

Should a Clinical Research Coordinator Be a Nurse?

By Judy Katzen

Fourteen years in medical supply and pharmaceutical sales exposed me to operating rooms and some of the science behind clinical trials. The experience helped me obtain a position as a clinical research coordinator (CRC) in the Division of Trauma, Critical Care and Emergency General Surgery at Virginia Commonwealth University (VCU). Subsequently, I obtained a degree in nursing and continue to work as a CRC. I can thus speak from personal experience on the question, "Should a clinical research coordinator be a nurse?"

What Makes a Good CRC?

A good CRC tends to have the following characteristics, among many others:

- A clinical background of some kind.
- The ability to multitask, prioritize and be flexible.
- Good communication skills in writing, on the phone, and in person with people of all backgrounds, one on one and in groups.
- A propensity to ensure that all study tasks are completed accurately and in a timely manner. CRCs do much of the work themselves, but must be able to motivate others to do the rest.
- The ability to work as a team player. Besides the investigator and other CRCs, CRCs may work closely with subinvestigators, pharmacists, laboratory technicians, residents, nursing units, and other departments.
- Desire to be a life-long student. Every study is different. There is an inexhaustible supply of regulations and other requirements for new circumstances. Good CRCs are not just familiar with their studies, they are experts.
- A backbone. Often, it is the CRC who runs the study and tells the investigator and other physicians what to do, and perhaps what they are not doing correctly. Some site monitors have a more forceful personality than warranted by their expertise. A good CRC cannot be afraid to stand up for the subject, the study, and the site.

Do Nurses Have These Characteristics?

Clinical care nurses obviously have the first characteristic: a clinical background. Their training is probably applicable to a broad range of therapeutic areas and studies. However, they may or may not have the other characteristics listed above. In part, it depends on their clinical care role and the way their healthcare facility is organized. For example, most nurses in small private practices draw blood, while in some hospitals, only floor, unit or phlebotomy nurses draw blood.

There are many different types of nurses.¹ Their roles vary enormously, but in simple terms, their responsibilities become increasingly complex as their levels of training and license increase. Licensed practical nurses (LPNs) - in Texas and California, known as licensed vocational nurses (LVNs) - are trained in basic and bedside nursing care. They are typically task-oriented and may work under the supervision of a registered nurse. Registered nurses (RNs) earn licensure and an entry-level nursing position via one of three types of training: a diploma from an approved hospital-based program, an Associate's Degree in Nursing (ADN)

from a community or junior college, or a 4-year Bachelor of Science in Nursing (BSN) degree from a college or university.² RNs are trained in more advanced care than LPNs, including some of the underlying science. Those with BSN degrees may learn some administrative functions. At the next level up, advanced practice nurses (APNs) have a Masters of Science in Nursing (MSN) or equivalent degree. Nurse practitioners (NPs) can handle many tasks normally performed by physicians.

The argument for hiring nurses as CRCs is that investigators can delegate certain responsibilities to them, which their license and training allows them to perform. For example, in many states, a nursing license is legally required to dispense drugs. Because of their training and experience, nurses are qualified to conduct certain medical procedures, such as collecting biological specimens. They can evaluate the health status of study subjects, notice odd combinations of signs, symptoms and medications, make sense of adverse events, and perform other activities that require clinical knowledge. They may be qualified to perform certain assays, tests and calculations. When obtaining informed consent, they are more likely than non-nurses to be able to explain the risks, answer medical questions, and detect cognitive problems.

However, depending on the study, certain non-nurses may also be qualified for some or all of these activities. For example, some members of ground and air ambulance crews dispense drugs and collect biological specimens. Within the hospital, active participation in a study by the investigator and/or unit/floor nurses may eliminate the reasons for the CRC to be a nurse.

The Best Candidate for an Open CRC Position

Some research sites and investigators employ only nurses in CRC positions, which may leave positions open for extended periods of time or result in hiring less-than-optimal candidates. Nurses tend to earn higher salaries than non-nurses. Many nurses do not like or are not good at the paperwork. They may not be well-suited for the autonomy and multitasking required of CRCs. It is therefore important to seriously consider whether a nurse is really required for an open CRC position. A more flexible set of requirements may yield better results.

Unless there is a legal licensure requirement, when posting open positions, judicious use of the terms "required" and "preferred" can open the field to exceptional candidates. For example, a foreign-trained physician certainly knows a lot about medicine. There are numerous "allied health professionals," such as physical therapists, nutritionists, emergency medical technicians (EMTs), and medical technologists. These professionals are likely to have useful clinical backgrounds within their specialties. Even a CRC without a clinical background can pick up a lot of expertise on the job.

Everybody has strengths and weaknesses. For example, strong interpersonal skills may be more important than experience with EKG testing. Non-nurses may have more clinical experience in certain areas than some nurses, e.g., in drawing blood or respiratory therapy.

When hiring a CRC, decide what is truly needed to conduct not only the current study, but future ones as well. Consider the work environment in terms of types of studies, allocation of responsibilities, personalities and research philosophy. A nurse may be required or preferred for the open position, but maybe not.

References

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