

COMMENTARY

The Statute of Traditional Chinese Medicine (TCM) in China

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Abstract: This commentary discusses the significance and improvement of the drafted regulation on Traditional Chinese Medicine (TCM) proposed by the Chinese government. The draft regulation is significant in emphasizing the need of evidence-based scientific and evaluation research of TCM; guiding the design of deliverable and high-quality TCM healthcare service to urban as well as rural communities in China; and confirming the scientific value of TCM. However, a few sections in the draft need to be readdressed and spelled out. Pharmaceutical formulae and medicine production shall require license and certification; experienced TCM professionals should be invited to teach and evaluated by students to substitute the "master-to-apprentice" training; specific plans that lead to qualitative change of TCM and legal liability related to TCM practice need to be elaborated; and the consequence of violation of the regulation shall be specified.

As the cradle of Traditional Chinese Medicine (TCM), China is responsible to embrace the application of TCM and take the leadership of its development. To achieve such a goal, the Chinese government has prepared a draft of the statute to promote TCM practice. Generally, the draft regulation designates the existing weakness of TCM application and addresses the related development in six areas: healthcare service, pharmaceutical production, education, research, evaluation, and legal liability. It significantly contributes to TCM education and related research in two specific areas. First, it proposes TCM related research in domains including international communication and collaboration, funding resources, laboratory experiment, and publications. Existing literature suggests that the effectiveness of TCM is not convincing due to lack of evidence-based research and scientific evaluation (Konkimalla & Efferth, 2008; Xu, Towers, Li & Collet, 2006). So far, randomized case-control studies with large sample sizes based on clinical trials are generally accepted as the gold standard for research of TCM (Yu et al., 2006). For instance, Kampo, the unique system of Japanese herbal medicine, derives from TCM, is widely practiced in Japan and the West, which is fully integrated into the modern healthcare system. The success of Kampo is due to its ready-to-use formulae, which is based on clinical evidence and laboratory studies (Yu et al., 2006). Additionally, evidence based on laboratory experiment reveals that herbal extract from traditional Chinese medicine reduces lipid levels among mice with obesity as effectively as the Western obesity drug Rimonabant (Qiu, 2007). In recent years, Chinese researchers used qualitative methods exploring self-reported effectiveness of TCM practice among Chinese with cancer to develop clinical evaluation programs for TCM (Xu et al., 2006). What is more, clinical research utilized metabonomic method along with fingerprint and target analyses to examine potential mechanisms of berberine action in the treatment of type 2 diabetes and dyslipidemia among Chinese patients (Gu et al., 2010). Despite these efforts, the number of clinical research of TCM in China is limited. The draft regulation will provide a foundation for more research to provide clinical evidence for TCM efficacy and international quality standards for TCM products. Second, the draft highlights the importance of integrating Western medicine and TCM for disease diagnosis and treatment. In the West, TCM is used as a complement to Western medicine, particularly in pain management and supplementary therapy for cancer (Konkimalla & Efferth, 2008). In China, integrating Western medicine and TCM is perceived as the optimal therapy by patients with cancer in various stages in the clinic (Xu et al., 2006). Whereas, such a regulation is practically meaningful in improving the communication between physicians in Western medicine and TCM in order to effectively serve patients.

Regarding healthcare service, the draft emphasizes extending professional TCM healthcare service supply and delivery to communities, particularly communities in rural China. Access to professional TCM programs or certified TCM practitioners is insufficient in most urban communities, and those are even rarer in rural China (Arcury et al., 2006; Xu, Toobert, Savage, Pan & Whitmer, 2008b). Due to lack of professional guidance, TCM practice is not a promising healthcare approach. Such a regulation would guide the design of deliverable and high-quality TCM healthcare service to urban as well as rural communities in China.

The draft also affirms the value of TCM as medicine and a significant Chinese culture. TCM has been practiced for at least 2000 years in China. It is characterized with two important theories: *yin-yang* theory and five element theory. The first theory posits the equilibrium of *yin* and *yang* that ensures the harmony of the body (Lao, Xu & Xu, 2012). The second theory describes the relationship between the human body and the external environment (Lao et al., 2012). These theories imply two substantial philosophies. First, health is not merely the absence of physical disease or infirmity, but a state of complete physical, mental, and social well-being, which corresponds to the concept of health defined by the World Health Organization (WHO) in its constitution since 1948. Second, in contrast to Western medicine, which uses disease-based diagnosis, TCM emphasizes patient-based diagnosis and the dynamic progression of disease (Yu et al., 2006). Diverse TCM modalities including herbal medicine, acupuncture, moxibustion and massage are rooted in these philosophies. As one of the oldest continuously surviving means to treat diseases and maintain good health, TCM has been recognized as the major and the largest category of complementary and alternative medicine (CAM) by WHO, the National Center for Complementary and Alternative Medicine in the U.S., and other authoritative medical organizations worldwide (Yu et al., 2006). Compared to other CAM strategies, TCM is based on a clear rationale, a complete diagnosis-to-treatment system, and a well-established theoretical framework (Xu et al., 2006). Since the beginning of this century, TCM has been widely utilized by individuals with chronic disease, such as cancer and diabetes, to manage their disease and associated complications along with Western medicine in the West (Xu et al., 2006; Lao et al., 2012).

Although the draft is promising in multiple ways to guide the development of TCM, some sections need to be readdressed and spelled out. First, registration for producing pharmaceutical medicine is not sufficient to control for the quality of pharmaceutical formulae albeit traditional methods. Pharmaceutical formulation shall require license and certification. Standards should be constructed and used to evaluate and monitor the pharmaceutical products and the formulating process. These standards must be applied to any level of government-funded and private healthcare institutions. Furthermore, punishment for infringements against the regulation needs to be specified. Second, the “master-to-apprentice” education is lack of professionalism, thus not beneficial for systematic TCM training and scientific development of TCM. Experienced TCM professionals should be invited to teach in TCM educational institutes. Their teaching has to be evaluated by students and their peer colleagues. Launching TCM education to the public is in favor of its sustainable development. Third, the current draft is ambiguous in addressing “how to do” in healthcare service, education, and management and evaluation. Without specific principles, strategic plans might not occur to lead to qualitative change. Last, the drafted regulation is unclear in elaborating specific legal liability related to TCM practice. The legal responsibility of related authorities, which monitor and reinforce the regulation, is not specified. Additionally, the consequence of violation and related punishment is not explicit. Certainly, major concerns from the Chinese public are execution of these principles and monitoring to the execution. After all, TCM would prosper only if the written propositions are translated into actions.

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