
The Brown Bag Problem and Traditional Chinese Medicines

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Background

The practice of Tradition Chinese Medicine (TCM) has been a treasured element of the Chinese cultural heritage as we know it and respect it. Chinese herbal medicines (CHM), a component of TCM, in particular has gained an augmented global popularity and vigilance in recent decades. With the influx of Chinese immigrants to the United States on the rise, the utilization of CHM has permeated the Chinese-American health care system¹. In addition, CHM has come into vogue with the non-Asian health conscious generation, posing more challenges to the already stressed health care system. Despite the availability of advance modern therapeutic modalities, a confluence of factors have contributed to CHM consumers remaining ardent in their choices. Although the popularity of CHM is undulating, it has not received the same vigilance as allopathic medicines due to its non-drug status in the U.S.²

When used properly, traditional CHM has been perceived as safe and is well accepted as an effective therapeutic modality by its users. However the misuse, abuse, improper preparation and adulteration of certain CPM may lead to co-morbidity and toxic situations. As more people turn to alternative medicines, the brown bag problem will inexorably engender a tremendous challenge for consumers and practitioners alike. Since patients who utilize herbal products may not always be candid with their allopathic practitioners about their complementary regimen, potential herb-related adverse effects and interactions may be overlooked and remained unreported. Despite the wide array of products on the market, having a general knowledge of some common herbal ingredients and their properties will be helpful in avoiding certain adverse incidences.

Although advances in computer informatics have raised the level of cognizance and prudence in the utilization of CHM among the general population, studies have shown a lag between awareness and communication among the medical communities. The lack of published data and resources is considered as a major area of deficiency.³ In a health care system where Eastern and Western medicines co-exists, the public health agenda must encompass raising the level of awareness and knowledge of complementary practices. Allopathic practitioners must have the confidence to suspect adverse reactions and diagnose toxicities related to the use of CHM and promptly report them to the FDA. Effective communication on all levels is imperative in ensuring safety and preventing co-morbidity in patient care.⁴

Objectives

- Define the practice of CHM.
- Discuss problems associated with foreign and domestic CHM.
- Discuss various CHM related adverse reactions.
- Discuss various herb-drug interactions and co-morbidities.
- Discuss recent recalls and warnings.
- Provide useful websites resources.

I. The practice of Chinese herbal medicine

- **Chinese Herbal Medicines (CHM) ? ? ?** – A component of TCM that utilizes medicinal botanicals for healing and promotion of health based on accumulated empirical experiences.
- **Chinese Herbal Formulas (CHF)-? ? ? ?** - CHM prescriptions comprise of herbs, plants, minerals and dried animal parts which requires meticulous preparation into decoctions or teas before consumption.
- **Chinese Patent/ Proprietary Medicines (CPM)-- ? ? ? ?**
Processed CHF that are formulated into pill or liquid form for ease of use. CPM products are readily accessible on the shelves of Chinese stores without a prescription.⁵

CHM products are considered dietary supplements in the U.S.; hence the FDA does not regulate it as drug substances. Under the FDA **Dietary Supplement Health and Education Act of 1994 (DSHEA)**, manufacturers and consumers can enjoy the profits of these products with few restrictions. Although the offices of the FDA have been given the authority to establish Good Manufacturing Practices (GMPs) regulations and guidelines that restricted product advertisements to claim cures for illnesses, the policing by the administration is a daunting task⁶

II. Problems with CHM

A. Product QA Factor

- Inter-product variability – same brand of product manufactured and distributed by different companies presents differences in quantity and quality of ingredients.
- Intra-product variability – same brand of products lacking uniformity in quality and quantity of ingredients from lot-to-lot.
- Errors in substitution of herbs- replacing original ingredients with more toxic ones.
- Adulteration with western medicines – intentional incorporation of western drug entities to enhance the effects of the product.
- Heavy metals were detected as intended ingredients or as adulterants in products causing health consequences.
- Product labeling– some labels do not reflect the actual ingredient. Product information differences in Chinese and English, often making health claims in the Chinese only.
- Products lack expiration date and handling instructions.^{2,7,12}

B. Adverse Reactions and toxicity

- ADR to naturally occurring medicinal in the compounds (i.e. ginseng, licorice)
- ADR to natural toxins in the compound (i.e. cinnabar, aconite)
- ADR to contaminants in the compounds (i.e. western drug entities, heavy metals)
- ADR due to over dosage (i.e. ma huang , ch'an su)
- ADR due to herb-drug interactions (i.e. dang gui and warfarin)
- ADR due to complication from pre-existing diseases (i.e. hepatic, renal)

III. Diagnosis and Evaluation of Co-Morbidities

A. **Herb-drug interactions** can be a potential problem when patient presents with a multi-regimen profile. It is especially important if patients are concomitantly using other pharmaceutical products with narrow therapeutic indexes. Practitioners must exercise prudence in screening patient’s medical history and encourage discussion of concerns.

Table 1. Selected herb-drug interactions ^{5,9,10,11,16,19,18,20}

Herb ? ?	Drug ? ?	Signs & Symptoms	Mechanism
Dan-shen ? ?	Warfarin	Inc.INR; gastric bleeding	Possibly additive action due to coumadin.
Dong quai? ?	Warfarin	Inc. INR, bruising	Herb acts as Cox inhibitor
Ginko biloba ? ?	Trazadone	Coma	Herb has antiplatelet activity. May decrease effect of warfarin.
Panax Ginseng ? ?	Warfarin Aspirin	Parietal hemorrhage Hyphema	Herb has antiplatelet activity. May decrease effect of warfarin.
	Warfarin Phenelzine(MAOI)	Dec. INR Manic s/s, insomnia, headache, tremor, visual hallucinations.	
Licorice ? ?	Hydrocortisone	Hyperglycemia Vaginal bleeding Pseudoaldosteronism Hypertension Accute flaccid tetraparesis Hypokalemia	Estrogenic effects Potentiates the cutaneous vasoconstrictor response. Na retention
	MAOI Spironoactone	Hypertension	Estrogen sites binding.
	Warfarin Warfarin	^INR, ^bleeding ^INR, ^bleeding	Potent thromboxane synthetase inhibitor
Ginger ? ?			
Chan su ? ?	Digoxin	Digoxin like reaction. Dig. toxicity	
Black Cohosh ? ?	Estrogen products Warfarin Iron		Estrogen sites binding Forms tannin complex that inhibits Fe absorption.
Dahuang ? ?	Antibiotic Vit. B1 & B6 Salicylates Caffeine	Dec. effect Dec. effect of both	Alters absorption Irriversible binding
Fenugreek ? ? ?	Warfarin Estrogen products	^bleeding ^ uterine contraction	

Methyl Salicylate	Salicylates	Salicylism	Over dose
? ? ? ?			

B. Herb-disease co-morbidity is an important consideration when certain herbs are used in patients with existing disease and conditions. Disease states that may alter the immune response, metabolism and excretion of herbs are particularly of concern. The lack of safety statistics warrants contraindications in pregnancy and breastfeeding. Factors that may influence the diagnosis of herb related morbidity includes method of preparation, dose ingested and duration of exposure to the herbal product.

Table 2. Selected herb-disease co-morbidities^{16,20,25}

Disease/ Condition	Herb	Effect
Neurological	Datura metel L. Borneol	Neurpathy Lowers seizure threshold
Gastrointestinal	Realgar, Cinnabar and other gastric irritants.	Various GI disorders
Cardiac	Licorice Bufo secreta	Hypertension Dig-like effects
Hepatic	Artemisia scoparia, coptis chinensus, huanglaim	hyperbilirubinemia
Renal	aristolochic acid	Interstitial renal fibrosis Proteinuria
Hematologic	gingko, dang gui, ginger, ginseng, licorice	Increase bleeding Effects glucose tolerance

C. Products Warnings and Recalls.

Since herbal medicinal are not regulated as drugs in the U.S., it is not required to be intensively tested for safety and efficacy before marketing. The FDA monitors public safety through the **MedWatch** system, and is reliant on information provided to the administration by various sources. Public safety warnings and recalls are issued when a reported adverse event related to a product has been investigated. The poison control center network plays an important role in managing cases and data collection. Although not mandated, the collaborative efforts of the general public and health care community in the reporting of herbal product related adverse effects are necessary in providing more studies and resources.

MedWatch

Website : <http://www.fda.gov/medwatch>

Telephone : 1-800-FDA-1088

Fax: 1-800-FDA-0178Medwatch FDA Office of Emergency : 301-443-1240

IV. Patient Communication

A. Mis-communication Factors

- Language barriers between patients and practitioners.
- Patients are apprehensive about revealing their CHM usage fearing disapproval.
- Patients view CHM, as natural products therefore do not need prudence.
- Allopathic practitioners avoid discussions with patients due to lack of knowledge.

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- Foreign patients seeking temporary health care without known medical history.
 - Under reporting of ADR and co-morbidities due to lack of education & resources.

B. Practical guidelines for patients using herbs

- Purchase herbs only from reputable suppliers.
- Do not take large quantity of any one herbal preparation.
- Do not use herbs if you are pregnant or nursing.
- Do not give herbs to young children without professional advice.
- Discontinue use if suspecting adverse effect.
- Communicate your supplementary product usage to your physician.²⁶

Conclusion

As people become more health conscious, there is a propensity for personal autonomy in health care decisions. The choice of treatments often reflects variables that are congruent to an individual's own values and beliefs regarding health and illness. Given a modernized and well-controlled milieu, Traditional Chinese Medicine would be invaluable in the fight against diseases. However, in a multi-cultural health care system where Eastern and Western medicine co-exists, inadequate training of practitioners and lack of resources can lead to potential problems. Since CHM is considered dietary supplements, the FDA have limited authority to regulate its market in the U.S. Hence consumers are placed in a "take at your own risk" situation where "safety" is addressed only after products has been proven "unsafe".^{6, 8} The sale and use of CHM will continue to grow in light of soaring health care costs. The medical community must be cognizant of the growing trends of alternative practices and be prudent in screening and documenting their patient population for possible herb related co-morbidities. A particular attention must be directed towards health care needs of the growing population of Chinese-American in our communities. Language and cultural barriers must not be a hindrance in proper care of this group of population who are prevalent users of CHM.

Helpful Websites

- ❑ <http://www.LISTSERV@VM.CFSAN.FDA.GOV>
- ❑ <http://www.cfsan.fda.gov/~dms/>
- ❑ <http://www.NaturalhealthWeb.com>
- ❑ <http://www.Cathayherbal.com>
- ❑ <http://www.Cintcm.ac.cn/edata/index>
- ❑ <http://www.Icm.cuhk.edu.hk/icm>
- ❑ <http://www.Ncbi.nlm.nih.gov/PubMed>
- ❑ <http://www.familydoctor.com.cn>
- ❑ <http://www.medonline.com.cn/>
- ❑ <http://www.cmj.com>
- ❑ <http://www.nutrition.org>
- ❑ <http://safetyalerts.com>

27 But PPH, Modernization of Traditional Chinese Medicine Needs Five Finger Mountain And Golden Head Ring. Drug Discovery and Traditional Chinese Medicine: Science, Regulatory Globalization, 137-144. Kluwer Academic Publishers. 2001

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