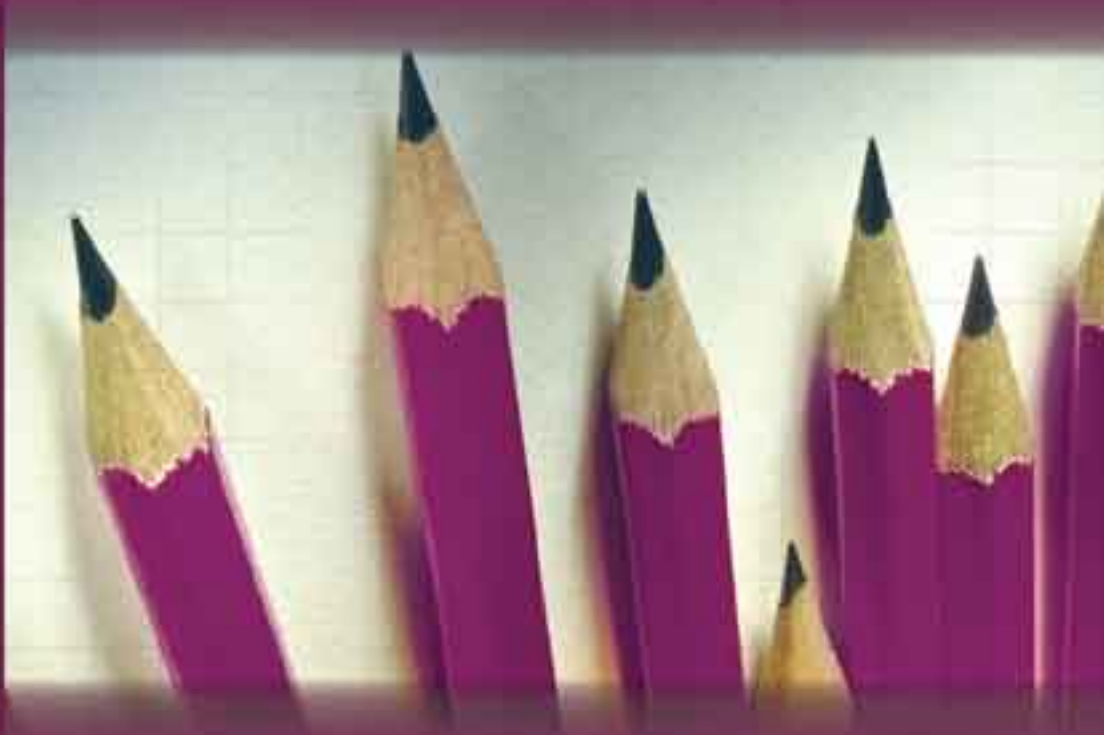


How to Evaluate Claims of New Heart Failure Treatments and Cures

The Heart Failure Society of America (HFSA) is a non-profit organization of health care professionals and researchers who are dedicated to enhancing quality and duration of life for patients with heart failure and preventing the condition in those at risk. These educational modules have been developed to help patients, their families, and individuals at risk for heart failure understand and cope with the disease. For more information about the Society please visit our web site www.hfsa.org.

www.hfsa.org



Heart Failure Society
of America

Contact Information

Please write down important contact information in the space below. You may also want to share this information with family members and friends.

Doctor Treating Me for Heart Failure:

Name:

Address:

City:

State:

Zip code:

Phone number:

Fax:

E-mail:

Other Important Phone Numbers:

Ambulance, fire department, or emergency services: **911**

Pharmacy:

Other doctors or nurses:

Introduction

It may seem that every time you open a magazine, listen to the news, or search the Internet, you find out about a food, vitamin, mineral, or homeopathic medicine that can treat or cure an illness. You may have even read or heard about natural remedies (sometimes called complementary or alternative therapies) that claim to help heart failure. The problem is figuring out how to evaluate this information.

Just because something is natural does not mean it is safe. Even substances such as vitamins or nutritional supplements that are generally harmless may not be safe for someone with heart failure. These substances may interact with the medicines your doctor gives you. Most "natural" or herbal remedies and supplements have not been reviewed by the U.S. Food and Drug Administration (FDA). The FDA is the federal agency that evaluates prescription medicines for use in treating diseases. The FDA does not review and approve natural remedies and supplements. Many times these natural remedies are removed from the market only after many adverse events occur.

This module does not approve or disapprove of any particular natural remedy or approach to treating heart failure. Instead, it will provide you with tools you can use to evaluate information and claims about treatments for heart failure. While this module focuses specifically on natural remedies, you can also use the tools and techniques described to help evaluate information about other new therapies for heart failure including medicines and devices.

Introduction



This module will provide information on:

- Tools you can use to review claims about new treatments for heart failure.
- How major scientific journals review articles before publication.
- How the FDA evaluates heart failure therapies.
- How to recognize a false claim.

It will help you:

- Evaluate claims made about natural remedies for heart failure treatments.
- Decide which information about heart failure treatments you may want to bring up with your doctor.



How to Review a Claim



Probably the best way to evaluate a claim is to ask the following questions:

- Who said the natural remedy is effective?
- What are the qualifications of the person supporting the claim?
- Where did you read or hear about the claim?
- Where was the remedy evaluated and studied?

Who Is Making the Claim?

Reliable sources of information include people speaking on behalf of a well recognized professional medical organization or a well respected academic institution. A person who has conducted research on a particular disease and who has not received financial support from the company making or selling the product could be considered a reliable source of information. A person who represents the company who makes or sells the product might not be a reliable source of information.



How to Review a Claim

What Is the Background of the Person Making the Claim?

Factors to consider are whether the person making the claim is well recognized for his or her work in the field for which the claim is being made. Is the person an MD or PhD? Does he or she work for a government agency? A claim coming from a well recognized academic institution or a governmental organization such as the National Institutes of Health (NIH) or the FDA would be considered more reliable than a claim from the company that makes or sells the product.

Where Did You Read or Hear about the Claim?

You may have read about a treatment in a magazine or heard about it on television or radio. These may not be the best places to find out about treatments for heart failure.

Well recognized scientific journals have developed reputations for reliable and trustworthy information. These journals only publish articles after they have been reviewed by experts in the subject being discussed. If a study has been published in one of these journals, you can trust that the information is reliable.

You can find peer reviewed medical articles on specific subjects by using the Internet to search the PubMed database of medical literature. You can visit a medical library to access PubMed or make copies of articles. Examples of peer reviewed scientific journals include: The New England Journal of Medicine, Nature, the Journal of the American College of Cardiology, the Journal of Cardiac Failure, Circulation, and the Journal of the American Medical Association.

With other publications, look for signs of credible reporting. Reporters use what they know, read, or have been told when writing a story or column. Evaluating the sources the reporter uses can help you determine the reliability of the information. For example, if the reporter quotes medical journals or medical experts, the information may be more reliable than if the reporter quotes individuals who work for the company that makes or sells the product. Look for a straightforward style you can understand, conclusions based on evidence, and a balanced point of view.

How to Review a Claim



What about Web Sites?

The Internet is a rich source of information - both good and bad. The methods recommended for evaluating a news story or magazine article also work well when reviewing a web site. Ask questions about the sources used to develop the information presented on the web site. Evaluate the organization sponsoring the web site, examine the background of people quoted, and review the quality of the references that may be listed supporting any claims.

Evaluating How a Treatment Was Tested

As you review a natural remedy, evaluate how it has been tested. For example, find out whether it has only been tested in laboratory animals, or whether it has been thoroughly tested in humans. To test a treatment in humans, a clinical trial involving many participants may be conducted.

In a clinical trial, the treatment may be tested against a placebo. A placebo is an inactive treatment such as a sugar pill that does not contain any medicine or active ingredients.

In a placebo controlled study, 50 percent of the people receive the real treatment, and the other 50 percent receive a placebo treatment. Depending on the type of treatment being tested, the doctors and patients participating in the study may not know who is receiving the real treatment and who is receiving the placebo treatment.

The patients in both groups are followed for an extended period of time, and the data are evaluated on a continuing basis by a specially appointed board of experts. When the study is over, the data are evaluated to determine the effectiveness of the treatments that were studied.



When Is a Heart Failure Treatment Considered Beneficial?

A remedy for heart failure can be viewed as beneficial if strict testing shows that it can do at least one of the following:

- Help people with heart failure live longer.
- Increase the amount of exercise they can do.
- Decrease the number and severity of symptoms of heart failure.
- Decrease hospitalizations for heart failure.
- Slow, stop, or reverse the progression of heart failure.
- Improve quality of life.

Signs of a Bogus (False) Claim

Typically, a bogus claim is broad and general. A claim is suspect if it:

- States that a remedy is **always** beneficial or that it works for everyone.
- Contradicts all other reports you have read or heard about heart failure treatments.
- Requires you to discard something you trust or believe.

Other Things to Look for When Evaluating a Remedy

When you read or hear about a remedy, you should be cautious if:

- The remedy has not been tested thoroughly in a scientific study.
- The results of a study are mixed with both good and bad effects.
- The remedy has been tested in only one small study.

Be especially careful if the remedy has been tested on only a small group of people at a single center. Wait for the results of other studies to see whether the treatment is really safe and effective in a broader group of people.

Keep in mind that if a researcher gets good results with a therapy, others will try to duplicate the results. They will want to make sure that the remedy is effective in many different types of people.

As you review remedies, keep in mind that companies use marketing to sell or push their products to consumers. Just because a remedy has clever advertising and is expensive does not mean that it is safe and effective.

Remember the saying, buyer beware. If something sounds too good to be true, it probably is.

Work with Your Doctor, Nurse, or Pharmacist

Share the information you have gathered about a new food, vitamin, mineral, or homeopathic remedy with your doctor, nurse, or pharmacist before you begin to use it. Some natural remedies may interfere with the medicines your doctor has prescribed. Discussing information about a new remedy or cure with your healthcare provider can help you decide whether it may help or hurt you. Bring the information you have gathered with you, because your health care provider may not know the latest news about every remedy. It is important to evaluate the information together.

Learn More



You can learn more about how to take control of your heart failure by reading the other modules in this series. You can get copies of these modules from your doctor or nurse. Or you can visit the Heart Failure Society of America web site at: www.hfsa.org.

The topics covered in the other modules include:

- Introduction: Taking Control of Heart Failure
- How to Follow a Low-Sodium Diet
- Heart Failure Medicines
- Self-Care: Following Your Treatment Plan and Dealing with Your Symptoms
- Exercise and Activity
- Managing Feelings About Heart Failure
- Tips for Family and Friends
- Lifestyle Changes: Managing Other Chronic Conditions
- Heart Rhythm Problems
- Advance Care Planning



These modules are not intended to replace regular medical care. You should see your doctor or nurse regularly. The information in these modules can help you work better with your doctor or nurse.

Notes:



Acknowledgment

This is the last in the series of educational modules on heart failure for patients, their families, and individuals at risk. The HFSA would like to extend a special thank you to Debra K. Moser who spear-headed this activity along with the other members of the HFSA Nursing Committee (Nancy M. Albert, Susan Ammon, Susan J. Bennett, Sandra B. Dunbar, Mariann Piano, Barbara J. Riegel, Susan Ziesche) for their time and effort in developing these materials.