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Study Subject Prescreening Strategies in a Hospital Cardiovascular Program

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The Cardiovascular Clinical Trials program at Christiana Hospital provides clinical trial resources to all the service lines within the Center for Heart and Vascular Health. In the past year, we enrolled a total of 167 patients, typically with 20 studies actively enrolling. Five nurse coordinators support this research.

A physician practice site or clinic can identify likely study subjects ("prescreen") by reviewing patient charts, searching a database of patients, or checking patients scheduled for outpatient visits. In our department, this process is more complicated because many of our studies are for acute conditions that are, by definition, unscheduled and can appear as new admissions or in current inpatients. We monitor multiple procedure schedules (e.g., for MRI scan, cardiac catheterization, treadmill stress test), admission records for admitting symptomatology from the emergency department and targeted nursing units, lab reports for specific markers that might denote the designated study population, and results from diagnostic tests.

Our system for finding study subjects has evolved over the years:

Strategy 1. Dedicated Pre-Screener

When our program was smaller, one part-time nurse was responsible for all prescreening activities and had no other responsibilities. This strategy worked well until the workload increased beyond her capacity, and we were unable to dedicate a full-time person to prescreening. In addition, the prescreening role did not provide patient or subject interaction, which our nurse coordinators valued.

Strategy 2. Self-Sufficient Coordinators

We then had each study coordinator prescreen for his or her studies. When possible, a coordinator would conduct multiple studies that drew subjects from the same sources. When two coordinators conducted studies that drew subjects from the same sources, they combined efforts, with one focusing on some sources and the other on other sources. However, coordinators found it difficult to remember the individual nuances of similar studies. They also needed a well-documented system for deciding which study to present to a patient.

Despite our attempts to maximize efficiency, this strategy seemed inefficient, with too much time devoted to finding too few study subjects. Prescreening competed with other coordinator responsibilities, causing inconsistent attention to both.

Balancing coordinator workload was challenging. While finding potential subjects for procedure-based studies was relatively easy, it was much more time-consuming for other types of studies. Coordinators inevitably focused on the studies that were easier to enroll.

A side effect of making coordinators self-sufficient was to create challenges in coverage for vacations and holidays. We could not expect coordinators to be available for after-hours, acute admissions that required immediate attention.

Strategy 3. Buddy System

We then instituted a "buddy system." In this strategy, two coordinators worked together as partners. This strategy addressed the after-hours, vacation and holiday issues. Buddies were able to divide prescreening work. However, it took substantial effort to fully train two coordinators on each study.

Strategy 4. Self-Sufficient Coordinators

When we lost a position, leaving us with five coordinators, an odd number, we decided to try Strategy 2 again, with each coordinator again screening for his or her own studies.

Strategy 5. Random Assignments

One of our coordinators found it time-consuming, boring and discouraging to run around to all the patient sources every day, so she proposed a very novel strategy:

We divided all the studies into three groups with comparable workloads and, where possible, prescreening efficiencies. Every two weeks, we randomly assigned our six coordinators to one of the three groups. In other words, every two weeks, a randomly selected team of two coordinators worked together to prescreen a new group of studies. (Other study activities, including informed consent, did not move around.)

As you can imagine, this strategy was received with some skepticism. Learning how to prescreen for all the studies would be time-consuming. Coordinators would no longer be self-sufficient. Some coordinators preferred to work with certain other coordinators. Some groups of studies might require more effort than others. Investigators might not be happy seeing new faces every two weeks. Nevertheless, the coordinators were dissatisfied with previous strategies and intrigued by the novelty of the new strategy, and so they agreed to give it a try.

The coordinators documented their prescreening process in detail so other coordinators would know what to do. (Over time, with multiple contributors, the processes evolved.) We then met together to explain the processes and divide the studies into groups.

We identified the members of each two-person team by drawing names from a basket. Each team then drew the name of its study group — A, B or C— from the same basket. Two weeks later, we repeated the process. (When we had only five coordinators, the odd coordinator worked alone on pre-screening.)

It took time for some teams to gel and fully understand the prescreening process, but within three cycles, Strategy 5 was working smoothly. Enrollment became more consistent and, in some cases, increased slightly. Teamwork and morale improved because of the variety of activities, the increased interaction, and the shared knowledge of all the studies. The investigators did not seem to notice (or care about) the change.

Strategy 6. Self-Sufficient Coordinators

When the portfolio of studies we were conducting evolved to consist mostly of procedure-based studies with straightforward patient sources, Strategy 5 became unsuitable, so we reverted to Strategy 2: Self-Sufficient Coordinators.

Conclusion

We did not try every possible strategy and variation thereof, so our experience only demonstrates that different strategies work best in different circumstances. Sometimes, it

might be worth changing strategies just to reinvigorate the coordinators with new challenges.

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