Trial Spotlight: EROS (E1Q11) – Engendering Reproductive Health Within Oncologic Survivorship

The E1Q11 / EROS trial is a behavioral intervention study in premenopausal females of reproductive age (15-55) with cancer. Its primary aim is to evaluate the ability of an educational program for health care providers to improve patients' understanding of their reproductive risks and receipt of appropriate treatment to achieve their reproductive health goals. The NCI is funding EROS through its NCORP grant mechanism. EROS opened in September of 2015 and is at 54% of enrollment (364/668).

EROS is the only trial of its kind. The NCI cites it as exemplary cancer care delivery research for its potential to offer every young woman with cancer an assessment of her goals for fertility and family planning to make the most of cancer treatment and preserve her future reproductive health.

The EROS study team is implementing three novel strategies to boost accrual to this trial.

**Shorter Follow-up:** A January protocol amendment slashed the follow-up period from five to two years. This change should make participation in the trial more attractive and less burdensome for patients and clinicians alike, and thus, increase the pace of accrual. Participants meet the primary endpoint at three months after baseline and the secondary endpoints at six months. These evaluate females' attitudes, functioning, and practice related to sexuality during the two years after a cancer diagnosis.

**The EROS Trial Challenge:** Participating NCORPs are being asked to enroll three patients per month per NCORP for five months. If each of the 21 participating NCORPs (with a total of nearly 80 affiliate sites) takes the pledge, study leaders are confident that they can complete accrual within months.

**Focus on Pediatrics:** The EROS leadership is reaching out to currently participating NCORP sites who have access to pediatric patients or have pediatric components and asking them to invite their pediatric colleagues to join the study as an affiliate. They are also welcoming new NCORP sites that serve pediatric patients.

Many eligible women in the NCORP programs have been missed, according to the study team. The omission is due mainly to personnel not feeling comfortable talking to women about contraception and reproductive health. Also, some clinicians did not want to be study participants themselves.

Chairing the trial is Ashlesha Patel, MD, MPH (Stroger Hospital of Cook County Minority Underserved NCORP). The co-chairs are Howard Zaren, MD (Georgia NCORP), and Erika Radeke, MPS (also at Cook County).

Currently, providers have minimal information available to help guide discussions with their patients about such issues as fertility and sexuality during cancer care. This study concerns all stages of female reproductive health, which early on pertain to the ability to become pregnant and carry a child to term. Later stages are early menopause or ending of menstruation, pain or discomfort from sexual intercourse, or lack of intimacy from anxiety or distress due to early menopause.

As a quality-of-life objective, all subjects are part of a longitudinal study using the PROMIS sexual function survey. The first 200 registered patients who agreed to participate are part of a study following endocrine markers of fertility (reproductive health, fertility status, and endocrine disruption).

*Learn more about E1Q11 / EROS.*