Noni on the 99

- Kills harmful microbes, lowers blood pressure – H. Sim (1993)

- Inhibits growth or completely eradicates some cancers such as Lewis lung carcinoma and Sarcoma-180 by stimulating the immune system – A. Hirazumi (1997)
Noni on the 99

- Good source of potassium and vitamin C – N. Peerzada (1990)

- Morinda and its distributors make no curative claims for its product
Noni on the 99

- ‘A simple gift from a pristine paradise has set in motion a mission that will capture the attention of the world’
- Sales in Canada and US: $72,000,000 in first year
- Lucrative leadership bonuses – pays 8 levels
Noni Juice

- Case: hyperkalemia despite adhering to low potassium diet

- Upon questioning, had started noni juice purchased from health food store

- Asked to stop consuming noni juice because other juices known to have high potassium content

- Heard from relative that noni juice had cured him of cancer

Am J Kidney Dis 2000:35(2);310-2
Noni Juice

- Brother who also had renal disease took noni juice and instructed him to take noni juice regularly to improve energy level

- “did not understand the power of noni juice”

- Never returned to clinic

Am J Kidney Dis 2000:35(2);310-2
Noni Juice – Literature Search

• No information on internet or medical literature on potassium content
• Lab assay: potassium = 56.3 mEq/L
• Orange Juice: potassium = 51 mEq/L

Am J Kidney Dis 2000:35(2);310-2
- Natural Kidney Flush Herbal Tea
75% Canadians have used herbal medicine

More common in people with chronic conditions

Women > Men

75% world population depend on botanical medicines for basic health care

How many of you have used a herbal product?

- Not for or against
- Next year may be saying something different
- Evidence based
Why are you taking herbal supplement?

- Medical system too impersonal
- Holistic approach is not taken by health care providers whereas it is with alternative health care practitioners
- Patient centered vs treatment centered
Historical Perspective

- Post second world war
  - ↑ synthetic drugs
    - Science vs blind faith
  - ↓ herbal products
Prescribed Medications

- Birth defects
- Severe side effects
- Prescribed medications
  - Artificial
  - Toxic

- Herbal products
  - Natural
  - Safe
Plants

- Synthesize complex molecules for structure and function
- Rich source of chemicals
Purified chemicals from plants have been used as medicines
- Digoxin, morphine
- >50% of western drugs are derived from plants

Parts of plants or crude extracts
- Herbal medicines
  - Hundreds of chemicals
    - Influenced by species, variety, part of plant
    - Conditions of growth (soil, temperature, water)
Standardization

- Unique identifier
- Not necessarily active ingredient
- Difficult
- Seldom accomplished
National Institutes of Health

Glucosamine

Could not find satisfactory source of glucosamine and chondroitin for study
  - Batch to batch variability

Manufactured it themselves
  - How are patients going to access this?

Medical Letter 2002:44(1140);84-86
Natural Health Product Regulations

- Natural health products can be sold either as food or drugs
  - Voluntary
- Drug
  - Drug Identification Number
- Food
  - Do not provide adequate safety information on their labels
Drug Identification Number (DIN)

- Lack of DIN does not imply inferiority
- DIN does not guarantee safety or quality
- Applying for DIN is voluntary
  - Same product can be sold as drug (DIN) or food (no DIN)
Kava and Liver Failure

- Used for many indications including insomnia
- Study at VGH
- Four cases of liver toxicity in Canada
- Thirty-nine cases of liver injury in Germany
  - 3 fatalities
Kava may be identified as:

- kava
- kava kava
- kava-kava
- kava root
- kava-kava root
- kavain
- kava pepper
- kavapipar
- kawa
- kawa kawa
- kawa pepper
- kawapfeffer
- maori kava
- rhizoma di kava-kava

- ava
- ava pepper
- ava root
- awa
- gea
- gi
- intoxicating pepper
- intoxicating long pepper
- kao
- Piper methysticum
- Macropiper Latifolium
- Piper inebrians

- maluk
- meruk
- milik
- kew
- Rauschpfeffer
- sakau
- tonga
- Wurzelstock
- yagona
- yangona
- yaqona

The Challenge

- Some of these products have drug identification numbers, others do not
Chinese Herbal Product for Weight Loss Causes Renal Failure

- 70 patients required dialysis, transplantation
- 18 developed urothelial cancer
- Cause
  - Aristolochic Acid
    - Probably included in product by mistake

Medical Letter 2002:44(1140);84-86
PC Spes for Prostate Health

- contaminated with
  - Warfarin
  - Alprazolam
  - Indomethacin
  - Diethylstilbestrol

Medical Letter 2002:44(1140);84-86
Tung Shueh

- Promoted for problems of the heart, liver and kidney
- Chemical analysis per pill:
  - 3.86mg indomethacin
  - 16mg mefenamic acid
  - 8mg diclofenac
  - 0.73mg diazepam
- Directions: 4 pills three times per day

Annals of Pharmacotherapy 1996:30;79-80
Tung Shueh

- Lists 21 active ingredients
- Diazepam and mefenamic acid
  - Not included
  - Synthetically derived
  - Adulterated purposefully
Red Yeast Rice and Rhabdomyolysis

- 28 y.o. renal transplant patient
- Refused statin therapy
- Opted to naturally lower cholesterol
- CPK in 2 months was 2600 U/L (N< 130 U/L)
- CPK ↓ 600 U/L 2 weeks after herb discontinued

Canadian Adverse Reaction Newsletter 2003:13(3)
Red Yeast Rice and Rhabdomyolysis

- Contains an ingredient similar to lovastatin
- Statins interact with cyclosporine increasing statin levels

Canadian Adverse Reaction Newsletter 2003:13(3)
Chinese Herbal Remedies

- Multi-ingredient combinations
- Difficult to find information
- Powerful radio/TV advertisements
- Very expensive
Natural Health Products – New Regulations

WHAT DOES NEW LABELLING MEAN FOR YOU?
Informed Choice
Assurance of the Product’s Safety, Quality and Claim
Confidence in knowing that what is on the label is in the bottle

What does the new labelling mean?

- Informed choice
- Assurance of the product’s
  - Safety
  - Quality
  - Claim
- Confidence in knowing what is on the label is in the bottle
Product Safety

A lot number and contact information will facilitate reporting on concerns and assist with recall action in the event of a product safety issue.

Dr. D's HINACEA TABLETS

Relieves sore throats due to colds

Health claim
All natural health products will display their recommended use or purpose which is appropriate and truthful.

Natural Product Number
The Natural Product Number indicates that Health Canada has assessed this product for its safety, quality and claim and has authorized it for sale in Canada.

A complete listing of all medicinal and non-medicinal ingredients will help you make an informed choice allowing you to include and/or avoid ingredients which are important to you.

Recommended use or purpose: Traditionally dose (adults): Take orally 1 tablet 3 times per day. Each tablet contains 1000 mg of medicinal ingredients: Microcrystalline cellulose, cellulose microcrystalline, and magnesium stearate. Risk information: Use of this product may be harmful if ingested. Usage or fins recommended: Utilisé traditionnellement par le rhume. Dosage recommandé (adultes): Peut être utilisé sur une période de 10 à 21 jours de racine d'échinacée à feuilles étroites médicinaux: Cellulose microcrystalline, plus et stéarate de magnésium. Information concernant une altération. Consultez un professionnel de la santé.
ECHINACEA TABLETS

for the relief of sore throats due to colds. Recommended with water. May be used up to 10-21 days. Medicinal grade Echinacea angustifolia (Echinacea) root. Non-dicalcium phosphate anhydrous, silicon dioxide, stearic acid. Not use if you are pregnant or breastfeeding. Consult a health care professional.

Complete conditions for use

Complete conditions for use, in both official languages, including any warnings and or/cautions will assist you in using the product in a safe and appropriate manner.
Natural Health Product Regulations

- Effective January 1, 2004
- Transition period
  - 2 years
    - Site licensing and employ good manufacturing processes
  - 6 years
    - Product licensing, DIN products will be transferred to NPN or DIN-HM (homeopathic medicine)

http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpds-nhpt/nhp_regs_e.html
when elevated. Severe hypertriglyceridemia imposes a significant risk for pancreatitis, and patients with a TG level higher than 10 mmol/L on optimal lifestyle therapy require drug treatment. Available options include a fibrate, niacin and salmon oil supplementation.
Traditional Chinese Herbalists

- Treating people with CKD for thousands of years
- Concoctions include diuretics + herbs
Combination of 12 herbs used in China and Japan for kidney disease

- Animal studies
  - Decreased blood pressure and protein excretion
- Pediatric IgA nephropathy
  - Decreased protein excretion
- Insufficient evidence to recommend at this time

Wojcikowki et al J Lab Clin Med 2006;147:160-6
St. John’s Wort

- **Antidepressant**
- **Proposed mechanism of action**
  - Inhibits reuptake of serotonin, dopamine, norepinephrine
- **Effectiveness**
  - Mild to moderate depression
St. John’s Wort

- **Toxicity**
  - Generally well tolerated
  - Insomnia, anxiety, headache

- **Dose**
  - Variable depending on standardization
St. John’s Wort

- **Drug interactions**
  - Many serious interactions reported
  - Can decrease cyclosporine levels by 30-70%
    - Has led to transplant rejection
  - Banned in France due to many drug-herb interactions

[www.naturaldatabase.com](http://www.naturaldatabase.com)
Kidney Disease: Special Considerations

- Unpredictable pharmacokinetics
- Polypharmacy
  - St. John’s Wort and Cyclosporine
- Dialyzability
- Calcium Carbonate
  - Health food store instead recommended calcium citrate with magnesium
Watch out for herbals with:

- Anti-inflammatory activity
  - May affect kidney function

- Weight loss activity
  - May affect electrolytes
  - May affect blood pressure

- Diuretic activity
Monitoring

• If you wish to use, be informed, monitor closely

• Record brand and ingredients

• Always maintain same brand

• Include in your medication list
Monitoring

• Keep a diary
  – start low and increase slowly
  – consider starting at half the dose recommended on the label
  – report adverse reactions
  – reassess, reassess, reassess
Limitations

• Product used in studies not necessarily what is available on the market
• Long-term safety not generally known
• Qualifications of individual providing products
Guiding Principles

- Do no harm
- Need for dialogue
  - With patients
  - With other health care providers
- Take responsibility for recommendations
- Respect patient autonomy

Heather Boon, B.Sc.Pharm, PhD
Reporting Adverse Reactions

- Phone: 1-866-234-2345
- Fax: 1-866-678-6789
- Online: www.healthcanada.gc.ca/medeffect
- Form: available in the CPS – last page
References

- **www.naturaldatabase.com**
  - Available free on-line if you have UBC library card

- **www.quackwatch.com**


- Cochrane Database of Systematic Reviews
  - Chinese medicinal herbs for diabetic kidney disease