

Lessons in herb safety from The Cleveland Clinic Chinese Herbal Medicine Program

Clinic reports only six mild adverse events since 2014

Nationally board-certified acupuncturist and Chinese herbalist at the Cleveland Clinic Galina Roofener shared safety data and lessons learned from the Cleveland Clinic Wellness Institute's Traditional Chinese Herbal Medicine (TCHM) Program at her keynote delivered at the American Herbal Products Association's (AHPA's) 7th Annual Botanical Congress presented on Nov. 10 in Las Vegas at the SupplySide West trade show.



“It is wise to draw from traditional systems of medicine such as Ayurveda and traditional Chinese medicine and apply accumulated knowledge to facilitate the development of a patient-centered approach to modern medicine,” Roofener said. “Herbal medicine always has been a part of human health care, while conventional medicine focuses primarily on single-chemical compound to address a specific symptom, and similarly, Western herbalism uses a single herb for a specific symptom, on a contrary, traditional Chinese herbal medicine is centered on a multi-herbal formula approach to address a patient specific pattern, that includes all signs & symptoms that a person presents”.

The Cleveland Clinic opened in January 2014 one of the first hospital-based herbal clinics in the U.S., as part of its integrative medicine services that provides supplementary options for patients seeking a holistic, natural approach to their care. Roofener has 30 years of experience in health care, serves on the state medical board of Ohio's Acupuncture and Oriental Medicine Advisory Panel.

Roofener reported data from the program between January 1, 2014 and November 2, 2018. During this nearly five-year span, the program has provided 2,407 prescriptions, totaling 154,449 doses (518,968 grams) with only 6 mild adverse events:

- One panic attack with tunnel vision due to interaction of ginseng with excessive caffeine
- Two high-risk patients with preexisting, multiple drug sensitivities
- One aggravation of initial symptoms due to insufficient dose of herbs

- One true allergic reaction with hives
- One undetermined due to aggravation of preexisting celiac disease or true herbal adverse event

She stressed that this data illustrates Traditional Herbal Chinese Medicine as practiced at Cleveland Clinic is likely to be safe. This includes TCHM formulas custom compounded by Crane Herb Pharmacy (USA) from concentrated 5:1 water-decocted extract granules manufactured according to ISO/IEC 17025:2005 testing lab international standards and FDA regulation Title 21 CFR 111. by Kaiser Pharmaceutical Company (Taiwan), and prescribed according to Traditional Chinese Medicine principles by a licensed Chinese Herbalist. Roofener cautioned against using this data to make statements about the safety of broader herbal use and provided several tips to help ensure safe-use.

“There are endless applications for herbal medicines,” she said. “We just need to continue to be diligent in our manufacturing, marketing, and practice standards.”

Roofener said that adverse reactions related to Chinese herbs fit into six general categories:

1. Wrong identification of herb
2. Contamination with heavy metals
3. Contamination with Western drugs
4. Wrong use through self-medication
5. Administration of Chinese herbs in combination with Western drugs by practitioner not trained in Chinese herbology
6. Wrong use of an herb (wrong diagnosis)

Several of these issues are mitigated by U.S. regulatory requirements for the manufacturing. Roofener noted that Chinese herbal medicines are regulated by the FDA and must be manufactured in a manner that complies with current good manufacturing practice (cGMP) requirements for dietary supplements, which include required procedures to ensure products contain what is on the label and don't contain hidden or prohibited substances.

To reduce the risks associated with herb-drug interactions, Roofener highlighted several drugs that practitioners, manufacturers and distributors should consider, including:

- Anticoagulants/Antiplatelet
- Diuretics
- Anti-diabetics
- Sedatives/Hypnotics
- Specific Interactions (accutane, interferon, immunosuppressant's, cytotoxic drugs)

“Today's herbal products industry should learn from traditional Chinese medicine which have established rules of herb combinations that can be applied to drug-herb combinations in order to avoid negative adverse events or enhance positive interactions, along with modern scientific research studies,” Roofener said.

She also provided practitioners, manufacturers and distributors with suggestions to reduce risks associated with herbal use, including.

- Involving TCM herbalists in the development of nutraceutical formula composition.
- Creating recommendation for practitioner-use according to patient's TCM pattern

differentiation.

- Compiling list of toxic and potentially dangerous herbs that should administered by prescription only and can be prescribed by State-licensed herbal medicine practitioner only with a strict dosage recommendation and electronic medical records (EMRs), such as Fu Zi and Ma Huang.
- Developing a database for herbal formula adverse effects and drug – herbal formula interactions based on research and clinical observation.