Hype: A Rational Approach to Evaluating Claims in MS
Thomas M. Stewart, M.S., J.D., PA-C

FDA-Approved MS Therapies
- Highly regulated by the federal government
- Very strong evidence of efficacy
  - better than placebo or other treatment known to be effective based on RCCT
- Everyone with relapsing remitting form of MS should be using one of these

Making Decisions About FDA-Approved MS Medications
- Decide in consultation with expert physician factoring:
  - Prognostic clues
  - Risk and severity of known side effects
  - Risk and severity of unknown side effects (especially therapies)
  - Your own risk tolerance
  - Financial, insurance factors

What About Unconventional Treatments MS?
- The end of alternative medicine?
  - Multiple agents
  - Many excellent patient assistance programs
  - Oral agent
  - Long-term studies
- What about complementary medicine?
  - Purpose?
  - Disease management vs. symptom management
  - Biological vs. nonbiological

NCCAM Definition and Classification Unconventional Therapies
- Definition:
  - Therapies not considered “conventional;” therapies not generally prescribed by physicians
- Categories:
  - Biologically-based practices
  - Energy medicine
  - Manipulative and body-based practices
  - Mind-body medicine
  - Whole medical systems

Pascal’s Wager
<table>
<thead>
<tr>
<th></th>
<th>God Exists</th>
<th>God Doesn’t Exist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Believe</td>
<td>Eternal Reward</td>
<td>Status Quo</td>
</tr>
<tr>
<td>Don’t Believe</td>
<td>Eternal Damnation</td>
<td>Status Quo</td>
</tr>
</tbody>
</table>
Deciding About Therapies with Little Risk (Tai Chi, Massage, Spirituality)

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Massage Produces No Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Try Therapy</td>
<td>Receive Benefit</td>
</tr>
<tr>
<td>Don’t try massage</td>
<td>Status Quo</td>
</tr>
</tbody>
</table>

Consult Risk, Cost, and Other Factors

- RCCT for drug therapies
- Same standard for other therapies?
  - Yoga
    - Anecdotal evidence may be enough
  - Expensive multi-day IV treatment claiming dramatic results in slowing down disease?
    - Need RCCT first. Should only be done through IRB-approved clinical trial

Evaluating the Evidence

- Minimally Persuasive
  - Anecdotal Evidence
  - Laboratory Evidence
- Moderately Persuasive
  - Animal Evidence
  - Observational Evidence
- Most Persuasive
  - Experimental Clinical Evidence

Researching Claims

- Consult your health care provider
- Databases of peer-reviewed scientific literature that are accessible on the internet,
  - (1) CAM on PubMed
    [www.nlm.nih.gov/nccam/camonpubmed.html](http://www.nlm.nih.gov/nccam/camonpubmed.html) maintained jointly by the NCCAM and the National Library of Medicine,
  - (2) the International Bibliographic Information on Dietary Supplements (IBIDS) Database
    [ods.od.nih.gov/databases/ibids.html](http://ods.od.nih.gov/databases/ibids.html) maintained by the National Institute of Health Office of Dietary Supplements (ODS).
- Local library, especially a medical library if one is available, and talk with a librarian.
- General internet search engines such as Google
  [www.google.com](http://www.google.com), Yahoo
  [www.yahoo.com](http://www.yahoo.com), and MSN Search
  [search.msn.com](http://search.msn.com)

Credibility

- Sources
  - MS Experts Collaborative Statements
  - Non-profit MS organizations
  - Government or university vs commercial site selling products
  - Third-party quality endorsements
- Content
  - Should include facts upon which conclusions drawn
  - Should include references
  - Other cues: “quick cure” “miracle cure”
Selected Reasonable Unconventional Therapies

- Acetyl L-carnitine
  - 1000 mg twice per day reduced fatigue as compared with amantadine; 36 people, 3 months; no significant SEs—Tomassini, 2004
- Mindfulness Meditation
  - As compared to regular medical care decreased scores of depression and fatigue, increased quality of life; 150 people, 8 weeks—Grossman, 2010
- Yoga
  - As compared to wait list control group, people who participated in yoga had decreased fatigue; 69 people, six months—Oken, 2004

Placebo Effect?

<table>
<thead>
<tr>
<th>Placebo groups</th>
<th>Pre-Trial Attack Rate</th>
<th>On-Study Attack Rate</th>
<th>Relative Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betaseron</td>
<td>1.8</td>
<td>1.27</td>
<td>29%</td>
</tr>
<tr>
<td>Avonex</td>
<td>1.2</td>
<td>0.82</td>
<td>32%</td>
</tr>
<tr>
<td>Copaxone</td>
<td>2.9</td>
<td>1.68</td>
<td>42%</td>
</tr>
<tr>
<td>Rebif</td>
<td>1.5</td>
<td>1.28</td>
<td>15%</td>
</tr>
<tr>
<td>Tysabri</td>
<td>1.5</td>
<td>0.78</td>
<td>48%</td>
</tr>
</tbody>
</table>

Special Considerations Regarding Biologically Based Therapies

- 1994 Dietary Supplement Health and Education Act, or DSHEA
  - Consumers and manufacturers have an increased responsibility for evaluating the safety of dietary supplements and for determining the truthfulness of label claims
  - Pay attention to reputation of manufacturer
  - “Natural” is no guarantee of safety
  - Some supplements dangerous
    - FDA website: chapparal, yohimbe, comfrey

Conclusion

- Using unconventional therapies
  - can open doors to a new kind of wellness;
  - can be a way to take charge of your own health;
  - may even be a way to manage some symptoms.
- But there are also risks. Many CAM therapies, like medical therapies, can cause harm.
- The responsibility for identifying risks and rewards and for making decisions falls squarely on you, the consumer of healthcare. Take that responsibility for education and decision-making seriously and carefully.
- Resources in handout