



HERBAL MEDICINE

Herbal Medicine Continues to Evolve

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Product manufacturers, industry partners, distributors and practitioners work as a collective Traditional Chinese Herbal Medicine (TCHM) community to produce high quality TCHM prescriptions that bring low-risk healthcare to thousands of patients everyday. TCHM product labels help practitioners, patients and doctors easily locate important information about the formula. What information do we expect to be given about the products we prescribe? What information about herbal prescription must be recorded in a patient chart at a hospital? I pose these questions to Galina Roofener, lead herbalist at Cleveland Clinic and her answers may give you some inspiration.

Shellie: Many TCHM products in the marketplace do not list formula details, and in some cases list "proprietary formula." Is it important to the TCHM practitioners at Cleveland Clinic to list all TCHM formula ingredients with their percentages? How does this affect recommended dosages for your prescriptions?

Galina: Absolutely! Whether you work in a hospital or a private practice, knowing a formula's ingredient ratio is a must in order to prescribe correctly. This is the only way to determine if a formula fits our patient's diagnosis. At Cleveland Clinic, we solve this problem by only prescribing custom formulas for patients. We also modify formulas for patients. For example, Chai Hu Tang, used for Shaoyang syndrome, has modifications that recommend 12 grams in the presence of fever, 6 to 9 grams when Liver Qi stagnation occurs, and 3 to 6 grams for Spleen Qi sinking. If I don't know the formula ratios, I can't modify the formula and adjust the dosage for the patient. Practitioners need to be informed about the product for professional prescriptions to be made. If you ask your MD, "How much of the active ingredient in this pharmaceutical drug is necessary for my condition?" And the reply was, "I don't know, it is proprietary information." What would your reaction be? This is an unacceptable practice for us to allow in the hospital, so we outsource compounding to solve this problem, and to address any issues with labeling for the patient and their medical team.



Shellie: Your team at Cleveland Clinic worked around the lack of transparency in certain finished products, or patents, by choosing to outsource. This provided your team the ability to custom compound your prescription, knowing exactly which herbs and how much of each were compounded, in addition to the option to modify each formula. What was your rationale behind this decision?

Galina: The Cleveland Clinic is a huge organization with multiple locations both nationally and internationally. We wanted to insure that we created a model of a practice that would allow us to potentially offer classic Chinese herbal medicine in all locations. No U.S. hospital currently has a Traditional Chinese Herbal Medicine (TCHM) pharmacy. It is unrealistic to expect hospitals to carry a full inventory. Space in the hospital is expensive. We are providers, paid per service, and herb compounding is time consuming and financially unfeasible for the hospital to pay qualified staff to do it. Employing unqualified supportive personnel, we open doors to medical errors. Those who maintain an extensive herbal inventory may be familiar with the exhaustive herb pharmacy issues like expiring herbs, space, sanitation procedures and specialized equipment requirements. Compounding is best performed by professional herb pharmacies because the various issues are too many to manage. In healthcare, each profession has a scope of practice. It is important not to encroach on another scope of practice, like the "dry needling" issue. How do we focus on our area of mastery if we run everything? For Cleveland Clinic, the choice was clear, we outsource, or we do not have a Traditional Chinese Herbal Medicine Clinic. We knew we were not interested in running a Chinese Herbal Medicine pharmacy, but rather, we wanted to focus on the medicine aspect of healing.

Shellie: There are specific regulations for dietary supplement labels under FDA cGMP, including listing potential allergens. TCHM finished products are regulated by the FDA as dietary supplements; small-business are granted exemptions from listing all information in the Herbal Supplement Facts Box like herbal formulation ratios. This creates a wide variety of labels for TCHM products. How does TCHM labeling affect your work at Cleveland Clinic? Did this variability

in the law and labeling affect how you chose products? What criteria brought you to your selected pharmacy vendor?

Galina: Our hospital required access to the highest quality products with the widest range for selection of formulas and single herbal granules for prescriptions. It was necessary that the herb pharmacy be fully FDA compliant in its practices, have easy to use online prescription software and impeccable practitioner and patient service. Each hospital has a legal department that insures that any activity within a hospital is legally compliant. The label for the products we chose had to be fully compliant. If the only information provided is the formula name in pinyin, or "chicken scribble," on a baggy of herbs, then that prescription is not professional and potentially illegal! Our vendor provides a FDA compliant label that works for our needs at Cleveland Clinic. This label greatly increases patient confidence and compliance with their herb treatment. More information on FDA labeling regulations, [click here](#).

Shellie: This label showcases a lot of important areas, beginning with the right column: it shows Pin Yin, Latin Binomial, as well as the part of the herb used. Most importantly, it lists the ingredients by weight and shows the amount of each. The label shows the formula name, patient name and address, prescribing practitioner name and address, and the address of the compounding facility. Dates are given for the date the formula was prescribed, the date it was filled and even a date for when the formula expires. Allergen warnings, dosage and dosage instructions, in addition to specific information regarding capsule quantity and milligrams per capsule are all listed clearly. This label goes beyond what is often seen in practice of Traditional Chinese Herbal Medicine practice. It's also a different label from a pharmaceutical drug. This label bridges two cultures of medicine, describing an Eastern formula in a Western regulatory prescriptive format.

Shellie: Do labels like this help you carry this same language of TCHM prescription into your electronic patient records? How do you file your TCHM formulas in your notes?

Galina: The main page of a patient record that provides a summary of patient conditions besides my SOAP notes must include allergies, medications, supplements and Chinese Medicine herbs. No conventional Electronic Medical Records system is built for recording Custom Multi-component Chinese Herbal Formulas. It took Cleveland Clinic a lot of time, and a close partnership with our IT department, to figure out how to record herbs in our EMR system "Epic." During a patient visit, I perform an intake then I go to the Crane Herb pharmacy website, and submit a prescription of a custom formula. To make this work, I copy the Herb Formula record from the text format field on the Crane Herb site, and paste it into my notes with my existing system in Epic and a summary page in Epic. Follow up appointments are 30 minutes, including everything from walking the patient in, to closing the patient's chart. Printing their follow up summary must be accomplished in that time frame.

Shellie: Your work at Cleveland Clinic showcases labeling and charting tricks that private practice practitioners might want to implement in their practice. How can folks learn more about your system? Would you like to discuss recording side effects of herbs next month? I would love to hear how Cleveland Clinic is tracking safety data!

Galina: I would love to share our process of recording and handing both serious and non-serious events in collaboration with TCHM therapies.

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