

Dynamic of modernizing traditional Chinese medicine and the standards system for its development

Ruoyan Gai^{1,2}, Huanli Xu^{2,3}, Xianjun Qu², Fengshan Wang², Hongxiang Lou²,
Jinxiang Han⁴, Munehiro Nakata^{2,5}, Norihiro Kokudo³, Yasuhiko Sugawara^{3,4},
Chushi Kuroiwa^{1,2}, Wei Tang^{2,3,4,*}

The "Japan-China Joint Team for Medical Research and Cooperation":

¹ Department of Health Policy and Planning, The University of Tokyo, Tokyo, Japan;

² China-Japan Cooperation Center for Drug Discovery & Screen, Shandong University, Jinan, China;

³ Hepato-Biliary-Pancreatic Surgery Division, Department of Surgery, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan;

⁴ Shandong Academy of Medical Sciences, Jinan, China;

⁵ Department of Applied Biochemistry, Tokai University, Kanagawa, Japan.

ABSTRACT: This article reviewed the process of Traditional Chinese Medicine's modernization on a global scale. This process is motivated by the potential need for traditional medicine as a result of health transitions and increasing drug R&D based on know-how from TCM. The established standards system for modern medicine serves as a basic model yet has limitations in terms of comprehensively evaluating TCM. Spurred by policy commitments, research to provide supplements suited to TCM's features and principles is underway. Advanced and interdisciplinary technology and methodology is expected to play an essential role in TCM development.

Keywords: Traditional Chinese Medicine, Standards system, Drug development

Traditional Chinese medicine (TCM) has assembled both empirical and theoretical know-how over its long history in China. An essential component of the health care system, TCM accounts for around 40% of all health care provided in China. Modernizing TCM has been a long-term national effort since 1997, when TCM modernization was an essential goal of the Resolution of Health Sector Reform and Development issued by the State Council (1).

This effort by the Chinese government is prompted by two recent trends in global society. One is the

*Correspondence to: Dr. Wei Tang, HBP Surgery Division, Department of Surgery, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-8655, Japan;
e-mail: tang-sur@h.u-tokyo.ac.jp

potential need for traditional medicine accompanying health transitions. Epidemiological and demographic changes have created an opportunity to integrate traditional medicine into the health system (2). Recent studies have indicated a dramatic shift in the distribution of global mortality and the disease burden from infectious, maternal, perinatal, and nutritional causes to chronic, lifestyle-related, and debilitating diseases causes (3,4). Meanwhile, social and economic development results in most developing countries still shouldering "double burdens," namely, both non-infectious diseases and emerging and re-emerging infectious diseases such as HIV/AIDS and malaria. Moreover, the manner of medical practice has changed from disease treatment alone to integrated approaches including prevention, health care, treatment, and rehabilitation (5). The World Health Organization (WHO) emphasizes that traditional medicine can play an important role in achieving the goal of "Health for All" and is dedicated to facilitating the integration of traditional medicine with Western medicine worldwide (6). Thus, traditional medicine such as TCM has received greater attention worldwide as an alternative to established modern medicine and its legitimization has joined policymakers' agenda in order to solve complicated issues resulting from health transitions.

Another is increasing drug development from herbal remedies. Due to relatively high costs and long periods for development of new chemical drugs, enterprises have recently focused on herbal remedies to identify active ingredients and to isolate one or several bioactive compounds for drug development. An epoch-making successful case dates back to the 1970s, when Chinese scientists isolated artemisinin from Qinghao (*Artemisia annua*). On a global scale, many bioactive compounds, such as atropine, reserpinum, digoxin,

ergometrine, levodopa, ephedrinum, and camptothecin, are isolated from herbal remedies. The abundant know-how assembled over the long history of TCM provides a clue to discovery: there are 12,807 kinds of crude remedies and numerous prescriptions described in the voluminous literature on TCM (7). Policymakers believe TCM's rich know-how and biodiversity would benefit its development in China.

Thus, TCM modernization has been regarded as a crucial strategy for Chinese pharmaceutical industry development, helping to fuel China's economic growth. Paralleling Western practices, the Chinese government has over the past ten years formulated and implemented a series of standards to regulate the pharmaceutical industry, such as Regulations for New Drug Approval, Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacture Practice (GMP) (8), Good Supply Practice (GSP), and Good Agricultural Practice for crude herbal and animal remedies (GAP) (Table 1). Currently, TCM development is also following the standards system. Moreover, large Chinese pharmaceutical companies with innovative natural drugs, such as Zhejiang Kanglaite Pharmaceutical Co., Ltd. (Zhejiang, China), have opted to submit to regulatory systems in Western countries and have had some success (9,10).

On the other hand, there are limitations to the established Western standards system for TCM development (10). In most cases of TCM, the prescription is usually complex involves a mixture of various bioactive compounds that have diverse mechanisms of action and synergistic/combinational effects. Moreover, the diagnostic principles of TCM emphasize the overall condition of the individual patient and a holistic approach rather than a particular disease process and allopathic approaches. Additionally, the active ingredients of TCM are affected by environmental conditions and are too unstable to be precisely measured. All of these factors have contributed to the controversy on whether TCM remedies can be approved as "drugs." In fact, some professionals in China are skeptical and critical of TCM; they are concerned that it has been based on inaccurate and mysterious interpretations and experientialism rather than scientific evidence such as definite pharmacokinetic analysis, toxicity testing, and double-blinded clinical trials (11). Therefore, Chinese policymakers now emphasize a comprehensive approach to develop methodologies to test traditional features and principles of TCM in addition to earlier attempts to screen and isolate active ingredients from herbal remedies (12).

In 2007, a new plan was issued to expedite innovation in TCM with a comprehensive approach (13). It aims to establish scientific standards specially tailored to TCM, in terms of interpretation of the following technicalities of TCM in multiple languages:

Table 1. China's current standards for the pharmaceutical industry paralleling international practices

Years implemented	A series of standards
1999	Regulations for New Drug Approval
1999	Good Clinical Practice
1999	Good Laboratory Practice
2000	Good Supply Practice
2001	Good Manufacture Practice
2002	Good Agriculture Practice

TCM clinical practice guidelines, evaluation of the efficacy and safety of TCM, management and quality control in plantation, conservation, preparation and manufacture, and drug approval. Through the new plan, the government set a course towards TCM modernization (13). With this policy commitment, huge investment has flowed into related research programs such as the Herbalome Project (11), which is expected to provide the scientific evidence for establishment of a standards system for TCM.

Advanced experimental technologies and methodologies in molecular biotechnology, pharmacokinetics, and bioinformatics, such as chromatography, fingerprint analysis, genomics, proteomics, metabonomics, and computer pattern interpretation, have been used to trace herbal remedies and to identify active ingredients (14). This progress favors a recent attempt to treat bio-active compounds in several herbal remedies as one target for pharmacological tests and consequently identify various compounds and interactions, opening the door for TCM development (15).

In conclusion, TCM modernization represents increasing medical pluralism with health transitions and economic incentives for potential expansion of the global pharmaceutical market. There is an urgent need for systematic scientific standards to objectively evaluate the safety and efficacy of TCM and to strictly control its quality, which are key aspects of international criteria for drug approval and should be central to the ongoing standards system for TCM. The established standards system for modern medicine can clearly serve as a basic model, but further research is definitely needed to provide supplements suited to TCM's features and principles. This long-term challenge is now in its initial stages. Advanced and interdisciplinary technology and methodology is expected to play an essential role in TCM development.

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