



Oncofertility Best Practices CCHMC Panel Presentation

Comprehensive Fertility Care & Preservation
Program
November 2015



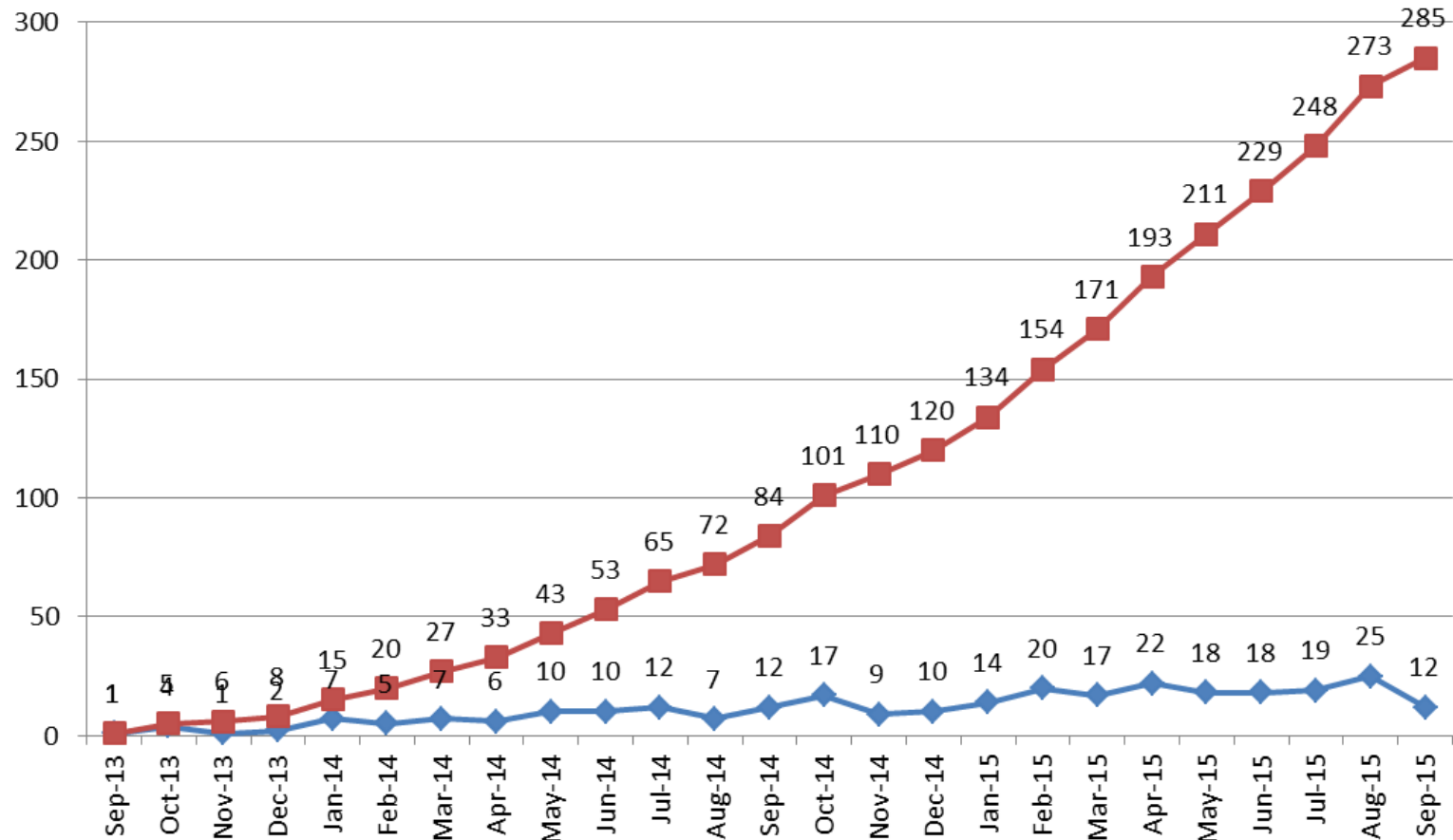
- Karen Burns, MD
 - Pediatric Oncology, Co-Director CFCPP
- Holly Hoefgen, MD
 - Pediatric Gynecology, Co-Director CFCPP
- Lesley Breech, MD
 - Pediatric Gynecology Division Director
- Janie Benoit, MD
 - Pediatric Gynecology Fellow
- Olivia Jaworek Frias, MSN
 - Fertility Navigator
- Julie Sroga, MD
 - Reproductive Endocrinology, University of Cincinnati
- Seth Risner, MS, PA(ASCP)
 - Pathology
- Tara Schafer-Kalkhoff, MA
 - Clinical Research Coordinator
- Abbey Franklin, PA
 - Pediatric Urology
- Mary Anne Lenk
 - Quality Improvement Consultant

- First established in 2009
 - Goal to see all eligible patients (new and relapsed)
 - Available Options:
 - Lupron
 - Sperm Banking
- Partnered with UC Reproductive Medicine
 - Embryo cryopreservation
 - Oocyte cryopreservation
- Ovarian Tissue Cryopreservation
 - Protocol opened at CCHMC (2012)
- Testicular Tissue Cryopreservation
 - Available via University of Pittsburgh (2014)
 - IRB pending at CCHMC

- Struggles with consults and timing
 - Which patients should be seen?
- Tremendous growth in institutional oncology program
 - Multiple teams within oncology
- Initially unable to track consults
- September 2013
 - Oncofertility Navigator Role Identified
 - Oncofertility database creation
 - New work flow established
 - Navigator to Care Manager communication
 - Fertility Consult Note created in Epic
- Staff education sessions beginning in 2014
- Formalized process for BMT patients 2015

- Current Goal: Fertility Consultation on all at risk patients in CBDI
- Accepted Exclusions from Consultation
 - Surgery only
 - Observation only
 - Palliative/Phase I treatment
 - *Second opinion/Consult only
 - Previous fertility consult completed
 - without change in infertility risk
 - Family declines fertility consultation

Eligible* Patients Receiving a Fertility Consult** September 2013 - Present

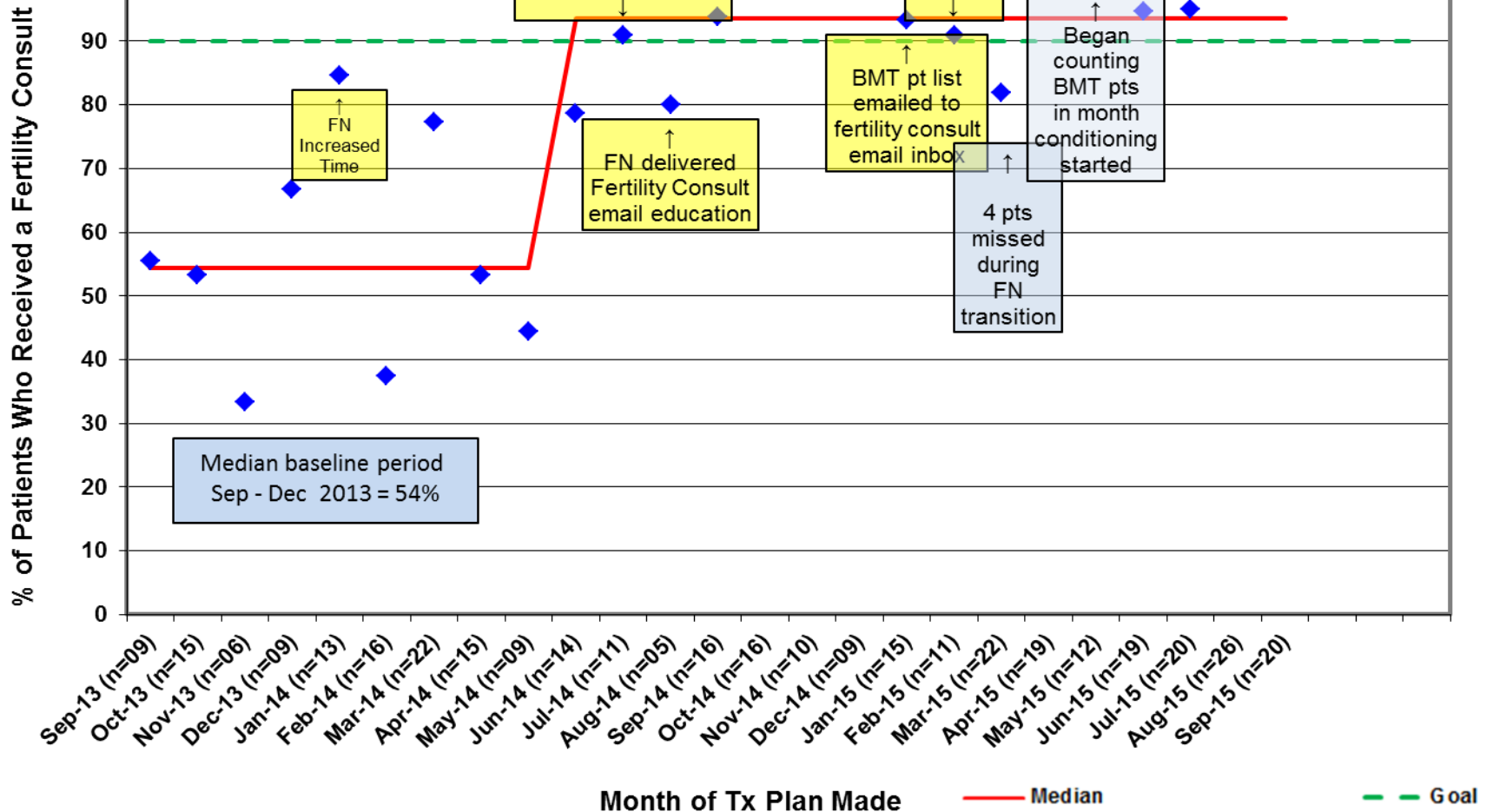


*Ineligible criteria: observation only, palliative or <20% expected survival, phase I, previous fertility consult/intervention, consult only, surgery only, family declined, severe cognitive delay

**Fertility consult counted on date of documented consult

◆ Fertility Consult Count ■ Cumulative Count

Percent of Eligible Patients Receiving a Fertility Consult* September 2013 - Present



FN = Fertility Navigator

*Ineligible criteria: observation only, palliative or <20% expected survival, phase I, previous fertility consult/intervention, consult only, surgery only, family declined, severe cognitive delay

FERTILITY CONSULTATION WORKFLOW

Fertility Navigator

- Obtain initial contact information
- Review records for any previous fertility team contact
- Reach out to the Oncologist on-call to address Gonadotoxic Risk Calculation
- Reach out to the Gynecologist or Urologist On Call to make aware of pending consultation
- Assist with consultations as required and available

Oncologist On Call

- Assess risk calculation for previous cancer treatments
- Assess risk calculations for expected future treatments
- Discuss patient's plan of care with oncology colleagues
- Discuss findings with the Gynecologist or Urologist On Call

Gynecologist and Urologist On Call

- Review risk calculation with Oncologist On Call
- Discuss patient history and consultation request with Fertility Navigator
- Conduct Fertility consultation, document in Fertility Consult Notes, bill consultation

Fertility Navigator

- Contact Research Coordinator for any patients requesting research protocol treatment
- Contact University of Cincinnati for female REI services
- Contact appropriate sources for sperm banking
- Assure patients and families have all required contacts, direct to follow-up appointments and assist with further process steps as required
- **** Follow up with "maybe" patients within 72 hours ****

Research Coordinator

- Work with research institutions (Pitt, Northwestern)
- Consent patients for research protocol procedures
- Assure all appropriate paperwork completed for research portion of procedures

Goal: Assist the patient/family through the Oncofertility process as seamlessly as possible

- Obtain initial consult information:
 - Fertilityconsult@cchmc.org
 - Pager
 - Desk phone / Message line
 - Interdisciplinary meetings
 - EPIC in-basket
 - Review of weekly patient lists (Oncology)
 - Review of BMT schedule/calendar
 - Tumor Board
- Initiate fertility consult/process chart review
 - Identify previous treatment & future treatment
 - Identify urgency of consult (Solids, Liquids, Neuro-Onc, BMT)

- Contact the on call fertility oncologist for risk assessment
- Coordinate fertility consult with patient's care manager
 - CBDI clinic / GYN clinic / Inpatient
- Contact GYN/Urology on call to notify of pending fertility consult
- Prep consult
 - Shared Decision Making Tool
 - Patient folder (male / female)

- Facilitate in the actual Fertility Consultation
 - Ensure appropriate lab testing is performed
 - Review financial considerations
- Navigate the research Process
 - Contact research coordinator with potential research candidates
- Notify Pathology/Surgery Scheduling of OTC patients
- Contact REI (oocytes/embryos/sperm) - fax notes and labs

- Provided by oncology members of CFCPP
- New patient plan is discussed with primary oncology team
 - Identify protocol, address any protocol deviation
 - Determine window of time before initiation of therapy
- Cumulative doses of chemotherapy and/or radiation in protocol
- Provide assessment of previous and planned treatment regimens

- Tools for calculating risk:
 - SaveMyFertility
 - Fertile Hope
 - Summed Alkylating Agent (SAA score)
 - Cyclophosphamide Equivalent Dosing (CED) calculation
 - Literature searches on new / unfamiliar medications & protocols

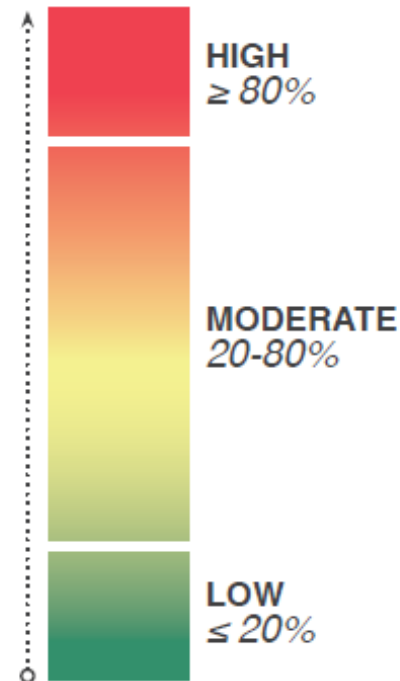
- **Cyclophosphamide equivalent dose (CED) calculation:**
 - 1.0 * (cumulative cyclophosphamide dose (mg/m²))
 - + 0.244 * (cumulative ifosfamide dose (mg/m²))
 - + 0.857 * (cumulative procarbazine dose (mg/m²))
 - + 14.286 * (cumulative chlorambucil dose (mg/m²))
 - + 15.0 * (cumulative BCNU dose (mg/m²))
 - + 16.0 * (cumulative CCNU dose (mg/m²))
 - + 40 * (cumulative melphalan dose (mg/m²))
 - + 50 * (cumulative Thio-TEPA dose (mg/m²))
 - + 100 * (cumulative nitrogen mustard dose (mg/m²))
 - + 8.823 * (cumulative busulfan dose (mg/m²))

- Identify Risk Category:
 - Low
 - (<20% develop infertility)
 - Intermediate
 - (20-80% develop infertility)
 - High
 - (>80% develop infertility)

WHAT IS MY INFERTILITY RISK?

It is important for you to know that every patient has a different infertility risk.

This visual shows you an estimate of your infertility risk based on your condition and treatment.



Provider to select assessed infertility risk

Fertility Preservation Options

EGG FREEZING
(OOCYTE CRYOPRESERVATION)



EMBRYO FREEZING
(EMBRYO CRYOPRESERVATION)



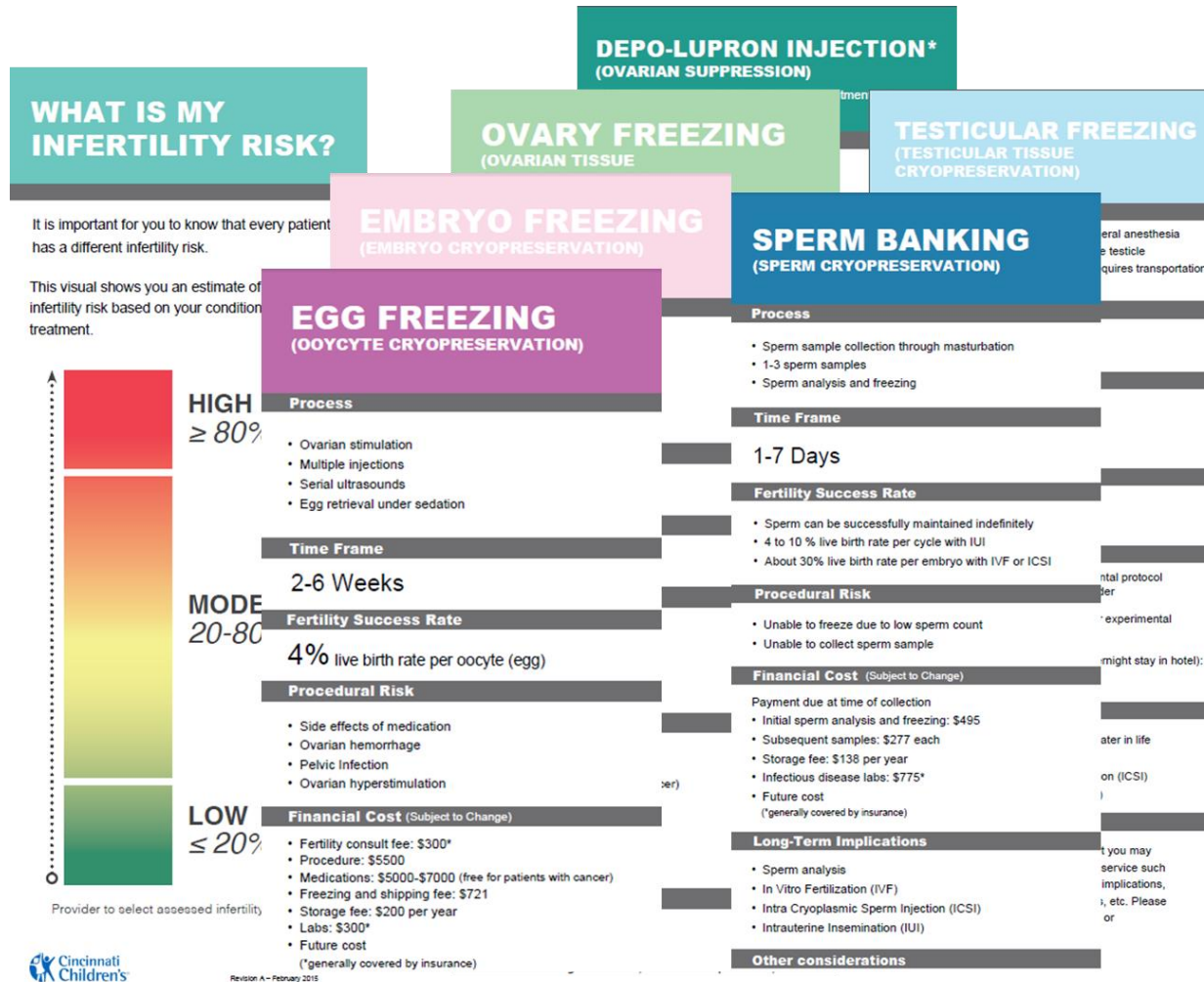
OVARY FREEZING
(OVARIAN TISSUE CRYOPRESERVATION)



DEPO-LUPRON INJECTION
(OVARIAN SUPPRESSION)



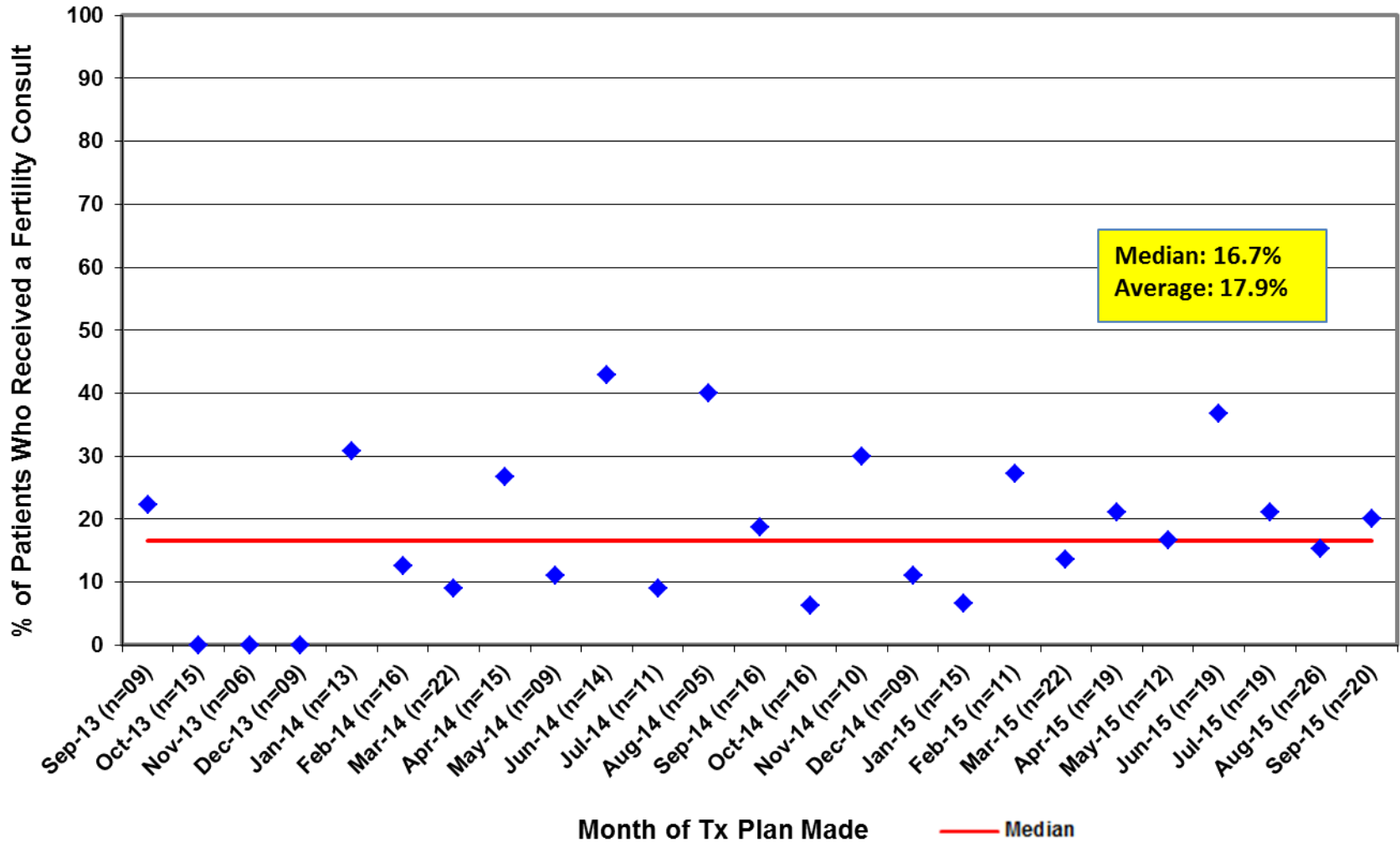
WEEK 1 WEEK 2 WEEK 3 WEEK 4 WEEK 5 WEEK 6
DAY 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 TIME REQUIRED FOR FERTILITY OPTION



- Initiation of Shared Decision Making

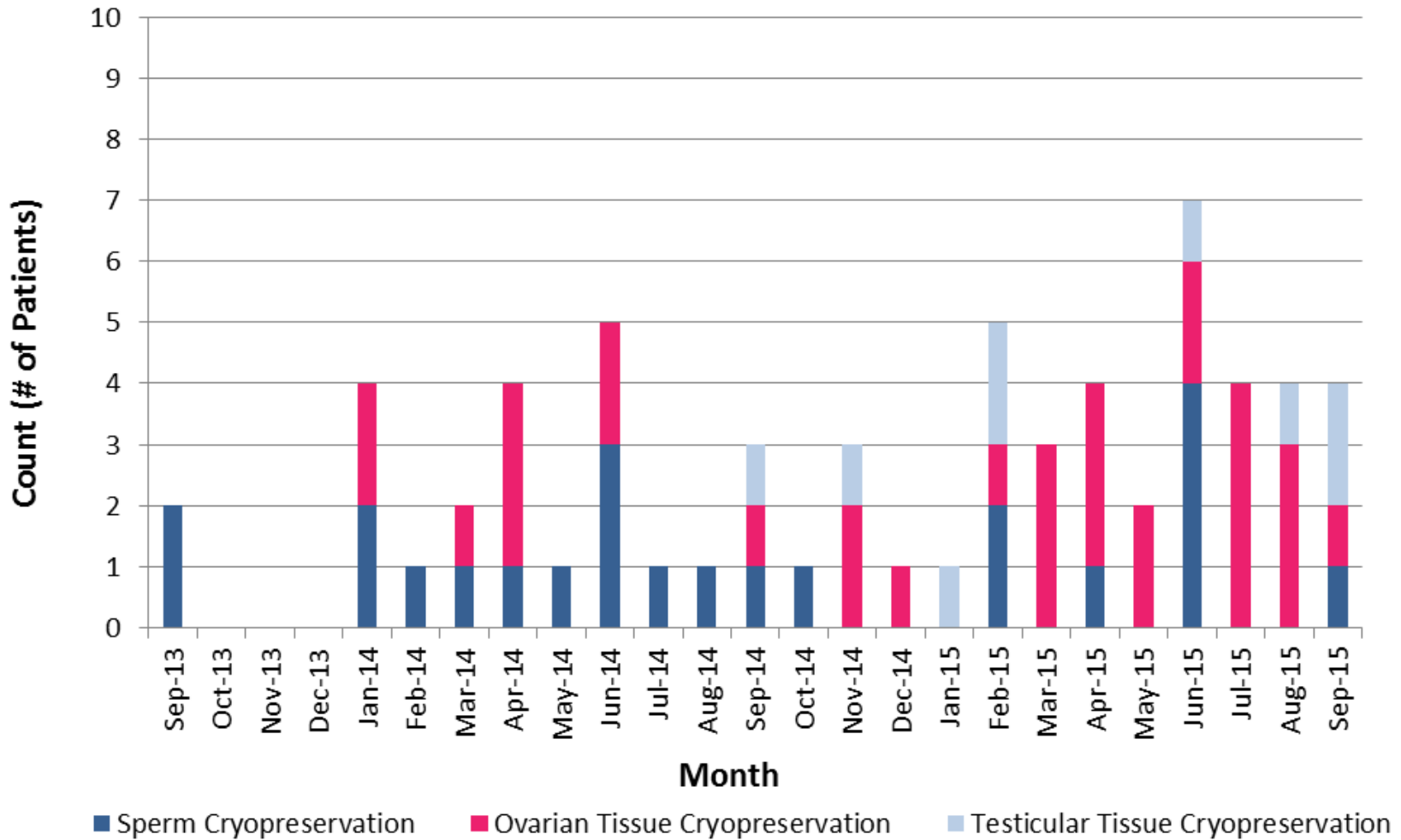
- **Goal:** follow up call within 72 hours
 - Decision time frame dependent of care
- Fertility Navigator contact information given
- Patients may request follow up consult with Fertility Navigator / Providers
- Survivors
 - Goal: Annual GYN/Fertility follow up

Percent of Eligible Patients Electing a Fertility Preservation Option September 2013 - Present



*Ineligible criteria: observation only, palliative or <20% expected survival, phase I, previous fertility consult/intervention, consult only, surgery only, family declined, severe cognitive delay

of Patients Electing Fertility Preservation by Option Sep. 2013 - Present



Preservations Options Completed

(Based on currently available date)

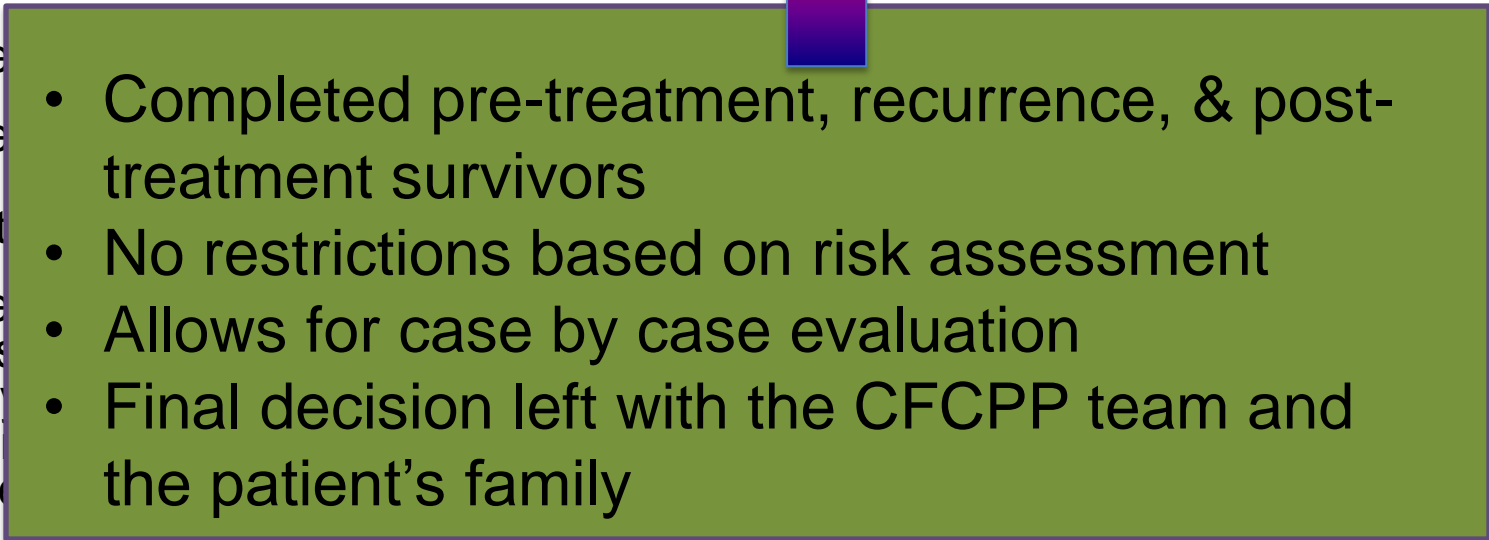
- Females
 - Ovarian Tissue Cryopreservation: 44
 - 22 since 1/2015
 - Oocyte Cryopreservation: 8
 - Embryo Cryopreservation: 0
- Males
 - Sperm Cryopreservation: 22
 - Testicular Tissue Cryopreservation: 8
 - 6 since 1/2015

STEPS TO OVARIAN TISSUE CRYOPRESERVATION ...

Determine patient eligibility based on the study's inclusion and exclusion criteria.

- 1) Females, \geq **1 month** and \leq 41 years of age.
- 2) Undergo surgery, chemotherapy, drug treatment, and/or radiation for the treatment or prevention of a medical condition or malignancy expected to result in permanent and complete loss of subsequent ovarian function.
- 3) Or, have a medical condition or malignancy that requires removal of all or part of one or both ovaries.
- 4) Subject may have newly diagnosed or recurrent disease.
- 5) Subject who already has stored cryopreserved ovarian tissue in a frozen state prior to undergoing cancer treatments (surgery, chemotherapy or radiation) will be eligible for enrollment with informed consent.
- 6) Signed an approved informed consent and authorization permitting the release of personal health information. The subject and/or the subject's legally authorized guardian must acknowledge in writing that consent for specimen collection has been obtained, in accordance with institutional policies approved by the U.S. Department of Health and Human Services.
- 7) Is not a candidate for or chooses not to utilize embryo or oocyte banking.

- 1) Females, ≥ 1 month and ≤ 41 years of age.
- 2) Undergo surgery, chemotherapy, drug treatment, and/or radiation for the treatment or prevention of a medical condition or malignancy expected to result in permanent and complete loss of subsequent ovarian function.
- 3) Or, have a medical condition or malignancy that requires removal of all or part of one or both ovaries.
- 4) Subject to CFCPP review
- 5) Subject to state radiation regulations
- 6) Signed release, legally specified policies
- 7) Is not a candidate for or chooses not to utilize embryo or oocyte banking.

- 
- Completed pre-treatment, recurrence, & post-treatment survivors
 - No restrictions based on risk assessment
 - Allows for case by case evaluation
 - Final decision left with the CFCPP team and the patient's family

- 1) Women with psychological, psychiatric or other conditions which prevent giving fully informed consent.
- 2) Women whose underlying medical condition significantly increases their risk of complications from anesthesia and surgery.
- 3) Women who have a large mass in the ovary that is being removed will not be enrolled in the study. That is, ovarian tissue cryopreservation will not be performed on portions of the ovary that contained a large mass as the tissue may not be suitable for future use due to limited or no follicles.
- 4) Serum FSH levels above 20 mIU/ml.

Patient Consent Process

OTC Consent Preparation

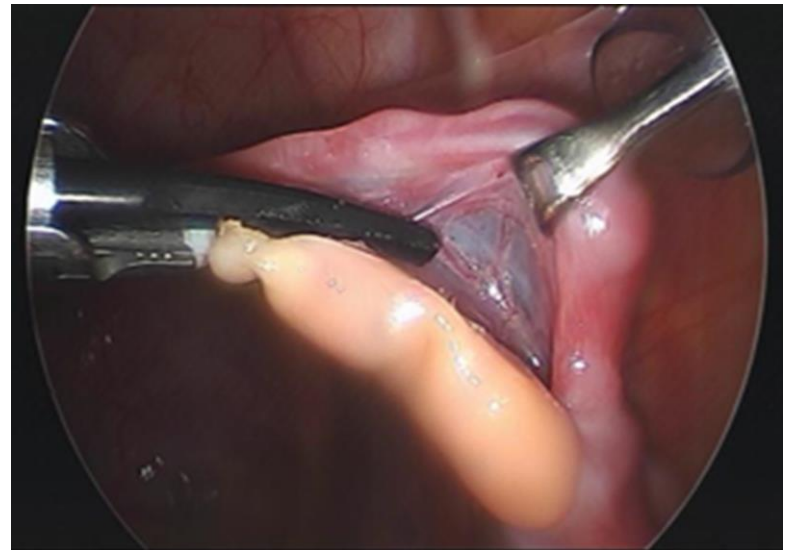
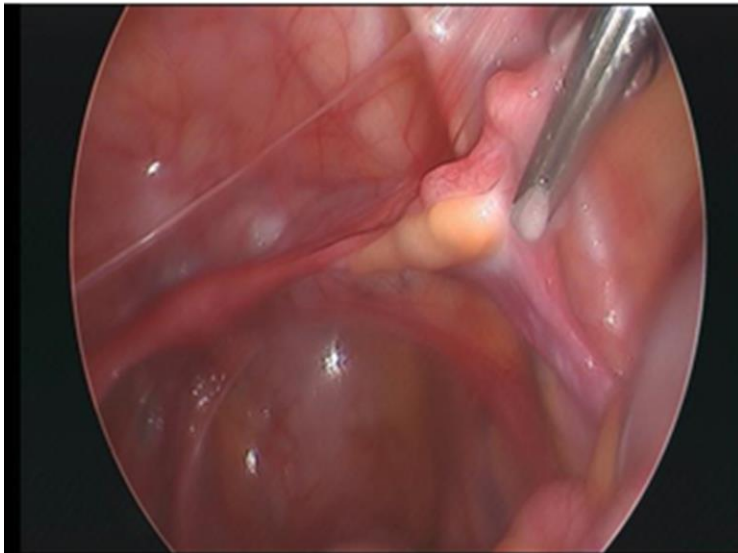
- Prepare patient folder with OTC Study paperwork.

Consent the Patient

- Consent Forms used based on age: Adult Consent Parental Permission, Assent
 - ≥ 18 years: Adult Consent completed by patient
 - ≤ 17 years old
 - For all: parent or legal guardian completes Parental Permission
 - ≤ 10 years: patient asked for verbal assent, if age appropriate
 - 11 to 17 years: patient asked to provide written Assent
 - 16 to 17 years: patient asked to sign Adult Consent as well as Assent
- Consent Forms used based on language spoken: Full or Short Form Consent
 - Full Consent Form: used for English speaking patients
 - Short Form Consent Form: used for non-English speaking patients
 - Currently translated into Arabic and Spanish.

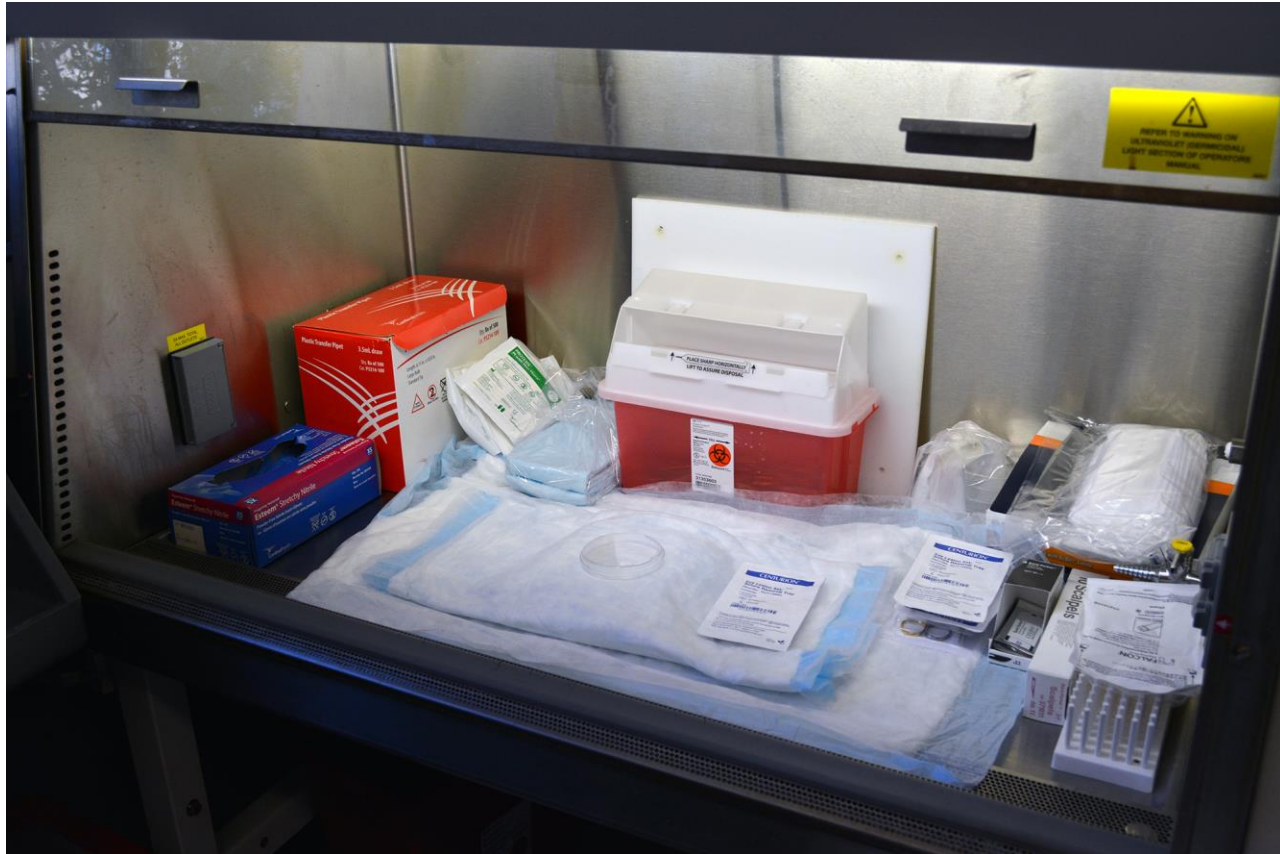
Ovarian Tissue Cryopreservation – Procedure

- Combined vs Solo procedure
- Laparoscopic (Open option available)
- Remove Single Whole Ovary
- Ovary removed via easiest accessible direction



Ovarian Tissue Cryopreservation - Processing.

- Recently moved to in-house processing
- Requires FDA licensing and oversight

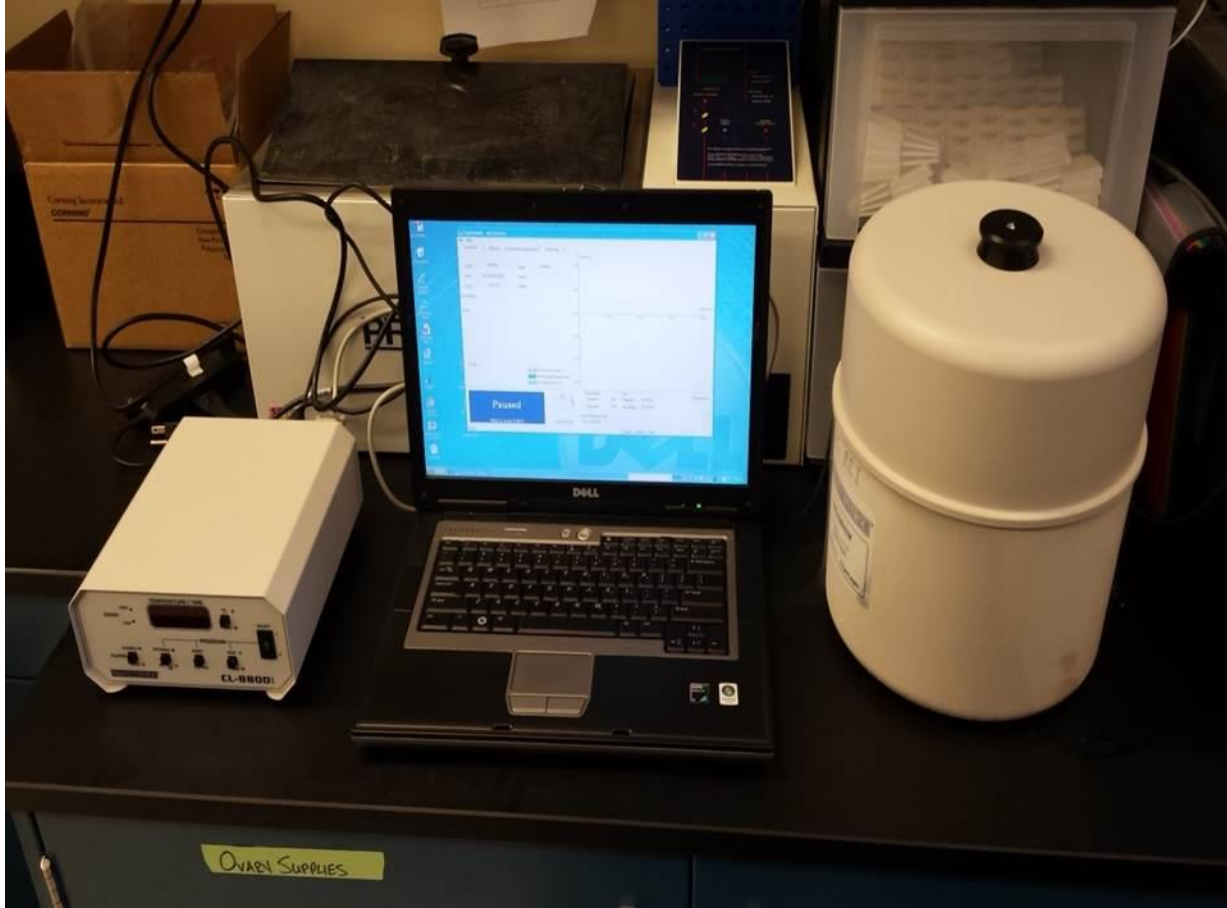














- Provided via University of Cincinnati Center for Reproductive Health
 - Oocyte Cryopreservation
 - Embryo Cryopreservation

- Oocyte and embryo cryopreservation
 - Explanation of process: ovarian hyperstimulation and oocyte retrieval, cryopreservation, and storage
 - Pregnancy rates for oocytes and embryos
 - Determine cycle stimulation start based on cancer treatment
 - Traditional follicular phase start
 - Immediate start for late follicular- luteal phase
 - Financial counseling for cryopreservation and storage
 - Special considerations in adolescent/young adult population
 - Virginal status with transvaginal monitoring/aspiration
 - Relationship status – counseling in regards to legal implication to embryo cryopreservation
- Options for using gametes in the future
 - Uterine radiation – need for gestation carrier
 - FDA labs obtained if at risk for needing gestational carrier
- Contraception and Hormone replacement discussions

- 19 patients referred for gamete cryopreservation since 1/2014
- 13 pre-treatment and 6 post-treatment consults
- Age: 17-26
- AMH: Pretreatment 0.88-3.9; post treatment 0.03-0.7
- 8 proceeded with oocyte cryopreservation with 3 canceled cycles
 - 5 to 22 oocyte cryopreserved
 - Cancelled per patient desire, poor response, enlarging complex ovarian mass
 - 0 embryo cryopreservation cases
- 4 pending stimulation starts for post treatment patients

- Testicular Tissue Cryopreservation
 - Counselor for all pre-pubertal males who meet study criteria
 - Currently made available through the University of Pittsburgh
- Sperm Cryopreservation
 - Counselor for all pubertal male patient's regardless of risk stratification
 - Made available through University of Cincinnati
 - In-house room available for banking at CCHMC

▼ New Oncology Patient Consults Manage My Version — Required Add Order

▼ Fertility Preservation — Required

▼ Fertility Preservation — Required

Fertility Preservation Consult Request

Fertility Preservation Consult Request Not Indicated

Additional Consults

▶ Consults 2 of 2 selected

CBDI School Intervention Consult Request
● Routine, ONCE First occurrence Today at 2251, Call or page consulting department in addition to placing this order.

BMCP Neuropsych Testing
■ Routine, Internal Referral, Referral to facility - CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER 1 visit, Routine

Fertility Preservation Consult Request Not Indicated Accept Cancel

Routine, ONCE First occurrence Today at 1404, Specify the reason why the Fertility Preservation Consult Request is not indicated.

Priority: Routine STAT

Process Inst: Specify the reason why the Fertility Preservation Consult Request is not indicated.

Questions:

Prompt	Answer
1. Reason ●	<input type="text"/>

Single response

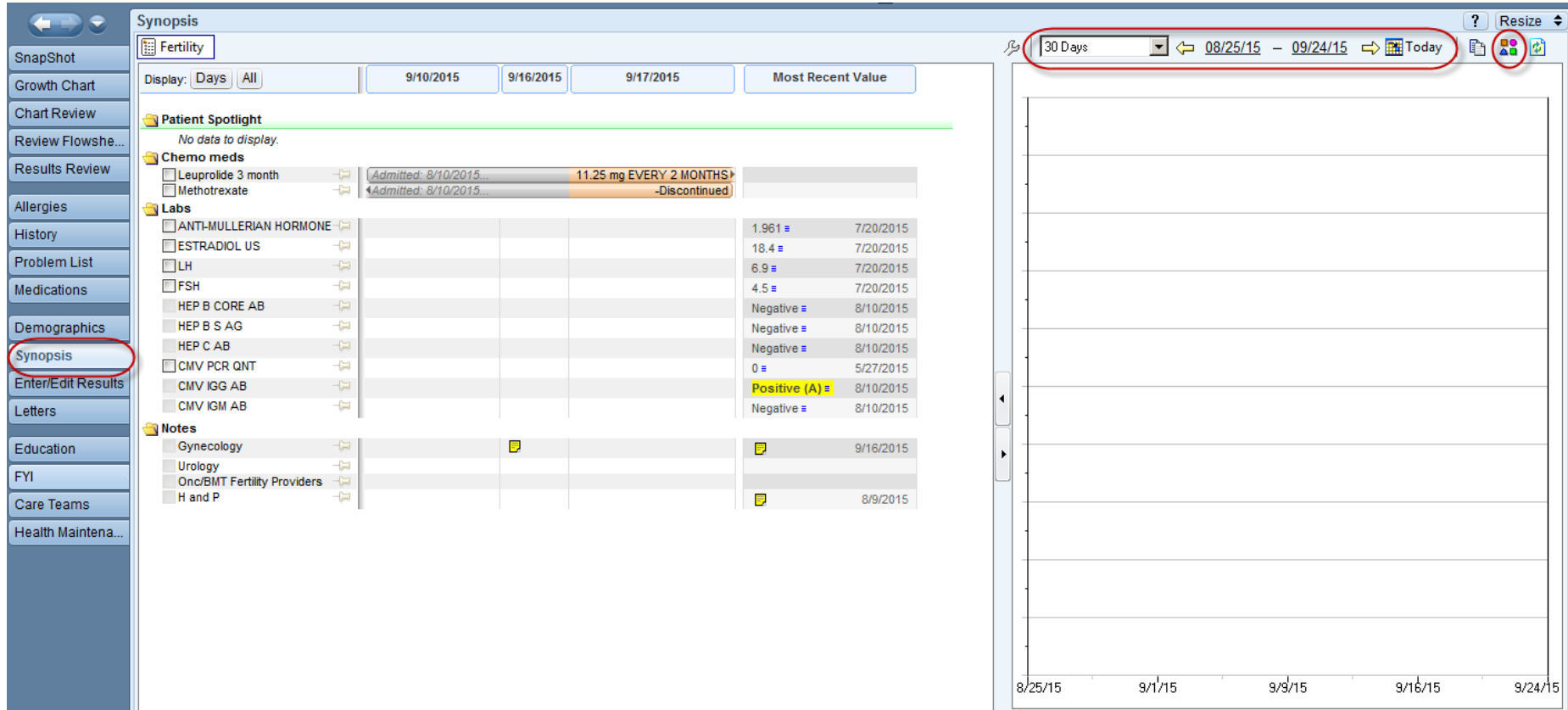
Comments (F6) [Click to add text](#)

Item Select

Search:

Title
Surgery or Observation Only
Palliative or Less Than 20% Expected Survival
Phase I Trial
Fertility Consult Completed - No Change in Fertility Risk
Previous Fertility Intervention
Family Declined Consult
Medically Inappropriate, i.e. Acutely Ill, Severe Cognitive Delay

New Oncology Patient Order Set



Synopsis

Fertility

Display: Days All | 9/10/2015 | 9/16/2015 | 9/17/2015 | Most Recent Value

Patient Spotlight
No data to display.

Chemo meds

- Leuprolide 3 month Admitted: 8/10/2015... 11.25 mg EVERY 2 MONTHS
- Methotrexate Admitted: 8/10/2015... -Discontinued

Labs

<input type="checkbox"/> ANTI-MULLERIAN HORMONE	1.961	7/20/2015
<input type="checkbox"/> ESTRADIOL US	18.4	7/20/2015
<input type="checkbox"/> LH	6.9	7/20/2015
<input type="checkbox"/> FSH	4.5	7/20/2015
HEP B CORE AB	Negative	8/10/2015
HEP B S AG	Negative	8/10/2015
HEP C AB	Negative	8/10/2015
<input type="checkbox"/> CMV PCR QNT	0	5/27/2015
CMV IGG AB	Positive (A)	8/10/2015
CMV IGM AB	Negative	8/10/2015

Notes

Gynecology		9/16/2015
Urology		
Onc/BMT Fertility Providers		
H and P		8/9/2015

30 Days | 08/25/15 - 09/24/15 | Today

8/25/15 9/1/15 9/9/15 9/16/15 9/24/15

EPIC Fertility Synopsis (Testing Phase)

- Currently using Excel Spreadsheets
- Considering REDCap vs other Data Management options
 - Interested in multi-center shared database

- Process for capturing consults
- Coordination of fertility care (No fertility navigator)
- Data management / Monitoring of completed consults
- Lack of fertility team specific contact information
- Tissue processing in outside facilities
 - Time to processing, Scheduling
- Lack of Research Assistant
- Lack of Institutional support & oncology buy-in
- Need for overall staff education
- Logistics of 3 oncology services + BMT
- Financial Barriers

- Data management
 - Remains in Excel
- Unable to process sequential ovaries in a single day
- Continued education throughout departments
- Resource management
 - faculty/fellow time, staff time, OR time, clinic utilization
- Funding

- Protocol & consent improvements
- Increased participation in Oncofertility Consortium
- Initiation of Shared Decision Making Tool
- New Name, New Website
- Hiring of Clinical Research Coordinator

- New gynecology
- Protocol &...
- Amendme...
- Increased...
- Monthly
- Participa...
- TWO ch...
- Adoles...
- Emergi...
- Initiation o...
- New Name, New Website
- Hiring of Clinical Research Coordinator

Comprehensive Fertility Care & Preservation Program (CFCPP)

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Comprehensive Fertility Care & Preservation Program (CFCPP)
Services Available
Females
Males

The Comprehensive Fertility Care & Preservation Program

At Cincinnati Children's Hospital Medical Center, we believe that fertility is an important aspect of medical care for every patient, which requires consideration even during childhood. The goal of the Comprehensive Fertility Care & Preservation Program (CFCPP) is to meet with patients whose medical condition or treatment regimens place them at risk for fertility complications in the future. By educating patients and families early on about the fertility risks of their diagnosis and treatments, they can determine if fertility preservation is available and right for them. We help the patient and family to understand the strengths, limitations, successes and science behind each option. We have teamed with the University of Cincinnati Center for Reproductive Health to provide all available fertility preservation options to our patients, utilizing the best and most up-to-date processes and techniques. We also work closely with the patient's primary medical team at Cincinnati Children's to assure the best quality of care for all patients that fits well into their proposed treatment plan.

Services Available



The Comprehensive Fertility Care & Preservation Program offers a full spectrum of fertility services for both male and female patients, including embryo freezing and sperm banking.

[READ MORE](#)

Fertility Consultation and Preservation for Oncology Patients | Cincinnati Children's



Services for women include freezing and storing eggs or ovarian tissue for later use. For men, freezing and storing testicular tissue or sperm.

[Cancer and Blood](#)
[Adolescent and Young](#)

Related Areas

- [Cancer and Blood Diseases Institute](#)
- [Turner Syndrome Center](#)
- [Transgender Health Clinic](#)

- Patient centered-improvements
 - Continue testing, improvement and spread of SDM tool
 - Increase information available to our international patients in their preferred language
 - Increased presence in survivor population
- Increase our national presence
- Expand & improve workflow model
 - Increased participation of urology with male consults
 - Defined roles of Fertility Navigator, CRC, etc ...
- Expand data-driven decision making & QI
 - Measure timely consults, Follow up of patient receiving fertility preservation methods, Monitoring the role of finances on decision
- Expand research protocols
 - TTC protocol currently with IRB for approval at CCHMC

QUESTIONS

&

ANSWERS

