TCM Needs TQM!

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Abstract

Although there is an enormous history of use of Traditional Chinese Medicines (TCM) a better understanding of these preparations and formulae within the scientific and international community is needed. The aim of this paper is to present the case for improving the quality of Chinese medicines, select botanicals and natural products and to provide scientific data that could substantiate the health claims. There is a need to improve and promote the scientific inquiry on the study and use of TCM in general. Not only are the sourcing and quality of botanicals of considerable importance, the approach of a Total Quality Management (TQM) system should be considered to secure global acceptance of a much wider variety of botanical drugs and TCM.

Improving TCM Preparations

A majority of people in the world continues to rely heavily on natural products as herbal remedies for their primary health care. In fact, over the past several decades, literature, both scientific and popular reflects an increased interest in natural products by the general public, and has helped fuel a greater scientific awareness of the uses of drugs from nature and botanical medicines. The increasing migrations of people across countries has been accompanied by the movement of their respective traditional medicines. Western medicines move to developing countries, and a there is a counter-flow of traditional medicines from China, for example, and from other countries to the West. This renewed interest in traditional herbal medicines has also contributed to a resurgence of interest in Western herbal medicine (and natural products), particularly in the United States and Europe, and a desire for more chemical information, and a desire for information about safety and efficacy [1]. However, there remains the challenges of conducting sound scientific studies of botanicals - from the sourcing of appropriate products to details on the preparation of the products and understanding the types of scientific inquiry that will advance this field. Scientific leadership and high-quality scientific research are required to achieve higher-quality preclinical and clinical studies of herbal preparations and better-quality herbal products.

There is an enormous history of use of Chinese medicines. In modern China, traditional Chinese medicine (TCM) has been institutionalized and incorporated into the state medical system, given full backing in the universities and administered by the State. From ancient times, TCM support has continued from its traditional base, surviving historical events in China and is now mainstream in modern China, however, a road map forward is needed, to better understand and gain acceptance of these preparations and formulae within the scientific and international community. Some specific areas include a) harmonizing standards and international collaborations, b) further improving the research methodologies required to understand the actions of the botanicals and natural products for development better remedies and c) developing the research strategies to provide scientific data that could substantiate the health claims and provide progress toward total quality management of the 19th C, coinciding with China's growing unease of its place in the world, especially feeling humiliated over the Opium Wars and threatened on all sides, the country struggled for a path forward. By the 1920s, the Nationalist government took a great interest in public health for China's revival. There was a need to organize and regulate doctors - but by this time traditional and Western doctors had now formed separate medical associations. In 1929, there were efforts ongoing to abolish TCM.

However, after a nationwide strike with the closing of pharmacies and clinics across the country, the result was the
formation of two separate and parallel government institutions for doctors: 'Chinese' and one 'Western'. In 1935 a resolution was passed demanding 'Equal treatment for Western and Chinese medicine'.

The political needs of the early People's Republic required TCM as part of health care. Even with the events of the Cultural Revolution, TCM organizations remained virtually intact. By 2012, TCM institutes and companies received an extra $1 billion in government money, over and above the regular budget. Indeed, TCM is a $60 billion industry in mainland China and Hong Kong. Almost every major Chinese city has a TCM hospital and university.

In contrast, by the 18th-19th C, in the developing history of modern Western Medicine, science was revolutionized by three important aspects: a) germ theory, b) anesthesia, and c) public sanitation. It was inevitable that the gulf between the West and medicine in China would widen. Eventually with elements of misunderstandings, mistrust and lack of quality parameters, skepticism began to take hold.

Growing Importance of TCM

Two important aspects cannot be overlooked. Firstly, not only have botanicals or herbal medicines been used for thousands of years, more recently, the use of botanicals and natural products as therapeutic agents has gained popularity and has expanded globally. These botanical medicines and herbs have long been used in primary health care of under-developing countries. They continue to be their major source of medicines and are gaining an ever-wider acceptance in developed countries as many health issues associated with the modern living style cannot be treated effectively with conventional medicine. Examples include preparations and formulae of TCM, Ayurvedic Medicine, Kampo Medicine, African Traditional Medicinal Plants and American Indian Traditional Medicine. Furthermore, botanicals are also the source of many conventional drugs. The long time use of these herbal remedies suggests some measures of pharmaceutical activity. However, to-date, large scale evidence-based clinical studies, conducted on single-herb botanicals have been reported in some cases as no more effective than placebo.

Despite the worldwide efforts in the last century, scientific inquiry of botanical mixtures remains a very challenging task. They usually contain complex chemical mixtures and their interaction in the human body may be much more complicated. The reductionist approach – to isolate compounds and evaluate their individual activities - has not been sufficient to fully elucidate the biological interactions of the botanicals in the body. The recent advances in systems biology, metabolomics and chemometrics offer new technological platforms to study complex mixtures and to evaluate corresponding, biological responses more effectively. These approaches are holistic, more integrated, and can provide a new tool to advance our understanding of the complex actions of botanicals and natural products in our body at an unprecedented level and some perspectives were recently reviewed [2-4].

**TCM needs TQM (Total Quality Management)**

There is clearly a need to examine, explore and design acceptable means in the scientific studies of botanicals and natural products, which include TCM, to link both a suitable chemical marker to a biological signal that can be linked to the therapeutic use. However, the idea of applying rigorous evidence-based methods, may be difficult and unacceptable. Among TCM researchers, many are not accepting the "Western norm of science" in their lab results and may correctly consider that this approach is entirely "unsuitable" for TCM. In which case, what is the best path forward?

Specifically, systematic studies of the health effects of botanicals and natural products require the collaboration of experts from many different disciplines including the proper collection or cultivation of source materials, botanical identification and authentication, chemical analysis, evaluation of the biological response and clinical studies leading to a "total quality system" - the integration of these various technical platforms and strategies that could contribute to more robust and effective evaluation of the therapeutic potential of botanicals that current evidence-based clinical studies have not been able to achieve to date. These are important techniques to authenticate the herbls samples, which are crucial for all scientific investigation of botanicals [5,6].

**Conclusion**

Significant research efforts in different parts of the world have been applied to examine the efficacy and chemical compositions of botanicals and herbs. Specifically, Hong Kong, the traditional hub for the international trading of Traditional Chinese Herbal Medicine, has played an important role in advancing the scientific knowledge. Yet, despite these efforts, we have not developed efficient research platforms capable of untangling the chemical compositions and linking them to the biological effects of the botanicals and herbs.

New approaches and opportunities of scientific inquiry can be integrated and applied to further the study and use of botanicals and natural products for the purposes of

a) Harmonizing standards and international collaborations of botanicals, health products and Chinese medicines,

b) Adapting the latest research methodologies required to evaluate the actions of botanicals and natural products for development of better remedies and

c) Developing the research strategies to provide scientific data that could substantiate the health claims to support a wider acceptance of botanicals and herbs in the world.

The long-time use of these herbal remedies suggests some measure of pharmaceutical activity. Despite these ongoing efforts, we have not as yet developed efficient research platforms...
capable of assuring our international colleagues (both clinicians and in respective foreign governments) that Chinese medicine is evidence based. More advanced techniques will be required to examine the actions of these complex mixtures in the human body. Presentations were given designed to present state-of-the-art concepts and address ways to improve the modernization of Chinese Medicine and recommend possible pathways forward that future research should take. However, this is not an isolated task for academics and there will always be a need to integrate the challenges of government, regulation, safety and culture, and help industry find the path to successful commercialization.

We believe these key scientific aspects presented herein are important and timely, as both the industry and regulatory authorities in China, Hong Kong and elsewhere seek better and harmonized approaches to maintain safety and the highest standards of botanical preparations. There are opportunities for harmonizing standards, adapting the latest research methodologies including "omics" and spectroscopy tools now in use to evaluate the actions of botanicals and natural products for development of better remedies. In this way, we hope to contribute new research strategies to provide scientific data that could substantiate the health claims to support a wider acceptance of botanicals and herbs in the world.

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