The Pharmacist: Past, Present and Future (CAM)

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Learning Objectives

• Discuss trends in CAM use in the US
• Discuss regulations regarding supplements (labeling and health claims) – FDA and FTC
• Discuss efficacy, effectiveness and safety related to nutritional supplements
• Discuss the pharmacists’ role in clinical nutrition (supplements and herbals) counseling
• Discuss opportunities for improving patient care and the bottom line through clinical nutrition counseling

When interviewing students that wish to be considered for admission to pharmacy school, I often ask

“Why do you want to be a pharmacist?”
• the answers often revolve around
  – “I want to be a “healer”
  – “help patients get better”
  – “improve the health and lives of our patients”
  – “improve health outcomes” and the like……..

Let’s begin with an open mind

I, student
• We are all learners learning together
• Everything is open to discussion and academic questioning
Not everything that is written is true
and
Not everything that is true is written
Goar Alvarez (ciren 2012)

• We use < 10% of our brain and although this is significant (it has taken us to the moon and back) is it fair to assume that our bank of knowledge and understanding still has a way to go?

• 0.125mg of Digoxin – effect on heart of a 150lb individual

• NTG 1/200 gr (0.0000769mg)

• Consider the infinitesimal amounts of trace minerals needed for bodily functions (in the micrograms), vitamins, minerals and amino-acids (in the milligrams)
  - B12 (2.5 micrograms), B6 (1.5mg), Fe (5mg), etc, etc....

• Homeopathy “hocus pocus”? 
Just because we cannot see it, does it mean it does not exist?

Before electron microscopes, telescopes and satellites did atoms, protons, electrons, viruses, and Pluto not exist?

I am in no way suggesting that we use this analogy, only that we keep an open mind. We can be “skeptical idealists”

• With the same breath..............we as pharmacists have a PROFESSIONAL responsibility that our patients receive from us unbiased, scientifically based “safe and effective” treatments and advice that empowers them and allows them to make better health care choices
• PROFESSIONAL – a learned individual, autonomous, having a high understanding, exhibiting high moral & ethical behavior, altruistic, selfless, having the other persons' best interest in mind

Pharmacist’s Role

• Pharmacists have long been the most accessible healthcare professional and a natural bridge between CAM and conventional medicine
• The role of CAM, and specifically herbal medications, in conjunction with conventional therapy is a dilemma faced by pharmacists every day
• Policy-makers need to be creative in order to collect data on safety first and then effectiveness for a public that is already using these services
• The quandaries pharmacists face on these issues are a microcosm of what researchers and governments must deal with in creating policies that respect patient autonomy and at the same time protect public safety
Origin

- Pharmacy in its’ origins primarily dealt with plants, animal parts, minerals, and the like to prepare medicinal products with which to treat patients
  - Egyptian “Pharmacist” – priest, pharmacist, physician
  - Bible “according to the art of the apothecary”
  - First “medical specialist”

Art of the Apothecary (2,600BC) – practitioner was priest, pharmacist and physician

The history of pharmacy

- The Profession of Pharmacy has existed in a rudimentary form from time immemorial.
- Many Sumerian late 4th millennium BC, early 2nd millennium BC cuneiform clay tablets record prescriptions for medicines.
- Ancient Egyptian pharmacological knowledge was recorded in various papyri such as the Ebers Papyrus (1550 BC).
- The earliest known Chinese manual on materia medica dates back to the 1st century AD.
- Dioscorides, De Materia Medica, Byzantium, 15th century.
- In Ancient Greece, according to Edward Kreiner and Glenn Sonnedecker, “before, during and after the time of Hippocrates, there was a group of experts in medicinal plants. Most important representative of these was Hippocrates of Cos. In 4th century BC. He is considered to be the source for all Greek pharmacological treatises.
- The Latin translation De Materia Medica (Concerning medical substances) was used as a basis for many medieval texts, and was built upon by many middle eastern scientists during the Islamic Golden Age.
The history of pharmacy

- In Japan, at the end of the Asuka period (538-710 AD) and the early Nara period (710-794 AD), the men who fulfilled roles similar to those of modern pharmacists were highly respected. The place of pharmacists in society was expressly defined in the Taihō Code (701) and re-stated in the Yōrō Code (718). Ranked positions in the pre-Heian Imperial court were established; and this organizational structure remained largely intact until the Meiji Restoration (1868). In this highly stable hierarchy, the pharmacists were assigned status superior to all others in health-related fields such as physicians and acupuncturists. In the Imperial household, the pharmacist was even ranked above the two personal physicians of the Emperor.

- In Baghdad, the first pharmacies were established in 754 AD. By the 9th century, these pharmacies were state-regulated.

- In Europe, in 1240, Emperor Frederic II issued a decree by which the physician's and the apothecary's professions were separated.

How did we allow this to become...

This!!
We allowed others to determine what we are and what we do

Pharmacists have the historical and traditional right to recommend safe and effective supplements and herbals

There was a time when these could only be found in a pharmacy

Background

• Alternative and complimentary therapies account for $33.9 billion in out of pocket expenses as of 2007
  – $14.8 billion being spent on supplements
• 38% of Americans use some form of complimentary therapy
  – Herbal supplements, meditation, chiropractic, and acupuncture
CAM Out-of-Pocket Spending: Self-Care\* vs. Practitioner Costs

- Total Costs = $333.5 billion
  - Total Self-Care Costs: $220.6 billion (66.1%)
  - Total Practitioner Costs: $112.9 billion (33.9%)

* Self-Care costs include: herb products, teas, and materials.
1. Practitioner techniques include: nutrition, guided imagery, progressive relaxation, and deep breathing exercises.

CAM Use by U.S. Adults and Children

- Adults: 36.0%
- Adults (2007): 38.3%
- Children (2007): 91.0%

CAM Use by Age - 2007

- Ages: 0-4, 5-11, 12-17, 18-29, 30-44, 45-59, 60-64, 70-84, 85+
- % Use: 7.8%, 10.7%, 16.4%, 36.3%, 38.6%, 40.1%, 44.1%, 41.0%, 32.1%, 24.2%
Statistics

- Percentage of the U.S. population who used at least one multivitamin/multimineral product increased from 30% in 1988–1994 to 39% in 2003–2006, with use more common among women than men.

CAM is consumer driven and to some extent consumer directed.

Assuring Safety and Efficacy – one of Pharmacy’s core values

- What is safety and how do we measure it?
  - Pharmacovigilance (PV or PhV) is the pharmacological science is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to:
    - Identifying new information about hazards associated with medicines.
    - Preventing harm to patients.
Safety

- Likely Safe
  - Generally considered appropriate to recommend
- Possibly Safe
  - Appear to be safe, but do not have enough high-quality evidence to recommend for most people
- Possibly Unsafe
  - People should be advised NOT to take these products
- Likely Unsafe:
  - People should be advised NOT to take these products
- Unsafe
  - People should be advised NOT to take these products

Assuring Safety and Efficacy – one of Pharmacy’s core values

- What is Efficacy and how do we measure it?
  - In medicine, efficacy indicates the capacity for beneficial change (or therapeutic effect) of a given intervention
    - (e.g. a drug)
    - If efficacy is established, an intervention is likely to be at least as good as other available interventions, to which it will have been compared
    - Comparisons of this type are typically made in ‘explanatory’ randomized controlled trials, whereas ‘pragmatic’ trials are used to establish the effectiveness of an intervention.

Assuring Safety and Efficacy – one of Pharmacy’s core values

- In pharmacology, efficacy is
  - the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances
  - the ability of a drug to produce the desired therapeutic effect (i.e. drug A is more effective than drug B)
Efficacy vs. Effectiveness

- **Efficacy** ($E_{max}$) refers to the maximum response achievable from a drug.
- **Effectiveness** refers to the ability of a drug (or other) to produce a beneficial effect:
  - Effectiveness relates to how well a treatment works in practice, as opposed to efficacy, which measures how well the treatment works in clinical trials or laboratory studies.

Effectiveness

- Likely Effective
  - Evidence consistently shows POSITIVE outcomes for a given indication without valid evidence to the contrary.
- Possibly Effective
  - Evidence consistently shows POSITIVE outcomes for a given indication without significant valid evidence to the contrary.
- Possibly Ineffective
  - Evidence shows NEGATIVE outcomes for a given indication without substantial valid evidence to the contrary. Some contrary evidence may exist; however, valid positive evidence outweighs contrary evidence.
- Likely Ineffective
  - Evidence consistently shows NEGATIVE outcomes for a given indication without significant valid evidence to the contrary.
  - Avoid use
- Ineffective
  - Evidence consistently shows NEGATIVE outcomes for a given indication without valid evidence to the contrary.
  - Avoid use

Third Party Quality Assurance

- USP verified
  - Label reflects what is in the product
  - Does not assess efficacy
Resources

- Natural Medicines Comprehensive Database
- Natural Standard
- German Monograph E
- Pharmacists’ Letter
ORGANIC REFERENCES


- Free-Range Eggs Contain More Vitamin D According to Mother Earth News Study http://www.organicsconsumers.org/articles/article_17588.2f5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5faced3e7/3/5
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3. Natural Standard Available at www.naturalstandard.com
6. Pharmacist Letter Available at http://pharmacistsletter.therapeuticresearch.com

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