



## 10 tips for family caregivers

- 1 Seek support from other caregivers. You are not alone!
- 2 Take care of your own health so that you can be strong enough to take care of your loved one.
- 3 Accept offers of help and suggest specific things people can do to help you.
- 4 Learn how to communicate effectively with doctors.
- 5 Caregiving is hard work so take respite breaks often.
- 6 Watch out for signs of depression and don't delay in getting professional help when you need it.
- 7 Be open to new technologies that can help you care for your loved one.
- 8 Organize medical information so it's up-to-date and easy to find.
- 9 Make sure legal documents are in order.
- 10 Give yourself credit for doing the best you can in one of the toughest jobs there is!

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their own health problems, the challenges of running a household (sometimes while still working full time), and the need to manage finances. It may be helpful to refer caregivers to support groups or to such resources as the [Caregivers page](#) on MedlinePlus and the [Caregiver Action Network](#), which has useful tips. (See *10 tips for family caregivers.*)

### Cornerstone of care

Communication is the cornerstone to ensuring effective and consistent care for our patients. Making certain that the voices of caregivers are heard and communicating with them effectively will improve their ability to provide appropriate care and help prevent pressure ulcers. ■

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## What does it mean to participate in a wound care clinical trial?

By Susan Beard, RN, BS, CWOCN

Suppose you're reading an article on a new product that states the product has been through a series of clinical trials before marketing. What does this mean? Who was involved? As a clinician, could you initiate or be involved in a clinical trial of a new product? Who are clinical trial subjects, and what's it like for them to be involved in a clinical study?

A clinical trial starts as an idea. As clinicians, we often use our critical-thinking skills to imagine a product or method of practice we think could be created or improved on to better meet our patients' needs. The idea begins to grow and a series of events begins.

An idea for a new medical product may be presented to an individual or organizational sponsor who shares an interest in the product and is willing to fund a series of clinical trials. A clinical trial is a way to study a new product for safety and effectiveness. Clinical trials are conducted in four phases, as defined by the U.S. National Library of Medicine and the National Institutes of Health. (See *Phases of a clinical trial.*)

In my experience as a research coordinator, patients may choose to participate

## Phases of a clinical trial

Clinical trials for a new medical product proceed in a series of four phases.

- A *phase 1* trial is a safety study conducted with a limited number of healthy, voluntary subjects to help identify an appropriate dosage range for the new product and the presence of adverse effects.
- A *phase 2* trial involves more subjects than the phase 1 trial to further evaluate the product's safety and effectiveness.
- A *phase 3* trial has even more subjects, which allows investigators to evaluate the product's safety and effectiveness more specifically and to observe for adverse effects. This is the last phase before the Food and Drug Administration approves the product (if it does approve it) and the product is marketed.
- A *phase 4* clinical trial collects information on the product's effectiveness and adverse effects linked to long-term use in the general public.

in a research study because it may provide clinical information (through laboratory studies, X-rays, and other tests) about their medical problem at little or no cost to them. It also may give them access, at no cost, to advanced medical treatment not yet available. Patients may even be compensated for travel expenses related to study participation. (See *Online patient education resources*.)

### Safety first

The safety and protection of volunteer subjects participating in clinical trials are vitally important. Once a sponsor decides to conduct a clinical trial, a master plan called a protocol is created. A protocol states the objective of the trial, outlines the study design, and details the number and types of subjects who will participate, along with additional information on how the trial will be conducted. Not all clinical trials follow the same protocol, but in a given trial, the same protocol is followed for all participants. The protocol is re-

viewed and the clinical trial is monitored by an independent committee of medical professionals and others, called an institutional review board, which makes sure the trial is conducted ethically and participants' rights are protected.

A sponsor may use a clinical research organization (CRO) to conduct the study. A CRO works with the clinician on behalf of the sponsor to carry out the details of the study protocol efficiently and ethically.

### Inclusion and exclusion criteria

The type of subject needed for a particular study trial is defined by a list of inclusion and exclusion criteria, as outlined in the study protocol.

- *Inclusion* criteria may include the presence or absence of a particular medical problem, such as diabetes with an acceptable glycosylated hemoglobin level for a clinical trial on diabetic foot wounds. For such a trial, wound duration and size also may be specified.
- *Exclusion* criteria may include a particular medical problem that would affect the study negatively, such as a chronic disease or use of a specific medication.

The patient must meet all inclusion and exclusion criteria to be considered for participation in a particular clinical trial.

### Introducing patients to a clinical trial

Patients who meet all qualifications for a clinical trial receive an informed consent form (ICF) to review, which includes details of the trial and how they will be asked to participate. The ICF describes the risks and potential benefits of participating in the study. Patients get ample time to review the ICF and ask questions. Then, if they desire,

they sign the form, indicating their interest in participating in the study. After the investigator conducts the informed consent discussion and reviews the consent with the participant, the research coordinator may obtain the signatures needed for the ICF. Patients are assured they can withdraw from the study at any time without risking negative consequences. (For details on what the ICF must include, visit [www.hhs.gov/ohrp/policy/consentckls.html](http://www.hhs.gov/ohrp/policy/consentckls.html).)

### Run-in period

After patients agree to participate in the study, a so-called run-in period occurs, during which they undergo laboratory tests, X-rays, and other studies as listed in the protocol and ICF. Test results are included in the final analysis of study results.

The run-in period usually lasts 2 to 3 weeks; patients receive standard-of-care treatment during this time. For instance, if your patient has agreed to be in a clinical trial, you might measure the wound and collect other specific information during the run-in period. Measurements at the beginning and end of the period will be compared to identify patients whose healing rate is acceptable with standard-of-care treatment only. These patients may be excluded from the study.

### Treatment period

After the run-in period ends and the patient has been determined to qualify for the study, the treatment period begins. The patient receives the study product or possibly a placebo as outlined by the protocol and ICF. Patients are assigned randomly to receive either the study product or a placebo; neither the patients nor investigators know which patients are receiving which. Called a double-blind study, this

## Online patient education resources

Direct patients seeking general information about clinical trials to the websites below.

 [www.nlm.nih.gov/medlineplus/clinicaltrials.html](http://www.nlm.nih.gov/medlineplus/clinicaltrials.html)

This Medline Health (National Institutes of Health [NIH]) website provides information on clinical trials in easy-to-understand language. The interactive tutorial is in both English and Spanish.

 [www.nih.gov/health/clinicaltrials/](http://www.nih.gov/health/clinicaltrials/)

 [www.clinicaltrials.gov/ct2/info/understand](http://www.clinicaltrials.gov/ct2/info/understand)

 <http://clinicalcenter.nih.gov/participate/studies.shtml>

These NIH sites provide comprehensive information, including the basics of clinical trials, benefits of being in a clinical trial, how to find a clinical trial, a list of registries, and personal stories of patients who've been in trials.

 [www.youtube.com/watch?v=9MpUwsgXLxw](http://www.youtube.com/watch?v=9MpUwsgXLxw)

This patient education video provides basic information, including informed consent and patient protections.

 [www.nlm.nih.gov/medlineplus/tutorials/clinicaltrials/htm/\\_no\\_50\\_no\\_0.htm](http://www.nlm.nih.gov/medlineplus/tutorials/clinicaltrials/htm/_no_50_no_0.htm)

This interactive tutorial on clinical trials is also available in Spanish at [www.nlm.nih.gov/medlineplus/spanish/tutorials/clinicaltrials/spanish/htm/index.htm](http://www.nlm.nih.gov/medlineplus/spanish/tutorials/clinicaltrials/spanish/htm/index.htm).

type of study guards against bias.

If your patient is enrolled in a clinical trial studying a wound care product, for instance, you'd assess wound characteristics and measure the wound at each visit. Using a standard device provided by the sponsor, you would take a photo of the wound and send it to the sponsor or CRO. Whether they're receiving the study product or a placebo, all subjects receive the identical standard of care, as outlined by the protocol.

During each study visit, the coordinator confirms with the patient that he or she wishes to continue to participate in the study. Each step of the study visit is documented carefully on a source worksheet and entered into an electronic case report form, which is sent to the CRO for review. The CRO may generate questions about this documentation, which are submitted to

the coordinator in the form of a query. The coordinator is responsible for responding to all queries. Some queries identify errors in documentation or transcription; when appropriate, the coordinator responds that the data entered were correct.

The treatment phase of the study lasts several weeks, as long as the study protocol requires, or until the patient heals (if that occurs before the treatment phase ends).

### Post-treatment phase

The post-treatment (observational) phase of the study may last 2 to 4 weeks or even longer. During this time, you would continue to monitor the patient, assess the healed wound, photograph the site at each visit, and make sure required follow-up lab tests, X-rays, and other studies are performed.

The opportunity to participate in a clinical trial is exciting and interesting for both the clinician and patient, allowing them to watch an idea grow into a clinical trial and a potential new product. Those who participate come to appreciate the many people who contribute to development of a new product. To get started participating in a clinical trial, visit <https://clinicaltrials.gov/> and search for a study that fits your clinical practice. ■



#### Watch: Clinical trials explained

1. Patient Education
2. Drawn to Science

#### Selected references

National Institutes of Health. About clinical studies. Last reviewed August 2012. <http://clinicaltrials.gov/ct2/about-studies>. Accessed November 26, 2014.

NIH Clinical Center. For researchers and physicians. Last updated September 26, 2014. <http://clinicalcenter.nih.gov/researchers.shtml>. Accessed November 26, 2014.

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## Translating the language of health care

By Catherine E. Chung, PhD, RN, CNE, WCC

As a wound care clinician, you teach patients about medications, wound treatments, the plan of care, symptoms of complications, wound physiology—you teach a lot. And most patients probably smile and nod when you ask, “Do you understand?” However, health literacy research has shown that only 12% of the U.S. population is fluent in the language of health care. As health care has become increasingly complex, it has become increasingly difficult for patients to understand. Fortunately for your patient, you can translate.

### Health literacy and your patient

According to the U.S. Department of Health and Human Services, health literacy is “the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Health literacy has little to do with someone’s ability to read or write. Rather, health literacy is about the person’s ability to acquire, understand