

ECOG Proposal: The Incorporation of Comprehensive Reproductive Health into Cancer Care

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ASCO recommendations

- **Fertility preservation options** should be addressed by oncologists and physicians as part of **standard care** for cancer patients who are in their **reproductive years**, according to guidelines developed by the American Society of Clinical Oncology (ASCO) and published in the June 20, 2006 *Journal of Clinical Oncology*.
- "As part of education and informed consent before cancer therapy, oncologists should address the possibility of infertility with patients treated during their reproductive years and be prepared to discuss **possible fertility preservation options or refer appropriate and interested patients to reproductive specialists**," the authors noted. "Clinician judgment should be employed in the timing of raising this issue, but discussion at the earliest possible opportunity is encouraged."



Reproductive Health in Oncologic Care

Case Series

(Pts admitted to cancer care 6/03 – 5/06)

Case No	Age Yrs Gravidity/ Parity	Stage of Disease Diagnosis	Treatment Plan	Diagnosis of Pregnancy
Case 1	42 7/6	Stage II B Infiltrating Ductal Ca. R. Breast		During chemotherapy treatment
Case 2	27 1/0	Stage IV Nodular Sclerosing Hodgkin's Lymphoma	Chemotherapy in 2nd trimester (ABVD regimen)	1 month after cancer diagnosis
Case 3	25 1/0	Stage IV Adeno Ca. Colon	Sigmoid colectomy, Chemotherapy	Prior to cancer diagnosis
Case 4	39 2/1	Stage III B Inflammatory Ca. L. Breast	Chemotherapy	During work up of cancer
Case 5	32 8/5	Stage II B (ER/PR-) Infiltrating Ductal Ca. R. Breast	a) Chemotherapy b) Radiation	a) At cancer diagnosis b) Pre-radiation work up

Cancers in Reproductive Age Group

According to the American Cancer Society, the estimated new cancer cases in women during the year 2006 approximated to 679,000. Of which 10 % of women were in the reproductive age group (15-49yrs). *(SEER Stat Database; Jemal et al, CA Cancer J Clin. 2006 Mar-Apr; 56(2):106-30)*

Cancers in Reproductive Age Group

The most common cancers diagnosed in women of childbearing age are breast carcinoma, melanoma, cervical carcinoma, non Hodgkin's lymphoma, leukemia (*Jemal et al, CA Cancer J Clin. 2006 Mar-Apr; 56(2):106-30; Lee et al, J Clin Oncol. 2006 Jun 20; 24(189):2917-31*)

and rarely colon cancer. (*Heise et al, Mayo Clin Proc. 1992 Dec; 67(12):1180-1184; Minter et al, Cancer Control. 2005 Jul; 12(3):196-202*)

Chemotherapy

The risk of gonadal damage due to chemotherapy is progressive and irreversible and is directly influenced by the patients' age, type of the drug as well as cumulative dose of the drug. (*Blumenfeld, et al J Soc Gynecol Investig. 1999 Sept-Oct; 6(5): 229-39*)

Chemotherapy

High risk	Intermediate risk	Low/no risk
Cyclophosphamide	Cisplatin	Methotrexate
Cholarambucil	Adriamycin	5-Fluorouracil
Melphalan		Vincristine
Busulfan		Bleomycin
Nitrogen mustard		ActinomycinD
Procarbazine		

Cytotoxic agents according to degree of gonadotoxicity.

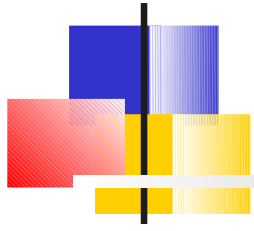
(Hum Reprod Update. 2004 May-June; 10(3): 251-66)

Radiation Therapy

Gonadal damage due to radiation can be temporary or permanent and occurs by direct exposure as in pelvic or low abdominal irradiation, but also is seen due to scattered radiation. *(Meirow, et al, Hum Reprod Update. 2001; 7(6): 535-543)*

Fertility

As more cancer patients are surviving due to the various advancements in screening and treatment modalities, currently the emphasis is on the quality of life. Several web based surveys revealed that fertility after treatment remains a major concern for many of the female cancer survivors. *(Partridge et al, J Clin Oncol. 2004 Oct; 22(20): 4174-4183)*



ONCOFERTILITY CONSORTIUM

AREAS OF COLLABORATION

- Important two way exchange of scholarly work and patient care options.
- Opportunities to address important quality of life issues from a research and real world perspective.
- Provide fertility preservation options for all patients.
- Opportunity to address important cultural differences in how patients view their reproductive futures.
- Nationwide opportunities for research and enhanced patient care.

Research

Hypotheses-based Research

vs.

Observational (Trend)-based Research



Reproductive Health in Oncologic Care

Case Series

Recognition of Need for Multidisciplinary Approach

Pilot Study

Assessment of the Issue

Komen Grant

Formalization of Collaborative Agreement

Development of Protocol

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National Protocol for QOL Study

Pilot Study: Assessment of the Issue

The purpose of this study was to pilot a survey instrument to develop descriptive data on the reproductive goals of reproductive aged women (15-44 yrs) presenting with cancer.

The spectrum of reproductive health issues may range from:

- prevention of unintended pregnancy
- prevention of premature loss of fertility
- optimization of a desired pregnancy

Provision of such care may include:

- access to family planning
- reproductive health technology
- obstetric and gynecologic services

Papers that Resulted from this Research

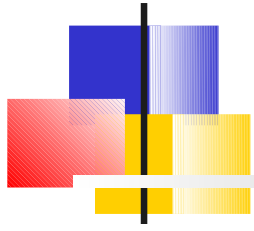
- Reproductive Health Issues in Women with Cancer: A Case Series, *Journal of Oncology Practice: March 2008, pp 101-105*

Submitted for publication:

- Reproductive Health Assessment in Women with Cancer: A Pilot Study
- Reproductive health assessment and management for cancer patients: An Algorithm

ECOG Proposal
**The Incorporation of Comprehensive Reproductive
Health into Cancer Care**

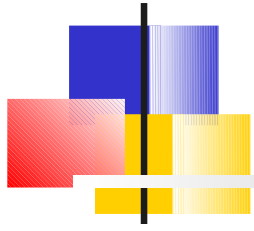
- ❑ Sexual Health / Sexuality
- ❑ Fertility Suppression / Prevention
- ❑ Fertility Preservation



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The Incorporation of Comprehensive Reproductive Health into Cancer Care

- Reproductive health goals of reproductive aged women with cancer are often not assessed or understood.
- Fertility preservation for young cancer survivors has research and public interest
- Uncertainties surround future fertility, pregnancy and cancer survival.
- Evaluation and treatment of cancer must include assessment of goals for fertility and family planning.
- Tremendous impact on the care of young woman to maintain tenable reproductive health goals in the context of cancer care.



ECOG Initiatives

Reproductive Health in Oncologic Care

- Goals:
 - Improve and evaluate reproductive health as a key component of quality of life for cancer survivors.
 - Provide a mechanism for incorporation of reproductive health considerations into oncologic care.
 - Apply the research findings to clinical practice.
 - Study the decision-making process regarding patients' reproductive health.
 - Serve as an educational resource for disease-induced, reproductive health-related questions by the community



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The Incorporation of Comprehensive Reproductive Health into Cancer Care

- Descriptive and interventional study
- Aimed at assessing women's choices regarding their reproductive health in relation to their cancer diagnosis.
- Based on each individual's situation, an algorithm will be followed to promote proper and adequate attention to reproductive goals and effective cancer treatment.
- Integrated cancer management and reproductive health plan developed and implemented.



ECOG Proposal

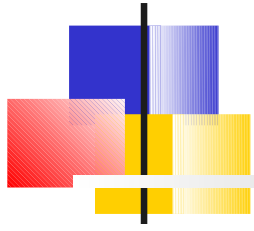
The Incorporation of Comprehensive Reproductive Health into Cancer Care

- Primary Objective

- To evaluate the success of implementation of the reproductive health programming.

Secondary Objectives

- To assess the degree of discrepancy between patients and their physicians in estimates of significance of the reproductive health goals for the patient.
- To assess baseline and follow-up reproductive health and sexuality assessment.
- To develop and implement a reproductive health care plan in the context of cancer care plan for each patient.
- To identify clinical and demographic factors predictive of reproductive health care needs.



ECOG Initiatives

Reproductive Health in Oncologic Care

Schema

- Eligible Patients

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- Sign Informed Consent

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- Initial Assessment

- Patient Survey and Data Form

- Reproductive Health Contraceptive Assessment

- Sexual Function Satisfaction Survey

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- Laboratory Tests

-

- Follow-Up Assessments

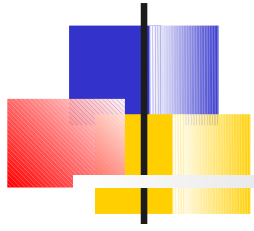
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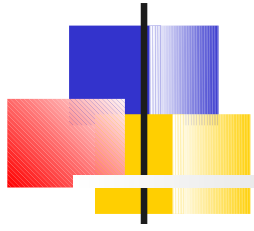


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Eligibility criteria

- Female
- Age 18-55
- Any form of cancer
- Evidence of ovarian function (represented by menstruation).



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Exclusion criteria:

Male

Post-menopausal

No longer menstruating

Age < 18 or > 55

Hysterectomy

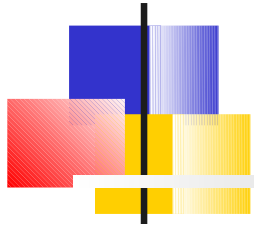


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Reproductive Health in Oncologic Care Tools

Reproductive Health Survey

- ❑ Algorithm for Multidisciplinary Treatment Plans
 - ❑ Reproductive Health Care Program
- ❑ Sexual Health / Sexuality
 - ❑ Survey Instrument Reference
(www.femalesexualdysfunctiononline.org)
- ❑ Fertility Suppression / Prevention
 - ❑ ARHP module *(www.arhp.org)*
- ❑ Fertility Preservation
 - ❑ NPC presentation

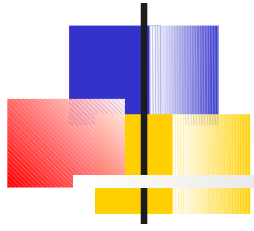


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Reproductive Health in Oncologic Care

Conclusions from this study should:

- Aid clinicians navigating through the issues of reproductive health in the context of cancer care.
- Identify clinical demographic, healthcare delivery, and socioeconomic factors concerning adequacy of reproductive health management in cancer patients.
- Help optimize the achievement of reproductive health objectives of women with cancer



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Reproductive Health in Oncologic Care

The results of this study will:

- Provide Important information on primary outcomes and performance of intervention
- Provide Important information to fuel further studies in the area
- Continue to develop a standard of care in this unexplored area of Reproductive Health and Cancer Care



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Reproductive Health in Oncologic Care

Questions?