Conducting Outreach Programs

David A. Smith, MD, receiving his practice's Clinical Trial Participation Award from Allen S. Lichter, MD, ASCO Chief Executive Officer, and Gabriel N. Hortobagyi, MD, ASCO Immediate Past President.

Conducting clinical trials with timely and full enrollment requires recruitment of eligible patients. Outreach programs to increase the awareness of potential patient participants and providers contribute to the success of clinical trials. Representatives of practices recognized by presentation of the American Society of Clinical Oncology (ASCO) 2007 Clinical Trials Participation Awards (CTPAs) discussed how they conduct their outreach programs to increase awareness of their clinical trials.

Patient Awareness

David A. Smith, MD, Medical Director of Research and Cochair, US Oncology Lung Committee at Northwest Cancer Specialists, Vancouver, Washington, says his practice relies on its physicians to bring up the topic of clinical trials whenever appropriate, especially when they are seeing new patients. The practice has made it part of their standard of care to discuss clinical trials with their patients early in the process of developing relationships. Patients have access to flyers describing the concepts of clinical trials in general, and lists of open trials are available in patient areas of the clinic. Generic information about trials is also provided in new patient packets. Smith notes that they use the actual trial consent forms as the official written print medium for a trial. "The majority of people already know about trials, and it is not a surprise when we bring it up," he says. "They want to be part of it and have a lot of altruism," he observes. Many patients will spontaneously add that they want to participate in trials "even if it doesn't help me."

Lyndon V. Evans, RN, is Clinical Research Manager at the Cancer Center of the Carolinas, Greenville, South Carolina. "We have information about our trial capabilities available on our Web site," she says. "We have posters in the clinic areas

regarding symptom management trials. We have flyers in each office advertising our ASCO award and trials program. We take every opportunity to speak on clinical trials in the community." She notes that although the practice uses posters for symptom management trials, it rarely uses them for treatment trials. "The infusion nurses are kept up to date on symptom management trials because of their relationship with the patient. Research is a standing agenda item at the nurses meetings," she says.

Northwest Cancer Specialists conducts all types of trials, from phase I through phase III, as well as cancer control trials including prevention trials and trials that address symptom management and quality-of-life issues. They also have participated in what Smith characterizes as "purely scientific" trials, for which blood or other samples are collected from patients with a specific disease with no direct benefit to the patient. He notes that the type of trial for a given patient is determined by their diagnosis and "where they are in their battle with cancer." Their recruitment strategies are the same regardless of trial type. They have occasionally used electronic medical records to identify patients for specific trials (eg, patients who may be seen infrequently). This is done to help physicians remember patients who might be eligible for a given trial, but it is still up to the physician to suggest that trial to the patient. Also, Smith notes, from time to time the treatment standards may change or a trial will become available to test alternative follow-up or long-term treatments. In those instances, a research nurse will look at records of new patients who are about to be seen and remind physicians about the new trials that are available. "What works best for us is having access to a full slate of trials. We generate enthusiasm among the physicians so they know they always have something available to meet everyone's need," Smith says.

Evans says that in their practice accruals and referrals are also physician driven, because they feel that their best trial advocates are the providers. "We do conduct chart reviews as time allows, but again, the physicians' dedication to research drives the program."

The Cancer Center of the Carolinas rarely uses print or broadcast media or advertising to recruit patients. Smith says, "We don't take out ads in newspapers, and don't do direct mail or other advertising" to recruit patients to clinical trials. "Cancer is not like other diseases, or like obesity," he observes. "Cancer clinical trials are very specific. In my experience, when we have done direct advertising, it has not been very effective."

Minority Awareness

The patient population served by the Cancer Center of the Carolinas includes minorities. Says Evans, "We take

advantage of opportunities to speak about research to minority community organizations. During the SELECT (Selenium and Vitamin E Cancer Prevention Trial) prostate cancer prevention trial accrual period, we enrolled one particular minority leader, which lead to an increase in minority accruals to this trial.” This individual, a local African-American pastor, challenged his church members to enroll in the trial after he did, and screening was held at the church. The Cancer Center of the Carolinas also used direct mail as a recruitment strategy for this trial. Enrollment to SELECT increased from nine patients in 2001 and 31 in 2002 to 193 in the period when direct mail was used to recruit, 2003 to 2005. Although only 43 of 233 enrollees were African American, the practice feels that continuous exposure in the community will slowly increase the understanding of the importance of clinical trials in general as well as the importance of minority participation in particular.

Smith says their patient population includes a “pretty small” group of minorities and they are not specifically targeted in recruitment. However, they have looked at the demographics of the regions they serve as well as the demographics of their patient population, and note that participants in their clinical trials reflect the make-up of the area’s population.

Paul Thomas, MD, is principal investigator for the Children’s Oncology Group at the University of Texas Health Science Center at San Antonio/Christus Santa Rosa Children’s Hospital, Department of Pediatric Hematology/Oncology, San Antonio, Texas. Thomas notes that this practice serves a primarily Mexican-American population due to its location. Although most of these patients speak English, up to 20% do not, so the practice has put together a multiethnic and multilingual team. Print materials are available both in English and Spanish, and expertise in other languages is also available. The Children’s Oncology Group also collaborates in care with hospitals in Mexico, and intends to promote further collaboration on clinical trials for children in the border area of Mexico and Texas.

Oncology Hematology Care (OHC) Inc, Cincinnati, Ohio, did not have any centralized focus on clinical trial participation before 2001, and patients in the area were usually referred to research centers outside the greater Cincinnati area. Since then, OHC has been establishing an infrastructure to support its own research initiatives, and this includes a commitment to treat minority populations. Efforts to target specific minority populations include attendance at a local health fair focused on bringing better health care opportunities to low income and minority populations. Clinical trial brochures have been sent to area health clinics caring for underserved and minority populations. OHC is also collaborating with the urology group to develop a program to recruit patients with prostate cancer, including members of minority populations, into clinical trials. Other efforts include programs to recruit patients for other clinical

trials and to provide translators at clinic sites. Their bone marrow transplant group has also participated in donor drives specifically targeting minority populations, who are grossly under-represented in current bone marrow registries.

Provider Awareness

Primary care physicians and surgeons are the primary providers referring to the Cancer Center of the Carolinas’ medical and radiation oncologists. Evans says that they have identified a need to increase referring physician awareness. One of their goals for 2008 is to target the office staff of referring physicians by offering “lunch and learns” as well as finding opportunities to speak to community physician groups. “We are exploring a procedure to send the referring physician a patient-specific, detailed explanation of the research treatment plan generated by the research staff. We feel that the referring physician often has a trusting relationship with the patient, and is a key target to educate on our trial capabilities.”

All of the new protocols at the Cancer Center of the Carolinas are presented to the protocol review and oversight committee. This committee meets monthly and includes medical oncologists, radiation oncologists, surgeons, and pharmacists. “This group reviews the protocol with some often lively discussion and, as appropriate, includes pathologists and radiologists. This committee serves to increase awareness as well as serving as a voice for participating physicians,” Evans says.

Smith says his practice does outreach to other physicians in the community, primarily to raise awareness of clinical trials. They receive referrals from surgeons, pulmonologists, and primary care physicians. The practice has published an annual report of its research activities for the past 2 years which is sent to local physicians, as is a newsletter about clinical trials that is published approximately quarterly. They also send out specialty-directed letters to pulmonologists about available lung cancer trials, or to oncologists to make them aware of phase I trials that are not available at other locations in the area. Northwest Cancer Specialists also sponsors educational talks to physician groups (eg, local medical society meetings), especially targeting primary care physicians, about trial opportunities that are available, and provide information to local and Seattle-based university hospitals about trials that are unique to their practice that might be of interest to oncologists at the other locations.

“You can’t move forward without clinical trials,” says Smith. “Oncologists have always wanted to participate in trials.” In doing so, he concludes, oncology is a specialty that has shaped the destiny of its own field.

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