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NC Department of Health and Human Services
Providing Basic Infertility Services in Title X Clinics
December 7, 2022

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Objectives

By the end of this presentation participants will be able to:

- Define infertility and its common causes
- Optimize preconception health for individuals seeking fertility care
- Identify pertinent medical history questions and labs to assist in diagnosing infertility
- Identify lifestyle changes that will maximize fertility
- Define Polycystic Ovary Syndrome (PCOS), understand it's causes and lifestyle factors

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Why are we talking about this?

Provision of High-Quality Family Planning Services

Title X recipients must:

- 1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, **basic infertility services**, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services)...(Section 1001, PHS Act; 42 CFR § 59.5(a)(1))

Basic infertility services include services for both partners of an infertile couple. These services include understanding the client's reproductive life plan and the client's and partner's difficulty in achieving pregnancy through a medical history, sexual health assessment and physical exam, in accordance with recommendations developed by professional medical associations. Basic infertility services also include infertility counseling. (QFP, pp.15-16, https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf)

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Why are we talking about this?

Part of basic infertility counseling includes preconception health services. These family planning services are important because they improve women's and men's health and can influence a person's ability to conceive or to have a healthy birth outcome.

Preconception health services include counseling on folic acid; reproductive life planning; sexual health assessment; medical history intake; screening for intimate partner violence; alcohol and other drug use, and tobacco use; immunizations; depression; height, weight, and body mass index; blood pressure. (QFP, pp.16-17, https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf)

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What we will not do today

We will not ask you to offer anything more than basic screening, diagnosis, and referral for infertility for individuals.

Clients diagnosed with infertility who desire further evaluation and treatment should be referred to a specialist for more detailed work-up or for advanced procedures, such as in vitro fertilization (IVF).

It is important to know what the agency parameters are for referrals to other providers. The referral thresholds should be based on your agency 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.

National Clinical Training Center for Family Planning (NCTCFPP) Protocol Template: Basic Infertility Services, July 18, 2022; <https://www.ctfdp.org/protocol-template-basic-infertility-services/>

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Definitions

- **Fertility** refers to the capacity to conceive
- **Fecundity** refers to capacity to produce a live child
- **Gravidity** is defined as the number of times that a woman has been pregnant
- **Parity** is defined as the number of times that a woman had given birth to a fetus with a gestational age of 24 weeks or more
- **QFP-Providing Quality Family Planning Services Recommendations** of CDC and the U.S. Office of Population Affairs (OPA)
- **Preconception health services:** services directed at improving the health of people during their reproductive years with a focus on parts of the health that have been shown to increase the chance of having a healthy baby

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Gender Affirming Care in Infertility

- For the purposes of this talk, we will use the term "male" to refer to individuals who have male reproductive organs/assigned male at birth and "female" to refer to individuals who have female reproductive organs/assigned female at birth
 - Some topics in presentation only relate to partners with opposite gender anatomy
 - Other topics relate to anyone who may become a parent
- Individuals of diverse gender identities and diverse stages of transitioning medically and/or surgically may be interested in carrying or conceiving a pregnancy and people of all gender identities should receive equitable support to do so:
 - 25-50% of transgendered individuals desire to or have already become parents
- For individual patient counseling, the individual's preferences for pronouns and for words to use for body organs and functions should be elicited and used during patient-centered counseling
- Fertility preservation may be an important topic for gender diverse individuals

Cheng et al. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6626312/>

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What is Infertility?

- Not being able to conceive after 1 year of unprotected intercourse
- Subfertility: prolonged time of unwanted non-conception
 - 6 cycles of trying to conceive with no conception
 - Early evaluation if >35 years, oligo-amenorrhea, suspected uterine or tubal disease or endometriosis, or partner subfertility
- Sterility: inability to conceive
- Impaired fecundity: difficulty getting pregnant or carrying to term in 1 year
 - Infertility PLUS Miscarriage/Recurrent Miscarriage

CDC. Infertility FAQ and American Society for Reproductive Medicine (ASRM). Optimizing Natural Fertility 2022

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How Common is Infertility?

- Infertility can be measured at the level of the couple (most common) or the individual
 - Female Infertility: 1 in 5 heterosexual women 15-49 years
 - 50% with one year and no conception will conceive at some point in the following year
 - 40-50% is related completely or in part with infertility of the male partner
 - 1 in 4 couples have impaired fecundity
 - Male Infertility: unclear prevalence (possibly 1 in 10)
 - No difference by race, ethnicity, education, income, citizenship, insurance, location of care

CDC FastStats from NSVG 2015-2019 data: <https://www.cdc.gov/nchs/fastats/infertility.htm>
Agarwal 2015 and Kelly 2019

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Infertility Care Gaps

- Only 38% of women with current infertility have ever used infertility services
- Less than 50% of women with infertility have spoken to any doctor about this
- 81% of women have had no treatment for infertility

https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_us-pdfmembers.pdf

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Infertility Care Disparities

In the United States, as in many other countries, economic, racial, ethnic, geographic, and other disparities affect both access to fertility treatments and treatment outcomes.

- Income
- Education
- Geographic
 - IVF providers are not evenly dispersed
- Cultural
 - Stigma
- Citizenship
- Racism

https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/disparities_in_access_to_effective_treatment_for_infertility_in_the_us.pdf#members.pdf

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Reproductive Justice

What is reproductive justice? The right to have a child, the right to not have a child and the right to raise your children. Everyone should have that. It's not that hard to explain—it's just hard as hell to achieve.

Loretta Ross

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How to Ask About Infertility?

- Would you like to be pregnant now or in the next year?
(One Key Question)
- How long have you been trying to conceive?
 - Trying means different things to different people
- How long have you been having unprotected intercourse with your opposite sex partner?
- Have you had other times in your life where you had unprotected intercourse with an opposite sex partner and you/they did not conceive?
 - If yes, for how long? How many months/cycles?
- Has your male/female partner previously conceived with another partner?
 - Insemination?

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What Causes Female Infertility?

- Ovulatory dysfunction (40%): PCOS, Thyroid dysfunction, Prolactin dysfunction, Obesity
- Ovarian failure: premature ovarian failure, chemotherapy
- Cervical factors: stenosis, cervicitis
- Uterine factors (16.2%): polyps, fibroids, adhesions
- Tubal factors: Chlamydia, Endometriosis, Past Surgery
- Peritoneal factors: endometriosis, pelvic adhesions

American Society for Reproductive Medicine (ASRM) 2021

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What causes male infertility?

- Note: Both male and female partners should have a concurrent assessment of infertility causes if they have been trying unsuccessfully to conceive.
- Causes
 - **Abnormal sperm production or function:** STIs, Diabetes, Varicocele, marijuana, steroid use, heat exposure, environmental chemicals, obesity, hormonal disorders, testosterone use
 - **Inability to deliver sperm to the female genital tract:** premature ejaculation, cystic fibrosis, traumatic injury
 - **Testicular failure:** chemotherapy, radiation, surgical

Dr. Peter N. Schlegel Professor of Urology & Reproductive Medicine at Weill Cornell Medicine, New York, New York. 2021 Updated male infertility guidelines

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What To Do Once you Identify Infertility/Subfertility/Subfecundity?

- Offer patient-centered, supportive counseling
- Optimize general health and well being (Preconception Health)
- Evaluate for underlying causes of infertility
- Provide education and advice about timing intercourse
- Refer patients as appropriate

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Case Study

A 30-year-old Title X patient G2P0020 has been trying to conceive with her 35-year-old partner for over a year.

- Two pregnancy terminations >8 years ago
- Mirena IUD removed 18 months ago
- BMI 32
- Hypertension on lisinopril
- Partner BMI 35 and family history of diabetes
- Cousin with Down's Syndrome
- Both treated for uncomplicated chlamydia 10 years ago

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Supportive Counseling

- Patient-centered
- Non-judgmental
- Open-ended questions
- Honest discussion of individualized pregnancy risk
 - Consider Maternal Fetal Medicine referral for preconception

What are some judgments that could be made in patient case?

Gravin L, Pazol K. Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015. <http://dx.doi.org/10.15585/mmwr.mm6509a3externalicon>.

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Quotes from NC Women of Color Seeking Preconception Healthcare

- *Race. A lot of times that does come into play...I have hypertension and the first question is what is your diet like. I know you like to eat these types of foods. That can be a big part of how I react to a doctor.*
- *I'm worried there's a conspiracy against women of color to even have babies. It doesn't even seem like people want us to have babies with the way we are treated.*
- *My partner was told he couldn't get a test for sickle trait because he wasn't Black (Native woman with sickle disease).*

Verbiest et al. Health Services Research 2022

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Preconception Health Opportunity

• **Individuals of all genders who present to discuss pregnancy planning should have preconception counseling and education**

- Folic Acid supplementation: 400mcg daily
- Access to Primary Care/Management of Chronic Conditions
 - A1c
 - Teratogenic Medications
- Family History Review
 - Carrier Screening
- Immunizations
- Exposure to environmental toxins
- Sexually transmitted infections (STI)
- Substance use screening
- Mental Health Screening
- Intimate Partner Violence Screening
- Nutrition and Physical Activity

Frayne AJOG 2016 and RHNTC Preconception Checklist

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Goals of Optimizing Preconception Health

- **Lifelong wellness for all**
- Improved potential fertility/fecundity
 - Infertility can be a sign of underlying chronic illness
- Improved health of potential pregnancies

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Optimizing Preconception Health

- Optimizing Preconception Health
- Role of healthy lifestyle in fertility



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Healthy Weight

- Research about healthy weight and fertility
 - Overweight
 - Underweight
 - Partner
- Weight is only ONE measure of health

<https://www.womenshealth.gov/healthy-weight/weight-fertility-and-pregnancy#references>

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Diet Quality & Fertility

- Nurse Healthy Study II
 - "Fertility diet" included whole grains, unsaturated fats, vegetables, fruits, fish, full-fat dairy, plant-based proteins, iron and high folate
 - 66% lower risk of infertility related to ovulatory disorders
 - 27% lower risk due to other causes
 - Not following the "fertility diet" was the attributable factor in 46% of cases of infertility, which was higher than all other independent risk factors (e.g., BMI, physical activity)
 - Improves measures of semen quality, including morphology, motility, and concentration

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6079277/pdf/pubh-06-00211.pdf>

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Favorable Dietary Patterns for Life

- Mediterranean Diet
 - Physical activity
 - Healthy fats
 - Plant-based protein
 - Full-fat dairy foods
 - Whole grains
 - Fruits & vegetables
 - Limited saturated fat, red meat and refined grains

THE HEALTHY EATING PYRAMID
Department of Nutrition, Harvard School of Public Health

1. OILS, NUTS, SEEDS, AND SOY PRODUCTS

2. FISH, SEAFOOD, AND LEAN MEATS

3. EGGS, DAIRY, AND TOFU

4. GRAINS, BEANS, AND LENTILS

5. VEGETABLES, FRUITS, AND NUTS

6. LIMITED SATURATED FAT, RED MEAT, AND REFINED GRAINS

7. LIMITED ALCOHOL


Copyright © 2008. For more information about The Healthy Eating Pyramid, please see The Nutrition Source, Department of Nutrition, Harvard T.H. Chan School of Public Health, www.thenutritionsource.org, and Eat, Drink, and Be Healthy, by Walter C. Willett, M.D., and Patrick J. Skerrett (2005). Free Press/Simon & Schuster Inc.
<https://www.hsph.harvard.edu/nutritionsource/what-should-you-eat/>

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Nutrition-done simply

- My plate
- More vegetables
- Water!
- Eat consistently
- Have a plan!

 **What's one thing you'd like to focus on this week?**

<https://www.myplate.gov/myplate-plan>

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Women of Reproductive Age


- Micronutrients of concern
 - Folic Acid
 - Iron
 - Iodine
- Macronutrients
 - Polyunsaturated
 - Omega-3-fatty acids

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Lifestyle Behaviors

- Body Movement
- Sleep
- Stress
- Eating Patterns
 - Intuitive Eating and mindfulness



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Tips for Sustainable Change

- Start small
- SMART goals
- Motivation + Accountability
- Don't fall for quick fixes
- Motivational Interviewing

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What is the Workup for Female Infertility

History and Physical

- STI Screening, including gonorrhea, chlamydia, syphilis and HIV
- Confirmation of ovulation if long/irregular cycles or hirsutism
 - Fertility Awareness-Based Method
 - Progesterone: Day 21 or expected menses minus 7
- Laboratory Testing
 - Thyroid stimulating hormone, anti-mullerian hormone
 - Glucose, lipids
 - Other Labs: prolactin, follicle stimulating hormone, estradiol, testosterone, dehydroepiandrosterone sulfate, 17 hydroxyprogesterone, Vitamin D3
- Pelvic Ultrasound
- Hysterosalpingogram

American Society for Reproductive Medicine (ASRM) 2021
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What is the Best Evaluation for Male Factor?

- History and Physical exam
 - Medications, substances, toxin exposure, sexual function
 - Blood pressure, BMI, Genital exam
- Semen analysis
 - Must be fertility specific (<https://www.reprosource.com/>)
- Laboratory testing
 - If impaired libido, erectile dysfunction, oligozoospermia or azoospermia, atrophic testes, or evidence of hormonal abnormality on physical evaluation: Testosterone, FSH, LH, TSH, Prolactin, Vitamin D3
- Preconception screening: Diabetes screen/Lipids
- STI testing

Shiegel et al. 2020. https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines-for-non-members/diagnosis_and_treatment_of_infertility_in_men-usa-asrm_guideline_part_1.pdf
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What is the Fertile Window?

- Biological
 - The period of time during which an act of penile-vaginal intercourse could lead to a pregnancy
 - 12-24 hours after ovulation PLUS
 - 5 days of sperm survival in the female genital tract prior to ovulation
- Patient-Defined
 - The period of time during which a fertility awareness-based method suggests a high probability of conception from an act of penile-vaginal intercourse

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What are Fertility Awareness Based Methods (FABMs)?

- Methods that allow people to track one or more biomarkers to determine the days during each menstrual cycle when the chances of conception would be highest and lowest (fertile window).
- FABMs can be used to:
 - Avoid pregnancy
 - Plan pregnancy
 - Monitor health

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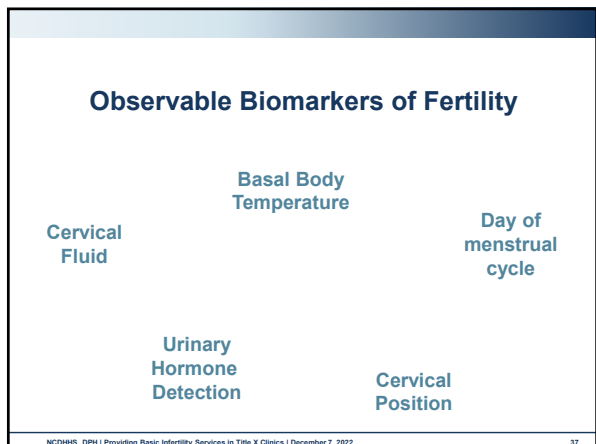
35

Review of Menstrual Cycle Hormones

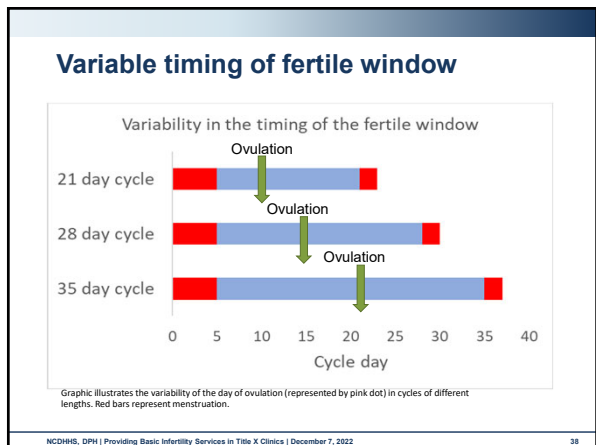
Merck Manual, The Menstrual Cycle
<https://www.merckmanuals.com/home/women-s-health-issues/biology-of-the-female-reproductive-system/menstrual-cycle>

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Categories and selected examples of FABMs

| FABM category | Examples of FABM methods |
|--|---|
| Calendar-based (menstrual cycle) | Rhythm Method |
| | Standard Days Method/CycleBeads |
| | Clue Birth Control |
| Cervical mucus-based | Billings Ovulation Method |
| | TwoDay Method |
| Temperature-based | Natural Cycles (temperature plus cycle day) |
| Symptothermal (multiple indicator methods) | Sensiplan, Taking Charge of Your Fertility |
| | Symptothermal Marquette |
| Urinary hormone-based | Persona |

Note: Table is not comprehensive of all FABMs, and inclusion does not indicate endorsement; table intended to orient providers to selected examples of FABMs patients may inquire about.

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Recommendations for Timed Intercourse with FABMs

- Intercourse at least every other day in the fertile window or during entire cycle if fertile window is not known
- FABMs can be used to guide timing of intercourse
 - Use of an app along with FABM indicators may be helpful

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Other Recommendations for Optimizing Natural Fertility

- Tobacco, alcohol and other substance treatment/cessation as applicable
- Promote healthy mood and anxiety: (<https://resolve.org/get-help/find-a-support-group/>)
- Promote healthy diet and lifestyle: Weight loss; Optimal exercise; Diet high in healthy fats, low in complex carbohydrates, high in vegetable sources of protein, no trans-fats, multivitamins daily, Daily Folic Acid
- Limit exposure to endocrine disrupting chemicals in food, air, water and personal care: www.skindeep.com; water filters; pesticide free foods (dirty dozen)
- Treat insulin resistance
- Treat anxiety (cognitive behavioral therapy; RESOLVE support groups)

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Polycystic Ovarian Syndrome (PCOS)

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PCOS Risk Factors

- Genetic
 - 20-40% prevalence if mother or sister has PCOS
 - DENND1A variant
- Epigenetic
 - Maternal Diabetes
 - Testosterone exposure in utero
- Environmental
 - Endocrine disrupting agents
- Insulin resistance/Diabetes
- Obesity
- Medications
 - Antiepileptics, Atypical Antipsychotic agents

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Diagnosis of PCOS: Rotterdam Criteria

- Two of three criteria:
 - Irregular periods/anovulation
 - Hyperandrogenism
 - Clinical (hirsutism)
 - Biochemical
 - Polycystic appearing ovaries on ultrasound

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Treatment Goals

- Optimal ovulation
- Improved pregnancy health
- Improved long-term health

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Lifestyle Factors in PCOS

- First line of treatment for the management of women with PCOS but is not an alternative to its pharmacological treatment
- Weight management (when applicable)
- Diet focused on improving insulin resistance
- Exercise

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8308732/>

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Nutrition & PCOS

- Mediterranean diet
- No significant difference in diets modifying overall macronutrient levels
- Calorie Reduction + Low Glycemic Index
 - Decreased fasting insulin, LDL, TG, waist circumference and total testosterone
 - Reduced ghrelin and increased glucagon in women with PCOS
- Good resource for clients: https://www.fammed.wisc.edu/files/webfm-uploads/documents/outreach/im/handout_ai_diet_patient.pdf

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8308732/>

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Exercise & PCOS

- Vigorous intensity exercise may have the greatest impact on cardiorespiratory fitness, insulin resistance, and body composition
- 120+min/week
- Aerobic exercise resulted in improvements in menstrual cyclicity and/or ovulation in around 50% of women with PCOS
- Benefits beyond weight loss

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7358428/>


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Sleep & PCOS

- Sleep deprivation is associated with increased risk of insulin resistance (IR), obesity, and type 2 diabetes
- Connections with sleep + Mental health disorders
- Treating sleep-related conditions should be an integral part of treating women with PCOS
- Screen for sleep apnea



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8308732/>

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Weight Loss & PCOS

- PCOS patients have more challenges to losing weight than those without given usually higher leptin and insulin levels
 - Extra challenging in PCOS, ? Higher leptin levels
- Modest calorie reduction (500-1000kcal/day) and
- 5-10% weight reduction
- Only for those who are overweight or obese
- Recommend working with Dietitian and medical team for safe and sustainable weight loss

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8308732/>

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Supplements

- Multivitamin
- Vitamin D and Vitamin A
 - Cod Liver Oil: high in vitamin A and D and omega-3s
- Myoinositol 2000-4000mg daily: some evidence on effectiveness in reducing insulin and androgens and improving ovulation
- Vitex or Chasteberry: an herb with some evidence to improve ovulation among patients with PCOS

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Treatment of Comorbidities in PCOS

- Metformin (B12 and folic acid supplementation)
 - First line treatment for PCOS
 - 75% of patients with PCOS have insulin resistance
- Thyroid Dysfunction
 - Low threshold to treat TSH >2.5 in the setting of ovulatory dysfunction
- Prolactin Dysfunction
- Sleep Apnea
- Obesity

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Conclusions

- Infertility is common
- Male, female, and gender diverse partners deserve a basic workup
- FABMs may help individuals target intercourse and identify problems
- PCOS is a very common cause of infertility and is modifiable
- Improving lifestyle is helpful for male and female partners
 - Avoiding infections
 - Avoiding substances, environmental toxins
 - Regular exercise
 - Healthy diet
 - Healthy coping with stress
 - Healthy weight

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Tools/Resources

- Preconception Checklist: https://rhntc.org/sites/default/files/resources/fpntc_precn_cpntn_counsel_chklist_2019-06.pdf
- Mediterranean Diet: https://www.fammed.wisc.edu/files/webfm-uploads/documents/outreach/im/handout_ai_diet_patient.pdf
- Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm>
- Title X Program Expectations <https://opa.hhs.gov/grant-programs/title-x-service-grants/key-resources-title-x-grantees>
- National Clinical Training Center for Family Planning (NCTCFP) Protocol Template: Basic Infertility Services: <https://www.ctcfc.org/protocol-template-basic-infertility-services/>

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