

Protocol Template: Basic Infertility Services

Introduction

[NAME OF SETTING] offers basic screening, diagnosis, and referral for infertility for females and males.

This protocol does not include guidance related to the comprehensive diagnosis and management of female or male infertility. Clients diagnosed with infertility who desire further evaluation and treatment should be referred to an Obstetrics/Gynecology or Urology practice for more detailed work-up or to a reproductive endocrinology and infertility subspecialist for advanced procedures, such as in vitro fertilization (IVF).

NOTE: This protocol includes laboratory testing which may be beyond the scope of your setting or that of Title X services. If your setting does provide infertility management, insert the level of management here. If not, list where clients should be referred, either internally or to providers in the community. The referral thresholds for your practice should be based on your expertise and resources, and should be explained to the client early in the infertility evaluation. Having an explicit relationship with one or more community practices to whom you will refer infertility clients may improve outcomes:

- More consistent work-up plans
- Availability of consultation during the work-up
- Mutually agreed upon referral thresholds
- Maintenance of continuity of care

What is Infertility?

Infertility is defined as the inability of a couple to become pregnant after 12 months or longer of regular, unprotected vaginal intercourse. This timeline is advanced to 6 months for:

- Females 35 years of age or older, infertility for >3 years, a major maternal medical condition, those with oligo- or amenorrhea, or with a history of endometriosis, or a known or suspected uterine or tubal disease/anomaly.
- Males with previously diagnosed conditions associated with subfertility or infertility, such as diabetes, testosterone use, varicocele, or cryptorchidism with or without surgery.

Screening for Infertility

Female History

- Pregnancy history
 - Gravidity, parity, time to pregnancy, fertility treatments, pregnancy outcome, delivery route, and any complications
- Duration of infertility and results of any previous evaluation/treatment
- Menstrual history
 - Age at menarche, cycle intervals/lengths/characteristics, presence of premenstrual symptoms, and onset and severity of dysmenorrhea
- Fertility awareness and signs of ovulation
 - Positive urine ovulation tests, cervical mucus changes or biphasic basal body temperatures
- Coital frequency and timing during the month
- Sexual dysfunction
 - Especially dyspareunia/pain with sex and description – insertional or with deep penetration
- Gynecologic history
 - Endometriosis, leiomyomas/uterine fibroids, pelvic inflammatory infections (PID), other sexually transmitted infections (STI)
- Current medications and supplements, with an emphasis on identifying allergies and potential teratogens
- Review of selected organ systems
 - Thyroid disease, galactorrhea, hirsutism, pelvic or abdominal pain
- Chronic medical conditions
 - Diabetes, heart disease, autoimmune conditions
- Past surgery (procedures, indications, and outcomes) with focus on abdominal and pelvic procedures
- Hospitalizations, serious illness, and injuries
- Previous abnormal cervical cancer screening tests and treatment
- Family history of birth defects, developmental delay, early menopause, or reproductive problems
- Occupation and exposure to environmental hazards
- Use of nicotine products, alcohol, recreational or illicit drugs, or misuse of prescription drugs
- History of depression and treatment
- Previous methods of contraception
- Sexual history (adapted from CDC, STI Treatment Guidelines, 2021)
 - Partners (“What are the genders of your partners? Does your partner have other partners?”)
 - Practices (“What kind of sexual contact do you have or have you had? Vaginal, oral, or anal?”)
 - Protection from STIs (condom use, immunizations, pre-exposure prophylaxis (PrEP))
 - History of STIs (if not addressed previously in history)

Screening for Infertility

Female Physical Exam

- Blood pressure, heart rate
- Weight and height measurements to compute body mass index (BMI)
- Skin and hair exam with a focus on androgen excess
 - Polycystic Ovarian Syndrome (PCOS): male pattern facial, chest, and pubic hair growth; alopecia; acne or oily skin; or acanthosis nigricans
 - Cushing's Syndrome: abdominal striae
- Thyroid exam for nodules, enlargement, or tenderness
- Breast exam for galactorrhea and nodules
 - Tanner staging of breasts, axillary, and pubic hair, as indicated
- Abdominal exam for masses, organ enlargement, or tenderness
- Pelvic examination
 - Vagina (discharge, muscle support)
 - Cervix (mucopus, visible lesions)
 - Uterine size, shape, mobility (fibroids, uterine anomalies)
 - Uterine corpus tenderness (PID, adenomyosis)
 - Adnexal masses or tenderness (PID, endometriosis)
 - Cul-de-sac masses; uterosacral ligament tenderness or nodularity (endometriosis)

Documentation of Ovulation

- Regular menstrual cycles with intervals of 24–35 days
- Consistent pattern of pre-menstrual molimina
- Positive ovulation prediction kit
- Mid-luteal phase progesterone >3 ng/mL
 - Time blood draw 7 days before expected menses
 - Evaluate result relative to onset of actual menses
- Pelvic ultrasound evidence of ovulation
- NOTE:** Basal body temperature is no longer considered the best or preferred method for evaluating ovulatory function

Female Assessment/Diagnosis

- Infertility/subfertility
- Tubal/peritoneal factors (tubal scarring from PID, pelvic adhesions, endometriosis)
- Ovulatory dysfunction (PCOS, hyperprolactinemia, hypothalamic amenorrhea, luteal phase insufficiency)
- Decreased ovarian reserve
- Anatomical causes (uterine anomalies)
- Cervical factor (hostile or scant mucus, infection)

Plan of Care for Female

NOTE: Not all settings will perform all lab tests. Most sites will not use Title X funds for testing.

LABORATORY TESTING, AS INDICATED

- Thyroid stimulating hormone (TSH) - if ovulatory dysfunction or signs of thyroid disease
- Serum progesterone (to confirm ovulation) - mid-luteal phase (e.g., cycle days 27-29 for someone with 35 day cycles)
- STI screening, including gonorrhea, chlamydia, syphilis, and HIV
- Ovarian reserve testing for clients who are over age 35 years; have a family history of early menopause; have a single ovary or history of previous ovarian surgery, chemotherapy, or pelvic radiation therapy; have unexplained infertility; or who are planning treatment with assisted reproductive technology (ART)
 - Follicle-stimulating hormone (FSH) and estradiol cycle day 2–4
 - Anti-mullerian hormone (AMH) any cycle day

REFERRAL

- For further evaluation if history, physical examination, or laboratory assessment findings are abnormal
- For further evaluation if laboratory and other diagnostic testing is not performed at this setting
- For infertility treatment

Screening for Infertility

Male History

- Prior fertility; especially having caused a pregnancy within the past 3 years
- Coital frequency and timing
- Any evidence of sexual dysfunction, including erectile or ejaculation issues
- Duration of infertility
- Childhood illnesses, anatomic diagnoses, and developmental history (such as mumps, chicken pox, cryptorchidism or varicocele with/without surgery, or signs of genetic disorders such as Klinefelter's syndrome)
- History of, or current systemic medical illness (diabetes mellitus, hypertension, etc.)
- Cigarette smoking, recreational or illicit drug use, misuse of prescription medications, and alcohol use
- Previous surgery
- Medication use, including anabolic steroids and supplements (e.g., testosterone), and allergies
- Sexual history (adapted from CDC, STI Treatment Guidelines, 2021)
 - Partners ("What are the genders of your partners? Does your partner have other partners?")
 - Practices ("What kind of sexual contact do you have, or have you had? Penile, oral, or anal?")
 - Protection from STIs ("Condom use, immunizations, PrEP")
 - History of STIs, especially gonorrhea or chlamydia
- Exposure to gonadal trauma or environmental toxins

Male Physical Exam

- Blood pressure, heart rate
- Height, weight, BMI
- Secondary sex characteristics (facial and chest hair)
- Genital Exam
 - Examination of the penis, including the location of the urethral meatus
 - Palpation of the scrotum and contents
 - Palpation of the testes and measurement of their size
 - Presence and consistency of both the vas deferens and epididymis
 - Presence of a varicocele

Plan of Care for Male

LABORATORY TESTING

- Semen analysis (quantitative microscopic evaluation of sperm parameters). Check with your lab for their collection rules
- STI testing, including gonorrhea, chlamydia, syphilis, and HIV

REFERRAL

- For further evaluation if history, physical examination, or laboratory assessment findings are abnormal

Counseling for Males and Females

Females should be educated about peak days and signs of fertility, including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other signs of ovulation.

Females with regular menstrual cycles should be advised that vaginal intercourse every 1–2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant.

Methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital applications, or cycle beads) should be discussed.

Encourage healthy weight and BMI (>19 kg/m² and <30 kg/m²).

Limit caffeine intake (<3 cups per day).

Smoking, consuming alcohol, using recreational drugs, and using most commercially available vaginal lubricants should be discouraged as these might reduce fertility.

Pre-pregnancy advice, including folic acid supplementation for females, review of medications (to identify and discontinue potentially teratogenic drugs), and immunization history (to take advantage of pre-pregnancy immunization for rubella, hepatitis B, human papillomavirus (HPV), COVID-19, as well as seasonal influenza vaccination). For diabetic females, address the importance of achieving glucose levels as close to normal as is safely possible, ideally A1C <6.5%, to reduce the risk of congenital anomalies, preeclampsia, macrosomia, preterm birth, and other complications.

This tool was adapted from ACOG Committee Opinion Number 781 'Infertility Workup for the Women's Health Specialist' (June, 2019); American Diabetes Association 'Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes—2022' (December 2021); Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Reproductive Endocrinology and Infertility 'Optimizing natural fertility: a committee opinion' (January, 2022); and Centers for Disease Control and Prevention, 'Providing Quality Family Planning Services. Recommendations of CDC and the U.S. Office of Population Affairs'. MMWR (April 25, 2014); 'Sexually Transmitted Infections Treatment Guidelines', 2021 MMWR / July 23, 2021 / Vol. 70 / No. 4.

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