Herbal Interventions in Primary Care

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Speaker

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Disclosure

- No financial interests
- No conflicting affiliation

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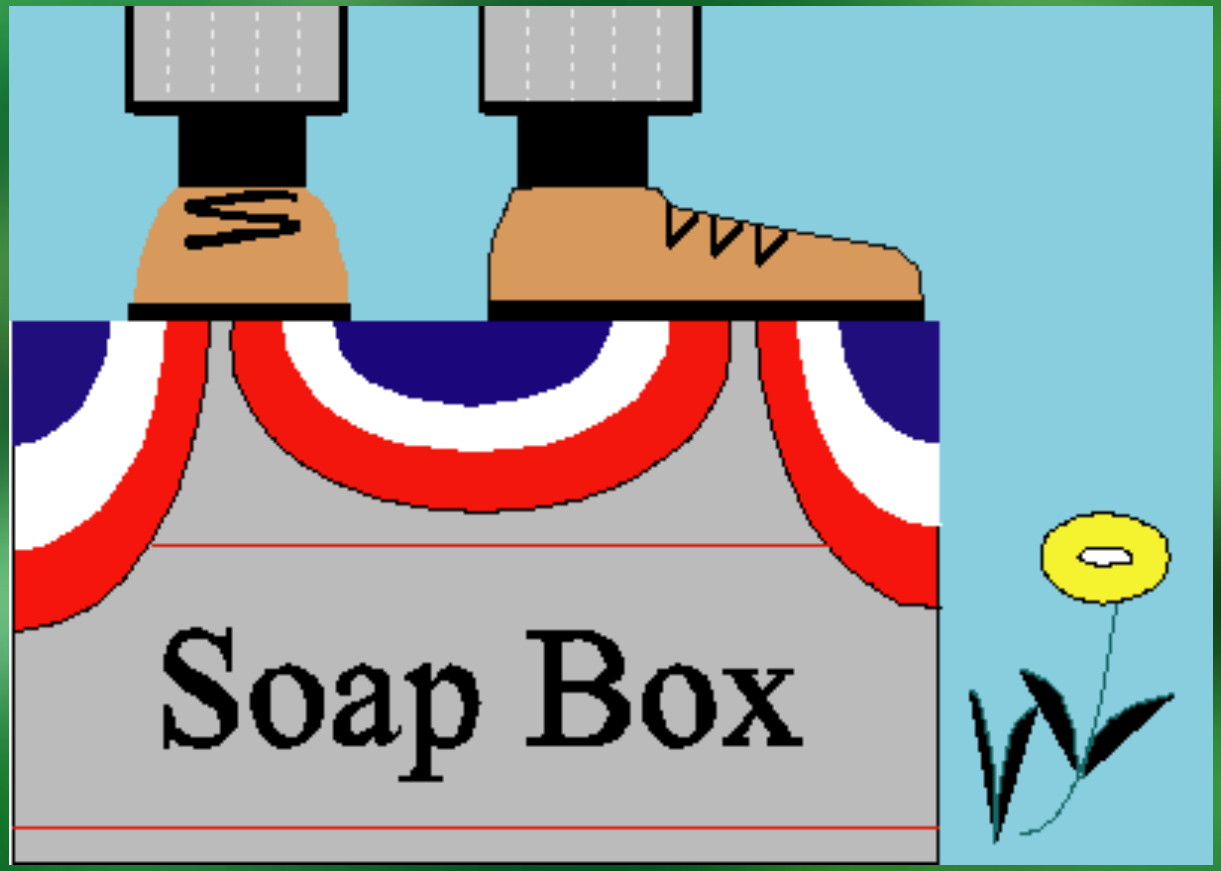
Context



Courtesy of AccurateDemocracy.com

Need for a Paradigm Shift

- The current model of medical diagnosis and treatment to successfully address the chronic disease burden in our society is failing (Hyman, (2004).The end of "Normal Science" in medicine. *Alternative Therapies,10(5)*.

Broken Model

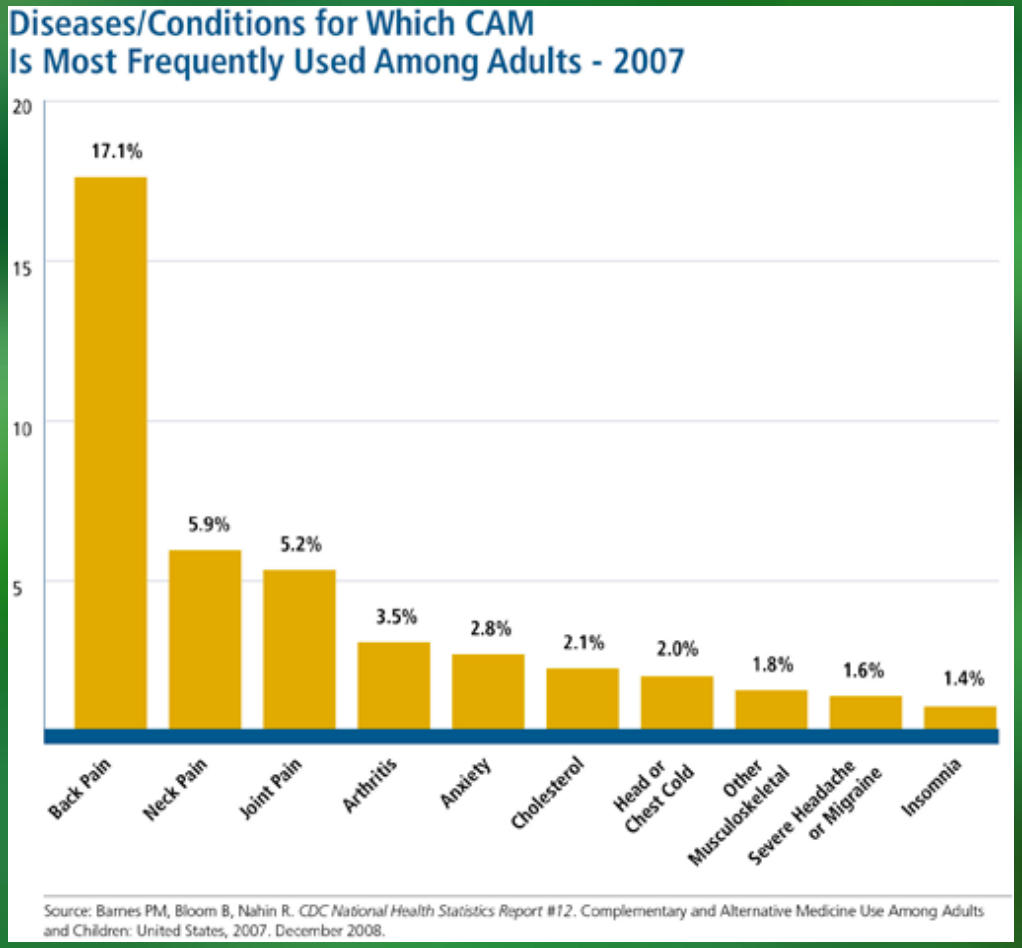
- Current Model is WRONG
  - **Acute Based**-Patients receive only 55% of recommended chronic and preventive services
  - (Ann. Fam Med. September/October 2012 vol. 10 no. 5 396-400)
  - **Symptom Focused**
  - **Reductionist**
  - **Diagnosis** has becomes the focus, not the Person
- Treats the **Branches** not Roots: From Annals of Family Medicine (September/October 2012 vol. 10 no. 5 396-400)
  - *One-half of US adults have at least 1 chronic condition*
  - *Fifty percent of people with hypertension have uncontrolled blood pressures*
  - *More than 80% of people with hyperlipidemia have not attained cholesterol control*
  - *43% of people with diagnosed diabetes have not achieved glycemic control*

Broken Model

- According to the CDC & National Center for Health Statistics the United States is experiencing a trend in increased healthcare utilization
  - This increase is a direct result of the aging population.
- On average, people have four visits to a provider per year
  - with 50% having multiple conditions.
- The five most common conditions, in order, are: hypertension, arthritis, hyperlipidemia, diabetes, and depression.
- Additionally, 70% of visits to physicians, outpatient providers, or hospitals resulted in at least one drug being prescribed.

Patient Driven Care

- Direct Correlation (NCCAM, 2000; CDC, 2008).
- Indirect associations



Polypharmacy

- Multimorbidity (presence of 2 or more conditions) is now the average

- In a retrospective review of 980 records from 21 family practice offices, it was found that 90% of patients had at least one chronic condition. The prevalence of multimorbidity was as high as 68% in the 18-44 year old age range and increased with age for both men and women to 97% and 89% respectively over the age of 65 (Fortin, Bravo, Hudon, Vanasse, & Lapointe, 2005).

- Of particular concern is the management of multiple conditions through **polypharmacy** prescriptions.
  - 1.5 million people in the United States are injured or killed directly related to medication error. Particularly highlighted, was drug to drug interactions that occur when new prescriptions are written (Kaufman, 2006).

Most common Rx

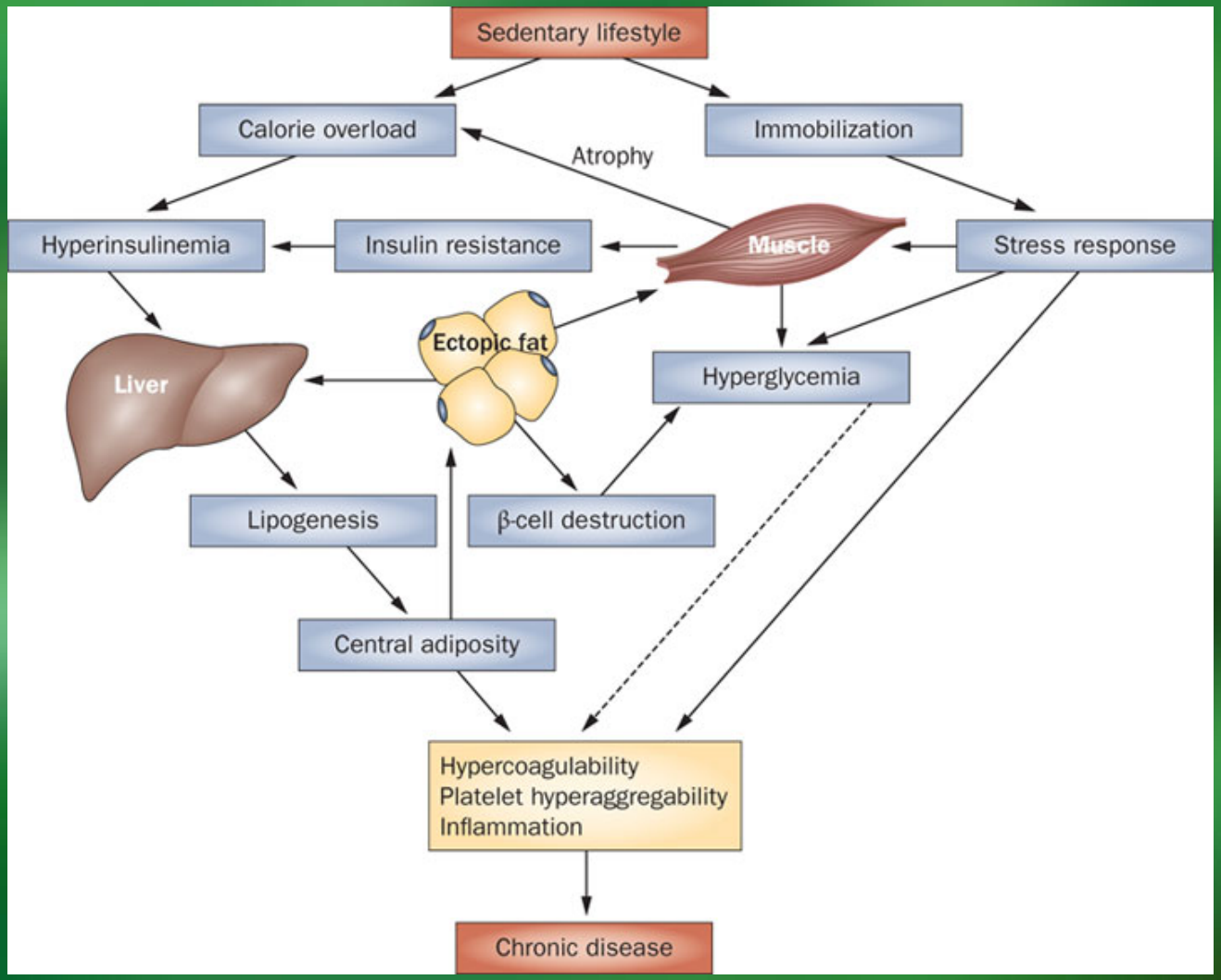
- www.theatlantic.com, April 2011

Drug	Prescriptions (millions)	Condition
Vicodin	131.2	Pain
Zocor	94.1	High cholesterol
Lisinopril	87.4	High blood pressure
Synthroid	70.5	Hypothyroid
Norvasc	57.2	High blood pressure
Prilosec	53.4	Acid reflux
Zithromax	52.6	Bacterial infection
Amoxicillin	52.3	Bacterial infection
Metformin	48.3	Diabetes
Hydrochlorothiazide	47.8	High blood pressure
Xanax	46.3	Anxiety
Lipitor	45.3	High cholesterol
Furosemide	43.4	High blood pressure
Metoprolol tartrate	38.9	High blood pressure
Ambien	38.0	Insomnia

Implication

- Majority of medications are related to poor cardiometabolic profiles
  - Metabolic syndrome
- Argument can be made for nutrient depletion, chronic stress
  - Depression
  - Anxiety
  - Sleep disturbance
- Argument can be made for lifestyle induced immune alteration
  - Epidemic rates autoimmunity
  - Food sensitivities & response GMO
  - Lingering pathogens-chronic infections: altered microbiome
- Further case can be made for xenobiotic burden
  - Neuroendocrine disruption
  - Hormonal imbalance
- **All these conditions have modifiable factors**

Lifestyle Biochemistry



Nature Reviews Cardiology **7**, 468-472 (August 2010) | doi:10.1038/nrcardio.2010.68

My Rx will save me …
My Dr. says herbs are dangerous, don't work etc….

Choosing Wisely®

An initiative of the ABIM Foundation

The American College of Medical Toxicology and
The American Academy of Clinical Toxicology

Five Things Physicians and Patients Should Question

1 Don't use homeopathic medications, non-vitamin dietary supplements or herbal supplements as treatments for disease or preventive health measures.

Alternative therapies are often assumed safe and effective just because they are "natural." There is a lack of stringent quality control of the ingredients present in many herbal and dietary supplements. Reliable evidence that these products are effective is often lacking, but substantial evidence exists that they may produce harm. Indirect health risks also occur when these products delay or replace more effective forms of treatment or when they compromise the efficacy of conventional medicines.

Low Risk DHI

- A review of the literature demonstrated that beliefs about herb–drug interactions are mainly **theoretical** considerations, and not **clinically** observed facts.
  - Herb–drug interactions do occur but, equally, common foods such as broccoli, grapefruit juice, alcohol, and cigarette smoking may cause interactions (Butterweck V, Derendorf H, Gaus W, Nahrstedt A, Schulz V, Unger M. Pharmacokinetic herb-drug interactions: are preventive screenings necessary and appropriate? *Planta Med*2004;70:784–91)
- A review of devil's claw, ginkgo, and garlic RE: antiplatelet or anticoagulant effects, potentially exacerbating the risk of gastrointestinal bleeding from non-steroidal anti-inflammatory drugs or corticosteroids.
  - No direct evidence supports these claims (*Ann Rheum Dis* 2005;**64**:1527-1528)

Cautions

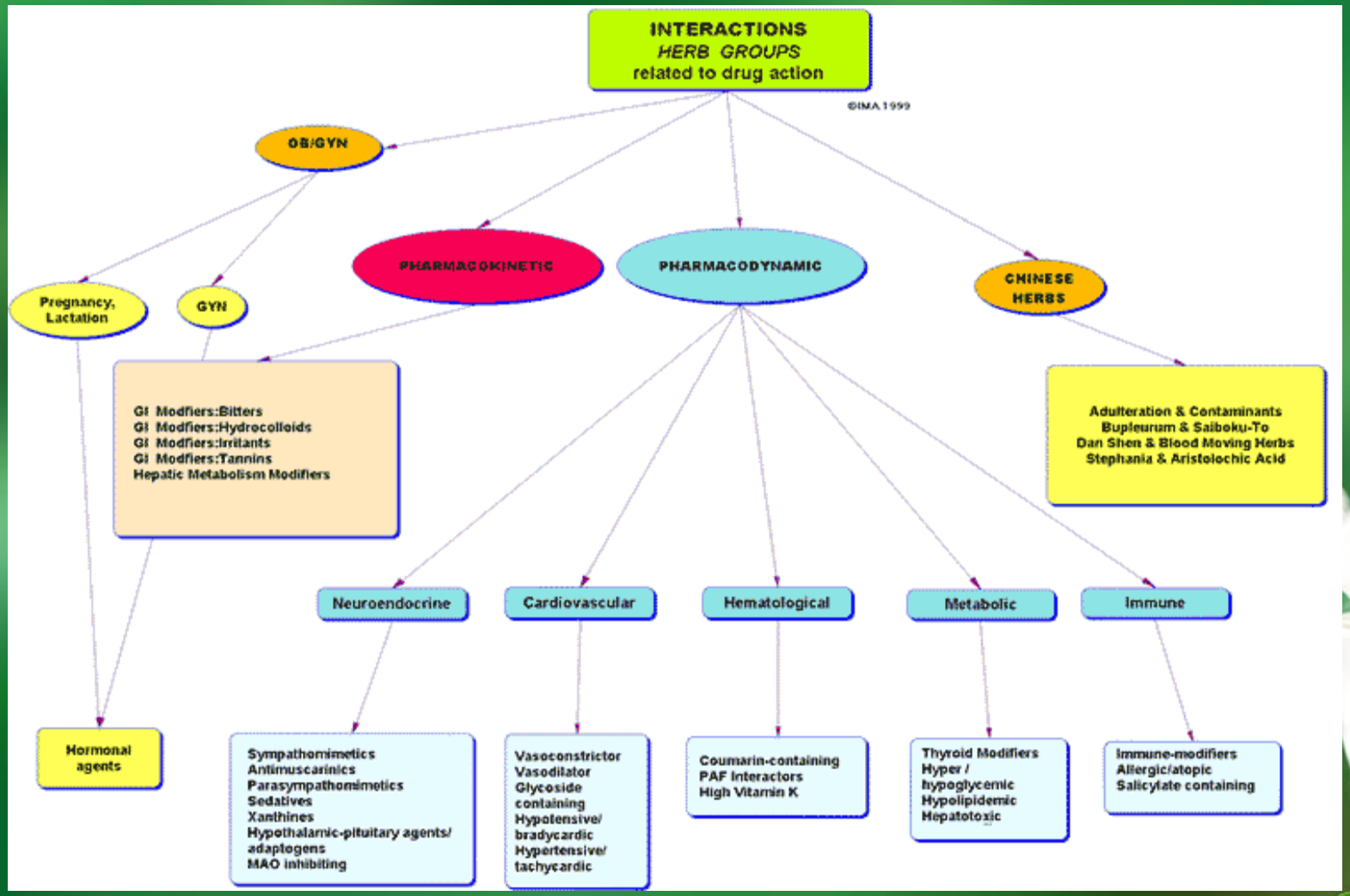
- **General Interactions**
- „ Anticoagulants / Antiplatelets
- „ Diuretics
- „ Antidiabetics
- „ Sedatives / Hypnotics
- CYP upregulators/inhibitors

Courtesy of www.pointofreturn.com

Resources:

- University of Michigan Drug-herb Interaction Summary
  - www-personal.umich.edu/~mshlafer/Lectures/herbdrug.pdf
- Database by Mitch Stargrove, ND
  - www.interactionssguide.com
- Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategie
  - Mitchell Stragrove, ND, L.Ac; Jonathan Treasure MA MNIMH, RH (AHG), MCPP; D ght L. McKee MD
- Indiana University Cytochrome P450 Interaction Table
  - http://medicine.iupui.edu/clinpharm/ddis/

Considerations



Cautions

- Herbs with **anticoagulant** effects: Caution w/ antiplatelet drugs
- „ Dan Shen (Radix **Salviae** Miltiorrhizae)
- „ Dang Gui (Radicis **Angelicae** Sinensis)
- „ Chuan Xiong (Rhizoma **Ligustici** Chuanxiong)
- „ Tao Ren (Semen Persicae)
- „ Hong Hua (Flos **Carthami**)
- „ Shui Zhi (Hirudo)

Chen and Chen. Chinese Medical Herbology and Pharmacology. „ 2004

Cautions

- **Antidiabetic** herbs: Use with caution with antidiabetic drugs
  - Zhi Mu (Radix Anemarrhenae)
  - Shi Gao (Gypsum Fibrosum)
  - Xuan Shen (Radix Scrophulariae)
  - Cang Zhu (Rhizoma **Atractylodis**)
  - „ Huang Qi (Radix **Astragali**)
  - Shan Yao (Rhizoma **Dioscoreae**)

Chen and Chen. Chinese Medical Herbology and Pharmacology. „ 2004

„

Cautions

- Sedatives & nervines / Herbs that calm shen (spirit)
  - often potentiates the sedative effect of sedative / hypnotic drugs.
- Many categories of drugs induce sedation
  - antihistamines, narcotic analgesics, barbiturates, benzodiazepines

Chen and Chen. Chinese Medical Herbology and Pharmacology. „ 2004

Commensurable reframing

- Three main models of "integrated medicine" exist:
  - The "**founding approach**" which trains conventional providers in CAM
    - Green Allopathy > coincides with EBM
  - "**architectural approach**" practice model of putting various providers in one space, but keeping them separate
  - "**collaborative model**" whereby conventional and CAM providers see the same patient and work together to develop an individualized treatment plan

(McCloud, 2008)

- All theories need to have a framework in order to be implemented.
  - Framing is both descriptive, when and how to use it, as well as predictive, describing why to use it
  - Current model is "framed" by "Evidence"
- **Herbs in primary care must be properly framed within the existing model**

The Ideal

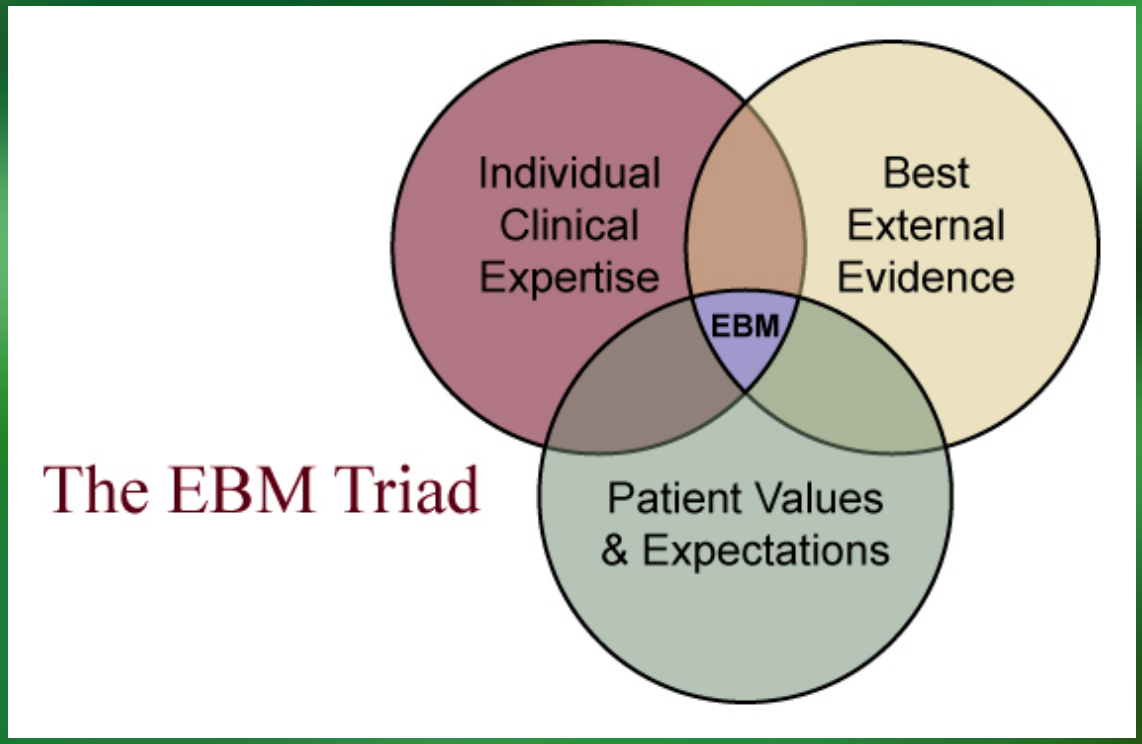
- Most current "integrated" models are architectural rather than collaborative or "adaptive"
- Requires an "adaptive model", the blending of incommensurable models into each other in order to create a commensurable model (Kleronomos, 2007)
  - Language & Framing

Question: Is an adaptive model practical given current parameters?

- Education
- Access and Billing
- Infrastructure retooling
- New research models

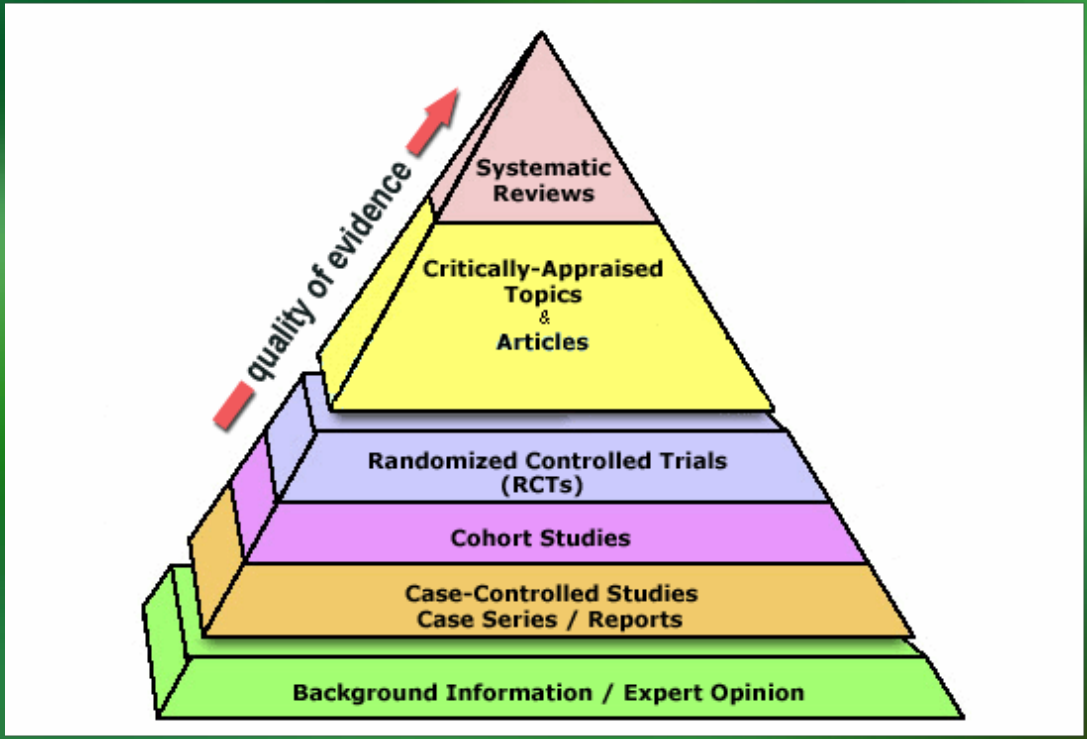
Evidenced Based Medicine

- Evidence-based medicine is a systematic approach to clinical problem solving which allows the integration of the best available **research** evidence with clinical **expertise** and **patient values**.
  (Sackett DL, Strauss SE, Richardson WS,et al. Evidence-based medicine: how to practice and teach EBM. London: Churchill-Livingstone,2000)



Is EBM/P Rationale or profitable?

- Current form considered best practice ignores key principles
- Establishes standard of care (Western/Biomedical)
- Heavily influenced & biased
- Has medical-legal connotations
- Drives reimbursement



(MD Anderson Clinical Research Library)

Bias=$$$

JAMA®
The Journal of the American Medical Association

- Bias toward the publication of positive results.
- Positive results more likely to be published, but studies that were not positive, "were often published in a way that conveyed a positive outcome."
- For example: Literature suggests that 67% of antidepressant trials have positive results
    - Stahl (2008)
  - Actual number of remission rates is closer to 27%, and only with multiple changes in antidepressants over time.
- Madhukar, et al (2006)
  - Clinical expectation is 30-50% improvement over 3-6 month

Problems with an Adaptive Model

- Evidence is only considered evidence if it has been studied in the appropriate manner.
- Reviewing evidence is critical
  - current philosophical bias towards a pharmaceutical-based model
- Current best practice principles utilizes a system whereby western biomedical research is valued, while simultaneously devaluing traditional models (Porter & O'Halloran, 2009)

Makes integration of herbal medicine into primary care difficult

Problems with an Adaptive Model

- Three factors that become problematic when evaluating traditional medical evidence: **Language & Framing**
  - Western scientific method is designed to measure single variables in relation to outcome.
    - This is the drug-based, or pharmaceutical model used in EBM
  - Definitions pose a unique problem for CAM. The scientific method cannot be used to measure things which have yet to be physically defined by western science.
    - "Qi", "Prana" or "*Vis*", "Yin" and "Yang", "Vatta", "Kapha" and "Pita"
  - Outcome in traditional medicine are typically determined by empirical, rather than experimental diagnostic measures

What is Science?

"Those who control access to funding and the channels of scientific communication tend to be believers in the established views."

– RD Laing

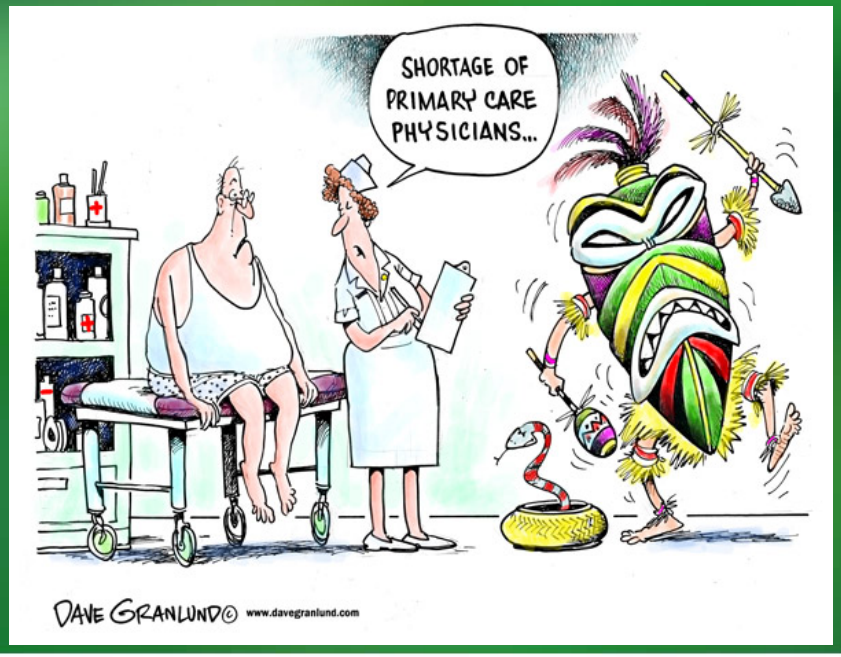
"There are three kinds of lies: lies, damned lies and statistics."

- Leonard H. Courtney, (1832-1918), & *Mark Twain's Own Autobiography: The Chapters from the North American Review*

Now What?

Question: How do you incorporate herbs into primary care?

- Incommensurable models of care and delivery
- Conflict with established standard of care
- Shortage of primary care physicians even inclusive of naturopaths
- Cost and access i.e coverage
- Consider societal level intervention
  - **Philosophy versus practical**




GUERRILLA
WARFARE

Where & How to intervene

Given current parameters

- Advocating **GREEN ALLOPATHY**
  - Frame Herbs within EBM model
  - Recognizing -Short term solution
  - Designed for the "Bell Curve"
- Target most relevant conditions
  - Cardiometabolic & Pain
- Decrease polypharmacy
  - Harm reduction
- Create Opportunity for change & teaching- holistic models

Green Allopathy

- Integration of CAM therapies offers a validated means of providing adjunctive care, thereby improving outcomes, as well as increasing the safety margin of multimorbidity management by decreasing polypharmacy use.
- In less complex conditions, it is possible to replace prescription drugs with safe, proven CAM alternatives. This can potentially decrease overall morbidity, improve quality of life, and allow providers to lower dosage and decrease polypharmacy

(Kleronomos, 2007)

What do you know?

How do you know that?

Claim + Evidence
+ Reasoning = Explanation

Why does your evidence support your claim?

Evidence Rubric and Sources

- Evidence grading systems were utilized to focus the literature review
  - *Natural Standard evidence-based validated grading rationale™*
    - A Jadad score of 0-5 is given, with 5 being the highest quality
  - *Healthnotes™*
    - Rating scale from 1 to 3 stars. Three stars indicate that the evidence for that treatment is based on "Reliable and relatively consistent scientific data showing a substantial health benefit
  - *Rakel's Evidence versus Harm Scale©*
    - Strength of Recommendation Taxonomy (SORT)
      - Evidence of benefit is graded from A to C
      - Potential harm of a therapy is graded from 1 (little or no risk of harm) to 3 (potential to result in death or permanent disability).
  - *German Commission E Monographs*
    - Federal multidisciplinary commission
    - Reviews and analyzes available data, to form clinical recommendations
  - Natural medicine Comprehensive Database
    - Critical Appraisal of literature: relevance, validity and consistency
      - Lists effective, possible, ineffective, and insufficient. Level and A-C for Quality
  - American Botanical Council
    - Advisory council of experts look at evidence- modern scientific and traditional
      - Not a true evidence-graded system

Nutrition

Many common **drugs known to cause nutrient deficiencies**

- Diuretics= hyponatremia, magnesium deficiency
- Metformin, Insulin = B1, B12, Magnesium
- Statins= CoQ10
- H2 Blockers= Iron, Vit C
- Tylenol, ASA, NSAID's= Vit C, Glutathione, Iron, Folic acid
- ABX= multiple, particular B's and GI microflora

(http://naturaldatabase.therapeuticresearch.com/ce/ceCourse.aspx?pc=08-40&cec=0&pm=5)

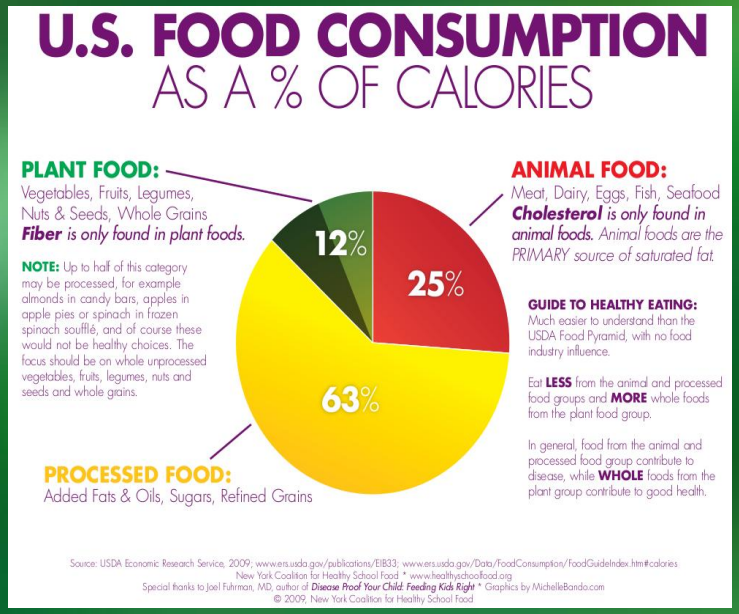
Other:

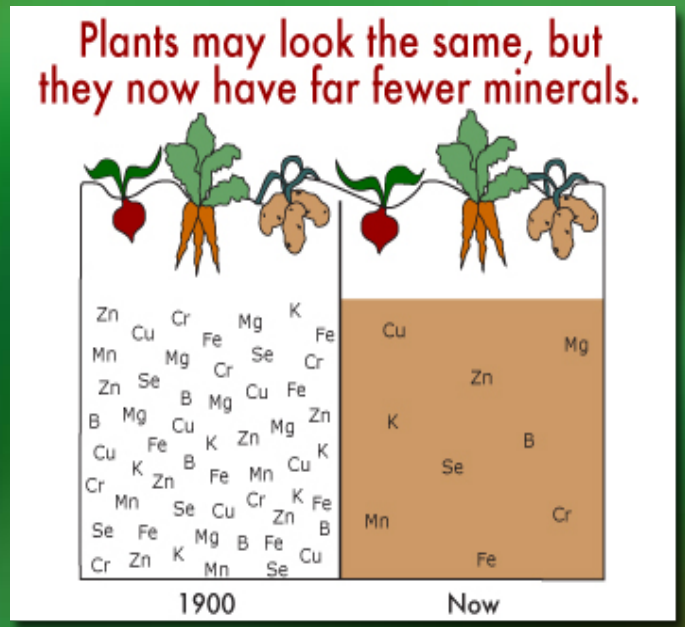
- Vitamin D secondary to geography, lack of exposure
- Calcium secondary to Vit D Def & Magnesium deficiency

Nutrition

Most Common Nutrition deficiencies in the USA:

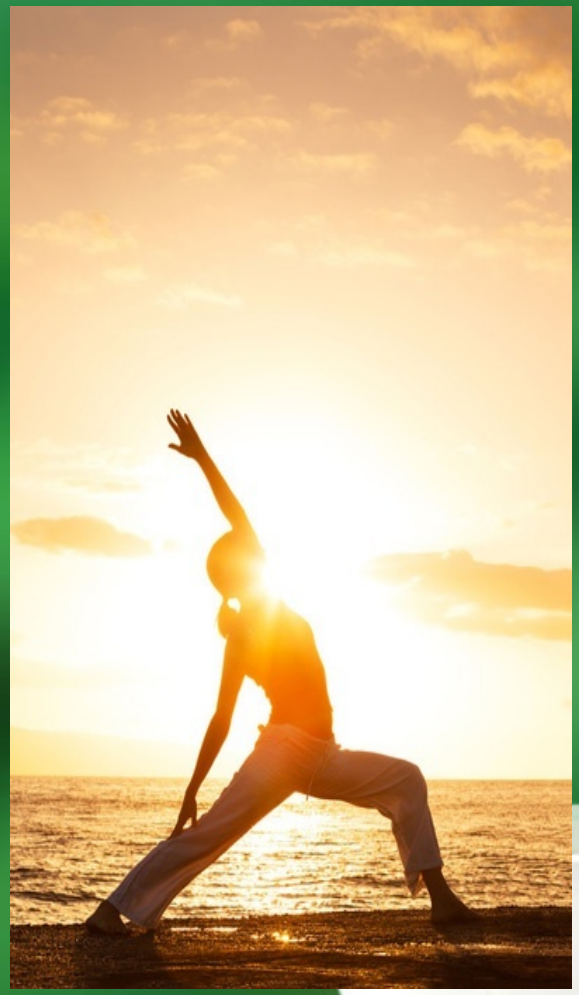
- Iron defiency (*Am Fam Physician.* 2007 Mar 1;75(5):671-678.)
- Calcium (http://www.accessscience.com/studycenter.aspx?main=13&questionID=5438)
- Vit D (Nutr Res. 2011 Jan;31(1):48-54. doi: 10.1016/j.nutres.2010.12.001.)
- B Vitamins





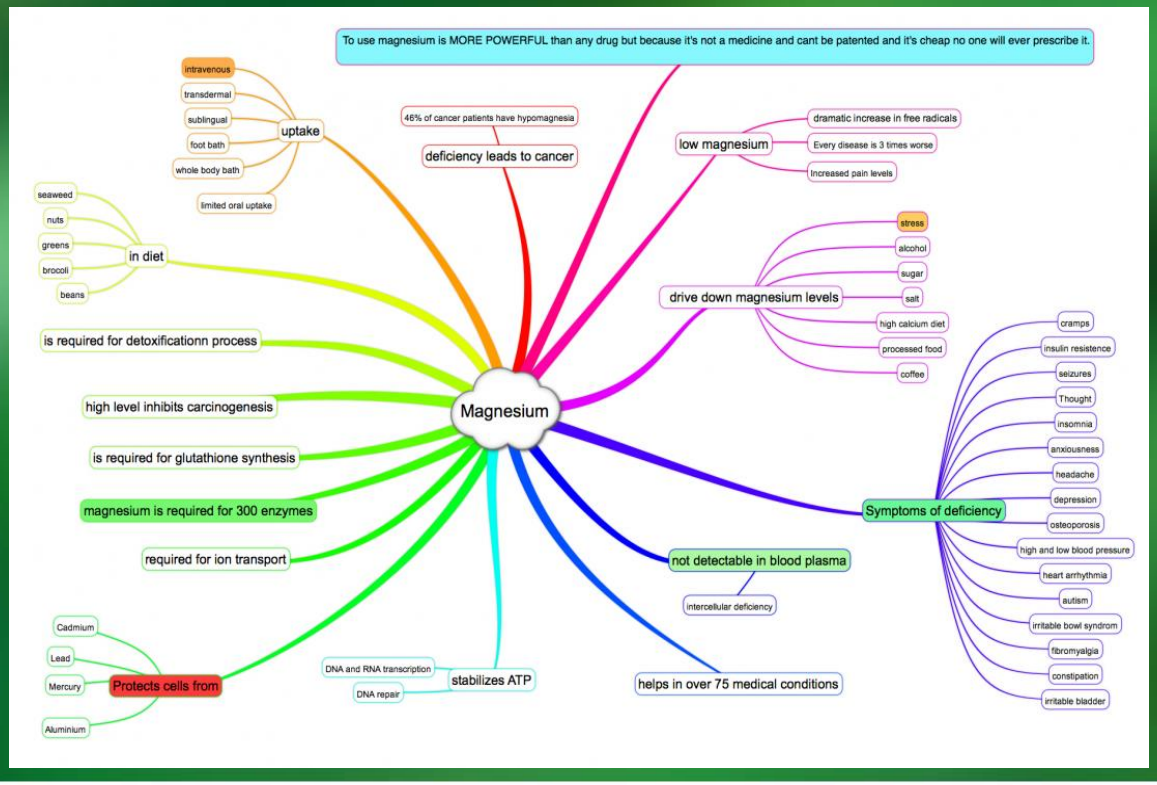
Reasonable start- clinical Basics

- Initiate **dietary** discussion
  - Modified Paleo- Mediterranean-anti-inflammatory
    - Increased veggies
    - Low CHO/Low glycemic, Grains vs. Gluten free???
    - Non-GMO
    - Animal Protein???
- Initiate **exercise** or activity program / discussion
- **Evaluate** for common nutrient deficiencies & drug induced depletions
  - 27,000 calories to meet all of the RDIs for micronutrients (http://www.jissn.com/content/pdf/1550-2783-7-24.pdf Research article Prevalence of micronutrient deficiency in popular diet plans -Jayson B Calton)
  - Metformin inhibits B12, Statins deplete CoQ10



Reasonable start- Clinical Basics

- **Supplements**:
  - Whole Food **Multi-vitamin** daily or Medical Food shake
  - Vit **D3** 4000IU daily
  - Mixed **fatty Acids** (EPA/DHA/GLA)
  - **Probiotics**
    - Kombucha etc.
  - **B-complex** (active forms)
  - **Magnesium**
  - **CoQ10**
  - **Green Tea**
  - **Bitters-** healing begins with the Gut / Broad systemic effect
  - **Urine alkalinization-** Standard for toxicity treatment
    - concentrated greens with minerals


To use magnesium is MORE POWERFUL than any drug but because it's not a medicine and cant be patented and it's cheap no one will ever prescribe it.
Magnesium
uptake
intravenous
transdermal
sublingual
foot bath
whole body bath
limited oral uptake
46% of cancer patients have hypomagnesia
deficiency leads to cancer
low magnesium
dramatic increase in free radicals
Every disease is 3 times worse
Increased pain levels
in diet
seaweed
nuts
greens
brocoli
beans
drive down magnesium levels
stress
alcohol
sugar
salt
high calcium diet
processed food
coffee
is required for detoxificationn process
high level inhibits carcinogenesis
is required for glutathione synthesis
magnesium is required for 300 enzymes
required for ion transport
Symptoms of deficiency
cramps
insulin resistence
seizures
Thought
insomnia
anxiousness
headache
depression
osteoporosis
high and low blood pressure
heart arrhythmia
autism
irritable bowl syndrom
fibromyalgia
constipation
irritable bladder
not detectable in blood plasma
intercellular deficiency
helps in over 75 medical conditions
stabilizes ATP
DNA and RNA transcription
DNA repair
Protects cells from
Cadmium
Lead
Mercury
Aluminium


FISH OIL


Ginger
Lemon
Peppercorns
Gentian Extract
Cinnamon
AROMATIC
1895
GENTIAN

"Bitters"

- **Broad physiologic effect on system**
  - Based on physiological function rather than on chemical structure.
    - Largest found among the terpenes- particularly the monoterpene iridoids and secoiridoids, Also sesquiterpene lactones & Alkaloids Flavonoids can be either bitter or sweet
- Bitters can be used for **any atonic condition** of the G.I tract and increase GI mucosal regeneration.
- Anti-inflammatory
- Antimicrobial
- Influences Microbiome

- Generally, bitters are dosed 5-10 drops in an ounce of water sipped slowly 1 minutes before the meal
- Correct dosing of bitters is important:
  - **Smaller** doses seem to stimulate function
  - **Large** doses constrict tissues and decrease secretion.

(Bitters Monograph. Nancy Welliver. 2006)

- Hot vs Cold formulation

"Bitters"

Taste Buds + Bitter

↓

Gastrin

↓

Increases:

- Gastric Acid & Pepsin Production- increase digestive secretions
- Pancreatic Digestive Secretion
- Hepatic Bile Flow-flow increasing the excretion of toxins and stimulating the bowel.
- Bicarbonate Production- protect gut mucosa and counteract stomach acid.
- Brunner's Gland Secretion- protect gut mucosa and counteract stomach acid.
- Intrinsic Factor Secretion
- Insulin, Glucagon, and Calcitonin- an influence on normalizing blood sugars
- Increase muscle tone of the gastro-esophageal sphincter
- Muscle Tone of Stomach and Small Intestine
- Cell Division & Growth of Gastric & Duodenal Mucosa
- Cell Division & Growth of Pancreatic Cells

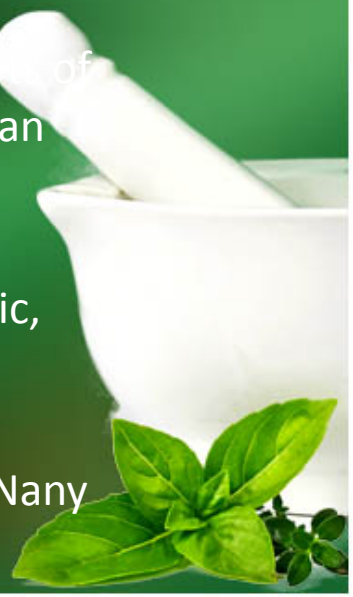
(Simon Mills book Out of the Earth; An Essential Book of Herbal Medicine p.32)

Bitters- Combinations

- Fixed combinations of dandelion root , celandine herb, and Artichoke leaf
  - Spastic epigastric discomfort due to functional disorders of the biliary system - German E Commission Approved (American Botanical Council)
- Digestive Bitters Compound by Herb Pharm Inc (Mixed Formula)
  - Evidence range is effective to insufficient. No evidence of harm. (Natural Medicine Comprehensive Database)
- Fixed Combinations of Peppermint leaf, Caraway seed, and Chamomile
  - Dyspeptic discomfort, especially with mild spasms in the gastrointestinal region, flatulence, and a sensation of fullness- German E Commission Approved (American Botanical Council)

Digestive Herbs- Warm/Hot

- **Zingiberis rhizoma**, ginger root (Pungent)
  - Dyspepsia, prevention of motion sickness
- **Cinnamomi cassiae cortex**, Chinese cinnamon (carminative, antiglycemic, Antimicrobial, anti-inflammatory)- German E Commission Approved (American Botanical Council)
  - Loss of appetite, dyspeptic complaints such as mild spasms of the gastrointestinal tract, bloating, flatulence- German E Commission Approved (American Botanical Council)
- **Millefolii herba**, yarrow herb (Neutral)
  - Loss of appetite, dyspeptic ailments, such as mild, spastic discomfort of the gastrointestinal tract- German E Commission Approved (American Botanical Council)
  - Bitter tonic, astringent, diaphoretic, peripheral vasodilator, anti-inflammatory, styptic, antifungal, antiseptic, anodyne, antispasmodic, menstrual regulator.
  - It soothes the digestive system by relieving muscle spasms in the intestines, promotes the flow of digestive bile (Bastyr Monograph. Nany Welliver 2006)



Digestive Herbs – Cool/Cold

- **Gentianae radix**, gentian root (Bitter, Gastric stimulant, Sialagogue, Cholagogue, Anti-inflammatory)
  - Digestive disorders, such as loss of appetite, fullness, flatulence- German E Commission Approved (American Botanical Council)
  - Hypochlorhydria, Low level depressed states with gastrointestinal complaints, Anemia (Bastyr Monograph. Nany Welliver 2006)
    - Priming effect on the upper digestive system mediated by a nerve reflex from the bitter taste buds (Bastyr Monograph. Nany Welliver 2006)
- **Menthae piperitae aetheroleum**, peppermint oil (Carminative)
  - Spastic discomfort of the upper gastrointestinal tract and bile ducts, irritable colon, catarrhs of the respiratory tract, inflammation of the oral mucosa- German E Commission Approved (American Botanical Council)
- **Taraxaci herba**, dandelion herb (Bitter)
  - Loss of appetite and dyspepsia, such as feeling of fullness and flatulence- German E Commission Approved (American Botanical Council)

Hypertension

- **General**: Studies have linked LOW dietary fiber intake to an INCREASED risk of hypertension
  - 15g Psyllium/d can modestly lower blood pressure after 8 weeks

- **Garlic**:
  - 2 star Evidence *Healthnotes*
  - *German E Commission* Approved
  - Strong Evidence Natural Standards
  - Garlic review for peripheral arterial occlusion was inconclusive (Cochrane database)

Hypertension

- **Pomegranate**
  - Some research shows that pomegranate reduces ACE about 36% (Natural Medicine Comprehensive Database)
  - Grade C Evidence (Natural Standards)
    - No nsignificant effects on overall systolic BP, but significant in subjects with systolic **pre**hypertension.
  - Not E Commission approved for HTN

- **Hawthorne**: cardiovascular tonic with multiple actions
  - 2 star *Healthnotes*
  - B1 evidence *Rakel*
  - *German E Commission* Approved
  - Overall no evidence harm (Yarnell. Crateagus Monograp, 2006)

- **Hibiscus**: Traditional Chinease and Ayurvedic herb
  - Good Scientific Evidence Natural Standards
    - hibiscus standardized extract worked as well as captopril

Hypertension

- **Cacao**
  - Flavonoids contained in chocolate stimulate formation of nitric oxide, increase vasodilation, and reduce endothelial dysfunction (Natural Med Comp Databse)

- **Tea**: population research links consumption of green tea and oolong tea (partially fermented), with a significantly decreased risk of developing hypertension
  - Epigallocatechin gallate (EGCG) and other flavanols in tea have an anti-inflammatory effects and seem to inhibit nitric oxide synthase (Natural Medicine Comprehensive Database)

Hyperlipidemia Intro

- Some researchers think that measuring LDL **particles** or LDL particle size may be more relevant than assessing LDL **cholesterol** levels
- **apolipoprotein B**, also known as apoB.
  - Each LDL particle contains a molecule of apoB.
  - Measuring apoB appears to be a more accurate way to determine total number of LDL particles and risk of adverse cardiovascular outcomes
- New consensus report from the American College of Cardiology Foundation & American Diabetes Association suggests treating to specific targets including ApoB, LDL-C, and non-HDL-C in high-risk patients with metabolic risk factors

- **Note**: Unclear if following evidence is inclusive of this concept

Hyperlipidemia

- **Natural Medicine Comprehensive Database** Likely effective Herbs:
  - **Oats**: modestly reduces total and LDL
    - 3.6-10 grams of beta-glucan, i.e. soluble fiber
  - ***Avena sativa* Medicinal actions:** Antidepressant, nervous system trophorestorative, cardiac tonic
    - Observed to act as a tonic to improve energy of myocardium. (Bastyr Monograph)

  - **Beta Glucans**: meta-analysis of clinical research shows beta glucans (barley) in doses of 3-10 grams/day significantly lowers total and low-density lipoprotein (LDL) over 4-6 weeks of treatment.
    - Did not significantly affect high-density lipoprotein (HDL)
    - Effect of barley on cholesterol is dose dependent

Hyperlipidemia

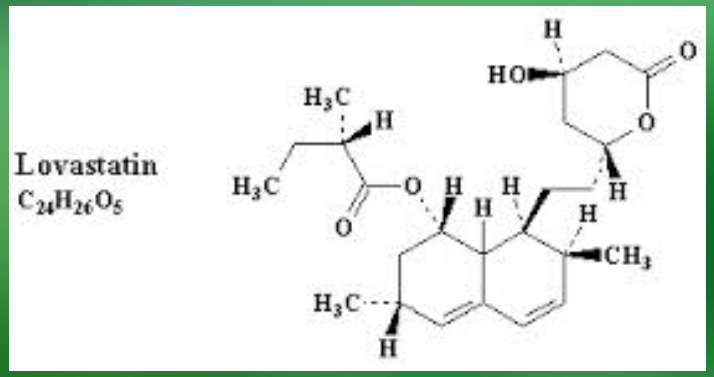
- **Psyllium**: reduces cholesterol mild to moderate hypercholesterolemia.
  - Psyllium seed husk or seed 10-12 grams daily significantly reduces the LDL to high-density lipoprotein (HDL) ratio after 6 months
  - Natural Standards Grade A
  - Health Notes Grade B
  - Level A2 Rakel
  - German E Commission approved as fiber for constipation and diarrhea

- **Garlic**:
  - Natural Standards Grade B
  - Health Notes 2 Stars
  - German E Commission Approved

Hyperlipidemia

- **Natural Medicine Comprehensive Database** Herbs Possibly Effective
  - **Flaxseed**:
    - Significantly reduces total cholesterol & (LDL) cholesterol
  - **Avocado**:
    - Related to monounsaturated fatty acids
      - Influences Inflammation cascade
  - **Artichoke**:
    - Modestly reduce total and low-density lipoprotein (LDL) cholesterol, & the LDL/high density lipoprotein (HDL) ratio
    - Isolated **cynarin** did not show effect
    - Action related to choleretic
    - German E Commission Approved only for Dyspeptic problems

Hyperlipidemia



Red Yeast Rice - *Monascus purpureus*:

- Long history of use TCM
- Same as Statin- "Active" compounds in red yeast rice is monacolins.
  - **Monacolin "K"** is also known as mevinolin or **lovastatin**
  - Multiple clinical studies demonstrate positive response for: (Kurn and Shook. Integrated medicine for Neurologic Disorders, Health press. 2008.)
    - Reducing total cholesterol
    - Reducing LDL
    - Raising HDL
    - Lowing Triglycerides
- **Same Side effects**= Caution (Mercola.com. Sept 2009. By Ray Ellis. www.SaveYourHeart.com)
  - Depletes CoQ10 > inhibits mitochondria
- Statins activates the atrogin-1 gene > rhabdomyolysis & Mylagias
  - Most common side effect

HTN & Hyperlipidemia Bottom Line

- Evidence is lacking
  - Available evidence is good
- Better evidence for nutrients i.e. EDA/DHA, Niacin
  - Fish oil has strong evidence for lowering triglycerides and VLDL (Cochrane database)
  - Niacin is Grade A Evidence for both Natural Standards and Rakel, and 3 Star for Health Notes.
- Reasonable to incorporate:
  - Psyllium , Garlic and Oats as 1st line therapies
  - Support whole food primarily plant based diet
    - Plant Sterols- Grade A Evidence for both Natural Standards and Rakel, and 3 Star for Health Notes
  - Evidenced herbs as adjunct per clinical picture
    - Hawthorne (Crateagus) and Cinnamon

Insulin resistance & Diabetes

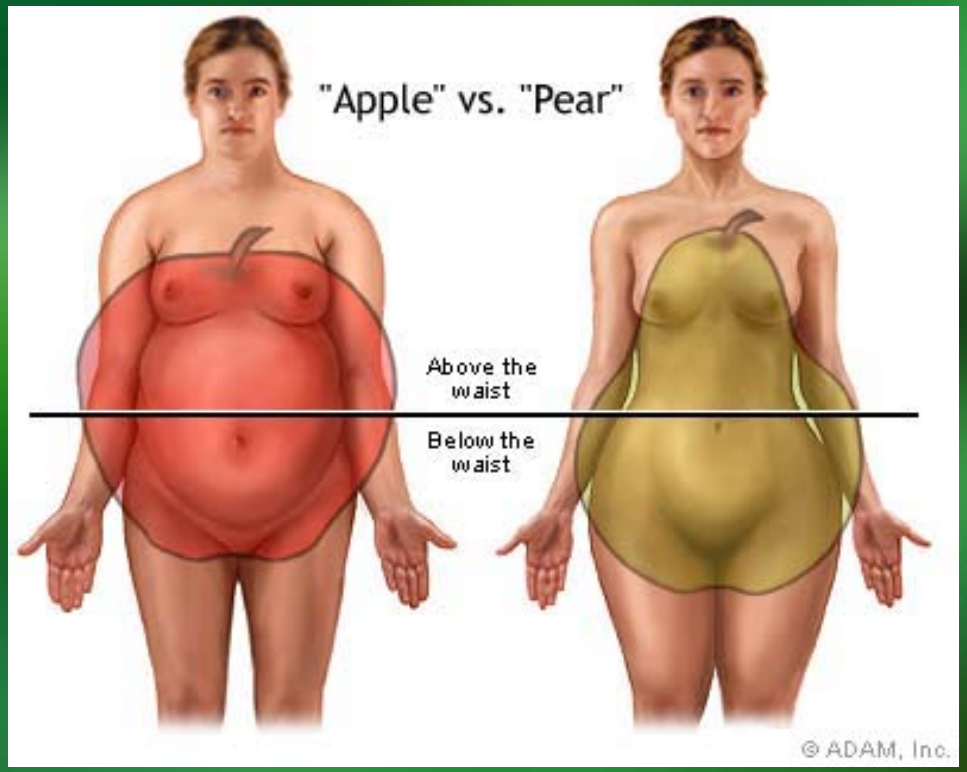
- Metabolic Syndrome and insulin resistance is a **"physiological defense mechanism"** to maintain metabolic balance or homeostasis
  - Designed to reduces lipid-induced damage to tissue by excluding glucose from cells, which decreases glucose-derived lipogenesis
- Underlying metabolic derangement leads to systemic inflammation, low hormetic tone, mitochondrial aging, and metabolic inflexibility

- **ATP III guidelines**: any 3 of the following positive for metabolic syndrome:
  - Abdominal obesity Waist circumference
    - >102 cm (>40 in) men
    - >88 cm (>35 in) women
  - Triglycerides >150 mg/dL
  - HDL cholesterol: Men<40 mg/dL; Women<50 mg/dL
  - Blood pressure >130/>85 mmHg
  - Fasting glucose >110 mg/dL

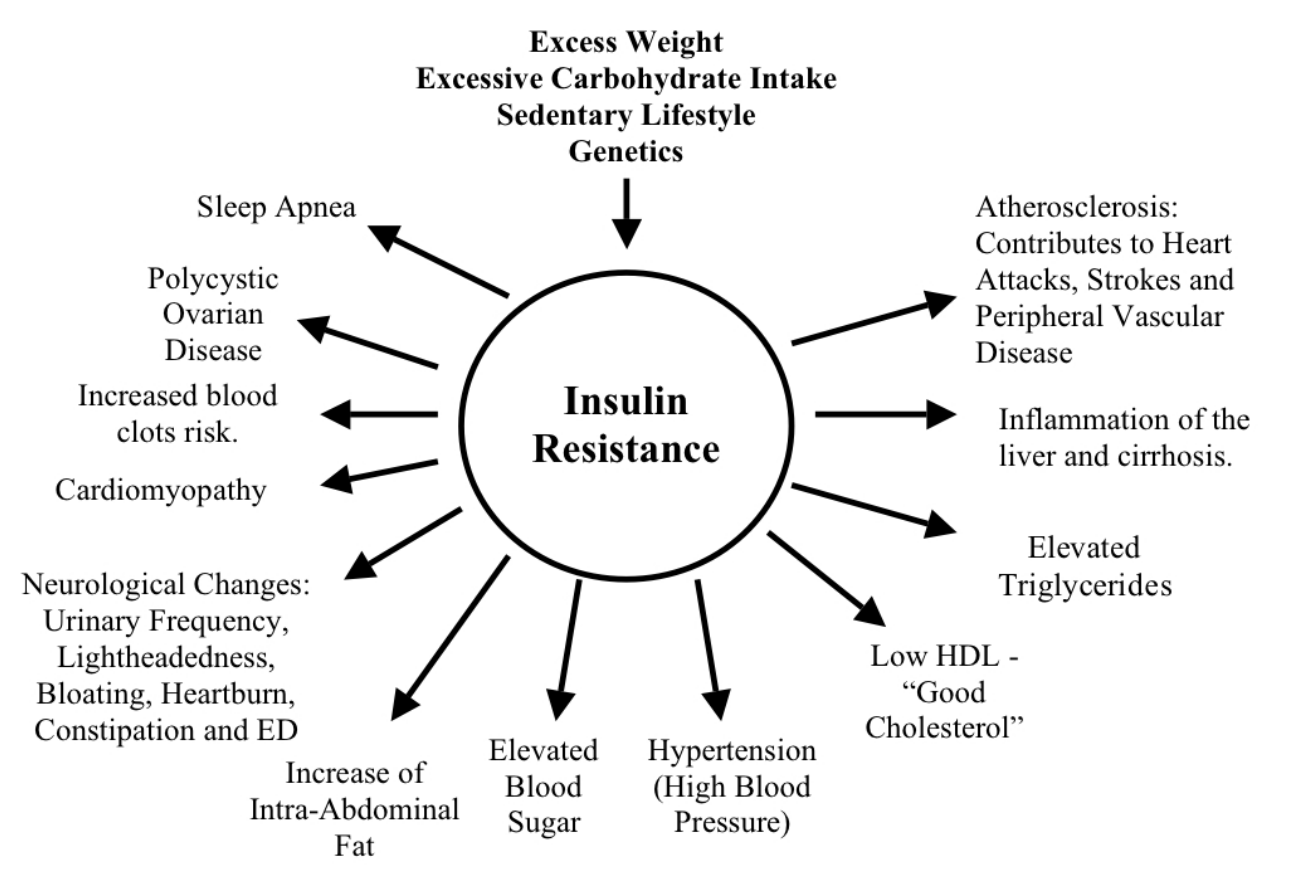
Insulin resistance & Diabetes

- Distinction between ATP III vs International diabetes guidelines.
  - Over FAT= pear shape (subcutaneous fat)

  vs.
  - Over Vat (Visceral adipose tissue) = apple shape - **Key risk**



Insulin resistance & Diabetes



Insulin resistance & Diabetes

- A review of traditional herbs used in diabetes demonstrated positive hypoglycemic action.
- Herbal preparations and formulas showed improved outcomes when combined with standard pharmacological therapy.
  - Overall quality of methodology was poor.
- No adverse effects or safety issues reported with herbal use.

(Cochrane Database)

Insulin resistance & Diabetes

- **Gingko** - *Gingko biloba*:
- **Medical actions:** anti-PAF, antioxidant, tissue perfusion enhancer, circulatory stimulant, nootropic, anti-inflammatory, anti-platelet aggregation, anti-thrombotic (Bastyr Monograph)

- **Evidence**:
  - B1 Level Evidence Rakel
  - Health Notes 1 Star
  - German E Commission approved for Vascular Complications

Insulin resistance & Diabetes

- **American Ginseng** - *Panax quinquefolius*
- 3 grams orally, up to two hours before a meal, can significantly reduce postprandial glucose levels in patients with type 2 diabetes
  - Doses greater than 3 grams do not seem to offer any additional benefit (Natural Medicine Comprehensive Database)
- Ginseng demonstrates synergy with blood sugar lowering medications (Natural Standards)
- **Evidence**:
  - Possibly effective Natural Medicine Comprehensive Database
  - Grade B Natural Standards
  - Health Notes 2 Stars
- Essentially interchangeable- *Panax spp.*
  - **Adaptogens** in general likely effective
    - Modulating influence on the HPA axis- influences glycemic control

Insulin resistance & Diabetes

- Gymnema - *Gymnema sylvestra*:
  - Long history of traditional use in Ayurveda for "honey urine"
  - Gymnema may be beneficial in patients with type 1 diabetes mellitus or type 2 diabetes mellitus (Natural Standards)
    - Insulin secretagogue action may worsens the underlying problem.
      - Beta-cell regeneration has been documented (animal models)
    - Crude gymnema extracts may deplete iron

(Bastyr Monograph-Yarnell, 2006)

Insulin resistance & Diabetes

- **Fenugreek** - *Trigonella foenum-graecum*
  - Recorded use dates to ancient Egyptian medicine
    - First mentioned in the Ebers papyri (ca. 1500 B.C.E.) (ABC)
- **Medical Action**:
  - Both insulin sensitizing and lipid correcting (Bastyr Monograph-Yarnell, 2006)
  - Fenugreek seeds have demonstrated significant anti-diabetic effects in experimental and clinical studies. (Bastyr Monograph)
- **Evidence**:
  - Health Notes 3 Stars
  - German E Commission Approved as appetite stimulator & digestive aid
    - ABC review found it to be an effective adjunct for diabetes (Herb Clip, 1996- Australian Journal of Medical Herbalism, Vol. 7, No. 2, pp. 35-40)

Insulin resistance & Diabetes

- **Bilberry-** *Vaccinium myrtillus*:
  - Decoction (leaves) appears to have a hypoglycemic effect.
    - The collagen strengthening effects and inhibition of sorbitol formation protects vasculature from diabetic complications
  - Vaccinium reduces serum cholesterol and triglyceride
    - May prevent arteriosclerotic plaque formation as well

(The Textbook of Natural Medicine, 2nd ed. Pizzorno & Murray)

- **Medical actions:** astringent (leaf), antiseptic, absorptive, antieme[illegible] antidiarrhei, hypoglycemic. Classically (King) diuretic (Bastyr Mono[illegible])

- **Evidence**:
  - Natural Standards Grade C
  - Health Notes 2 Stars
  - Level B2 Rakel
  - German E Commission Approved

Insulin resistance & Diabetes

- **Cinnamon-** *Cinnamomum verum / cassia*
  - Long History of use in TCM
    - One of most common herbs (Gui Zhi / Rou Gui)
    - Distinguishes between bark and branch

- **Medicinal Action**: Everything! Anti-microbial, Immune stimulating, Bitter tonic, astringent, diaphoretic, peripheral vasodilator, anti-inflammatory, antifungal, antiseptic, anodyne, antispasmodic, menstrual regulator

- **Evidence**:
  - Health Notes 2 Stars
  - Natural Standards Grade C
  - German E Commission Approved
  - Insufficient Evidence to rate -Natural Medicine Comprehensive Database

Insulin resistance & Diabetes

Cinnamon- *Cinnamomum verum / cassia*

- Great deal of emerging research in regards to its hypoglycemic action
- Traditionally has been used for symptoms of anorexia, gas and bloating, polyuria, and immune system weakness.
  - These are traditional symptoms classified as Qi deficiency in Oriental Medicine
  - Correspond to the German Commission E evidence for those indications

Insulin resistance & Diabetes

Bitter Melon (*Momordica charantia*)

- Long history use in China , India and Africa

- **Medicinal Action**:
  - Insulin sensitizer & Lipid corrective
  - Bitter melon is a digestive bitter stimulant
  - Demulcent
- **TCM actions: bitter, tonifies kidney yang, clears heat, detoxifies**
  - cold, enters lung, heart, and stomach channels

(Bastyr Monograph- Yarnell, 200

- Extract appears to have structural similarities to animal insulin
- Found to lower blood glucose levels in animal studies & weak metho al human trials
- Been associated with reduced apolipoprotein B (apoB)

(Natural Standards)

Insulin resistance & Diabetes

- **Bitter Melon** (*Momordica charantia*)
  - Decreases hepatic gluconeogenesis, & increases glycogen synthesis
  - Increases pancreatic insulin secretion, & increases peripheral glucose oxidation

(Natural Medicine Comprehensive Database)

- **Evidence**: Overall inconclusive but strongly suggestive
  - Natural Standards Grade C
  - Health Notes 2 Star
  - Not E Commission Approved
  - Insufficient Evidence to rate -Natural Medicine Comprehensive Database

Anti-inflammatory

Devils' Claw - *Harpagophytum procumbens*:

- Dual Anti-inflammatory and anodyne actions

- Action though to be due to the presence of a glycoside
  - harpagoside that reduces inflammation in the joints

- **Evidence**:
  - Cochrane Database review -Strong evidence for use in chronic back pain demonstrated (with Salix, Cayenne and Devil's Claw)
  - Grade B (Natural Standards)
  - 2 Star (Healthnotes)
  - Commission E approved for loss of motor function & coordination

(Welliver. Botanical Medicine 2, Bastyr University, 2005. & Cochrane Databse & American Botanical Council)

Depression

- **St John's Wort-** *Hypericum perforatum*
  - Hyperforin extracts shown to modulate neurotransmitter levels
    - including serotonin, norepinephrine, and dopamine
- St. John's Wort extract was significantly more effective than placebo in reducing Hamilton Depression scores (Chochrane Database Review)
    - Standardized extract of St. John's wort (500 mg/day) was comparable to fluoxetine (20 mg/day) in a multicenter randomized double-blind trial

(Linus Pauling Institute, OSU)

  - **Evidence**:
    - Natural Standards Grade A Evidence
    - Level A2 Rakel
    - Health Notes 2 Star
    - German E Commission Approved

Depression

- **5-HTP** orally seems to significantly improve symptoms of depression, including in patients with treatment-resistant depression.
  - There is evidence that 5-HTP might be comparable to the conventional antidepressants
    - fluvoxamine (Luvox) and imipramine (Tofranil)

- Natural Sources 5-HTTP (as Tryptophan):)
  - *Griffonia simplicifolia* & Whey Proetein
  - turkey, chicken, milk, potatoes, pumpkin, sunflower seeds, turnip and collard greens, and seaweed

(University of Maryland 4/09/2011http://umm.edu/health/medical/altmed/supplement/5hydroxytryptophan-5htp)

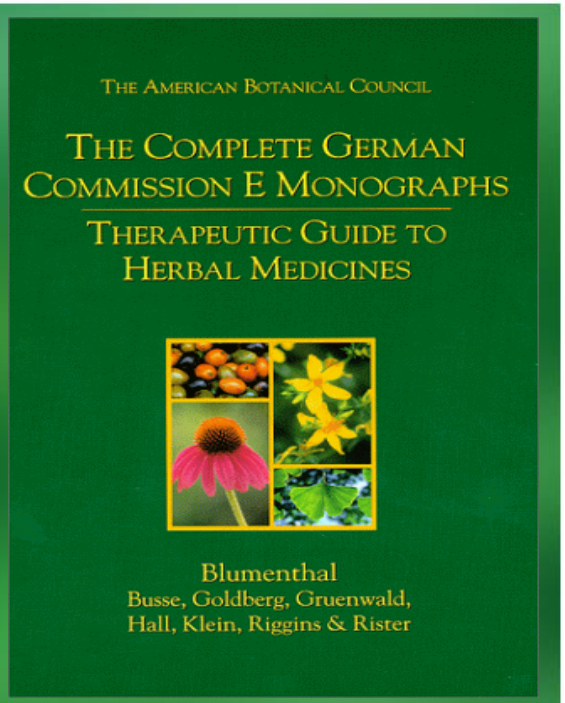
- **Evidence**:
  - Natural Standards Grade B
  - Health Notes 2 Star

Depression

- **Gingko** - *Gingko biloba*
  - **Medical actions:** anti-PAF, antioxidant, tissue perfusion enhancer, circulatory stimulant, nootropic, anti-inflammatory, anti-platelet aggregation, anti-thrombotic
  - Medical benefits of *Ginkgo biloba* extract are attributed primarily to two groups of active components
    - flavone glycosides
    - terpene lactones

- **Evidence***:*
  - Natural Standards Grade D
  - Health Notes 2 Star
  - German E Commission Approved
    - symptomatic treatment of disturbed performance
      - Organic brain syndrome
    - Cerebral insufficiency and geriatric depression (Bastyr Monograph)

Anxiety



- **German E Commission Approved Herbs**
  - **Kava**: nervous anxiety, stress, and restlessness
  - **Passionflower**: Nervous restlessness
  - **Hops**: Mood & sleep disturbances, and anxiety
  - **Valarian:** sleeping disorders based on nervous conditions
  - **St John's Wort:** Psychovegetative disturbances, depressive moods, anxiety and/or nervous unrest
  - **Indian Snakeroot:** tension of the sympathetic nervous system

Anxiety

- **Kava-Kava** - *Piper methysticum:*
- **Medicinal Actions**: Nervous tension (anxiety), stress and agitation, insomnia
  - Kava pyrones (lactones) have central muscle-relaxing, anticonvulsive, hypnotic/ sedative effects by interaction with ion channels and GABA sites
- **Evidence**:
  - Natural Standards Grade A Evidence
  - Head to Head comparison to benzodiazapines showed equal efficacy for anxiety
  - Effects reported to be similar to buspirone (Buspar®)
- **Safety**:
  - Studies show safe use for up to six months
  - 68 documented liver failures even with short term use
    - Adulterated
  - Different lactones have different effect
    - Ethnobotanical sources not followed

(Natural Standard Database & Gaby. *The Natural Pharmacy*, 2006)

Anxiety

- **Kava** is the only herb with strong scientific evidence
  - Standardized to 70% kavalactones

- Good scientific evidence for **peppermint**
- Some evidence that **passionflower** can reduce symptoms of anxiety.
  - Research shows that a liquid extract 45 drops daily is comparable to oxazepam (Serax) 30

(Natural Medicine Comprehensive database; Natural Standards; American Botanical Council; Up-to-Date Clinical database)

Sleep

- **Valarian** - *Valarian officinalis*
  - Primarily a sedative
    - valerenic acid- binds to GABA-A receptors
  - Classically (King) describes cerebral stimulation
    - Deficiency conditions

- **Medicinal actions: Tonic Sedative,** hypnotic, nervine, hypotensive, antispasmodic, carminative, sedative (paradoxical stimulant)
  - Reduces sleep latency (time to fall asleep)
  - Improves time spent in restorative- deep sleep

- **Evidence**:
  - Natural Standards Grade C
  - Health Notes 3 Star
  - German E Commission Approved
  - **C/I**: MAO inhibitors

(Yarnell. Bastyr Monograph, 2006 ., Gaby. *The Natural Pharmacy*, 2006 and Natural Standard database)

Clinical Summary

- Small number of herbs can effectively treat multiple conditions
- Targets key concerns in Primary care- CardioMetabolic Syndrome
- Broad systemic actions- mutually supportive
  - Digestion, inflammation, Sleep, Sympathetic Tone, HPAA,
- Commesurable with current "EBP" system
- Can be implemented in a "typical" setting :
  - 1st line
  - Reduces Harm & decreases polypharmacy
  - Low medical-legal risk
  - Creates opportunity

Future

- Ultimately, if the model is incommensurable…..”It won’t be conquered by adding new or unconventional tools (e.g., botanical medicine, acupuncture) to a failing model.” (Bland, Jeffery. ICHNFM, Presentation, Sept 13, Portland)

Bland Health Continuum

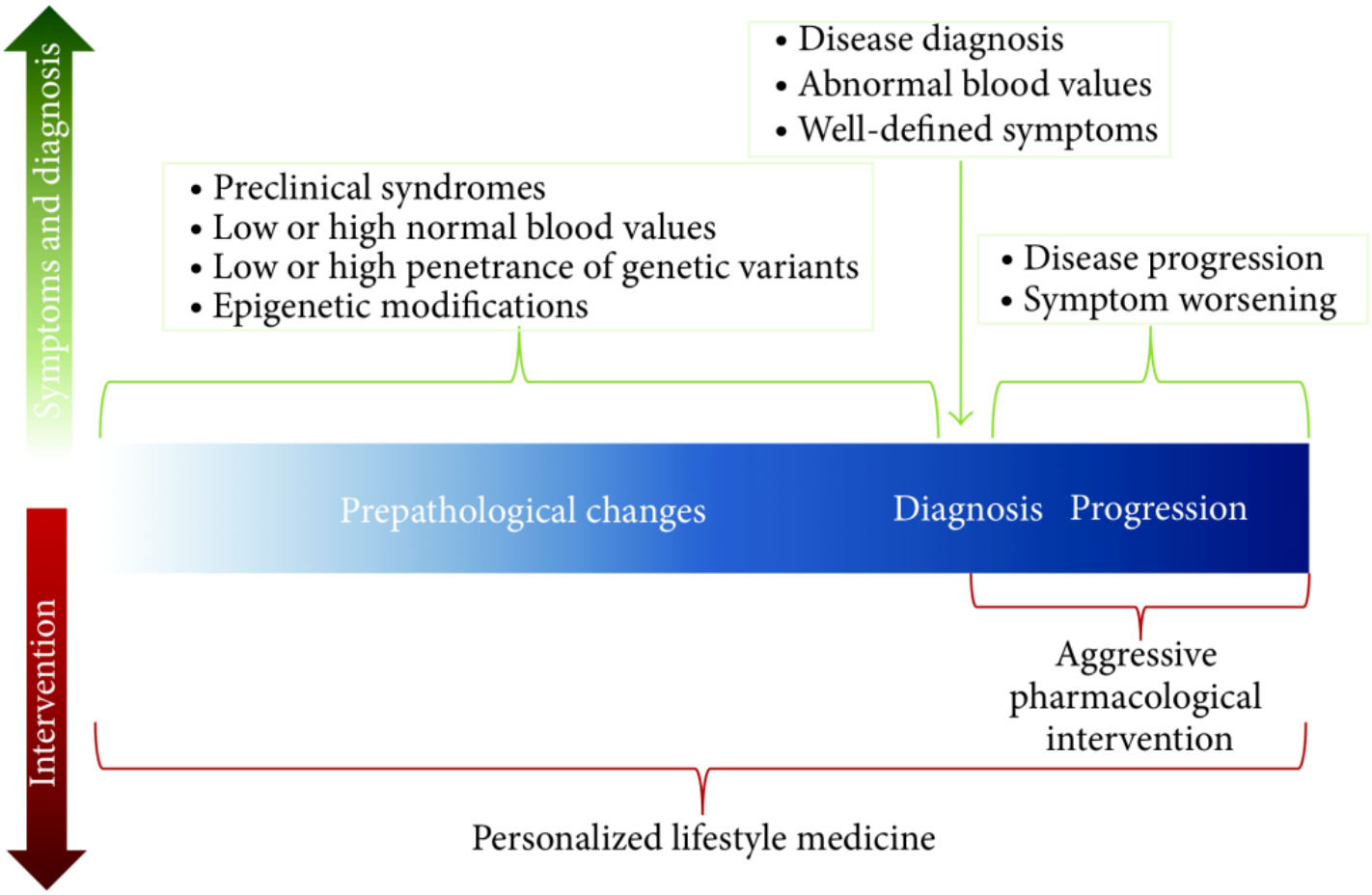


FIGURE 2: The trajectory of disease and role for personalized lifestyle medicine.

Future Direction

- **Epigenetics-** Chronic disease is a food-and lifestyle-driven, environment- and genetics-influenced phenomenon.
- **Prevention** is key i.e. Education
- **Address the underlying causes** of disease, using a systems-oriented approach and engaging both patient and practitioner in a therapeutic partnership" (www.functionalmedicine.org/about/whatisfm/)
- Managing acute, high risk and non-responsive signs and symptoms with drugs and surgery

The 6 Pricinciples of Naturopathic Medicine

Primum No Nocere ~ **First, do no harm**
Vis Medicatrix Naturae ~ **The healing power of nature**
Tolle Causam ~ **Identify and treat the root cause**
Tolle Totum ~ **Treat the whole person**
Docere ~ **Physician as teacher**
Praeventio ~ **The best cure is prevention**

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Questions, Comments, Arguments