**RATIONAL USE OF DIETARY SUPPLEMENTS AND HERBAL PRODUCTS**

Tami Remington, PharmD
Clinical Pharmacist and Clinical Professor
Michigan Medicine and University of Michigan College of Pharmacy

**Objectives**

- Look at how dietary supplements are regulated
- Learn about reliable, respectable sources of information about dietary supplements
- Help a patient decide whether to take particular dietary supplements

**Taking dietary supplements**

**Assisting and empowering patients**

- Why do you want to take a supplement?
- Review options
- Evaluate and select a supplement
- What do you expect?
- Begin treatment
- Monitor for benefits and risks
- Review experience
- Decide whether it is working and safe
- Make a long-term plan
- Continue, stop or adjust treatment


**Case example – Clara**

Clara has noticed her memory isn’t as sharp as it used to be. Others are noticing too.

She overheard her children discussing with her husband their concerns about her asking the same questions over and over, and her inability to pull together a large family meal like she always has been able to do.

Her husband shared their concerns, and added that she is having more problems managing their finances.

Clara’s daughter is suggesting she try a dietary supplement called Prevagen. Her friend’s mother is using it and it seems to have helped her memory quite a bit.

**How are dietary supplements regulated?**

Dietary Supplement Health and Education Act of 1994

Dietary supplements are regulated as foods, not drugs

- Made dietary supplements easily available to the American public
- Places a large burden on consumers regarding the risks (side effects, fraud) of these products

How are dietary supplements regulated?

Implications of DSHEA

Available on the US market

FDA approved +

R&D +

Available on the US market

R&D +
Taking dietary supplements

Assisting and empowering patients

Why do you want to take a supplement?

Review options

Evaluate and select a supplement

What do you expect?

Begin treatment

Monitor for benefits and risks

Review experience

Decide whether it is working and safe

Make a long-term plan

Continue, stop or adjust treatment

Prevent

Cure

Relieve symptoms

Slow progression

Why do you want to take a supplement?

INTEGRATIVE?

COMPLEMENTARY?

ALTERNATIVE?

Taking dietary supplements

What other options are there?

I am willing to try Prevagen.
I like the idea of improving my memory naturally. I don't have a lot of faith in prescription drugs for memory, and besides, I'm not that bad!

Taking dietary supplements

Assisting and empowering patients

## Sources of Information

### Evaluating product claims

- Illegal labeling or advertising
  - Supplements cannot claim they “diagnose”, “treat”, “cure”, or “prevent” disease
- Too good to be true
  - “Miracle cure”, “magical”, “breakthrough”
- Pseudo-medical jargon
  - “Hunger stimulation point”, “purify”
- Claim to work for a variety of illnesses

### Websites/ads

Who? … runs the Web site? Can you trust them?
What? … does the site say? Do its claims seem too good to be true?
When? … was the information posted or reviewed? Is it up-to-date?
Where? … did the information come from? Is it based on scientific research?
Why? … does the site exist? Is it selling something?

### Reputable on-line sources for patients

- Medline Plus
  https://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html
- Natural Medicines
  https://naturalmedicines.therapeuticresearch.com/
- National Institutes of Health National Center for Complementary and Integrative Health (NCCIH)
  http://nccih.nih.gov/
- National Institutes of Health Office of Dietary Supplements
  http://dietary-supplements.info.nih.gov/
- Using Dietary Supplements Wisely:
- Cancer Alternative Therapies
- Herbs at a Glance
  https://nccih.nih.gov/health/herbsataglance.htm
Sources of information
Selecting a product

http://www.usp.org/USPVerified/
http://www.consumerlab.com/
http://www.nsf.com/CertifiedDietary/

Tainted Products Marketed as Dietary Supplements, CDER

https://www.youtube.com/watch?v=Kit0LCvo6bI

Preveagen

Madison Memory Study

In a double-blind, placebo-controlled trial, Prevagen demonstrated the ability to improve aspects of cognitive function in participants with either normal cognitive aging or very mild impairment, as determined by pretrial screening.

The group of participants taking Prevagen improved certain aspects of cognitive function, according to computer-based testing. The adults were over 60 years old and took one capsule daily (10 mg) for 90 days.

VIEW THE STUDY

RESULTS

While no statistically significant results were observed over the entire study population, there were statistically significant results in the Aβ8 0-1 and Aβ8 0-2 subgroups. These subgroups contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging.

Table 2 shows participants’ characteristics and baseline test outcomes. In the Aβ8 0-2 and Aβ8 0-1 subgroups, no statistically significant differences were noted in baseline values between the Experimental and Control groups in any of the nine variables. The randomization was successful.
Does it work?
Yes
No

Is it safe?
Yes
OK to take
Be cautious
Monitor effectiveness
Do not take
Be cautious
Monitor safety

 Hmm. I’m worried about taking Prevagen if the government thinks it should be treated like a drug. But, it seems safe, at least in studies the manufacturer did…
I wonder what I should do.
Taking dietary supplements

Assisting and empowering patients

Why do you want to take a supplement?
- Review options
- Evaluate and select a supplement
- What do you expect?

Begin treatment
- Monitor for benefits and risks

Review experience
- Decide whether it is working and safe

Make a long-term plan
- Continue, stop or adjust treatment


Taking dietary supplements

Beginning treatment
- Choose a reliable or tested product
- Directions for use?
  - What are expected benefits?
    - How will I know if it is working?
    - When will I know if it is working?
  - What are possible side effects?
    - How will I know if they are happening?
    - What should I do if they happen?
  - How long is a reasonable trial?

Reviewing experience, making a plan

STOP
- Not working and/or
- Undesired side effects

ADJUST
- What can help it work better?
- How can unwanted effects be mitigated?

CONTINUE
- Working
- Well-tolerated
- How long to continue to take?

Well, I've been taking Prevagen for a month. I'm having trouble sleeping, but it's not from Prevagen. My daughter thinks it is helping my memory. I'll keep taking it for a total of 3 months.

Taking dietary supplements

More tips

1. A healthy diet is better than taking supplements
2. Avoid mega-doses of vitamins
3. Avoid some products
   - Weight loss aids
   - Treatments for cancer
   - "Male enhancement" products
   - Body building supplements

More tips

5. Avoid products containing ingredients associated with serious harm or death
   - Aconite
   - Bitter orange
   - Chaparral
   - Colloidal silver
   - Coltsfoot
   - Comfrey
   - Androstenedione
   - Country mallow
   - Germanium
   - Greater celandine
   - Kava
   - Lobelia
   - Yohimbe
   - Ephedra

http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?filter=&sortColumn=3a&sd=tainted_supplements_cder&displayAll=true

http://www.consumerreports.org/cro/2012/05/dangerous-supplements/index.htm
More tips
6. Carefully evaluate blends; use single-ingredient products instead?
7. Use reputable brands
8. Partnering with a knowledgeable doctor or pharmacist can help

In conclusion…
Dietary supplements are commonly used for health maintenance, disease prevention, and treatment
Regulation as foods means it is hard to find reliable information to help guide decisions about using them
They should be treated like other medical treatments we consider
• Learn from reliable sources
• Compare to other treatment options
• Select reputable or tested products
• Watch to see if it is effective
• Anticipate safety problems and reduce risk if possible

Case example - Victor
Victor is a 72 year old man who was in good health until about 3 years ago. At that time, he developed a skin infection that required antibiotics. While in hospital, it was discovered he has diabetes and high blood pressure.
About 3 months ago, he had a mild heart attack and had 2 stents placed.
He wonders about taking a fish oil supplement because he does not like to eat fish.

PMH
MI, stents
HTN
T2DM
Mild depression
OA – knee pain

Medications
Aspirin
Metformin
Plavix
Lisinopril
Lipitor
Advil
Zoloft

Taking dietary supplements
Why do you want to take a supplement?

INTEGRATIVE?
COMPLEMENTARY?
ALTERNATIVE?

Prevent  Cure  Relieve symptoms  Slow worsening
Information learned

- **Likely effective** for heart disease. Adding fish oil to a “statin” might not offer any benefit.
- **Possibly effective** for high blood pressure.
- **Likely safe** when taking 3 g/day or less. Taking more than this can increase chance for bleeding.
- **Use high doses of fish oil only with medical supervision.**
- **Minor interaction:** may increase chance for bleeding with aspirin and Plavix (Zoloft and Advil are not mentioned)
- **Side effects** include belching, fishy breath, heartburn. Refrigerating capsules or taking with meals can help.

Taking dietary supplements

Evaluating a supplement

Does it work?
- Yes: OK to take
- No: Be cautious Monitor effectiveness

Is it safe?
- Yes: Be cautious Monitor safety
- No: Do not take

Taking dietary supplements

Beginning treatment

<table>
<thead>
<tr>
<th>Directions for use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish oil providing 0.3 - 6 g of EPA and 0.6 to 3.7 g of DHA</td>
</tr>
<tr>
<td>More commonly 1 - 4 g fish oil per day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are expected benefits?</th>
</tr>
</thead>
<tbody>
<tr>
<td>It will reduce his chance of having a heart attack or sudden death</td>
</tr>
<tr>
<td>It’s hard to know if it is working</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are possible side effects?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding, indigestion, fishy breath</td>
</tr>
<tr>
<td>Store in fridge or freezer</td>
</tr>
<tr>
<td>Take with meals</td>
</tr>
<tr>
<td>Check with MD or RPh about bleeding</td>
</tr>
<tr>
<td>Minor bleeding is expected</td>
</tr>
<tr>
<td>Watch for major bleeding; risk can be reduced:</td>
</tr>
<tr>
<td>Aspirin dose can be lowered or</td>
</tr>
<tr>
<td>Plavix can be stopped or</td>
</tr>
<tr>
<td>Zoloft can be switched or</td>
</tr>
<tr>
<td>Use acetaminophen instead of Advil</td>
</tr>
</tbody>
</table>

When should I judge whether to keep taking it?
- If no problems, can continue treatment indefinitely

- If side effects are troublesome, stop and see doctor
- If high doses are used: medical supervision