

Enhancing Clinical Trial Awareness and Outreach

This article is the sixth in a continuing series of articles focusing on the exemplary attributes of successful research in clinical practice. ASCO described a core group of standards and exemplary attributes of clinical trial sites in the initial article of the series in July 2008. This article addresses clinical trial awareness and outreach, which covers the following elements of the statement: clinical trial education programs, diversification of trial mix, multidisciplinary involvement, and high accrual.

Background

As noted in the ASCO statement, only a small percentage of patients with cancer participate in clinical trials, which is due to many issues including a lack of available clinical trials, as well as a lack of awareness that clinical trials are a treatment option, or even what a clinical trial is. Although awareness of clinical trials is increasing, participation rates are not, suggesting other barriers to participation. Clinical trial education programs can be used to inform referring physicians and potential participants about available trials. In addition, awareness programs can be used to inform potential participants about the role of clinical trials in general. A multidisciplinary approach that includes medical specialties like radiation oncology, surgery, radiology, and primary care in addition to medical oncology, as well as nonphysician healthcare providers, such as nurses, patient navigators, pharmacists, and clinical research assistants, can increase practitioner participation. Likewise, outreach programs that include patient advocate and other community groups can contribute to increased awareness and interest.

Outreach to Under-Represented Populations

A variety of barriers to accrual to clinical trials in addition to lack of awareness may be operative. These include reduced participation of the elderly because of comorbidities that result in exclusion from trials, or because the physician who might have referred them assumed they could not tolerate on-trial treatment. Minorities may be under-represented in trials not just because they are under-represented in a particular geographic area, but because of cultural sensitivities and/or fear, as well as presumptions by researchers that they might not be interested in a clinical trial. According to Andrea Denicoff, RN, MSN, ANP, National Cancer Institute (NCI; Bethesda, MD), “We don’t do well recruiting minorities on a national level,” noting that there are 13 Minority-Based Community Clinical Oncology Programs with an overall 60% minority rate of accrual. In addition to their locations in high-minority areas, their success may be due in part to the presence of minority staff members devoted to educating patients. Deborah Collyar, president, Patient Advocates In Research, and co-chair, Cancer and Leukemia

Group B Committee on Advocacy, Research Communication, Ethics, and Disparities, believes that unconscious issues of biases we all have can have an effect on trial diversity. “Ageism is alive and well,” she observes, noting that misconceptions or assumptions about race, ethnicity, majority or minority status, socioeconomic status, and other patient factors may have an effect on the decision of a practitioner to even mention a clinical trial to a potential participant.

Raising Community Awareness

Robin Zon, MD, FACP, Northern Indiana Cancer Consortium, Community Clinical Oncology Program, Michiana Hematology Oncology (South Bend, IN), has given presentations at the ASCO Clinical Trials Workshop on raising clinical trial awareness in the community. Dr Zon and Ms Denicoff comoderated a breakout group on marketing and outreach at the 2007 Clinical Trials Workshop. A summary document outlining strategies discussed during the breakout group is posted online at jop.ascopubs.org, as well as on the ASCO Web site at www.asco.org/ClinicalTrialResources.

Dr Zon says her practice makes use of many of these strategies to target patients, research staff, and the community. Different strategies are necessary for different audiences, and individual sites or programs need to decide on strategies based on the types of studies they are doing, but the message is similar in raising awareness. Television, radio, and newspapers can reach the general public, and those same modalities, plus newsletters, brochures, and a presence at tumor boards can reach the clinical audience for many types of clinical trials. Raising public awareness of the existence of different types of trials is particularly important for cancer prevention trials because participants do not have cancer, and so would not be in contact with the individuals running those trials. This can be true as well for symptom control and survivorship studies.

Using National and Local Resources

Dr Zon’s practice uses radio spots and public service announcements. She says that although they had to pay for an initial recording, they are able to use it repeatedly, and try to have something every month on the local station. They also piggyback on the various cancer awareness months (eg, March for colorectal cancer and October for breast cancer) to tie local activities to national awareness efforts. Health editors and writers for local newspapers are usually eager to have someone contribute information to tie in with these disease awareness efforts. Spots can refer potential patients to a Web site or contact telephone number. Dr Zon notes that lack of Internet access is rarely an issue for patients, whatever their

age, because most people know someone (eg, a relative or friend) who will search for information.

Involvement of Community Physicians in Trial Design

Ms Denicoff reviews quality of life and patient outcome end points in protocols for clinical trials proposals. The inclusion of community oncologists and patient advocates in the protocol review process at NCI is part of an effort to maximize accrual. The input of community oncologists is important. This input improves trial design, and should help avoid approval of a trial that community oncologists might not participate in because of lack of staff, facilities, or other barriers. NCI provides clinical trial education and cancer education services, including materials that can be used in community outreach.

Promoting Trial Involvement Within Your Practice

“You have to do ‘inreach,’ too,” observes Ms Denicoff. “A top barrier is doctors not talking to patients. Inreach is needed if a practice has several physicians who are not engaged.” She says that one practice awards higher recruiting physicians with an additional title as a way to encourage accrual. Practices have to inreach to their own physicians, oncologists, surgeons, and primary care practitioners. “It’s about building good relationships and rapport,” she says. “I used to send thank you letters to all referring doctors and let them know what happened to their patients,” she says, “so they wouldn’t feel like they were losing their patient to the oncology practice.” Sites should also consider employing clinical navigators or clinical research nurses to identify potentially eligible patients to increase accrual. There needs to be a culture of clinical trials, from the person at the front desk right through to the CEO of a practice, Ms Denicoff observes.

Community Involvement

Ms Collyar says that it is important for a practice to be active in its community and connect with social groups, including senior centers, churches, and other places potential participants go for support and answers (eg, support groups and organizations for patients with cancer). Local practices can set up a process to update these groups regularly on research in general and specific trials they have open. She also suggests the use of patient advocates or patient navigators who can talk to potential participants about clinical trials in general. “One problem is that people are hit with clinical trial information at the same time they receive a diagnosis of a life-threatening illness. It’s a lot of information,” she observes. “I think it might help to work more with the referral base to provide more general information. I’d love to see if it would work to give people different messages about clinical trials throughout their journey” through the health care system. The oncology office is the last place they should hear this

information for the first time, Ms Collyar suggests. For example, during screening, patients could hear how trials have led to better screening tools. “This plants seeds over time, and trials become a more normal part of the process,” she explains. Trials should also be presented as one of many therapeutic options, not as a separate “by the way, there’s also a clinical trial” footnote to the list of treatment options.

Patient Advocates

Mary Lou Smith, JD, MBA, is the cofounder of the Research Advocacy Network (Plano, TX), and co-chair, Eastern Cooperative Oncology Group Patient Representative Committee. She thinks that patient advocates can play an important role in outreach and increasing accrual. She says that having a dedicated staff member on site who knows how a particular practice works and who can provide continuity is essential to working with community advocates. Current patients, family members, and survivors could be invited to programs at a site to learn what research is conducted, and what this means to patients and the community at large. A presentation at a meeting might include a discussion by both an investigator and a patient about the importance of being on a clinical trial to increase awareness of trials as a treatment option. Advocates could be recruited from those attending the program. She says such programs might attract 100 people, of whom 10 to 20 might volunteer to act as community advocates. An alternate strategy would be to handpick a couple of patients to act as advocates. The nurses of a practice would know who might be interested. Roles for patient advocates include community outreach, fundraising, participation on institutional review boards, and peer support. Ms Smith cites an example of a couple of advocates who raised thousands of dollars used at a site for things not covered by insurance but necessary for patient participation, such as transportation and childcare. “This is definitely grassroots,” she observes, noting that online social networking (eg, Twittering) might be a good way to talk about research.

Diversification

To diversify clinical trials, practices have to assess the needs of patients in their own practice and geographic area. “Even if you don’t have a trial for that person, you can still explain what trials do. Existing cancer survivors are an untapped group. Newly diagnosed patients usually talk to survivors, who could tell them where today’s treatments have come from,” Ms Collyar says. “This could plant the seed when we talk to new patients, but we don’t do it.” “One of my take home points,” says Dr Zon, “is that an effective awareness program must identify their needs, target audiences, and local resources, and consider engaging a champion, which could include investigators and patient advocates. I recommend developing a strategic plan for implementation and budgeting for your awareness programs. Practices may want to consider

ASCO Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites

The ASCO statement addresses the minimum requirements for sites conducting quality clinical trials as well as the attributes of exemplary sites. Both minimum requirements and exemplary attributes were determined on the basis of a review of the literature, current regulatory requirements, and consensus among community and academic clinical researchers. To conduct quality clinical research, sites should meet the minimum requirements. It should be noted, however, that the exemplary attributes are voluntary and suggested as goals, not requirements. Not all attributes will apply to all clinical trial sites, and many sites may be able to conduct high-quality clinical trials without accomplishing all attributes.

References:

Zon R, Meropol NJ, Catalano RB, et al: American Society of Clinical Oncology Statement on minimum standards and exemplary attributes of clinical trial sites. *J Clin Oncol* 26:2562-2567, 2008

ASCO outlines minimum standards and exemplary attributes for research sites: Previews tools to be provided. *J Oncol Pract* 4:185-187, 2008

Zon R: Guidance for quality research. *J Oncol Pract* 4:186-187, 2008

free or low-cost readily available material to enhance their awareness programs.”

Upcoming Events

ASCO will hold conference calls in 2009, during which content providers to the series will discuss these topics in more detail and be available for discussion. See ASCO's Web site at www.asco.org/clinicaltrialresources for more information.

The next article in this series, to be published in the September issue of *Journal of Oncology Practice*, will discuss how to work with your independent review board(s).

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