg/kg	1	[c]LOQ (0.1)	/	0.1	/	/
	Dieldrin, mg/kg	0.05[b]	[c]LOQ (0.01)	/	0.01	/	/
	Total BHC, mg/kg	0.3	[c]LOQ (0.2)	/	0.2	/	/
	Aldrin, mg/kg	0.05	[c]LOQ (0.01)	/	0.01	/	/
	Endrin, mg/kg	0.05	[c]LOQ (0.01)	/	0.01	/	/
	Captan, mg/kg	/	/	/	2	/	/
Sulfur dioxide (mg/kg)		√	30	/	30	/	/
Aflatoxins	Aflatoxin B1 μg/kg	√	/	/	/	√	/
	Aflatoxins (B1, B2, G1, G2) μg/kg	√	/	/	/	√	/

NOTES: √: items need to be determined. /: not available. [a]Loss on drying. [b]Aldrin and dieldrin (sum of). [c]LOQ: the tested result is no more than the Limit of Quantitation (LOQ). Values in the brackets refer to corresponding LOQs.

traditional morphological markers (e.g., the "six-ridged" criterion) with modern multi-component quantification holds significant practical significance. Such an initiative will promote the standardization-globalization nexus, providing the necessary empirical and scientific scaffolding for the sustainable growth of the *He Zi* international market.

5 Conclusion

The transregional dissemination history of *He Zi* serves as a quintessential example of the dynamic cross-cultural adaptation and knowledge reconstruction of medicinal plants revered as the "King of Medicines". Its dual-track diffusion via the overland and maritime Silk Roads—systematically tracing its trajectory from South Asia, Southeast Asia, and southern China to East Asian production hubs—demonstrates that the globalization of traditional medicine hinges on the creative transformation of knowledge systems rather than mere transplantation. This study constructs a methodologically transparent "dissemination-interpretation-standardization" analytical framework grounded in primary sources (e.g., *Charaka Samhita*, *Jing Zhu Ben Cao*, and *Xin Xiu Ben Cao*) to reveal the following: The identity transformation of *He Zi*—from records in classical South Asian materia medica to its localized interpretation in Chinese Xizang medicine and TCM materia medica *Zhe Bu Song Tang* (哲布松汤 Three Fruits Decoction), and further to a key herb in TCM for sophisticated bidirectional regulation (balancing the actions of "clearing lung qi" when raw and "stabilizing intestines" when

prepared)—fundamentally reflects the divergent interpretations of the same medicinal resource by different medical paradigms. This differentiation stems not only from geographical and ecological variations, such as the holistic regulatory strategies shaped by the plateau hypoxic environment in Chinese Xizang medicine, but also from cultural-cognitive disparities, such as the philosophical divergence between TCM's "Yin-yang balance (阴阳平衡)" and Ayurveda's "Tridosha" theory. The core tension in contemporary standardization manifests as the opposition between scientific positivism and cultural relativism. Our critical phytochemical evaluation establishes a congruence between traditional morphological indicators—such as the "six-ridged" preference—and the accumulation of bioactive secondary metabolites, effectively bridging sensory evaluation with quantitative content determination. This tension is concretely embodied in the differentiated quality standards: the ChP emphasizes safety markers and marker-based quantification; the Chinese Xizang medicine processing standards rely on morphology-efficacy correspondence and "taste transformation" theory; while the API prioritizes high extractive thresholds to ensure total polyphenol yield. Accordingly, a coordination pathway should be established based on "methodological pluralism"—aiming for the development of ISO international standards that reconcile cultural characteristics, such as TCM processing techniques and Xizang sensory evaluation, while simultaneously achieving a dialectical unity between scientific standardization and cultural respect. This can be realized through measures including raw material mutual recognition, unified safety benchmarks, the parameterization of traditional processes, and other relevant strategies. The limitations of this study lie in fragmented historical documentation and scarce empirical data from ethnic medical systems. Future research requires deepening through the integration of plant microfossil analysis from Silk Road archaeological sites, ITS2 sequence-based phylogeography, and the digital preservation of traditional knowledge.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by the author.

Author contributions

SUN Hongbing and YANG Huijie drafted and reviewed the manuscript. ZENG Rui and TANG Yi'na guided and revised the article. All authors agreed to publish the contents.

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The authors employed DeepL Write to polish the manuscript's English. All AI-proposed edits were reviewed and revised, and the authors bear full responsibility for the final content.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Chattopadhyay RR, Bhattacharyya SK. PHCOG REV: Plant review *Terminalia chebula*: an update. *Pharmacognosy Reviews*. 2007;1(1):151–156.
[2] Ahmed S, Ding X, Sharma A. Exploring scientific validation of Triphala Rasayana in ayurveda as a source of rejuvenation for contemporary healthcare: an update. *Journal of Ethnopharmacology*. 2021;273:113829.
[3] Belapurkar P, Goyal P, Tiwari-Barua P. Immunomodulatory effects of triphala and its individual constituents: a review. *Indian Journal of Pharmaceutical Sciences*. 2014;76(6):467–475.
[4] Wang CJ, Zhang HF, Wang XD, et al. Comprehensive review on fruit of *Terminalia chebula*: traditional uses, phytochemistry, pharmacology, toxicity, and pharmacokinetics. *Molecules*. 2024;29(23):5547.
[5] Su J. *Newly Revised Materia Medica* (新修本草). Shang ZJ, edited. Hefei: Anhui Science and Technology Publishing House; 1981. p. 358. Chinese.
[6] Tang SW. *Revised Zhenghe's Classified Materia Medica for Emergency* (证类本草重修政和经史证类备急本草). Shang ZJ, edited. Beijing: Huaxia Publishing House; 1993. p. 405. Chinese.
[7] Kim HL, Choi BK, Yang SH. *Terminalia chebula* medicinal uses: a review of in vitro and in vivo studies. *Biotechnology and Bioprocess Engineering*. 2022;27(5):729–739.
[8] Charaka S. *Charaka's Compendium of Medicine* (*Charaka Samhita*). Vol.1. Sharma PV, edited. Varanasi: Chaukhambha Orientalia (A House of Oriental and Antiquarian Books); 2003. p. 209–210. Sanskrit.
[9] Li SJ. *The Grand Compendium of Materia Medica* (本草纲目). Liu HR, Liu YS, et al., edited. Beijing: Huaxia Publishing House; 2007. p. 1360–1362. Chinese.
[10] Deumar TP. *Crystal Materia Medica* (晶珠本草). Shanghai: Shanghai Scientific and Technical Publishing House; 1986. p. 54. Chinese.
[11] Linghu DF. *History of the Zhou Dynasty*: *Volume 50* (周书：卷50). Beijing: Zhonghua Book Company; 1971. p. 920. Chinese.
[12] Wei S. *History of the Wei Dynasty*: *Volume 102* (魏书：卷102). Beijing: Zhonghua Book Company; 1974. p. 2270–2271. Chinese.
[13] Xu JZ. *Collection and Research of Dunhuang Poetry Manuscript Fragments* (敦煌诗集残卷辑考). Beijing: Zhonghua Book Company; 2000. Chinese.

[14] Zhang ZJ. *Essential Prescriptions of the Golden Cabinet* (金匮要略). Beijing: China Traditional Chinese Medicine Press; 2022. p. 63. Chinese.
[15] Ji H. *Plants of the Southern Regions* (南方草木状). Guangzhou: Guangdong Science and Technology Publishing House; 2009. p. 45. Chinese.
[16] Li X. *Materia Medica from the (Southern) Seaboard Area* (海药本草). Shang ZJ, edited. Beijing: People's Medical Publishing House; 1997. p. 63. Chinese.
[17] Zhou QF. *Representative Answers from the Region beyond the Mountains* (岭外代答). Yang WQ, edited. Beijing: Zhonghua Book Company; 1999. p. 193–196. Chinese.
[18] Anonymous. *The Somaraza: The King of Moon's Diagnosis and Therapeutics* (月王药诊). Ma SL, Mao JZ, edited. Shanghai: Shanghai Scientific and Technical Publishers; 2012. Chinese.
[19] Yu T. *The Four Medical Tantras* (四部医典). Ma SL, et al., edited. Shanghai: Shanghai Scientific and Technical Publishers; 1987. p. 280–281. Chinese.
[20] Anonymous. *Collection of Golden Light Commentaries* (金光注释集). Da R, Luo B, et al., edited. Hohhot: Inner Mongolia People's Publishing House; 1998. Chinese.
[21] Lei X. *Master Lei's Discourse on Medicinal Processing* (雷公炮炙论). Nanjing: Jiangsu Science and Technology Publishing House; 1985. p. 69. Chinese.
[22] Chen CQ. *Supplement to "The Grand Compendium of Materia Medica"* (本草拾遗). Shang ZJ, edited. Hefei: Anhui Science and Technology Publishing House; 2002. p. 123. Chinese.
[23] Li JF. *Maps and Gazetteer of the Prefectures and Counties in the Yuanhe Period* (元和郡县图志). Beijing: Zhonghua Book Company; 1983. Chinese.
[24] Ouyang X, Song Q. *New History of the Tang Dynasty: Geography* (新唐书·地理志). Beijing: Zhonghua Book Company; 1975. p. 55. Chinese.
[25] Li Z. *Supplement to the History of the Tang Dynasty* (唐国史补). Shanghai: Shanghai Ancient Books Press; 2000. p. 197. Chinese.
[26] Zhang K. The travelogues of Buddhist monks and the knowledge of the Western Regions during the fourth to the sixth centuries. *Religions*. 2024;15(8):886.
[27] Su S. *Illustrated Classic of Materia Medica* (本草图经). Shang JZ, edited. Hefei: Anhui Science and Technology Publishing House; 1994. p. 416–417. Chinese.
[28] Tan C. *Records of the Superintendent of Mountains and Rivers in Yunnan* (滇海虞衡志). Song WX, Li DP, edited. Kunming: Yunnan People's Publishing House; 1990. p. 74. Chinese.
[29] Huang GX. *Seeking Accuracy in the Materia Medica* (本草求真). Liu LX, Pan QP, edited. Beijing: People's Medical Publishing House; 1987. p. 61. Chinese.
[30] Liubai YL. *Classic Canon of Mongolian Materia Medica* (蒙药正典). Beijing: The Ethnic Publishing House; 2006. p. 79–81. Chinese.
[31] China Pharmacopoeia Commission. *Pharmacopoeia of the People's Republic of China. Part 1* (《中华人民共和国药典》第一部). Beijing: Chinese medicines and Technology Press; 2025. Chinese.
[32] Ministry of Food and Drug Safety. *Korean Pharmacopoeia 13th Edition*. Cheongju: Ministry of Food and Drug Safety; 2026.
[33] Hong Kong Chinese Materia Medica Standards Committee. *Hong Kong Chinese Materia Medica Standards* (香港中药材标准). Volume 12, Chebulae Fructus. Hong Kong: Hong Kong Chinese Materia Medica Standards Committee; 2025. Chinese.
[34] Indian Pharmacopoeia Commission. *Indian Pharmacopoeia (10th Edition)*. Ghaziabad: Indian Pharmacopoeia Commission; 2026.
[35] United States Pharmacopeial Convention. *United States Pharmacopeia and National Formulary*. Rockville: United States Pharmacopeial Convention; 2026.
[36] Maruyama T. *The Japanese Standards for Non-pharmacopoeial Crude Drugs 2022* (日本薬局方外生薬規格2022). Tokyo: Yakuji Nippo, Ltd.; 2022. Japanese.

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Original Article

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OPEN

Bridging the Cultural Gap: Current Status, Standardization Approaches, and Prospects of TCM Core Term Translation

弥合文化鸿沟：中医药核心术语翻译的现状、标准化方法和前景

XU Gaonan (徐高楠)[1,✉]

Abstract

Traditional Chinese medicine (TCM) is an integral part of traditional Chinese culture, and the accurate translation of its core terms is the key to its international dissemination. However, the current translation of TCM core terms is plagued by problems such as conceptual network disruption, cultural connotation loss, and inconsistent functional application, and existing studies lack an integrated theoretical framework to guide systematic translation and standardization. Taking the core terms from *Huang Di Nei Jing* (《黄帝内经》*The Yellow Emperor's Inner Classic*) and *Shang Han Lun* (《伤寒论》*Treatise on Cold Damage*) as the research objects, this study systematically analyzes the translation dilemmas of TCM core terms by integrating Skopos Theory and Thick Translation Theory. This study finds that the root cause of TCM term translation challenges lies not in lexical gaps, but in the partial or complete failure of cultural transmission, cognitive mapping, and functional adaptation in the cross-cultural communication process. To address this, the study constructs a Cultural-Cognitive-Functional (CCF) Triad Model as the core theoretical framework, which clarifies the hierarchical relationship and internal logic of the three dimensions of TCM term translation: taking cognitive mapping as the foundation, cultural transmission as the core, and functional adaptation as the goal. Based on the CCF Model, the study further proposes a dynamic standardization pathway for TCM core terms with a three-layer architecture (Conceptual Anchor Layer, Cognitive-Cultural Annotation Layer, Functional Adaptation Layer) and a tripartite cross-disciplinary collaboration mechanism. This pathway transcends the traditional static annotation-based translation model and realizes the organic unity of TCM terms' conceptual stability and scenario-based functional flexibility. The study verifies the explanatory power and practical guiding value of the CCF Model through empirical case analysis, and provides a new theoretical framework and practical solution for the standardization and international dissemination of TCM core terms, which are of great significance for promoting the integration of TCM into the global health governance system.

Keywords: Terminology; Cross-cultural reconstruction; Term translation; Traditional Chinese medicine (TCM)

1 Introduction

Traditional Chinese medicine (TCM), as a cornerstone of Chinese traditional culture with distinct philosophical underpinnings and holistic health theories, has gained significant global attention, with an unprecedented acceleration in its international dissemination over the past two decades.[1] The formal inclusion of TCM in the World Health Organization's (WHO) International Classification of Diseases, 11th Revision (ICD-11), in 2019 marked a historic milestone in its global legitimacy and institutional recognition.[2] However, the cross-cultural dissemination of TCM remains severely constrained by long-standing translation challenges, particularly the accurate rendering of its culture-specific core concepts into Western languages.[3] This study addresses these critical gaps by developing a systematic framework for TCM terminology translation and standardization.

1.1 TCM globalization and the imperative of terminology translation

Driven by the global demand for integrative and holistic healthcare, TCM has evolved from a regional traditional medical system into a key component of global health

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governance.[2] The WHO's integration of traditional medicine into its global health framework, the expansion of TCM educational institutions and clinical practice centers across over 183 countries and regions, and the growing academic interest in TCM's clinical efficacy and theoretical systems all underscore its rising value in the international medical arena.[4] Against this backdrop, translation serves as the fundamental bridge for TCM's cross-cultural communication, as it determines the accuracy of knowledge transmission, the consistency of clinical application, and the recognition of TCM's academic legitimacy in the global context.[1]

However, TCM's cross-cultural transmission has long been plagued by entrenched translation dilemmas. Unlike modern Western medicine, which is rooted in reductionist biomedical models, many core concepts of TCM originate from ancient Chinese philosophical systems. These concepts carry multi-layered cultural, philosophical, and medical connotations that cannot be directly mapped onto corresponding terms in Western biomedical language.[5] This conceptual gap not only leads to pervasive misunderstandings of TCM theories among international audiences but also restricts the standardized clinical application of TCM and its academic recognition in global medical communities.[6] As TCM accelerates its integration into the global health landscape, overcoming translation bottlenecks and striking a balance between preserving cultural depth and ensuring academic precision have become an urgent and critical issue to be addressed.[7]

1.2 Critical review of existing research on TCM terminology translation

The standardization of TCM terminology translation has experienced three developmental stages in the past six decades.[8] The 1960s–1970s saw pioneering individual scholarly attempts, such as Manfred B. Porkert's Latin-based terminology system and Joseph Needham's flexible approach of neologism and transliteration, which laid initial foundations but failed to form a unified operable framework.[9,10] The 1980s–1990s witnessed the growing involvement of Chinese scholars and the development of institutional standards. During this period, Ou Ming's translation principles, the WHO's limited acupuncture nomenclature standard, and Nigel Wiseman's widely adopted literal-translation dictionary represented important advances, although they also had obvious limitations.[11–13] The 21st century has brought collaborative international standards, with China's 2004 norms, the WHO's 2007 terminology standard, and World Federation of Chinese Medicine Societies's (WFCMS) 2008 translation standard becoming three global pillars, and ISO/TC 249 advancing the draft international standard for TCM terminology. Despite these efforts, core term translation inconsistencies and insufficient systematicity remain prominent.[14,15]

Contemporary research on TCM terminology translation mainly focuses on term-specific studies, translation strategy research and standardization in the context of cross-cultural communication, and the field is plagued by four critical gaps, with the absence of an integrated theoretical framework tailored to TCM's unique cultural and cognitive attributes as the core pain point. This core deficiency further leads to fragmented standardization focusing on isolated terms, static translation strategies that overlook contextual and cognitive dynamics in cross-cultural communication, and a weak connection between theoretical construction and practical application. All the above gaps make it impossible to realize the systematic cross-cultural reconstruction of TCM's holistic conceptual system through translation.

To address these gaps, this study develops a Cultural-Cognitive-Functional (CCF) Triad Model, which frames the core challenges of TCM terminology translation as failures in cultural transmission, cognitive mapping, or functional adaptation. By integrating this model with a dynamic standardization pathway (including multi-version translation analysis, and culturally annotated knowledge graphs), the study bridges the research gap between fragmented term-level studies and holistic standardization, and offers a theoretically grounded and practically applicable solution for TCM terminology translation.

2 The theoretical dilemma and way forward for TCM terminology standardization: a Cultural-Cognitive-Functional Triad Model

The persistent challenges in TCM terminology translation stem not from a scarcity of translation attempts or annotation techniques, but from the absence of a theoretical framework capable of systematically explaining and guiding the cross-cultural reconstruction of conceptual systems. Current standardization efforts are often confined to the level of "term equivalence", failing to address the fundamental conflict between the internal structure of TCM knowledge and its expression across languages. This section proposes a CCF Model to provide an explanatory and actionable theoretical blueprint for standardizing TCM terminology translation.

2.1 The theoretical dilemma: from "Term Inequivalence" to "Conceptual Network Disruption"

The fundamental challenge in translating TCM terminology extends far beyond finding "correct equivalents". It lies in the fact that the TCM conceptual system is rooted in a holistic, relational, and process-oriented cognitive paradigm, which structurally differs from the Western medical model based on entities, classifications, and causal

chains. Simply translating "qi (气)" as "energy" or "*Bian Zheng Lun Zhi* (辨证论治)" as "pattern differentiation" is not merely semantic distortion; it leads to conceptual network disruption—the severing of a term's systemic connections and dynamic meanings within its native theoretical web. Existing standardization attempts (e.g., by WHO and WFCMS) provide term lists but lack the "conceptual maps" linking these terms.[16] Consequently, translation practice is reduced to the substitution of isolated symbols, incapable of conveying the holistic logic of TCM, and it is difficult to establish a standardized system that adapts to different communication scenarios and audience needs.

2.2 Model construction: theoretical integration of cognition, culture, and function

To overcome this dilemma, the CCF Model posits that effective terminology translation must simultaneously address three interrelated dimensions with a clear hierarchical structure: cognition as the foundation, culture as the core, and function as the ultimate goal. The three dimensions are not isolated but interconnected, thereby forming a comprehensive theoretical system for TCM terminology translation and evaluation.

Cognitive dimension focuses on the mental models and conceptual structures behind the terms. Translation requires cognitive mapping to reveal TCM concepts (e.g., "yin-yang", "five elements") as relational networks rather than independent entities. This can be aided by visualization, analogy, and system diagrams to help target readers construct corresponding cognitive frameworks.[17]

Cultural dimension focuses on the philosophical views, values, and worldview carried by the terms. Translation requires strategies like Thick Translation (e.g., annotations, introductions, comparative explanations) to reconstruct the cultural context, preventing terms from being simplified as exotic curiosities or forcibly subsumed into Western categories.[18,19]

Functional dimension focuses on the communicative purpose of terms in specific contexts. Guided by Skopos Theory, translation strategies should be stratified according to the audience (clinicians, researchers, students, the public) and text type (classics, textbooks, clinical guidelines, popular science), creating a functional spectrum from "scholarly precision" to "public readability".[19]

Crucially, the CCF Model operates as a meta-theoretical decision-making framework at the upper level of translation practice, rather than a replacement for specific translation approaches and strategies. Instead, it provides a systematic, evidence-based rationale for the selection and combination of concrete translation methods—including literal translation, free translation, transliteration, and thick translation—resolving the long-standing arbitrariness in strategy selection that plagues traditional dichotomous thinking.

2.3 Model application: from theory to standardization pathway

The CCF Model (Fig. 1) suggests that standardization is not a static list of unified terms, but the establishment of a dynamically corresponding conceptual system. Its implementation pathway involves the following three aspects.

Firstly, building a core conceptual network map for TCM. Based on classics like *Huang Di Nei Jing* (《黄帝内经》*The Yellow Emperor's Inner Classic*) and *Shang Han Lun* (《伤寒论》*Treatise on Cold Damage*), map the semantic, logical, and pathological relationships among core terms (e.g., qi, yin-yang, zang-fu, six meridians).[20,21]

Secondly, developing stratified translation protocols. For a single term, first develop a core anchored translation (e.g., "qi") to ensure unique conceptual identification, then a cultural-cognitive annotation explaining its systemic position within Chinese philosophy and medicine, and finally a functional variant translation (e.g., "pattern" for clinical contexts, "balance of forces" for popular science).

Thirdly, constructing a "Term-Context-Function" relational database. Dynamically link terms with their original classical contexts, authoritative translation examples, applicable scenarios, and cultural annotations to support intelligent retrieval and contextualized translation recommendations.

This model does not negate the practical value of literal or free translation, nor does it avoid the necessary selection between these core approaches in translation practice. Instead, it transcends the long-standing, oversimplified binary opposition of "literal vs. free translation"—which has trapped the field in unproductive, context-agnostic debates over the superiority of a single method—and moves beyond the formulaic, one-size-fits-all "translation + annotation" approach. By establishing a three-dimensional evaluative system, the CCF Model provides a clear, theoretically grounded decision-making path for the flexible selection, combination, and optimization of translation strategies: for instance, it defines the applicable scenarios for literal translation to preserve cognitive structural integrity, the conditions for free translation to achieve functional communicative goals, and the standard for deploying thick translation (with layered annotations) to compensate for cultural and cognitive gaps. In doing so, it reframes TCM terminology translation as a systematic, cross-cultural knowledge reconstruction process, rather than a fragmented lexical choice between literal and free rendering, thus offering a new integrated framework for the theory and practice of TCM terminology standardization.

3 Challenges in translating TCM terms: an analysis through the CCF Model

The translation of TCM terms into Western languages faces significant obstacles due to linguistic, cultural, and

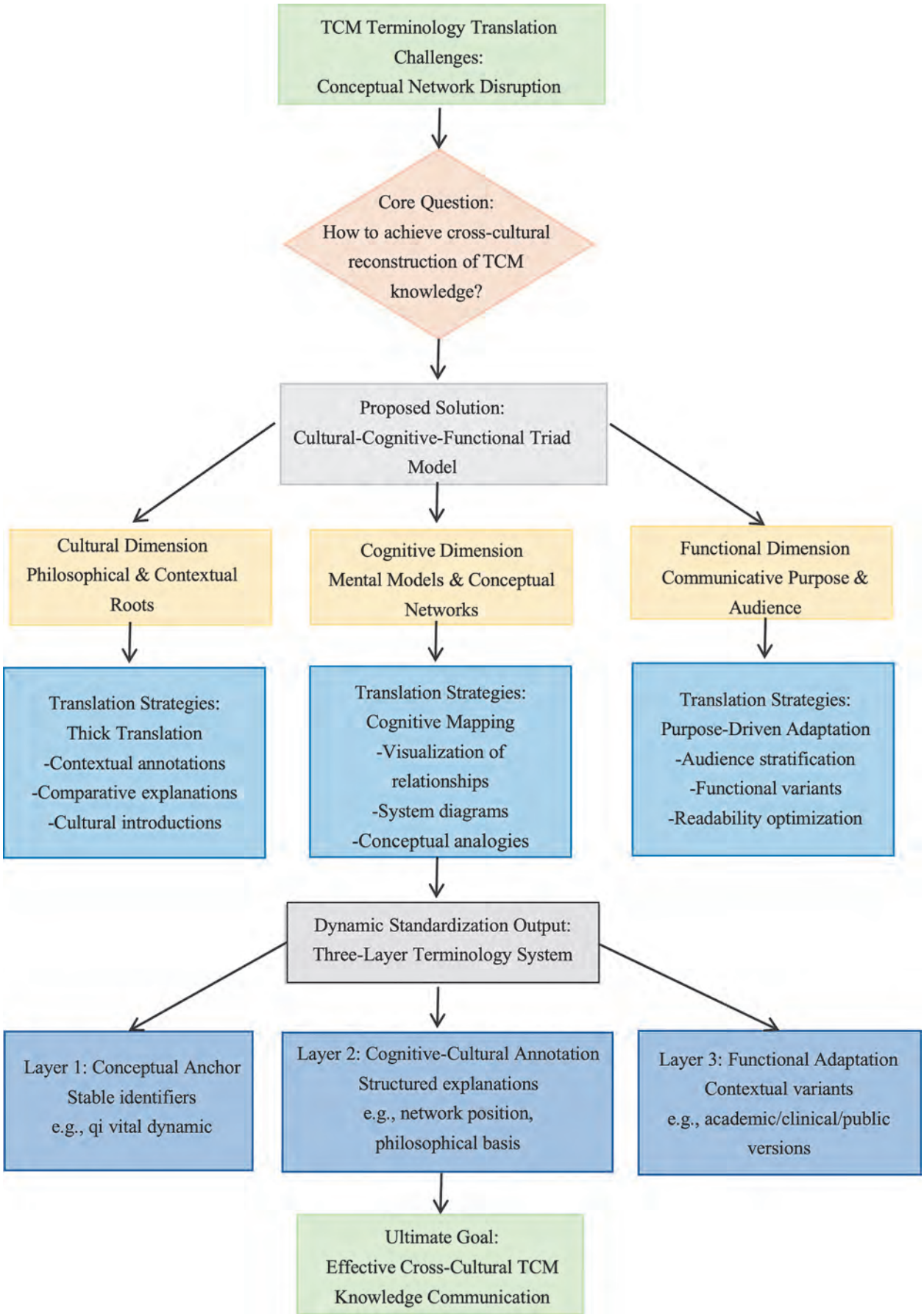


Figure 1 CCF Model (source with permission from: picture made by the author)

standardization issues. These challenges are manifestations of partial or complete failures in one or more dimensions of cultural transmission, cognitive mapping, and functional adaptation from the perspective of the CCF Model. Unlike traditional classifications of translation difficulties, this section provides an in-depth analysis of three major challenges—linguistic untranslatability, cultural misinterpretations, and terminological inconsistencies—with concrete examples and theoretical explanations.

3.1 Cognitive dimension failures: linguistic and conceptual barriers

Cognitive mapping is the core link of TCM terminology translation, which requires the translator to reconstruct the unique holistic, relational, and process-oriented cognitive paradigm of TCM in the target language. The so-called "linguistic untranslatability" in TCM translation is not an independent challenge, but the superficial linguistic manifestation of cognitive dimension failure—the mismatch between the TCM cognitive system (emphasizing synthesis and imagery), and the Western cognitive system (emphasizing analysis and entities) is reflected in the conceptual gap, semantic expression, and structural form of language. All linguistic barriers ultimately point to the failure of cognitive mapping, making it impossible for target language readers to construct a cognitive framework consistent with TCM theory.[22]

3.1.1 Conceptual gaps: cognitive paradigm mismatch

Many TCM core terms lack direct equivalents in English or other Western languages because they originate from a unique holistic cognitive paradigm of TCM, which is a typical cognitive mapping failure caused by paradigm mismatch. Based on *Huang Di Nei Jing*, the literal translation of "*Shang Huo* (上火)" describes a TCM-specific syndrome of internal qi imbalance caused by exuberant yang fire or stagnation of pathogenic heat, involving clinical manifestations such as sore throat, oral ulcers, and dry stools. Its core connotation is the dynamic imbalance of the internal environment rather than the fixed biomedical concept of "fever" or "inflammation". Translating it as "excessive heat" or "fire rising" only captures the literal semantic meaning, but fails to map the TCM cognitive logic of "taking the image to name the syndrome and judging the state by the syndrome". For Western readers with a biomedical cognitive background, this kind of translation will lead to the misconstruction of cognitive concepts, which is the direct result of the failure to realize cross-cultural cognitive mapping.[23,24]

Another typical example is "*Shi Qi* (湿气)", which is not the simple "moisture" in the physical sense in TCM cognition, but a pathogenic factor with the characteristics of "sticky, heavy, and stagnant" that causes sluggish visceral qi movement and metabolic disorders. Translating it as "dampness" only conveys the physical attribute of moisture, but cannot map the TCM cognitive connotation of "pathogenic factor and its pathological effect", resulting in the disconnection between the term and the TCM cognitive system.

3.1.2 Semantic overload: cognitive connotation compression

The semantic overload of single TCM terms is a cognitive dimension failure caused by the compression of complex conceptual connotations—TCM terms condense multilayered cognitive connotations of philosophy, physiology and pathology, and a single target language word cannot carry the complete cognitive information, leading to the loss of cognitive connotation in translation. Taking "*Shen Ji* (神机)" and "*Qi Li* (气立)" from *Huang Di Nei Jing* as examples, the two terms form a high-level cognitive system of the TCM view of life second only to the yin-yang and five elements theory, which condenses the cognitive connotation of TCM on the origin, operation and essence of life. "*Shen Ji*" refers to the internal regulatory mechanism of life activities based on the combination of spirit and qi, and "*Qi Li*" refers to the external existence state of life relying on the exchange of qi between the human body and the natural environment. The two complement each other and constitute the holistic cognitive understanding of life in TCM.[23,25]

Directly translating "*Shen Ji*" and "*Qi Li*" as "metabolism" only compresses the complex TCM cognitive connotation into a single Western biomedical concept, ignoring the holistic and relational cognitive characteristics of TCM on life activities. This translation method fails to map the multi-dimensional cognitive connotation of the original term, and leads to the simplification and distortion of TCM cognitive model, which is a typical cognitive dimension failure in the translation of semantically overloaded terms.

3.1.3 Structural discrepancies: cognitive expression barrier

The grammatical and syntactic structural differences between classical Chinese and Western languages are the cognitive expression barriers in the cognitive dimension. The linguistic structure of TCM classics is rooted in the TCM cognitive model of "holistic connection and intuitive understanding", and its conciseness, imagery and implicitness are the external expression of TCM cognitive thinking; while Western languages emphasize logical explicitness and structural completeness, which are the linguistic embodiment of Western analytical cognitive thinking. The structural discrepancy between the two languages leads to the failure of cognitive expression in translation, making it difficult to convey the TCM cognitive logic through the target language structure.[26,27]

Simply put, TCM terminology and classical sentences often adopt the principle of "concise words with rich meaning" and omit core semantic elements, which requires readers to supplement implicit information based on TCM cognitive background. For example, "liver constraint (肝郁)" means "constraint of liver qi (肝气郁结)". The term doesn't explicitly mention "qi", but the meaning of "qi" is actually implied. TCM terminology also frequently omits core semantic elements in a highly condensed form, requiring readers to fill in the implicit information through context and professional knowledge. This feature of "concise words with rich meaning" can easily lead to semantic gaps in English translation. To raise another example from *Huang Di Nei Jing Su Wen Ju Tong Lun* (《黄帝内经·素问·举痛论》*The Yellow Emperor's Inner Classic: Basic Questions: Discourse on Pain*), the phrase "*Nu Ze Qi Shang, Xi Ze Qi Huan* (怒则气上，喜则气缓)"[11] uses emotion nouns like "anger (怒)" and "joy (喜)" directly as subjects relating to "qi rising (气上)" and "qi relaxing (气缓)", omitting the premise of "when a person is in a certain emotional state" and the logical verb "causes". This syntactic structure is the embodiment of TCM cognitive thinking that "emphasizes the state and the relationship between things rather than the explicit logical connection". A literal translation of "Anger causes qi to rise; joy causes qi to relax" conforms to the grammatical structure of English, but fails to convey the TCM cognitive logic of "seven emotions injure the internal organs and affect the movement of qi". The core reason is that the translation only realizes the surface structural conversion, but fails to express the underlying TCM cognitive thinking through the target language structure, resulting in the failure of cognitive expression in the cognitive dimension.

Secondly, TCM often presents causes of disease (病因 etiologies), pathogenesis (病机), or patterns (症候) in formulaic structures by using parallel nouns. While these expressions may seem simple, they contain complex pathological relationships, making it difficult to balance concise form and conceptual completeness in English translation. For example, if we directly translate "*Feng Han* (风寒)" as "wind cold", it sounds unnatural in English and may hinder understanding of the term's connotations. In *Huang Di Nei Jing Su Wen Bi Lun* (《黄帝内经·素问·痹论》*The Yellow Emperor's Inner Classic: Basic Questions: Discourse on Blocks*), the phrase "When wind, cold, and dampness assail the body together, they combine and cause *Bi* (风寒湿三气杂至，合而为痹也)" is a typical example of this formulaic expression. The three terms "wind, cold, and dampness" are listed in parallel, referring not only to three external pathogenic factors, but also to the indication of the pathological mechanism of their combined action in causing disease. A literal translation such as "Wind, cold and dampness converge and cause bi syndrome" conveys the surface meaning, but fails to capture the synergistic pathogenic nature of the "three pathogens acting together" in TCM. Wind tends to move and change rapidly, while cold causes stagnation and contraction, and dampness is sticky, heavy, and turbid. The combination of these three leads to the complexity of bi syndrome, which far exceeds the effect of any single pathogenic factor. In such cases, it is appropriate to use supplementary annotations in translation: "Wind, cold, and dampness—when these three pathogens assail the body together, they combine to cause bi syndrome which is a disorder characterized by pain, stiffness, or numbness in the joints or muscles". By adding the term "pathogens" to clarify their etiological nature and providing a note to explain the meaning of "bi syndrome", this approach balances conciseness and professionalism in translation.

3.2 Cultural dimension failures: conceptual simplification and misinterpretation

Cultural transmission is the fundamental guarantee for the translation of TCM terminology, which requires the translator to retain the complete cultural connotation and philosophical foundation of TCM terms in the translation process. Cultural dimension failure refers to the simplification, distortion, or complete loss of the cultural connotation of TCM terms in translation, which is manifested in the separation of TCM terms from their original cultural and philosophical context, and the forced subsumption into Western cultural and medical categories. This kind of failure is the main cause of cross-cultural misinterpretation of TCM theory, and is most prominent in the translation of core terms of *Shang Han Lun*, the foundational work of TCM pattern differentiation and treatment.[28,29]

The core cultural connotation of TCM terms is rooted in traditional Chinese philosophical thoughts such as the unity of man and nature, yin-yang and the five elements theory, and the holistic view of life. Translating TCM terms without their cultural context is equivalent to stripping them of their soul. For instance, the cultural connotation of "*Shang Han* (伤寒)" is not limited to the literal meaning of "external contraction of cold pathogen", but also encompasses a broad cultural concept rooted in the TCM holistic view of disease. This concept includes the complete six-meridian pattern differentiation system, the pathogenic mechanism of "struggle between vital qi and pathogenic qi", and the treatment principle of "treating diseases according to the stage of pathogenesis", which is the core framework of TCM diagnosis and treatment of exogenous diseases. Some translations simplify it as "cold damage", only emphasizing the literal meaning of "cold pathogen causing injury", and sever the connection between the term and the TCM cultural and theoretical system. This translation method leads Western readers to misinterpret "*Shang Han*" as the Western biomedical concept of "upper respiratory tract infection", ignoring its cultural connotation as the core diagnostic and therapeutic

framework of TCM, which is a typical cultural dimension failure caused by conceptual simplification.[30,31]

Another example is "*Wei Jia Shi* (胃家实)" in the "Yangming Disease" chapter of *Shang Han Lun*, whose cultural connotation is closely linked to the TCM zang-fu (脏腑) correlation theory and the eight-principle pattern differentiation system. "*Wei Jia* (胃家)" is not a simple anatomical concept of "stomach", but a cultural concept in TCM that includes the stomach and large intestine based on meridian connection and functional correlation; "*Shi* (实)" is not just the "excess" in the physical sense, but a core diagnostic concept in the TCM eight principles that reflects the pathological state of "exuberant yang heat and stagnation of food and stool in the gastrointestinal tract". Translating it as "excess in the stomach" only maps the Western anatomical cognitive concept, strips the term of its cultural connotation linked to the TCM zang-fu correlation theory, and makes it impossible for target language readers to understand the TCM cultural logic of "zang-fu organs are interconnected and their functions are mutually restricted". This kind of translation is a cultural dimension failure caused by conceptual distortion, which directly leads to the cross-cultural misinterpretation of TCM theory.

The essence of cultural dimension failure is the deconstruction of the cultural ecosystem of TCM terms. TCM is an organic combination of traditional Chinese culture and medical practice, and its terms are the core carriers of cultural connotation. When translators simplify or distort the cultural connotation of TCM terms for the convenience of translation, they not only make the terms lose their cultural identity, but also lead to the disconnection between the TCM theoretical system and its cultural root, making it difficult for international audiences to truly understand the essence of TCM theory.

3.3 Functional dimension failures: terminological confusion and systemic discrepancies

Functional adaptation is the practical goal of TCM terminology translation, which requires the translator to formulate targeted translation strategies according to the specific communication context, target audience, and functional purpose of the term. Functional dimension failure refers to the lack of systematic functional adaptation in TCM terminology translation and standardization, which is manifested in the confusion of term translation and the discrepancy of standard systems. The failure to unify the core term anchors and formulate stratified translation strategies according to the functional needs of different scenarios leads to the fragmentation of TCM terminology translation, which seriously hinders the practical application of TCM terms in international clinical practice, academic research, and public communication. This is the most prominent practical challenge in current TCM terminology translation, and its core manifestations are the two aspects of multiple translations for one term and discrepancies between major translation systems.[19]

3.3.1 Multiple translations for one term

Multiple translations of a single TCM term result in functional dimension failure due to the lack of a unified core anchor for functional adaptation. For the same core term, different translators adopt different translation strategies according to their own understanding, without considering the functional unity of the term in different application scenarios, leading to the loss of the unique identification of the term and the confusion of its practical application. This phenomenon is most common in the translation of TCM core theoretical terms that are widely used in clinical, academic, and public communication scenarios.[2]

Taking "qi" as an example, the fundamental concept of "qi" has various English translations, such as "qi" (transliteration), "vital energy", "vital force", "energy flow", and "vital breath". Each translation has its own emphasis: "qi" preserves the cultural uniqueness but may be hard for readers unfamiliar with TCM terminology to understand; "vital energy" highlights its dynamic, life-sustaining aspect but oversimplifies its overall meaning; "energy flow" emphasizes its cyclical nature but overlooks its role in regulating physiological functions.

Similarly, "yin-yang" is translated as "yin and yang" (phonetic-semantic translation), "negative and positive" (Western philosophical analogy), or "female and male principles" (an anthropomorphic interpretation), with each version only reflecting one aspect of the dialectical essence of the concept in TCM theory. These translations are oriented to different functional scenarios, but the lack of functional adaptation norms leads to the misapplication of translations: "negative and positive" is a Western philosophical concept, which is not suitable for TCM clinical practice scenarios, but it is often used in clinical translation, leading to the distortion of the functional connotation of "yin-yang" in TCM diagnosis. The essence of this problem is the failure of functional dimension—without a unified core anchor and stratified functional adaptation strategy, the term translation loses its practical functional value.[2,13]

Table 1 presents typical high-frequency core terms with multiple coexistent translations, and the selection

Table 1 Multiple translations of single TCM terms

Chinese Term	Common English Translations	Issues
气虚 (*Qi Xu*)	"Qi deficiency", "Energy deficiency"	"Energy" is too vague; "Qi" is opaque
痰湿 (*Tan Shi*)	"Phlegm-dampness", "Damp-phlegm"	Word order varies
太阳病 (*Tai Yang Bing*)	"Greater Yang disorder", "Taiyang disease"	Inconsistent capitalization

of terms strictly follows three criteria: 1) All terms are foundational core concepts in the TCM theoretical system, and appear frequently in *Huang Di Nei Jing* and *Shang Han Lun*; 2) There are significant and widespread divergences in their international translations; 3) Translation divergences directly lead to cross-cultural communication barriers in academic, clinical or public communication scenarios.[2]

3.3.2 Discrepancies between major translation systems

The discrepancies between the TCM terminology translation systems advocated by authoritative international organizations are a functional dimension failure caused by the lack of coherent functional standardization. WHO and WFCMS formulate translation standards according to their own functional positioning, but without a unified theoretical framework to coordinate the functional stratification, leading to systemic discrepancies in TCM terminology translation standards. These discrepancies further exacerbate the confusion of term translation and hinder the formation of a unified global discourse of TCM.

The functional positioning of different authoritative organizations leads to the differences in their translation standards: WHO's translation standard in *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region* (2007) is oriented to the global biomedical communication function, emphasizing the readability and compatibility of TCM terms in the Western medical system; WFCMS's *International Standard for Chinese-English Translation of Basic TCM Nomenclature* (2008) is oriented to the TCM academic and clinical inheritance function, emphasizing the authenticity and systematicness of TCM terms in reflecting the original theory. The differences in functional positioning led to systemic discrepancies in the translation of core terms, and the official translations of the two standards are verified and corrected as follows:

For the core term "*Jing Luo* (经络)", the WHO system prefers "meridians and collaterals", aligning with long-standing Western academic conventions and emphasizing their anatomical pathway-like attributes. In contrast, the WFCMS favors "channels and collaterals", which highlights their functional role in the flow of qi and blood, thus reflecting a perspective closer to that of traditional Chinese medicine itself. Another example is the core diagnostic and treatment principle "*Bian Zheng Lun Zhi*". The WHO translates this as "syndrome differentiation and treatment", while the WFCMS uses "pattern identification and treatment". The core difference between "pattern" and "syndrome" lies in their functional positioning: "pattern" better reflects the dynamic, holistic connotation of TCM's "*Zheng* (证 pattern)" in academic and inheritance scenarios, while "syndrome" has better compatibility and readability in global biomedical clinical communication scenarios. The coexistence of the two translations is not a simple right or wrong issue, but the lack of a unified theoretical framework to guide the functional stratification of the two standards leads to the random coexistence of different translations in the same functional scenario, making it impossible for the term to form a stable functional expression in international communication.

Table 2 illustrates the different translations of the same term in different periods. It clearly illustrates the different translations of the term by various authoritative institutions. The evolution of the translation of zang-fu organ terms by authoritative organizations since the 1980s (Table 2) also fully reflects the functional dimension failure caused by the lack of coherent standardization. The repeated changes in term translation in different standards, without a unified functional adaptation principle based on communication scenarios, make TCM practitioners, educators, and translators struggle with scattered guidelines, and seriously hinder the functional application of TCM terms in international academic exchange, clinical cooperation, and public communication.

Table 2 shows the evolution of translations for zang-fu organs by authoritative bodies since the 1980s.

Different authoritative organizations promote their own standards, each justified either by the readability of the target language, cultural authenticity, or clinical practicality. However, this competition among standards has led to a fragmented terminology system, forcing practitioners, educators, and translators to struggle with scattered guidelines, ultimately hindering the formation of a unified global discourse for TCM.

The coexistence of multiple standards reveals that without a theoretical model like the CCF Model to guide

Table 2 Evolution of English translations of basic TCM terms

	Editorial Team 1980 (Note 1)	Committee of Nomenclature 2005	WFCMS 2007	WHO WPR	WHO 2022
脏腑	The solid and hollow organs	Zang-fu viscera	Zang-fu organs	Viscera and bowels	Zang-fu
五脏	Five solid organs; five viscera	Five zang viscera	Five zang-organs	Five viscera	Five zang organs
六腑	Six hollow organs	Six fu viscera	Six fu-organs	Six bowels	Six fu organs
奇恒之腑	Peculiar hollow organ	Extraordinary fu-viscera	Extraordinary fu-organ	Extraordinary organs	Extraordinary fu organs
五行	Five elements	Five phases	Five elements; five phases	Five phases	Five elements; five phases

the stratification of functions and the anchoring of core concepts, standardization efforts will remain fragmented and self-contradictory.

In summary, the functional dimension failure of TCM terminology translation is the most direct obstacle to the internationalization of TCM. The core of solving this problem is to take the CCF Model as the guide, establish a unified core conceptual anchor for TCM terms, and formulate stratified functional adaptation strategies according to different communication scenarios and target audiences, so as to realize the coherence and systematization of TCM terminology translation standardization.

3.4 Summary

As the above analysis shows, all challenges in TCM terminology translation can be systematically interpreted as the failure of one or more dimensions of the CCF Model, and the three dimensions are interrelated and mutually restrictive: cognitive dimension failure is the fundamental root cause (the mismatch of cognitive paradigms leads to linguistic and conceptual barriers at the terminology level), cultural dimension failure is the core connotation loss (the simplification of cultural and philosophical connotation leads to the distortion of TCM theoretical essence), and functional dimension failure is the final practical manifestation (the lack of functional adaptation leads to the confusion of term application in international communication). A single dimension failure will inevitably trigger a chain reaction of the other two dimensions: for example, the cognitive mapping failure of "*Shen Ji*" and "*Qi Li*" will further lead to the loss of their cultural connotation and the confusion of their functional application in different scenarios.

4 Case studies

Huang Di Nei Jing and *Shang Han Lun* are foundational classics representing the theoretical framework and clinical practice of TCM, respectively. *Huang Di Nei Jing* establishes core conceptual frameworks such as "qi (气)", "yin-yang (阴阳)", and "five elements" and is rich in philosophical thought. Translating its terminology requires balancing cultural connotations with theoretical coherence. *Shang Han Lun*, regarded as the "ancestor of all prescriptions", is the first medical text to systematically integrate TCM theory, diagnostic principles, formula design, and medicinal application, with immense medical and cultural value. It focuses on pattern differentiation and herbal formula application, with terminology closely related to syndrome description and clinical practice, whose translation must balance clinical accuracy and practical guidance. While the terminological systems of these two works share common roots and are mutually intelligible, each has its own emphasis. Comparing the translation of their core terms provides a comprehensive view of how TCM medical terms are rendered from theoretical system to clinical practice, offering broad and in-depth empirical evidence for resolving terminological inconsistencies and advancing translation standardization.

This section conducts a systematic analysis of English translations of core terms from the two classics through the lens of CCF Model, with a unified analytical framework across all cases. Each case evaluates how different translation approaches succeed or fail in the three core dimensions of the model: cognitive mapping accuracy (whether the translation reconstructs the holistic, relational cognitive paradigm of TCM), cultural transmission fidelity (whether the translation preserves the philosophical and cultural connotations embedded in the term), and functional adaptation appropriateness (whether the translation matches the communicative purpose and target audience of the text). The three cases are selected to correspond to the three types of dimensional failures identified in Section 3, to verify the explanatory power of the CCF Model for practical TCM terminology translation challenges.

In this section, several authoritative translations are compared, including Nigel Wiseman & Ye Feng's (1998) *A Practical Dictionary of Chinese Medicine*, Paul U. Unschuld's (2016) *Huang Di Nei Jing Su Wen: An Annotated Translation*, the translation by Professor Li Zhaoguo (hereinafter referred to as "Li"); the translation by Chinese-American translators Wu Liansheng and Wu Qi (hereinafter referred to as "Wu"); and the translation by German TCM translator Paul U. Unschuld (hereinafter referred to as "Unschuld"). Among the numerous translations of *Shang Han Lun*, this study selects the version by Liu Guohui, which has been praised by scholars at home and abroad as "establishing a new paradigm for English translations of ancient medical texts" and "providing a comprehensive medical interpretation".[32] According to the Amazon bookstore, this book is a bestseller in multiple countries with a 5-star rating. In this section, representative terms from different translations are selected to comparatively analyze their translation strategies, advantages, and disadvantages, thereby exploring new translation paths.

4.1 Example 1: *Shen Ji* (神机) and *Qi Li* (气立)

This case targets the cognitive dimension failures identified in Section 3, focusing on the core terms "*Shen Ji*" and "*Qi Li*" from *Huang Di Nei Jing*. Table 3 presents

Table 3 English translations of *Shen Ji* and *Qi Li* in authoritative versions

Translator	Translation of "*Shen Ji*"	Translation of "*Qi Li*"
Unschuld	the transforming activity of the spirit mechanism[21]	the qi set-up
Li	Shenji (magic mechanism)[14]	Qili (configuration with qi)
Wu	life[32]	vitality

the core translation of the two terms in three authoritative versions, followed by a systematic evaluation through the three dimensions of the CCF Model.

The source sentence is the core expression of TCM's qi dynamics theory. "*Chu Ru* (出入)" refers to the material and energy exchange between the organism and the external environment (e.g., respiration and metabolism); "*Shen Ji*" refers to the internal regulatory mechanism of life activities based on the integration of spirit and qi; "*Sheng Jiang* (升降，rising and falling)" describes the internal dynamic movement of qi in the body; "*Qi Li*" refers to the external existential state of life relying on the exchange of qi between the human body and nature. The two terms form a high-level cognitive system of TCM's view of life, second only to yin-yang and five elements theory, and their translation must simultaneously address the cognitive, cultural, and functional dimensions of the CCF Model.[33]

1) Cognitive mapping dimension

Unschuld's translation retains the structural correspondence of the original terms, with "spirit mechanism" and "qi set-up" initially preserving the conceptual form of TCM's holistic life view. However, it fails to map the multi-layered cognitive connotation of the two terms (philosophical ontology, physiological regulation, pathological changes), resulting in incomplete cognitive mapping for readers without a TCM background. Li's translation uses transliteration to anchor the unique conceptual identity of the terms, but the bracketed annotations ("magic mechanism", "configuration with qi") severely distort the cognitive connotation of the original text: "magic mechanism" misinterprets the non-mystical life regulatory system of "*Shen Ji*" as a supernatural concept, leading to complete cognitive mapping failure. Wu's translation simplifies the two terms into "life" and "vitality", completely stripping the core cognitive connotation of TCM's qi dynamics theory, and compressing the complex holistic cognitive system into a single biomedical concept, which is the most severe cognitive dimension failure.

2) Cultural transmission dimension

Unschuld's translation retains the unique lexical form of TCM terms, avoiding forced subsumption into Western biomedical categories, and thus achieves basic cultural transmission fidelity. However, it lacks supplementary cultural context compensation (a core strategy of thick translation), failing to explain the philosophical origin of the two terms in the "unity of man and nature" worldview, resulting in insufficient cultural depth.[17] Li's transliteration strategy aligns with the principle of preserving TCM's cultural uniqueness, but the misleading annotations distort the non-mystical scientific essence of TCM, reinforcing the Western stereotype of TCM as "mysterious Oriental medicine", which is a typical cultural transmission failure.[34] Wu's translation completely abandons the cultural uniqueness of the terms, stripping them of their roots in traditional Chinese philosophy, and thus results in a total loss of cultural transmission.

3) Functional adaptation dimension

Guided by Skopos Theory, the functional appropriateness of a translation is determined by its communicative purpose and target audience.[19] Unschuld's translation is oriented to academic research scenarios, with formal correspondence to the original text, making it suitable for scholars with classical Chinese and TCM expertise. However, its obscure expression leads to communicative failure for general readers or clinical practitioners, with limited functional adaptation. Li's translation is designed for international TCM education scenarios, and the transliteration strategy lays a foundation for terminological standardization, but the misleading annotations make it impossible to achieve the educational purpose of accurately conveying TCM theory, resulting in functional adaptation failure. Wu's translation is oriented to public science communication scenarios, with extreme simplification to maximize readability for the general public. However, it completely loses the theoretical integrity of TCM, failing to achieve the core functional purpose of disseminating TCM's view of life, and thus has severe limitations in functional adaptation.

In summary, through the CCF Model, this case clearly demonstrates that translation focusing on only one or two dimensions will inevitably lead to deficits in the others. None of the three versions achieves a balanced performance in cognitive mapping, cultural transmission, and functional adaptation: Unschuld's version has moderate cognitive and cultural performance but weak functional adaptability; Li's version has a reasonable formal design for cultural and functional purposes but fails due to cognitive distortion; Wu's version prioritizes functional readability but completely abandons cognitive and cultural integrity. This verifies the core proposition of the CCF Model: effective TCM term translation must systematically address all three dimensions simultaneously, rather than focusing on single-dimensional lexical equivalence.

4.2 Example 2: Taiyang disease (太阳病)

This case targets the cultural dimension failures identified in Section 3, focusing on the core clinical term Taiyang Disease from *Shang Han Lun*, which is the foundational concept of the six-meridian pattern differentiation system.

Table 4 evaluates the translation of the term in three authoritative standards/versions through the three dimensions of the CCF Model, with a unified analytical framework consistent with the previous case. The following table compares different translations of the term "Taiyang disease" and analyzes their differences in accuracy, readability, and cultural fidelity.

Taiyang disease is the first category of the six-meridian pattern differentiation system in *Shang Han Lun*,

Table 4 English translations of Taiyang disease and CCF Model analysis

Translator	Translation	CCF Model Analysis
Unschuld	Tai Yang disorder[21]	**Cognitive Mapping Accuracy**: Medium. Uses Pinyin but drops "Greater" **Cultural Transmission Fidelity**: High. Avoids Western biomedical equivalence, preserves the cultural uniqueness of the six-meridian theory **Functional Adaptation Appropriateness**: Medium. Suitable for TCM academic research, but low readability for non-professional audiences
WHO	Greater Yang syndrome[12]	**Cognitive Mapping Accuracy**: Low. Uses "syndrome", a fixed biomedical concept, to distort the holistic disease system connotation of Taiyang Disease, resulting in cognitive paradigm mismatch **Cultural Transmission Fidelity**: Low. Forcibly subsumes the term into the Western medical category, stripping its cultural connotation in the six-meridian system **Functional Adaptation Appropriateness**: High. Aligns with global biomedical clinical communication norms, high readability for Western medical practitioners
Wiseman	Greater Yang disease[13]	**Cognitive Mapping Accuracy**: High. Accurately retains Tai Yang as a core TCM concept, completely maps its position in the six-meridian cognitive system **Cultural Transmission Fidelity**: Medium. Retains the cultural independence of the term, but relies on footnotes for cultural context compensation **Functional Adaptation Appropriateness**: Low. Unexplained Tai Yang creates a comprehension barrier for beginners, with limited applicability in public communication and basic education scenarios

which is not a single disease entity in the Western biomedical sense, but a holistic dynamic syndrome system covering the progression of external contraction diseases, the struggle between vital qi and pathogenic qi, and corresponding treatment principles. Its translation must accurately reconstruct the relational cognitive paradigm of the six-meridian system, preserve its cultural roots in TCM's holistic view of disease, and adapt to the functional needs of different application scenarios.

1) Cognitive mapping dimension

Wiseman's "Greater Yang disease" has the highest cognitive mapping accuracy: it retains the hierarchical connotation of "greater yang" in the six-meridian system, and uses "disease" instead of "syndrome" to avoid reducing the holistic dynamic system to a fixed pathological state, accurately reconstructing the TCM cognitive paradigm. Unschuld's "Tai Yang disorder" retains the core concept through pinyin, but omits "Greater" to weaken the cognitive logic of the six-meridian hierarchy, resulting in moderate cognitive mapping accuracy. The WHO's "Greater Yang syndrome" has the lowest cognitive accuracy: "syndrome" in biomedicine refers to a fixed combination of symptoms and signs, which fundamentally conflicts with the dynamic, holistic cognitive connotation of Taiyang Disease, leading to a complete mismatch of cognitive paradigms.[35]

2) Cultural transmission dimension

Unschuld's pinyin translation avoids the forced assimilation of TCM concepts into Western medical categories, maximally preserving the cultural uniqueness of the six-meridian system, and thus has the highest cultural transmission fidelity. Wiseman's translation retains the independent conceptual form of Tai Yang, but relies on additional footnotes to supplement its cultural and theoretical context, with moderate cultural transmission fidelity. The WHO's translation uses the biomedical term "syndrome" to subsume the TCM concept, completely stripping the term of its cultural connotation in the six-meridian pattern differentiation system, which is a typical cultural dimension failure identified in Section 3.

3) Functional adaptation dimension

The WHO's translation has the highest functional appropriateness in global clinical communication scenarios: it uses the familiar biomedical term "syndrome" to ensure immediate readability and acceptance among Western medical practitioners, perfectly matching the functional positioning of WHO's standards for global health governance. Unschuld's translation is functionally suitable for high-level TCM academic research, but has low readability for non-professionals, with limited functional adaptation. Wiseman's translation is accurate in cognitive and cultural dimensions, but the unexplained pinyin term creates a high comprehension threshold for beginners and general readers, with poor functional adaptability in basic education and public communication scenarios.

This case further verifies the analytical power of the CCF Model: the core dilemma of TCM term translation is the trade-off between the three dimensions, and a single fixed translation often optimizes one dimension at the expense of the others. The three versions show distinct strategic priorities in the three dimensions of the CCF Model, and none of them can adapt to all application scenarios with a single translation. This provides empirical support for the stratified translation strategy with a unified core anchor proposed in the CCF Model.

4.3 Example 3: *Bian Zheng Lun Zhi* (辨证论治)

This case targets the functional dimension failures identified in Section 3, focusing on the core diagnostic and therapeutic principle *Bian Zheng Lun Zhi*, which is the most representative term with inconsistent translations between international standards. Table 5 evaluates the official translations of the term by authoritative

Table 5 English translations of *Bian Zheng Lun Zhi* and CCF Model analysis

Translator	Translation	CCF Model Analysis
Unschuld	Differentiating [sic] signs to determine therapy[21]	Cognitive Mapping Accuracy: Low. "Signs" reduces the holistic concept of Zheng to individual symptoms, resulting in complete cognitive paradigm mismatch Cultural Transmission Fidelity: High. Avoids Western biomedical equivalence, preserves the cultural uniqueness of the six-meridian theory Functional Adaptation Appropriateness Functional Adaptation Appropriateness: Medium. Suitable for TCM academic research, but low readability for non-professional audiences
WHO	Pattern differentiation and treatment[12]	Cognitive Mapping Accuracy: Medium. Primary translation "pattern identification" matches TCM's cognitive logic; alternative "pattern differentiation" uses biomedical concepts, leading to partial cognitive distortion Cultural Transmission Fidelity: Medium. Primary translation retains TCM's cultural specificity; alternative translation prioritizes biomedical compatibility, with partial cultural connotation loss Functional Adaptation Appropriateness: High. Dual-translation design adapts to both global clinical communication and TCM professional scenarios, with the widest functional coverage
Wiseman	Pattern identification and treatment[13]	Cognitive Mapping Accuracy: Medium. Primary translation "pattern identification" matches TCM's cognitive logic; alternative "pattern differentiation" uses biomedical concepts, leading to partial cognitive distortion Cultural Transmission Fidelity: Low. Strips the term of its cultural connotation as the core of TCM's diagnostic system, reducing it to a simple symptom judgment process Functional Adaptation Appropriateness: Medium. High readability for Western biomedical readers, but fails to convey the core theoretical connotation of TCM
WFCMS	Pattern identification and treatment (primary); pattern differentiation and treatment (alternative)	Cognitive Mapping Accuracy: High. Primary translation accurately maps the dynamic cognitive connotation of Zheng; alternative translation provides clinical scenario compatibility Cultural Transmission Fidelity: High. Primary translation preserves the cultural essence of TCM's diagnostic principle; alternative translation ensures cross-scenario applicability Functional Adaptation Appropriateness: High. Stratified translation design aligns with both academic inheritance and international clinical application, with strong functional adaptability

institutions and scholars through the three dimensions of the CCF Model, and corrects the factual errors in the original version regarding the official translations of WHO and WFCMS, with clear source citations.

Bian Zheng Lun Zhi is the core diagnostic and therapeutic principle of TCM, and the essence of *Zheng* is a dynamic, holistic comprehensive summary of the body's pathological state, rather than a fixed "syndrome" or individual "signs" in Western biomedicine. The long-standing inconsistency in its translation is the most typical manifestation of functional dimension failure in TCM terminology standardization, and the CCF Model provides a clear analytical framework for evaluating the advantages and limitations of different translations.

1) Cognitive mapping dimension

Wiseman's and WFCMS's primary translation "Pattern identification and treatment" has the highest cognitive mapping accuracy: "pattern" accurately captures the non-substantial, dynamic, and holistic nature of *Zheng*, perfectly reconstructing the core cognitive logic of TCM's diagnostic thinking. The WHO's primary translation "Treatment based on pattern identification" also achieves high cognitive accuracy, while its alternative translation "syndrome differentiation and treatment" uses the fixed biomedical concept "syndrome", leading to partial cognitive distortion. Unschuld's "Differentiating signs to determine therapy" has the lowest cognitive accuracy: it reduces the holistic concept of *Zheng* to individual superficial "signs", completely mismatching the TCM cognitive paradigm, and resulting in severe cognitive dimension failure.

2) Cultural transmission dimension

WFCMS's primary translation has the highest cultural transmission fidelity: it retains the core cultural connotation of *Bian Zheng Lun Zhi* as the "soul of TCM", avoiding forced assimilation into Western medical categories, and preserving the uniqueness of TCM's diagnostic and therapeutic system. Wiseman's translation also achieves high cultural fidelity, while the WHO's dual-translation design balances cultural specificity and biomedical compatibility, with moderate cultural transmission performance. Unschuld's translation completely strips the term of its cultural and theoretical connotation, reducing the core principle of TCM to a simple technical operation, resulting in a total loss of cultural transmission.

3) Functional adaptation dimension

The dual-translation strategies of WHO and WFCMS have the highest functional appropriateness: they establish a unified core anchor translation ("pattern identification and treatment") for academic and inheritance scenarios, while providing an alternative translation ("syndrome differentiation and treatment") for global clinical communication scenarios, perfectly matching the functional needs of different audiences and application contexts. This stratified design directly addresses the functional dimension failure of "multiple translations for one term" identified in Chapter 3. Wiseman's translation is functionally suitable for professional academic and clinical scenarios, but has a high comprehension threshold for non-professionals, with limited functional adaptation. Unschuld's translation has high readability for Western biomedical readers, but fails to achieve the

functional purpose of accurately disseminating TCM's core theory, with severe functional limitations.

This case confirms that the CCF Model can effectively explain the root cause of terminological inconsistency in international standards: the lack of a unified theoretical framework to guide the stratification of functional adaptation and the anchoring of core concepts. The dual-translation design of WHO and WFCMS is essentially a preliminary practice of the stratified translation strategy proposed in the CCF Model, but it lacks a systematic theoretical framework to unify the core anchor and functional variants, leading to persistent terminological confusion in practical application. This provides direct empirical support for the dynamic standardization pathway based on the CCF Model proposed in this study.

4.4 Research findings: core laws of TCM terminology translation based on the CCF Model

Through a systematic comparative analysis of three representative core terms using the CCF Model, this study draws the following core findings, which directly respond to the translation challenges and dimensional failures identified in Section 3, and lay an empirical foundation for the dynamic standardization pathway proposed in Section 5 as well.

First, all translation failures of TCM core terms can be attributed to the partial or complete failure of one or more dimensions of the CCF Model. The case analysis shows that the root cause of poor translation is not the lack of lexical equivalents, but the inability to systematically address the three core dimensions: cognitive mapping distortion leads to the mismatch of TCM's holistic cognitive paradigm; cultural transmission failure leads to the loss of TCM's philosophical and cultural connotations; functional adaptation deficiency leads to the inability to match the communicative purpose of the text. None of the single fixed translations in the three cases can achieve a balanced performance in all three dimensions, which verifies the core proposition of this study: the essence of TCM term translation is the cross-cultural reconstruction of the TCM conceptual system, rather than simple lexical conversion.

Second, the CCF Model provides a unified, operable analytical framework for evaluating and optimizing TCM term translation, breaking the long-standing binary opposition of "literal vs. free translation". The traditional debate on literal and free translation cannot explain the complex trade-off between accuracy, readability, and cultural preservation in TCM term translation, while the CCF Model deconstructs translation quality into three measurable dimensions, clarifying the strategic priorities of translation in different scenarios. For academic research scenarios, the priority is to ensure cognitive mapping accuracy and cultural transmission fidelity, with transliteration + detailed thick translation annotations as the optimal strategy; for global clinical communication scenarios, the priority is functional adaptation appropriateness, with a "core anchor translation + biomedical compatible alternative" as the optimal strategy; for public science communication scenarios, the priority is functional readability, with "functional equivalence + selective retention of core cultural terms" as the optimal strategy.

Third, the core solution to terminological inconsistency and standardization dilemmas lies in the "unified core anchor + stratified functional variants" strategy based on the CCF Model. The case analysis shows that the long-standing problem of "multiple translations for one term" is not caused by the lack of a single fixed standard translation, but by the lack of a unified theoretical framework to coordinate the core conceptual anchor and scenario-specific functional variants. The dual-translation practice of WHO and WFCMS for *Bian Zheng Lun Zhi* shows that a stratified translation system with a unified core anchor can not only ensure the stability and uniqueness of TCM core concepts, but also adapt to the functional needs of different application scenarios, resolving the contradiction between terminological standardization and dynamic practical application.

Fourth, thick translation is the core operational strategy to achieve a balanced performance in the three dimensions of the CCF Model. The case analysis shows that simple literal translation or free translation often leads to the deficit of one or more dimensions, while thick translation strategies (bracketed annotations, supplementary explanations, contextual compensation) can effectively balance cognitive accuracy, cultural fidelity, and functional readability. For example, Liu's supplementary explanation for Taiyang Disease and the transliteration + annotation strategy for professional terms both achieve multi-dimensional balance through thick translation, which provides a clear operational method for the practical application of the CCF Model.

In summary, the case studies fully verify the explanatory power and practical guiding value of the CCF Model for TCM terminology translation. The optimal path for TCM term translation is not to seek a single fixed "correct translation", but to construct a stratified translation system with a unified core conceptual anchor, which systematically addresses the three dimensions of cognitive mapping, cultural transmission, and functional adaptation according to specific scenarios and audiences. This finding directly addresses the research gaps identified in the introduction, and provides a solid empirical basis for the dynamic standardization pathway based on the CCF Model proposed in the next section.

5 A dynamic standardization pathway based on the CCF Model

The translation of TCM terminology presents not a contradiction between dynamic practice and standardization, but the challenge of establishing a dynamic equilibrium

between "conceptual anchoring" and "functional adaptation". The key lies in constructing a standardization framework guided by a coherent theoretical model—the CCF Model. This study proposes a Dynamic Standardization Pathway that transcends the mere selection of fixed terms with annotations, aiming instead at the systemic cross-cultural reconstruction of TCM knowledge.

5.1 Three-layer architecture of the dynamic standardized terminology system

The core of this pathway is a CCF Model-derived three-layer terminology system, with clear, actionable implementation rules and specific technical landing forms for each layer to ensure standardization, flexibility, and operability.

First, Conceptual Anchor Layer (Core Identification) establishes unique, stable identifiers for core TCM concepts using "transliteration + core English descriptor in parentheses". This layer ensures stability and uniqueness across all translations, serving as the unified coordinate system.

Second, Cognitive-Cultural Annotation Layer (Networked Elucidation) provides structured, multi-level annotations for each anchored term, including cultural context (philosophical origins) and systemic position, which is the role within the TCM conceptual network (e.g., relationships in the five-element theory), as well as Conceptual Differentiation which means key distinctions from Western medical concepts. This layer is technically landed as an interactive knowledge graph with the following features:

1) Visualization. Dynamically displays semantic, logical, and pathological relationships between terms (e.g., the connection between "qi" and "zang-fu organs") through node-link diagrams, enabling intuitive cognitive mapping;

2) Retrievability. Supports keyword search, relationship tracing, and layered browsing (e.g., expanding "five elements" to view its correlations with zang-fu, meridians, and pathogens);

3) Expandability. Allows TCM experts to update annotations based on new research findings, with version control to ensure academic rigor.

The knowledge graph can be embedded in TCM textbooks, translation platforms, and international education systems, enabling "thick translation" and helping users navigate the holistic conceptual network of TCM.

Third, Functional Adaptation Layer (Strategy Repository) operationalizes the functional dimension of the CCF Model. For each core concept, it curates a set of context-appropriate translation strategies tailored to different communicative scenarios (defined by audience and text type). For example, using "transliteration + detailed annotation" in academic research, and "functional equivalence + concise explanation" in clinical guidelines, while "cultural analogy + vivid expression" in public communication.

5.2 Cross-disciplinary collaboration mechanism for sustainable implementation

The sustainable operation of this pathway relies on a structured tripartite collaboration mechanism guided by the CCF Model, with clear implementation steps for each stakeholder: linguists and translation theorists lead the refinement of annotation logic and functional stratification rules; TCM experts and clinicians are responsible for verifying the medical and theoretical accuracy of conceptual anchors and the clinical applicability of functional variants; policymakers and international bodies (WHO, WFCMS, ISO/TC 249) drive the global harmonization, official release and iterative update of this layered standard in TCM education, certification and clinical practice frameworks.

Crucially, this pathway fundamentally transcends earlier static annotation-based models. It is not a fixed term list with supplementary notes, but a theoretically guided, operable living terminology ecosystem. This system firmly anchors TCM's core conceptual network while enabling intelligent, context-driven functional flexibility, genuinely bridging the long-standing gap between rigorous academic standardization and effective cross-cultural communication of TCM.

6 Conclusion and prospects

This study takes the cross-cultural dissemination of TCM core terms as the research background, aiming to solve the long-standing dilemmas of conceptual network disruption, cultural connotation loss and functional application inconsistency in TCM term translation and standardization. By breaking the binary opposition of "literal translation vs. free translation" and the limitations of a single static standard in existing research, the study constructs a CCF Model and conducts an in-depth analysis of the translation challenges and typical cases of TCM core terms from the perspective of this model, and finally proposes a targeted dynamic standardization pathway. The main conclusions of the study are as follows:

First, the essence of TCM core term translation is the cross-cultural reconstruction of the TCM conceptual system, rather than simple lexical equivalent conversion. The root cause of all translation failures is the partial or complete failure of one or more dimensions of the CCF Model: cognitive mapping failure leads to the mismatch between the holistic relational cognitive paradigm of TCM and the analytical entity cognitive paradigm of Western medicine, resulting in linguistic and conceptual barriers; cultural transmission failure leads to the simplification or distortion of the philosophical and cultural connotations of TCM terms, resulting in cross-cultural

misinterpretation; functional adaptation failure leads to the confusion of term translation and the discrepancy of standard systems, resulting in the low practical application efficiency of TCM terms in different scenarios. The three dimensions of the CCF Model are interrelated and mutually restrictive: cognitive mapping is the foundation of accurate translation, cultural transmission is the core of preserving the uniqueness of TCM, and functional adaptation is the practical goal of term translation, and effective TCM term translation must achieve the balanced development of the three dimensions.

Second, the CCF Model provides a unified and operable analytical and decision-making framework for TCM term translation and standardization. The model deconstructs the translation quality of TCM terms into three measurable dimensions, clarifies the strategic priorities of translation in different scenarios (academic research, clinical practice, public communication), and provides a theoretical basis for the rational selection and combination of specific translation methods (literal translation, transliteration, thick translation, etc.). The empirical case analysis of "*Shen Ji*/*Qi Li*", "Taiyang disease" and "*Bian Zheng Lun Zhi*" verifies that the CCF Model can effectively explain the advantages and disadvantages of different translation versions, and is a scientific theoretical tool for evaluating and optimizing TCM term translation.

Third, the dynamic standardization pathway with three-layer architecture and cross-disciplinary collaboration mechanism is the optimal solution to the standardization dilemma of TCM core terms. The three-layer architecture of "Conceptual Anchor Layer-Cognitive-Cultural Annotation Layer-Functional Adaptation Layer" realizes the organic unity of TCM term conceptual stability and scenario-based functional flexibility: the conceptual anchor layer ensures the unique identification of core terms, the cognitive-cultural annotation layer reconstructs the conceptual network and cultural context of TCM terms, and the functional adaptation layer provides targeted translation strategies for different audiences and text types. The tripartite collaboration mechanism of "translation scholars-TCM experts-international organizations" ensures the sustainable operation and global promotion of the dynamic standardization system, and solves the problem of fragmented standardization in existing TCM term translation.

Fourth, thick translation is the core operational strategy to achieve the balanced development of the three dimensions of the CCF Model. Simple literal translation or free translation often leads to the deficit of one or more dimensions of the CCF Model, while thick translation strategies such as bracketed annotations, contextual compensation and knowledge graph visualization can effectively make up for the cognitive and cultural gaps between TCM and Western medicine, and realize the balance of cognitive accuracy, cultural fidelity and functional readability in TCM term translation.

This study fills the four major research gaps in the current TCM term translation research: constructing an integrated theoretical framework adapted to the unique attributes of TCM, realizing the shift from fragmented term-level research to holistic conceptual system research, breaking the static translation strategy and proposing a dynamic scenario-based adaptation model, and establishing a close connection between theoretical construction and practical application. The CCF Model and dynamic standardization pathway proposed in the study not only enrich the theoretical system of TCM translation studies, but also provide practical guidance for the standardization of TCM core terms and the international dissemination of TCM, which is of important theoretical and practical significance for promoting the integration of TCM into the global health governance system and enhancing the international discourse power of TCM.

Based on the CCF Model and the research conclusions of this study, combined with the development trend of TCM international dissemination and translation studies, the future research on TCM core term translation can be further deepened in the following three directions, focusing on the theoretical deepening, technological integration and practical application of the CCF Model:

First, theoretical deepening and expansion of the CCF Model: On the basis of this study, further explore the intersection of the CCF Model with cognitive linguistics, terminology science, knowledge translation theory and cross-cultural communication theory, and enrich the theoretical connotation of the three dimensions of the model. Expand the research scope of the model from the core terms of *Huang Di Nei Jing* and *Shang Han Lun* to the entire TCM terminology system (including acupuncture, herbal medicine, and health preservation), and verify the universality of the CCF Model in TCM term translation. In addition, further study the translation strategies of TCM terms in different languages (excluding English) to form a multilingual TCM term translation framework based on the CCF Model, adapting to the multi-cultural communication needs of TCM international dissemination.

Second, technological integration and digital construction of the dynamic standardization system: Integrating the CCF Model with artificial intelligence, big data and knowledge graph technology to develop a digital TCM term translation and standardization platform based on the three-layer architecture. The platform will include a conceptual anchor database, an interactive cognitive-cultural knowledge graph, and a scenario-based functional adaptation strategy library, realizing the intelligent retrieval, contextualized translation recommendation and real-time update of TCM core terms. The knowledge graph will visually display the semantic, logical and pathological relationships between TCM terms, helping international readers construct a holistic TCM conceptual network

and solve the problem of "isolated term learning" in current TCM international education.

Third, practice-oriented application and global promotion of the CCF Model: Promote the integrated application of the CCF Model and dynamic standardization pathway in TCM international education, clinical practice and public communication. In TCM international education, compile textbooks and teaching materials based on the CCF Model, realizing the stratified teaching of TCM terms according to different learning stages and audiences; in international clinical cooperation, formulate TCM clinical term translation guidelines based on the functional adaptation layer of the model, ensuring the accuracy and consistency of TCM term use in clinical communication; in public science communication, adopt the cultural analogy and vivid expression strategy of the model to translate TCM terms, reducing the cognitive threshold of the general public for TCM. At the same time, promote the international recognition of the CCF Model and dynamic standardization pathway through academic exchanges and cooperation with international organizations such as WHO, WFCMS and ISO/TC 249, and promote the formation of a unified global discourse system of TCM core terms based on respect for cultural differences.

In general, the translation and standardization of TCM core terms are a long-term and arduous cross-cultural project, which requires the joint efforts of translation scholars, TCM experts, policymakers and international organizations. The core goal of this project is not only to realize the accurate conversion of TCM term language, but also to spread the profound philosophical thoughts and health preservation concepts contained in TCM, and to make TCM, a treasure of Chinese civilization, play a unique role in global health governance and contribute to the construction of a global community of health for all.

Notes

1. The earliest teams involved in compiling bilingual Chinese medicine dictionaries were mainly from Guangzhou, Beijing, and Changsha, with the Ou Ming team from Guangzhou College of Traditional Chinese Medicine (now Guangzhou University of Chinese Medicine) being particularly notable. Their work, "Commonly used Chinese-English terms of traditional Chinese medicine", published a draft translation under the name of the editorial team (abbreviated as the Editorial Team) in the journal *New Chinese Medicine* in 1980 before the book was officially released, widely soliciting feedback. This effort is regarded as pioneering research in the translation of TCM.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

XU Gaonan participated in research design, paper writing, research implementation, and data analysis, and contributed new reagents or analytical tools.

Declaration of generative AI and AI-assisted technologies in the writing process

The author declares that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The author declares no financial or other conflicts of interest.

References

[1] Bai QQ, Yang F. Study on the English translation strategy of cross-cultural communication and international dissemination of traditional Chinese medicine (中医学跨文化交流与国际传播的英译策略研究). *Journal of Hunan University of Chinese Medicine*. 2022;42(6):1032–1036. Chinese.

[2] World Health Organization. International Classification of Diseases 11th Revision (ICD-11). Available from: https://icd.who.int/. [Accessed on 18 May 2025].

[3] Zhang ZY, Guo Q. Western Translation of TCM Terms in the 19th Century (1815–1866): Centered on the English-Chinese Dictionary Compiled by Missionaries (19世纪西方对中医术语的翻译（1815–1866）——以传教士编纂的英汉词典为中心). *Chinese Medical Culture*. 2023;18(6):572–580. Chinese.

[4] Zhang YR, Shi H, Zhang ZM. Research Status and Enlightenment of Overseas Dissemination of English Versions of Shang Han Lun: Based on Analysis of Statistics from Amazon and World Cat (《伤寒论》英译本海外传播现状及启示：基于Amazon和WorldCat的统计分析). *Journal of Basic Chinese Medicine*. 2022;28(12):2035–2039. Chinese.

[5] Jing MX. A Corpus Study on the Power of Cultural Dissemination of Traditional Chinese Medicine Terms: Taking English Translation of "Meridian (Jingmai)" as an Example (基于语料库的中医术语翻译文化传播研究：以"经脉"英译为例). *Journal of Liaoning University of Traditional Chinese Medicine*. 2025;27(2):216–220. Chinese.

[6] Wu QY. Vocabulary classification and translation strategies of TCM diagnosis and treatment terms (中医诊疗术语词汇分类及其翻译策略). *Journal of Mudanjiang Medical University*. 2024;45(1):150–153. Chinese.

[7] Lei S. Current status and prospects of TCM translation research in China based on CNKI bibliometric visualization analysis (基于CNKI文献计量可视化分析的国内中医翻译研究现状与展望). *Shanghai Journal of Translators*. 2025;182(3):34–37. Chinese.

[8] Ye X, Zhang HX. A historical review and discussion on the standardization of English translation of TCM terms (中医术语

英译标准化的历史回顾与探讨). *Classics and Culture of Chinese Medicine*. 2021;(2):379–394. Chinese.
[9] Porkert M. *The Theoretical Foundations of Chinese Medicine*. Cambridge: MIT Press; 1974. p. 1–368.
[10] Needham J, Lu GD. *Celestial Lancets: A History and Rationale of Acupuncture and Moxa*. Cambridge: Cambridge University Press; 1980. p. 1–427.
[11] Ou M, Li YW. English translation of commonly used traditional Chinese medicine terms (常用中医术语英译). *Shanghai Journal of Translators for Science and Technology*. 1986;(4):18–22. Chinese.
[12] World Health Organization. *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*. Manila: WHO Regional Office for the Western Pacific; 2007.
[13] Wiseman N, Ye F. *A Practical Dictionary of Chinese Medicine*. 2nd ed. Brookline: Paradigm Publications; 1998. p. 1–946.
[14] Li ZG, Liu XR. *Yellow Emperor's Canon of Medicine: Plain Conversation* (《黄帝内经·素问》英译). Xi'an: World Book Publishing Xi'an Company; 2005. Chinese.
[15] Xie ZF. *English Translation of Commonly Used TCM Nomenclature* (中医名词术语的英译). Beijing: China Press of Traditional Chinese Medicine; 2004. Chinese.
[16] Miller NL, Cañas AJ, Novak JD. Use of the CmapTools recorder to explore acquisition of skill in concept mapping. In: Cañas AJ, Reiska P, Åhlberg M, Novak JD, editors. *Concept Mapping: Connecting Educators. Proceedings of the Third International Conference on Concept Mapping*; 2008 Sep 22–25; Tallinn, Estonia & Helsinki, Finland. p. 1–8.
[17] Appiah KA. Thick translation. *Callaloo*. 1993;16(4):808–819.
[18] Hermans T. Cross-cultural translation studies as thick translation. *Bulletin of the School of Oriental and African Studies*. 2003;66(3):380–389.
[19] Nord C. *Translating as a Purposeful Activity: Functionalist Approaches Explained*. Manchester: St. Jerome Publishing; 1997. p. 1–154.
[20] Unschuld PU, Tessenow H. *Huang Di Nei Jing Su Wen: An Annotated Translation of Huang Di's Inner Classic—Basic Questions*. Vol. 1. Berkeley: University of California Press; 2011. p. 237, 344–345.
[21] Unschuld PU, Tessenow H. *Huang Di Nei Jing Su Wen: An Annotated Translation of Huang Di's Inner Classic—Basic Questions*. Vol. 2. Berkeley: University of California Press; 2011.
[22] Lakoff G, Johnson M. *Metaphors We Live By*. Chicago: University of Chicago Press; 1980. p. 1–242.
[23] Gu F. Categories and English translations of "qi-related" terms in Huangdi Neijing (《黄帝内经》中"气"系词语的类型及英译). *Chinese Science and Technology Terms*. 2019;32(4):55–58. Chinese.
[24] Chen Y. Metaphor and cognition: a study on the translation of TCM conceptual terms (隐喻与认知：中医概念性术语翻译研究). *Chinese Science & Technology Translators Journal*. 2021;23(1):23–28. Chinese.
[25] Xie SW. Cognitive Semantics of "Exterior-Releasing Therapy" and "Purgative Therapy" Treatment Methods ("解表"与"攻下"治法的认知语义研究). *Modern Linguistics*. 2025;13(10):227–234. Chinese.
[26] Mi YZ, Li XH. Analysis of the Explicitation in the English Translation of the "Up and Down" Spatial Metaphor in The Yellow Emperor's Inner Classic-Simple Questions: A Case Study of Li Zhaoguo's Translated Version (《黄帝内经·素问》中"上下"方位隐喻的英译显化程度分析——以李照国译本为例). *Journal of North China University of Science and Technology (Social Science Edition)*. 2025;25(2):83–89. Chinese.
[27] Wang WB. *Cognitive Construction and Interpretation of Metaphors* (隐喻的认知构建与解读). Shanghai: Shanghai Foreign Language Education Press; 2007. Chinese.
[28] Yu JP. The impact of cultural differences on the understanding of word meaning and semantics in English-Chinese translation (文化差异对英汉翻译中词义和语义理解的影响). *Chinese Translators Journal*. 2000;(3):28–30. Chinese.
[29] Lyu J. The Ontological Return of Translation Studies–A Reflection of the Cultural Turn in Translation Studies (论翻译研究的本体回归——对翻译研究"文化转向"的反思). *Journal of Foreign Languages*. 2004;(4):53–59. Chinese.
[30] Chen X. Skopos theory and TCM terminology translation: a functionalist perspective. *Translation and Interpreting Studies*. 2023;18(3):78–92.
[31] Li ZG. TCM terminology standardization: challenges and strategies. *Journal of Traditional Chinese Medicine*. 2023; 43(2):123–134.
[32] Wu LS, Wu Q. *Yellow Emperor's Canon of Internal Medicine* (《黄帝内经》英译). Beijing: China Science and Technology Press; 1997:336, 369–370. Chinese.
[33] Wang H. Professor Yang Zongmeng's application of the Shenji Qili theory in gynecological clinical practice (杨宗孟教授运用神机气立学说在妇科临床中的应用). *Guide of China Medicine*. 2014;12(24):280–281. Chinese.
[34] Jiang CX, Wen SD. An exploration of "thick translation" in the English versions of the Huangdi Neijing (文树德《黄帝内经》英译本的"深度翻译"探究). *Chinese Translators Journal*. 2019;40(5):112–120, 190. Chinese.
[35] World Federation of Chinese Medicine Societies. *International Standard for Chinese-English Translation of Basic TCM Nomenclature*. Beijing: People's Medical Publishing House; 2008.

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Standardization for Chinese Medicine and Acupuncture: An International and Australian Perspective

中医药与针灸标准化：国际及澳大利亚视角

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Abstract

The development of standards has been an important growth area for traditional Chinese medicine and acupuncture. This review examines the four major organizations that have been instrumental in developing international standards for traditional Chinese medicine and acupuncture. The current standards developed by each of the four organizations will be reviewed and classified into major categories to facilitate an overview of the focus of the standards and to determine how each of the organizations/associations has focused on specific areas. This review will also briefly introduce the potential impact of Artificial Intelligence (AI) on standard development and how this may influence the development of future standards. Finally, this review will also look at the role of Australia in contributing to standard development over the last two decades.

Keywords: Standardization; Internationalization; Acupuncture; Traditional Chinese medicine (TCM)

1 Introduction

The advancement of international standards for both traditional Chinese medicine (TCM) and acupuncture has been an important development for countries such as China, Japan, and the Republic of Korea, but also for other nations like Germany, Italy, and Australia. Organizations such as the International Organization for Standardization (ISO), the World Federation of Acupuncture-Moxibustion Societies (WFAS), the World Federation of Chinese Medicine Societies (WFCMS) and the World Health Organization (WHO) have been instrumental in developing standards for particular aspects of speciality clinical areas (diseases and illnesses), as well as for devices, individual herbs, herbal products, and the rapidly growing field of technology and informatics. This paper will give an overview of the four organisations that have been producing standards and highlight the importance and need for standard development within TCM. With the adoption of Artificial Intelligence (AI) in many areas of health and allied health, the issues associated with incorporating AI within TCM standardization will also be reviewed. Furthermore, the issues for internationalization of standards will be highlighted as well as appraising standardization from an Australian perspective.

The development of standards for TCM (acupuncture and Chinese herbal medicine) has been occurring over the last three decades. But what are standards, and why are they important for the future development of TCM?

Standards Australia (SA) defines a standard as "voluntary documents that set out specifications, procedures, and guidelines that aim to ensure products, services, and systems are safe, consistent, and reliable".[1] ISO defines a standard as a "formula that describes the best way of doing something. It could be about making a product, managing a process, delivering a service or supplying materials-standards cover a huge range of activities. Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent—people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators".[2]

Standards can be regarded as living agreements that can have an extensive influence on things that deserve

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to be taken seriously—such as the safety, reliability, and efficiency of machinery, tools, and medical devices.

A standard details uniform technical specifications, criteria, methods for processes, services or practices, using a common language and often states safety criteria and best practice principles. Furthermore, in some countries, standards are regulated by legislation; however, most are voluntary and provide guidance to manufacturers and users of products and devices.

During this time of standard growth, we have also seen the development of Clinical Practice Guidelines (CPGs). CPGs focus on supporting the clinical "decision-making processes in patient care" and are based on the "best available evidence derived from a systematic evidence-based review of available data".[3]

There have been four main international organisations driving the standardization process forward for TCM (Table 1). These are: ISO/TC 249, Technical Committee for Traditional Medicine; World Federation of Chinese Medicine Societies (WFCMS); World Federation of Acupuncture-Moxibustion Societies (WFAS); World Health Organization (WHO). It should be noted that both the WFAS, WFCMS as well as the WHO are all liaison A organisations to ISO/TC 249.

2 ISO/TC 249 and the technical standardization of traditional medicine

ISO/TC 249 (Traditional Medicine) was established in 2009, and as of May 2026, it has published 137 standards with 74 under development.[2] Of these 137 published standards, 74 are related to Chinese herbal medicine, 31 are related to medical devices (acupuncture needles and other devices), and 20 are related to informatics and technology. Currently, 24 member countries are participating in the development of standards under TC 249. These countries range from Asia (China, Japan, and the Republic of Korea), Europe (Germany, Italy, and the Netherlands), but also as widespread as Uganda, India, and Saudi Arabia. The secretariat is the SAC (Standardization Administration of China), which has located its secretariat offices in Shanghai. In addition, there are 21 observing member bodies to TC 249 as well, who can follow standard development but are not able to vote.

The TC 249 website states that "The committee focuses on the quality and safety of raw materials, manufactured products, and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices and medicine, but not into the clinical practice or application of those products".[2]

Since 2009, ISO/TC 249 has focused explicitly on the development of standards for TCM. In 2025, the structure of TC 249 changed with the addition of another subcommittee for Ayurveda and Yoga being initiated within the structure of the technical committee. This subcommittee is named Subcommittee 2 (ISO/TC 249/SC 2) and is outside the scope of this review. This meant a change in name and scope for ISO/TC 249 from "Traditional Chinese Medicine" to the broader field of "Traditional Medicine". This review examines the standardization work that has been developed since 2009 within ISO/TC 249, more specifically the Subcommittee 1 (SC1), which is responsible for developing specific standards for TCM (see Fig. 1 for the structure of ISO/TC249). The current chair of ISO/TC 249 is Professor Shen Yuandong (沈远东) and the committee manager is Professor Guo De'an (果德安). The chair of ISO/TC 249/SC 1 is Dr. Sang Zhen (桑珍). The website of ISO/TC 249/SC 1 states its focus as the "standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. Both traditional and modern aspects of these systems are covered".[2]

Within SC 1 there are five working groups (WGs) associated with developing the ISO Chinese medicine standards. Every year, there is an annual plenary meeting held where working group experts, delegates and

Table 1 Features of the four organizations; ISO, WFAS, WFCMS and WHO

Organization	Members	Establishment Date	Objectives
ISO	24	2009	Quality and safety of raw materials, manufactured products and medical devices and of informatics
WFAS	70 (246 societies)	1987	Promotion of understanding and cooperation among global circles of acupuncture-moxibustion, enhance international academic exchanges, further develop acupuncture-moxibustion, continuously improve status and function of acupuncture-moxibustion in global health care, contribute to human health
WFCMS	78 (201 societies)	2003	Promotion of the international exchange, dissemination and development of traditional Chinese medicine, uniting colleagues in the Chinese medicine industry from all over the world, and actively striving to build the WFCMS into a link connecting Chinese medicine groups and practitioners in various countries and regions, and promote international exchanges of Chinese medicine
WHO	194	1948	Coordinate the world's response to health emergencies, promote well-being, prevent disease and expand access to health care. By connecting nations, people and partners to scientific evidence they can rely on, we strive to give everyone an equal chance at a safe and healthy life

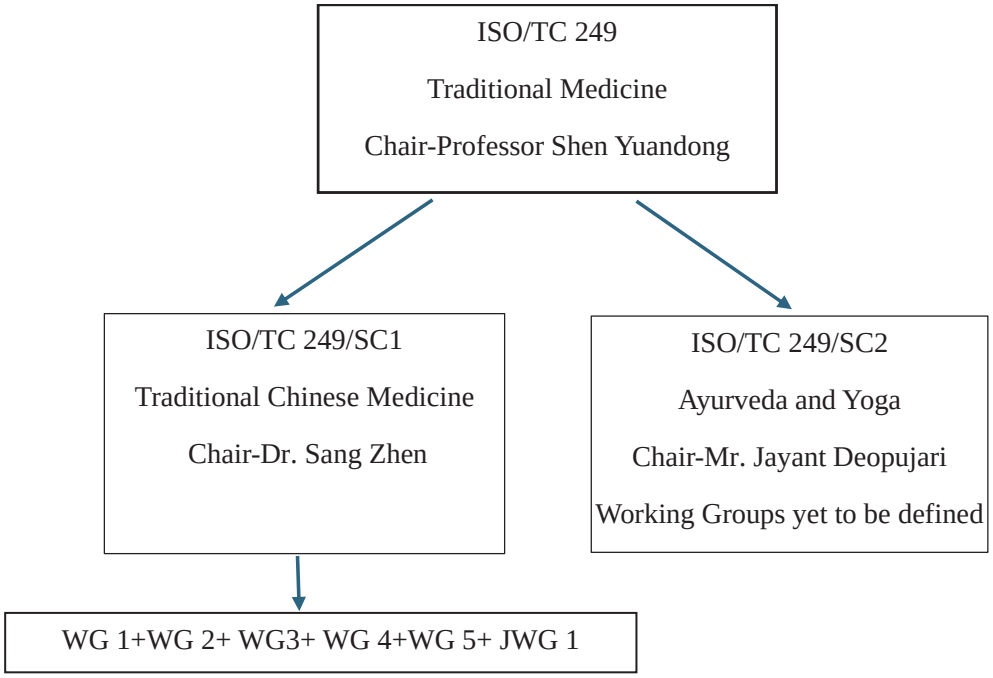


Figure 1 Structure of ISO/TC 249 with its two subcommittees (SC) and associated working groups (WG) (source with permission from: picture made by the author)

observers can meet and discuss face to face, potential new work items and progress those standards and technical reports that have already commenced.

The subcommittee (SC 1) has five main international working groups and a joint working group with a related technical committee of Health Informatics (TC 215) (Fig. 1). The working groups are:

1) **Working Group 1 Quality and safety of raw materials and traditional processing.** This working group develops standards for individual crude herbs and traditional herb processing. An example of a standard developed by this working group is *"Traditional Chinese medicine—Glycyrrhiza uralensis and Glycyrrhiza glabra seeds and seedlings"*.
2) **Working Group 2 Quality and safety of manufactured TCM products.** The focus of this working group is the development of standards associated with processed herbal products. A standard developed within this working group was *"General requirements for manufacturing procedures and quality assurance of granules"*.
3) **Working Group 3 Quality of acupuncture needles and safe use of acupuncture.** This working group developed standards exclusively for acupuncture needles. The first published standard within this WG was *"Sterile acupuncture needles for single use"*.
4) **Working Group 4 Quality and safety of medical devices other than acupuncture needles.** This working group develops standards associated with devices used in the practice of traditional Chinese medicine and acupuncture. Several of these devices are associated with diagnostics, and an example of a published standard is *"Traditional Chinese medicine—Computerized tongue image analysis system"*.
5) **Working Group 5 Terminology and informatics.** This working group plays an important role in developing standards for use with devices and informatics. A good example of a standard developed in this area *is "Traditional Chinese medicine—Vocabulary for diagnostics Part 2: Pulse"*.
6) **Joint Working Group 1.** This is a joint working group that coordinates projects between TC 249 and TC 215 Informatics, another ISO/TC that develops standards for technology and informatics.

The working groups meet for discussion and progression of the standards at the annual plenary meeting held in conjunction with the secretariat. At the completion of the 4-day plenary, consensus is reached, and resolutions are made that progress the developing standard. In addition, the working groups meet at least once every year between the plenary meetings (face to face or online), to discuss and facilitate standard progression.

The most active group has been Working Group 1, which is rapidly developing standards for individual raw (crude) herbs. It has developed a technical report (TR)—"*Traditional Chinese medicine-Priority list of single herbal medicines for developing standards"*—which is a priority list that guides potential project leaders in deciding which herbs should be selected for standards development.

Key principles for ISO standard development are:

1) New standards are developed in response to an industry sector, manufacturer, consumer body or

a member body (country) whereby an argument is made on a "needs basis". A project leader is identified, and a new work proposal is then submitted to an appropriate technical committee. It usually takes three years to publish a standard following rounds of consultation, feedback, and discussion.
2) The development of a standard is led by a project leader who requests a panel of international experts to be involved in developing the standard. They meet regularly and provide feedback to the project leader on all aspects of the standard.
3) An important aspect of the development of the standard is that the criteria are based on consensus from the experts and member bodies, not by the project leader independently.[4]

An essential component of a standard is conformity assessment, whereby certain safety or quality features are identified and tested to ensure that the standard is met. TC 249 (SC1) has been central in developing standards with conformity criteria for devices, acupuncture needles, herbs, and herbal products, and many of these standards have been adopted by several countries for their devices and herbal products.

Another important area has been health terminology and informatics. These standards, developed within WG 5 and the JWG 1, are central to standardizing communication and information technology. This will be important in the future for issues associated with the development of AI within TCM clinical practice.

An important feature of standardization is the regular review and updating of an existing published standard. Standards are reviewed every five years, and the option of updating or changing the standard is possible. As of December 2025, fifty-one standards have undergone a systematic review with all reviewed and approved.

3 WFCMS and the professional standardization of TCM

The WFCMS has also published a large number of standards (*n*=156), including international standards as well as committee-developed standards and technical reports. Standard publication dates from 2007, for example *"International Standard Chinese-English Basic Nomenclature of Chinese Medicine"* with the latest standard publications being listed as 2025, for example "*International Clinical Practice Guideline of Chinese Medicine Hashimoto's thyroiditis*". The WFCMS website states "Standards are the "universal language" and an important support for international economic and technological exchanges and competition".[5] On review, the standards can be further categorized into 9 groups as noted below:

1) **Clinical Practice Guidelines** (*n*=57). This group of WFCMS standards focuses on the diagnostic features and acupuncture treatment approaches for a variety of diseases and medical conditions. An example *is "International Guideline for Diagnostic and Treatment Principles of Chinese Medicine in Diabetes"*. These have all been developed by international experts in these clinical areas. Also informative for Clinical Practice Guidelines (CPGs) is the standard that has been developed *"Norms of development and revision of clinical practice guidelines of Chinese medicine and integrated Chinese and Western medicine"* that was published in 2018.
2) **Clinical practice** (*n*=24). Examples are "*Specifications for International Chinese Medicine Telemedicine Service*" and *"Requirements for Prescription, Dispensing, Delivery, Decoction, and Taking of Chinese Medicine—Part 1: Requirements for Prescription of Chinese Medicine"*. These documents relate to procedures and processes within clinical practice but are not CPGs.
3) **Individual herbs** (*n*=32). These are monographs on herbs and herbal products. One example is *"Circulation Specification & Grading of Chinese Materia Medica–Min Dang Gui"*. These are the second largest grouping of standards after the CPG group.
4) **Education** (*n*=6). These are related to formal learning and speciality education areas. Examples include *"Specifications for International Chinese Medicine Distance Learning Service"* and "*World Standard of Chinese Medicine Undergraduate (Pre-CMD) Education"*.
5) **Standardization** (*n*=9). An example in this area *is "Directives for Standardization—Part 1: Procedures for Standard Development, Revision, and Publication"*. These documents provide guidance for those writing and developing standards.
6) **Acupuncture and moxibustion** (*n*=7). These are clinically focused standards. Examples include *"Normalized Manipulations of Fu's Subcutaneous Needling Therapy"* and *"Standardized Manipulations of Heat-sensitive Moxibustion Therapy"*.
7) **Nomenclature (terminology)** (*n*=10). These are related to different language translations for key terms used in the practice of Chinese medicine. Examples include *"International Standard Chinese-English Basic Nomenclature of Chinese Medicine"* and *"International Standard Chinese-French Basic Nomenclature of Chinese Medicine"*.
8) **Research** (*n*=4). These documents relate to research, and examples include *"Requirements for Ethics Review System of Biomedical Research Involving Human Participants"* and *"Basic Requirements for Chinese Medicine Clinical Research Paper Writing"*.
9) **Technical Reports** (*n*=7). These are a collection of reports that cannot be easily categorized into one area and tend to be more recent in publication date

(2020–2024). Examples include "*Expert Consensus on the Intervention of Chinese Medicine in Aging*" and "*Reporting Guidelines for Diagnostic Criteria of Chinese Medicine Syndromes*".

The WFCMS standards focus heavily on clinical practice, especially Chinese herbal medicine services, and provide high-quality references for practitioners, clinical services and the identification of research priorities. Two additional categories that warrant comment are the nomenclature standards for various languages and the standards for the individual herbs. Nomenclature is important for communication and understanding and is essential in the globalized market, while individual herb standards will drive commercialization and the quality of herbal medicine.

WFCMS has stated that "Standardization construction of traditional Chinese medicine has always been an important work of the WFCMS"[5] and this is reflected in the large number of standards produced. WFCMS produces both international organization standards, branch organization standards, and standardization technical reports, and they are published in both English and Chinese by the International Standards Department. WFCMS also states it runs standardization training for both local experts and those abroad to enhance standard quality.

The WFCMS website states that their aim is to "show and introduce the excellent technology and essence of Chinese medicine to the whole world through this platform, so as to bring benefits to the health of all mankind and contribute to the Chinese program for human health".[5]

4 WFAS and the international standardization of acupuncture practice

Another important international organization that has been producing standards, especially for acupuncture, has been the World Federation of Acupuncture-moxibustion Societies. Currently, there are 25 WFAS standards. The first four standards were published in 2013, and a further 21 in 2023. The WFAS website lists as one of its responsibilities to "formulate and promote organizational standards and international standards of acupuncture-moxibustion".[6] The most recent listing is from 2023 (*n*=21) and there was an earlier collection in 2013 (*n*=4). These standards were approved by the WFAS Standards Committee and filed by the Executive Committee of WFAS.[7] They focus exclusively on acupuncture and are available for review online on the WFAS website. The WFAS standards can be classified into seven areas:

1) **General drafting documents** (*n*=2). An example of a standard in this area *is* "*WFAS 006.1–2023 Technical benchmark of acupuncture and moxibustion—General rules for drafting*". This standard outlines the procedures and processes for drafting the technical benchmarks.
2) **Safety of acupuncture** (***n*=1**). The only standard in this area is the "*WFAS 005.1–2023 General requirements for the risk control in the safe use of acupuncture*". As stated in the document, this standard addresses the common problems that can arise when using different types of needles and how to apply strategies to minimize the risks.
3) **Clinical research** (***n*=2**). These two standards are related to clinical research: "*WFAS 008.1–2023 Guideline for registry of acupuncture-moxibustion clinical research*" and "*WFAS 009.1–2023 Good clinical practice of acupuncture-moxibustion research*". The first standard aims to provide guidance for the development of an online registry for acupuncture clinical trials while the second concerns the development and formatting of a CPG.
4) **Technical benchmarks** (***n*=8**). These benchmarks aim to provide guidance to the correct and safe procedures associated with the administration of devices and needles. One example is "*WFAS 006.6–2023 Technical benchmark of acupuncture and moxibustion—Electroacupuncture*". In addition to this benchmark there are also benchmarks for *Tou Jiu* (头灸), *Gua Sha* (刮痧), periocular acupuncture, scalp acupuncture, cupping, moxibustion manipulations and filiform needling.
5) **Clinical Practice Guidelines** (*n*=8). These are important guidelines for clinical practice and outline how practitioners can go about identifying the treatment approach and administering acupuncture and moxibustion for these diseases. One example is "*WFAS 007.8–2023 Clinical guideline on acupuncture and moxibustion—Migraine*", but also published are another seven CPGs for adult depressive disorder (mild–moderate degree), chronic constipation, allergic rhinitis, female urinary incontinence, non-specific low back pain and Gastroesophageal reflux disease (GERD).
6) **Education** (***n*=3**). These three standards are educational/clinical in content showing the location of auricular acupoints and various treatment approaches that can be applied during auricular acupuncture "*WFAS 002–2013 Names and location of auricular acupuncture points*", as well as for scalp acupuncture "*WFAS 004–2013 Scalp acupuncture manipulation*" and during moxibustion "*WFAS 003–2013 Moxibustion manipulations*".
7) **Device standard** (***n*=1**). The standard "*WFAS 001–2013 Acupuncture needles*" is the only device standard and is specifically for the filiform needle.

The largest number of standards are concerned with clinical aspects such as technical benchmarks (*n*=8) and CPGs (*n*=8), and there is only one standard for a device, that of the filiform acupuncture needle. As noted, more attention has been given to the clinical practice standards, and they offer the practitioner evidence-based consensus on how to approach and treat several common diseases and conditions. The WFAS also has a close relationship and communication with TC 249 and, as stated, is a Category-A liaison organisation to ISO/TC 249.

5 WHO and the global governance framework for traditional medicine

Finally, the WHO has historically been instrumental in developing standards, especially in the area of terminology, practice, and research, for both Chinese herbal medicine and acupuncture. Over the last 3 decades, the WHO has released several important standard-focused documents across a range of areas for research, terminology, and practice. Examples include:

1) **General guidelines for methodologies on research and evaluation of traditional medicine.** This guideline, published in 2000, while not specifically about TCM, aimed to address some of the difficulties and issues associated with research in traditional medicine. In doing so, it introduced some new approaches and also addressed some unclear definitions.[8]
2) **WHO benchmarks for the practice of acupuncture.** This benchmark document was published in 2020 and provides essential information relating to acupuncture practice involving acupuncture treatment, the clinical environment, and key safety procedures.[9]
3) **WHO benchmarks for the training of acupuncture.** This benchmark document, also published in 2020, outlines several different educational levels for acupuncture, for example, students with no medical background, students with a medical background, and those with a traditional medicine background. The benchmark also identifies and details the core subject areas for the three acupuncture education levels.[10]
4) **WHO international standard terminologies on traditional Chinese medicine.** Published in 2022, this standard supports the development and use of these benchmarking documents as well as other TCM technical materials. By setting related norms and standards, this document helps to address the issues related to terminology on TCM.[11]
5) **International Statistical Classification of Diseases and Related Health Problems (ICD).** The first example of a standard adopted by WHO is the ICD-11 which provides a list of diagnostic categories to collect and report on Traditional Medicine conditions in a standardized and internationally comparable manner.[12]
6) **Evidence-based Chinese medicine Clinical Monographs.** The WHO Collaborating Centre for Traditional Medicine at the Royal Melbourne Institute of Technology (RMIT) in Australia has collaborated with Guangdong Provincial Hospital of Chinese Medicine and has co-authored 29 evidence-based Chinese medicine monographs on conditions commonly treated by Chinese medicine. These landmark monographs form the volumes in the Evidence-based Clinical Chinese Medicine Book Series.[13]

As can be seen, the four international organizations have been pivotal in driving the standardization and development of both Chinese medicine and acupuncture. The organizations have taken different approaches and have specific areas which they have focused on. For example, ISO/TC 249 on herbal products, needles, devices and informatics, WFCMS on herbal medicine practice, WFAS on acupuncture practice, and WHO on education. Combined these four organizations and their publications have supported safe practice of Chinese medicine, professional behaviour, and effective treatment approaches for disease. The four organizations also collectively state they have an agenda to develop future standards and to continue the support for acupuncture and Chinese herbal medicine. However, over the last five years, there appears to be another factor that will impact future standard development, that of AI.

6 Artificial intelligence and the future of TCM standardization

One issue that has become very high profile in recent years is the impact of artificial intelligence on health care. A recent publication from WHO titled "*Mapping the application of artificial intelligence in traditional medicine—Technical brief*" (2025) highlighted several areas where AI can be used in traditional medicine development.[14] These included:

1) **Clinical practice and records**. This would involve development in the clinical and governance areas of:
   a. Diagnosis and prediction-based diagnosis;
   b. AI-based clinical decision support systems;
   c. Utilizing hospital management information systems;
   d. Online repositories for TM knowledge;
   e. Data governance models;
   f. Defensive protection against biopiracy.

This area is well suited for AI development; however, issues such as patient consent, standardization of the

terminology of diagnostics and treatment approaches, and data security need to be addressed.

2) **Herbal medicine.** AI can be used to develop Chinese herbal medicine through:
   a. Application of AI for medicine development and health research;
   b. Pattern recognition for drug development;
   c. Identification and direct utilization of TM plants;
   d. Conservation and identification of biodiversity.

This area has implications for both the commercial aspect of herbal medicine, such as quality assurance, and research. Of importance are the implication for the ecology and sustainability of mass-produced herbal products.

3) **Research and Education.** Obviously, the design and implementation of research can be optimized by AI in the areas of:
   a. AI-powered trial design;
   b. Automated literature reviews;
   c. Translating indigenous knowledge.

This final area of AI implementation has already begun with many researchers utilizing AI for the design, literature review, statistical analysis, and the writing of research publications. Again, issues such as data security and the potential for misleading or erroneous outcomes need to be scrutinized and addressed.

What is apparent from these AI development areas is the need for standardization, especially for terminology and its relationship to informatics and databases. This requires standardization of diagnostic systems, treatment principles, and treatments. AI will never wholly replace the human aspect of clinical practice but will greatly assist and improve the efficacy of clinical practice. In addition, both herbal production and research will also benefit from AI. Herb production and quality assurance will be enhanced, leading to increased commercialization and integration in modern health science. Research capabilities will also benefit in that clinical design and clinical decision-making can be compared and analyzed for similarities, differences, and enhancement for future research integration. Furthermore, hospital and clinical records and databases can be mined for relationships as well as novel patient responses. In addition, intricate clinical presentations can be modelled for future patients and relationships.

The report also noted that when the Chinese government released the 14th Five-Year Plan, it noted that "TCM will be strengthened and further enhanced with information technologies, and the TCM industry will be supported to transform and upgrade through digitalization".[13]

It should also be noted that AI development and integration into clinical practice come with a caveat, that is, any devices, technologies, and systems used in any nation or country will have to abide by the regulatory, legal, and professional frameworks within that country. And while there are many advantages to developing AI, it is essential that human clinical oversight will still be required, and AI will not replace Chinese medicine practitioners.

7 Australia's contribution to international TCM standards

Australia has played a supportive role in developing standards for all four organizations: ISO, WFAS, WFCMS, and the WHO.

Standards Australia was a founding member of ISO/TC249. Delegates have attended the plenary meetings on an annual basis since its establishment. Australian delegates have also attended many of the working group meetings. The Australian committee, known as He-031, meets monthly for discussion and submitting the ballot votes. The He-031 committee consists of representatives from educational institutions, community, industry, and professional Chinese medicine associations. Standards Australia has allocated a support project manager to coordinate the He-031 activities and the submission of the ballots to ISO/TC 249.

Australia has nominated experts to contribute to many projects for both informatics, acupuncture needles, other devices, and Chinese herbal medicine. This often involved comments to the committee drafts as well as delivering plenary seminars on informatics and terminology.

Of the 25 WFAS standards, Australian clinicians and researchers have contributed to 10 standards across a range of different areas, including CPGs and technical benchmarks.

Australian academics have also contributed to several important WHO documents, including the WHO international standard terminologies on traditional Chinese medicine (2022) and the benchmarks for the practice of acupuncture and the training of acupuncture. Two Australian representatives were also involved in the *Global traditional medicine strategy 2025–2034* which requests that member states "Develop standards, guidelines, and codes of conduct to promote responsible and accountable TCIM practices".[15]

8 Conclusion

The development of standards has been an essential step for the advancement, clinical relevance, international regulatory alignment, and worldwide commercialization of Chinese medicine and acupuncture. As Chinese medicine continues to grow internationally, the need for standardization across many areas is a necessity in the increasing AI-dominated health care systems. Standards are a way of ensuring a common professional dialogue among nation states and within healthcare professions.

The relationships among ISO/TC 249, WFAS, WFCMS, and the WHO are crucial so that organizations can

support each other's positions and standards. These organizations collectively cover many disparate and professional areas, including clinical practice, technology development and manufacturing, commercial trade, terminology, technical benchmarks for practice, and regulatory policy. Organizational collaboration through standard development can help facilitate international recognition and approval by modern healthcare organizations and regulatory bodies. Furthermore, organizational cooperation will ensure that standards continue to be valid, culturally considerate, consensually based, clinically effective where appropriate, as well as supportive of the Chinese medicine profession.

The impact of AI will also be significant, and standards need to be developed to align and support, where necessary, the future work within this area. Modern healthcare is seeing the emergence of big data storage and analytics, digital health care records, and AI-supported clinical decision-making systems, whereby clinical reasoning is subsumed by AI apps and technology. It is crucial that these systems reflect clinical relevance and practitioner clinical agreement. To do so will require that clinical data and terminology, treatment procedures, and cross-technology approaches be standardized. In addition, future informatics and technology standards need to incorporate ethical guidance, data security, and secure cross-digital frameworks.

The international Chinese medicine professional bodies need to support standard development to ensure the advancement and internationalization of TCM. This imperative is equally relevant at the national level, as evidenced by Australian engagement in standard development.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

Christopher Zaslawski wrote the first draft and revised the paper. ZHAO Hong and CHEN Huan reviewed the manuscript and provided comments for review.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Standards Australia. What is a standard? Available from: https://www.standards.org.au/standards-development/what-is-standard. [Accessed on August 27 2025].
[2] International Organization for Standardization. ISO/TC 249/SC 1: Traditional Chinese medicine. Available from: https://www.iso.org/committee/10892726.html. [Accessed on May 15 2026].
[3] Australian Government Department of Health. QuPP review - clinical practice guidelines. Available from: https://www1.health.gov.au/internet/publications/publishing.nsf/Content/qupp-review~qupp-clinical-practice-guidelines. [Accessed on February 1 2026].
[4] International Organization for Standardization. Standards. Available from: https://www.iso.org/standards.html. [Accessed on August 22 2025].
[5] World Federation of Chinese Medicine Societies. Standardization construction. Available from: https://www.wfcms.org/en/index.php/list/38.html. [Accessed on August 22 2025].
[6] World Federation of Acupuncture-Moxibustion Societies. Acupuncture standards. Available from: https://en.wfas.org.cn/site-enwfas/c743. [Accessed on August 27 2025].
[7] World Federation of Acupuncture-Moxibustion Societies. WFAS published 21 international standards on acupuncture and moxibustion (2023). Available from: https://www.wfas.org.cn/site-enwfas/a52090.html. [Accessed on August 27 2025].
[8] World Health Organization. General guidelines for methodologies on research and evaluation of traditional medicine. Available from: https://www.who.int/publications/i/item/9789241506090. [Accessed on August 27 2025].
[9] World Health Organization. WHO benchmarks for the practice of acupuncture. Available from: https://iris.who.int/handle/10665/340838. [Accessed on August 27 2025].
[10] World Health Organization. WHO benchmarks for the training of acupuncture. Available from: https://iris.who.int/handle/10665/341723. [Accessed on August 27 2025].
[11] World Health Organization. WHO international standard terminologies on traditional Chinese medicine. Available from: https://www.who.int/publications/i/item/9789240042322. [Accessed on August 28 2025].
[12] Harrison JE, Weber S, Jakob R, et al. ICD-11: an international classification of diseases for the twenty-first century. *BMC Medical Informatics and Decision Making*. 2021;21:206.
[13] RMIT University. Evidence-based Chinese medicine clinical monograph series. Available from: https://www.rmit.edu.au/research/centres-collaborations/multi-partner-collaborations/cairccm/publications/evidence-based-chinese-medicine-clinical-monograph-series. [Accessed on May 13 2026].
[14] World Health Organization and International Telecommunication Union. *Mapping the Application of Artificial Intelligence in Traditional Medicine: Technical Brief*. Geneva: World Health Organization and International Telecommunication Union; 2025.
[15] World Health Organization. Global traditional medicine strategy 2025–2034. Available from: https://iris.who.int/server/api/core/bitstreams/cf37a4ad-4d27-4244-a7ee-001de39841ee/content. [Accessed on January 27 2026].

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Policy Review

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Synergizing Global Health Governance: WHO and ISO Frameworks in Advancing Traditional Chinese Medicine Standardization

协同推进全球卫生治理：世界卫生组织与国际标准化组织框架下的中医药标准化建设

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Abstract

The international standardization of traditional Chinese medicine (TCM) is pivotal for its global acceptance and integration into global health systems. The World Health Organization (WHO) and the International Organization for Standardization (ISO) lead these efforts, yet their overlapping roles necessitate coordination. This study examines their contributions to TCM standardization and their implications for global health policy. The study analyzed WHO and ISO documents, including strategies, standards, and reports, using a comparative framework across macro (strategic planning), meso (organizational approaches), and micro (specific standards) levels. WHO provides foundational, public welfare-oriented standards, while ISO offers market-driven technical specifications. Overlaps in terminology and Chinese materia medica (CMM) standards highlight coordination gaps, potentially causing inconsistencies. Enhanced collaboration between WHO and ISO can harmonize TCM standards, eliminate redundancies and ensure coherence. Policy recommendations include clarifying roles, establishing joint coordination, and implementing post-publication standard evaluation.

Keywords: Traditional Chinese medicine (TCM); World Health Organization (WHO); International Organization for Standardization (ISO); Standardization; Global health policy

1 Introduction

The international standardization of traditional Chinese medicine (TCM) is primarily driven by two key institutions: the World Health Organization (WHO) and the International Organization for Standardization (ISO). Since the 1980s, WHO has spearheaded foundational efforts in TCM standardization, while ISO formalized its commitment in 2009 through the establishment of the Technical Committee for Traditional Chinese Medicine (ISO/TC 249). These dual platforms now represent complementary approaches to harmonizing TCM practices globally.

WHO's engagement in TCM standardization initially started in the Western Pacific Region. From the 1980s onward, the Western Pacific Regional Office published over 10 standards encompassing terminology, education, health care institutions, health policies, and herbal medicine. Subsequently, in the 1990s, WHO Headquarters established a dedicated Department of Traditional, Complementary and Integrative Medicine, responsible for traditional medicine (TM) policy and standard development. To date, WHO has published over 20 TCM-related standards, addressing areas such as terminology, *Tui Na* (推拿 Chinese massage), acupuncture, herbal medicine, disease classification, and consumer guidelines.

Within the ISO framework, ISO/TC 249 and the Technical Committee for Health Informatics (ISO/TC 215) have collaboratively developed and published TCM international standards since 2009. Cumulatively, ISO/TC 215 and ISO/TC 249 have published over 100 TCM standards, covering a broad spectrum, including the quality and safety of raw materials and finished products, medical devices, terminology, informatics, and service delivery. ISO, therefore, functions as a complementary and increasingly significant platform to WHO

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in TCM standardization, providing technical specifications and quality assurance frameworks to support TCM's role in global health governance.

Academic inquiry into the WHO's role in global health governance often focuses on its political engagement, paradigm shifts, and inherent challenges, with limited specific attention to its TM initiatives.[1–3] Some scholars have explored WHO's TM-related contributions in terms of safety, efficacy assessment, health-system integration, and practitioner education,[4] and others have proposed evidence-based standardization methods for TCM terminology and clinical guidelines.[5,6] Nevertheless, a systematic analysis of the WHO's TCM standardization framework remains absent. Concurrently, research on ISO is generally confined to disciplinary standardization studies, with limited dedicated studies on the organization itself, especially concerning its non-governmental status. While ISO guidance documents and strategic plans are recognized as foundational for standardization work, dedicated research on ISO's specific contribution to TCM standardization is notably absent. The critical issue of synergizing WHO's and ISO's TCM standardization efforts remains an underexplored yet vital research area.

The overlap in the scope of WHO and ISO underscores the critical need for effective coordination mechanisms in TCM international standardization. This research addresses the crucial yet underexplored synergy between WHO and ISO in advancing TCM standardization. While both organizations play pivotal roles, their standardization efforts, though complementary, may exhibit areas of overlap, divergence, or potential conflict. Understanding how these two influential frameworks interact, complement each other, and potentially diverge is essential for crafting a coherent and resilient global health governance strategy for TCM. Consequently, this study analyzes their standardization activities to draw comparative insights for refining the overarching TCM international standardization framework, with the objective of ensuring harmonization between WHO and ISO standards and ultimately contributing to the high-quality and sustainable development of TCM globalization.

2 Methods

This study employed a comprehensive, multi-level comparative analysis to evaluate the contributions of WHO and ISO to the international standardization of TCM. The research methodology involved a systematic review and synthesis of primary and secondary sources, including official WHO and ISO documents such as strategic plans, technical reports, and published standards. These documents were retrieved from the organizations' websites.

The analysis was structured across three distinct levels: macro, meso, and micro. At the macro level, the study examined the strategic planning frameworks of WHO and ISO, focusing on their overarching goals, scope of consensus, and alignment with global health and trade objectives. At the meso level, organizational approaches were compared, including governance structures, funding mechanisms, stakeholder involvement, and procedural rigor in developing standards. The micro level involved a detailed comparison of specific TCM standards, particularly in terminology and Chinese materia medica (CMM), to identify areas of overlap, divergence, and potential inconsistencies (Table 1).

To ensure analytical rigor, a qualitative comparative framework was developed, drawing on policy analysis and standardization theories. This framework facilitated the identification of synergies and gaps between WHO's and ISO's efforts. Data were organized thematically to highlight key differences in purpose, scope, and implementation. Additionally, stakeholder perspectives from published reports and expert consultations were integrated to contextualize the findings within the broader landscape of global health governance. The study also incorporated a review of historical documents to trace the evolution of TCM standardization efforts, providing a longitudinal perspective on the roles of both organizations. In this study, TCM is used to denote the specific system derived from ancient Chinese medicine, while "traditional medicine (TM)" refers to the broader category encompassing various medical systems (including TCM, Ayurveda, and Unani).

3 WHO's role in TM

3.1 Historical evolution of WHO's TM policies

The World Health Assembly (WHA), WHO's supreme decision-making body, has addressed TM since the late 1960s. Over five decades, WHO's engagement with TM has evolved through a series of resolutions, declarations, strategies, and technical guidelines (Table 2).

An examination of relevant documents reveals that WHO's TM policy has evolved through three distinct phases.

3.1.1 Recognition and prioritization (1969–1978)

During this initial phase, WHO focused primarily on addressing urgent health issues among member states,

Table 1 Analytical framework for comparing WHO and ISO in TCM standardization

Level of Analysis	Description	Key Focus Areas
Macro	Examination of strategic planning frameworks of WHO and ISO	Overarching goals, scope of consensus, alignment with global health and trade objectives
Meso	Comparison of organizational approaches between WHO and ISO	Governance structures, funding mechanisms, stakeholder involvement, procedural rigor in standards development
Micro	Detailed comparison of specific TCM standards	Terminology and CMM, identification of overlaps, divergences, and potential inconsistencies

Table 2 WHO resolutions and declarations on TM

Year	Document Title	Document Type	Document Number
1969	Resolution on Establishment of Pharmaceutical Production in Developing Countries	Assembly Resolution	WHA 22.54
1978	Declaration of Alma-Ata on Primary Health Care	Declaration	/
1978	Resolution on Medicinal Plants	Assembly Resolution	WHA 31.33
1987	Resolution on Traditional Medicine	Assembly Resolution	WHA 40.33
1988	Resolution on Traditional Medicine and Medicinal Plants	Assembly Resolution	WHA 41.19
1989	Resolution on Traditional Medicine and Modern Health Care	Assembly Resolution	WHA 42.43
1991	Resolution on Traditional Medicine and Modern Health Care	Assembly Resolution	WHA 44.34
2003	Resolution on Traditional Medicine	Assembly Resolution	WHA 56.31
	WHO Traditional Medicine Strategy 2002–2005	Development Strategy	/
2008	Beijing Declaration on Traditional Medicine	Declaration	/
	Global Strategy on Public Health, Innovation and Intellectual Property	Assembly Resolution	WHA 61.21
2009	Resolution on Traditional Medicine	Assembly Resolution	WHA 62.13
2013	WHO Traditional Medicine Strategy 2014–2023	Development Strategy	/
2014	Resolution on Traditional Medicine	Assembly Resolution	WHA 67.18
2016	Resolution on Strengthening Integrated, People-Centered Health Services	Assembly Resolution	WHA 69.24
2024	Beijing Declaration of the World Conference on Traditional Medicine 2024	Declaration	/
2025	Global Traditional Medicine Strategy 2025–2034	Development Strategy	/

particularly in newly decolonized African nations facing severe health care resource shortages. WHO acknowledged its importance through several resolutions, recognizing the extensive application of TM across various countries,[7] proposing the incorporation of traditional practitioners as potential health care workforce resources,[8] and establishing specific recommendations for training and research in TM.[9] The 1978 International Conference on Primary Health Care, jointly organized by WHO and the United Nations Children's Fund (UNICEF), launched the Declaration of Alma-Ata, which established the strategic goal of "Health for All by 2000" while affirming TM's crucial role in health care delivery, especially in developing countries.[10]

3.1.2 Technical guidance (1979–2001)

This phase coincided with global shifts toward multipolarity and the gradual dissolution of the bipolar world order. Despite emerging new political and economic paradigms, vast populations worldwide still lacked access to basic health care services. The adoption of Resolution WHA 31.33 on "Medicinal Plants" marked WHO's transition to providing technical guidance on TM. WHO subsequently focused intensively on medicinal plants, urging members to inventory, catalog, research, and protect these resources,[11] regulate and control their products to ensure sustainable development, and incorporate proven effective and low-risk treatments into national pharmacopeias.[12] The Director-General was tasked with allocating financial and technical resources to support members' TM initiatives. These efforts culminated in WHO publishing numerous technical documents covering terminology, education, training, health care institutions, health policy, and medicinal plants.

3.1.3 Policy development support (2003–present)

In this current phase, characterized by accelerated globalization and increasing global interdependence, WHO has shifted from primarily providing technical resources to supporting institutional and policy development. Following the United Nations Millennium Declaration, which established health-related development goals, and through its central role in managing international health emergencies, WHO has established more concrete objectives regarding TM policy development, research enhancement, standardization, and international cooperation. China has increasingly participated in shaping WHO's TM agenda by contributing staff and officials, collaborating on projects, and influencing key documents.

WHO published strategic frameworks in 2003 and 2013 that established four fundamental objectives: improving TM's safety, efficacy, accessibility, and quality assurance. In 2011, the Western Pacific Regional Committee adopted a regional TM strategy (2011–2020). Under Director-General Tedros Adhanom Ghebreyesus (since 2017), WHO has further emphasized standardization of TM as part of broader reforms to strengthen the organization's normative and technical functions. The *2019 WHO Global Report on Traditional and Complementary Medicine* provided comprehensive data from 179 members regarding legislation, administration, research, herbal medicine registration, practitioner regulation, and insurance coverage, establishing a foundation for future strategic planning.

3.2 Key WHO institutions and actors in TM

Due to the nature of its governance structure, WHO has relied on various entities at different historical junctures to advance its TM agenda. These include WHO regional offices, headquarters TM-related units, and WHO Collaborating Centers for Traditional Medicine, each playing a significant role in implementing TM strategies, conducting research, and developing technical guidelines.

From the 1980s, with support from the United Nations Development Programme (UNDP), WHO established a network of "WHO Collaborating Centers for Traditional Medicine". These centers, typically hosted by universities and research institutions, are part of a broader WHO inter-institutional collaborative network designed to support WHO's programs at national, inter-country, regional, interregional, and global levels. Currently, there are 21 WHO Collaborating Centers for Traditional Medicine worldwide. Since the signing of a memorandum of understanding on health technology cooperation between China's Ministry of Health and WHO in October 1978, China has established 9 such centers. These centers focus on areas such as theoretical and methodological research, experimental and clinical studies, information and knowledge dissemination, technical support and advice, international exchange and cooperation, as well as education and training. They leverage their respective disciplinary strengths and research expertise to address WHO's priorities and policy documents.[13]

During the early 1990s, WHO's governance structure was characterized by a high degree of decentralization, with regional offices enjoying considerable autonomy in leadership appointments, budgets, and priority setting. During this period, WHO regional offices played a crucial role in implementing TM strategies, conducting research, and publishing TM guidance documents. WHO has 6 regional offices: the African Region (AFRO), the Region of the Americas (PAHO), the South-East Asia Region (SEARO), the European Region (EURO), the Eastern Mediterranean Region (EMRO), and the Western Pacific Region (WPRO). Four of these—AFRO, EURO, SEARO, and WPRO—have actively engaged in TM initiatives and published related documents. To enhance the harmonization of technical standards for herbal medicine, WPRO initiated the establishment of the Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH) in 2002.

In the late 1990s, Director-General Gro Harlem Brundtland spearheaded significant reforms to WHO's structure, budget, and work mechanisms, improving its overall governance. Within this context, to implement the World Health Assembly's strategy for TM development, WHO established the Unit of Traditional, Complementary and Integrative Medicine within the Integrated Health Services Department. This unit is primarily responsible for formulating TM policies aimed at ensuring the safety, efficacy, and quality of TM practices. Under its organization and coordination, key documents such as *WHO Traditional Medicine Strategy 2002–2005*, *WHO Traditional Medicine Strategy 2014-2023*, and *WHO Global Report on Traditional and Complementary Medicine 2019* have been published.

In March 2022, WHO and the Government of India signed an agreement to establish WHO Global Centre for Traditional Medicine (GCTM) in Gujarat, India. Supported by an investment of USD 250 million from the Indian government, GCTM aims to harness the potential of TM from around the world through modern science and technology to improve the health of people and the planet. The center focuses on building a solid evidence base for policies and standards on TM practices and products, assisting countries in integrating TM into their health systems, and regulating its quality and safety for optimal and sustainable impact. As part of WHO's overall TM strategy, the GCTM's strategic priorities include evidence gathering, data analysis, equity and sustainability, and technological innovation to optimize the contribution of TM to global health and sustainable development.[14]

3.3 Key WHO publications in TM standardization

WPRO has published over 130 regional reports, national reports, and technical guidelines on TM since the 1980s.[15] Eleven of these publications focus specifically on TCM-related technical guidelines, covering areas such as terminology, education, health care facilities, health policy, and herbal medicine.

In the 1990s, WHO headquarters established a dedicated Unit of Traditional, Complementary and Integrative Medicine, primarily responsible for developing TM policies aimed at ensuring the safety, efficacy, and quality of TM practices. In recent years, WHO has strengthened its standard-developing role, encompassing TM terminology, training standards, and inclusion in the International Classification of Diseases. As of October 2025, WHO has released 70 documents on traditional and complementary medicine. These documents are categorized as standards, benchmarks, guidelines, publications, reports, and technical documents. They cover a wide range of topics, including policy and strategy, monitoring of national policies and regulations, promotion and protection of TM knowledge, quality and safety of herbal medicines, regulation of herbal medicines, research methodologies and clinical investigations in TM, conservation and sustainable use of medicinal plants, the role of TM in healthcare, acupuncture nomenclature and terminology, consumer information and education, and training and good practices.[16] Notably, the 11th revision of the International Classification of Diseases (ICD-11), released in 2018, includes 150 disease codes and 196 pattern codes related to TM, primarily based

on TCM. This represents a significant international standard for TM terminology and classification.

Among the standards, *WHO International Standard Terminologies on Traditional Chinese Medicine* (Fig. 1), published in March 2022, is particularly significant. This standard provides English translations and definitions for 3,415 TCM terms. It is the first official TCM terminology standard published by WHO headquarters for its 194 members, providing a unified bilingual (Chinese-English) reference for standardization and internationalization of TCM, and significantly supporting international communication and information exchange.

Among the benchmarks, WHO published a series of training benchmarks for TM practices in 2010. These covered *Tui Na*, Ayurveda, naturopathy, osteopathy, Unani, and Thai medicine. Subsequently, in 2021 and 2022, WHO updated the training and practice benchmarks for *Tui Na*, acupuncture, Ayurveda, and Unani. These benchmarks, with a central focus on consumer protection and patient safety, represent a broad consensus on the training and practice of TM practitioners. They provide a recognized standard for practitioners worldwide, thereby supporting countries in establishing appropriate regulatory frameworks for TM.

4 ISO's role in TM

4.1 Strategic planning of ISO in TM

The ISO General Assembly (ISO/GA), the highest governing body of ISO, is primarily responsible for formulating ISO's strategic plans. In September 2020, the ISO/GA approved the *ISO Strategy 2030*. This strategy articulates a vision of "making lives easier, safer and better" and a mission to, "through its members, develop international standards that support global trade, drive inclusive and equitable economic growth, advance innovation, protect health and safety, and contribute to a sustainable future". The strategy identifies four key drivers of change and development for ISO: economic, technological, societal, and environmental factors.[17]

Health and well-being, recognized as a fundamental human right, is a priority area for ISO. In alignment with the United Nations Sustainable Development Goal 3 (Good Health and Well-being), ISO actively contributes to standardization in the health sector. According to the *ISO Annual Report 2019*, health-related international standards constitute 6.8% of all published ISO standards, making it the fifth-largest technical standards area after information technology, engineering machinery, transportation, and non-metallic materials.[18] The publication "ISO and health" outlines the current status and future objectives of ISO's standardization work in the health domain. Currently, ISO has published over 1,400 health-related international standards, covering areas such as dentistry, ophthalmology, surgery, TCM, transfusion and infusion equipment, syringes, medical monitoring devices, assistive devices for persons with disabilities, sterilization of medical devices, and health informatics. These standards provide technical specifications for quality control, service evaluation, information exchange, data aggregation, and patient privacy protection within the health care industry.

ISO emphasizes broad stakeholder participation in the development of international standards. Stakeholders for ISO health-related standards include patients, physicians, manufacturers, cultivators and harvesters of natural medicines, researchers, educators, policymakers, and



Figure 1 *WHO International Standard Terminologies on Traditional Chinese Medicine* (source with permission from: https://www.who.int/publications/i/item/9789240042322)

regulators. Endorsed by the World Trade Organization's Agreement on Technical Barriers to Trade (WTO/TBT), ISO international standards facilitate the entry of health products and services into the global market and provide a technical basis for government regulatory bodies in different countries to formulate regulations and measures that better meet market demands.

Each ISO Technical Committee develops a Strategic Business Plan (SBP) at least every three years to define priority areas for future standardization. ISO/TC 215 updated its SBP in 2016 to include TM informatics within its scope of work. ISO/TC 249 updated its SBP in 2023, stating its commitment to maintaining health and improving health care through the use of TM. The committee focuses on the quality, safety, and efficacy of TM products and supports the trade of related products and services. Furthermore, it aims to promote legislation on public policies related to TM through the development of ISO international standards, safeguarding the health and safety of customers and consumers.

4.2 ISO's specialized bodies and key stakeholders in TM

Within the field of TM, China, as the largest stakeholder in the global development of TM, proposed the establishment of a technical committee on TCM to the ISO headquarters in March 2009. After a three-month voting process by its member bodies, the first technical committee dedicated to TM, ISO/TC 249, was formally approved at the 45th ISO Technical Management Board meeting held in South Africa in September of the same year. The secretariat of ISO/TC 249 is hosted by China.

Separately, in April 2009, ISO/TC 215 established a TM Task Force. This task force's primary responsibilities include identifying standardization needs within TM and developing health informatics standards related to the field. With the establishment of ISO/TC 249 and the TM Task Force within ISO/TC 215, ISO has formed a more comprehensive health and health care standardization system that encompasses TM.

The ISO employs a rigorous process management system for standard development, ensuring the quality and applicability of standards through procedural adherence. According to ISO Directives, the development process for each technical project proposal is divided into seven stages: Preliminary Work Item (PWI), New Work Item Proposal (NP), Working Draft (WD), Committee Draft (CD), Draft International Standard (DIS), Final Draft International Standard (FDIS), and International Standard (IS). From the proposal stage, the default timeline for developing a complete ISO international standard is 36 months.

The secretariats of the relevant technical committees and working groups are responsible for receiving new proposals from member bodies, organizing working group discussions, initiating balloting on proposals, and conducting working group consultations. The ISO Central Secretariat oversees the quality control of the Draft International Standard voting, Final Draft International Standard voting, and publication stages.

4.3 Key publications of ISO in TM standardization

Within the ISO organizational structure, ISO/TC 249 and ISO/TC 215 have been developing and publishing international standards for TCM since 2009. As of March 2025, ISO/TC 249 has published 119 international standards for TCM, covering areas such as the quality and safety of raw herbal materials, the quality and safety of finished products, the quality and safety of medical devices, terminology and informatics, and services. ISO has become a complementary platform to WHO for publishing international TCM standards, providing a technical foundation for quality and safety assurance, thereby facilitating TCM's participation in global health governance.

Regarding raw herbal materials, ISO/TC 249 has published international standards for Radix Notoginseng, Folium Artemisiae Argyi, Radix Salviae Miltiorrhizae, Ganoderma, Radix Isatidis, Flos Lonicerae Japonicae, Dendrobium Officinale, Rhizoma Gastrodiae, Radix Angelicae Sinensis, Radix Astragali Mongholici, Fructus Lycii, Radix Codonopsis, and Radix Paeoniae Alba, among others. In international trade, most herbal materials are traded as raw materials or agricultural products. This presents a challenge for regulatory agencies in various countries, as it is difficult to regulate them as pharmaceuticals. This lack of applicable standards hinders effective quality and safety supervision. ISO international standards for herbal materials address this regulatory gap, assisting regulatory bodies in ensuring the safety and quality of herbal materials and streamlining the process of additional review and approval during registration and inspection.

Regarding TCM products, ISO/TC 249 has published standards for the detection of heavy metals, pesticide residues, aflatoxins, microorganisms, sulfur dioxide, aristolochic acids, and benzopyrene in herbal medicines, as well as general standards for TCM products, covering aspects from raw materials to the final product. Due to different requirements for the identity, indications, and quality control of TCM products among countries and regions like the United States, the European Union, China, and Japan, international trade and overseas registration of these products face significant technical barriers. ISO standards can provide a common reference for international trade and overseas registration of TCM products, establishing quality control specifications and clinical efficacy evaluation methods suitable for the characteristics of TCM, within a framework that ensures quality and safety.

Regarding quality and safety of TCM medical devices, ISO/TC 249 has published international standards for

the quality, safety, and safe use of single-use sterile acupuncture needles, single-use sterile intradermal needles, glass cupping sets, scraping instruments, moxibustion devices, infrared moxibustion-like instruments, and fumigation therapy devices. The design, production, sales, and application of TCM medical devices are primarily concentrated in East Asian countries and regions, such as China, the Republic of Korea, and Japan. Western countries have not yet developed a significant industry in this area, with only a small portion of products being imported. However, with advancements in technology, TCM electromagnetic therapy and rehabilitation equipment products are emerging. The integration of methods like tongue diagnosis and pulse diagnosis with emerging technologies such as artificial intelligence (AI) represents a potential future direction for innovation in TCM medical devices. International standards in these areas will facilitate the global promotion and application of new products.

Regarding terminology, informatics, and services, ISO/TC 249 has published international standards for TCM coding systems, TCM clinical terminology and specialized terminology for CMM processing, tongue diagnosis, and pulse diagnosis. As a traditional medical system distinct from Western medicine, TCM terminology embodies both cultural and professional characteristics. These culturally embedded and self-contained terms are essential for the globalization of TCM. ISO international standards for TCM terminology follow principles of scientific rigor, standardization, and accuracy, with emphasis on defining distinguishing characteristics. The primary aim is to objectify information and establish a unified conceptual system. These terms, which represent condensed expressions of TCM theory and clinical therapeutic reasoning, require standardization to facilitate knowledge dissemination, clinical data exchange, and development of modern diagnostic and therapeutic devices.

5 Comparative analysis of WHO and ISO standards

5.1 Macro-level: strategic differences

At the macro level, the strategic approaches of WHO and ISO to TM differ in four key aspects:

First, the consensus level and scope differ significantly. WHO's TM strategy emerges from World Health Assembly resolutions, representing consensus among all member states. In contrast, ISO's TM strategy is developed by relevant technical committees, achieving consensus among member bodies, resulting in different levels of consensus.

Second, the organizational participants differ. WHO operates as a sovereign state platform with governmental endorsement. Health departments from member states participate in strategic planning, providing greater implementation capacity. ISO strategic planning involves national standard bodies that include both governmental agencies (such as Standardization Administration of the People's Republic of China) and non-governmental professional organizations (such as Deutsches Institut für Normung).

Third, coverage scope varies substantially. WHO's strategy encompasses all TM systems, including knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to different cultures. This includes TCM, Ayurveda, Unani, and various folk medicine systems worldwide. ISO/TC 249 focuses exclusively on TCM and medical systems derived from ancient Chinese medicine.

Fourth, strategic objectives differ. WHO approaches TM from the perspective that to maximize its potential as a health care resource, issues of policy, safety, efficacy, and rational use must be addressed. WHO's strategy consistently serves two fundamental goals: achieving universal health coverage and improving population health and well-being. ISO's international standardization strategy prioritizes industrial innovation, global trade support, sustainable development, inclusive economic growth, health and safety maintenance, with stakeholder participation as a key concern.

In summary, WHO, as a governmental organization within the UN framework with participation from national health departments, aims to provide technical and policy guidance to member states, promoting evidence-based, safe integration of TM into health systems to achieve the goal of universal health coverage. ISO, as a non-governmental organization with participation from official and unofficial standardization bodies, focuses on technical areas and developing market-oriented international standards aligned with UN 2030 Sustainable Development Goals. Both organizations share concerns regarding the quality, safety, and efficacy of TM products, supporting legislative and regulatory frameworks across countries.

5.2 Meso-level: organizational approaches

WHO and ISO exhibit significant differences in their institutional structures and procedures for developing international standards in TM.

5.2.1 Organizational approaches to developing standards

WHO adopts a top-down approach to developing standards. The primary bodies responsible include the Traditional, Complementary and Integrative Medicine Department, regional offices, and the International Regulatory Cooperation for Herbal Medicines (IRCH). These entities develop standards guided by World Health Assembly resolutions and strategic planning documents, securing funding and establishing relevant research projects. Projects are typically coordinated by WHO officials who invite experts from member states and TM

collaborating centers. A chairperson is appointed to lead each project, playing crucial roles in facilitating discussions, reconciling differences, advancing the project, and making final determinations. WHO generally uses minutes from global review meetings as evidence of consensus, without adopting strict voting procedures.

In contrast, ISO employs a bottom-up approach driven by market demands. Each participating member body within technical committees has the right to propose international standards based on national needs. Standard development requires participation from at least five member bodies and comprehensive consultation with stakeholders. The process involves multiple rounds of balloting at both technical committee and ISO levels, followed by review by the ISO Central Secretariat before final publication. ISO international standards thus follow more rigorous development procedures with longer development cycles, incorporating broader consensus among member bodies and stakeholders.

5.2.2 Funding mechanisms

WHO's TM projects are primarily funded through voluntary contributions from member states. The allocation of these contributions often reflects donor countries' preferences regarding projects and priorities. ISO headquarters provides no financial support for developing international standards. Funding typically comes from the organizations employing registered experts. In China, the Administration for Market Regulation at various levels establishes specialized funds for international standardization work according to the *Standardization Law of the People's Republic of China*, encouraging participation in international standardization activities and rewarding entities that successfully publish international standards.

5.2.3 Review of standards

ISO systematically reviews all published standards to determine whether they should be confirmed, amended, revised, converted to another publication type, or withdrawn. International standards are reviewed at maximum intervals of five years, technical specifications every three years, and publicly available specifications every three years, while technical reports have no specified review interval. For instance, ISO/TC 249 has systematically reviewed more than 50 published standards, approving them for continued use for the next five years. In contrast, WHO has not yet established a comparable review mechanism for its published standards and documents.

5.2.4 Copyright and accessibility

All WHO publications are freely available for non-commercial download. Significant WHO policy documents on TM are often available in multiple languages, including Arabic, Chinese, French, Italian, Russian, and Spanish. ISO standards, however, must be purchased, with pricing correlated to document length. English serves as the common language for ISO standards, with some also available in French.

In conclusion, from an organizational perspective, WHO standards follow a top-down, government-led model, while ISO standards utilize a bottom-up, multi-stakeholder approach. Procedurally, WHO standards offer greater flexibility, whereas ISO standards demonstrate much methodological rigor. Regarding influence, WHO standards emphasize breadth of application, while ISO standards focus on depth of technical specificity.

5.3 Micro-level: comparison of standards

Based on the strategic objectives of providing TM knowledge and supporting member states in developing TM policies, WHO international standards for TM primarily encompass herbal medicine quality and safety, TM terminology, TM classification and coding, and TM training and good practices.

ISO international standards for TCM mainly address raw materials, manufactured products, and medical devices and informatics—essentially covering the entire TCM industry chain. Through systematic comparison, there are notable overlaps between WHO and ISO standards in TCM terminology and CMM standards (Table 3). For instance, discrepancies between *WHO International Standard Terminologies on Traditional Chinese Medicine* and ISO's *Vocabulary for Diagnostics* have led to inconsistent English translations of diagnostic terms, complicating data exchange and AI-based applications. Similarly, differing test limits for heavy metals and pesticide residues in herbal materials between WHO monographs and ISO standards can result in conflicting import regulations and product rejections in international trade. Such overlaps create regulatory uncertainty for enterprises and hinder the mutual recognition of TM products across markets.

5.3.1 Terminological standards

WHO initiated its research and standardization work on TM terminology relatively early, with a broad scope of coverage. *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region* (Fig. 2) includes a total of 3,686 terms, encompassing fundamental concepts, basic theories, diagnostics, diseases, therapeutic principles, acupuncture, pharmacological treatments, and classical texts. The TM chapter of the ICD-11 encompasses 150 disease entities and 196 pattern diagnoses, primarily based on TCM. *WHO International Standard Terminologies on Traditional Chinese Medicine*, published in 2022, includes 3,415 bilingual (Chinese-English) terms and definitions, covering three major areas: basic theories and diagnostics, disease and pattern classification, and therapeutic principles and interventions.

Table 3 Overlapping international standards in TCM

Type	WHO	ISO	Inconsistencies	Potential Consequences
Terminology	• *WHO International Standard Terminologies on Traditional Chinese Medicine* • *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region*	• *ISO 23961-1:2021 Traditional Chinese Medicine—Vocabulary for diagnostics—Part 1: Tongue* • *ISO 23961-2:2021 Traditional Chinese Medicine—Vocabulary for diagnostics—Part 2: Pulse*	English translations and definitions	Data interoperability gaps; inconsistent digital health records; variation in practitioner training
CMM	• *WHO Monographs on Selected Medicinal Plants* (5 volumes)	• *ISO 22988:2020 Traditional Chinese Medicine—Astragalus mongholicus root* • *ISO 22584:2019 Traditional Chinese Medicine—Angelica sinensis root* • *ISO 22586:2022 Traditional Chinese Medicine—Paeonia lactiflora root—White peony root* • *ISO 22585:2022 Traditional Chinese Medicine—Codonopsis pilosula root* • *ISO 23965:2022 Traditional Chinese Medicine—Bupleurum chinense root*	Quality control and safety indicators	Regulatory misalignment; duplicated testing; trade and export delays

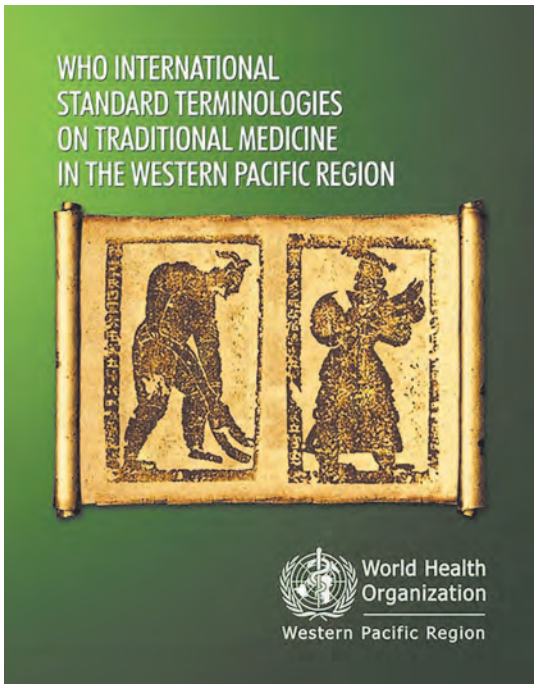


Figure 2 *WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region* (source with permission from: https://iris.who.int/items/fef5c980-1ce6-4ead-8a40-411631a63b12)

In comparison, ISO has taken a more limited approach to the standardization of traditional medicine terminology, currently focusing primarily on medicinal materials, processing methods, and diagnostic vocabulary.

WHO's terminological standards for TM generally include the following elements: Chinese and English terms, bilingual definitions, synonyms, and Pinyin. ISO standards for terminology related to medicinal materials typically consist of bilingual terms, Pinyin, both traditional and simplified Chinese characters, and Latin botanical names. Terminology for processing methods includes bilingual terms and English definitions. Diagnostic terminology standards include Chinese names, Pinyin, English terms, definitions, and references to classical sources, with annexes providing figures and corresponding terms in Japanese and Korean.

The primary goal of WHO's terminological standardization is to promote the application of TM and to provide reference standards for the development of textbooks and information exchange across countries. The English translation principles emphasize accurate reflection of the original concepts of TM, avoiding the creation of new terms, and prioritizing their medical significance. Consequently, the terminologies and definitions often reflect traditional medical theories and clinical diagnostic concepts, thereby exhibiting a high degree of medical specificity. In contrast, ISO's terminological standards for TM are mainly designed to facilitate information exchange in the context of goods and services trade. For example, *ISO 23961-1:2021 Traditional Chinese medicine—Vocabulary for diagnostics—Part 1: Tongue* and *ISO 23961-2:2021 Traditional Chinese medicine—Vocabulary for diagnostics—Part 2: Pulse* are intended to provide standardized terminology for various TCM diagnostic devices, serving as references for technologies such as telemedicine and AI-based diagnostics. The English translations of these terms and definitions typically adopt objective descriptions and intentionally avoid reference to clinical diagnostics and traditional medical theories.

5.3.2 Technical standards for CMM

WHO has published five volumes of *Monographs on Selected Medicinal Plants* (Fig. 3), covering 130 widely used medicinal plant species worldwide. Among these, 41 species are also listed in the 2020 edition of the *Pharmacopeia of the People's Republic of China*, including commonly used Chinese medicinal materials such as *Huang Lian* (黄连 Rhizoma Coptidis), *Huang Qi* (黄芪 Radix Astragali), *Chai Hu* (柴胡 Radix Bupleuri), *Ren Shen* (人参 Radix et Rhizoma Ginseng), *Gan Cao* (甘草 Radix et Rhizoma Glycyrrhizae) and *Dang Gui* (当

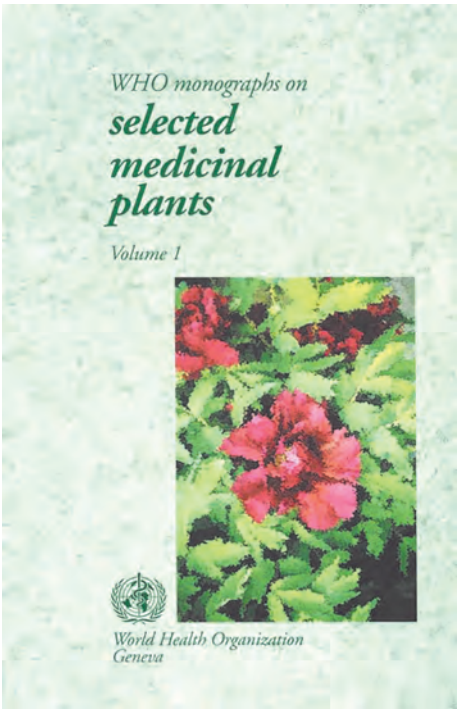


Figure 3 *WHO Monographs on Selected Medicinal Plants* (*Volume 1*) (source with permission from: https://www.who.int/publications/i/item/9241545178)

归 Radix Angelicae Sinensis). To be included in WHO monographs, a medicinal plant must meet two essential criteria: (1) it must be widely used in at least two or more WHO Member States, and (2) there must be sufficient data and documentation for evaluation.[19]

WHO Monographs on Selected Medicinal Plants provides detailed information across various domains, including pharmaceutical properties, pharmacology, toxicology, and clinical applications. These monographs offer comprehensive data on the three fundamental attributes of medicinal products: safety, efficacy (or clinical application), and quality control. In comparison, ISO standards for CMM primarily focus on quality and safety indicators. Quality requirements are the core component, including morphological features (appearance, color, dimension, fracture, taste, odor, etc.), tests (moisture, total ash, acid-insoluble ash), extractive, thin-layer chromatography (TLC) identification, contents of marker compounds, and safety requirements (heavy metals, pesticide residues, sulfur dioxide, aflatoxins, etc.).

As a global public health organization, WHO's aim in developing these documents is to guide clinical practice and provide comprehensive information. Therefore, its monographs include extensive literature reviews and detailed descriptions of therapeutic indications, pharmacological effects, precautions, and adverse reactions. The control limits for certain test items may be relatively broad to accommodate diverse clinical practices and contexts. In contrast, ISO, as a specialized international standardization body, focuses on facilitating international trade. Its standards emphasize product quality and safety. Given the variability in testing standards and limit values across national pharmacopeias, ISO/TC 249 prioritizes the development of standards for CMM with high relevance to international trade. The standards focus particularly on quality and safety control—such as testing for pesticide residues and heavy metals—to provide technical support for arbitration and dispute resolution in international trade.

6 Reflection and suggestions

6.1 Strengthening WHO's role in providing foundational public welfare standards

WHO, as the United Nations specialized agency for health, has outlined a TM strategy aimed at offering policy and technical guidance to its member states. This strategy advocates for the integration of evidence-based and safe TM into national health care systems, with a particular emphasis on assisting developing countries in achieving the goal of "Health for All".

In alignment with this mandate, WHO is well-positioned to develop foundational and guideline-based public welfare standards, which are characterized by a clear emphasis on collaboration rather than competition. These standards may include basic terminology and nomenclature, guidelines for the training and practice of TM practitioners, International Classification of Diseases (ICD) codes related to TM, and safety guidelines for the use of herbal medicines.

Such standards should primarily focus on the provision of essential knowledge to developing countries, the regulation of practitioner training and clinical practice, the protection of patient safety, and the establishment of disease classification and statistical systems. These efforts should avoid being entangled with commercial interests or creating competitive technical barriers.

Therefore, the development of international standards for TCM under the WHO framework should be government-led, with the active participation of research institutions and academic organizations. The focus should remain on the supply of foundational knowledge, aiming to establish public welfare-oriented and cooperative standards that support the safe use and cross-cultural exchange of TCM practices (Table 4).

6.2 Strengthening ISO's role in providing market-oriented technical standards

ISO is a non-governmental professional organization whose international standards directly impact international trade in goods and services. The primary stakeholders of ISO standards are enterprises and industry alliances. A key difference from WHO standards is their market-related "competitive" nature. Examples include commodity grades for CMM, technical specifications for acupuncture needles, and technical specifications for four-diagnostic devices. These standards are closely

Table 4 Classification framework for the development of international standards for TCM by WHO and ISO

Organization	Primary Purposes of Standardization	Type of Standard	Standardization Targets	Main Developers
WHO	Provision of knowledge related to clinical applications, cultural understanding, and basic education	Cooperative Standards	Basic terminology and nomenclature, International Classification of Diseases, practitioner training and practice guidelines, safety and quality of herbal medicines	Governments and authorized public agencies
ISO	Ensuring high quality and fair pricing in international trade	Competitive-Cooperative Standards (competition-oriented)	Grading and specifications of rare and high-value medicinal materials, TCM medical devices, innovative diagnostic and therapeutic devices	Enterprises, industry alliances, research institutions
	Provision of foundational norms for commercial trade	Competitive-Cooperative Standards (cooperation-oriented)	Terminology and information related to diagnostic equipment, classification and coding of CMM, traceability systems for herbal medicines, safety and quality of herbal products	Enterprises, industry alliances, research institutions

tied to the economic interests of different countries and represent the outcome of competition and compromise among various stakeholders.

Furthermore, ISO also develops and publishes standards with weaker "competitive" attributes, leaning more towards "cooperative" ones. Examples include coding systems for TCM, terminology for TCM diagnosis, and quality and safety standards for herbs and their preparations. While these standards may overlap to some extent with WHO's scope of work, their primary focus is on providing fundamental norms for international trade, rather than supplying knowledge related to clinical practice, culture, or basic education.

Consequently, international standards for TCM on the ISO platform are best suited for development led by technical teams primarily composed of industry alliances and research institutions. These standards should be oriented toward the international market, serve global trade, and satisfy the diverse and multi-level demands for standards in the international market. Particular priority should be given to products with high trade volume, high economic added value, and a significant impact on the commercial value of TCM.

6.3 Promoting dialogue and liaison mechanisms between WHO and ISO

First, establish a joint meeting mechanism between the two organizations. This mechanism should facilitate regular updates on work progress and future directions, and allow participation in key meetings related to strategic development planning. Second, clarify the respective priority areas for TM standardization work within the two organizations. This should aim to create a work pattern characterized by complementary strengths and differentiated development. For example, in the field of CMM, ISO could prioritize 100 widely used materials with high trade volume as well as significant safety and quality concerns, selecting standardization elements based on international trade requirements. WHO, on the other hand, compiles scientific evidence literature for widely used herbal medicines to guide clinical application. This approach can, to some extent, provide a beneficial complement to ISO's standards for CMM. Third, during the project initiation and evaluation phase for new standards, mandate a comprehensive review and comparison of all extant standards—both published and under development. This step is crucial for rigorously controlling the standard project approval process.

6.4 Emphasizing post-publication evaluation of standard quality and implementation effectiveness

Currently, the evaluation of quality and implementation effectiveness of international TCM standards remains in its nascent stage. The successful implementation of these standards requires broad participation from governments and all relevant stakeholders. Their application should be integrated with technology promotion, market access, qualification certification, and industry regulation, thereby establishing an implementation mechanism in which standards and conformity assessment systems are mutually supportive.

Relevant professional institutions should conduct quality and implementation evaluations of standards that have been published by either ISO or WHO for over one year. Standards that perform poorly in these evaluations should be revised or withdrawn during their scheduled review cycles. Evaluating the quality and effectiveness of standards will facilitate assessment of their normative rigor, applicability, advancement, harmonization, and interoperability. This, in turn, will provide valuable guidance for the future development of international standards for TCM.

7 Conclusion

The international standardization of TCM represents a critical step toward its integration into global health systems and its acceptance as a credible and effective health care modality. WHO and ISO serve as pivotal actors in this endeavor, each bringing distinct yet complementary strengths to the process. WHO's emphasis on policy-driven, public welfare-oriented standards ensures that TCM aligns with global health objectives, such as universal health coverage and enhanced patient

safety. Meanwhile, ISO's focus on technical, market-oriented standards facilitates TCM's entry into international trade, promoting quality control and innovation across the industry chain. However, the overlaps in their scope—particularly in terminology and materia medica—pose the risk of inconsistency, which could undermine the global credibility and efficacy of TCM standards.

Addressing these challenges requires a robust framework for coordination between the WHO and ISO. By leveraging WHO's expertise in policy guidance and ISO's proficiency in technical specifications, a harmonized approach can be developed to streamline regulatory process and ensure global coherence. Such collaboration would not only enhance the safety, efficacy, and accessibility of TCM but also strengthen its role in global health governance. Furthermore, regular evaluation of published standards, coupled with stakeholder engagement, will ensure their ongoing relevance and adaptability to evolving global health needs. Ultimately, a unified WHO-ISO collaboration strategy will enable TCM to make positive contributions to global health equity, economic growth, and sustainable development.

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Ethical approval

This study does not contain any studies with human or animal subjects performed by any of the authors.

Author contributions

HUANG Yiran was responsible for drafting and revising the manuscript. ZHU Gerui assisted in data analysis. LI Jing participated in the design of the study.

Declaration of generative AI and AI-assisted technologies in the writing process

The authors declare that no generative AI or AI-assisted technologies were used during the preparation of this work.

Conflicts of interest

The authors declare no financial or other conflicts of interest.

References

[1] Siddiqi J. *World Health and World Politics: The World Health Organization and the UN System*. Columbia: University of South Carolina Press; 1995.
[2] Brown TM, Cueto M, Fee E. The World Health Organization and the transition from "international" to "global" public health. *American Journal of Public Health*. 2006;96(1):62–72.
[3] Lee K, Kelley L. The World Health Organization (WHO). In: Weiss TG, Wilkinson R, eds. *Global Health Institutions*. London: Routledge; 2008.
[4] Akerele O. WHO's traditional medicine programme: progress and perspectives. *WHO Chronicle*. 1984;38(2):76–81.
[5] Choi SH. WHO traditional medicine strategy and activities "Standardization with Evidence-based Approaches". *Journal of Acupuncture and Meridian Studies*. 2008;1(2):153–154.
[6] Li ZG. Issues on international standardization of traditional Chinese medical terminologies: from WHO/ICD-11 to ISO/TC249 (中医术语国际标准化的若干问题探讨:从WHO/ICD-11到ISO/TC249). Journal of Integrative Medicine. 2010;8(10):989–996.
[7] World Health Organization. WHA22.54 Establishment of Pharmaceutical Production in Developing Countries. 1969. Available from: https://www.who.int/medicines/areas/traditional/wha2254.pdf?ua=1. [Accessed on December 31 2020].
[8] World Health Organization. WHA29.72 Health Manpower Development. 1976. Available from: https://www.who.int/medicines/areas/traditional/wha2972.pdf. [Accessed on December 31 2020].
[9] World Health Organization. WHA30.49 Promotion and Development of Training and Research in Traditional Medicine. 1977. Available from: https://www.who.int/medicines/areas/traditional/wha3049.pdf?ua=1. [Accessed on December 31 2020].
[10] World Health Organization. Declaration of Alma-Ata. 1978. Available from: https://cdn.who.int/media/docs/default-source/documents/almaata-declaration-en.pdf?sfvrsn=7b3c2167_2. [Accessed on December 31 2020].
[11] World Health Organization. WHA40.33 Traditional Medicine. 1987. Available from: https://www.who.int/medicines/areas/traditional/wha4033.pdf?ua=1. [Accessed on December 31 2020].
[12] World Health Organization. WHA41.19 Traditional Medicine and Medicinal Plants. 1988. Available from: https://www.who.int/medicines/areas/traditional/wha4119.pdf. [Accessed on December 31 2020].
[13] Fei F. Study on the functions of WHO collaborating centers under the influence of WHO Traditional Medicine Strategy (WHO传统医学战略影响下其合作中心职能研究). *Journal of Nanjing University of Traditional Chinese Medicine (Social Science Edition)*. 2014;15(4):256–259. Chinese.
[14] World Health Organization. WHO Establishes the Global Centre for Traditional Medicine in India. Available from: https://www.who.int/news/item/25-03-2022-who-establishes-the-global-centre-for-traditional-medicine-in-india. [Accessed on April 26 2022].
[15] World Health Organization. Publications. 2022. Available from: https://www.who.int/westernpacific/publications/i?publishingoffices=8fbbfc75-7625-469f-b844-494c5d930e85. [Accessed on May 15 2022].
[16] World Health Organization. Publications/overview. 2022. Available from: https://www.who.int/publications/i?healthtopics=7b989a66-ebf4-4d1a-9bde-59f12b3d3590&publishingoffices=&publishingoffices-hidden=true®ionscountries-hidden=true. [Accessed on May 15 2022].
[17] International Organization for Standardization. ISO Strategy 2030. 2020. Available from: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100364.pdf. [Accessed on January 30 2022].
[18] International Organization for Standardization. ISO Annual Report 2019. 2019. Available from: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100385.pdf. [Accessed on June 25, 2021].
[19] Zhang XQ, Xiong Y, Huang QQ, et al. Analysis of *WHO Monographs on Selected Medicinal Plants* (WHO植物药专论解析). *Chinese Traditional Patent Medicine*. 2019;41(9):2192–2196. Chinese.

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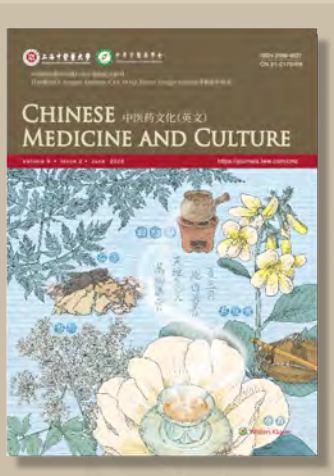
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融通古今，放眼世界

——走进《中医药文化（英文）》

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《中医药文化（英文）》（*Chinese Medicine and Culture*）是上海市教育委员会主管，上海中医药大学、中华中医药学会联合主办的全英文中医药人文领域学术期刊，旨在推进中医药自然科学与人文科学领域研究者的交流与对话，为中医药跨学科研究搭建交流平台，全面反映中医药在医学、文化交流、历史传承等领域的高水平和最新研究成果。2019年成功入选“中国科技期刊卓越行动计划高起点新刊”，2020年实现国内正式创刊，为中医药学的国际学术交流搭建了新平台，逐渐成为引领中医药文化走向世界的一张国际名片。目前被ESCI，Scopus，DOAJ，CAS，Ulrich，Ovid，EBSCO Publishing's Electronic Databases，Ex Libris–Primo Central，Google Scholar，Hinari，Infotrieve，Netherlands ISSN Centre，ProQuest，TDNet，Baidu Scholar，CNKI (China National Knowledge Infrastructure)，Wanfang Data，CSTJ等国内外知名数据库收录。入选“2021年中国卓越科技期刊十大最美封面”，2021—2025年连续入选《科技期刊世界影响力指数（WJCI）报告》，2024年入选第二届中医药文化国际传播案例征集活动“十大典型案例”，荣获2024年度上海市“银鸽奖”国际传播产品（出版）最佳奖，入选2025年度上海市“中华文化国际传播”项目，期刊影响力显著提升。

Chinese Medicine and Culture (《中医药文化（英文）》) is a full-English academic journal in the field of traditional Chinese medicine (TCM) humanities. It is co-sponsored by Shanghai University of Traditional Chinese Medicine and China Association of Chinese Medicine, and is supervised by Shanghai Municipal Education Commission. It aims to promote exchanges and dialogue between researchers in the fields of natural sciences and humanities of TCM, build an exchange platform for interdisciplinary research of TCM, and comprehensively reflect the high-level and latest research of TCM in the fields of medicine, cultural exchanges, historical inheritance, etc. In 2019, it was successfully selected as a new high-level journal of the “Excellence Action Plan for Chinese Sci-tech Journals”, and in 2020, it was officially launched in China, building a new platform for international academic exchanges of Chinese medicine, and gradually becoming an international calling card leading Chinese medicine culture to the world. It has been indexed in ESCI, Scopus, DOAJ, CAS, Ulrich, Ovid, EBSCO Publishing's Electronic Databases, Ex Libris-Primo Central, Google Scholar, Hinari, Infotrieve, Netherlands ISSN Centre, ProQuest, TDNet, Baidu Scholar, CNKI (China National Knowledge Infrastructure), Wanfang Data, CSTJ and other well-known databases at home and abroad. Recognized among the “Ten Most Beautiful Covers of China’s Outstanding Science and Technology Journals” in 2021, *Chinese Medicine and Culture* has been continuously included in the World Journal Clout Index (WJCI) Report from 2021 to 2025. In 2024, it was selected as one of the “Top Ten Exemplary Cases” in the Second International Communication of Traditional Chinese Medicine Culture Case Collection and received the Best Award for International Communication Products (Publishing) at the 2024 Shanghai “Silver Pigeon Awards”. In 2025, the journal was selected for the Shanghai International Communication of Chinese Culture Programme. These recognitions reflect the journal’s growing influence and expanding international reach.

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Traditional Chinese Medicine International Standardization Team Led by Professor Shen Yuandong

Professor Shen Yuandong（沈远东）serves as the Chair of ISO/TC 249 (Traditional medicine), Honorary Dean of the Shanghai Academy of International Standardization for Traditional Chinese Medicine at Shanghai University of Traditional Chinese Medicine (SHUTCM), a tenured professor at Shuguang Hospital, and Advisor to the Internationalization Expert Advisory Committee of the National Administration of Traditional Chinese Medicine. He is a recipient of the 8th Cheung On Tak International Award for Outstanding Contribution to Chinese Medicine.



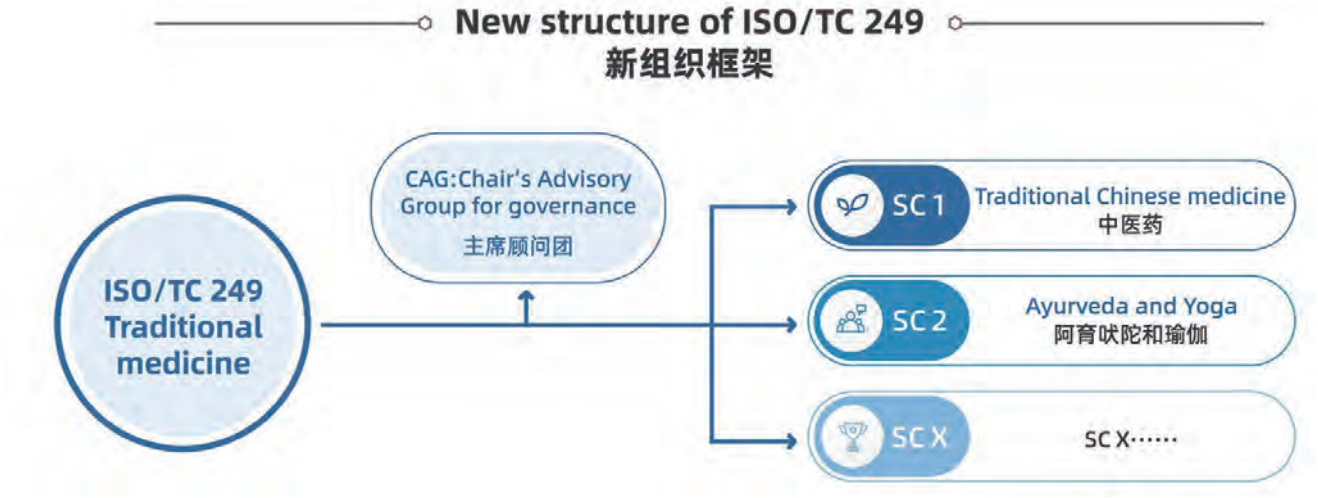
Under Professor Shen's leadership, the team currently hosts the Secretariat of ISO/TC 249 Traditional Medicine, the Secretariat of ISO/TC 249/SC 1 Traditional Chinese Medicine, Center for Research and Service Evaluation on the International Classification of Diseases for Traditional Medicine, and other research groups within the Shanghai Academy of International Standardization for Traditional Chinese Medicine, which is supported by the Shanghai Municipal Government. Over the past 16 years, the team has been dedicated to advancing the international standardization of traditional Chinese medicine (TCM). The team has managed the development and publication of 137 ISO international standards for TCM, with an additional 85 currently under development. The team also made a pivotal contribution to the WHO ICD-11 project, successfully integrating a traditional medicine chapter based on TCM into the classification system.

Under Professor Shen's guidance, the team initiated the Shanghai Forum on World Traditional Medicine and established the International Health and Wellness Alliance for Standardization. Its work has been recognized by the ISO Secretary-General as a model for all ISO technical committees, and its achievements have been selected three times among China's Top Ten News Stories of the Year in TCM development.

Professor Shen has presided over numerous research projects on TCM international standardization. He is the lead author or editor of several influential publications, including *Theory and Practice of ISO International Standards for Traditional Chinese Medicine* (a key national publication during China's 13th Five-Year Plan period) and *History, Present, and Prospect*

of World Traditional Medicine (available in both English and Chinese editions). As Chair of ISO/TC 249, he has been invited to deliver keynote speeches at many high-level international forums, such as the World Traditional Medicine Conference, the Euro-Asia Economic Forum, and the BRICS Health Ministers' Meeting. Under his leadership, ISO/TC 249 has grown from 19 to 45 member bodies and established liaison with 10 international organizations.

In 2025, in response to the global development needs of traditional medicine and in line with the ISO development strategy (Resolution ISO/TMB 86/2024), the function of ISO/TC 249 was further enhanced, and its title and scope of ISO/TC 249 were expanded to cover all traditional medicine. Two subcommittees were established: SC 1 (Traditional Chinese medicine), with its secretariat in China, and SC 2 (Ayurveda and Yoga), with its secretariat in India.



Guided by the vision of "Making lives easier, safer, and better", the team continues to promote the modernization and globalization of traditional medicine through standardization. Committed to building a high-level international cooperation platform, the team strives to contribute Chinese wisdom to global health governance.

