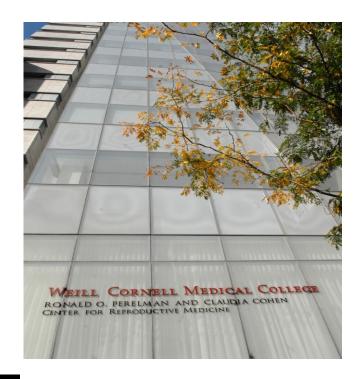
Introduction to CRM

Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine - CRM



CRM Locations

Upper East Side (Main Office) 1305 York Avenue, 6th Floor New York, NY 10021

Garden City, Long Island 1300 Franklin Avenue Garden City, NY 11530

open 7 days a week - 6:30 - 8:30am

Upper East Side (Satellite Office)
215 East 68th Street
New York, NY 10065
(no monitoring at this site – satellite for Dr. Melnick)

Mount Kisco, Westchester County 657 Main Street Mount Kisco, NY 10549

Tribeca255 Greenwich Street, Suite 540
New York, NY 10007

Upper West Side
2315 Broadway (corner of 84th and Broadway)
New York, NY 10024
(no monitoring at this site – satellite for Dr. Goldschlag)

Monitoring hours for each location available on the CRM website www.ivf.org and included in the orientation packet



The CRM Clinical Team

13 Attending Physicians

Each manage independent practices and office hours
Contribute to monitoring sessions at all sites
Rotate coverage in the IVF operating room

Fellowship Program for REI

3 year fellowship program that follows completed Obstetrical & Gynecology Residency Support the physician team with monitoring and office hours

Nursing Teams — (LPN's RN's, NP's and PA's)

Work collaboratively with CRM physicians
Work as teams to provide 7 day coverage
Support patient clinical and educational needs

Support Staff

Medical & Ultrasound Technicians





What is Ovulation Induction?

A treatment plan used to increase the chances of achieving pregnancy with a more conservative approach than IVF.

- Includes the administration of fertility medications (gonadotropins) to stimulate the development of an egg(s) (follicles) in the ovary
- Using both bloodwork and ultrasound evaluation, the follicles (cyst-like structures / fluid filled sac) are evaluated for development and maturity
- Once the recruitment process meets criteria, the ovary is "triggered" to ovulate with additional medication (hCG, Ovidrel or lupron)
- A "timed" sperm sample (fresh or frozen) is obtained, prepared in the lab and an insemination is done
- The insemination is an office procedure very similar to a speculum exam

IUI Cycle Overview

Cycle Day 1:

1st day of full flow of menses before midnight

Cycle Day 2 or 3:

- Office visit for baseline bloodwork and ultrasound
- Instructions to begin stimulation medications
- Follow-up evaluation and timing reviewed

Cycle Day 3-14:

- Near daily bloodwork and ultrasound monitoring
- Evening phone calls from nursing team with instructions

"Trigger" - Ovulation Day:

 hCG or Ovidrel injection administered 24-36 hours prior to insemination (IUI –intrauterine insemination)

IUI Day:

Sperm preparation in lab followed by the IUI



Why do Ovulation Induction?

- Increases the chance of pregnancy with regular cycles
- Have irregular menstrual cycles
- Have irregular ovulatory cycles
- Less expensive than IVF

A reasonable "first-line" treatment option before IVF



Treatment Timeline

- I. Initial Consultation
- II. Orientation Class
- III. Required Pre-testing
- IV. Getting Started
- V. Stimulation and Monitoring
- VI. Sperm prep and Insemination
- VII. Clinical Management
- VIII. Consents for included procedures
- IX. Follow-up Care

Initial Consultation for Infertility

Goal: The Reproductive Endocrinologist collects a medical, surgical and reproductive history from both female and male partner, if applicable. The consultation allows for a comprehensive evaluation of the factors that impact fertility including both female and male considerations, endocrine factors, genetics, anatomical or structural findings as well as age related implications.

Additional Considerations:

- Infertility history
- Prior treatment successes and failures
- Testing or surgical recommendations before treatment

Conclusion:

- Provide a plan of care with treatment options
- Review consents and risks vs. benefits
- Outline plan for next steps
 - Participation in orientation class and injection training
 - Required pre-testing





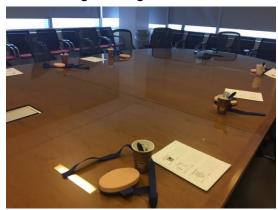
Orientation Class



Required part of the program at CRM:

Aim:

- Review specific insurance implications and the potential out-of-pocket expenses
- Provide and explanation of the "time-line" of treatment
- Clinical treatment options
- Procedure considerations
- Review medication and administration techniques
- Discussion related to required consent process
- Review plan, timing, outstanding testing



Required Prerequisite Testing

Female Partner:

Comprehensive panel of lab work including:

- Hormone evaluations
- Infectious disease screening (annual)
- Comprehensive Chemistry Panels
 - · Evaluates general health
- Cervical cultures (annual)
- HSG (Hysterosalpingogram) and/or SIS (Saline Infused Sonogram)
 - · Evaluates fallopian tubes and uterus
- Genetic Evaluations
- Ultrasound and uterine assessment

Male Partner: (if applicable):

Lab work:

- Infectious disease screening (annual)
- Genetic Evaluations
- Semen Analysis to evaluate sperm concentration, volume, count, morphology and motility



Sperm Source Considerations

Fresh Semen Sample:

- Produced the day of IUI in the andrology lab
- Second samples may be requested by lab
- Specific arrival times are provided
- Shower with an antibacterial soap morning of sample

Frozen Semen Sample:

Partner:

- Cryopreserved in anticipation as back-up
- May require additional consents

Donor:

- Transferred to CRM andrology lab from commercial labs
 - Shipments accepted Monday Thursday
 - Contact Andrology lab (646) 962-8448
- Must be at CRM prior to starting stimulation
- Nursing team will need:
 - Name of the donor sperm bank
 - Donor ID number
 - Number of vials stored at CRM
 - Recommend 2-4 ICI or IUI vials

Recommendations:

- Abstinence period of 2-5 days prior to retrieval (no more than 5)
- Instructions for semen productions provided including antibacterial soap shower on sample day
- Government issued Photo ID is required at the time of sample production
- If semen production is a concern notify the nursing team for planning
- It is critical to arrive at your assigned time to ensure the sample is prepared to coincide with IUI
- Additional consents are required for sperm storage at CRM, the Andrology lab will provide these forms
- Additional consents may be required for some samples





Stimulation and Monitoring

Stimulation

- Injectable medications stimulate the production of follicles in the ovary (follicle(s) are fluid filled sacs that may contain an "egg")
- Medication instructions provided in the evening of monitoring days
- Generally 8-14 days of sub-cutaneous injections
- Recommend taking as close to same time each day (7pm -10pm)
- Refrain from high-impact exercise, aerobics, pelvic twisting
 - Walking and acupuncture permitted
- No ibuprofen (Advil or Motrin products) or aspirin (unless instructed)
 - TYLENOL ONLY
 - No herbs or supplements (PNV permitted)

Common Side effects:

- Bruising or discomfort at injection sites
- Bloating and/or weight gain
- Mood swings
- Fatigue
- Headaches

Monitoring

- Near daily monitoring for bloodwork and or ultrasound is expected
- Ultrasounds performed by a CRM physician or ultrasound techs
 - Generally 8-14 days in total
- Each day that monitoring is performed nursing will call with instructions by 6:30pm
 - Please have an "identifying message" on voicemails
 - Ensure that voicemails are set-up and clear to accept to accept messages

Office hours differ by location – refer to CRM website

NOTE: Only the NYC Main office is open on

weekends & holidays

Recommendation:

Medication Log:

- Ensures supplies meets individual needs
- Refills are sent to all pharmacies upfront to avoid the need for additional medication requests





Taking the "trigger shot"

Based on ultrasound and bloodwork evaluation, the team determines timing for the "trigger" shot.

The "trigger" is given as:

~ hCG - an intramuscular injection (human chorionic gonadotropin) OR

lupron – a subcutaneous injection (leuprolide acetate)



OR a combination of both



Clear dosing instructions will be provided

Medications are ordered in advance to the pharmacy - be sure it is included in the shipment

Timing is **VERY** specific – critically important to take at the assigned time





The IUI Procedure

- Office procedure
 - Speculum exam
 - Takes approximately 5 minutes to perform
 - Little or no discomfort
 - Rest for 10-15 minutes following procedure
 - Cervix secures sample in cavity
 - No activity restrictions
 - May experience mild cramping
 - Procedure consent will be obtained
- Requires no anesthesia or admission
- Vaginal progesterone suppositories may be ordered to support the luteal phase and potential pregnancy
- Return to the office 14 days following IUI for pregnancy test
 - Test date will be provided

IUI Procedure Types:

- Natural Cycle:
 - Monitor the natural cycle and time an IUI or timed intercourse (TI)
- Medicated Cycle:
 - Oral Medication Clomid or Letrozole
 - With IUI or TI
 - Injectable Medication gonatropins
 - With IUI or TI

Possible Risks Associated with IUI

Ovarian Hyperstimulation Syndrome – OHSS

- Occurs when the body "over reacts" to the medication
 - Bloating, weight gain, urinary retention, distention
 - Contact the office for any of these symptoms
- OHSS is rare at CRM
 - Frequent and individualized monitoring

Cancellation related to response

- Aggressive response not candidate for IUI
 - Convert cycle to IVF in some cases risk of IUI too great for multiples
- Poor response
 - Cancel cycle and re-stimulate with more aggressive approach



Medication and Injection Planning

Medication Protocol

PRIOR AUTHORIZATION MAY BE REQUIRED

CONTACT INSURANCE BEFORE FILLING PRESCRIPTIONS

Failure to secure this information CAN impact your out-of-pocket expenses

- Confirm specialty pharmacy locations to fill prescriptions
 - May require one pharmacy for injectable needs and one for other prescriptions
- Clarify the in-network (insurance coverage) FSH (Gonal-f or Follistim) and antagonist (Cetrotide or Ganirelix)

NOTE: patients must confirm fertility coverage (treatment & medication) prior to starting treatment

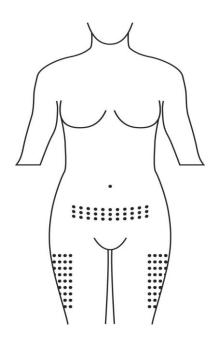
nursing cannot process the prior authorization



Injections Sites

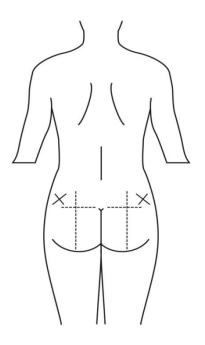
Subcutaneous Sites (sub-q):

- Location for medications used for stimulation
- Rotate sites as highlighted
- Sub-q sites for "daily" injections



Intramuscular Sites (IM):

- Used for hCG and progesterone injections
- Upper-outer quadrant of the butt
- Rotates sides each night





Sharps Disposal

Disposal Guidelines:

- Regulated biohazard sharps containers available at pharmacy
 - Puncture-proof containers only (as shown)
 - No needles can go in regular garbage
 - No alternative containers
- Sharps containers can be discarded at CRM
 - Never in regular garbage



Preparing for Daily Injections

Supplies:

- Alcohol wipes
- Gauze pads
- Antibacterial hand soap or hand sanitizer
- Sharps container
- Clean area for preparation and injection

Medications:

- Ensure medication inventory matches nursing instructions
- Review refill status on orders (additional medication and supplies are at pharmacy ie: no need for new prescription)
- Check that all needle supplies match needs
- Refrigerate medications as required



Medication Injection Training

Training will be presented at the class

- Both subcutaneous and intramuscular techniques
- Additional support is available on-line at Freedommedteach.com

Plan Ahead:

- Select a time for nightly injections between 7pm and 10 pm
 - As close to same time each day as possible
- If assistance with injections is needed anticipate needs
- Business and personal travel plans should be cancelled during stimulation
- Refrigeration requirements for medications



Psychological Support Services

The CRM clinical team recognizes and supports the impact that fertility treatment has on both your personal and professional life.

Specially trained psychologists are on staff and available for appointments – (646) 962-2764

Tuesday Morning "Women's Drop-In Group"

Free support group offered every Tuesday morning at 9am

Located in the main office

no appointment necessary





Reference Web Sites

- CRM site <u>www.ivf.org</u>
- Resolve Advocacy Organization <u>www.resolve.org</u>
- Injection references:
 - Freedom Pharmacy page <u>www.freedommedteach.com</u>
 - Ferring Pharmacy page <u>www.ferringusa.com</u>
 - Include training videos
 - Reconstitution and injection techniques





Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine

"We are passionate about helping our patients become parents"

Dr. Zev Rosenwaks

Director and Physician-in-Chief, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine



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