



Interviewed by Editor in Chief
Jennifer A. M. Stone, LAc

Galina V. Roofener, LAc, LCH is licensed and nationally board-certified in Ohio and Florida. She works for Cleveland Clinic as an acupuncturist and Chinese herbalist. She serves on the State Medical Board of Ohio's Acupuncture and Oriental Medicine Advisory Panel and is a member of the NCCAOM Hospital-Based Practice Task Force Committee.

Interview:

Galina V. Roofener, LAc, LCH, Practitioner at the Cleveland Clinic

"The Safety of Custom Traditional Chinese Herbal Medicine Practice at Cleveland Clinic" was presented as a poster at the April 2017 Society for Acupuncture Research Conference. The presenter of this preliminary research data, Galina V. Roofener, LAc, LCH, is interviewed by Meridians: JAOM Editor in Chief Jennifer A. M. Stone, LAc.

JS: Galina V. Roofener is a Chinese herbalist on staff at Cleveland Clinic's Wellness Institute and primary investigator for this research project. Galina, what prompted you to research safety of traditional Chinese herbal medicine as practiced at Cleveland Clinic? Can you share a bit of the history and details of this research?

GR: Our research is a retrospective observational study of safety data. We looked at the amount of adverse events in real life clinical practice. Our focus is very pragmatic; we are not evaluating a particular product but rather a practice model. The main reason that adverse events can result in banned products in the U.S. seems to be a problem of improper practice. This can include the lack of records, labeling standards, intake directions and knowledge of reporting procedures, not necessarily just a product itself.

In 2013, a law was enacted in the state of Ohio that permitted the practice of traditional herbal medicine. Jamie Starkey, LAc, manager of the Traditional Chinese Medicine Program at Cleveland Clinic's Wellness Institute, together with the late Tanya I. Edwards, MD, the former medical director of Cleveland Clinic's Center for Integrative & Lifestyle Medicine, initiated the creation of the Traditional Chinese Herbal Medicine Clinic (TCHMC) at Cleveland Clinic. Our major goal was to create a reproducible model of TCHMC—to be practiced by any hospital system or private practice at multiple locations within a hospital system, in different sites, and with clear safety measure standards and referral guidelines. Since different states have different rules, we wanted to create a program that was flexible across the board, with full hospital-based and practice-compliant procedures.

JS: Other hospital-based Chinese herbal medicine clinics were operational prior to Cleveland Clinic. What makes this model different?

GR: In the U.S., traditional Chinese herbal medicine is commonly practiced alongside acupuncture and prescribed at the same visit. We separated the acupuncture and herbal medicine treatments. The main reason is that not every patient condition is appropriate

for receiving both types of therapy, and we didn't want that to become confusing for the patient or referring physicians. We do not accept patients younger than 12 years of age, patients who are taking more than five pharmaceuticals, or patients who are on heavy anticoagulants or active chemo.

On the administrative level there is good reason to keep the programs separate as well. Billing and recordkeeping utilizing electronic medical records (EMR) is different for acupuncture than for Chinese herbal medicine.

Additionally, the State Medical Board of Ohio has stricter safety reporting requirements for Chinese herbal medicine—another reason we separated our acupuncture and Chinese herbal medicine service lines.

JS: Why did Cleveland Clinic choose to outsource Chinese herbal medicines?

GR: Creating a model that was reproducible and can go anywhere with no financial investment is more appealing to large hospital systems or small start-up private practices. For the best quality control consistency we chose to use a single manufacturer that is able to produce a wide range of formulas and single herbal granules and has extremely strict testing standards. Keeping this kind of inventory onsite would be a huge expense and complication.

It is time consuming to compound and dispense a formula; therefore, financially it is not feasible to do this in-house. Hiring in-house staff that are not trained in traditional herbal medical prescriptionology and not trained to run a traditional Chinese medicine (TCM) herbal medicine-compounding dispensary leads to a higher incidence of clinical error and mistakes. In addition, if we did this in-house, we would become subject to FDA herbal compounding pharmacy regulations for dietary supplement labels under FDA cGMP, including the listing of all potential allergens. This is more than a hospital can deal with and we would be limited to patent formulas only. That was not an option for our vision. The only solution was to utilize an established model of conventional medicine practice and outsource compounding to a specialized herbal pharmacy.

An effective practice model should include the ease of online prescription submission, the reliability of compounding practices, the labeling according to FDA laws, and the excellent customer service for our patients (which reduces any line of error on our part).

JS: Galina, how do you address common concerns MDs have that include the adverse effects of Chinese herbal medicines as well as herb/drug interactions?

“Hiring in-house staff that are not trained in traditional herbal medical prescriptionology and not trained to run a traditional Chinese medicine (TCM) herbal medicine-compounding dispensary leads to a higher incidence of clinical error and mistakes.”

GR: One of my key roles at Cleveland Clinic is to educate healthcare practitioners about TCM. The topic of herb/drug interactions is hot for discussion right now, although TCM is slow to be adopted and incorporated into current conventional healthcare models. The insufficiency of reputable research data on the safety of TCHM side effects, adverse events, and interactions with pharmaceutical medications remains TCHM's biggest obstacle. That was the main reason that prompted us to do our research project.

The majority of the adverse events reported in the past were associated with damage to the liver and/or kidneys. Dr. Edwards and Ms. Starkey designed a Chinese herbal clinic model based upon the principle of safety first. Use of a complete metabolic panel (CMP) is a standard tool to monitor the safety of drugs. In our model of practice, before a patient is able to receive a Chinese herbal medicine prescription we draw CMP labs to establish the baseline functions of liver and kidneys. We repeat CMPs after one month, six months, and one year after the start of TCHM treatment. Additionally, we have one dedicated physician who oversees and is constantly monitoring our CMP results. We are able to gather her clinical input and move forward with the safest and most effective plan for the patient.

Within the two years reflected in the research, the CMPs did not detect any changes caused by herbs. Patients reported three cases of mild adverse events, which included anxiety, nausea and pruritus that equals 1.46% rate of occurrence. All events were reported to the State of Ohio Medical Board according to Ohio law but none required FDA reporting.

This study illustrates THCM as practiced at Cleveland Clinic's Wellness Institute is likely to be safe. This includes TCHM formulas compounded from concentrated 5:1 extract granules manufactured according to ISO/TC249 international standards, compounded according to FDA regulation Title 21 CFR 111. and prescribed according to TCM principles by a licensed Chinese herbalist. I hope it will pave the pathway for incorporation of TCHM clinics into other hospitals.

Safety of Custom Traditional Chinese Herbal Medicine Practice at Cleveland Clinic

Galina V. Roofener LAc, LCH; Jamie Starkey LAc; Yanming Huang LAc, LCH; Susan Veleber LAc, LCH; Brenda Powell MD
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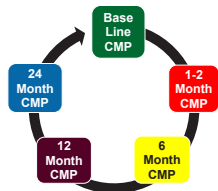
AIM

To evaluate the safety of Traditional Chinese Herbal Medicine (TCHM) as practiced at the Cleveland Clinic Center for Integrative and Lifestyle Medicine (CILM):

- Outpatient facility
- Vigorously tested herbs
- Custom prescriptions for each patient

TCHM AT CILM

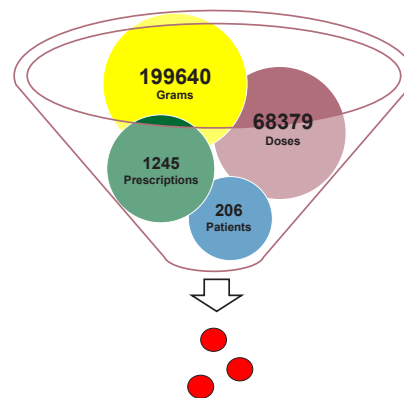
- Under supervision of a physician, licensed Chinese Herbalists prescribe custom herbal formulas based on TCHM diagnosis
- Patients are re-evaluated in person on an as-needed basis
- Detailed treatment plan, progress, adverse events and hospitalizations are documented in the patient's medical record
- A complete metabolic panel (CMP) is ordered at baseline, 1-2 months, 6 months, 12 months and 24 months of herbal intake



METHODS

- Review of medical records of patients referred to TCHM clinic from June 1, 2014 to June 1, 2016
- Exclusion criteria:
 - Patients younger than 12 years old
 - Patients on Heparin, Warfarin or Coumadin
 - Patients on Interferon or active chemotherapy
 - Patients with liver or kidney failure
 - Patients with a liver or kidney transplant
- Safety was evaluated using CMP results with emphasis on kidney and liver functions

24 MONTHS DATA



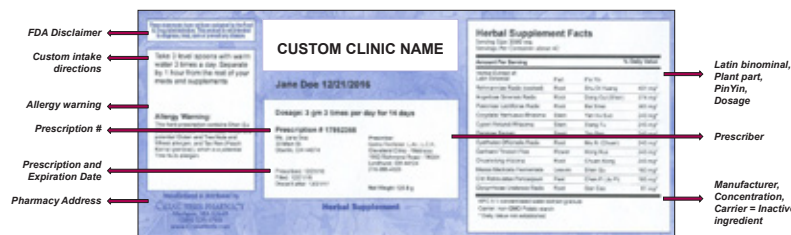
3 Mild Adverse Events

- No abnormal findings on CMP that could be attributed to herbs
- Three cases of mild adverse events (1.5%) were reported, which included anxiety, nausea and pruritus.
- These events were reported to The State of Ohio Medical Board according to Ohio law but none required FDA reporting

CONCLUSIONS

- This chart review illustrates TCHM, as practiced at Cleveland Clinic CILM, is likely to be safe

FDA ADHERANT TCHM LABEL



All TCHM formulas are custom compounded from concentrated 5:1 water-decocted extract granules manufactured according to ISO/TC249 international standards, ISO/IEC 17025:2005 testing lab and FDA GMP Title 21 CFR 111



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