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What we have learned about best practices for recruitment and retention in multicenter pregnancy studies

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ABSTRACT

For 30 years, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network has had significant impact on clinical practice in obstetrics. The MFMU Network has conducted 50 randomized clinical trials and observational studies designed to improve pregnancy outcomes for mothers and children. Each center has a designated clinical research nurse coordinator who coordinates the day-to-day operations of each trial and leads a research team that is responsible for recruitment and retention of participants. Some of the lessons learned by the nurse coordinators over the past 30 years are described with examples from recent studies. Best practices that we have amassed from our experience are also described.

Introduction

It is well known that multicenter clinical research studies that can change clinical practice require adequate numbers of participants to answer the scientific questions. Retention of those subjects is critical to minimize the loss of important data collected. The MFMU Network consists of 12–14 leading academic research institutions with access to approximately 150,000 annual deliveries and an infrastructure capable of handling multiple, large randomized clinical trials and observational studies concurrently. Because of the pace of recruitment and the volume of studies we have conducted, we have had to "learn our lessons" rather quickly. However, given the complexity of conducting good clinical research, we have found that no one technique to recruit and bring patients back works for all studies and at all centers.

It is acknowledged by the MFMU investigators that the coordinators are "the backbone" of the Network. Study success relies heavily on them as they play the primary role in all of the following facets of conducting and managing our studies: IRB submission, training and supervising study staff, maintaining regulatory files, monitoring study performance, supervising data entry, ensuring data quality, resolving data queries, maintaining study supplies, and most importantly, recruiting, enrolling, and retaining subjects.

One of the strengths of the Network is that the nurse coordinators are integrated into the organization. The MFMU Network Steering Committee is the decision-making body and consists of the clinical center, data coordinating center, and NICHD principal investigators. The Steering Committee meets quarterly and all of the nurse coordinators attend this meeting. The meeting provides an opportunity for the coordinators to meet separately face-to-face for several hours to share problems, accomplishments, and materials; problem-solve issues hindering recruitment and follow-up; and refine strategies in real time to maximize opportunities.

Each study is supervised by a protocol subcommittee which includes a subset of the Network clinical center principal investigators, the NICHD Project Scientist, representation from the data coordinating center and two nurse coordinators. The subcommittee assures that all aspects of the research are considered in study design. The two coordinators actively participate in protocol and operations development with a keen focus on the feasibility of recruiting and retaining pregnant women. Once the study begins the subcommittee monitors progress of the study; takes part in central outcome review, if required; discusses problems; clarifies study procedures; and recommends changes to the protocol or manual of operations to the Steering Committee. The two nurse coordinators are the liaison with the other coordinators and bring issues and problems for resolution to the subcommittee.

We have found that active monitoring is the key in establishing best methods for each individual study. Regular, ongoing scrutiny of screening, enrollment and follow-up efforts helps to ensure that efforts are commensurate with trial design and execution. Once studies are ongoing, weekly recruitment updates and monthly summaries provide a useful snapshot of screening and recruitment efforts. A quarterly report has more detailed information on data quality, protocol adherence, compliance, and retention. This article is intended to share some of the MFMU recruitment and retention strategies employed by the nurse coordinators. Following are some examples from specific trials.

Randomized trial of 17 alpha hydroxyprogesterone caproate (17-OHPC) for prevention of preterm birth in nulliparous women with a short cervix (SCAN)

This double-blinded trial was conducted to determine whether 17-OHPC treatment reduces the risk of preterm delivery in nulliparous women with a short cervix.[1] Nulliparous women were approached to consent for a screening transvaginal ultrasound to measure cervical length. The ultrasound was performed by a study-certified sonographer. This trial is an example of one where large volume screening in prenatal clinics is required. One of the most helpful components for recruitment is support from the OB/GYN department—for example if sonographers and physicians take the time to introduce their patients to the research staff. Although the clinic staff wish to be supportive, they do not always have the time to answer study-related questions in detail. Providing a constant presence of research staff members in the clinics to answer study questions generally ensures seamless and effective screening and recruitment.