Original Contributions

Power of an Effective Clinical Conversation: Improving Accrual Onto Clinical Trials

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Abstract

The National Cancer Institute (NCI) is actively transforming clinical trials to revitalize the clinical trials system and improve patient accrual. For more than 30 years, NCI has provided information and communication resources about cancer clinical trials. The Institute supports a clinical trials Web site (www.cancer.gov/clinicaltrials) that receives nearly a half million page views a month. In addition, NCI's Cancer Information Service (800-4-CANCER, chat and e-mail) responds to 1,750 clinical trial inquiries every month. Although these numbers suggest that a high volume of clinical trial information is being exchanged between NCI, the public, and providers, most patients decide whether to participate in clinical trials during the patient-provider interaction.

Introduction

Low accrual onto clinical trials is a dilemma that could significantly improve if all clinicians were to ensure that every patient is screened for and, when eligible, invited to participate in clinical trials.[1] However, many doctors identify clinical trials as one of the most difficult areas of discussion in a consultation,[2-4] so it is not surprising that trials may be offered only to patients they deem ideal candidates.[5-7] Patients require their own time, first to confront a new cancer diagnosis or recurrence, and then to process it sufficiently so they can make decisions about treatment.

Yet effective communication goes beyond telling patients that clinical trials are available; it also requires that clinicians invest time to build trust and educate patients about the phases of trials, randomization, and the possibility there might be no benefit from trial participation. All of these factors must be effectively conveyed if patients are to reach a full understanding of what it means to participate in a trial. In many cases, physician communication styles and patterns develop over time and become rote, without the benefit of reflection, self-appraisal, discussion with colleagues, or consideration for change. Not many clinicians and research teams periodically devote time to critique how they communicate about clinical trials, to ask whether their strategies are purposeful and evidence based, or to determine how they might be improved.

A significant body of published literature demonstrates how the science of communication—its theory, methods, and practices—plays an important role in the process of accruing patients onto clinical trials. Improving the communication skills that clinicians use when explaining trials could allay or resolve patients' concerns and thereby increase the likelihood of their participation.[6] Communications research has identified many ways to approach clinical communications, based on years of studying patient preferences, provider behaviors, and the interaction between the two. Effective clinical conversations create the opportunity for patients to understand their options and to gain a better foundation for informed decision making about clinical trials.

Below we present several evidence-based communication strategies, along with practical information and examples gleaned from successful programs, to improve clinical trial discussions. These strategies are low cost and intuitive, and they do not require complex processes to implement.

Strategies to Implement in Your Practice

Build Trust and Rapport

Building trust and rapport with patients appears so obvious that it can easily be taken for granted. However, the available evidence reinforces the critical need to focus on developing and using the behaviors that patients identify as important. For example, patients often report that certain qualities of their provider's communication—being reflective, patient-centered, supportive, and responsive—influence their decision to participate in a trial.[7,8] Providers can help patients overcome common concerns about trial participation, such as fear of adverse effects or cost of participating,[9] by building a trusting, cordial, and engaging relationship with their patients.

Part of this alliance-building process involves empathic listening to patients, as highlighted in focus group research by Ellington et al[8] with 55 English- and Spanish-speaking participants that examined the factors influencing clinical trial participation. According to this research,

- Participants report a desire to share their personal "cancer story" with their physician; being known to the physician by having their experience acknowledged was an important part of their comfort in making a decision about clinical trial enrollment.
- Spanish-speaking participants expressed the importance of feeling a personal connection with the doctor. One partic-

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ipant reported that her physician is someone who "listens, understands me," and that "she made me feel like I really mattered to her. I know I am important."
- Some participants cited examples of what they termed "disrespectful" treatment experiences (eg, being told they asked too many questions, or feeling they had been treated by their physician in a rushed, defensive, and patronizing manner). Such treatment led them to feel less than satisfied with their provider.

Stevens and Ahmedzai,[11] exploring why breast cancer patients decline entry into randomized clinical trials of adjuvant therapy, found that sensitivity to the timing and volume of information delivered is essential. One participant said, "Being pressured put me off; obviously they need to get started, I understand that, but you need time to think about the diagnosis, let alone to think about whether to take part in a trial."

In addition to insights from the literature, certain clinical practices may help build trust and rapport. Managers representing three community programs shared insights into successful practices:
- Research staff respond quickly to referrals and do not keep patients waiting. Establish rapport with the patient on the initial contact: conduct the conversation in a quiet and comfortable location, allow adequate time for discussion, and ensure that staff are well-informed and can speak confidently about the trial.
- Make arrangements with the patient for a follow-up conversation and provide contact information for the research nurse.
- Tailor information appropriately. One program manager described an early-career oncologist who gave an excellent academic description of the protocol, incorporating a lot of statistics, but unfortunately overwhelmed their low-literacy-level patients with that level of detail.
- Staff should actively participate in cultural competence training to build confidence and the ability to ensure that the appropriate decision makers are included in the discussion, that appropriate educational materials are provided, and that language needs are addressed.

Overall, patients who perceive a sense of fairness and trust in their doctors and research team are more willing to discuss clinical trials.[12,13]

Attend to Nuance and Perception

The seemingly small things in a clinical conversation are important and may influence the outcome of the decision process. Research conducted by Wade et al[14] identified three simple evidence-based strategies that providers can use to help participants articulate their concerns more effectively when discussing clinical trials: (1) use open-ended questions to elicit concerns, (2) use long pauses to give patients time to organize their thoughts, (3) readily cede the floor to patients when overlapping speech occurs.

Another easily overlooked element of the conversation is the use of metaphors to describe the randomization process. Although metaphors can be a helpful tool, they can also be problematic when greater sensitivity should be paid to different social and cultural contexts.[15] For example, the frequently used "flip of the coin" metaphor was clearly disliked by women and older members of the public in a 2002 study.[16] An unintended effect of its use was that some patients perceived this term as trivializing their situation. One study participant remarked, "If I had cancer I would not like to think of my fate resting on the toss of a coin." Physician biases, whether for or against participation, also can unduly influence a patient's decision to participate.[17]

Follow a Framework

Presenting information in a framework may enhance the quality and efficacy of the communication process. Research by Eder et al[18] and Yap et al[19] suggests the merits of a three-stage, sequenced approach when introducing the concept of a clinical trial to a prospective enrollee. The first stage is to discuss the diagnosis: the authors found it difficult to successfully move the presentation forward unless the patient and family understood both the meaning of the diagnosis and the need for therapy. The second stage is to present the standard therapy option, and then to present and discuss the clinical trial in the final stage. Presenters should emphasize and highlight the options for treatment, and adequate time should be provided to ensure that all questions and issues are understood and that the decision making is shared; potentially such a full discussion might take two meetings. Brown et al[20] refer to a similar sequenced approach and reinforce the need to give equal weight to information about both the standard treatment and the clinical trial option. Attending to the quality and organization of information, rather than its sheer quantity, may improve the outcome of the clinical trial discussion.

Normalize the Clinical Trials Discussion

Stevens and Ahmedzai[11] found that patients who were not prepared in advance to discuss clinical trials were more likely to be confused by the information they received and were also less confident about their level of understanding. Some said they felt shocked about the way they were approached, especially when that approach was made by somebody they had not previously met. Again, patients commented that they were not prepared for the request and, in some cases, misinterpreted the reasons why they had been asked to participate.

Preparing patients about clinical trials in advance of any treatment discussion can help normalize clinical trials as simply one other option to consider. Strategies to normalize trials include ideas about educating patients before they even walk in the door. These could include, for example, sending a welcome letter to new patients that describes clinical trials as a potential option for care,[21] or using patient navigators to provide information about clinical trials as part of the process of educating new patients. Placing NCI's "Ask me about clinical trials" posters in patient waiting areas or examination rooms and/or having

staff wear buttons with the same message are additional ways to normalize the idea of clinical trials and begin the conversation.

One successful effort to normalize clinical trials was a 2-year awareness campaign undertaken in the late 2000s by the Ohio State University Comprehensive Cancer Center (OSUCCC).[22] OSUCCC set a goal of accruing 2010 patients by the year 2010 and implemented a concerted center-wide initiative to increase awareness and acceptability of clinical trials as a treatment option for their patients to consider. Across their entire campus, OSUCCC ensured that its staff valued clinical trials and reviewed the potential eligibility of each patient. Floor-to-ceiling banners and posters were placed throughout the center and featured former trial patients encouraging new patients to ask their doctor about clinical trials. OSUCCC used their Web site to inform and highlight their available trials, and materials about clinical trials were sent to each patient's home. OSUCCC also reviewed its entire operating system to ensure that their own processes did not pose barriers (eg, health insurance) to patients who wanted to enroll. In all, OSUCCC embraced clinical research as key to its mission and actively worked to normalize trials as one treatment option. As a result of their efforts, they exceeded their accrual target and achieved their goal 4 months ahead of schedule.

Use a Team Approach

The experience of both academic and community programs highlights the importance of the team approach to success in trial accrual. One team communication model commonly cited by high-accruing programs is for the physician to first introduce the concept of a clinical trial, its objective, and treatment rationale. Maria Gonzalez, program manager at the St. Josephs Center for Cancer Prevention and Treatment in Orange, CA, describes an effective team approach. "At the first point of patient entry into our system, usually with a surgeon, the physician endorses clinical trials, provides an overview and says, 'If you are eligible, I hope you consider participating.' The research team then presents the trial-specific information with the patient and family. The partnership between physician, the research team, and the patient and family is pivotal." (personal communication).

In addition to the physician investigator, clinical trials team members may include research nurses, clinical research associates, research coordinators, data managers, patient navigators, and administrators. Given the complexity of conducting clinical trials, it becomes an effective exercise to match skills and capabilities with the tasks to be done. Marge Good, a nurse consultant, reflects on her many years of experience as the administrator of the Wichita Community Clinical Oncology Program. She notes that some nurses were very effective at scanning charts and determining eligibility but did not feel as comfortable explaining a trial protocol to a patient. The nurses who felt comfortable with that interaction typically performed well and were more successful recruiters.[23] Consistency of messages, integration of services, and smooth hand-offs among all team members are necessary to ensure that the patients receive accurate information, consistent education, and coordinated care.

Use Available Resources

NCI provides numerous resources to support busy clinicians who want to evaluate and improve their own clinical communication skills (text box). AccrualNet[24] contains an extensive collection of published literature, sample tools, and training materials to support clinical trial accrual.[25] In the study stage Recruiting and Enrolling Participants, a key activity is to emphasize the key role of the oncologist presenting the trial, and the stage includes access to 16 published journal articles that present the issues and evidence relevant to the provider-patient conversation, many of which reinforce the importance of gaining trust and introducing the idea of clinical trials.

NCI Resources to Support Communication With Patients About Clinical Trials

- General patient materials – cancer.gov/publications.
- Including clinical trials in your practice, an online course – cancer.gov/clinicaltrialscourse.
- AccrualNet, resources to support patient accrual – https://accrualnet.cancer.gov.
- Cancer Information Service – 1-800-4-CANCER.

NCI's Cancer Information Service can support the clinical team by providing basic clinical trials information to patients who are considering whether to participate in a study. Communicating in both English and Spanish, the information specialists offer patients and families clinical trial information through telephone, online chat, and e-mail. One focus group of patients indicated a desire to receive information about clinical research from an independent source.[11] The Cancer Information Service can fulfill this role by sharing NCI clinical trial information resources, reviewing the basics of clinical trials, and helping patients assimilate new information.

Brown et al[26] developed and tested a Question Prompt List for clinical trials that, based on the results, could be a valuable aid. At the time of this writing, additional research is underway to do more testing on whether consultations are useful and how they affect the overall communication process. NCI provides a list of questions for patients to ask their doctor on NCI's Clinical Trials portal site.[27] Several other clinical trial education and communication resources for the patient and the research team are also available on this site.

A key NCI resource for the research team is the online course, "Including Clinical Trials in your Practice."[28] This modular training not only describes for potential new investigators the components necessary for conducting clinical trials, but can also serve as a refresher for seasoned research team members, with tips on patient recruitment and how to talk to patients about clinical trials.

Consider Communication Skills Training

Communication skills are an essential component of clinical competence, yet many clinicians receive insufficient or inade-

quate training in this area.[29] Several studies have documented that training programs can improve the communication skills of providers,[30-32] but such training programs are not yet widely available, and busy clinicians may not be willing or able to participate in multiday training programs. It is critical that the oncology research community work with communication experts to address this gap and develop well-tested training opportunities that fit within the workflow of the busy research team.

Despite the paucity of available communication training programs, there are several practical recommendations to draw from the literature and existing programs that can be adopted by clinical research teams. These include (1) incorporate communications training into orientation of new staff and physicians; (2) include communication awareness topics in regular protocol or staff meetings and patient care conferences; (3) use peer mentoring, with newly hired physicians being mentored by more seasoned oncologists; and (4) seek feedback from patients to identify ways to help the team address challenges and build skills.

Online training modules can offer potential alternatives to face-to-face programs. Clinicians are now just as likely to participate in online continuing medical education training as traditional training.[33] When the content is relevant and physicians feel that the information is needed or important, they will seek the education, either in person or online. For example, more than 490,000 unique clinician users viewed online training based on edited material from the curriculum, *Education in Palliative and End-of-Life Care for Oncology*, a collaboration between NCI and Medscape, beginning in 2007. In an analysis of the first 7 months of data on the module, "Last Hours of Living," 20,061 health professionals completed the activity and earned continuing education credit. Eighty-four percent completed the postactivity evaluation survey, and a strong majority said that what they learned would affect their practice.[34]

Although maintaining long-term changes in provider behavior is challenging, at least one study found that oncologists who participated in a communication skills program retained some of their new skills 1 year later.[35] There is also evidence that post-training consolidation workshops enhance the effects of the training.[36]

Moving Forward

Increasing the number of patients who participate in cancer clinical trials is central to advancing new treatments and, ultimately, to saving lives. Yet it remains an ongoing challenge and requires continuous commitment by clinicians. Assessing eligibility and initiating a clinical trial discussion with all eligible patients are challenges that must be met if accrual rates are to be improved. One way to do this is through effective, consistent communication practices. Research has amassed evidence regarding helpful approaches that can be incorporated into clinical practice, and there are many health care provider tools available. Although improved communication with patients alone will not completely meet the challenge of low accrual onto clinical trials, the problem cannot be solved without it. Effective communication strategies are easy to overlook—but essential to consider—in the ongoing efforts to improve patient accrual onto cancer clinical trials.

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