Identifying the Elements of an Effective Research Team

Representatives of three practices that were recognized by the American Society of Clinical Oncology by presentation of its 2007 Clinical Trials Participation Awards have identified the elements of an effective research team. These practices include the Cancer Center of the Carolinas, the Cancer Research and Support Services of Summa Health System, and the Department of Pediatric Hematology/Oncology at the University of Texas Health Science Center at San Antonio/Christus Santa Rosa Children's Hospital.

Team Members and Roles

Cancer Center of the Carolinas

Lyndon V. Evans, RN, BS, is Clinical Research Manager, Cancer Center of the Carolinas, Greenville, South Carolina, a

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private practice. Their research team includes 14 medical oncologists, six radiologic oncologists, and six surgeons. Pathologists and radiologists are included as they are needed. Twelve nurses are involved with the physicians, taking care of obtaining consent, determining eligibility, reporting adverse events, and managing trials. The team also includes a dedicated, full-time pharmacy technician, which Evans says has been very helpful. Evans and an office

coordinator prepare for, but are not on, the independent institutional review board (IRB) that approves their trials.

There are two groups in the practice. The clinical research unit has nine staff members headed by a nurse practitioner and the experimental therapeutics director, and is responsible for phase I trials. "It's very unusual for a private practice to have a phase I unit," she says, "but we decided it was a good move for our practice. It provides a full array of trial options to benefit our patients, from phase I through prevention trials."

The other group, Evans' department, is the clinical research department, which is responsible for the phase II and III trials and prevention trials. This group has 26 staff members. "I think effectiveness of the team is due to inclusion of ancillary members responsible for the lab, infusions, and scheduling. They are the glue that keeps the team together."

Summa Health System

Joyce Neading, RHIT, CTR, Manager, Cancer Research and Support Services, Summa Health System, Akron, Ohio, says

they have several principle investigators (PIs) who are assigned clinical trials by their interests. PIs include a radiation oncologist and a PI for pharmaceutical trials. One research team supports all the PIs. As research team manager, Neading looks for protocols and takes care of contracts. A research specialist helps meet the regulatory requirements of the IRB, and an administrative assistant is responsible for outside adverse event reporting. Two clinical nurses not only provide treatment but do all of their own paperwork, and there is no separate data management team. Two other nurses manage the prevention trials as their primary responsibility. The nurses coordinate patients, and meet regularly with them for on-site testing, quality of life assessments, and pill exchanges. There is a part-time clinical research assistant for long-term follow-up, and they are adding another part-time clinical research assistant to help with that task.

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Children's Oncology Group

Paul Thomas, MD, is PI 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. "Dealing with children keeps you humble," he observes. Their research team is fairly large. There is a core group

Paul Thomas, MD

involved with research mechanics, including data managers, clinical research associates (CRA) and specialists, one IRB regulatory specialist dealing with cancer protocols, another CRA for hematology and research efforts, and core research office personnel including nurses and patients service members of the Children's Oncology Group. There is a nurse educator/advanced practice nurse who is part of the practice. Nurses are responsible for patient compliance, consent forms, order writing, and education. There are also two psychologists who are active in the Child Oncology Group, providing psychosocial support for families and helping communicate families' special concerns and problems. A Hispanic, multilingual psychologist helps translate consent forms and helps the staff understand the psychosocial issues of their Spanish-speaking population. They also have one social

worker and one case manager to help them appreciate the economic implications of the children's disease and to field questions from the children who are on studies.

Patient Advocates

None of the three practices include a patient advocate per se, although other team members and ancillary staff provide at least some patient advocate services. "One of my goals in the next year or two is to add a patient advocate to the research committee," says Evans. "There are lay people on the IRB, which serves in a sense as an advocate for patients. There are also patient support groups." At Summa Health Systems, there are care coordinators for patients with lung cancer and with breast cancer who discuss trials and put patients in touch with nurses. According to Neading, they act as patient navigators, helping them navigate through the system of finding appropriate clinical trials.

Thomas points out that in the absence of specific patient advocates they receive regular feedback from patient's families through the psychosocial team about issues they are dealing with. There is also a regular Child Life program in the hospital for outpatients and inpatients. With cross-service areas to provide support, in addition to Child Life and spiritual care, Thomas says they fulfill patient needs without a designated advocate.

Staffing Challenges

Challenges associated with staffing a research practice seem to fall into two areas, personnel challenges and the challenges of multiple locations and their distances from the main site. Summa Health System has multiple locations at which they keep a notebook with active protocols for trials of commercially available or National Cancer Institute-orally available drugs. There is a list of studies with protocols and consent forms that can be used. When physicians or their assistants call to see if one of their patients is eligible for a trial, a team research nurse can go over eligibility requirements with them, discuss what documents are needed, have consent forms signed, and discuss and order the tests needed for eligibility. This is all done by facsimile. The research nurse will hand carry the research drug to the site and explain dosing and other trial parameters to the patient in person, and call patients weekly. The sites cover a 50-mile radius, so it is about one hour's drive if nurses need to visit the sites. Their doctors are at the main center and cover the offsite centers as well.

For Evans, "geography is a challenge." They cover a 100-mile radius, including five primary locations and four hospitals. They have research staff at three locations, and staff travels to cover the rest. She notes that they do not yet have a fully functional electronic medical records system, but that getting one set up will help assess eligible patients. Accruals are affected by dedicated staff at each location. The hiring challenge for Cancer Center of the Carolinas is to find oncology-trained staff with research experience. "It's a challenge to train nurses in both oncology and research. It's not the same challenge to train the data staff. My philosophy is to hire the skills I don't have."

Thomas says that their program draws from a fair amount of south Texas, which can be up to 250 miles away. More distant locations like Laredo are staffed every other week. Their long-term follow-up program makes trips to more remote locations. In addition to distance, economic factors such as the cost of gasoline and lack of transportation can be problems. "We are fortunate in that we work in a facility that is faith-based," Thomas says. The hospital's philosophy allows it to give unfunded care that would otherwise be lacking in its patient population. "Texas has a fair number of children with no insurance," he observes, "but we are able to work with the hospital to provide care to indigent children." He says they are fortunate to have a stable staff of researchers, nurses, and caretakers who enjoy working with the patients and their families. The problem is not in finding qualified people, but paying them enough to keep them from going elsewhere.

The Bottom Line

According to Thomas, communication is key to an effective team. All three practices have regular meetings. Thomas emphasizes a work atmosphere where people feel they are contributing to the research effort and the health and welfare of patients and their families. Evans notes "our research program is physician-driven, and I think that is extremely key to it being successful. Also of importance is an engaged medical research director. It's trickle down. Everyone is engaged and has the same goals. Our monthly meetings are very well attended and are anything but dry. There is lots of banter and discussion on the science before we open a trial. We need to feel that the whole committee is engaged in the decision to open a trial." According to Neading, what makes Summa's team so effective is that "we're all friends and get along really well. We are all trying to find a cure for cancer."

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