The EROS trial:
engendering reproductive health within oncologic survivorship

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EROS Trial (E1Q11)

- **Primary Study**
  - EROS Trial - Engendering Reproductive Health within Cancer Survivorship

- **Secondary Studies**
  - Endocrine Disruption in Cancer Care
  - Sexuality in the First Years After Cancer Diagnosis
Primary Hypothesis:

- The reproductive health needs for women with cancer are not adequately assessed and addressed by cancer care providers.
- The implementation of the proposed reproductive health assessment and algorithm will optimize the reproductive health objectives of women with cancer.

Secondary Hypotheses

- Patients and clinicians have different perspectives regarding reproductive health objectives of women with cancer.
- There are certain clinical, demographic, healthcare delivery, and socioeconomic factors that affect patients with regards to adequacy of reproductive health management and treatment.
Objectives

Primary Objective:
The primary objective of this study is to evaluate the success of the implementation of reproductive health programming (Didactics, EROS Reproductive Health Assessment and EROS Trial Algorithm) among reproductive aged women (18-55) with cancer.

Secondary Objectives:
- To assess the degree of discrepancy between patients and their clinicians in estimates of significance of the reproductive health goals for the patient
- To evaluate baseline and follow-up reproductive health assessments for trends in reproductive health choices relating to oncofertility, oncocontraception and pregnancy over the 5-year study period
- To identify clinical and demographic factors predictive of reproductive health care management
Study Design

- 20 ECOG NCORP Institutions (focus on minority patients)
- Cluster Randomized Controlled
- Total 612 Patients Accrued/30-31-site
- 5 Year Following
- Data regarding Main Outcomes at 3.2 years
Ancillary Study #1
Reproductive Health Related Endocrine Disruption in Cancer Care

Background
- Conclusions of our pilot study demonstrate that women with cancer undergoing chemotherapy experience significant endocrine disruption affecting the ovaries and possibly thyroid function.

Hypotheses
- At least 80% of women will have significant endocrine disruption during chemotherapy.

Objective
- To perform a longitudinal study following endocrine markers of fertility for cohort of the first 200 women registered in the EROS trial who agree to participate.

Endpoint
- Laboratory tests (AMH, FSH, Thyroperoxidase antibody, and TSH) will be evaluated to assess fertility status and endocrine disruption at baseline and periodic assessments after treatment.
Ancillary Study #2
Longitudinal Study of Sexuality in Women with Newly Diagnosed Cancer

Background
- While sexuality is an important quality of life indicator, little is known about sexual function amongst women with newly diagnosed cancer.

Hypotheses
- Primary Hypothesis: Cancer survivors' sexual function decreases during initial cancer treatment, and then increases with time after treatment.
- Secondary Hypothesis: Cancer survivors have lower levels of satisfaction with their sex lives compared to age matched general population at baseline.

Objective
- To perform a longitudinal study of sexual function, using the PROMIS Sexual Function Survey, in all subjects participating the EROS Trial.

Endpoint
- Measurement of PROMIS Sexual Function Survey in the study subjects over the 5 year study period.
Pre-Study Actions/Documentation

- Set up sub-account with Quest Diagnostics (refer to Section 9.1 of the E1Q11 protocol for details)

- Complete and submit the Delegation of Responsibilities Log to CTSU (refer to Sections 4.2, 5.5.2 and 7.0, Table 1 of the E1Q11 protocol for details)

- All providers should sign the consent form (refer to Section 5.5.1 of the E1Q11 protocol for details)

- All providers should complete the online Reproductive Health Values Survey (General) in the Assessment Center (refer to Section 5.3 of the E1Q11 protocol for details)
What we need ...

- Quest Diagnostics Account
- Provider Consent
- Provider Values Survey
- Delegation of Responsibilities Form
- Intervention Training
- Intervention Documentation
- Lead Group Approval
Intervention sites have two additional steps in their timeline: 1) study training and 2) intervention documentation submission.
Current Status

- Accrual: 91 (as of 10/17/17)

- 20 main NCORP/MU-NCORP participating institutions
  - 12 NCORP sites
  - 08 MU-NCORP sites

- Of the 20, 19 NCORP sites have been randomized and are approved to accrue
  - Arm A: 10 NCORPs (53 affiliate sites)
  - Arm B: 9 NCORPs (31 affiliate sites)
EROS Actual Start-up Timeline

Study Flagged for low accrual

- Study Activated by ECOG-ACRIN
  9/30/2015

- Sites begin preparation of pre-acrual documentation
  10/1/2015

- First Wave of sites received Lead Group Approval
  7/15/2016

- Second Wave of sites received Lead Group Approval
  8/25/2016

- First Patient Accrued
  9/7/2016

- 10 of 20 study sites now have Lead Group Approval
  11/19/2016

- 19 of 20 sites now have Lead Group Approval
  6/6/2017

- Dayton replaced with SCOR
  7/19/2017

- 48 Patients Accrued
  6/14/2017

- 80th Patient Accrued
  9/20/2017
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**TOTAL**
Reported Barriers

- Lack of investigator interest
- Patient or partner sterilization
- Patient too overwhelmed to discuss reproductive health
- Patient identified outside of 30 day diagnosis window
- Lack of staff/staff turnover
- NCORP infrastructure issues

How Barriers Were Addressed

- Re-training
- Regular check-ins via phone and email directly with NCORP staff
- Monthly study update email
- Removal of partner sterilization from eligibility criterion
- 30 day from diagnosis timeframe removed from eligibility criterion
Open Discussion

- Interest in participation
- Barriers to participation
- Other Concerns
Questions?

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