

The Present State of Chinese Traditional Chinese Medicine Standardization

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1. Introduction

Traditional Chinese Medicine (TCM) has a long history of use in the treatment and prevention of illness [1]. The natural treatment of traditional Chinese medicine (TCM) is gaining popularity across the globe due to its safety, efficacy, and widespread usage [2]. Traditional Chinese Medicine (TCM) has expanded into a worldwide industry and has reached over a hundred nations, according to the World Health Organization's Traditional Medicine Strategy: 2014–2023. [3]. Unfortunately, the growth of TCM is hindered and the progress of globalization and modernization of TCM is greatly affected by the absence of necessary standards [4, 5]. China has a distinct TCM theoretical framework and efficient treatment procedures since it is the birthplace and primary user of TCM. While there have been tremendous strides in standardizing TCM in recent years—thanks to the ongoing evolution of both ideas and methods—certain challenges persist [6]. With the exception of acupuncture, moxibustion, and traditional Chinese medicines, this article mostly summarizes and analyzes studies on the present state of TCM standardization [7].

2. Current Status of Standardization of Traditional Chinese Medicine in China

The Chinese Government Places a High Priority on TCM Standardization (2.1). Following the principle of "uni-fication, simplification, coordination, and optimization" and making full use of it, traditional Chinese medicine (TCM) standardization involves creating and implementing rules for all aspects of TCM, including medical care, research, education, industry, culture, and management. The goals are to advance TCM in academia and spread its achievements, standardize its management, ensure its quality and safety, encourage its modernization and international communication for the benefit of society and the economy, and guide and support a range of initiatives aimed at the comprehensive development of TCM [8]. As part of its modernization, TCM must be standardized. An item mentioning "promoting the standardization of TCM" was added in the 2009 Opinions of the State Council on Supporting and supporting the Development of Traditional Chinese Medicine from the State Council of China.

"The construction for the standardization of TCM should be strengthened," emphasised Comrade Li Keqiang, a member of the Central Politburo Standing Committee of the Communist Party of China and Vice Premier of the State Council, during the 2011 National Work Conference on Traditional Chinese Medicine. "Promotion of standardization and normalization of TCM" is listed as an essential priority in the Twelfth Five-Year Planning Outline for National Economic and Social Development of the People's Republic of China by the National Development and Reform Commission. In the 2006–2020 Traditional Chinese Medicine Innovation Development Planning Outline, spearheaded by the Ministry of Science and Technology, TCM standardization was identified as a priority issue with the aim of becoming the worldwide standard for traditional medicine. Supporting traditional Chinese medicine (TCM) as a promising area for global innovation, the People's Republic of China's Standardization Administration has included almost hundreds of TCM standard items in its strategy for service standard development. Chinese Traditional Chinese Medicine's Standard System Is Mostly Defined in the Country. The TCM standard system was mostly formed during the "Eleventh Five-Year Plan" era. Standards for management, fundamental operations, technical operations, and working conditions make up the system [9], with an emphasis on the development and updating of the former two types of standards. Chinese Traditional Chinese Medicine (TCM) Basic Standards: Where We Are Now 2.2. Basic theoretical terminology, terminology of specific TCM subjects and their classification and codes, and other standards to achieve TCM terminology standardization were the initial foci of the formulation and revision of basic and general standards of Traditional Chinese Medicine. Five national standards of TCM have been issued in succession, namely, Classification and Codes of Diseases and ZHENG of Traditional Chinese Medicine (GB/T15657-1995) as China's first national standard for classification of TCM diseases stipulates the classification principles and coding methods of diseases and ZHENG of TCM and has the corresponding computer software, promoting the standardization of TCM clinical diagnosis; Clinic Terminology of Traditional Chinese Medical Diagnosis and Treatment-Diseases (GB/T 16751.1-1997), Clinic Terminology of Traditional Chinese Medical Diagnosis and Treatment-Syndromes (GB/T 16751.2-1997), and Clinic Terminology of Traditional Chinese Medical Diagnosis and Treatment-Therapeutic Methods (GB/T 16751.3-1997) specify the basic terminology of Chinese medicine (TCM), the Basic Theory Terminology of Traditional Chinese Medicine (GB/T 20348-2006) defines key terms used in TCM theories including Yin and Yang, the five elements, and main and collateral channels. This standard is vital for various aspects of TCM, including but not limited to: teaching, research, healthcare, management, and international exchange [10].

Where Things Stand with the Chinese TCM Technical Standards: A Status Report 2.3. Applying TCM in a clinical setting requires both medical knowledge and the theoretical framework of TCM. Academic societies within TCM have released more than 50 technical specifications between the years of 1980 and 2002, and TCM authorities have released

nearly 70 technical standards, including the Clinical Guidelines for Emergency Treatment of Internal Medicine of Traditional Chinese Medicine (YY228) and Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in TCM (ZY/T001.1-94) [6]. We have made significant progress in standardizing the TCM industry in China with the first industry standard, Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in TCM. This standard covers nine clinical departments and forty-six diseases and syndromes, including internal medicine, surgery, gynecology, and pediatrics.

After 2002, the formulation of industry technical standards was further strengthened, prevention and treatment of common diseases and major diseases were mainly focused on and diagnostic and treatment guidelines for clinical syndromes in TCM, and operation regulation of TCM clinic technology and others were formulated and revised as the priority. Completed standards by the State Administration of Traditional Chinese Medicine include 18 standards for the series of *Routine and Technical Operation Regulation of Nursing Care in TCM* (ZYYXH/T 1.1-2006~ZYYXH/T 1.18-2006) for nursing care of clinical departments such as internal medicine, surgery, gynecology, and pediatrics, 19 standards for the series of *Technical Specification of Health Preservation and Prevention of Chinese Medicine* (ZYYXH/T 158-2010~ZYYXH/T 176-2010) with massage on the spine, the whole body, pediatrics and moxibustion, medicinal liquor, acupoint sticking, cupping, and so on to guide and standardize technical operations of TCM health care of care physicians and technicians and make technical operations more standardized and more safe, 1 standard of *Classification and Determination of Constitution in TCM* (ZYYXH/T 157-2009) as the important reference basis for the clinical practice, to determine the specification and quality evaluation, 10 standards for the series of *Standard Specifications for Study and Compilation of Traditional Chinese Medicine Classics* (ZYYXH/T 362-2012~ZYYXH/T 371-2012) for proofreading TCM classics, 1 standard of *Clinical Guidelines of Chinese Medicine on Sub-Health* (ZYYXH/T 2-2006) for clarifying the understanding of subhealth of TCM, common syndromes, and intervention principles of TCM on subhealth to gain the scientific, standardized diagnosis and intervention on subhealth and provide evidences for the feasible health management plan and intervention measures on subhealth [11], 15 standards for the series of *Guidelines for TCM Diabetes Prevention and Treatment* (ZYYXH/T 3.1-2007~ZYYXH/T 3.15-2007) for the course, complications, and merged diseases of diabetes to have detailed and normative prevention and treatment strategy of TCM, achieving the standardized, scientific prevention and treatment of TCM of diabetes [12], 21 standards for the series of *Guideline for Diagnosis and Treatment of Tumor in TCM* (ZYYXH/T 136-2008~ZYYXH/T 156-2008) for the standard of differentiation of syndromes and signs for classification and diagnosis and treatment of TCM of

common malignant tumor (according to preliminary clinical statistics, 70–80% of cancer patients accepted the different levels of TCM treatments; Chinese medicine tumor has become an important part of modern Chinese medicine clinical disciplines; this “guideline” can improve the overall level of TCM prevention and treatment of malignant tumor [13]), and 386 standards for the series of *Guideline for Diagnosis and Treatment of Common Diseases in TCM*. In total, 397 diseases of 11 clinical majors were involved such as internal medicine, surgery, gynecology, pediatrics, ophthalmology, ENT, anorectal section, dermatology, and orthopedics, and the most common TCM clinical diseases were covered [9]. Three systems, namely, technical specification for clinical diagnosis and treatment of common TCM diseases, health care technology, and nursing care, have been formulated and the criteria for clinical diagnosis and treatment in TCM are further enriched.

2.1. Current Status of the Formulation and Revision of TCM Management Standards in China. TCM management standards are formulated to regulate the TCM industry and control matters required for uniform coordination in the management practice.

The State Administration of Traditional Chinese Medicine has combined with relevant departments to issue many management standards related to construction of traditional Chinese hospitals, construction of major TCM laboratories, classification of TCM research laboratories, TCM education management, and others [14] and covered TCM treatment, scientific research, education, and other fields, thereby laying foundation for the construction of TCM standard system.

In summary, 5 national TCM standards and over 480 TCM industrial standards have been formulated and issued for implementation and the TCM standard system is primarily established, which ensures the standardization of TCM development smoothly, and improves the standard for formulation and revision work. See the publication situations of current TCM standards in Table 1.

2.2. TCM Standardization Support System Has Been Basically Established. The support system is to promote and guarantee TCM standards, including management system, operation system, technical platform, professional team, implementation and guarantee, inspection and evaluation, and information service.

2.3. TCM Standardization Management System and Operation Mechanism Have Been Primarily Established. TCM Standardization Management Department of China Administration of Traditional Medicine is responsible for centralized management and coordinated planning of TCM standardization. The standardization office is specially built as the routine administrative office for TCM standardization to fully coordinate the standardization of the industry.

Several TCM standardization technology research centers have been established across the country to strengthen the organizational management on formulation, implementation, and supervision of TCM standards [15]. In September 2010, China Administration of Traditional Medicine

confirmed 42 base (pilot) construction units for TCM standardization research and promotion so as to provide a strong guarantee for implementation and promotion of TCM standards. China Administration of Traditional Medicine has released *TCM Standard Formulation Procedure* and *Interim Measures of State Administration of Traditional Medicine on Management of TCM Standardization Project*, in which the formulation and management procedure of TCM standards have been regulated [16].

2.4. TCM Standardization Technology Team Has Been Basically Formed. Talents are essential to promote the TCM standardization. With the constant establishment of TCM standardization research institutes and academic communities, the TCM standardization talent team is gradually expanding from scratch.

In 2006, the first National TCM Standardization Training Class was held in Wuhan and attracted over 120 TCM professional participants across the country in the technical training; in 2008, China Administration of Traditional Medicine established the pilot construction unit of “Acupuncture and Moxibustion Research Center of China Administration of Traditional Medicine” in Tianjin University of Traditional Chinese Medicine and “TCM Technical Training and Research Center of China Administration of Traditional Medicine in Hubei University of Traditional Chinese Medicine,” thereby providing important intelligent support and sufficient guarantee for implementation of TCM standardization development plan; and by 2009, over 800 researchers and experts participated in standardization projects, initially forming the TCM standardization team of a certain size [17].

2.5. Actively Participate in TCM International Standardization. In 2003, the World Federation of Chinese Medicine Societies was established and headquartered in Beijing. It enhanced the formulation, publicity, and promotion of TCM international standards. In 2007, WHO issued *International Standard Terminologies on Traditional Medicine*, which was prepared in corroboration by personnel from China, Korea, Japan, and other countries.

In September 2009, International Organization for Standardization (ISO) established Committee of TCM Standardization Technology with the code of ISO/TC249 (tentatively) [18]. In ISO/TC249, a total of 44 standard projects have been put forward since 2011, including 29 projects by China [19].

Upon the revision of *Codes of International Classification of Diseases (ICD-11)*, WHO has decided to include the traditional medicine, and China has actively participated in the preparation of traditional medicine. All of the works lay an important milestone for the international standardization of TCM and also are the important opportunities for China to regain the initiative in the international standardization.

3. Problems and Some Countermeasures of the Construction of TCM Standardization in China

Since 1980s, the constant exploration on the standardization of Traditional Chinese Medicine (TCM) has made certain

TABLE 1: The existing standards of Traditional Chinese Medicine in China (a total of 486).

	Serial number	Standard number	Standard title	Issuance date	Execution date	Release unit
National standard (a total of 5)	1	GB/T15657-1995	<i>Classification and Codes of Diseases and ZHENG of Traditional Chinese Medicine Clinic Terminology of Traditional Chinese</i>	25 July 1995	1 January 1996	AQSIQ; SAC
	2	GB/T 16751.1-1997	<i>Medical Diagnosis and Treatment-Diseases Clinic Terminology of Traditional Chinese</i>	4 March 1997	1 October 1997	AQSIQ; SAC
	3	GB/T 16751.2-1997	<i>Medical Diagnosis and Treatment-Syndromes Clinic Terminology of Traditional Chinese</i>	4 March 1997	1 October 1997	Chinese technical supervision bureau
	4	GB/T 16751.3-1997	<i>Medical Diagnosis and Treatment-Therapeutic Methods Clinic Terminology of Traditional Chinese</i>	4 March 1997	1 October 1997	Chinese technical supervision bureau
	5	GB/T 20348-2006	<i>Basic Theory Terminology of Traditional Chinese Medicine</i>	25 May 2006	1 October 2006	Chinese technical supervision bureau
Industry standard (a total of 481)	6	YY228	<i>Clinical Guidelines for Emergency Treatment of Internal Medicine of Traditional Chinese Medicine</i>	1 March 1994	1 March 1994	SATCM
	7	ZY/T001.1-94	<i>Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in TCM</i>	11 October 1994	1 January 1995	SATCM
	8	ZYYXH/T 2-2006	<i>Clinical Guidelines of Chinese Medicine on Sub-Health</i>	10 December 2006	10 December 2006	CACM
	9	ZYYXH/T1.1~1.18-2006	<i>Routine and Technical Operation Regulation of Nursing Care in TCM</i>	25 December 2006	25 December 2006	CACM
	10	ZYYXH/T3.1~3.15-2007	<i>Guideline for TCM Diabetes Prevention and Treatment</i>	28 July 2007	28 July 2007	CACM
	11	ZYYXH/T4~49-2008	<i>Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine Symptoms in Chinese Medicine</i>	22 July 2008	22 July 2008	CACM
	12	ZYYXH/T50~135-2008	<i>Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine Diseases of Modern Medicine</i>	22 July 2008	22 July 2008	CACM
	13	ZYYXH/T136~156-2008	<i>Guidelines for Diagnosis and Treatment of Tumor in Traditional Chinese Medicine</i>	30 November 2008	1 December 2008	CACM

TABLE 1: Continued.

Serial number	Standard number	Standard title	Issuance date	Execution date	Release unit
14	ZYYXH/T157-2009	<i>Classification and Determination of Constitution in TCM</i>	26 March 2009	9 April 2009	CACM
15	ZYYXHT158~176-2010	<i>Technical Specification of Health Preservation and Prevention of Chinese Medicine</i>	23 December 2010	11 January 2011	CACM
16	ZYYXH/T177~202-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Surgery in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
17	ZYYXH/T203~246-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Gynecology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
18	ZYYXH/T247~286-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Pediatric in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
19	ZYYXH/T287~306-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Otolaryngology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
20	ZYYXH/T307~321-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Otolaryngology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
21	ZYYXH/T322~341-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Coloproctology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
22	ZYYXH/T342~361-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Dermatology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
23	ZYYXH/T362~371-2012	<i>Standard Specification for Study and Compilation of Traditional Chinese Medicine Classics</i>	1 July 2012	1 August 2012	CACM
24	ZYYXH/T372~415-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Orthopedics and Traumatology in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM
25	ZYYXH/T417~441-2012	<i>Guidelines for Diagnosis and Treatment of Common Diseases of Spinal Orthopedics in Traditional Chinese Medicine</i>	1 July 2012	1 August 2012	CACM

AQSIQ, General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China; SAC, Standardization Administration of the People's Republic of China; SATCM, State Administration of Traditional Chinese Medicine of the People's Republic of China; CACM, China Association of Chinese Medicine.

achievements. However, on account of its long-term, arduous, and complex nature, the current TCM standardization still falls behind with the developmental needs of TCM.

It is necessary to reinforce awareness of TCM standardization (3.1). Many TCM practitioners still have a lack of awareness and different ideas about TCM standardization, which makes them feel unprepared, unmotivated, and responsible for the lack of progress in this area [20]. This is because TCM standardization is still in its early stages and has not yet been adequately publicized or implemented. To prepare for the eventual adoption of TCM standardization, it is imperative that we raise awareness among TCM practitioners via increased education and publicity about the need of synchronization between clinical practice and classroom instruction [21, 22].

There is a need to improve the TCM standardization system (3.2). Currently, published standards only address the basics of TCM, focusing on its basis and functioning rather than delving into all of its aspects. It is critically important to update and reinforce standards in health care, research, education, information, particularly management, and other areas of TCM in light of the international recognition that has been bestowed upon the incorporation of seven TCM clinical trials into clinical trials for eleven different types of gynecology diseases [23]. As a result, the whole TCM standardized system will be enriched and improved via the creation of balanced quantity, quality, structure, and benefit [24].

3.3.1 The Methods for TCM Standardization Requirements Must Be Fulfilled. There is a paucity of evidence-based medicine and clinical evidence that supports many of the current standardizations, which makes it difficult to use them in clinical practice [25]. Additionally, the "aging" of TCM standardization is caused by a flawed revision mechanism [20]. Clinic Terms of Traditional Chinese Medicine, for example, has remained unchanged since its release in 1997 and is currently the only national standard in the field. This means that TCM standards aren't up-to-date enough to match the current academic level and managerial needs of TCM, which renders them irrelevant and slows down their adoption and use [26].

In this case, TCM standardization may benefit from enhanced methodological study into the standard revision in order to find a redaction approach that works for TCM's unique characteristics.

3.4. Standardize Traditional Chinese Medicine's Support System. There has been tremendous increase in the development of TCM standards, but there has been very little progress in the associated support system, which is still in its early stages and needs more refinement. There is a lack of qualified individuals working in traditional Chinese medicine (TCM), and there is a lack of completion in the TCM standardized system's administration, implementation, and oversight [16]. Surveys and feedbacks on the system's applicability are also lacking. Traditional Chinese Medicine's State Administration released

a more thorough and organized development of the support system for TCM standardization is guaranteed to occur under the supervision of the Guidance on Strengthening the Standardization of Traditional Chinese Medicine.

3.5. Promptly Support the Global Standardization of Traditional Chinese Medicine (TCM). At the current time, there are very few worldwide TCM standards, and the majority of them are domestic. Furthermore, China should make the most of its position as a permanent member of the international standardization organization and its involvement in the secretariat of the TCM technical committee in order to actively participate in the establishment of development strategies, regulations, and projects related to TCM standardization. It is also important to take advantage of China's dominance in TCM international standardization to encourage the transition of TCM standards to international ones [27].

There is a steady march toward TCM standardization, which includes new developments in the field and advancements in academia. It is important to promote standardization under a comprehensive plan and top design and to continue with staged and planned measures because of the basic, strategic, and worldwide implications it will have on the development of TCM [28]. We are hopeful that the newly released Medium- and Long-Term Development Plan on the Standardization of Traditional Chinese Medicine (2011-2020) would lead to a more methodical and scientific advancement of TCM standardization for the benefit of people's health.

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