

Volunteer Leader Training Guide

Dietary Supplements and Herbs: Just Because They're Natural Doesn't Mean They're Safe!

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Introduction

You probably heard of “the next big miracle” either on the news, on the Internet, in magazines or newspapers or even from a friend. It seems everywhere you turn, there is a supplement that will cure cancer, make you lose weight or build fabulous muscles. You have to wonder, if all those weight loss cures are so miraculous...then why does this country have an obesity and chronic disease problem?

The supplement section in the drug store or pharmacy is almost as large and confusing as the over-the-counter drug aisles! There is a reason for all of this. The supplement industry is a booming one! In 2007, \$14.8 BILLION were spent by consumers on natural products. This did NOT include vitamin and mineral formulations! When polled, a little more than half the country is using some form of complementary therapy.

But what is of concern is that 70 percent of people do not tell their doctors about their use of dietary supplements. This is of concern because dietary supplements, although they are natural, may not always be safe – especially when a person has an underlying health condition or is already taking medications. Furthermore, while there are supplements that are beneficial and others that are promising, there are also some that are downright dangerous and should be used with caution. This lesson will help you understand how to purchase supplements and where to turn to if you have questions.

***Volunteer leaders:** Please read the special note under “Suggestions for Teaching.”

Target Audience

- EHC leaders
- Retired and senior citizen groups

Objectives

- Participants will learn the definition of dietary supplement and herb.
- Participants will learn the various types of supplements on the market.
- Participants will learn about FDA regulation of supplements.

- Participants will learn how to find more information about supplements to determine whether they are right for them.
- Participants will learn how to shop for supplements.

Main Teaching Points

- Define a dietary supplement.
- Identify at least five different types of supplements.
- Identify four types of supplement preparations.
- Understand the basic regulation of supplements that fall under FDA jurisdiction.
- Identify the three types of claims allowable on supplement formulations.
- Identify at least three ways to shop for supplements.
- Identify at least three resources that participants can turn to if they want to learn more about supplements.

Suggestions for Teaching

- Review the teaching guide, including “Note to Volunteer Leader.”
- Obtain copies of:
 - A Guide to Supplements
 - Pre-survey and post-survey (one page, front and back or stapled together)
 - Helpful but not necessary: Have a couple of various supplements or herbals handy so that people can follow along with some of the claims you will be discussing.
- **Give each participant a survey and ask them to complete the pre-survey section. PLEASE copy the evaluation front and back. In order to keep good quality data, the same person’s answers who respond to the pre-survey must be matched with the post-survey.**

Note to Volunteer Leader

This lesson is quite long. If you wish, you can separate it into two lessons. One suggestion is to go over the parts about regulations and the types of supplements out there and leave the tips for using and shopping for supplements for another time. The regulations section is important because it helps drive home the message about WHY supplements need to be used with caution.

The field of supplements is a large and diverse area, and many items can fall under the term “dietary supplement” including herbs. In addition, there are many types of formulations with various names such as tinctures, teas, decoctions, infusions and extracts. This lesson provides an explanation of what these terms mean.

Supplements are NOT BAD per se, and we do not want to raise fear. In fact, there are many supplements that actually can be beneficial and very effective. Medicinal plants (herbs) have been used for thousands of years, including today. However, items to drive home about supplements are these:

- 1) **Supplements are not tested nor approved before they hit the market.** For this reason, there are manufacturers who have been shady with their practices and supplements do not always have the dose of the ingredient listed on the label. Supplements sometimes have dangerous concoctions or are even contaminated

with things like lead, mercury, arsenic or other undesirable materials. The FDA CAN pull supplements off the market if they are found to be dangerous, but this can take years.

- 2) ***There are herbal ingredients on the market that can be extremely effective but highly dangerous if consumed in large quantities or over a prolonged amount of time.*** Therefore, herbs really need to be administered by a trained professional. Yet herbs are sold freely and are sometimes masked under alluring health claims or even given descriptive names, such as “Relax.” These products are sometimes combinations of various herbs. There is a list called the “Dirty 12” in the handout. Sometimes, these combinations of herbals will contain one or more of the “Dirty 12,” so it is important that people read labels. People tend to have the mind set that “more is better,” and we need to dispel this notion with supplements. Even in ancient times, herbals were given in minute quantities and only over the course of several days, not months or years as we tend to use them.
- 3) In ancient times, herbals came from the natural crushed plant itself. Today supplements tend to undergo more processing and may even have fillers...not always the same! This concept is similar to food. For example, lycopene is a phytochemical – a plant chemical – that provides health benefits and is oftentimes found in red foods such as tomatoes. You can purchase a supplement called “lycopene,” but this is not necessarily the same thing as eating a tomato. This is because researchers don’t know all the phytochemicals in produce, and sometimes these phytochemicals interact beneficially with other components of that food, which can either activate the health benefit or have a synergistic effect. The tomato is a good example because lycopene was discovered years ago, but researchers only recently found several new derivatives of lycopene in tomatoes. These derivatives would not be found in a supplement but could contribute to tomato’s health benefits.
- 4) Physicians have no training in supplements and herbal products unless they purposely seek to educate themselves outside of medical school. One should still report to the physician every supplement taken because it may interact with medications. A pharmacist will have access to many formulations and is an excellent resource for questions. However, there are also many resources available that people can read about on their own. Those resources are provided in this lesson.
- 5) Pregnant women and nursing mothers should never consume any kind of supplement or herbal (unless prescribed...such as a general multivitamin). Even teas can be dangerous. Children and the elderly must use caution with supplements as their bodies cannot handle the same dosages or even formulations that healthy adults can. There is very limited research conducted on these populations. It is especially important that people who are in these age groups and categories speak to a health professional before taking a supplement.

If you would like to read more about supplements, feel free to go to these FDA sites:

<http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110567.htm>

<http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110493.htm>

The lesson begins here.

What Is a Dietary Supplement?

Use the handout, **A Guide to Supplements**, to coordinate with the lesson.

A dietary supplement is a product that:

- Is intended to be **added** to the diet.
 - Garlic can be considered as a supplement or as part of the diet. When you cook with garlic, it is just another part of the diet. However, if you take a garlic pill or eat garlic over and beyond what you would consider a normal part of the diet, then in this instance, garlic is considered a dietary supplement.
- Contains one or more dietary ingredients.
 - A dietary ingredient can be vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissues, extracts, concentrates, metabolites or similar substances (or their parts).
 - An herb, therefore, falls under the category of dietary supplement. Some other names for herbs include phytochemicals, herbal products and botanical products.
- Must be intended to be taken **BY MOUTH**.
 - There are many forms: capsules, tablets, gelcaps, teas, tinctures, extracts and powders.
 - If you have a cream (such as one that contains hormones), it would be called an alternative therapy but not a dietary supplement.
- Is labeled on the front panel as a dietary supplement.

What Is That?

When you are ready to buy a supplement, you will notice that there are **MANY** different kinds on the market. But one very confusing thing about supplements is some of the terms.

- **Tea/Infusion**
 - A tea is made by adding boiling water to fresh or dry herbs/botanicals. Many times you will see these sold in tea bags in the grocery store, but you can create your own tea as well. A tea can be consumed hot or cold.
 - An example of teas is chamomile tea (for relaxation). Sleepytime™ tea is a brand that contains chamomile to promote sleepiness but also contains other herbs. Echinacea tea is commonly used to prevent colds.
- **Decoction**
 - A decoction is similar to a tea but is stronger.
 - Roots, bark and berries are simmered in boiling water for a longer time than for tea. This creates a more forceful “extraction.” It can be consumed hot or cold.
- **Extract**
 - An extract is a general term for a botanical in a liquid (either water, solvent or alcohol) that removes a specific type of chemical from the plant.
 - Extracts can either be used as liquids (that are made from the “extraction”) or evaporated to make a dry extract. Many times these dry extracts are sold as powders, tablets or capsules.

- **Tincture**
 - A tincture is a type of extract made by soaking a botanical in a solution of alcohol and water.
 - It is always sold as a liquid.
 - It is made in different strengths expressed as botanical-to-extract ratio. When you see two different tinctures with different prices, the more expensive tincture is probably stronger.

FDA Regulations of Supplements

In 1994, the FDA “let its hair down” so to speak. This was the start of deregulation of supplements. This is sort of like allowing a fox in the henhouse and then wondering why all the chickens are gone!

When the FDA regulates drugs or food additives, those items **MUST** be tested for safety and effectiveness **before** they enter the market. However, although it is encouraged that supplements be evaluated for safety and effectiveness before hitting the market, this is hardly ever done and manufacturers are not required to do so. Safety and effectiveness are evaluated only **AFTER** the supplement is on the market. Unsafe products are not allowed to be on the market, but it may take years for the FDA to catch on and recall them. This is why it is important to contact the FDA if you have taken a drug or supplement that has caused a bad side effect. Here is the toll-free number:

FDA MedWatch 1-800-FDA-1088

Dietary supplements can have labels, and the FDA requires that the label be truthful and not misleading. The label cannot claim that the supplement diagnoses, cures, lessens, treats or prevents a disease, but it **CAN** have any of the following claims:

- **Health claim:** Describes a relationship between a food, food component or supplement ingredient **AND** reduces the **risk** of a disease or health-related condition.
 - For example, Acai (pronounced “ah-sah-EE”) berry is a supplement. It is OK to market it as a product that will help maintain cholesterol at healthy levels but cannot claim to **lower** cholesterol levels.
- **Nutrient claim:** Describes the relative amount of a nutrient or dietary substance in a product.
 - For example, there is a product called Estroven® for managing menopausal symptoms. The product makes a nutrient claim because it says it contains soy, black cohosh, vitamins B₆ and E and calcium on the front of the box.
- **Structure/function claims:** Describes how a product may affect the organs or systems of the body. This kind of claim cannot mention any specific disease. The text on the claim must be sent to the FDA 30 days before marketing but also must have a disclaimer.
 - For example, products may contain such claims when you see phrases such as “increases energy” or “rapid weight loss.”

You may have seen some fairly suspicious claims. How can manufacturers get away with them? Eventually, if the claim is illegal, it will catch up with manufacturer and the product will be

pulled off the market. **The Federal Trade Commission (FTC) monitors advertising of supplements.** However, this can take years. In the meantime, what helps protect companies is the following disclaimer that is found on all dietary supplements (If you have a sample of dietary supplements, have participants look for this statement):

This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Manufacturers SHOULD practice good manufacturing practices (GMP). This should help consumers feel more confident that the supplement they are purchasing is safe, effective and free of contaminants. You will be able to find the **GMP seal** on products. There are also other standardization seals (talked about further on down). But don't assume that all products have followed GMP.

Are Supplements Safe?

Supplements can be safe. They can even be very beneficial. For example:

- **Folic acid** is a B vitamin that has been shown to prevent birth defects.
- Some **enzymes such as Beano**[®] can help digest hard-to-digest food safely.
- **Probiotics** (which are in yogurt or sold separately) have been shown to help your intestinal bacteria manage your digestive tract.
- **St. John's wort** is an herb that is showing promising results in helping manage mild to moderate depression.
- **Omega-3** is often recommended by doctors to be used as a heart disease preventive measure.

There are many other supplements and herbs that are safe and effective in helping with symptoms or prevention. However, even if they are effective, you still need to check with your doctor or pharmacist because:

- They may have a drug interaction if you take medications.
- They may not be right for you if you have an existing medical condition.
- You may be exposed to an allergy risk to some of the ingredients.

This is why you must check with your doctor or pharmacist first before you take any kind of supplement.

There are also supplements that may be highly effective yet downright unsafe in large doses or when given over a long amount of time – but are still on the market. Your handout lists some of the more known unsafe supplements. **Be watchful of these as they are oftentimes found in formulations with other dietary ingredients.** All herbals should be taken under the guidance of a professional such as a physician or pharmacist!

Why is it still a good idea to practice safety with supplements, even the good ones?

- Supplements can interact with some foods, medications, other supplements or pre-existing medical conditions.
- There is not enough research done on most supplements to determine effectiveness.
- Not all supplements have the amount of ingredients they claim to have [for example, a supplement may claim to have 100 mg of resveratrol (a compound found in grapes and wine) and only REALLY have 50 mg].

- Some supplements may be **contaminated** with ingredients such as lead and mercury or even grass clippings.
- Some supplements may include ingredients not on the label.
- Some supplements have misleading labeling.
- Pregnant and nursing mothers should not use supplements except under the care of a physician (such as prenatal vitamins). Children and the elderly should be very careful with supplements. There is very limited research in these populations, and their bodies cannot handle the same load of an ingredient as a healthy-bodied young adult.

How to Use Supplements?

If you want to take supplements, do a little research on your own before you buy anything. There are many resources you can check to read more about them. Your handout lists several resources such as web sites from major universities, the Office of Dietary Supplements and the FDA.

The Consumer Labs is a pay-only web site. It is the only one of its kind, to our knowledge. If you are serious about supplements, this is a small investment you may consider making. This is an independent testing lab that tests brands of supplements to determine whether the bottles have what they say they have or whether brands have been contaminated. They then give an approval rating. If the supplement brand was not approved, the reason is listed. This site does cost you money for a one-year subscription. Please note that this lab tests only the supplements the manufacturer is willing to submit, so not all brands will be listed. You can also subscribe for a free newsletter that will alert you to some of the hot topics regarding the supplement industry.

Finally, the book, *A Health Professional's Guide to Popular Dietary Supplements*, is a great resource to have on your shelf. It covers the research and recommendations on 107 dietary supplements. It is published by the American Dietetic Association, but it is a technical book. You may want to see if your library carries it, or it may carry another book about supplements that can be helpful as you do research.

Here are some tips to help you get started:

- Discuss with your doctor or pharmacist the supplements you want to take.
 - If you have articles on the supplement, bring them with you.
 - Make sure your doctor and pharmacist knows of all the medications you currently take. Sometimes supplements have similarly-acting ingredients as medications. This can be hazardous to your health if you take both! For example, red yeast rice extract and guggulipid both act as statin drugs. If you are already taking a statin, taking an additional supplement can bring your cholesterol down to dangerously low levels.
- Select major brands of supplements. Examples we all know of include Centrum®, One A Day® or Nature Made® – but there are many others that can fall under this category. They tend to be sold in larger pharmacies and grocery stores.
- Read the label and be careful about dosing. With supplements, more is not necessarily better.
 - Even if it is a time-proven supplement (such as a multivitamin), you still need to “check in with yourself” because your body can change over the years and how it handles the things you put into it may also change.
 - Formulations also change over time.

- It is never recommended that you take supplements for extended amounts of time except under the direction of a health care professional.
- Spend money wisely.
 - Call the manufacturer to learn more about the product or talk to a pharmacist. Many times the more a supplement costs does not necessarily mean it is better. A pharmacist can usually help you select a brand. If you are at a health food store, sometimes a knowledgeable clerk can also provide you with some help with brands.
- Stick with European, Canadian or U.S. brands, but beware of products from other countries.
 - Europe and Canada have strict regulations about supplements on the market; however, other countries, such as China and Mexico, are more likely to produce contaminated products.
- Look for standardized seals or the GMP seal.
 - Manufacturers who have tested for the integrity of their product and followed production standards will have labels, or seals, that indicate this. In order to get the seal, the product will have had to be tested at an independent, third-party lab. This can help you feel better that the product is not contaminated, but it is still up for criticism as the industry is still fairly unregulated.
 - Labels to look for are GMP (or NNFA), Consumer Labs, NSF, Good Housekeeping or USP.
 - These labels should be listed on the web site if you prefer to order from the internet.
 - If the product does not contain a seal, you can call the manufacturer. Just because it doesn't have a seal doesn't necessarily mean they're shady. They should be able to provide you with reports from independent, third-party labs. If they don't, you can file a complaint with the Federal Trade Commission (FTC).
- If you want to buy an herbal product, you are safer choosing products that have one herb rather than several because you have less chance for an adverse reaction.
- If you want to buy vitamins or minerals, choose multivitamin formulations with minerals, unless suggested otherwise by your doctor.
 - For example, minerals can prevent absorption of other minerals, and fat-soluble vitamins may be toxic in high amounts. Vitamins and minerals work better in concert with each other. However, a physician may prescribe a single vitamin or mineral based on your condition. For example, iron is commonly prescribed for anemia; however, you would probably never take iron pills indefinitely and your doctor would need to monitor you. Some of the water-soluble vitamins such as B and C are not as risky since you will excrete them once your body absorbs what it needs.
- Be careful if you are pregnant, nursing, under 18 or over 65.
 - Pregnant or lactating women should not use any dietary supplement except under the direction of their physician. However, supplementation with a prenatal multi-vitamin and mineral supplement (with attention to folic acid, iron and calcium) will probably be expected.
- Never substitute medications with supplements before talking to your doctor.
- Never take vitamins (especially fat-soluble vitamins such as A, D and E) or any minerals that exceed upper safety limits.
- Remember that just like drugs and food, you can have an allergic reaction to a supplement.

Resources

There are many resources that you can find online or in book form that will help you read about supplements, their safety and effectiveness. Some are listed in your handout.

The Consumer Lab is a fee-only web site. This is an independent testing lab that tests for the integrity of brands of supplements. It costs about \$30 a year for a subscription, but it also provides a useful resource to learn about supplements. You can also subscribe for a free newsletter that will alert you to some of the hot topics regarding the supplement industry.

Conclusion

In conclusion, remember that supplements are meant to supplement your diet, not replace food or cure. They can be beneficial, such as supporting your immune system or helping you meet nutrient requirements if you do not have an adequate diet. However, be aware that supplements can interact with food, medications and other supplements. Finally, be safe. Do not self-diagnose. Talk with your doctor and pharmacist before you plan on taking supplements. If a health care professional is not aware of the supplement you are proposing, ask him/her to refer you to someone who can help you.

Evaluation

Tell each participant to turn the survey over they filled out in the beginning of class and ask them to complete and return the post-survey. Provide evaluations to your county Extension agent – family and consumer sciences.

Thank everyone for taking the time to fill out the survey and inform them their information is anonymous and will greatly serve Extension Service in continuing to provide quality educational information to Arkansans.

Resources

- University of Maryland Medical Center
www.umm.edu/altmed
- Food and Drug Administration (FDA)
<http://www.fda.gov/Food/DietarySupplements/default.htm>
<http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/default.htm>
- Office of Dietary Supplements and Herbs (National Institute of Health)
<http://ods.od.nih.gov>
- U.S. National Library of Medicine
<http://Dietarysupplements.nlm.nih.gov/dietary>
<http://sis.nlm.nih.gov/enviro/dietarysupplements.html>
http://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html
- Fragakis, A.S., and C. Thomson. *Popular Dietary Supplements*, 3rd edition. American Dietetic Association, 2007.