The ABC’s of Setting Up a Successful Oncofertility Medical Practice

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Who Is At Risk?

- More than 1.4 million people are diagnosed in the U.S. with cancer annually.
- 10 million new cases of cancer are diagnosed globally each year.
- 10% of these individuals are in their reproductive years (up to 45 years old).
- Approximately 11% of breast cancer patients are diagnosed before the age of 40 years old.
How Big is the Problem?

In 2006, estimated 1,700,000 female cancer survivors in US who were <45 at diagnosis.

20% reduction in achieving first pregnancy in pediatric survivors.

50% decrease in women diagnosed as young adults.

Estimate that 748,000 currently have had their childbearing interrupted (plus another 38,500 per year).

Endocrine Concerns

Chemotherapy

- Targets rapidly dividing cells (including germ cells)
- Can cause mutations, DNA adducts, and structural breaks
- Oxidative damage in both somatic and germ cells

Radiation

- Pelvic and cranial radiation can induce sterility

Exact impact of chemotherapeutic agents depends upon

- Age of patient
- Young patients are particularly susceptible
- Type of chemotherapy (particularly Alkylation agents)
- Doses and type of radiation
Fertility Concerns Beyond Cancer

- Patients with rheumatologic diseases such as lupus, RA, and ulcerative colitis
- MS patients receiving new generation treatments
- Patients undergoing bone marrow or stem cell transplants for an indication
- Individuals with genetic mutations that lead to loss of fertility and early menopause (e.g., Turner Syndrome, Fragile X Carriers)
- Individuals who carry a mutation that predisposes that individual to certain types of cancer and anticipated treatment-induced risk of infertility (BRCA, MLH, MSH, APC, MEN)
- Patients with disorders of sexual development (DSD)

Green D et al, J Clin Oncol, 2006; Leslie Schover, OCC, 2010

Contraception in Adolescent Cancer Patients

The WHO also classifies contraception based on efficacy into four tiers:

- Tier 1 (Most Effective): Sterilization, Implants, Intrauterine devices
- Tier 2: DMPA, Combined hormonal methods
- Tier 3: Barrier Methods
- Tier 4: Behavioral Methods
Contraception

Planning for the Future

**Females**
- Embryo banking
- Egg banking
- Adoption/Surrogacy
- Natural Pregnancy
- Ovarian Tissue Cryopreservation

**Males**
- Sperm Banking
  - Ejaculated or Testicular Sperm Extraction (TESE)
- Donor Sperm
- Adoption/Surrogacy
- Testicular Tissue Cryopreservation

Complex Decisions Require Large Teams

*Duncan et al., Reproductive Endocrinology, 7th Edition*
Building Your Team

Clinicians involved in treating oncofertility patients should follow national guidelines and recommendations

- Oncologists
- ObGyn
- Urologist
- Nurse
- Physician Assistants
- Genetic Counselor
- Patient Navigator
- Social Worker
- Psychologist
- Reproductive Endocrinologist
- Pharmacist
- Primary Care Provider
- Rheumatologist

Clinical Guidelines

**American Society for Clinical Oncology**
- Discuss FP with all patients of reproductive age (and with parents or guardians of children and adolescents) if infertility is a potential risk of therapy
- Refer patients who express interest (or ambivalence) in FP
- Address FP as early as possible; before treatment starts
- Document discussions in medical record
- Refer patients for psychosocial consultation if experiencing distress

**Clinical Guidelines**

**American Society for Reproductive Medicine**
- Clinicians should inform patients about options for FP and future reproduction prior to treatment initiation
- Experimental procedures (such as OTC and TTC) should be offered only in a research setting with IRB oversight.
- All available FP options should be offered and can be performed alone or in combination, often without causing significant delay to cancer treatment
- Parents may act to preserve fertility of cancer patients who are minors if the child assents and the intervention is likely to provide potential benefits to the child
Clinical Guidelines
Association of Pediatric Hematology/Oncology Nurses
- Discuss at the earliest possible moment potential fertility impairment
- Prompt referral to qualified specialist if patient is interested
- Promote clinical trials to advance state of knowledge

American Academy of Pediatrics
- Parents may act to preserve fertility of cancer patients who are minors if the child assents and the intervention is likely to provide benefits to the child

National Physicians Cooperative
Mission Statement
To protect and preserve reproductive health through the continuum of care and across the lifespan of patients.

Vision Statement
The National Physicians Cooperative will investigate ways to mitigate the effects of any diseases or treatment on ovarian and testicular function and develop physician-guided tools that will facilitate communication and translation between basic research and clinical practice.

The NPC is a national network of centers dedicated to preserving the fertility of their patients.
- NPC sites in 27 different states
- Global Partners in 17 countries

Clinical Members
- Must offer FP services to patients
- Agree to share FP metrics with the NPC
- Consider participating in NPC survey studies regarding practice patterns

Research Members
- Provide human ovarian or testicular tissue to the OC under IRB-approved protocols
Referral Assistance

• Referrals made for fertility preservation consultation through the FERTline
  – (866)708-FERT (3378)
  – Patient or provider driven
• Provide patients information on FP options
  – Egg, Embryo banking, Ovarian Tissue Cryopreservation
  – Sperm Banking, TESE, Testicular Tissue Cryopreservation
• Provide information on financial services
  – Livestrong Sharing Hope
• Consultation with LOCAL providers and specialists
  – REI, Urology, Gyn Onc.
  – Coordination with Oncology staff
• Patient follow-up

Tissue Freezing Protocols

OTC
• First protocol opened in 2007 at Northwestern University
• Currently, 30 NPC sites with IRB-approved OTC protocol
• 21 of these NPC sites enroll pediatric patients
• Age range from 0-45+ (site specific)
• XXX patients enrolled
• 375 research tissue samples collected
• Protocol and consent templates available through NPC

TTC
• First protocol opened in 2014 at University of Pittsburgh under Dr. Kyle Orwig
• Currently, 6 sites in process to obtain IRB-approval for TTC protocol
• Age range from 0-45+ (site specific)
• 20 patients enrolled
  – 20 tissue samples collected
  – 17 with germ cells present
• Protocol and consent templates available through the NPC in April 2015

Obtaining IRB Approval

Downloadable templates available on the Oncofertility Consortium website
• Protocol
• Consents
  – Adult consent
  – Pediatric consent and assent
• Access to IRB assistance
  – By phone or email
• Billing resources
  – Letters of appeals
• OTC Users Manual
  – OTC Tissue Transport Logistics
  – Patient Flow Example
• Laboratory Procedures
OTC Through the NPC

Oncofertility FAQs

Oncofertility FAQs
The FERTline is used by patients and providers to:

- Get connected with an established fertility preservation program
- Refer patients for a fertility preservation consultation or procedure
- Receive latest information from leaders in the field
- Access resources, tools, and support
Resources: iSaveFertility

Patient-specific information with a tap of a finger

Resources: Provider Pocket Guides

- Fertility Preservation – Where Does It Fit?
- Options for Fertility Preservation
- Cancer Therapy and the Risk of Infertility
- Starting the Conversation
- References

Resources: Oncofertility Textbooks

Coming Soon! 5th Oncofertility Textbook: Oncofertility Pediatric Practice
Resources: Repropedia

- A free lexicon of reproductive terminology
- 380+ reproductive terms (and expanding) that are reviewed by an expert global editorial board
- Education through multi-media approaches (text, pictures, and videos)
- Terminology can be incorporated and hyperlinked to any website
- Since 2011, Repropedia has received more than 53,000 visits from 183 countries and territories

Resources: YouTube Channel

Resources: YouTube Channel
Resources: Social Media

@oncofertility

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