

Attributes of Exemplary Research

Engaging Referring Physicians in the Clinical Trial Process

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Referring physicians play a vital role in facilitating patient access to clinical trials. Introducing the concept of clinical trials to their patients before referral to the treating oncologist, as well as referring only to oncologists who participate in clinical trials are two simple approaches that can help increase the number of patients willing to participate in clinical research. Educating referring physicians about clinical trials is thus an important and yet overlooked mechanism for increasing accrual to cancer clinical trials.¹ A survey conducted by investigators at Michigan State University found that primary care provider (PCP) attitudes and attendance at education sessions about cancer clinical trials consistently predicted referrals.²

Although referring physicians can play an important role, they often have little knowledge about cancer clinical trials and do not discuss this treatment option with patients. The National Cancer Institute (NCI) conducted a survey of 706 PCPs and found that 98% of respondents referred their patients to cancer specialists without discussing the topic of clinical trials.³ Of these respondents, 37% stated that they were unaware that clinical trial participation might be an option for their patients.³ These data highlight an important missed opportunity to improve clinical trial participation.

This article, part of the series on exemplary attributes of clinical trial sites,⁴ provides practical advice on how oncologists can engage referring physicians in the clinical trial process. The article is accompanied by a Data Supplement consisting of a slide presentation that parallels this article and is designed to be used by oncologists when talking with referring physicians about clinical trials.

Build Relationships

Relationships with referring physicians can be initiated through formal or informal presentations; conversations at conferences, grand rounds, or meetings; or even during casual conversations with colleagues. In discussing the services offered by the oncologist or available in his or her practice, we suggest mentioning the added value to patients of being offered opportunities to participate in cutting-edge research. This also gives the oncologist the chance to allay common fears, address common misconceptions, and recast trial participation as a high-quality treatment option. A way to begin the conversation might be by saying something like, “I provide a full range of treatment op-

tions to patients with cancer, including clinical trials” or “I provide quality care that includes clinical trials.” The oncologist should then offer to answer any questions the referring physician has about clinical trials and welcome continued contact.

There are a number of ways to build relationships, and another effective option is to offer to travel to the office of the referring physician and provide an interactive talk over breakfast or lunch, if the oncology practice has sufficient resources to do so. These discussions provide the occasion to answer questions and educate PCPs and their staff about the role of clinical trials in cancer care. We cannot underestimate the importance of a solid endorsement of research participation on the part of PCPs. If patients are discouraged or even warned against participating in clinical trials before they even meet the oncologist, then it is extremely unlikely that they will change their mind on meeting the specialist. Such education has been shown to have a positive effect on PCP attitudes and behaviors.^{1,2,5} A study conducted by the Education Network to Advance Cancer Clinical Trials found that PCPs who attended an education program about clinical trials had a statistically significant increase in knowledge about the training content and an increase in “positive attitudes about the role of a PCP for CCT referrals.”⁵ The training focused on discussions PCPs could have with patients and their families about clinical trials and the role of clinical trials as an element of quality care.⁵

When holding meetings at the office of a referring physician, it is important to involve nurses and other ancillary staff at the practice. These individuals can be very influential and often serve as “research champions.” For example, ancillary staff members may be responsible for ensuring that literature about clinical trials is available to patients and reminding the referring physician to refer patients to oncologists who also conduct research. Ideally these planned didactics should include several members of the research team so that relationship building can occur among all levels of personnel, not only at the level of physicians.

Once a trusting relationship with a referring practice has been established, frequent contact is needed to maintain it. This could be done through repeat visits and the timely exchange of progress notes on referred patients. Sharing trial results with the PCPs and thanking them for their referral is also important. It recognizes them for their efforts to help obtain the answer to

research questions and further educates them about the importance of clinical trials. Not all trials have positive results, but most provide information that advances cancer care. PCPs need to know they played an important and valued role in this process. Time pressures may pose additional challenges for oncologists seeking to maintain in-person contact with referring physicians, but we suggest these efforts might be worth the investment.

Set the Record Straight on Clinical Research

Referring physicians need to have a realistic understanding about clinical trials because their opinions can greatly influence patient decision making. Informal polls indicate that PCPs have little understanding about the design of clinical trials, phases of research, and criteria for patient safety. When talking with referring physicians and their staff about clinical trials, it is helpful to have talking points prepared. This will help normalize the conversation and ensure that the most important information is conveyed. For example, it is important to reinforce that

- Clinical trials are a component of high-quality care.
- Patients who enroll in clinical trials are treated well.⁶
- Randomization is a common component of clinical trials, but patients with active disease will never receive an option that is considered inferior to standard treatment.
- The data gathered through clinical trials are instrumental in moving the field forward.
- Patients do not have to travel extensive distances to participate in clinical trials because participation is often available in the communities where they live.

In addition, common misconceptions that should be addressed include those listed below. Care should be taken to dispel all of these myths, as they constitute significant attitudinal barriers to timely referral.

- Fear that patients will be treated like “guinea pigs.”
- Beliefs that clinical trials are a last-resort option and never appropriate for first-line treatment.
- Concerns that patients may be randomly assigned to receive only a placebo.

Oncologists may also choose to discuss the specific types of trials offered at their research site, including trials related to symptoms management and quality of life that can be offered to patients who are not able or willing to participate in treatment trials but whose participation is nonetheless indispensable to advance our knowledge about treatment effects. As opposed to talking about specific trials, it is often more effective to broadly discuss the types of trials available at the site and the concept that clinical trials are a quality treatment option. This strategy is recommended because it is outside the purview of the PCP to determine whether a patient is eligible for a specific treatment trial and because it becomes overly burdensome to update the PCP about every trial that opens and closes at the research site. In some instances, it is beneficial to provide a local “success story” to garner excitement and inspire providers to change their behavior.

In order to normalize the procedural aspects of trial enrollment, we suggest to oncologists that they consider discussing trial mechanics, that is, the typical flow of events after a patient decides to enroll, with the referring team. To address this, the oncologist might briefly explain the informed consent process and how the patient will be monitored closely by a member of the research team. The specific information needs of a referring physician and their team will vary, but it is important to help them acquire some knowledge in addition to developing an interest in clinical trials.

Recommend Actions for the Referring Physician

There are several actions a primary care physician can take to help ensure their patients are informed about the option to participate in clinical trials, even if it is simply validating a patient’s choice to enroll. Actions that can be suggested include

- Refer patients to an oncologist that conducts clinical trials.
- Generally introduce clinical trials as a viable treatment option.
- Provide patients with print information about clinical trials.
- Encourage patients to ask their oncologist about clinical trials.

The referring physician should also be encouraged to introduce the concept that clinical trials are a treatment option and encourage the patient to ask the oncologist about clinical trials. Research has shown that only 10% to 20% of patients with cancer are informed about clinical trials, an unsettling statistic that referring physicians can help improve.⁶⁻⁸

Establish Expectations

It is important to set realistic expectations of the referring physician and their team. It goes without saying that they will be less likely to collaborate if they believe another burden is being added to their work. Having a transparent discussion about the role of each party will prevent future frustration and ensure that patients receive the best possible care. For example, it is imperative that everyone is in agreement regarding who patients should report adverse effects to and what treatment each physician is responsible for. The oncologist should emphasize that the research team is prepared to do the work necessary and that the expectations of the referring office will be no greater than when a patient they refer is treated with standard anticancer therapy.

The oncologist should also inform the referring physician that they will provide updates regarding the progress of patients they have referred, just as they would with a patient receiving standard care. In addition, PCPs may need assurance that referred patients will return to their care when appropriate and will not be lost because they participate in a clinical trial. The oncologist can greatly strengthen the relationship with the referring physician by committing to ongoing communication about all patients that are referred to the oncologist and ensuring that the primary care physician remains involved in the treatment of the patient.

Data Highlights

- The National Cancer Institute conducted a survey of 706 primary care physicians and found that 98% of respondents referred their patients to cancer specialists without discussing the topic of clinical trials.²
- Research has shown that only 10% to 20% of patients with cancer are informed about clinical trials, an unsettling statistic that referring physicians can help improve.^{5,6,7}

Conclusion

This article provides practical advice on talking with referring physicians about clinical trials. As another resource, the authors developed slides that can be used by oncologists during discussions with the referring physicians and staff (Data Supplement). Referring physicians play an important role by introducing the concept of clinical trials to their patients and referring patients to oncologists who participate in clinical trials. Building relationships with referring physicians is an important step in promoting a

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research-oriented culture and, coupled with interventions targeting public awareness of the value of medical research, will help speed up the process that will ultimately give us better treatments for future patients.

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