



GENERAL ACUPUNCTURE

Safety First, Protecting the Patient: A Herbal Certification Program by the NCCAOM

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The acceptance of acupuncture and Oriental (East Asian) medicine in the U.S. has made tremendous strides over the last 30-plus years. AOM/TCM is no longer "alternative or complementary" medicine. Yet, as acupuncture has become more mainstream, acceptance of herbal medicine has lagged behind.

According to the American Botanical Council's 2016 HerbalGram Herb Market Report and data from the *Nutrition Business Journal*, U.S. retail sales of herbal supplements was \$7.45 billion. Currently, very little of this profit is Chinese or East Asian herbal medicine, in part because of the public perception of poor quality and safety for our (AOM) herbs.

Trusting East Asian Herbs

Concerns about hepato-toxicity and pesticide adulteration of TCM herbs has led many to avoid use of Chinese herbs. In order for this perception to change, herbal medicine providers must demonstrate that they can be trusted to be a part of integrative medicine. This includes being able to embrace and follow *best practice* guidance when compounding and dispensing granule or raw herb prescriptions. In 2007, the FDA finalized its guidelines for cGMP (current Good Manufacturing Practice) for the U.S. With compliance expected by 2010, there was initial alarm and a brief push amongst many practitioners using raw herbs and granules to ensure we (those who prescribe herbal medicine) would be able to continue doing so.

The FDA stated that they would use "enforcement discretion" regarding practitioners if they have "appropriate training." That stated "enforcement discretion" might remain in place until there were highly publicized cases of people being injured by custom formulas. To date, there have been no currently accepted standards for compounding and dispensing by individual practitioners.

Creating New Standards

In 2017, the NCCAOM surveyed practitioners to get a sense of how the profession felt about the possibility of creating such standards (numerous herbal suppliers and individual practitioners had approached the NCCAOM about the need for such standards), and the majority of AOM respondents agree that competency verification of safe compounding and dispensing of herbal medicine is needed to protect our patients.

As a result, the NCCAOM Chinese Herbal Safe Compounding and Dispensing Taskforce is moving forward in creating a voluntary Certificate of Qualification. Currently there are a few courses/training that fit in with the framework that the FDA cGMP and the AHPA white paper on Herbal Safety have established. NCCAOM will base the subject matter content in line with best practices related to good compounding and dispensing protocols with a major focus on safety, cleanliness, record keeping and documentation. Here are some essential aspects that will be included:

- Tracking sources and lot numbers for all granule and raw herbs. According to FDA cGMPs, individual practitioners are personally liable for herbal prescriptions.
- Ensure that AOM practitioners fully understand the FDA, cGMP regulations and best practice standards to avoid any potential adverse effects.
- How to evaluate herbal suppliers compliance with cGMP.
- Document and maintain a designated clean work area/packaging materials.
- Maintain accurate and clean measuring equipment.
- Proper Labeling of all custom formulas: all ingredients and amount per dose, patient and practitioner name, herb compounding date.

The goal of this Certificate of Qualification Program would be for herbal medicine to gain acceptance and to demonstrate that the AOM profession is proactively taking responsibility for patient safety. Our profession has the opportunity to embrace changes needed to present our traditional medicine responsibly. This is a service to our patients and the profession as a whole and one that will likely ensure continued self-regulation of our medicine.

Resources

- Smith T, Kawa K, et al. Herbal Supplement Sales in US Increase 7.7% in 2016. *Herbalgram*, 2017;115.
- Teschke R, Larrey D, et al. Traditional Chinese Medicine (TCM) and Herbal Hepatotoxicity: RUCAM and the Role of Novel Diagnostic Biomarkers Such as MicroRNAs. *Medicines*, 2016 Sep; 3(3):18.

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