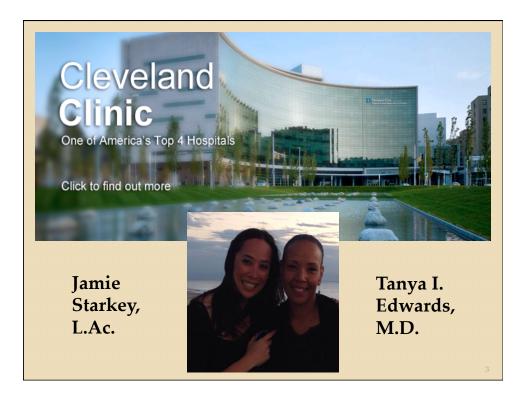
**TCM Herbal Practice Safety Standards **Medical Errors Prevention Guidelines: Cleveland Clinic Model



1

Disclaimer

- All files reflected in this presentation are fully FDA compliant reflecting imaginary patients.
- All EHR screen pictures are reproduced with permission of the companies.
- Author has no financial interests with any of the companies referred to in this presentation.
- Author has no intentions to promote a specific product or a company reflected in this presentation



Syllabus

Logistics:

- Informed consent specific to Chinese Herbal clinic.
- Communication with Western health care providers.
- Contraindications and referral guidelines for herbal clinic.
- Scheduling patients preselecting guidelines.
- Insurance reimbursement.

Herbal safety

- Herbal pharmacy selection guidelines.
- Identifying Red flags lab work, vital signs and symptoms.
- Reporting herbal side effects.
- Avoiding drug herbs interactions based on TCM guidelines and modern research discoveries.

Electronic records

- A hospital standard guideline for SOAP notes writing.
- Medical error prevention guidelines for herbal prescription writing.
- Patient's after visit summary and follow up communication.

LOGISTICS

"Do you know that Dracula in fact was a lawyer?" (From a poster in a lawyer's office)

5

OH Law

- Prior to treating a patient, the individual shall advise the patient that oriental medicine or acupuncture, as applicable, is not a substitute for conventional medical diagnosis and treatment.
- (2) On initially meeting a patient in person, the individual shall provide in writing the individual's name, business address, and business telephone number, and information on oriental medicine or acupuncture, as applicable, including the techniques that are used.

Cleveland Clinic Tanya I. Edwards MD Center for Integrative Medicine Chinese Herbal Therapy Information

Chinese herbal medicine is a major part of Traditional Chinese Medicine. It has been used for centuries in China, where herbs are considered fundamental therapy for many acute and chronic conditions. Chinese herbs can treat a variety of disorders, but they are not a substitute for conventional medical treatment and diagnoses.

I understand that different disorders may require different length of the treatment that may range from few days to a few years. I am aware that it may take a few weeks to notice subtle changes and up to 3 months for the herbal formula to reach its therapeutic potential. It is also important to note that because everyone responds to treatment differently, an herbalist cannot guarantee the outcome of the treatment.

I understand that the herbs and nutritional supplements (which are from plant, animal, or mineral sources) that have been recommended are traditionally considered safe but allergic reactions or other side effects (i.e. nausea, gas, stomach ache, vomiting, headache, diarrhea, and rashes) may occur. In rare cases, the herbs may cause a life-threatening event.

I understand that it is important to provide complete information about all medications and nutritional supplements that I am taking to reduce any possible interactions with Chinese herbs.

I confirm that counseling and treatment instructions have been provided to me, including but not limited to the need for herbal therapy, patient instructions on how to take the herbal therapy, explanation of possible contraindications and adverse reactions.

I have been instructed on sources of care in case of an adverse reaction. I have been instructed to inform my health care providers (Physicians, pharmacists, etc.) of the herbal therapy that has been provided to me.

I, the undersigned, have read and understand the above statements and have had the opportunity to ask questions regarding my treatment.

Signature of Patient	Date

OH Law

(C)(I)Before treating a patient for a particular condition, an oriental medicine practitioner or acupuncturist shall confirm whether the patient has undergone within the past six months a diagnostic examination that was related to the condition for which the patient is seeking oriental medicine or acupuncture and was performed by a physician ... acting within the physician's scope of practice. Confirmation that the diagnostic examination was performed may be made by obtaining from the patient a signed form stating that the patient has undergone the examination.

(C)(2) If the patient does not provide the signed form specified in division (C)(1) of this section or an oriental medicine practitioner otherwise determines that the patient has not undergone the diagnostic examination specified in that division, the practitioner or acupuncturist shall provide to the patient a written recommendation to undergo a diagnostic examination by a physician

INFORMED CONSENT SPECIFIC TO CHINESE HERBAL CLINIC

For Patient Review Regarding Diagnostic Exam Please sign one of the two options below:

Option I:

I have received a diagnostic exam by a physician within the last six months regarding the condition for which I am seeking treatment.

Patient Signature _____ Date ____

Option 2:

I have NOT received a diagnostic exam by a physician within the last six months regarding the condition for which I am seeking treatment. Ohio law requires that a Licensed Acupuncturist / Oriental medicine practitioner/ Herbalist recommend that you receive a diagnostic examination from a physician or a chiropractor regarding the condition for which you are seeking treatment.

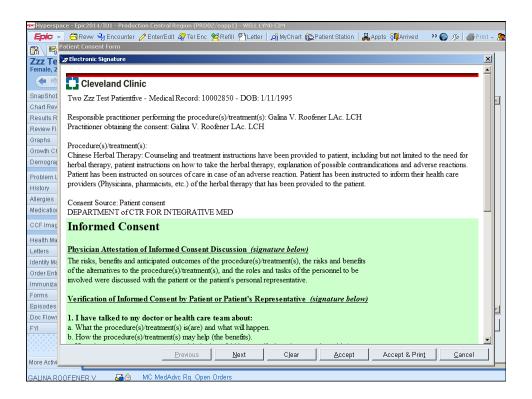
I understand this recommendation.

Patient Signature Date

Licensed Oriental Medicine Practitioner

Signature ______ Date _____

■Hyperspace - Epic2014/IU1 - Production Central Region (PRD02/eapp1) - WELL LYND CIM Fpoic → ⑤ Reww 🎝 Encounter 🌶 Enter/Edit 🦃 Tel Enc 🙎 Refill 🖺 Letter | ⋈ MyChart 🚱 Patient Station | 🖁 Appts 🕅 Arrived 💛 🔘 沙 | ഐ Print → 🧶 Log Out → Zzz,Loopdedoo Zzz Test Patientfive... MRN: 10002850 Female, 20 year old, 01/11/1995 PCP: (None) Allergies: Bee Sting, Penicillins, Advi... Code: None MyChart: Active Bed: None H ÷ Chart Review (Last refresh: 11:22:29 AM) Encounters Lab Imaging Proc Cardiac Other Ord Meds Episodes Letters Notes/Trans Misc Reports RT Scanned Docs Auth SnapShot ‡ Eilters □ Preview - ☑ Refresh ■ Select All ■ Deselect All ■ Review Selected ■ Route Chart Review Results Review 20 records match filters, more records to load
☐ Canceled/Inpatient ☐ Resulted Review Flowsh. Filters: Canceled/Inpatient Graphs 1 Medications and orders also exist in active treatment plans: ONCOLOGY REGIMEN, NON-CHEMO 1, THERAPY PLAN, NON-CHEMO 2, NON-C Growth Chart □ Description Date 05/26/2015 Status Provider Demographics Problem List BREAST PROSTHESIS, SILICONE CONSULT TO CLEVELAND CLINIC AT HOME 04/22/2015 Chopcinski, Janice (Rn), RN 03/24/2015 Ricchetti, Eric T OREU History Digennaro, Heidi (Cnp) Digennaro, Heidi (Cnp) 03/18/2015 CONSULT TO ANESTHESIOLOGY CC-OP Allergies 03/18/2015 CONSULT TO INT MED-IMPACT CC-OP Medications 02/11/2015 DIAB SHOE FOR DENSITY INSERT Dunbar, Michelle ACMOB 01/08/2015 BLOOD MANAGEMENT REFERRAL Chu, Mabel (Res) CC-OP CCF Images 12/30/2014 IV DISCONTINUE Amb, Doctor MADI Health Mainten.. 12/30/2014 IV START MADI Amb, Doctor ADVANCED DIRECTIVE QUESTIONNAIRE Identity Manager Final result CC-OP 11/11/2014 EMMLPT ED DIGESTIVE DISEASES. Srinivas Arun CONSULT TO FAMILY PRACTICE Amb, Doctor Order Entry 11/06/2014 CONSULT TO ENT Amb. Doctor BEAC CONSULT TO DERMATOLOGY 11/06/2014 BEAC Amb, Doctor Healy, Amy (Rn), RN 09/17/2014 CHEMO SCHEDULING Pending CC-OP Episodes of Care CONSULT TO NEUROLOGY CC-OP 09/11/2014 Pending Mazanec, Daniel J Doc Flowsheets BONE MARROW ASPIRATE &BIOPSY 09/11/2014 Pendina Mazanec, Daniel J CC-OP EMMI PT ED MISC FVCFM 09/09/2014 Pearson, Courtney CHEMO SCHEDULING 09/03/2014 Samaras, Christy J CC-OP Z Patient Chart Ad Searched through 5/26/2012. Search Further MC MedAdvc Rq Open Orde 11:22 AV SALINA ROOFENER ↑ 11:22 AM 5/26/2015



Communication with MD

- I. formal letter
- 2. informal email or message



Obtaining Physician's (MD or DO) Referral

- If a Physician is in doubt to refer write a letter to a physician:
- a. Include short Bio describing level of your education,
- b. Include data supporting quality of Chinese herbs that you use in your practice.
- c. Describe tools that you will use to monitor herbal safety (lab work, etc.)
- d. Include few studies supporting benefits and safety of Chinese herbal therapy for the patient's condition.
- Send a thank you note for the referral.
- Periodically send progress report to a referring MD.

13

Example A - I - my chart message

Good morning

I saw Mrs. YYY this morning for her routine follow up and she had advised us that she needed a prescription to say that she was free to take herbal supplements and Chinese herbs. I explained that were weren't able to write this without knowing which herbs/ supplements she was requesting, as she is on several prescription medications that could possibly interfere with natural supplements.

We do have a resource here at main campus (and probably available at the satellites as well) that cross checks prescription medications and disease with herbal supplements or alternative medications. If you could please send me the names of the medications / herbs that you were considering ordering for this pt, I can then do a check to assure safety.

Please advise - thank you xxxxxx CNP

Example A - 2

Dear xxxxxx, CNP

Thank you for your inquiry

Upon careful evaluation of her medication, and health history the following herbal formula may be considered: Shi Quan Da Bu Tang. Panax ginseng (Ginseng), Angelica sinensis (Dong quai), and Astragalus will be eliminated and substituted with Ling Zhi (Ganodernma)

You are welcome to look at exact constituents and cancer research documents at

http://www.mskcc.org/cancer-care/herb/shi-quan-da-bu-tang

Primary goal of the herbal therapy is to support immune system, improve mood, and support hematopoiesis during chemotherapeutic treatment for Mrs. yyyy

Herbs are not a substitute for her medications rather it is an adjunct therapy aiming to prologue time of survival of the patient

Thank you for a consideration Galina V. Roofener L.Ac, LCH

15

Example A-3

From: xxxx

Sent: Wednesday, March 11, 2015 7:19 AM

To: Roofener, Gálina **Cc:** xxxxd, M.D.

Subject: FW: yyyy(date of birth 0/0/1981)

Good morning -

Our Drug Information center has done a thorough review of the suggested herbal supplementation in conjunction with her current medications / disease processes. Please see their response below. Based on their feedback / review / recommendations, this is NOT a supplement plan that we would support. Please review their response and let us know if you have other suggestions / concerns or questions regarding the same.

Thanks xxxxxx

Example B - I

From: xxxxxxxxx]

Sent: Friday, August 01, 2014 2:29 PM

Galina

We have a nice 39 y.o. female with lupus nephropathy. she is having significant difficulty with low albumin as well as albuminuria. (>1000 mg/L) She is on azathioprine and prednisone to reduce the rate but she is hoping to reduce the prednisone dose. Her and her husband are both engineers so not easily fooled by internet herbal sales. They came across Kidney SP created by an doctor here in CA which they were intrigued by:

http://www.fumanatural.com/Kidney-SP.html

Kidney+SP was formulated from 6 herbs: Polyporus umbellalus, Ligusticum wallichi, Orthosiphon aristatus, Ludwigiua adscebdens, Radix astragalus and Rehmania glutinosa in a specific ratio and concentration that have shown very positive effects for balancing the body for people suffering chronic glomerulonephritis with high proteinuria (high protein spillage in urine).

I am wondering if you can give me your opinion as far as:

- Formula vs those made by Crane or others I couldn't find any clinical on this formula but there might be for similar formulas?
- Have you heard about this company

Other thoughts? And many thanks for your expertise

xxxxxxxxx

Director of Pain Management Scripps Center for Integrative Medicine 10820 N.Torrey Pines Rd, Maildrop FC2

La Jolla, CA 92037

17

Example B - 2

On Aug 4, 2014, at 12:30 PM, Roofener, Galina < ROOFENG@ccf.org wrote: Hi Dr. xxxxxxxx

Without seeing the patient (tongue and pulse) I cannot tell is a prescription correct for this particular patient or not.

That particular preparation does not discloses doses of herbs in it. Therefore, what concerns me: the patient is on azathioprine, one of herbs in the formula Astragalus is dose dependent Immune system modulator (in low dose stimulates, in high dose selectively suppresses) and it may counteract effects of immunosuppressive drugs.

http://www.ncbi.nlm.nih.gov/pubmed/17498486

http://www.ncbi.nlm.nih.gov/pubmed/?term=astragalus+combined+with+azathioprine

Did she actually saw that doctor or just diagnosed herself? It is not safe to assume anything themselves than buying formula from internet.

Definitely, it would be beneficial for the patient to see licensed Oriental Medicine Doctor (that the title accepted in CA) who will review her meds and create a custom formula based on Chinese Syndrome Differentiation Diagnosis taking in account western drugs.

In regards of company credentials, I am not familiar with them personally. Their website does not tell anything about manufacturing facility.

Example B - 3

Galina, thanks for your thorough response. I had some of the same thoughts:

- I. when I saw the astragalus, my first thought was the azathioprine
- 2. wouldn't it be great to get her a full TCM evaluation as opposed to having her search on her own.
- 3. The label was not that specific
- 4. yes, I was very impressed with the Crane approach as you mentioned in the clinic and below $% \left(1\right) =\left(1\right) +\left(1$

for now i will reach out to Bill Egloff and see if there might a local practitioner who might be able to see her and create a custom formula using crane.

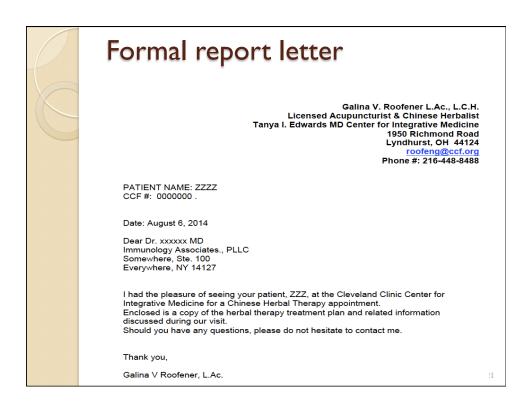
If you happen to know any colleagues locally that you would recommend that would be great as well.

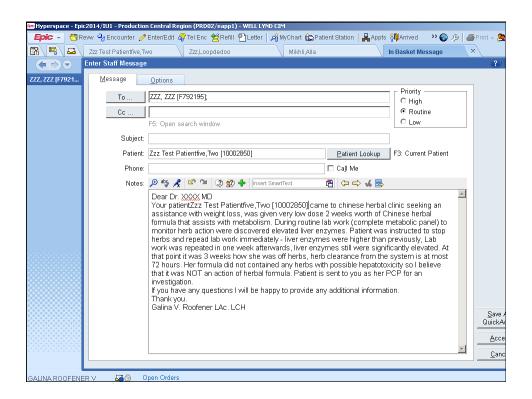
Wish we had this in house as you have exemplified but hopefully at some point in the future!

19

OH Law

As specified in the referral or prescription, the oriental medicine practitioner or acupuncturist shall provide reports to the physician .. on the patient's condition or progress in treatment and comply with the conditions or restrictions on the practitioner's or acupuncturist's course of treatment.





Legal Scope of Practice versus Courtesy Scope of Practice within Multidisciplinary Team

Ohio Law

(D) "Herbal therapy" means the use of foods, herbs, vitamins, minerals, organ extracts, and homeopathy.

Florida Law https://www.flrules.org/gateway/ruleno.asp?id=64B1-4.004

64B1-4.004 Herbal therapy means the use, prescription, recommendation, and administration of herbal therapy/phytotherapy which consists of plant, animal, and/or mineral substances and shall include all homeopathic preparations to promote, maintain and restore health and to prevent disease.

Courtesy Law

Prescribe Chinese Herbs ONLY, Refer to Integrative Medicine MD for Nutraceutical Supplements, etc

23

Contraindications for Chinese Herbal Medicine

- If patient is on: Coumadin,
 Warfarin, Heparin, Interferon.
- Active Chemo only with written referral of their oncologist
- If patient has: Liver or Kidney failure (elevated liver enzymes)



Referral Guidelines to Chinese Herbal Clinic

- Vague multiple symptoms
- Poor response to conventional treatment
- Does not want to take pharmaceuticals
- Developed resistance to pharmaceuticals
- To counteract side effects of pharmaceuticals
- To aid in fertility treatment
- Digestive disorders
- Chronic constipation/diarrhea/irritable bowels &bladder
- Poorly understood diagnosis of "syndrome"
- To restore convalescent patient after serious disease treatment (ex: post chemo, etc)
- Preventative treatment (ex: easy catching flu)
- Chronic pain that did not responded to acupuncture

25

Scheduling

Herbal Clinic Call Center Questionnaire

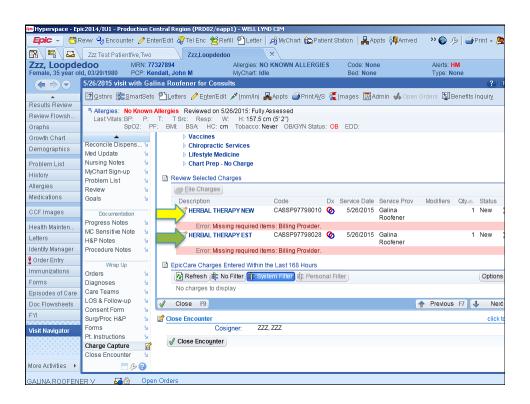
To be eligible to schedule an appointment:

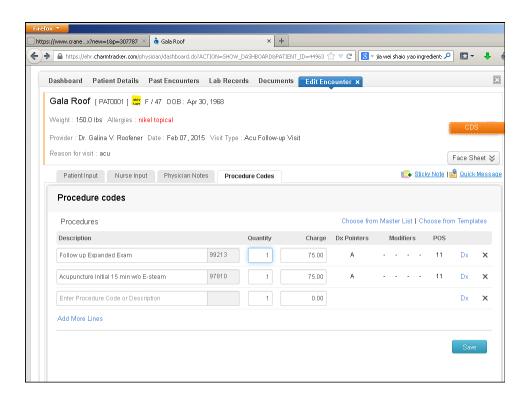
- Patient must be 12 years of age or older.
- Patient must not currently be taking
 - · Warfarin or Coumadin
 - Interferon therapy
 - Active chemotherapy
- Patient must not have had a liver/kidney transplant or have a failing liver/kidney.
- Patient should be taking no more than 5 pharmaceutical medications.
- Patient must obtain written MD or DO referral to Chinese Herbal Clinic prior to scheduling an appointment.
- Patient must be able to <u>come in person</u> for initial visit, follow up visit in 2 week, and thereafter on as needed basis.

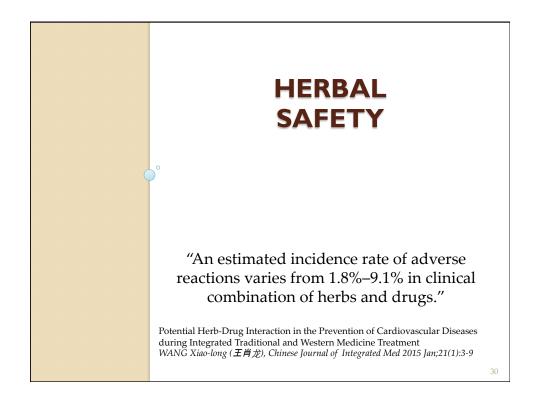
Scheduling

Instructions once patients are scheduled:

- If patient is not an established Cleveland Clinic patient they must provide their medical records including most resent lab work on/or before an initial appointment, either in person or via Fax (216-448-8615).
- Patient must bring all medications and supplements that he/she is taking to the initial appointment.
- Please do not eat or drink any colored food on the day of appointment (ex. coffee, black tea, cough drops, candy, colored gum, mints, etc.).
- Please do not brush/scrape your tongue starting 2 days prior to appointment.







FDA Regulations for Chinese herbs

- Chinese Herbal Medicines ARE regulated by the FDA.
- Chinese Herbal Medicines are held to cGMP regulation under Title 21 CFR 111.



Herb Compounding Guidelines for TCM Practitioners pdf - Handout

31

Herbal pharmacy selection guidelines

- Quality of herbs used by a pharmacy.
- Adherence to the FDA guidelines for compounding practices.
- Ease of prescription software use.
- Wide range of single herbs and formula options. available for custom formula compounding.
- Allergy warning on the label.
- Quick shipment options of custom and patent herbal formulas directly to the patient.
- Prescription pick up monitoring options.
- High customer service standards.

Manufacturing facilities and industry safety standards

Certifications:

- •<u>TGA-PIC/S GMP</u> (Therapeutic Good Administration)
- •<u>USDA-NOP</u> (United States Department of Agriculture, National Organic Program)
- •NSF-cGMP (National Sanitation Foundation)
- •Kosher
- •Halal
- •ISO 9001:2008 (International Accredited Forum)
- •ISO 17025:2005 (Taiwan Accreditation Foundation)
- •GMP (Good Manufacturing Practice)

Source: http://www.kpc.com/

Florida Law

64B1-3.001 Definitions.

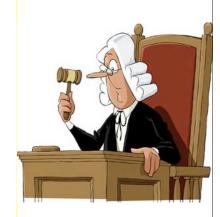
- (5) Adjunctive therapies shall include but not be limited to:
- (a) Nutritional counseling and the recommendation of nonprescription substances which meet the

Food and Drug

Administration labeling

requirements, as dietary supplements to promote health;

Specific Authority 457.102, 457.104 FS. Law Implemented 457.102 FS. History—New 8-13-84, Amended 9-19-84, Formerly 21AA-3.01, Amended 12-14-87, 9-3-89, 5-30-91, 1-26-92, 2-27-92, Formerly 21AA-3.001, 61F1-3.001, 59M-3.001, Amended 9-6-06.





The possible explanation of adverse reactions to Chinese herbs could be classified as follows:

- Wrong identification of herb
- Contamination with heavy metals
- Contamination with Western drugs
- Wrong use through self-medication
- Administration of Chinese herbs in combination with Western drugs by practitioner not trained in Chinese Herbology
- Wrong use of a herb, i.e. wrong diagnosis

http://www.scribd.com/doc/86928517/Safety-of-Chinese-Medicine-Giovanni-Maciocia#scribd

Aristolochic acid - The Original Situation in Belgium

- The case started in 1992 in Belgium with 2 women who died of end-stage renal disease (ERD). Both were involved in the same weight-loss program.
- Later, 100 patients belonging to the same weight-loss program had renal failure requiring dialysis. (Between 1500 and 2000 people were enrolled in that program)
- Chemical analysis of the herbs used revealed that while fáng jř (Radix Stephaniae Tetrandrae) was prescribed in the formula, guăng fáng jǐ (Radix Aristolochiae Fangchi) was actually used. Aristolochic acid was assumed to be the main causative nephrotoxic agent.



This is case of a medical mistake - Inappropriate use of the wrong herb

Slimming regimen in Belgium

5 drugs and 2 herbs

- fenfluramine,
- diethylpropion,
- acetazolamide,
- cascara powder,
- belladonna extract,
- Fen Fang Ji (Radix Stephaniae Tetandrae)
- Hou Po (Cortex Magnoliae Officinalis)



Most likely not only Guang Fang Ji but a combination of factors had its bad effect







Case of Ma Huang (Ephedra)

In 2004, the FDA banned the U.S. sale of dietary supplements containing ephedra.

Between 1995 and 1997, the FDA registered **37** cases of serious adverse events such as stroke, heart attack, and sudden death

Estimated number of users of ma huang products in the U.S. (1999): 12 million



HydroxySlim



This is case of a medical mistake: Use of excessive dose for a wrong purpose, for too long time.

39

Pharmaceutical drugs

Deaths and Serious Patient Outcomes from FDA-Approved Drugs

Source: "AERS Patient Outcomes by Year," FDA (Washington, DC: U.S. Department of Health and Human Services, 03/31/2010).

Year	Death	Serious
2000	19,445	153,818
2001	23,988	166,384
2002	28,181	159,000
2003	35,173	177,008
2004	34,928	199,510
2005	40,238	257,604
2006	37,465	265,130
2007	36,834	273,276
2008	49,958	319,741
2009	63,846	373,535
2010	82,724	471,291
Total 2000-2010	452,780	2,816,297

Chinese herbs

Deaths and Serious Patient
Outcomes

Source: February 6, 2004 FDAissued a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra)

Herb	Year	Death
Ma Huang (USA)	1995 - 2004	37
Guăng Fáng Jĭ (Belgium)	1990 - 1994	102



Comparison to pharmaceutical drugs

Natural Products are a Common Source of Chemotherapeutic Agents



Catharanthus roseus (Periwinkle) Vinblastine



Taxus brevifolia (Yew Tree) **Paclitaxel**



Irinotecan



Camptotheca acuminata (Happy Tree) Podophyllum pelatum (Mayapple) **Etoposide**

Chinese Herbal Toxicology

Serious poisonings due to Chinese herbal medicine in China occurs d/t:

61% by aconite roots:

- Chuan Wu (Radix Aconiti), → Not used in USA
- Cao Wu (Radix Aconiti Kusnezoffii), → Not used in USA
- Fu Zi (Radix Aconiti Lateralis Praeparata), → has low toxicity and used very seldom with extreme caution

15% by herbs with anticholinergic properties:

- Yang Jin Hua (Flos Daturae), → Not used in USA
- Bing Lang (Semen Arecae), → used very seldom with extreme caution
- Da Fu Pi (Pericarpium Arecae), → used very seldom with extreme caution (last 2 are primarily used for its anti-parasitic action or more severe and acute manifestations of long-term digestive disorders involving dysbiosis or parasites.)

24% others → (such as toad venom, blister beetles, arsenic, cinnabar and realgar) these are not commonly used in traditional formulas anymore & not used in US

http://www.scribd.com/doc/86928517/Safety-of-Chinese-Medicine-Giovanni-Maciocia#scribd

Possible Side Effects

- Nausea and vomiting
- Constipation or diarrhea
- Headache
- Allergic reaction



| Custom Pharmacy Prescription | Mattps://www.crane...x/new=18p=307787 | Mattps://www.crane...x/new=18p=3007787 |

	RED FL	AG	- LA	BW	ORK			
Component	Latest Ref Rng		7/2/2014	7/7/2014		9/10/2014	12/25/201	4/22/2015
						6:00 PM		
Protein, Total	6.0 - 8.4 g/dL	6.7	6.1	6.1	6.4	6.1	6.2	
Albumin	3.5 - 5.0 g/dL	4.2	4.3	4.2	4.3	3.9	3.9	
Calcium	8.5 - 10.5 mg/ dL	8.8	9.1	9.4	9.3	9.0	9.1	
Bilirubin, Total	0.0 - 1.5 mg/dL	0.5	0.5	0.7	0.4	0.7	0.6	
Alkaline Phosphatase	40 - 150 U/L	30 (L)	48	49	46	45	61	
AST	7 - 40 U/L	23	94 (H)	95 (H)	79 (H)	24	31	27
Glucose	65 - 100 mg/dL	98	108 (H)	99	III (H)	113 (H)	128 (H)	
BUN	8 - 25 mg/dL	14	16	13	14	11	20	
Creatinine	0.7 - 1.4 mg/dL	0.86	0.89	18.0	0.90	0.69 (L)	1.12	
Sodium	132 - 148 mmol/L	138	138	141	138	140	142	
Potassium	3.5 - 5.0 mmol/ L	4.1	4.2	4.5	4.5	3.7		3.9
Chloride	98 - 110 mmol/ L	106	104	104	102	103		104
CO2	23 - 32 mmol/L	22 (L)	24	24	27	25		27
Anion Gap	0 - 15 mmol/L	10	10	13	9	12		11
ALT	0 - 45 U/L	21	179 (H)	207 (H)	167 (H)	46 (H)		37

Where East meets West Positive Measurable Outcomes





Saliva		Range		Reference
Test				
Cortisol	morning	0.2	L	3.7-9.5 ng/ml
Cortisol	noon	0.3	L	1.2-3.0 ng/ml
Cortisol	evening	0.4	L	0.6-1.9 ng/ml
Cortisol	night	0.2	L	0.4-1.0 ng/ml

Saliva		Range	Reference
Test			
Cortisol	morning	4.2	3.7-9.5 ng/ml
Cortisol	noon	2.0	1.2-3.0 ng/ml
Cortisol	evening	0.9	0.6-1.9 ng/ml
Cortisol	night	1.1 H	0.4-1.0 ng/ml

Dietary Supplement and Non-prescription Drug Consumer Protection Act

PUBLIC LAW 109-462-DEC. 22, 2006

(I) ADVERSE EVENT

- .—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.

http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm102797.pdf

47

Dietary Supplement and Non-prescription Drug Consumer Protection Act

PUBLIC LAW 109-462-DEC. 22, 2006

- (3) SERIOUS ADVERSE EVENT- 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).

Reporting herbal side effects.

Ohio Law

(3) The oriental medicine practitioner shall report to the state medical board any adverse reactions reported by the patient under division (E)(2)(c) of this section.

According to 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)
- explain the individual circumstances under which the adverse reactions occurred.

49

CLEVELAND CLINIC HERBAL STATISTICS

Date Range	Totals were calculated from prescriptions purchased by patients	Reported AE/SE, all mild
01/01/2014 - 08/22/2015	913 Prescriptions 131,559 grams 47,527 doses 176 Patients had a Custom Prescription	1 – panic attack with tunnel vision due to interaction of Ginseng with excessive caffeine 1 – d/t preexisting multiple drug sensitivities 1 – aggravation of initial symptoms d/t insufficient dose of herbs 1 – undetermined: d/t aggravation of preexisting celiac disease or true herbal AE Total: 4

To monitor Chinese Herbal medicine safety - Complete Metabolic Panel was drawn at the base line, 1 month and 6 months from the start

Example of Chinese Herbal Medicine AE report 1

Please email to: Sallie Debolt State Medical Board of Ohio Sallie Debolt@med.state.oh.us Fax: (614) 728-5946

Center for Integrative Medicine, Cleveland Clinic Chinese Herbal Therapy: Adverse Event Reporting Tool

AE#	Date occurred	Date Reported to Cleveland Clinic Integrative Medicine	Date Reported to Ohio Medical Board	Was this an SAE?	Name of Herbal Formula Compound	Ingredients
1	06/24/2014	06/24/2014	06/30/2014	No	Wen Jing Tang	Pinellia 13.2%
Ι'						Ophiopogon 13.2%
1						Evodia Fruit 10%
1						Ginger(fresh) 10%
1						Tangkuei 6.7%
1						Ligusticum 6.7%
1						Peony(white) 6.7%
1						Ginseng 6.7%
1						Cinnamon Twigs 6.7%
1						Moutan 6.7%
1						Licorice 6.7%
1						Gelatin 6.7%
2	6/28/14	6/28/14	7/2/14	No	Liu Jun Zi Tang	Ginseng 16.7%
1-	0/28/14	0/28/14	112/14	140	Liu Juli Zi Tang	Atractylodes(Alba) 16.7%
1						Poria 16.7%
1						Pinellia 16.7%
1						Licorice(baked) 8.3%
1						Citrus Peel 8.3%
1						Ginger(fresh) 8.3%
						Jujube-dates(red) 8.3%
3	9/29/14-	9/29/14	10/2/14	No	-Du Huo Ji Sheng	-Bie Jia Turtle Shell 6.0% - Single Herb
1	9/30/14				Tang (without Xi	
1					Xin) Tuhuo and	-Mu Gua Chaenomeles 3.0%-Single Herb
I					Loranthus	
I					combination	-Niu Xi (Chuan)Cyathula Root 3.0%-Single Herb
I					formula	D. H. I St. T. (wid at V. V.) Talan
I					-Si Ni San	-Du Huo Ji Sheng Tang (without Xi Xin) Tuhuo
I					OZ Z 1Z IOUZZ	and Loranthus combination formula ingredients:
1	1		l	1	Bupleurum and	Du Huo Tuhuo Angelica 10.00%

Example of Chinese Herbal Medicine AE report 2

Summary of Findings

Observation

Response

35 years old female patient with preexisting Celiac disease (severely allergic to gluten - Gliadin Ab, IgG 53 (H) - reference range: <20 Units) with intermittent left side abdominal pain.

Medications: amitriptyline (ELAVIL) 50 mg tablet, Drospirenone-Ethinyl

Estradiol (YAZ, 28,) 3-0.02 mg per tablet

05/28 initial visit to Chinese Herbal Clinic: fibromyalgia. Secondary complaints: Severe Gluten intolerance, left lower quadrant abdominal pain

TCM Tongue Dx: Pale- pink, with slightly yellowish on the St moderate coat TCM Pulse Dx: uneven, thready

She was prescribed Chinese Herbal Custom Formulas (all were compounded by Crane Herb Pharmacy from 5:1 concentration granulated herbal powder manufactured by KPC administered in capsules). Patient was instructed to take Chinese herbs separated by 2 hours from her medications.

Baseline Labs: Complete Metabolic Panel (CMP) from 05/21/15 was norma

On 05/30/2015 started with 2 grams 2 times a day of Pin Yin Pharmaceutical Name

Xiao Chai Hu Tang 94% Yu Jin Curcumae Radix 69

<u>06/04/15 visit 2:</u> Patient reported she has tolerated formula well, has improvement in generalized body pain level.

TCM Tongue Dx: Pale- pink, with less yellowish on the St moderate coat

TCM Tongue Dx: Pale- pink, with less yellowish on the St moderate coat TCM Pulse Dx: uneven, thready

At the same time the patient has returned to her stressful job full time after 3 months of medical leave of absence.

On 06/07/15 started with 3 grams 2 times a day of modified formula

Upon results of CMP, dated 7/28/15, patient was instructed to stop Chinese herbs immediately and follow up with her referring physician, which she did the same day. Ultrasound of the right upper quadrant of the abdomen was performed on 08/06/15 – no pathologic findings except probability of mild fatty liver was found.

Labs: Hepatic Function panel from 08/06/15 AST 102 (H) 7 - 40 U/L, ALT 245 (H) 0 – 45U/L

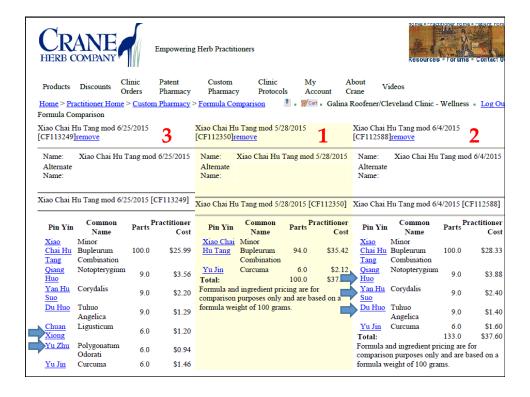
Eollow-up visit to Chinese Herbal Clinic 08/06/15: patient reported, "I feel much better in my lower abdomen, cramping pain is not as bad as it has been. The painful flare ups from the fibromyalgia have been bad, and the pain in my upper abdomen, especially during the ultrasound are still there, but overall I'm feeling better than I was a couple weeks ago"

Conclusion: It is unclear if patient's abdominal pain were a direct result of Chinese herbal therapy. Potential causative factors include the patient's existing Celiac disease, with abdominal pain as past documented sequel of Celiac Disease; potential food contamination of gluten; and increased levels of stress.

Since Chinese herbs were introduced prior to the patient's elevated liver enzymes and complaint of abdominal pain, patient was advised to immediately and permanently discontinue Chinese herbal

Pharmaceutical Name Pin Yin therapy. Referring physician was notified and patient labs are being followed. To date, she had labs drawn 1 week following initial elevation (labs Xiao Chai Hu Tang 75.2% Notopterygii Rhizoma 6.8% Corydalis Yanhusuo Rhizoma 6.8 Angelicae Pubescentis Radix 6.8% performed on 8/6/15). She has a repeat hepatic panel pending per her physician. Qiang Huo Yan Hu Suo 6.8% Du Huo Yu Jin Curcumae Radix 4.5% 6/24/15 visit 3: Patient reported she continues to have intermittent pains. although she is able to get through the day longer before feels exhausted and in pain, able to introduce more activities in her daily routine. Sleep is better wakes up less. Had less "flu like symptoms before last period" as well. Had lesser intensity of menstrual cramping but lasted longer for 5 days, had less purple clots. Still had headaches. Labs: CMP from 06/22/15 was normal TCM Tongue Dx: Pink, thin white coat TCM Pulse Dx: uneven, thready, weaker on both rear more so on the left On 06/28/15 started with 3 grams 2 times a day of modified formula Pharmaceutical Name Xiao Chai Hu Tang 69% Notopterygii Rhizoma Qiang Huo Yan Hu Suo Corydalis Yanhusuo Rhizoma 6.2% Angelicae Pubescentis Radix 6.2% Chuanxiong rhizoma 4.1%
Polygonati Odorati Rhizoma 4.1%
Curcumae Radix 4.1% Chuan Xiona Yu Zhu Yu Jin 07/23/15 visit 4: patient reported that for past 2 weeks she has 2-4 hours of restful sleep, has burning pain on the surface on the skin, has severe pain in the stomach primarily in the evening - sharp pain (like stabbing knife) on the left side radiating into the ribs, it comes and goes throughout the day, pain started after the period, Feels hot, like she is having a fever but it is not present on the thermometer. Today is day 14 of the cycle, every 2 years used to have ovarian cysts. Last period was average, less pain Had no clotting.

Had return of "Flu like symptoms" for last 2 weeks, had very itchy skin rashes on her lower legs. Had lots of mucus in the stool, Stool vary widely in color from dark to light, has brown streaks that may alternate with red streaks. Labs: CMP from 07/28/15 had: AST 360 (H)7 - 40 U/L, ALT 479 (H) 0 - 45 U/L



Component	Latest Ref Rng	7/28/2015	8/6/2015	8/13/2015
AST	7 - 40 U/L	360 (H)	102 (H)	41 (H)
Glucose	65 - 100 mg/dL	91		
BUN	8 - 25 mg/dL	8		
Creatinine	0.70 - 1.40 mg/dL	0.94		
Sodium	132 - 148 mmol/L	140		
Potassium	3.5 - 5.0 mmol/L	4.8		
Chloride	98 - 110 mmol/L	106		
CO2	23 - 32 mmol/L	27		
Anion Gap	0 - 15 mmol/L	7		
ALT	0 - 45 U/L	479 (H)	245 (H)	68 (H)

Dietary Supplements - Adverse Event Reporting



The FDA has created, through the Safety Reporting Portal (SRP), a convenient secure, and efficient method for letting FDA know when industry or consumers finds a problem with a dietary supplement.

This new reporting method is an allelectronic version of the MedWatch 3500, 3500A, and 3500B forms, (used by industry and consumers to report problems with FDA regulated products) <u>tailored exclusively for</u> <u>dietary supplements.</u>

 $\frac{http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm}{http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/UCM295636.pdf}$

What to Report on Form FDA 3500 Voluntary Adverse Event Report Form

 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.

To submit your voluntary report:

- Complete voluntary Form FDA 3500 online
- Call I-800-FDA-1088 to report by telephone
- <u>Download form</u> or call I-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to I-800-FDA-0178

http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM295636.pdf

57

Dietary Supplement and Non-prescription Drug Consumer Protection Act

PUBLIC LAW 109-462-DEC. 22, 2006

"(B) PERSONALLY - IDENTIFIABLE INFORMATION

.—Not-withstanding any other provision of law, <u>personally-identifiable</u> information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory,

shall not-

- "(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or
- "(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary

Instructions - form 3500

A1: Patient identifier - Do not use the patient's name, medical record number or social security number

A2: Age at Time of Event or Date of Birth

A3: Sex A4: Weight

B1:Adverse event and/or Product problem B2: Outcomes attributed to adverse event

B3: Date of Event

B4: Date of this Report

B5: Describe Event or Problem

B6: Relevant Tests/Laboratory Data, Including Dates

B7: Other Relevant History, Including Preexisting Medical Conditions:

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM295636.pdf

59

Instructions - form 3500

SECTION C: SUSPECT PRODUCT(S)

CI: Name

C2: Dose, Frequency & Route Used

C3:Therapy Dates

C4: Diagnosis for Use

C5: Event Abated After Use Stopped or Dose Reduced

C6: Lot

C7: Expiration date -Include ONLY with all product problem reports and events involving human cells, tissues, and tissue and cellular-based products (HCT/Ps).

C8: Event Reappeared After Reintroduction

C9: NDC # or Unique ID - Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) must have a Unique ID number to track the product

C10: Concomitant Medical Products and Therapy Dates

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM295636.pdf

What Not to Report on Form FDA 3500

- Vaccines Reporting, Veterinary Medicine Reporting and Internet Fraud
- Mandatory Device Reporting
- Mandatory Drug/Biologic Reporting (including IND, BLA Reporting)

Adverse events that occur during clinical studies are to be reported to FDA as specified in the investigational new drug/biologic regulations.

61

Avoiding drug - herbs interactions based on TCM guidelines and modern research discoveries.



Some Criteria Considered as Potential Risks for Occurrence of Drug to Drug Interactions

- DD interactions of 2 or more drugs observed in clinical practice for confirmations
- Drugs with steep dose-response curve (a small concentration changes lead to exaggerated effects)
- Drugs with small therapeutic range especially in combination dosage forms
- Drugs with problematic disposition or pharmacokinetics
- Drugs used for long-term treatment having effects on drug accumulation, enzyme induction, etc.
- Drugs prescribed simultaneously by several physicians intentionally or unintentionally
- · Drugs self-medicated by patients
- Drugs showing genetic polymorphism in metabolic elimination (CYP2D6, CYP2C19, etc.)

Herb-Drug Interaction Considerations

- Anticoagulants / Antiplatelet
- Diuretics
- Antidiabetics
- Sedatives / Hypnotics
- Specific Interactions (Accutane, Interferon, Immunosuppressant's, Cytotoxic drugs)





Mechanism of Adverse Chinese Herbal Medicines (CHM)– Prescription Drug (PD) Interactions

- 1: Form insoluble complexes during absorption phase leading to therapeutic failure
- 2: Affect transport of drug molecules in the body by CHM leading to reduced effects
- 3: Affect function of PD diuretics and body electrolyte balance by CHM medications
- 4: Destroy amylase in some CHM medications by PD antibiotics
- 5: Destroy glycosides in some CHM products by acidic PD
- 6: Release toxic cyanide from CHM medications by some PD
- 7: Affect liver metabolizing enzymes that eliminate PD by CHM products.

Mechanism of Beneficial CHM-PD Interactions

- 1: Combining antibiotics with CHM products producing added beneficial effects
- 2: Combating infection with antibiotics and immune-strengthening CHM products
- 3: Augmenting cardiovascular PD treatment with CHM products
- 4: Augmenting anti-inflammatory action of PD with CHM Products
- 5: Reducing adverse effects due to PD chemotherapy of cancers by CHM products.



Formula-Drug Case Study

Xiao Cheng Qi Tang (Minor Order the Qi Decoction) – Opioid Drugs - induced constipation and nausea:

Ma Zi Ren Wan (Hemp Seed Pill) **Antipsychotic Drugs -** induced constipation:

Xiao Cheng Qi Tang relieved constipation and nausea caused by excessive use of opioid analgesics in 40 patients with terminal cancer.

For constipation, the study reported complete recovery in 30 cases, improvement in 8 cases, and no benefit in 2 cases.

For nausea, the study reported complete relief in 19 cases and improvement in 9 cases.

No serious adverse effects were reported

Constipation caused by antipsychotic drugs in 80 individuals was treated with marked success using Ma Zi Ren Wan.

The herbs were given at 9 to 15g per dose, three times daily. For those with severe constipation, the form was switched from pills to decoction.

From 80 patients, the study reported complete recovery in 62 cases, improvement in 13 cases, and no effect 5 cases.

No serious adverse effects were reported

Techniques for combining herbs

These techniques can also be applied to herb/drug interactions.

1. Mutual accentuation

Two herbs used together that have a similar effect and are used to increase the main action of those herbs

2. Mutual enhancement

Two or more herbs used together in which one enhances the therapeutic effect of the other, but does not individually have the same effect as the other

3. Mutual counteraction

The toxicity or side effects of one herb are diminished by another. Ginger is often used in this kind of situation to moderate.

4. Mutual suppression

Similar to the above, but here the emphasis is on the herb that acts on another herb that has some toxicity or side effects.

5. Mutual antagonism

One herb can decrease the effectiveness of another herb.

6. Mutual incompatibility

The combination of two herbs that creates toxicity or side effects that are not seen in the use of each of the individual herbs.

7. Single effect

Therapeutic use of a single herb

Herb-Drug Interactions



Counteraction

Enhancement



Acetaminophen + Niu Bang Gen (Radix Arctii) has marked hepatoprotective effects.

Niu Bang Gen suppressed the elevated SGOT and SGPT levels induced by carbon tetrachloride or acetaminophen in a dose dependent manner.

It also alleviated the severity of liver damage based on histopathological observations.

The mechanism of this hepatoprotective action is based on the antioxidative effect of *Niu Bang Gen* on hepatocytes

Huang Qin (Radix Scutellariae) + Antibiotics:

Concurrent use of baicalin, a flavone isolated from Huang Qin, was found to have synergistic antibiotic effect with

 beta-lactam antibiotics, such as ampicillin, amoxicillin, methicillin and cefotaxime.

The addition of baicalin restored the effectiveness of these drugs against

- beta lactam- resistant Staphylococcus aureus
- methicillin-resistant staphylococcus aureus (MRSA)

Accentuation

Herbs with anticoagulant effects:

- Dan Shen (Radix Salviae Miltiorrhizae)
- Dang Gui (Radix Angelicae Sinensis)
- Chuan Xiong (Rhizoma Ligustici Chuanxiong)
- Tao Ren (Semen Persicae)
- Hong Hua (Flos Carthami)
- Shui Zhi (Hirudo)

Use caution w/ anticoagulant or antiplatelet drugs

Example of interaction of Salviae Miltiorrhizae (Dan Shen) with Coumadin (warfarin)

- Increase the absorption rate constant
- Increase in AUC (area under the curve)
- Increase in maximum concentration
- Increase in elimination half-life
- Decrease in clearance
- Decrease in volume of distribution







=



Dosing Guidelines



71

Age-to-Dose Dosing Guideline



Age	Recommended Daily Dosage
0 – 1 month	1/18 - 1/14 of adult dose
1 – 6 month	1/14 - 1/7 of adult dose
6 – 12 month	1/7 - 1/5 of adult dose
1 – 2 years	1/5 – 1/4 of adult dose
2 – 4 years	1/4 – 1/3 of adult dose
4 – 6 years	1/3 = 2/5 of adult dose
6 – 9 years	2/5 − 1/2 of adult dose
9 – 14 years	1/2 = 2/3 of adult dose
14 – 18 years	2/3 – full adult dose
18 – 60 years	adult dose
60 years and over	3/4 or less of adult dose

Weight-to-Dose Dosing Guideline



Weight	Recommended Daily Dosage
30 – 40 lbs	20% – 27% of adult dose
40 – 50 lbs	27% – 33% of adult dose
50 – 60 lbs	33% - 40% of adult dose
60 – 70 lbs	40% - 47% of adult dose
70 – 80 lbs	47% - 53% of adult dose
80 - 100 lbs	53% – 67% of adult dose
100 – 120 lbs	67% – 80% of adult dose
120 - 150 lbs	80% - 100% of adult dose
150 lbs	adult dose
150 - 200 lbs	100% – 133% of adult dose
200 – 250 lbs	133% – 167% of adult dose
250 – 300 lbs	167% – 200% of adult dose

Brand	Herb Made Unlisted		Unlisted	Tablets per	Prep	Tablet	DSHEA label	Likely	
	Origin	Origin In Ingredients?		bottle &	Method	Size/Shape	compliant?	Grade	
				Dosage				of Herbs	
	China	USA	No	90 tab/ 3-6	Baked	750 mgs/	Yes	Α	
DR SHEN'S YIN CHIAO				200 tab/ 3-8	whole herbs	oval			
	China USA No		No	15 tab/	Baked	750 mgs/	Yes	A	
DR SHEN'S COLDSTOP				3-6	whole herbs	oval			
al a	China	China	No	96 tabs/4-6	Baked	600 mgs/	Yes	В	
TIAN JIN YIN CHIAO					whole herbs	lozenge			
DUME ONED SHOP	China	China	May contain	60 tabs/3-4	Extracts	200 mg	No	В	
PLUM FLOWER SUGAR			pulegone			candy coated			
COATED									
<u></u>	Taiwan	Taiwan/USA	No	60 tabs/ 3-4	5:1 Water	-	No,	A/B	
GOLDEN FLOWER				240 tabs/ 3-4	Extracts		practitioner		
							line		
100	China	USA	No	60 tabs 2-4	Extracts	750 mgs	Yes	A/B	
PLANETARY FORMULAS				120 tabs 2-4		oval			
•	China	USA,	No	-	Extracts	525 mg	practitioner	A	
PINE MOUNTAIN		Formula			or powder		line		
		altered							
	China	China	May contain: Caffeine,	60	Extracts	250 mg	No	B/C	
UNITED			Acetaminophen, Chlorpheniramine						
			Oniorpneniramine						
http://yinchiao.com/plumflower.	htm	-		+	-	-	-	-	

Calculating the dose

Jin Yin Hua (Flos Lonicerae Japonicae)...9-15g
Lian Qiao (Fructus Forsythiae Suspensae)...9-15g
Jie Geng (Radix Platycodi Grandiflori)...3-6g
Niu Bang Zi (Fructus Arctii Lappae)...9-12g
Bo He (Herba Menthae Haplocalycis)...3-6g
Dan Dou Chi (Semen Sojae praeparata)...3-6g
Jing Jie (Herba Seu Flos Schizonepetae Tenuifoliae)...3-6g
Dan Zhu Ye (Herba Lophatheri Gracilis)...3-6g
Xian Lu Gen (Rhizoma Phragmitis Communis recens)...15-30g
Gan Cao (Radix Glycyrrhizae Uralensis)...3-6g

Total: $60 - 108g \rightarrow average 75g \rightarrow 1:5 extract = 15 g \rightarrow 0.5g$ capsules = 30 capsules a day \rightarrow 5 capsules X 6 times a day (every 4 hours)

Reference: Benskey & Gamble 1993, Chinese Herbal Medicine Formulas and Strategies, Seattle Washington, Eastland Press Inc.

ELECTRONIC RECORDS

Before you purchase an EHR, perform your due diligence by discussing and confirming privacy and security compliance requirements and product capabilities.

75

Florida law

64BI-I0.001 Content and Retention of Medical Records.

- (I) Acupuncturists are required to maintain written medical records justifying the course of treatment of each patient. These records must include for each patient at least the following:
- (a) Patient's Medical History;
- (b) Acupuncture Diagnostic Impressions;
- (c) Points Used and/or Treatment Procedures Administered at Each Visit;
- (d) Acupuncturists' Recommendations;
- (e) Patient Progress Notes;
- (f) Laboratory test results when appropriate and medically necessary; and
- (g) Imaging films, reports or test results when appropriate and medically necessary.
- (2) All medical records must be maintained by the acupuncturist for a period of five (5) years from the date of the last entry to the record.

Specific Authority 457.104, 457.109(1)(m) FS. Law Implemented 457.109(1)(m) FS. History—New 5-24-87, Amended 12-21-87, Formerly 21AA-10.001, Amended 12-26-93, Formerly 61F1-10.001, 59M-10.001, Amended 2-26-01.

Cleveland Clinic Licensed Provider Documentation Guidelines

- Chief complaint or reason for consult
- History of present illness
- Past medical and surgical history
- Current medications and dosages
- Allergies
- Family history Social history
- Review of systems (ROS)
- Nutrition/Function Assessment
- Physical examination

- Relevant diagnostic data
- Provisional diagnosis
- Treatment plan
- Impression
- Recommendations
- Progress Notes-Accurately documents care, treatment and services provided and the patient's response
- Documentation of credentialed staff involvement

77

The Legal Medical Record – What Every Clinician Should Know

- The Legal Medical Record of any patient is combined documentation and information from both paper and electronic records.
- A medical record must, by definition, meet all statutory, regulatory, and professional requirements for clinical purposes as well as for business purposes.
- All polices, rules and regulations governing the Legal Medical Record apply equally to both paper and electronic medical records.
- Information contained within the paper or electronic medical record is, and has always been, available to the patient.
- This documentation includes notes, plans, telephone encounters, orders, etc. Accordingly, all documentation within a patient record should be clear, concise and professional.

The Legal Medical Record – What Every Clinician Should Know

What you should do:

- Use appropriate documentation in order to provide the best patient care
- Document facts and medical opinions
- Use clear, concise descriptions describe behaviors, don't label them
- Document properly, as all documentation is discoverable and may be released
- Document plan of care, treatment given, and patient response
- Be comprehensive, particularly when noting unusual occurrences
- Use approved format
- Chart drug names, doses, routes, and regimens meticulously

The Legal Medical Record – What Every Clinician Should Know

What you should do:

- Document why medications or treatments were omitted:
 - o Patient refusal
 - o Off the floor
 - o Left AMA
- Chart nursing interventions, advice given, and patient's response
- Chart only care you provided, observed, or supervised
- Document with signs, symptoms, and diagnoses and not with lab values and results
- Avoid using up and down arrows in reference to lab values
- Do document in professional tone and content

The Legal Medical Record – What Every Clinician Should Know

What you should not do:

- Don't chart until you check the name on the patient's record
- Don't chart unit or personnel issues (i.e. staffing shortages)
- Don't document internal, operational matters, take these matters through the appropriate channels for resolution
- Don't have disputes about people, personalities, or quality
- Don't obliterate, erase, falsify, or destroy records
- Don't use humor in the medical record. What is funny to you may not seem funny to others
- Don't create gaps or omissions in the record

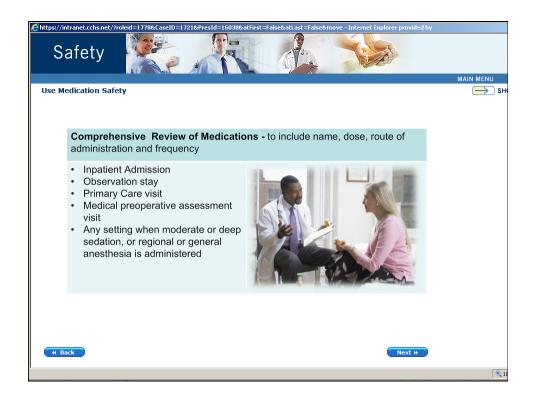
The Legal Medical Record – What Every Clinician Should Know

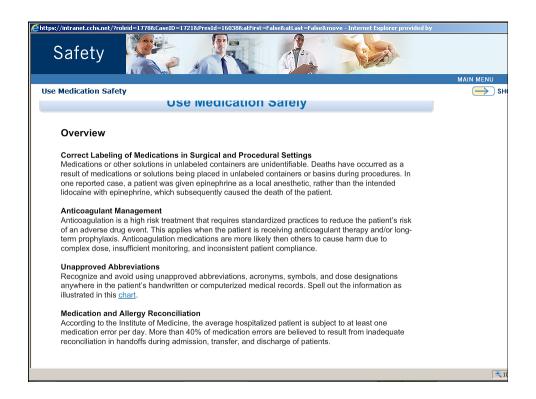
What you should not do:

- Don't make subjective or inflammatory remarks about patient or family.
- Don't make prejudicial comments
- Don't rant in a note
- Don't sacrifice patient detail for speed: modify and use free text whenever needed
- Avoid references to Ombudsman, Legal, incident reports, quality concerns
- Avoid abbreviations from the *Do Not Use* list
- Avoid indiscriminately copying and pasting documentation and duplicate/redundant information provided in other parts of the medical record









Scope of Practice	PSR/Med Sec	Clinical Techs	MA/Nursing Student	МА	LPN	RN	Allied Health	PA/APN without prescriptive authority	Pa/APN with prescriptive authority	Medical Student	Residents	Fellows	мр/ро
	Х	Х	Х	Х	х	х	X	Х	Х	х	x	X	X
to user)							-						
Reason for visit/Chief complaint	Х	Х	Х	Х	Х	Х	X	X	Х	Х	Х	Х	X
Vital Sign		Х	Х	Х	Х	Х	X	X	Х	Х	Х	Х	X
Allergy Update		Х	Х	Х	Х	Х	X	Х	Х	Х	Х	Х	X
History update (social, family, medical, and surgical)		X	Х	Х	Х	Х	X	X	X	Х	Х	Х	Х
	Х	Х	Х	Х	х	Х	X	X	Х	Х	X	Х	X
Health Maintenance				Х	X	X		X	X	X	X	X	X
	'n	- 1											
Medication Update Documentation Flowsheets		х	X	X	X	X	X	X	X	Х	Х	X	X
-	_	X	X	X	X	X	X	X	X				
Nurses Notes	-	Х	X	Х	Х	X				_			
Nursing Assessment Nursing Care Plans	_	-		-	Н	X							
Problem List Updates	\rightarrow	_		-	Н	^		X	Х	Х	Х	X	X
Progress Note Section (H & P Procedure		х	X	Х	Х	Х	X	X	X	X	X	X	X
and MC Sensitive)		^	^	^	^	^	^	^	^	^	^	^	^
Documentation Note Section (Telephone and Refill Encounter)	X	Х	Х	Х	Х	Х	X	X	X	Х	Х	X	X
Patient Instructions	-	х	X	Х	Х	Х	X	X	X	Х	X	X	X
Patient Instructions Patient Education		^	^	^	^	X	X	X	X	X	X	X	X
Serves as scribe for provider		\dashv		Х	Х	X	^	X	X	X	X	X	^
History of Present Illness (HPI)		-		^	^	^		X	X	X	X	X	X
Review of systems (ROS			х	Х	Х	Х		X	X	X	X	X	X
Physical Exam			^	^	^	^		X	X	X	X	X	X
Assessment and Plan					Н			X	X	X	X	X	X
Immunization documentation		х	Х	Х	Х	Х	X	X	X	X	X	X	X
Consent *		X	X	X	X	X	X	X	X	X	X	X	X
Order Entry *		X	X	X	X	X	X	X	X	X	X	X	X
Diagnosis *		^	X	X	X	X	X	X	X	X	X	X	X
Medication Reconciliation								X	X	X	X	X	X
	_	Х	Х	Х	Х	х	X	X	X	X	X	X	X

Herbal Follow up Appointment Flow

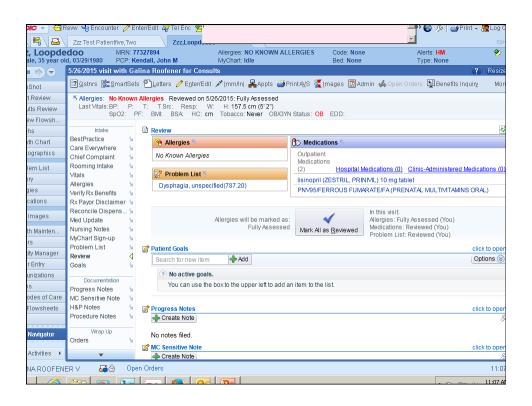
 5-10 min to review medications and allergies, gather the new symptoms and change of previous symptoms, ask only about diagnosis relevant symptoms! (I like to have an eye contact during this process)

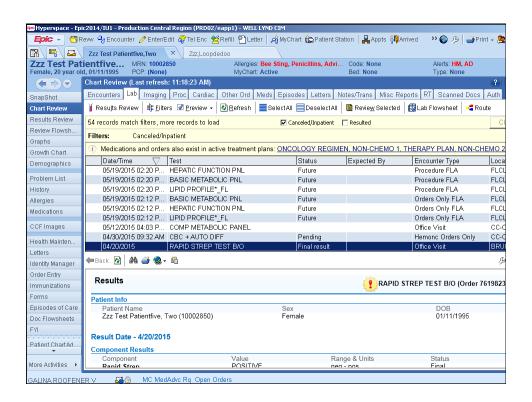
so I \boldsymbol{record} only those symptoms that are important for formula modification

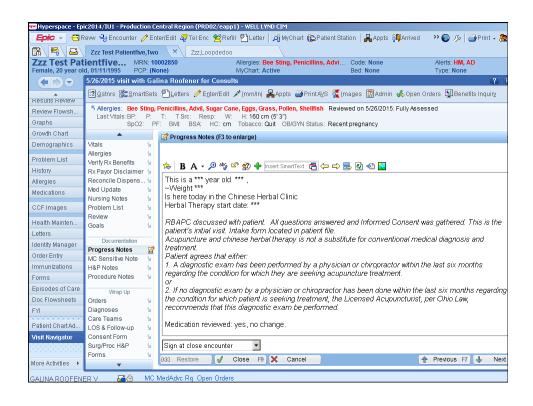
- 5-10 min are devoted to patient education end explanations
- 5-10 min for Epic/EMR soap note writing, Crane website prescription modification and Epic/EMR chart closing.

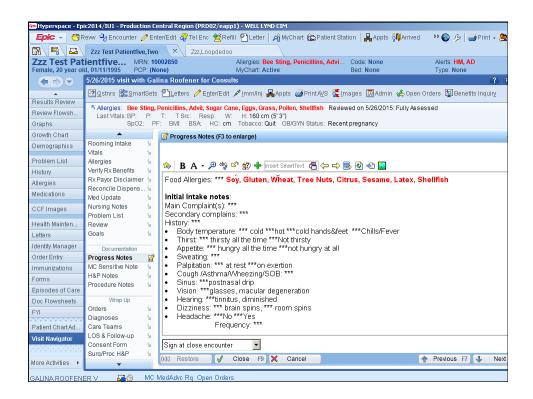
If I can not complete this at the appointment I leave it for later admin time to be done. Epic/EMR chart MUST be closed within 24 hours

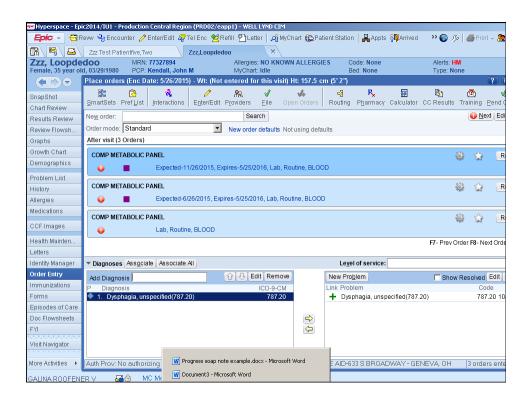
- 5 min to walking patient in and out
- total follow up appointment time is 30 min

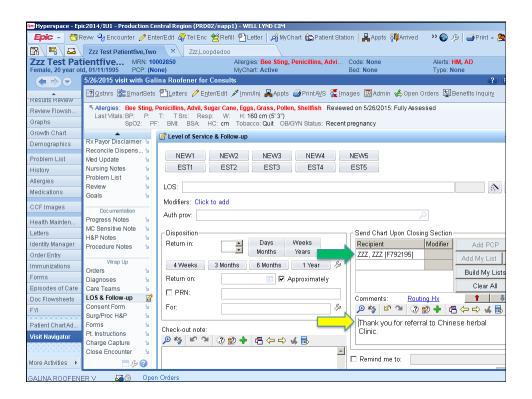


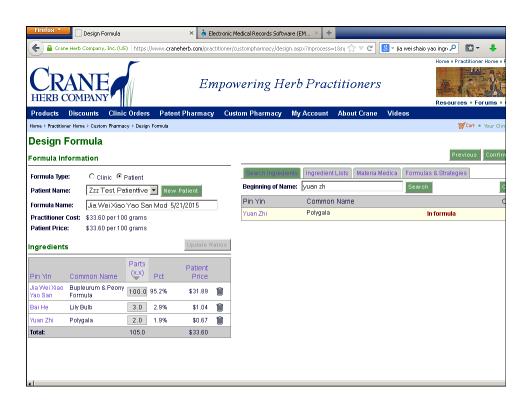


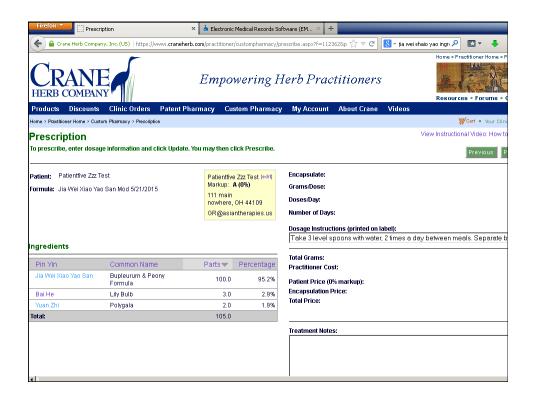




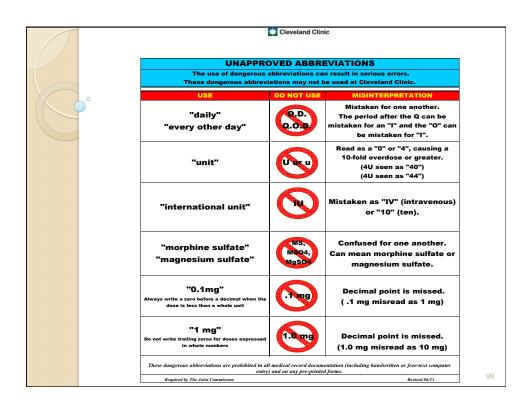


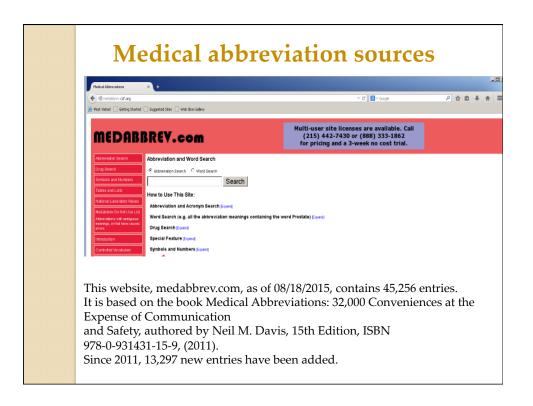


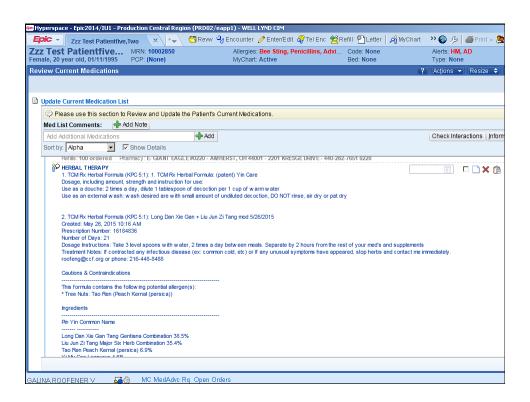


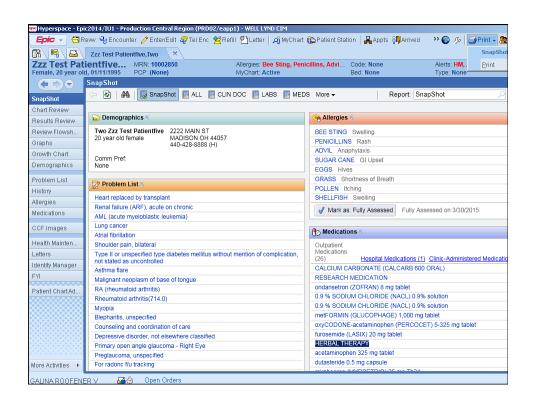


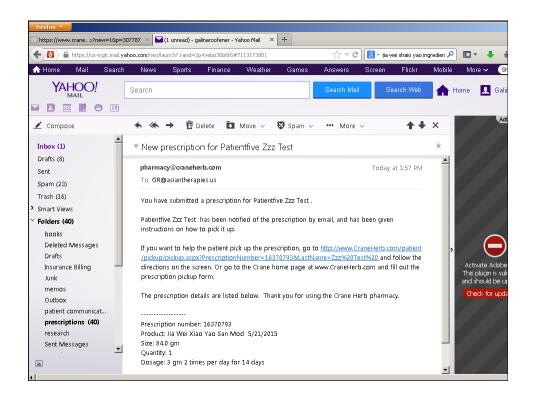


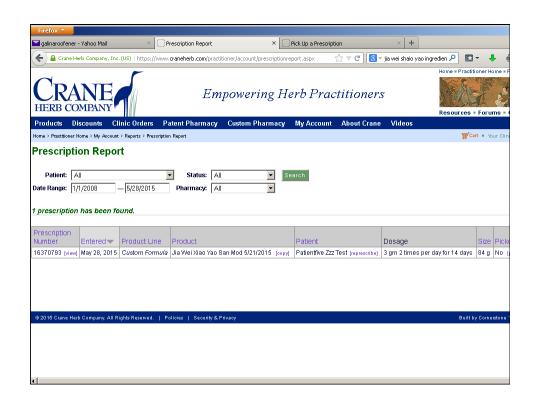


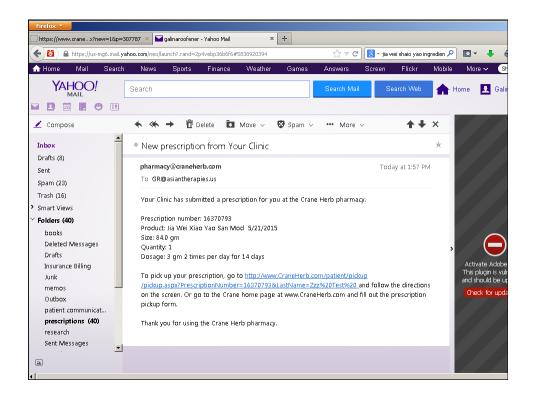


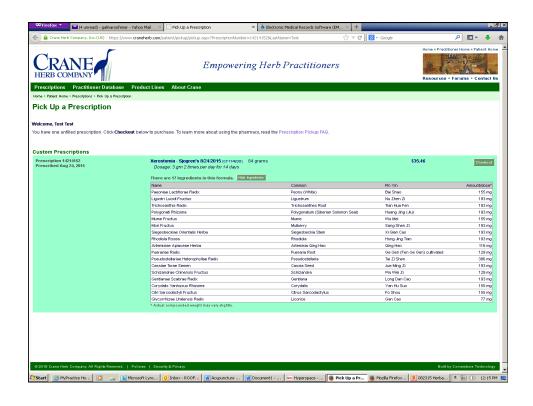


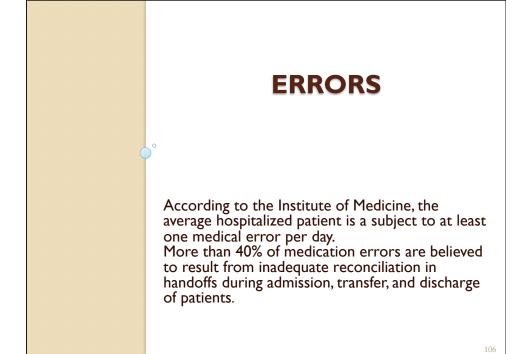












Annie

I am so sorry being a pain in your rear end I have med students non-stop shadowing me for last few weeks, today I have 3!! they distract me tremendously. So I try to double check myself on my lunch break, and of course I make mistakes Please delete the following prescription I will resubmit the correct one

Thank you so much GR

----Original Message-----

From: pharmacy@craneherb.com [mailto:pharmacy@craneherb.com]

Sent: Thursday, May 14, 2015 11:29 AM

To: Roofener, Galina

Subject: New prescription for ZZZZ

ZZZZ has been notified of the prescription by email, and has been given instructions on how to

If you want to help the patient pick up the prescription, go to

http://www.CraneHerb.com/patient/pickup/pickup.aspx?
PrescriptionNumber=14968052&LastName=ZZZZ and follow the directions on the screen. Or go to the Crane home page at www.CraneHerb.com and fill out the prescription pickup form. The prescription details are listed below. Thank you for using the Crane Herb pharmacy.

Prescription number: 14968052

Product: Huang Lian Jie Du Tang mod 5/14/2015

Size: 50.0 gm Quantity: 1

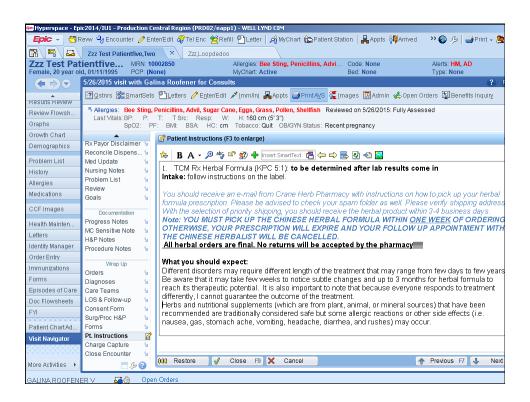
Dosage: 1 gm 2 times per day for 25 days

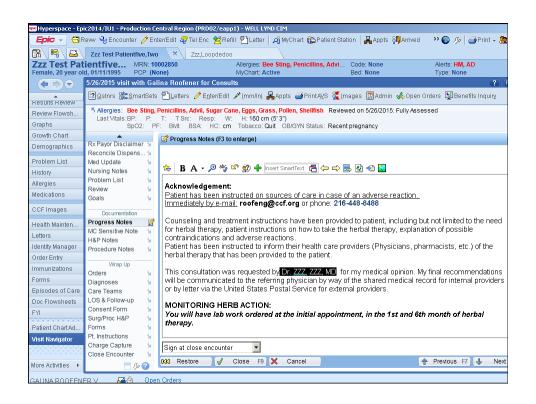
COMMUNICATION WITH THE PATIENT

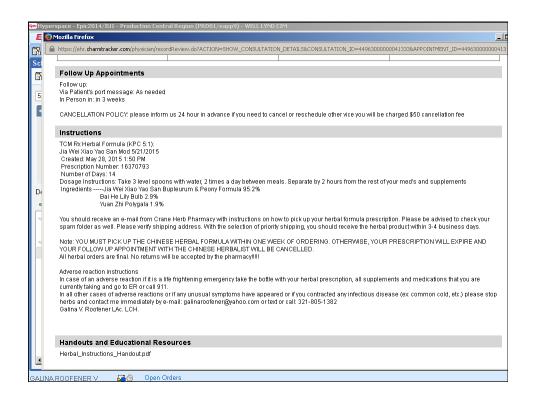
Patient's after visit summary and follow up communication.

Ohio Law

- (E) In an individual's practice of oriental medicine by using herbal therapy in the treatment of a patient, all of the following apply:
- (I) The oriental medicine practitioner shall provide to the patient counseling and treatment instructions. The treatment instructions shall do all of the following:
- (a) Explain the need for herbal therapy;
- (b) Instruct the patient how to take the herbal therapy;
- (c) Explain possible contraindications to the herbal therapy and provide sources of care in case of an adverse reaction;
- (d) Instruct the patient to inform the patient's other health care providers, including the patient's pharmacist, of the herbal therapy that has been provided to the patient.







What you should expect while taking Chinese herbs

Different disorders may require different length of the treatment that may range from few days to few years. Be aware that it may take few weeks to notice subtle changes and up to 3 months for herbal formula to reach its therapeutic potential. It is also important to note that because everyone responds to treatment differently, I cannot guarantee the outcome of the treatment.

Herbs and nutritional supplements (which are from plant, animal, or mineral sources) that have been recommended are traditionally considered safe but some allergic reactions or other side effects (i.e. nausea, gas, stomach ache, vomiting, headache, diarrhea, and rushes) may occur.

Please be advised do NOT buy any herbal supplements at the health food store or Internet without prior consultation with me d/t potential interaction with prescribed Chinese Herbal formula or the rest of your medication and supplements. As well quality of herbal products purchased outside of Asian Therapies Acupuncture Clinic may be questionable. We use Herbal products produced by most reputable manufactures in the world. Our products are compliant with FDA and extensively monitored for quality.

Acknowledgement

Counseling and treatment instructions have been provided to patient, including but not limited to the need for herbal therapy, patient instructions on how to take the herbal therapy, explanation of possible contraindications and adverse reactions.

Patient has been instructed to inform their health care providers (Physicians, pharmacists, etc.) of the herbal therapy that has been provided to the patient

Adverse reaction instructions

In case of an adverse reaction if it is a life-frightening emergency take the bottle with your herbal prescription, all supplements and medications that you are currently taking and go to ER or call 911. In all other cases of adverse reactions or if any unusual symptoms have appeared

or if you contracted any infectious disease (ex: common cold, etc.) please stop herbs and contact me immediately. by e-mail: <u>GR@AsianTherapies.us</u> or text or call: <u>321-805-1382</u>

Sincerely

Galina V. Roofener L.Ac., L.C.H.

113

Guide to Privacy and Security of Electronic Health Information. Version 2.0 .April 2015.

Email and Texting

- In this environment of more online access and great demand by consumers for near real-time communications, you should be careful to use a communications mechanism that allows you to implement the appropriate Security Rule safeguards, such as an <u>email system that</u> <u>encrypts messages or requires patient login, as with a patient portal.</u>
- If you use an EHR system that is certified under ONC's 2014
 Certification Rule, your EHR should have the capability of allowing
 your patients to communicate with your office through the office's
 secure patient portal.65
- You might want to avoid other types of online or electronic communication (e.g., texting) unless you first confirm that the communication method meets, or is exempt from, the Security Rule.66

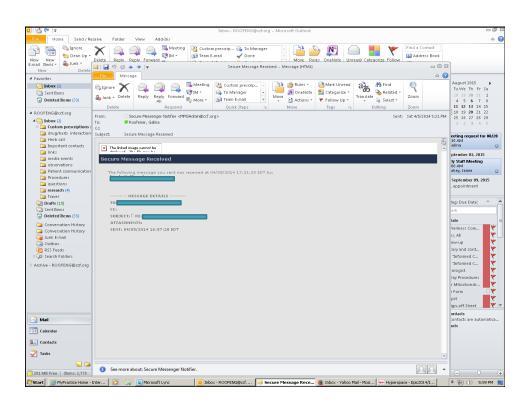
www.healthit.gov/.../files/pdf/privacy/privacy-and-security-guide.pdf

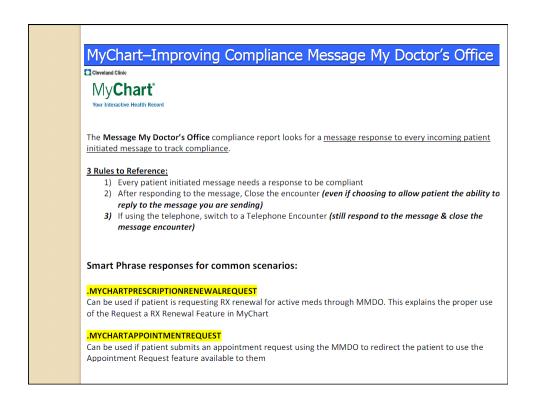
Guide to Privacy and Security of Electronic Health Information. Version 2.0 .April 2015.

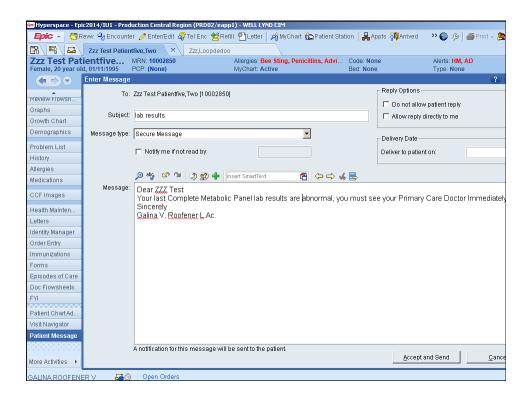
Email and Texting

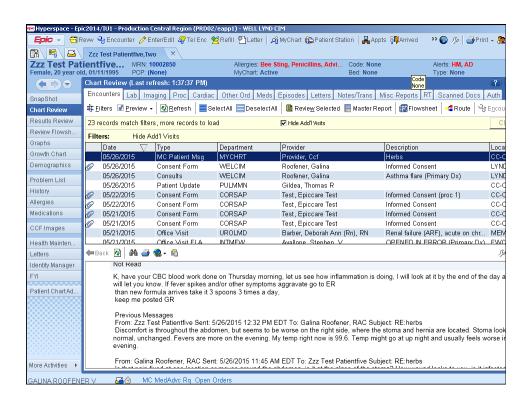
- Consumers increasingly want to communicate electronically with their providers through email or texting.
- The Security Rule requires that when you send ePHI to your patient, you send it through a secure method and that you have a reasonable belief that it will be delivered to the intended recipient.
- The Security Rule, however, does not apply to the patient. A
 patient may send health information to you using email or
 texting that is not secure. That health information becomes
 protected by the HIPAA Rules when you receive it.

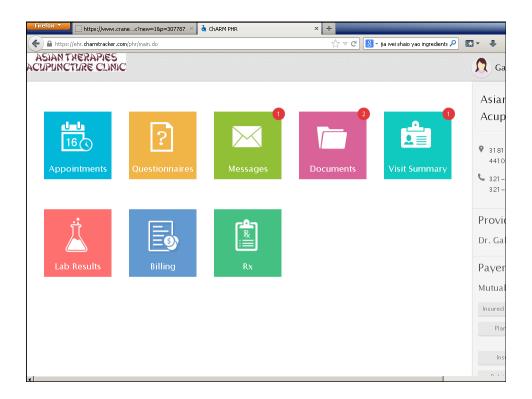
www.healthit.gov/.../files/pdf/privacy/privacy-and-security-guide.pdf

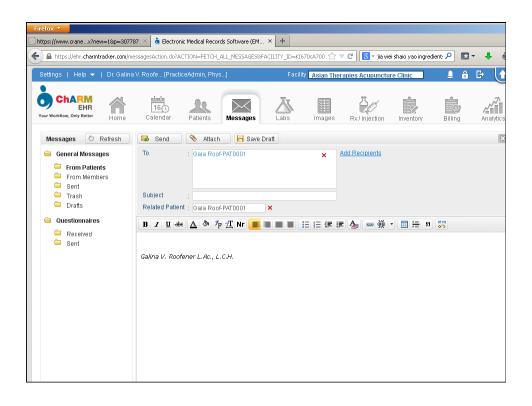


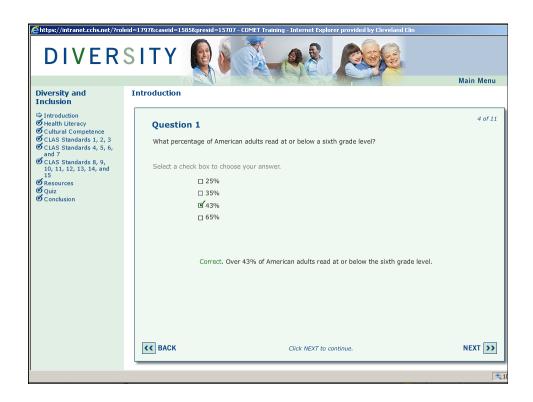














Short-term clinical observation on compound *Xiatianwu* combined with methotrexate in treating rheumatoid arthritis.

Zhao SS¹, Wang J. Dongyang Hospital Affiliated to Wenzhou Medical College, Dongyang 322100, China. zssay2005@sina.com

OBJECTIVE: To observe the short-term clinical efficacy of compound Xiatianwu combined with methotrexate (MTX) in treating rheumatoid arthritis.

METHOD: One hundred and four patients with rheumatoid arthritis were randomly divided into two groups: 64 cases in the combined treatment group who was treated with compound Xiatianwu combined with MTX, and the remaining 40 cases in the control group which was only treated with MTX. The changes in ACR20, ACR50, ACR70 and laboratory indexes including anti-cyclic citrulline polypeptide, rheumatoid factor, erythrocyte sedimentation rate, high sensitivity creative protein were compared before and after treatment. Adverse reactions in the two groups were observed as well

Treating rheumatoid arthritis patients of Shen deficiency and cold invading syndrome by bushen quhan zhiwang decoction combined methotrexate: an evaluation of clinical efficacy and safety.

Wang JM¹, <u>Tao QW, Zhang YZ, Xu Y,</u>
<u>Yan XP.</u> TCM Rheumatology, China-Japan
Friendship Hospital, Beijing 100029, China.

OBJECTIVE: To evaluate the clinical efficacy and safety of bushen quhan zhiwang decoction (BQZD) combined methotrexate (MTX) in treating rheumatoid arthritis (RA).

METHODS: A prospective, randomized controlled study was carried out. RA patients of Shen deficiency and cold invading syndrome in the treatment group (120 cases) were treated with BQZD and MTX (10 mg/week), while those in the control group (120 cases) were treated with MTX (10 mg/week) alone. The therapeutic course for all was 24 weeks.

A one-year evaluation of radiographic progression in patients with Rheumatoid Arthritis treated by *Qingre Huoxue Decoction*.

Jiang Q1, Zhou XY, Wang L, Yu W, Wang P, Cao W, Tang. 1School of Rehabilitation Medicine, Fujian University of Traditional Chinese Medicine, Fuzhou, 350003, China.

OBJECTIVE: To investigate the effects of Qingre Huoxue Decoction , clearing heat and promoting blood flow; QRHXD), on the radiographic progression in patients with rheumatoid arthritis (RA) by X-ray imaging.

METHODS: Eighty-six patients with active RA diagnosed as dampheat and blood stasis

Syndrome were randomized into a QRHXD group and a QRHXD plus methotrexate (MTX) group, with 43 cases in each group. After one-year of treatment, 21 cases in each group (42 in total) were evaluated.

Proposed Herbal Medicine Item Descriptor

- · Chinese Character name for each herbal ingredient and the formula
- Pinyin name for each herbal ingredient and the formula
- · Latin binomial name for each herbal ingredient and the formula
- The part(s) of plant used to produce the product or extract
- The type of product used [e.g., raw (fresh or dry)
- Extract concentration (e.g. 5:1)
- · Amount of each ingredient
- The type and concentration of extraction solvent used (e.g., 80% ethanol, 100% H2O, 90% glycerin) and the herbal drug to extract ratio
- List of inactive ingredients (e.g. fillers and carriers (e.g. granules carrier potato starch non-GMO)
- Allergy warning
- Lot #
- Expiration date
- The name of the manufacturer of the product.

FUTURE

Universal data – base

of herbal formula side effects, drug - herb interactions and adverse effects based on research & clinical observation

