



Del Mar Caregiver Resource Center
A program of Health Projects Center

Fact Sheet

Evaluating Medical Research Findings & Clinical Trials

Hardly a day goes by without a story on television, in the newspaper, or on the Internet about new medical research findings. You might hear about a new drug to treat Alzheimer's, a promising "cure" for cancer, or a breakthrough discovery in Parkinson's disease. Or you might see articles about particular foods or dietary supplements that are said to promote health or prevent or slow the course of illness. Should you try to get these drugs for a family member who is sick? Should the person change his diet? Take more vitamins?

It's confusing when research findings are contradictory. Conflicting health news stories—for example, drinking a glass or two of wine is good or bad for you, taking vitamin A may prevent one form of cancer but cause another to worsen—leave everybody, caregivers and health professionals alike, wondering what to do next.

It is possible to find your way through the massive amounts of information and misinformation and make informed decisions about your health, and the health of your loved ones. Reaching that point takes effort, awareness, and trust in your own powers of perception.

Before deciding whether to investigate news reports further, consider the following:

- Is the headline or story presentation sensationalized—a tactic used mainly to grab attention?
- Is there "context" for the story—for example, background information that
- can help you evaluate the importance of a new finding?
- Is there "fair balance" in the reporting—that is, presentation of varying points of view?
- If the story is on television or radio, does it somehow tie in to one of the show's advertisers? If on the web or in print, is the story positioned near a related advertisement? On close inspection, is the story identified as an advertisement? Does the story's originator also sell the product?

If, after considering these factors, the new finding or treatment seems possibly helpful to a loved one, then it's time to get more details. The following guidelines can help you evaluate the research, separate fact from hype, and identify stories that may be misleading, inaccurate or incomplete.

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General Guidelines for Evaluating Medical Research

First, try to find the *original research article* by contacting the website, newspaper, radio or television station responsible for the news story. This may be easier to do online or at a library, or by calling the institution that sponsored the research; a journalist may or may not get back to you. Once you locate the article, read it thoroughly. Keep in mind that understanding articles written by physicians or scientists for their peers (other members of the scientific community) can be a challenge. The writing style is often technical. Many of the words will be unfamiliar, and you should be prepared to look them up in a medical dictionary or glossary.

Here are some questions to help you assess whether an article might be of interest.

- **How was the study conducted?** In the laboratory, with animals, or with people? Laboratory research, or research with animals, is usually years away from use in a clinic. The results of research with people are more likely to be meaningful to you and your loved one.
- **Where was the article published?** If it appeared in a peer-reviewed medical journal, it has more credibility than if it is posted only on the investigator's web site or in a company's brochure. If the study is reported at a medical meeting, but has not been published in a journal, then the treatment probably needs to undergo further study.
- **Who conducted the study?** A group of researchers based at a reputable university or research institution, or an individual without clear affiliations? Be particularly cautious about accepting claims about treatment effectiveness in articles by people who intend to sell the treatment.
- **Who funded the study?** If a researcher received funding from an independent granting agency that uses a peer-review process for evaluating and awarding funds, the findings may be more credible and less subject to bias than if the funding agency has a vested interest in the results. If a study is sponsored by a commercial entity, this should be disclosed. But although sponsorship may influence the authors'

conclusions in some instances, this is not always the case. There are many research partnerships among industry, university-based researchers, and institutes, so this can be a difficult issue to assess.

- **How many people were tested?** How many completed the study? A small number of participants does not mean the study is invalid, but the small number could lead to questionable results. In most cases, particularly when investigating causes and treatments of chronic illnesses, researchers need to study a large population over a long period of time to ensure that any observed differences are not simply the result of chance.
- **What were the characteristics of the people who participated in the study?** Sometimes, treatments are effective only for certain groups of people—for example, a particular age group, or those whose disease is at a particular stage. Did the researchers study people like your family member? Studies of groups of people who differ from your age, gender, health status, and ethno-cultural background may or may not apply to you.
- **Have the results of the study been repeated by other investigators?** If this is the only study of its kind, then further research is needed to validate and/or repeat the results.
- **If a drug was tested, were there any side effects?** If so, do they outweigh the potential benefits of using the drug? Has the drug been approved by the Food and Drug Administration? If not, are clinical trials of the drug underway? When does the manufacturer estimate that the drug will be available? It often takes many years of testing before drugs are deemed safe enough for use by the public.

Getting Information from the Web

A news story about a treatment may lead you to do additional research on the web. Perhaps you'll go online to find more about a family member's illness, or to join a support or discussion group in which people like you discuss how they are coping and what treatments seem to help their loved ones.

Assessing health information on the web can be complicated. A few years ago, users could safely be told to steer clear of sites with commercial sponsorship. But that is not necessarily true today. Some commercial sites offer good health content for patients and professionals, and many nonprofit and university-run health sites accept commercial sponsorship in order to remain viable.

Although much of the information you find on the web will be valuable, it is important to remember that websites can spring up rapidly, and just as quickly disappear, leaving no one accountable for the false or misleading information that may have been posted on the site. Therefore, it is important to carefully assess any website that offers health or medical information. Following is a checklist to guide you.

- **Who runs the site?** It should be easy for people to learn who is responsible for the site and its information. Check the “About” section carefully for the names, credentials and contact information of the people in charge. Be sure that the site author is qualified to develop and distribute the information you’ve found. Be aware that if the people responsible for the site are selling a commercial product or service, this may influence the content on the site or the context in which the content is placed.
- **What is the purpose of the site?** Generally, the purpose is related to who runs and pays for the site. The “About” section should clearly state the purpose and help users evaluate the trustworthiness of the information offered.
- **Who funds the site?** Websites should state their advertising and sponsorship policies, and how their editorial policy relates to these policies—for example, if a site receives funding from a commercial company, are the funds “unrestricted,” meaning that, in theory at least, the site editors are not influenced by advertisers or sponsors? If there are no such policies, or they are difficult to find, you should assume you’re reading “advertorials” (content that is really advertiser-driven).
- **Where does the information come from?** Many health and medical sites post information collected from other websites or sources. If the person or organization in

charge of the site did not write the material, the original source should be clearly identified. Be aware that information developed for some government sites and publications is not copyrighted, so anyone can post this material on any site. Therefore, a site that is promoting bogus treatments may try to look “legitimate” by including related information from—and links to—government sites such as the National Institutes of Health. The presence of articles from a government source or links to websites of respected organizations does *not* ensure that all the content on a website is reliable.

- **How do you know if the content is valid?** In addition to identifying the original source of the material, the site should state the evidence upon which the material is based. Medical facts and figures should have references (such as citations of articles in medical journals). Opinions or advice should not be presented as “evidence-based” (that is, based on research results).
- **How current is the information on the site?** Sites should be reviewed and updated on a regular basis. It is particularly important that medical information be current, and that the most recent update or review date be posted. Even if the information has not changed, it is helpful to know that the site owners have reviewed it recently to ensure that the information is still valid.
- **How does the site choose links to other sites?** Some medical sites do not link to any other sites; some link to any site that asks or pays for a link; others link only to sites that have met certain criteria, which often are posted on the site.
- **What information does the site collect about users, and why?** Who, if anyone, has access to this information? Many health sites ask the user to “subscribe” or “become a member.” In some cases, this may be done so that they can collect a user fee or select relevant information for the user. In all cases, the subscription or membership will allow personal information about the user to be collected by the website owners. If sites intend to provide users’ contact information to third parties, or to send announcements or

advertisements, users should have the choice of “opting out” (refusing to allow their information to be used for these purposes).

- **How does the site handle interactions with users?** There should always be a way for users to contact the site owners with problems, feedback and questions. If the site hosts a chat room or other online discussion areas, it should state the terms of using the service. It’s a good idea to spend time reading the discussion first, without joining in, to feel comfortable with the environment before becoming a participant.

Participating in Clinical Trials

A clinical trial is a research study with human volunteers to answer specific health questions. “*Interventional*” trials assess whether experimental treatments or new ways of using known therapies are safe and effective. “*Observational*” trials address health issues in large populations.

All clinical trials have guidelines about who can participate in a study, based on such factors as age, type of disease, medical history and current medical condition. Some trials seek volunteers with specific illnesses or conditions, while other trials need healthy volunteers.

Factors that allow you to participate in a study are called “*inclusion criteria*” and factors that keep you from participating are called “*exclusion criteria*.” The criteria are used to identify appropriate participants and keep them safe, and to help researchers ensure they will be able to answer the questions they plan to study.

Clinical trials are conducted according to strict scientific and ethical principles. Every trial must have a protocol, or action plan that describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. It should include details such as criteria for patient participation; schedule of tests, procedures, and medications; and length of the study.

Clinical trials in the United States must be approved and monitored by an *Institutional Review Board (IRB)* to make sure the risks are as low as possible and don’t outweigh any potential benefits. An IRB is a committee of physicians, statisticians, patient advocates and other members of the community

which reviews the protocol to ensure that the study is ethical and the risks are minimized.

People are recruited to clinical trials in various ways, including advertising, announcements in newspapers and other publications, and on the web. Caregivers and family members who use the web to locate clinical trials are faced with two important decisions: Is a clinical trial appropriate for the family member with a chronic illness? And if so, how do you locate a clinical trial in your area?

Clinical trials are sponsored or funded by different organizations, including medical institutions, universities, foundations, voluntary groups, pharmaceutical companies and federal agencies such as the National Institutes of Health. Trials can take place in different locations, such as hospitals, universities, doctors' offices and community clinics.

If you think a clinical trial might be appropriate for your situation—for example, your loved one seems to meet the inclusion criteria and the trial is taking place at a respected nearby institution—here are some points to consider:

- Make sure you are clear about your reasons for participating in the trial and aware of what is involved. Is your family member really well enough to participate? Be aware that if your loved one has illnesses or conditions in addition to the disease for which a treatment is being tested, he or she might not be accepted in a drug study.
- Weigh the potential benefits and risks of participation. Clinical trials may offer access to new treatments before they become available, as well as expert medical care during the trial. However, there may be unpleasant or serious side effects to the new treatment; the treatment may not work for the participant (or, in a randomized, placebo-controlled trial, the participant may not receive the new drug); the time involved may be more than you originally anticipated and may include travel, hospital stays or complicated dosing schedules.
- Before signing the informed consent document, know:
 - The purpose of the study.
 - Who will be participating, and for how long.

- Whether the treatment has been tested before and if so, what were the results?
- The number, types of tests, treatments involved, and whether hospitalization is required.
- Potential risks and side effects, and how they compare with current treatments. This is critical information, and must be explained to you in clear, direct language.
- Who pays for the treatment, necessary travel and complications from side effects.
- What type of follow-up is involved, and how you will be informed of trial results.

Websites that have been developed to help people more easily locate and enroll in clinical trials should be assessed in the same way that you would assess any medical website, using the criteria discussed above in “Doing Research on the Web.” As noted, the following information should be readily accessible: the site’s mission, funding sources, advertising and editorial policies, privacy policy and feedback mechanism.

Additional considerations include:

- Where do the site’s clinical trials listings come from—federal agencies, academic medical centers, or private organizations? Does the site state how it compiles listings?
- Are companies or organizations who run the trials required to pay to be listed on the site? Does the site have any exclusive agreements with any trial sponsors? If so, then you may not have access to all trials of a new treatment that are currently underway.
- Do trial sponsors pay a fee for each participant who signs up for a trial through the website? (Note: users should not be charged a fee to participate in a trial.)
- Can you search the site anonymously for trials, or must you provide personal information before you gain access to the listings?
- Are trial listings up to date? Do you know which trials are still enrolling, versus those

that are closed because they have met their enrollment goals?

- Does the site clearly explain what you must do and whom to contact to be considered for a trial? Trial information should include:
 - Location of the trial
 - Eligibility criteria
 - Understandable summaries of the research
 - Potential risks and benefits of the trial
 - The trial phase (I, II, III)
 - Full contact information, including phone number, of those in charge of the trial.

If the site offers a clinical trial, how and by whom will you be contacted? How soon after your inquiry will you be contacted? Is there a phone number or e-mail address provided for you to call if you are not contacted?

Talk with Your Healthcare Provider

Before taking action—that is, before purchasing an over-the-counter remedy you heard about on the news or on the web, for example, or taking steps to enroll in a clinical trial—**be sure to discuss the information with your healthcare provider.** Decisions to try new treatments should not be made in a vacuum. Someone familiar with your family member’s medical and family history can provide valuable assistance in decision making. Your provider may also be able to answer some of your questions and give you information that was not included in the material you heard or read.

Your healthcare provider may be a researcher and suggest that your loved one participate in a trial. Make sure that the provider has no conflict of interest—such as a relationship with the trial’s funder—that might influence his or her recruitment practices. However, many researchers do have relationships with pharmaceutical companies which they are obligated to disclose to potential research participants.

Be aware that not every provider is up to date on the latest research, and that providers may also be influenced by previous clinical experience, personal

bias, or links to pharmaceutical companies. Also, some providers are more receptive than others to discussing information you've found on the web.

To prepare for a visit with your healthcare provider, consider:

- Informing your provider in advance that you would like to discuss a new treatment, and trying to gauge his or her receptiveness.
- Printing out and bringing with you all relevant information, including, if applicable, the web addresses or names of the discussion groups where you found the information.
- Making a list of questions to ask, and being prepared to write down or tape record the answers.
- Keeping an open mind during the discussion.

Remember, researchers are working continually to find cures or more effective ways to manage symptoms of serious health conditions. As a valued member of the care team, you are in an excellent position to follow up on promising leads, evaluate whether a new treatment might help your loved one, and work with your provider to decide whether participation in a clinical trial is warranted. Stay abreast of the latest treatment news, get the facts, and don't give up hope!

Internet Resources

There are many good resources on the web for information and support. The following sites are good starting points. Be sure to check the "links" section on these sites for other potentially useful sites. Also, many of the organizations listed offer a wealth of materials in print.

General Health/Medical Websites

Healthfinder

<http://www.healthfinder.gov>

Health on the Net Foundation

<http://www.hon.ch>

MedicineNet.com

<http://www.medicinenet.com>

Medline Plus

<http://medlineplus.gov>

National Institutes of Health A-Z Guide to Health Information

<http://health.nih.gov>

Chronic Illnesses

Alzheimer's Association

<http://www.alz.org>

Alzheimer's Disease Education and Referral Center

<http://www.alzheimers.org>

American Cancer Society

<http://www.cancer.org>

American Diabetes Association

<http://www.diabetes.org>

American Heart Association

<http://www.americanheart.org>

American Lung Association

<http://www.lungusa.org>

American Parkinson Disease Association

<http://www.apdaparkinson.org>

American Stroke Association

<http://www.strokeassociation.org>

Centers for Disease Control and Prevention

<http://www.cdc.gov>

Food and Drug Administration

<http://www.fda.gov>

National Cancer Institute

<http://www.nci.nih.gov>

National Heart, Lung, and Blood Institute

<http://www.nhlbi.nih.gov>

National Institute of Arthritis and Musculoskeletal and Skin Diseases

<http://www.niams.nih.gov>

National Institute of Diabetes & Digestive & Kidney Diseases

<http://www.niddk.nih.gov>

National Institute of Allergy and Infectious Diseases

<http://www.niaid.nih.gov>

National Institute of Mental Health

<http://www.nimh.nih.gov>

National Institute of Neurological Disorders and Stroke

<http://www.ninds.nih.gov>

National Parkinson Foundation
<http://www.parkinson.org>

Osteoporosis and Related Bone Diseases National
Resource Center
<http://www.osteoporosis.gov>

Clinical Trials

AIDS Clinical Trials Information Service
<http://www.aidsinfo.nih.gov>

Clinical Trials.gov
<http://www.clinicaltrials.gov>

Centerwatch
<http://www.centerwatch.com>

ECRI: Should I enter a clinical trial?
http://www.ecri.org/Patient_Information/Patient_Reference_Guide/summary.pdf

Office of the Inspector General of the Department of
Health and Human Services
Clinical Trial Web Sites: A Promising Tool to
Foster Informed Consent
<http://oig.hhs.gov/oei/reports/oei-01-97-00198.pdf>

Evaluating Health Information

Consumer's Guide to Taking Charge of Health
Information
<http://www.health-insight.harvard.edu/guide.html>

How to Evaluate Health Information on the Internet
http://cis.nci.nih.gov/fact/2_10.htm

Quackwatch
<http://www.quackwatch.com>

Sites for Caregivers

Family Caregiver Alliance
<http://www.caregiver.org>

Administration on Aging
<http://www.aoa.gov>

ElderCare Locator
<http://www.eldercare.gov>

Medicare.Gov
<http://www.medicare.gov>

National Council on the Aging: Benefits Checkup
<http://www.benefitscheckup.org>

National Family Caregivers Association
<http://www.nfcacares.org>

National Institute on Aging
<http://www.nia.nih.gov>

Resources

MONTEREY COUNTY

Health Projects Center's

Del Mar Caregiver Resource Center

(831) 424-4359

Web site: <http://www.delmarcaregiver.org>

SANTA CRUZ COUNTY

Health Projects Center's

Del Mar Caregiver Resource Center

(831) 459-6639

Web site: <http://www.delmarcaregiver.org>

SAN BENITO COUNTY

Health Projects Center's

Del Mar Caregiver Resource Center

(831) 459-6639

Web site: <http://www.delmarcaregiver.org>

Del Mar Caregiver Resource Center supports and assists caregivers of brain-impaired adults through education, research, services and advocacy.

For residents of Central California, Monterey, Santa Cruz and San Benito Counties, Del Mar CRC provides direct family support services for caregivers of those with Alzheimer's disease, stroke, head injury, Parkinson's and other debilitating brain disorders that strike adults.

This fact sheet was prepared by Family Caregiver Alliance in cooperation with California's statewide system of Caregiver Resource Centers, and reviewed by Jean E. Coleman, R.N., MS, N.P., University of California, Davis Alzheimer's Disease Center. Funded by the California Department of Mental Health. ©2004 Family Caregiver Alliance. All rights reserved.