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GENERAL ACUPUNCTURE

Building Bridges with Discipline

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As practitioners of traditional Chinese herbal medicine, our role is to educate patients and medical practitioners about the various safety aspects of our medicine. Medical doctors that embrace Chinese medicine want to collaborate and include Chinese herbal medicine in more aspects of clinical care to support their patients. Common concerns these doctors have include the side effects of Chinese herbal medicines, as well as herb/drug interactions. Chinese herbal medicine may have a decent safety record, but some claim this is due to the fact that as a collective, we fail to report side effects. After all, we are required to report only serious adverse events. I interview Galina Roofener of the Cleveland Clinic about how she educates physicians, about her work, the medicine, and her diligence surrounding patient safety. Galina defines adverse events and shares how she reports and tracks potential side effects of traditional Chinese herbal medicines in her practice.

Shellie: Galina, how do you deal with the various concerns medical doctors at Cleveland Clinic have regarding potential herb/drug interactions?

Galina: One of my key roles at the Cleveland clinic is to educate healthcare practitioners about traditional Chinese medicine. The topic of herb/drug interactions is hot for discussion and a reason why traditional Chinese herbal medicine is slow to be adopted and incorporated into current conventional heath care 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. To overcome this, we must master an art of an adverse event reporting.

Shellie: This mastery needs to begin with programs that monitor patients prior to implementing Chinese herbal therapy, to truly distinguish the effects they are having positively, or negatively. In the general population, this could be challenging, but in a hospital environment, it's possible to collect this information since a patient is enrolled in a therapeutic model requiring a practitioner, before a Chinese herb is prescribed. Cleveland Clinic has designed stop-gap measures to assure that inappropriate patients are screened and protected. What does this process look like?

Galina: The majority of the adverse events reported in the past were associated with the destruction of vital organs such as the liver and kidney. Tania Edwards, MD, and Jamie Starkey, LAc, of Cleveland Clinic designed a Chinese herbal clinic model based upon safety first. This requires that patients undergo a Complete Metabolic Panel (CMP) to measure liver enzymes, creatinine, and electrolytes before they are able to receive a Chinese herbal medicine prescription. We then draw baseline labs again, one month and six months after a Chinese herbal medicine prescription is given. CMP is our standard tool to monitor the safety of drugs, Chinese herbs and also the collaboration of herbs and drugs in the body. So far, we have an excellent safety record.

Shellie: If an event were to occur and you became aware a patient had an adverse reaction to a Chinese herbal medicine, or perhaps you see evidence of a potential herb/drug interaction, what is the protocol in your department for reporting?

Galina: In order to report drug/herb interactions, we must to know the definition of side effects and adverse events to be able to act in accordance with a state and federal law. To the best of my knowledge, the majority of the states in the U.S. (except Ohio) use as a default federal law in regards of Chinese herbal medicine adverse event reporting. The state of Ohio mandates the reporting of any adverse event to the State of Ohio Medical Board. Federal law requires reports to the FDA of only serious adverse events. "The term ‘serious adverse event' is an adverse event that:

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A)."[1]

"An adverse event is not necessarily FDA reportable. The term ‘adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including:

(A) an event occurring from an overdose of the drug, whether accidental or intentional;

(B) an event occurring from abuse of the drug;

(C) an event occurring from withdrawal from the drug; and

(D) any failure of expected pharmacological action of the drug."[1]

A side effect is not necessarily FDA reportable as well. "The term ‘side effect' means any result of a drug or therapy that occurs in addition to the intended effect, regardless of whether it is beneficial or undesirable. Example Chemotherapy–Fatigue, N&V, anemia, hair loss, mouth sores."[2]

An electronic filing of "FDA Form 3500 should be used by healthcare professionals and consumers for voluntary reporting of adverse events noted spontaneously in the course of clinical care."[3]

Shellie: What do you report to the State of Ohio Medical Board in the event of a TCHM adverse event?

Galina: Ohio law mandates us to report not all adverse events. Within the 2.5 years of our program, we have reported five adverse events, none of them were FDA reportable. I prepared them following the guidelines of FDA form 3500. We must be very thorough when describing an adverse event. According to Giovanni Maciocia, most of the reports fail to:

- put the incidence of adverse reactions into context (i.e. what is the proportion of adverse reactions in the total of all therapeutic interventions with herbs); or
- explain the individual circumstances under which the adverse reactions occurred.

If we fail to describe an adverse event in detail, we could end up with situations like what

happened with Ma Huang. Here is the big picture: 37 deaths during 1995-1997 year period among 12 million users.[4] Comparatively: "Each year, use of NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) accounts for an estimated 7,600 deaths and 76,000 hospitalizations in the United States."[5] Still, consumers are trained to self-administer Ibuprofen like candy.

All reported deaths of Ma Huang were from inappropriate uses of the herbal supplement for conditions such as weight loss and NO deaths were reported from prescriptions from properly trained TCM practitioners. Bad media created paranoia around Ma Huang and as a result, it was banned and we lost access to a very important clinical tool.

Shellie: The Ma Huang example is a classic case for why we need to take an active role in the dietary supplement community, and have a voice in the misuse of single products from the classical Chinese herbal formulary. What are your thoughts on adverse events from Chinese herbal medicine?

Galina: Natural does not mean safe! Contrary to some of my colleagues belief that prescribing Chinese herbs without regards to concurrent medications taken by the patient is safe, I practice an evidence-based approach, and carefully review patients medications and labs. Many medications as well as supplements may interact with herbs, any medication with a narrow pharmaceutical safety margin index such as warfarin or chemo has a potential to interact with an herbal product Eastern or Western. Even in the realm of TCM, we have classic lists of incompatibilities and counteractions dating back centuries years old. "An estimated incidence rate of adverse reactions varies from 1.8% to 9.1% in clinical combination of herbs and drugs."[6]

Drug/herb interactions data is constantly growing, unfortunately it is very difficult to keep current, due to the amount of research that is at an avalanche level and a lack of a single source comprehensive database on formula/drug interactions. Hopefully, such a database creation will be undertaken in the near future. It should include not only data from research, but also observational data reported by practitioners, very much like the practice in Taiwan.

Shellie: Galina, I imagine many agree with the need to protect patient safety first and to be aware of any potential reactions within a TCHM formula, and/or between TCHM and Western drugs. Taiwan integrative hospitals are working with these issues daily and have been for some time, building significant high quality data along the way. Perhaps we can discuss our work with Taiwan in our next article?

Galina: I will be happy to talk next time about our Taiwan visit and our collaborative projects in the U.S. and globally.

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