

## Cleveland Clinic's Chinese Herb Clinic

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It must have been just another day at Crane Herb Co. for me in January 2013 when I received a call from a buyer at Cleveland Clinic looking to create an account. We hadn't had any previous business or communication with Cleveland Clinic and our experience with other hospitals was only about purchasing acupuncture needles and then not getting paid for 90 days. I was unimpressed with hospitals to say the least. I told one of our customer reps to say I was busy. Fine, don't waste my time. I vaguely knew that Cleveland Clinic was a very major hospital system.

Probably late March 2013, we received another call from Cleveland Clinic and this time it was Jamie Starkey who was the lead acupuncturist and she didn't want to talk about needles; she wanted to talk about Chinese herbs. Jamie had heard about Crane and our online custom herb prescription service from Galina Roofener who had been hired to practice acupuncture in their Acupuncture Clinic. Jamie wanted to learn about Crane while I was asking who, why and what was Cleveland's goal. How could Crane offer a practical solution for their goal?

Dr. Tanya Edwards, MD had opened the Center for Integrative Medicine (CIM) in 2004 with acupuncture as an outpatient service. CIM became a part of the Wellness Institute under the leadership of Dr. Michael Roizen, MD who was the Chief Wellness Officer at Cleveland Clinic from 2007 to 2019.

Dr. Edwards, MD wanted to offer Chinese herbs to some of their acupuncture patients? How could that be practical in a huge hospital system like Cleveland?

Underlying Cleveland Clinic's incredible medical advances is an entrepreneurial drive that supports new initiatives by doctors. Dr. Toby Cosgrove, MD, cardiac surgeon and CEO from 2004 to 2017, had frequently said that the future of medicine was also focusing on Prevention and Wellness. Who was he going to listen to? Dr. Cosgrove found his champion in Dr. Edwards, MD.

But it came down to "**how**" could Cleveland Clinic develop this new eastern herbal medicine clinic and not jeopardize their integrity, prestige and patient confidence? Would Patients seeking non-surgical and non-pharmaceutical treatment options actually come to Cleveland Clinic?

Let's not forget that the goal of a Chinese Herb Clinic was part of a long-term strategy of Dr. Edwards, MD and Cleveland Clinic. Cleveland Clinic had already used their political clout while working with the Ohio legislature and medical board to create a new category of Oriental Medicine Practitioner.

1. Acupuncturists could not prescribe Chinese Herbal Medicine unless they met the requirements of being an Oriental Medicine Practitioner (OMP).
2. Acupuncturists had to be certified by NCCAOM as a Diplomate of Chinese Herbology and actively met their yearly requirements.
3. Acupuncturists had to have taken an FDA-compliant cGMP course on herbal compounding and there was only one course at that time.
4. The patient had to be referred by a medical doctor for the first year of an OMP's licensure.
5. All Adverse Events had to be reported to the Ohio Medical Board. The FDA only requires Serious Adverse Events be reported by healthcare practitioners to MedWatch.

These state standards were (and are) the most rigorous in the USA. This level of practitioner clinical integrity was very important for Cleveland Clinic to attempt to create their ground-breaking new Chinese Herb Clinic. Cleveland Clinic and Ohio should be recognized for their courage, diligence and wisdom in wanting to design safe standards for this new herbal medicine to be prescribed by Ohio's Oriental Medicine Practitioners.

So in March 2013, with the state requirements in place, Jamie Starkey, LAc. called me to discuss the very specific hospital needs and Crane's services. Cleveland Clinic was limited by a number of factors.

1. Expensive space
2. Start-up cost of compounding lab equipment and software.
3. Cost of training pharmacists and employees.

For 10 years, Crane had already been compounding custom herb prescriptions for licensed TCM practitioners on the East and West Coast. Specifically, Crane was compliant with all the USP and FDA herb supplement compounding cGMP regulations. Cleveland wanted to analyze Crane's system of details and see if we could work together.

Crane could offer a proven secure turn-key online solution for specific Cleveland-approved OMP practitioners to prescribe patent or custom herb prescriptions. Patients would pay for their herb prescription and it would be shipped to their home. We agreed that it made every sense to outsource all the compounding, payment and business functions.

What about the very real questions about herb quality, identification, adulteration, bioload, pesticide, sulfites, heavy metals, etc. testing? Crane only compounded concentrated granules from KP (Kaiser Pharmaceutical) in Taiwan who met the requirements of Australia's TGA (Therapeutic Goods Administration) cGMP standards and certified by PIC/S (Pharmaceutical Inspection Co-operation Scheme). It was critically important that KP was certified to meet these PIC/S standards. The pharmacists on the Cleveland Clinic supplement committee were reassured all quality issues would not be a problem. The lawyers and marketing team were also reassured.

These details were starting to make sense but we needed to discuss in detail Crane's herb compounding compliance with FDA and USP's herb supplement compounding guidelines. After several other phone meetings, I went to Cleveland in June 2013 and met with Dr. Tanya Edwards, MD, Jamie Starkey and their committee of admin, legal, pharmacists, marketing, staff and Dr. Michael Roizen, MD. We had also answered questions from the Massachusetts Board of Registration in Pharmacy's lawyer who had called me and asked why we were calling our company a pharmacy. I said that we were not a pharmacy and that we were an herb pharmacy. Crane Herb Pharmacy, Inc. was an S-Corp since 2004 and we did not sell pharmaceuticals. We only sold Chinese herbs to the patients of state-licensed and nationally board-certified TCM practitioners. And we did not allow the public or patients to self-prescribe herbs or products. Patients paid for their herb prescriptions on Crane's secure website and the herb prescriptions were shipped to the patient's home.

Jamie and I continued to talk about different issues from their departments thru the summer. Patient personal contact information (not medical records) would be HIPAA-compliant on Crane's website and, by contract, we would never be selling any personal or business data. Crane personnel would not be sharing any Patient or business data. Informed consent guidance regulations and EPIC charting requirements would be followed.

Any marketing materials needed prior approval by Cleveland's Marketing Department and they would not allow Crane to say that Cleveland Clinic was partnering with Crane Herb Co. How would patients find out about the Chinese Herb Clinic? I never knew. The hospital's doctors were responsible for referring appropriate patients and some patients were excluded at the very beginning.

#### **Patient exclusion criteria:**

1. Patients can be taking a maximum of 5 pharmaceutical drugs
2. Patients younger than age of 12
3. Patients on Heparin, Warfarin or Coumadin
4. Patients with Cancer
5. Patients on Interferon or active chemotherapy
6. Patients with Liver or Kidney failure
7. Patients with a Liver or Kidney transplant

**Patient was also required to give a Complete Metabolic Panel (CMP):**

1. Baseline, 1-2 months, 6 months, 12 months, 24 months
2. Liver enzyme and creatinine are the main concerns
3. Patient pays cash (usually \$1,000. per blood test)

Cleveland Clinic's goal was to start in January 2014. Imagine all the training and protocols needed to coordinate acupuncturists, patients, medical doctor referrals, schedulers, herbalists and administration.

**The Chinese herbalists needed to meet certain requirements:**

1. Communication and supervision with medical doctors
2. Basic Western pharmacology knowledge
3. Communicate Chinese medicine into Western medicine concepts
4. Communication with patients
5. Herb-drug interaction knowledge and monitoring.

Clinically, the herbalist had 60 minutes for the first patient visit and then 30 minutes for all subsequent visits to meet the patient, diagnose and document a treatment plan on EPIC and design a custom herb formula on Crane's platform and prescribe the herb prescription. That is asking a lot of the herbalist. The process had to be very efficient!

After the Chinese herb clinic started in January 2014, all the media was asking the same question. Why was Cleveland Clinic offering Chinese herbal medicine in addition to acupuncture? TIME Magazine, the Wall Street Journal, the TODAY Show, Katie Couric, Dr.Oz and many other journalists and pundits wanted to comment and mostly criticize.

The start-up phase for such a unique service seemed to be working smoothly enough and after 3 months, the Audit of all the patient visits revealed some needed changes. Some MD Referrals were missing from some of the charts. Some of the Baseline Labs were missing. Some of the One Month labs were missing. It was also very time-intensive for the herbalist and the MD so the visit cost had to be increased.

**The 3 Month Audit of 100% Patients required some changes:**

1. The schedulers needed extra education.
2. Increased education with pre-screen for MD referrals prior to the visit.
3. No herbal formula was given until after the Baseline Labs were complete.
4. No herbal refills were given until after the One Month labs were complete.
5. Adjusted scheduling for the herbalist to enter charting and prescription build-time.
6. Increased price-point for both initial visit and follow-up visit.
7. Tighten the communication between the herbalist and MD in EPIC.
8. Tighten the communication between the herbalist and the Patient in MyChart.
9. Increased education for all parties.

**The 6 Month Audit of 100% Patients was better but protocols needed to be followed**

1. Some of the 6 Month Labs were missing.
2. Some of the Patients were lost in the follow-up communication.
3. Ultimately, the Program flow remained the same.

**Nine months** after the Chinese Herb Clinic had been open, the Cleveland Clinic Center for Functional Medicine (CFM) opened on September 23, 2014. It was the first Functional Medicine (FM) practice in the United States to be located within an academic medical center. Dr. Mark Hyman, MD and Dr. Patrick Hanaway, MD had outstanding national reputations and were rewarded with the most prestigious location of all the Cleveland Clinic hospitals. In contrast to the shock and criticism that the Chinese Herb Clinic attracted, the Functional Medicine Center drew praise and excitement for offering innovative preventive and wellness medical science. The medical doctors in the Wellness Center had a greater understanding of FM and felt more comfortable referring patients to FM than to the Chinese Herb Clinic. Unsurprisingly, patient referrals by MDs to the Chinese Herb Clinic slowed down.

Along with educating different hospital departments about Chinese herbal medicine came the opportunity to prove the safety to patients. The Two Year **“Safety of Custom Traditional Chinese Herbal Medicine Practice at Cleveland Clinic”** report was released with IRB approval in 2016. After 206 patients received 1,245 custom herb prescriptions, only 3 temporary mild Adverse Events were reported to the Ohio Medical Board. Anxiety, nausea and pruritis. Safety data was remarkable after 68,379 doses with 199,640 grams of extracted and concentrated herb granules. The occurrence rate was 1.46%.

#### **Four Year Audit – changes**

1. Complete Metabolic Panel eliminated except for some patients
2. No MD referral
3. Primary care MDs in Wellness Institute eliminated
4. Only Patient self-referral

#### **Crane Herb Pharmacy**

1. **Custom herb prescriptions**
  - a. Patient-specific and time-specific custom formula
  - b. Patient can not buy their custom formula from other companies
  - c. Labeling: FDA and USP standards
  - d. Allergen Warning on label is FDA required
2. **Third-party herb compounding outsourced to Crane Herb Pharmacy**
  - a. No need for in-hospital herb-trained pharmacist
  - b. Crane is compliant with all FDA and USP herb compounding/labeling requirements
  - c. Patient Herb Prescription is copied into EPIC.
3. **Patient pays for their herb prescription directly to Crane**
  - a. No additional financial burden to Cleveland Clinic
  - b. Shipped same day by USPS Priority Mail if paid by 2pm
4. **Herb Prescription label**
  - a. Herbal Supplement Facts Box: All ingredients and weight for Dosage
  - b. Compliant with all USP and FDA cGMP requirements for custom herb compounding
  - c. Dosage: #gm per dose, #doses per day and #treatment days
  - d. Provider and Patient name
  - e. Day it was prescribed
  - f. Day it was paid and herb compounded
  - g. Day to discard
  - h. Additional Dosage instructions
  - i. Contact information for Crane Herb Pharmacy