Supporting a Patient’s Decision to Enroll in a Clinical Trial:

Tips and Talking Points

Research shows that YOU, your recommendation and your support are key to a patient’s decision to enroll in a clinical trial. Talking with a patient about participating in a clinical trial requires a unique set of communication skills and an understanding of the factors that influence the decision. The following tips provide information on how to best support and talk with a patient deciding to enroll in cancer clinical trials.

Why patients say YES:

It is important to understand why and how patients agree to participate in a clinical trial. People enroll for two reasons:

- They believe they will get newer and better treatments for their cancer, and/or
- They want to help others and give back

Depending on the individual, the “others” may be their family or friends or other cancer patients. Therefore, it is important to know something about the life, work and family of the patient whom you are talking with about enrolling.

A patient is most likely to say yes when these four criteria are met:

- Costs are manageable
- Their doctor demonstrates supportive behavior
- Side effects are manageable
- Family opinion supports enrollment

How you can support a patient’s decision to enroll in a clinical trial:

- Build trust by demonstrating technical competence, understanding the patient’s individual experience, expressing caring, communicating clearly and completely, building partnership/ sharing power, being honest and demonstrating respect for the patient.
- Consider cultural issues and how they may influence decision making. In some cultures health care decisions are deferred to the family rather than being made by the individual.
- Convey enough science and evidence-based information for understanding without overwhelming the patient. During your conversation, check with the patient often to see if the amount of information you’re providing is aiding or interfering with informed decision-making.
- Create consistency of messages among members of your clinical trial team. Be consistent in the words you and your team use to talk about clinical trials. If at all possible it may be helpful for a physician and a nurse to be in the room together when talking to a potential participant.
- If a treatment trial is not available or appropriate for your patient, consider offering a symptom management or behavior intervention trial.
- Allow adequate time to explain a clinical trial to the patient. You may find it more efficient to have your staff prescreen patients.
- Be specific about when you will follow-up with the patient about his or her decision to enroll in a clinical trial. Don’t leave it up to the patient to call you.
- To encourage patients to ask about clinical trials, you can provide information in the waiting room, posters in exam rooms, and flip charts in resource areas or libraries.

Why patients say NO:

Patients say “no” because they don’t have the information they need to say “yes.” That information may include direct costs for treatment as well as details about transportation, parking and reimbursement, time commitment and lost time from work and family.
The following talking points provide information on how to best support and talk with a patient deciding to enroll in cancer clinical trials.

- **Make the offer specific:** Make a clear offer of a clinical trial, since research shows some patients did not realize they were offered a clinical trial.

  **Suggested phrase:** I would like to speak with you about a clinical trial that might be a treatment option for you.

- **You and your patient are a team:** Choose words that convey alliance between you and your patient. During your conversation, frequently use words like “we” and “us.”

  **Suggested phrase:** We would like for you to consider a clinical trial as part of your treatment plan. While this is a very personal decision we are here to take care of you and support you. By participating in this trial, you’ll help us learn more about treatment for patients with your type of cancer.

- **Ask who makes decisions:** Determine who the primary decision maker/influencer is; it may not be the patient. Cultural, ethnic and generational differences play a role in decision making and the acceptance of offers of inclusion in clinical trials. Ask the patient if anyone else is important to the decision to enroll, and include that individual in the discussion, either in person or by phone.

  **Suggested phrase:** Is there someone important in your life you would like to talk about this? Is he or she here with you today? If not, can we call right now so he or she can join our discussion by phone?

- **How to discuss randomization:** When explaining randomization do not use the phrases “coin toss” or “randomly assigned” because they reinforce a patient’s concern over loss of control.

  **Suggested phrase:** Randomization is a process that assigns you to a group. Some trials randomize the same number of patients to each group. This means you would have an equal chance of being in either group. Randomization is very important because it helps make sure each group is alike and that the results are due to treatment, not other factors.

- **Explain placebos:** If applicable explain the use of placebos in cancer clinical trials. Misunderstanding can lead to mistrust and a decision not to enroll in the trial.

  **Suggested phrase:** A placebo is an inactive treatment that does not have any effect on the cancer. It is often given in the same way as the active treatment. For example, if the active drug is given as a pill, the placebo will be a pill. A placebo is used to make sure results are due to treatment, not other factors.

- **Address myths:** Candidly address medical research mistrust and patient concerns about taking part in a study or being experimented upon. You may have to probe to raise these concerns.

  **Suggested phrase:** Do you know what a clinical trial is? What are your thoughts about clinical trials? What have you heard about being in a clinical trial?

- **Discuss side effect management:** Explain side effects in language a patient can understand. Side effects are easier for a patient to accept when you also describe how you will manage them.

  **Suggested phrase:** This drug may cause something called peripheral neuropathy. Peripheral neuropathy is sometimes described as tingling in the hands and feet. If it is very serious it can make it difficult to button your shirt or hold a coffee cup with one hand. We will monitor you very closely. That way, if this happens, we can reduce the dose of the drug or take you off the drug for a few weeks so it does not become serious. -OR- This drug causes most people to lose their hair. Other patients have found it helpful to have a wig available if this happens. We can write you a prescription for a wig and have a list of shops where you can find a wig and have it cut to your own preferred hair style.

- **Don’t say biopsy:** When offering a trial that includes biospecimens for research, use the phrase “tissue sample” rather than “biopsy.” Research done using patient interviews has found patients don’t like the term biopsy because it means you are looking for cancer.

  **Suggested phrase:** This clinical trial asks you to provide a tissue sample so researchers can study the biology of cancer. This does not have a direct impact on your care, but it may help future patients with your type of cancer.

- **Encourage questions:** Encourage patients to ask more questions and be more direct with their questions.

  **Suggested phrase:** If I were in your shoes right now, I would be concerned about... Is there anything you’re still confused about? Is there anything you would like me to explain in more detail? Are there any issues you are concerned about that we could address? (Probe for barriers concerning cost, transportation, work issues andblinding.)

- **Ask what the patient heard:** Verify what the patient has heard. Many times what is said and what is heard are different. It is important to be aware of what the patient thinks you said so you can correct any misconceptions.

  **Suggested phrase:** I’ve given you a lot of information. Let’s take a minute to make sure we’re on the same page. Would you please summarize for me in your own words what we just discussed? Is there anything you would like me to repeat?

- **Repeat the ask:** Make a clear offer of a clinical trial, since research shows some patients did not realize they were offered a clinical trial.

  **Suggested phrase:** Now that we have discussed this clinical trial, would you consider enrolling in it? I will give you this copy of the informed consent to read over. I’ll also give you a brochure about the clinical trial that describes the information we’ve talked about. At our next appointment, we can talk about your decision and discuss any other questions you may have.

**REFERENCES USED IN DEVELOPING THIS MATERIAL:**