Proceedings of ICMMGH 2026 Symposium: Cell and Molecular Biology: Understanding Immune Cell Functions
DOI: 10.54254/2753-8818/2026.PJ30731

Analysis on the Current Situation of Standardization of Traditional Chinese Medicine Planting and Preparation Technology

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Abstract. The standardization of Traditional Chinese Medicine (TCM) is pivotal for its internationalization and modernization. This paper focuses on the planting of Chinese medicinal materials and the preparation technologies of TCM, systematically reviewing the current status and challenges of their standardization development. It elaborates on the progress in planting standardization from the aspects of Good Agricultural Practices (GAP), germplasm resources, and cultivation techniques. The practices and explorations in preparation technology standardization are analyzed from the perspectives of decoction pieces processing, preparation production, quality control, and the medication instruction system. Based on this analysis, the paper reveals core existing issues, including insufficient coordination within the standard system, weak quality control at the source, unclear quality transmission law during preparation, and limited discourse power in international standards. Targeted solutions are proposed. Finally, the paper looks to the future, emphasizing the need to take technological innovation as the core driving force to construct a more scientific, rigorous, open, and internationally compatible TCM standard system, providing a practical path to ensure the safety, efficacy, and quality consistency of TCM products and enhance their core competitiveness.

Keywords: TCM, standardization, standards system

1. Introduction

During the COVID-19 pandemic in 2020, the integrated treatment with Chinese and Western medicine played a significant role in China. How to effectively promote the standardization and modernization of Traditional Chinese Medicine (TCM) and facilitate its international development has become a hot topic and an urgent issue [1]. Although research on China's TCM standard system started relatively late, it has developed rapidly in recent years, leveraging profound cultural heritage, growing market demand, and strong government support [2]. However, the complexity and particularity of TCM pose natural barriers to its standardization process. Firstly, complex composition: The multi-component, multi-target characteristics of TCM make it exceptionally difficult to clarify its pharmacodynamic material basis and quality markers. Secondly, unique processes: Traditional processing and preparation techniques contain profound empirical wisdom,

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but key parameters such as "heating intensity" and "degree" are difficult to quantify. Thirdly, strong agricultural attributes: As agricultural products, the quality of TCM is influenced by various factors such as origin, climate, and planting techniques, making it difficult to guarantee consistency at the source. Precisely for these reasons, the standardization of TCM planting and preparation technology is both a priority and a challenge. This article will analyze the current status of TCM standardization, focusing on these two aspects, identify existing problems, and provide references for the future construction of the TCM standard system.

2. Standardization of TCM

2.1. Standardization of Chinese medicinal materials planting

2.1.1. Policies, regulations, and GAP promotion

China began trial implementation of the Good Agricultural Practices for Chinese Medicinal Materials (GAP) in 2002, aiming to regulate the planting, cultivation, harvesting, and primary processing of Chinese medicinal materials [3]. In 2022, an announcement was issued to formally implement GAP, which mandates detailed management of the entire process, including production base site selection, germplasm origin, cultivation management, pesticide and fertilizer use, harvesting and processing, packaging, storage, and transportation. As a demonstration area for standardized planting of Chinese medicinal materials, Longxi County in Gansu Province implements standardized planting according to GAP, specifically manifested in the use of mechanical tools for loosening soil and digging, selection of high-quality seedlings, and rational fertilization based on planting area, effectively improving the uniformity and stability of herb quality [4].

2.1.2. Germplasm resources and elite variety breeding

The standardization of TCM germplasm resources is the foundation for the research and development of TCM [5]. Environmental degradation, reduced biodiversity, over-exploitation, and misuse of resources pose severe threats to many medicinal materials, making the protection of TCM germplasm resources urgent [6]. To this end, the state has initiated the construction of germplasm resource banks and elite seed breeding bases for Chinese medicinal materials. DNA barcoding technology can provide relatively accurate basic data for the classification and evolution of medicinal plants based on their unique genetic background and gene pool, and it also promotes the breeding and germplasm improvement of medicinal plant varieties [7]. For example, addressing the confusion in Bupleurum cultivation species that are difficult to distinguish using traditional methods, Zhao Qing et al. took Bupleurum chinense DC. as the research object and established a species identification method for Bupleurum chinense seeds based on the internal transcribed spacer (ITS) sequence of ribosomal DNA, ensuring the accuracy and reliability of the seed species, providing technical support for the standardized management of Bupleurum chinense seeds in market circulation, and safeguarding the clinical medication safety of Radix Bupleuri [8]. In terms of elite variety breeding, selecting and promoting new varieties of Chinese medicinal materials that are high-quality, high-yield, and disease-resistant, such as "Jishen 1" ginseng and "Yunling 1" Poria, is a key step towards achieving planting standardization.

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2.1.3. Standardization of cultivation management techniques

The standardization of cultivation techniques is crucial for ensuring stable yield and quality of medicinal materials. Currently, China has developed detailed Standard Operating Procedures (SOPs) for specific medicinal materials, covering land preparation, sowing, seedling raising, transplanting, fertilization (advocating the use of organic fertilizers, strictly controlling the ratio of nitrogen, phosphorus, potassium, and trace elements), irrigation (promoting water-saving irrigation techniques), green pest and disease control (prioritizing agricultural, physical, and biological control, scientifically and rationally using low-toxicity and low-residue pesticides), etc. The government has established 11 single-variety standardized planting demonstration gardens for medicinal materials like Bo White Peony, Bo Chrysanthemum, and Bo Pollen in Qiaocheng District, Bozhou City, Anhui Province. By strictly controlling product quality and establishing the entire quality management system including seed and seedling sources, input management, product testing, and base exit, a long-term mechanism for quality safety traceability has been achieved, helping to expand the scale of standardized planting of Chinese medicinal materials citywide [9].

2.2. Standardization of TCM preparation technology

2.2.1. Standardization of decoction pieces processing

The standardization of decoction piece processing aims to unify processing techniques, excipients, and quality control standards. The processing specifications for Chinese medicinal decoction pieces in the Chinese Pharmacopoeia (2020 Edition) clearly define the processing methods, finished product characteristics, identification, testing, and content determination for commonly used decoction pieces. Modern research is devoted to transforming traditional "empirical control" into "parameter control." Chelimuge from Beijing University of Chinese Medicine designed orthogonal experiments, used metabolomics and liquid chromatography-mass spectrometry to determine the chemical components of Aconitum kusnezoffii (Caowu), and used the content changes of total alkaloids and ester alkaloids as indicators to determine the optimal processing conditions for processed Aconitum kusnezoffii [10].

2.2.2. Standardization of Chinese medicine preparations

The standardization of Chinese medicine preparations (Chinese patent medicines) covers the entire process from prescription, extraction, concentration, and drying to final formulation. Currently, the Good Manufacturing Practice (GMP) from the modern pharmaceutical industry has been fully and mandatorily implemented in the production of Chinese medicine preparations, ensuring the cleanliness of the production environment, the stability of the process flow, and the reliability of data. While meeting enterprise GMP review requirements, Li Changwu, Zhou Xiaoyu, and others from the Intelligent Manufacturing Research Institute of Heilongjiang Academy of Sciences integrated automatic control technology, computer technology, and communication technology to design an intelligent production line management and control system for TCM production processes. This system achieves fully automatic and precise control, possesses a complete and reliable real-time production process database and relational database, and realizes the standardization, precision, and intellectualization of the TCM production line management and control system [11].

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2.2.3. Standardization of TCM quality control

The quality control model for TCM has evolved from single-indicator component content determination to a multi-dimensional comprehensive quality control system including simultaneous determination of multiple components, overall control by fingerprint/specific chromatogram, and bioassay.

Chinese medicinal materials contain various unique active ingredients, such as flavonoids, alkaloids, glycosides, anthraquinones, and phenolics, which provide important support for the study of TCM chemical components and play a significant role in disease prevention and treatment [12]. Papaya is rich in triterpene acids, which have a repairing effect on gastric mucosal damage. Li Zhirong et al. established an LC-MS/MS method to simultaneously determine the content of seven triterpene acid components, including rosmarinic acid, tormentic acid, and maslinic acid, in Chaenomeles speciosa, providing a reference for its quality control [13]. Sun Qian et al. established a fingerprint of Sonchus arvensis L. using HPLC-IT-TOF/MS technology, identifying 17 common peaks with good separation, reflecting the component information of Sonchus arvensis L. and assisting in the identification of the authenticity of the medicinal material [14].

Furthermore, researchers have attempted to introduce the "Quality by Design" (QbD) pharmaceutical management concept into the complex system of TCM. Applying the QbD concept to risk prevention and control in links such as extraction, separation and purification, drying, and formulation can clarify the drug quality indicators affected by each process, further determine the evaluation indicators for key processes, and ensure the stable transmission of quality from intermediates to finished products [15].

2.3. Standardization of the TCM medication instruction system

Although this aspect falls within the scope of clinical application, it is closely linked to preparation technology and relates to the final efficacy of standardized products. Its standardization includes prescription standardization (promoting the use of standard prescriptions from classical formulas and experienced senior TCM practitioners), dispensing standardization (use of electronic scales to ensure accurate measurement), decoction standardization (promoting automatic decoction machines and establishing unified decoction SOPs, including special handling like decocting first, adding later, and wrapped decoction), and medication guidance standardization (providing unified written medication instructions, including administration methods, contraindications, etc.). The "Chinese Herbal Decoction Medication Instruction Service System" put into use in 2018 at Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, was developed by a working group consisting of pharmacists and software engineers. By referencing relevant standards of clinical TCM service systems and selecting appropriate elements for the construction of informational data sources, it effectively solved the pain points and difficulties in the current drug dispensing and instruction process. In the first half of 2018 alone, it cumulatively served 1.34 million patients, with a patient satisfaction rate of 100% [16].

3. Existing problems and solutions

3.1. Incomplete standard system and insufficient implementation

Fragmentation among national, industry, and local standards, especially for decoction pieces, leads to regulatory challenges [17]. Many standards are non-mandatory and updated slowly.

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Solution: Strengthen top-level design led by the National Pharmacopoeia Commission to unify and integrate standards. Convert core safety and efficacy standards (e.g., residue limits, key technology parameters) into mandatory regulations with strengthened enforcement [2].

3.2. Weak source quality control and traceability

Despite GAP, decentralized farming dominates, leading to quality variability and traceability gaps [4].

Solution: Implement "extended inspection" and leverage digital technologies (e.g., QR codes, IoT sensors, GIS) to create a transparent, full-chain traceability system capturing data from planting to distribution [18].

3.3. Unclear quality transmission and weak efficacy link

The material transformation from herb to product is not fully understood, and many quality controls lack strong clinical correlation.

Solution: Deepen QbD application to map critical quality attributes. Employ integrative pharmacology (systems biology, metabolomics) to identify clinically relevant Quality Markers (Q-Markers) [19].

3.4. Obstacles to international integration

Differences in concepts and regulatory frameworks between TCM and international botanical drug standards hinder global acceptance.

Solution: Conduct high-quality clinical trials following international Good Clinical Practice (GCP) and employ modern science to elucidate TCM mechanisms, fostering international understanding.

4. Conclusion

The standardization of TCM planting and preparation technology is a grand and complex systematic engineering endeavor, serving as a critical nexus that bridges traditional wisdom with modern science and technology, and propels the high-quality development of the TCM industry. Through decades of unremitting efforts, China has laid a solid foundation in this field, establishing a core standard framework centered on GAP, GMP, and the Chinese Pharmacopoeia. Significant progress has been achieved in areas, such as germplasm resource conservation, production process control, and quality analysis technologies.

Nevertheless, considerable challenges lie ahead. Four major obstacles persist: the coordination and enforcement of the standard system, the robustness of quality control at the source, the depth of understanding regarding quality transmission during preparation processes, and the discourse power in international standard-setting. Looking forward, we must adhere to the principle of inheriting tradition without being shackled by antiquity, and fostering innovation without departing from its essence. With technological innovation as the core driver and clinical value as the guiding principle, we must continuously refine and elevate the TCM standardization system. This will be achieved by strengthening top-level design, embracing digital technologies, deepening fundamental research, and expanding open cooperation. Only through such concerted efforts can we ensure that TCM, a treasure of the Chinese nation, radiates even more brilliantly on its journey to safeguard public health, serve national strategies, and advance onto the global stage.

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It is noteworthy that this study primarily conducts a systematic review and analysis based on macro-level policies, existing technical frameworks, and publicly available literature, which may entail certain limitations. For instance, it lacks large-scale primary research data and in-depth case analyses regarding the practical operational difficulties encountered by enterprises in implementing specific standards (e.g., GAP, GMP), as well as cost-benefit analyses and technology transfer efficiency. Furthermore, the discussion on the latest developments in international botanical drug standards and their specific points of divergence from Chinese TCM standards remains relatively macro-level. Future research could undertake more detailed comparative analyses in these areas.

References

[1] Zhou, Y., Feng, P., Feng, M., et al. (2020) Standardization of Traditional Chinese Medicine: A Necessity for Its Modernization and Internationalization [J]. Modern Business Trade Industry, 41(33): 46-47. DOI: 10.19311/j.cnki.1672-3198.2020.33.020.

[2] Yu, Z., Yan, X. (2025) Research on the Development of TCM Standardization and Countermeasure Suggestions [J]. China Standardization, (04): 60-65.

[3] National Medical Products Administration, et al. (2025) Announcement on the Issuance of the Good Agricultural Practices for Chinese Medicinal Materials (No. 22, 2022) [A/OL]. [11-18]. https: //www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20220317110344133.html.

[4] Dong, M., Guan, Q. (2023) Problems and Countermeasures in the Standardized Planting of Chinese Medicinal Materials in Longxi County [J]. South China Agriculture, 17(20): 130-132.

[5] Lin, Y., Tian, B., Qu, X., et al. (2019) Analysis of the Current Situation and Countermeasures for the Sustainable Development of Chinese Medicinal Material Resources [J]. Pharmacy and Clinics of Chinese Materia Medica, 10(Z2): 1-3+7.

[6] Xu, F., Wan, Y., Wen, Z., et al. (2025) Construction Pathway and Implementation of a DNA Bank for Chinese Medicinal Material Germplasm Resources [J]. Pharmacy and Clinics of Chinese Materia Medica, 16(04): 7-14.

[7] Zhang, Z., Lu, J., Xu, J., et al. (2024) Research Progress on DNA Barcoding and Molecular Marker Techniques in Medicinal Plants [J]. Journal of Shenyang Pharmaceutical University, 41(05): 653-661. DOI: 10.14066/j.cnki.cn21-1349/r.2023.0251.

[8] Zhao, Q., Xie, H., Yang, L., et al. (2020) Molecular Identification of Bupleurum chinense DC. Seeds Based on DNA Barcoding Technology [J]. Chinese Journal of Experimental Traditional Medical Formulae, 26(14): 182-189. DOI: 10.13422/j.cnki.syfjx.20200650.

[9] Li, J. (2025) Analysis of Problems and Countermeasures in the Standardized Planting of Chinese Medicinal Materials in Qiaocheng District, Bozhou, Anhui [J]. New Farmer, (28): 25-27.

[10] Chemelige, Naseng. (2020) Study on the Determination, Extraction Process, and Chemical Components of Alkaloids in Mongolian Medicine Aconitum kusnezoffii (Caowu) [J]. Journal of Medicine & Pharmacy of Chinese Minorities, 26(02): 44-47.

[11] Li, C., Zhou, X., Zhang, B., et al. (2021) Design of an Intelligent Production Line Control System for TCM Preparations Compliant with GMP Requirements [J]. Automation Technology & Application, 40(12): 138-141.

[12] Zheng, X., She, Y., Zhang, Y., et al. (2025) Research Progress on the Application of Liquid Chromatography-Mass Spectrometry in Quality Control of Traditional Chinese Medicine [J]. Brand & Standardization, (03): 192-194+198.

[13] Li, Z., Xiao, X., Feng, M., et al. (2023) Simultaneous Determination of Seven Triterpenic Acids in Chaenomeles speciosa by LC-MS/MS [J]. Journal of Chinese Medicinal Materials, 46(12): 3038-3043. DOI: 10.13863/j.issn1001-4454.2023.12.021.

[14] Sun, Q., Zhang, X., Zhang, D., et al. (2022) Study on HPLC-IT-TOF/MS Fingerprint of Sonchus arvensis L. and Its Application in Authentication [J]. Chinese Journal of Pharmaceutical Analysis, 42(11): 2029-2035. DOI: 10.16155/j.0254-1793.2022.11.20.

[15] Liu, Y., Wang, Y., Deng, L., et al. (2022) Research Progress on the Manufacturing Process of Traditional Chinese Medicine Preparations Based on the Quality by Design Concept [J]. Modern Chinese Medicine, 24(03): 523-528.

[16] Zhao, S., Liu, G., Wu, J., et al. (2023) Inheritance and Innovation of Clinical Pharmaceutical Services for Traditional Chinese Medicine Medication Instructions [J]. Chinese Journal of Medicinal Guide, 25(10): 983-989.

[17] Yu, W., Shen, M., Ni, G., et al. (2025) Regional Heterogeneity and Standardized Governance of Traditional Chinese Medicine Preparation Filing Policies in China [J/OL]. Chinese Journal of Hospital Pharmacy, 1-8 [11-18]. https: //link.cnki.net/urlid/42.1204.R.20250926.1402.002.

DOI: 10.54254/2753-8818/2026.PJ30731

[18] Deng, T., Bai, X., Ye, J., et al. (2025) Analysis of Problems and Suggestions in the Implementation of the New Edition of Good Agricultural Practices for Chinese Medicinal Materials Based on "Extended Inspection" [J]. China Pharmaceuticals, 34(07): 7-11.
[19] Liu, C., Chen, S., Xiao, X., et al. (2016) Quality Marker (Q-Marker) of Traditional Chinese Medicine: A New Concept for Quality Control of Chinese Medicinal Products [J]. Chinese Traditional and Herbal Drugs, 47(09): 1443-1457.