BY DENISE MYSHKO

The Coordinator
The HEART of a STUDY

The role of the clinical research coordinator in the **CONDUCT OF CLINICAL TRIALS** is often overlooked. **YET, MORE OFTEN THAN NOT** the coordinators are the ones who **CARRY THE RESEARCH GOALS FORWARD.**

Coordinators have been called the heart and soul of the study. They are the front line of clinical research and often are the unsung heroes. Their roles vary depending upon the trial setting and criteria, although almost all coordinate the critical logistics of a study. The role of the coordinator has expanded over time to involve myriad functions, such as patient recruitment and monitoring; data and regulatory documentation; keeping the inventory of trial supplies; tracking requests for payment; coordinating meetings; and most critically acting as the patient liaison. Most everyone agrees, clinical research coordinators (CRCs) are the ones who do much of the work to move a clinical study forward.

Certainly, as clinical trials have become larger in size, coordinators have been given more responsibilities, which requires them to have knowledge about a great number of different areas of competency.

"Coordinators are kept very busy," says Saul Shiffman, Ph.D., founder and chief science officer of invivodata Inc., and professor of psychology (clinical and health psychology) at the University of Pittsburgh. "A coordinator is the face of the study for the patient, which is why we consider it so important to train and certify a coordinator in the use of our electronic patient self-report solutions. While coordinators do get involved with patient recruitment, the most critical work they do is during the study."

"Our physicians are extremely busy either with office visits with patients or in surgery," says Ann

◀ Allison Grimmelsman

Recognizing the contributions of study coordinators is very important because they play a significant role in the success of a trial. Coordinators take a lot of pride in their accomplishments.

▼ Jaime Cohen

With experience on the front line, coordinators who know a disease category well can really help guide the study visit schedule or give information about patient compliance.

▲ Dr. Michael Barnett

For coordinators to get the appropriate training they have to be self-motivated. By and large, people who go into healthcare have signed up for a career path and lifestyle to which self-education is a necessity.

▲ Dr. Mark J. Cziraky

A good clinical trial coordinator goes a long way to successfully managing the running of a clinical trial. Coordinators drive studies.

Masuda, M.S., CCC-A, a clinical research coordinator at House Ear Institute. "They have very little time to work on their research studies. These tasks fall on the shoulders of the coordinators, who are responsible for making sure the project moves along. We are the gatekeepers, the motivators, and the educators of the study. It's important that the principal investigators are kept informed about the study so they know what progress is being made, but the mover and shaker of the study is the coordinator."

Because of the support and influence CRCs have on a trial, the respect that physicians have for them should be evident in their close working relationship on the healthcare team, says Lori Kronish, R.N., research coordinator, at Lynn Regional Cancer Center West, which is an outpatient department of the Boca Raton Community Hospital System. Ms. Kronish says her research program is attached to the physician practice affiliated with Salick HealthCare Inc.

"Research physicians realize that their jobs are many times easier and more efficient with a good coordinator at their side," she says. "We really are a true part of the healthcare team."

Physician investigators often have a great deal of flexibility in what they delegate to a particular coordinator, says Jeffrey Souza, U.S. director at i3 Pharma Resourcing.

"One of a coordinator's biggest responsibilities is the safety and well-being of study subjects," he says. "The coordinators are the first line of defense. Because they are getting the information first hand, if there is a potential safety issue they may be the first ones to recognize a problem. These are the people who have direct contact with the study subjects. In some cases, this is the only time a study subject identifies with the pharmaceutical product or the company."

Laurel Fisher, Ph.D., associate director of the clinical studies department, of the House Ear Institute, says coordinators might do some duties that were traditionally those of the physician, such as discussing informed consent and ensuring protocol compliance.

"The legal responsibilities of informed consent and protocol execution, case-record completion, validation of numbers, query requests and responses would fall to the coordinator, but not the duties of protocol development," she says.

According to Ed Ikeguchi, M.D., chief medical officer at Medidata Solutions Inc., once the consent form is signed, the physician will see the patient only for medical reasons.

"The coordinator then almost entirely carries forward the research goals," he says.

As research has become more complex owing to increased attention on enrollment and maintaining communications with the third-party service providers, the coordinator's role has expanded.

"Years ago, when I started in the research world, it was very unusual that a CRO was involved," Dr. Ikeguchi says. "Primarily, there was a direct relationship between the physician's office and the sponsor."

As part of their expanded responsibilities, the clinical research coordinators identify patients for participation, follow up with patients, and make sure these patients get enrolled in the study and stay enrolled in the study, says Matthew L. Kibby, leader of metrics and evaluations and TrialCentralNet teams at BBK Healthcare Inc.

"The fact that any of these studies get completed at all is largely due to the diligence and hard work of the clinical research coordinator," he says.

▲ Jeffrey Souza

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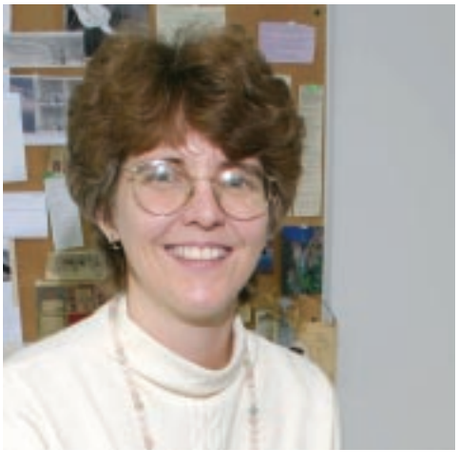
▼ Dr. Laurel Fisher

Certification makes sense. Coordinators would have real knowledge of the regulatory issues under their belt.



▲ Ann Masuda

We are the gatekeepers, the motivators, and the educators of the study. It's important that the principal investigators are kept informed about the study so they know what progress is being made, but the mover and shaker of the study is the coordinator.

The coordinator's contribution to data mining, for example, and dealing with the referrals has a direct correlation to the actual bottom line of study enrollment.

The role of the coordinator is so important that often the success of a study can depend on it, says Steven R. Peskin, M.D., CEO of Pharmaceutical Research Plus Inc.

The skills required for someone to be successful as a coordinator are extensive, says Laurie Considine, director of site support services at MediciGroup Inc.

"Coordinators have to have strong interpersonal and communications skills to establish relationships with patients," she says. "Attention to detail is extremely important. They have to be a team player because they work with the entire study team, including patients, the principal investigator, the CRO, the sponsor, and vendors. They have to be problem solvers. They have to be deadline oriented to meet critical timelines. They have to be consistent. They have to know regulations and adhere to those regulations. They have to know about, and be able to adhere to, the protocol. And they have to have good data-management skills as well. That is a pretty tall order."

A New Skill Set: Technology

Data management has become an important responsibility of coordinators, says Jaime Cohen, leader, site support services, at BBK Healthcare Inc.

"When I started out in clinical research, a coordinator would fill out a couple of forms and mail them in or fax them," she says. "Today, coordinators are working with multiple, complicated electronic systems. And then there are all the regulatory requirements on top of that. For example, the HIPAA regulations put a tremendous burden on the clinical research coordinator. They are the ones who have to make sure the proper language is incorporated into all the informed consent forms to meet HIPAA requirements. They have to review the new patient protections with currently enrolled patients. That effort alone is tremendous."

It used to be that coordinators were human document management machines, says Richard Jenkins, general manager of life sciences at Intralinks Inc.

"Now in the age of electronic regulatory documents and electronic data capture, coordinators must be technology savvy and responsible for the interface into electronic document and data systems while maintaining the quality of those documents and data," he says.

Coordinators are required to be more data savvy, agrees Mark J. Cziraky, Pharm.D., FAHA, executive VP at HealthCore Inc.

"Electronic data systems help out with the amount of paperwork that is involved and the amount of onsite visits that are required for certain studies, but these systems also require another level of sophistication," he says.

The coordinator is one of the more important users of clinical-research technology, Dr. Ikeguchi says.

"They are the most intimate with the software in terms of day-to-day usage," he says. "If we were to look at the volume of logins for any clinical study across all the various users, the data-entry staff and the coordinators have the largest number of logins because they interact with the system the most. Everybody else's functions comes to life because the coordinators are feeding the data into the system."

Is Certification Necessary?

In October 2003, the Association of Clinical Research Professionals (ACRP) conducted a compensation survey of its members, which included clinical research coordinators. Of those who responded to the survey, 35% were clinical research coordinators. The results showed that coordinators are predominantly female and have a BSN. On average a coordinator has seven years of experience with five of those years spent with the current employer. The typical full-time salaried CRC earns $50,000 a year in base salary.

The ACRP indicates that regardless of title, the coordinator is under the immediate direction and supervision of a principal investigator and ensures research activities are conducted under Food and Drug Administration and Good Clinical Practice (GCP) guidelines.

ACRP offers training classes and certification in both FDA and ICH processes. ACRP's certification is granted in recognition of documented and verified work experience and successful performance on a multiple-choice exam. ACRP offers three certification exams, one for clinical research associates/CRAs (monitor), one for clinical research coordinators/CRCs (site), and one for clinical research investigators

(CRIs). To date, ACRP has certified more than 10,000 clinical research professionals.

The ACRP survey of its members last year revealed that certification is encouraged by 50% of employers and certification had a positive impact on salary. Clinical study sites were most apt to require or encourage certification by a noticeable margin. Of the respondents, the percentage of those who held ACRP certification was 47.1% for certified clinical research coordinators and 20.6% of certified clinical research associates.

Dr. Fisher believes it would help sites if coordinators were certified.

"It does make sense for coordinators to have a modicum of the regulatory issues under their belt," she says. "If they don't have that knowledge, then I have to spend hours training them on regulatory issues."

And because certification requires continuing education hours, coordinators can remain up to date about changing regulations.

But many in the industry say there isn't a big push for certification.

"Certification would bring a level of standardization to the knowledge base of coordinators," Ms. Cohen says. "The best clinical research coordinators, certified or not, are going to be the ones with the experience who actually enjoy both the clinical and research aspects of their jobs. Certification may bring everyone to a level playing field and that may be helpful for hiring purposes. But I think the people who are exemplary stand out with or without the certification."

Ms. Kronish says certification doesn't necessarily mean that coordinators know how to do their jobs, it means that they've been able to study a book and take a test.

The Coordinator's Life

MANY CLINICAL RESEARCH COORDINATORS (CRCs) report that they are overburdened. A survey by BBK Healthcare Inc. found that coordinators focus the bulk of their time multitasking administrative, data, and regulatory requirements of study conduct. They commonly manage five studies each.

The CRC survey, which was conducted online, provides quantitative evidence about the scope of the patient-recruitment bottleneck and explores specific areas where CRCs can be empowered to make a difference in strengthening the patient-recruitment process.

"COORDINATORS HAVE TO PERFORM MYRIAD TASKS IN THEIR DAILY LIVES," says Matthew L. Kibby, leader, metrics and evaluations and TrialCentralNet teams, at BBK Healthcare. "They are responsible for many things, including administration of a study and patient-recruitment activities. They have to do lab work. They are communicating with regulatory bodies and with principal investigators, meeting with patients, working with study monitors. Most are responsible for data management."

THE BBK SURVEY FOUND THAT COORDINATORS DEVOTE ONLY 13% OF THEIR DAY TO FINDING PATIENTS. They struggle to support overall recruitment, enrollment, retention, and compliance goals in the very earliest stages of the clinical-research process because of their numerous and demanding responsibilities. The notion of patient recruitment as a dynamic process beginning as early as protocol design is a discipline that BBK refers to as "study relations." Each of the many parties involved in clinical research, including sponsors, recruitment agency staff, and CROs have a responsibility to apply study relations and consider recruitment early in the protocol-development process to help alleviate the recruitment burden at the site level. BBK Healthcare's survey also revealed that there might be less turnover among study coordinators than previously thought.

"WHEN WE ASKED OUR SET OF QUESTIONS, we were responding to an earlier survey that had been published by CenterWatch," Mr. Kibby says. "A 2002 CenterWatch survey found that more than half of all study coordinators leave their jobs within three years. That is a pretty high turnover rate and we wanted to verify that a year later."

HE SAYS THE RESULTS OF BBK HEALTHCARE'S SURVEY FOUND THAT 71% of the people surveyed indicated that they had been in their current position three or more years.

"ADDITIONALLY, 76% OF THE PEOPLE WE SURVEYED said they had more than five years of experience in a similar type of job," Mr. Kibby says. "The most telling finding was that 64% did not believe that their site had a high turnover rate among CRCs."

MR. KIBBY SAYS THE RESULTS SHOWED THAT 88% OF COORDINATORS were satisfied with their jobs.

FINALLY, MORE THAN 70% believed they were fairly recognized for their accomplishments.

▲ Matthew Kibby

The fact that any of these studies get completed at all is largely due to the diligence and hard work of the clinical research coordinator.

Richard Jenkins

The level of training for the coordinator has to be more than adequate. It has to be just-in-time training, and it has to be done outside the investigator meeting.

Dr. Saul Shiffman

The key role coordinators play is their interaction with the patient. To the patients who are involved in the clinical trial they are more visible than the physicians.

"Certification is not a substitute for experience," she says. "It would be a wonderful complement. Coordinators end up juggling many tasks at once, and the ability to do that only comes from experience."

Certification could help achieve consistency in skill levels across all sites, says Allison Grimmelsman, project leader, medical affairs, marketing and communications at Kendle International Inc.

"Many coordinators I've worked with haven't been certified, but are excellent coordinators," she says. "I'm certified as a CRA, and there is a financial and time commitment involved with that. If coordinators don't have support in gaining and maintaining their certification, that could be an issue."

More Training Needed

A survey by BBK Healthcare found that while coordinators do receive some training, it isn't necessarily in things that are important for coordinators' expanding roles, such as patient recruitment (for more information, see related box on page 28).

"The study found that coordinators received very little training in how to recruit and enroll patients," Ms. Cohen says. "They did receive training with the consent process."

While training is not necessary to start in the position of a coordinator, Ms. Masuda says, it is helpful.

"Time can be lost while the coordinator is receiving the appropriate training," she says. "The process of coordinating is pretty much the same in any environment, but the particular details may be a little different in every setting. Most of us just drop into the position."

Ms. Considine suggests that there could be more mentoring opportunities within the industry as well as a formal mechanism for coordinators to share best practices.

"Experienced coordinators are worth their weight in gold," she says.

Mr. Jenkins says it also is important to ensure that coordinators are trained properly in how to use new technologies.

"If we don't train and support the coordinators, then their lives become more difficult," he says. "Typically, when a new technology is deployed, training and support are always an afterthought. The level of training for the

coordinator has to be more than adequate. It has to be just-in-time training, and it has to be done outside the investigator meeting since many coordinators don't attend those meetings."

Kendle understands the importance of clinical research coordinators and provides the appropriate training to ensure a quality trial for the customer.

"As part of Kendle's protocol- and logistic-specific training, we develop and provide sites with the key materials to succeed in the trial, including study coordinator manuals, a quick guide for handling paperwork, and, as necessary, patient recruitment toolkits," Ms. Grimmelsman says.

According to Michael Barnett, M.D., Ph.D., senior VP, Dorland Global Health Communications, and director of the medical and scientific affairs at Dorland, training is self-motivated.

"The people who go into healthcare have signed up for a career path and lifestyle to which self-education is a necessity," he says. "Those coordinators who are motivated, who spend time developing initiatives, and put energy into clinical trials are the ones who make sure the study continues to do well."✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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