


LADIES & GENTLEMEN... iCARE Pharmacy Services, Incorporated

AN UPDATE ON WOMEN AND MEN'S HEALTH

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Speaker Disclosure
I do not have (nor does any immediate family member have):

- a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
- any affiliation with an organization whose philosophy could potentially bias my presentation

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PHARMACIST LEARNING OBJECTIVES

1. Compare varieties of the top hormonal and non-hormonal contraception available currently
2. Discuss the use of long-term oral contraception, as well as devices, and the expectations of family planning
3. Identify clinical strategies to appropriately prescribe hormonal and non-hormonal contraception
4. Discuss updates in male contraception
5. Identify the ongoing role of the pharmacist in regards to the safe and effective health counseling for both male and female family planning

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PHARMACY TECHNICIAN LEARNING OBJECTIVES

1. Identify the top hormonal and non-hormonal contraception available currently
2. Compare the differences between oral contraception and devices
3. Examine combinations of hormonal and non-hormonal contraception
4. Recognize male contraceptive treatments
5. Identify the role of a pharmacy technician in both female and male contraception in practice

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CONTRACEPTION
THE INS AND OUTS

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WHAT ARE THE FACTS?

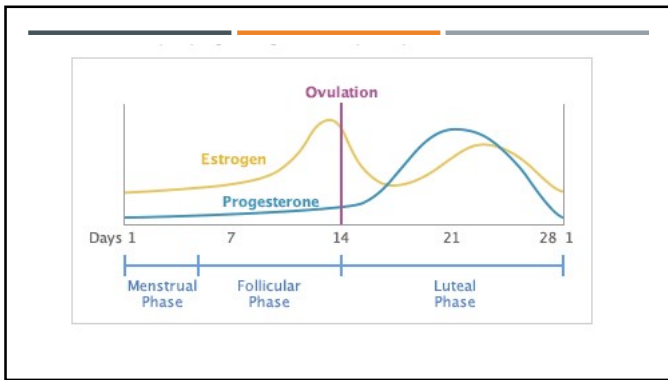
- Women of childbearing age (usually 16 to 45 years old) have a contraception window of ~30 years
- 72% of women in this women are at risk for **unplanned pregnancy**
 - Unplanned pregnancy constitutes conceiving at an unwanted time or not planned at all
- Per the CDC, 92% of women that recorded as having unplanned pregnancies stated they were from inconsistent use of contraception or complete lack of use

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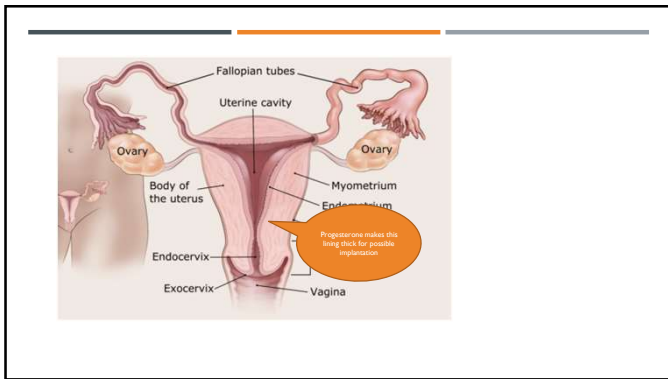
MAIN PLAYERS

- Gonadotropins: Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH)
- Estrogen
- Progesterone
- Testosterone

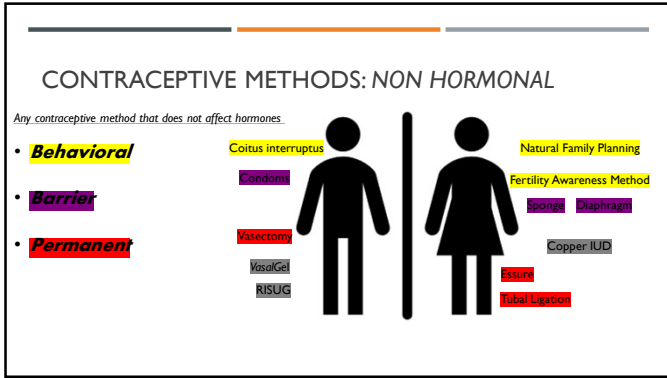
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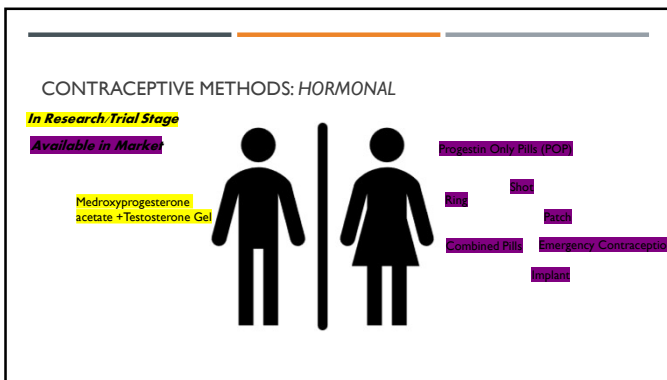
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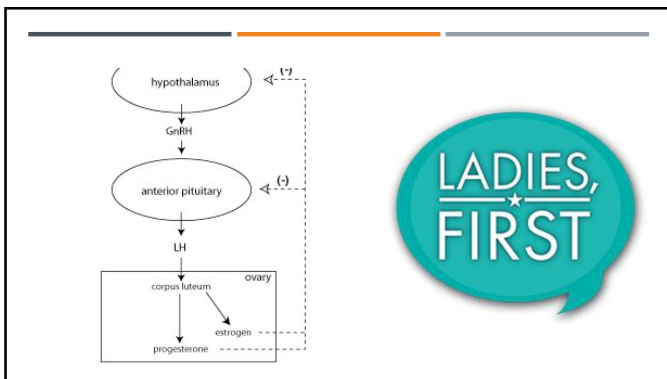
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ALWAYS CONSIDER...

Efficacy

Hormonal Content

Dosage Form

Frequency

Duration of Action









Side Effects

Reversibility

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EFFICACY

Efficacy in regards to contraception is usually referred to as the proportion of women out of 100 that will become pregnant over 12 months with the use of the method in question

Method	Pregnancies*	Method	Pregnancies*
 Sterilization surgery	Less than 1	 Birth control pills	9
 Intrauterine Device (IUD)	Less than 1	 Patch	9
 Implant	Less than 1	 Vaginal ring	9
 Shot	6	 Condom	18

*During the first year of typical use. This reflects the improper or inconsistent usage of these methods. Source: FDA. INSIDER


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FEMALE CONTRACEPTION

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FEMALE HORMONAL CONTRACEPTION



Progestin Only	Combined
<ul style="list-style-type: none">• Implant• Oral Pill• Shot• Intrauterine Device	<ul style="list-style-type: none">• Vaginal Ring• Oral Pill• Intrauterine Device• Transdermal Patch

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FEMALE HORMONAL CONTRACEPTION



Progestin Only	Combined
<ul style="list-style-type: none">• Implant• Oral Pill• Shot• Intrauterine Device	<ul style="list-style-type: none">• Thickens the mucus of the cervix causing sperm to have difficulty finding an egg• Slows down or stops egg release (i.e. ovulation)

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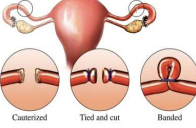
FEMALE HORMONAL CONTRACEPTION



Progestin Only	Combined with Estrogen
<ul style="list-style-type: none">• Estrogen in combination acts to suppress FSH production• Increases the binding of free moving androgens	<ul style="list-style-type: none">• Vaginal Ring• Oral Pill• Intrauterine Device• Transdermal Patch


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PERMANENT FEMALE CONTRACEPTION



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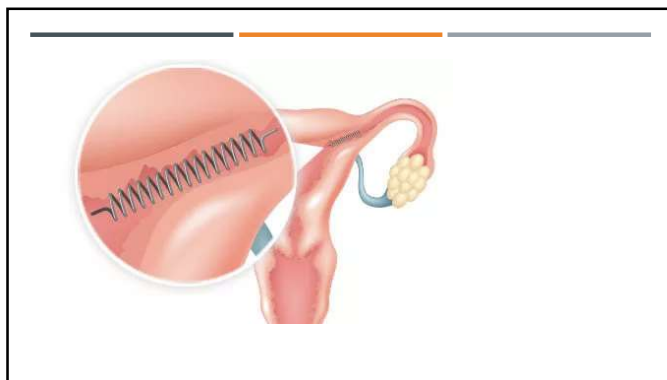
- Banding, burning, cutting, or cauterizing the fallopian tubes
- Usually **not** reversible
- However, reversibility can be expensive and depends on
 - Method of original surgery
 - Age
 - Overall health and anatomy



Essure®


- Tiny coil inserted into fallopian tubes
- Forms scar tissue over several months creating a barrier that prevents sperm from reaching an egg
- Phasing out due to chronic pain, perforations, severe medication reactions
- Reversal involves a laparoscopic salpingotomy, involving small cuts in fallopian tubes to remove Essure OR a complete hysterectomy
- Many patients report pieces of coil left in tubes after surgery


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Reversible Female Contraception: Long Acting







Birth Control Implant
 -Size of a matchstick containing etonogestrel (Nopplanon®)
 -Prevents pregnancy up to 5 years
 >99% effective
 -Safe for breastfeeding
 -Must be implanted by trained medical professional/suldesone in arm
 -Common S/E include extreme bleeding and spotting
 -Fertility MAY be delayed

Hormonal Shot
 -Progestin only (Depo Provera®)
 -IM or SC injection every 3 months, not recommended for use for several years
 ->99% effective
 -If dose is late (after 3 months) use backup contraception for a week
 -Fertility MAY be delayed
 -Common s/e include weight gain, spotting, mood change, lower bone density and heavy bleeding

Intrauterine Device
 -Progestin only
 -T-shaped inserted into the uterus
 -Can be readministered every few years depending on product
 -Common s/e include uterine perforation, infections, cramping, and less frequent periods
 -IMMEDIATE return of fertility is expected
 -It is important to assess for any STI that the patient has. IUD's should not be inserted if patient has any STIs

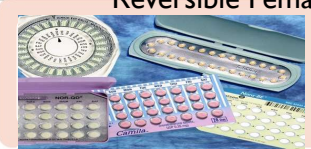
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COMPARISON OF LONG ACTING IUD OPTIONS

Type	FDA-approved duration	Total progestin	Initial release progestin/day	Final release progestin/day	Insertion device diameter	Amenorrhea rate by 1 year	Other Notes
Skylla	3 years	13.5mg	14mcg	5mcg	3.8mm	6-12%	
Kyleena	5 years	19.5mg	17.5mcg	7.4mcg	3.8mm	12-20%	
Mirena	5 years	52mg	20mcg	10mcg	4.4mm	20-40%	Doctors like the insertion device better
Liletta	6 years	52mg	20mcg	8.6mcg	4.4mm	20-40%	Sometimes more affordable


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Reversible Female Contraception



Progestin ONLY Pill (POP)

- Commonly known as the mini pill
- Contains no estrogen
- Not as efficacious as combined pill historically
- Commonly used with women breastfeeding
- MUST be taken at the same time daily to maintain progesterone level (within 3 hours)
- Start tablets the first day of menstrual cycle
- Common s/e include headache and heavy bleeding



Combined Pill

- Contains both hormones
- Estrogen used is ethinyl estradiol (EE), progestin, and 7 placebo tablets for adherence
- 92% effective
- Advised to take pill at the same time every day
- Improvement in acne is common s/e
- Other s/e include spotting, nausea, difference in mood
- Classification is based on EE content (very low, low, and high) and can be monophasic or multiphasic

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HORMONAL BIRTH CONTROL TABLET TIPS

- The goal is to **mimic a woman's natural hormones**
- There is no consistent way to predict efficacious response to mimicking a woman's natural hormones
 - Most women may try several different forms of tablets before finding one that works well for them
- It is **essential** to advise patients to not smoke tobacco
- EE is usually classified in ranges
 - 20-25mcg is very low
 - 30-35mcg is low
 - 50mcg is high

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- It is the duty of all medical professionals to consider a patient's comfort due to the sensitivity of these medications
- Contraceptive counseling is encouraged to assure all women, especially minorities, that eugenics are not tolerated
- Until 1970, 32 states allowed "forced sterilization"
- As a provider it is important to avoid implicit bias
- Historically minority women have not always been informed of all contraceptive options

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Table 2: Hormone Function and Relative Balance Side Effects in Contraceptives^{4,5}

	Function	Deficiency	Excess
Estrogenic effects	<ul style="list-style-type: none"> • Suppression of FSH and LH = partial inhibition of ovulation depending on dose • Alter secretory and cellular structures of the endometrium 	<ul style="list-style-type: none"> • Irritability, nervousness • Early and/or mid-cycle breakthrough bleeding • Increased spotting • Hot flashes • Hypomenorrhea • Amenorrhea • Painful intercourse 	<ul style="list-style-type: none"> • Nausea, bloating • Cervical mucorrhea • Hypermenorrhea • Hyperpigmentation • Uterine or leg cramps • Hypertension • Migraine headaches • Breast tenderness • Dizziness, vertigo • Cyclic weight gain • Fibroid growth
Progestational effects	<ul style="list-style-type: none"> • Suppression of LH = inhibition of ovulation • Thickening of cervical mucus • Decreased glandular development of endometrium = hampered implantation • Possible decrease in the sperm's capacity to 	<ul style="list-style-type: none"> • Amenorrhea • Late breakthrough bleeding • Hypermenorrhea • Weight loss 	<ul style="list-style-type: none"> • Increased appetite • Persistent weight gain • Tiredness, fatigue • Hypomenorrhea • Acne, oily scalp • Hair loss • Depression • Hirsutism • Breast regression • Changes in libido

FIND THE BALANCE




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COMPARISON OF HORMONAL SIDE EFFECTS

	Too Much	Not Enough
Estrogen	<ul style="list-style-type: none"> Bloating Breast Tenderness Mood Changes H/A and Nausea Heavy Menses Fibroid Cyclic Weight Gain 	<ul style="list-style-type: none"> Breakthrough bleeding early in cycle Light menses Spotting Vaginal dryness No withdrawal bleeding
Progestin	<ul style="list-style-type: none"> Acne Hirsutism Sex drive changes Depression Increased Appetite Non cyclical weight gain Low energy Yeast infection Hair Loss Arm and leg swelling 	<ul style="list-style-type: none"> Breakthrough bleeding late in cycle No withdrawal bleeding Heavy menses

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Reversible Female Contraception

 <p>Copper IUD</p> <ul style="list-style-type: none"> -ParaGard® Implant -Available with prescription -Can be left in place for ten years and considered long acting and non hormonal -Prevents fertilization using a cytotoxic inflammatory reaction that kills sperm and inhibits sperm motility ->99% effective -Can also be used for EC -Immediate return of fertility upon removal 	 <p>Vaginal Ring</p> <ul style="list-style-type: none"> -Etonogestrel/Ethinyl estradiol (NuvaRing®) -91% effective -Small, bendable plastic ring that is self inserted until no longer felt -Left in vagina for three weeks and taken out on fourth week -Gestosterone acetate/Ethinyl estradiol (Ammonarel) -97% effective -Reusable ring for a year to be rinsed with soap and water -A period is expected when ring free -See above 	 <p>Patch</p> <ul style="list-style-type: none"> -Transdermal patch, most common is Xulane® -Contains both hormones -Efficacy decreases if patient is over 200lbs -Commonly described as thin sticky plastic square -Replaced each week -Can be placed on arm, abdomen, buttock, or back -Blood clots may be seen due to higher amount of estrogen
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TEST YOUR KNOWLEDGE

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ASSESSMENT QUESTION ONE

I. Which of the following long acting reversible contraception options are non hormonal? Choose the best answer:

- A. Nexplanon®
- B. ParaGard®
- C. Mirena®
- D. Skyla®

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ASSESSMENT QUESTION ONE

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ASSESSMENT QUESTION TWO

2. Deanna is a 27 year old female who has recently had a baby. She does not plan on having any more children for three years. Her OB has recently informed her that she has tested positive for chlamydia and gonorrhoea. What is a safe contraceptive method for Deanna?

- A. ParaGard®
- B. Xulane® Patch
- C. The Mini Pill
- D. Mirena®

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- C. The Mini Pill
- D. Mirena®

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EMERGENCY CONTRACEPTION

Levonorgestrel

- PlanB®
- OTC either one or two step tablet
- 100% progestin tablet
- Commonly known as the "morning after" pill
- Most effective within the first three days after unprotected sexual encounter
- May not work as well with patients >200lbs

Copper IUD (ParaGard®)

- ParaGard® Implant
- Available with prescription
- Efficacy is best within five days of unprotected sexual encounter
- Can be left in place for ten years
- Prevents fertilization using a cytotoxic inflammatory reaction that kills sperm and inhibits sperm motility
- >99% effective

Ulipristal Acetate

- Ella® tablet that is available with prescription
- Progesterone agonist/antagonist that inhibits ovulation
- Women must wait five days before restarting hormonal birth control pills and also advised to use backup contraception

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A PHARMACIST'S DUTY

- Emergency contraception is not always 100% efficacious
- All EC are marketed to work within 5 days of unprotected sexual encounters
- It is essential to explain common side effects to patients requesting EC
 - Nausea, breast pain, stomach pain, and spotting are common
 - Bleeding is not necessarily caused by EC however it is essential to counsel women on taking a pregnancy test if next menstrual cycle is late by a week or more

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REMINDE YOUR PATIENTS:



CONDOMS ARE THE ONLY FORM OF CONTRACEPTION THAT PROTECT AGAINST SEXUALLY TRANSMITTED INFECTIONS

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THE CLINICAL APPROACH

- Many states have now allowed pharmacists to prescribe hormonal contraception for women under certain protocols
 - Usually do NOT include IUD's or implants
 - May include the patch, pills, rings, shot, or emergency contraception
- Always consider:
 - Age
 - Blood Pressure
 - Sexual Activity
 - Menstrual Cycle Schedule
 - Previous Births and Terminations

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THE CLINICAL APPROACH

- Long acting options should be discussed with all female patients
- Pharmacists **MUST** be equipped to explain all bridging treatments to patients
 - Bridging is assessing if **and when** a barrier contraception method is needed when beginning hormonal birth control
 - General rule: If treatment is started the **FIRST** day of a menstrual cycle, generally a barrier method isn't needed for 7 days
 - If treatment is started **after** menstrual cycle, encourage barrier method for at least 7 days

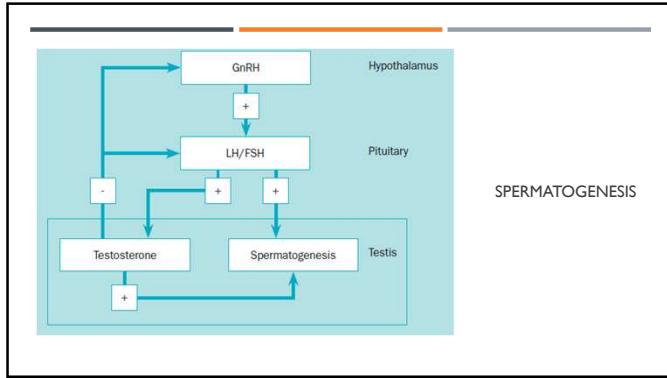
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MALE CONTRACEPTION



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GOAL OF MOST HORMONAL MALE CONTRACEPTION:
 INJECTING EXOGENOUS TESTOSTERONE, PROGESTOGENS, OR GONADOTROPIN-RELEASING HORMONE ANTAGONISTS TO SUPPRESS LH AND FSH SECRETION

THIS IS INTENDED TO LOWER SPERMATOGENESIS AND TESTOSTERONE PRODUCTION, LEADING TO A LOWER SPERM COUNT

IN HEALTHY MEN, WITHOUT THIS INTERRUPTION, SPERM

The hormonal basis of male contraception

NORMAL **CONTRACEPTION**

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PERMANENT MALE CONTRACEPTION

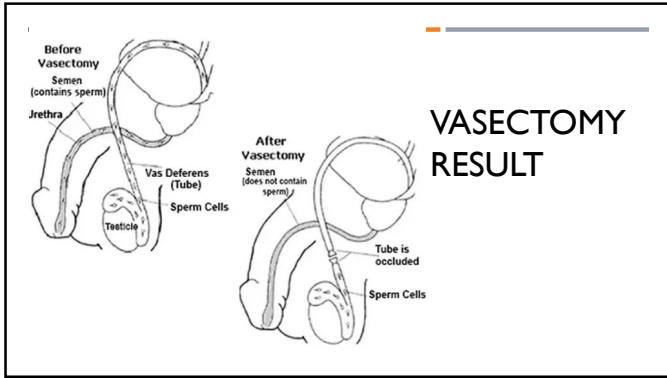
No Scalpel Vasectomy (NSV)

- Similar to traditional vasectomy however involves a small puncture wound that decreases trauma to scrotum
- No stitches and faster recovery

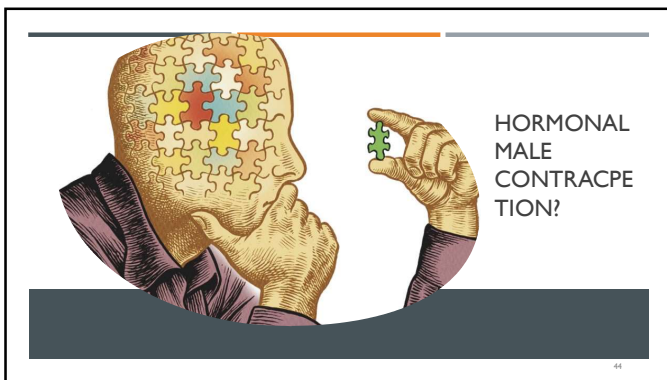
Traditional Vasectomy

- Bilateral scrotal incisions to the vas deferens
- Reversal is difficult and often discouraged

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RISUG®

- Reversible Inhibition of Sperm Under Guidance or RISUG
 - Concept to offer men an alternative to a vasectomy that is also similar to a vasectomy as well if reversibility is so desired
 - Delivered with no scalpel technique
 - Seen to have very little side effects
 - Still in Phase III trials or not available on US market

The diagram illustrates the RISUG procedure. Part A shows the vas deferens, epididymis, and testis. Part B shows a cross-section of the vas deferens wall with RISUG gel inserted, resulting in functionally impaired sperm. Part C shows a cross-section of the vas deferens wall with blocked sperm.

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VASALGEL™

- Long acting **non hormonal** male contraception option that is **meant** to be reversible (mimics RISUG®)
 - Meant to last up to **13 years**
 - Designed to be very similar to the no scalpel vasectomy
 - Gel is inserted in vas deferens
 - Reversibility is meant to be “flushed out” and the gel dissolved, resulting in returned healthy sperm count
 - Not yet available on US market

The diagram shows the male reproductive system with labels for the Bladder, Semi vesic, Prost., Urethra, Testes, and Vasalgel™. The Vasalgel™ is shown as a gel inserted into the vas deferens.

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MALE BIRTH CONTROL TABLET

- Dimethandrolone undecanoate (DMAU)
 - Still in experimental stages in tablet and injection
 - First introduced in 2002
 - Discontinuation is believed to yield immediate healthy sperm count
 - Side effects studied include
 - Weight gain
 - Hair loss
 - Decrease in HDL
 - Recent double blind, randomized, placebo controlled study published in 2019 completed a successful 28 day result with 200mg or more a day administration

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TESTOSTERONE BASED REGIMENS

- Testosterone enanthate
 - World Health Organization (WHO) Study
 - 200mg weekly IM administration
 - 95% success in study
- Testosterone undecanoate (TU)
 - Long acting IM injection 500mg monthly
 - 96% success rate
- For both regimens studied, success increased with addition of exogenous progestin

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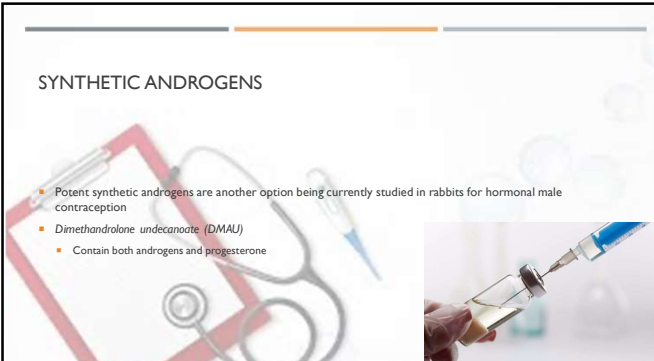
TESTOSTERONE BASED REGIMENS

- Testosterone Gel
 - Transdermal application that provided more consistency and stability for male patient
 - Used in combination with injectable medroxyprogesterone acetate
 - Great use with gonadotropin suppression
 - Still being researched

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SYNTHETIC ANDROGENS

- Potent synthetic androgens are another option being currently studied in rabbits for hormonal male contraception
- *Dimethandrolone undecanoate (DMAU)*
- Contain both androgens and progesterone



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MENT

- *7-alpha-methyl-19-nortestosterone or MENT*
- One year subdermal implant
- Azoospermia achieved in >85% of men and does NOT stimulate prostate growth
- Hopeful for the **first** long acting male hormonal contraception therapy option that will suppress sperm count **without** altering libido




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WHAT DO MEN WANT?




Oral Pill **IM/SC** **Gel**



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WHAT DO MEN WANT?

- A 2022 study found that men have a specific preference of who is going to prescribe their birth control....



SAMPLE FOOTER TEXT 55

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CONTRACEPTION JOURNAL, 2022 NOVEMBER

Regular Physician	Community Pharmacist
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SAMPLE FOOTER TEXT 56

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TEST YOUR KNOWLEDGE

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ASSESSMENT QUESTION THREE

3.The RISUG explores a very specific way to enhance which of the following for men? Choose the best response:

- A. Permanent Sterility
- B. Reversible oligozoospermia
- C. Protection against sexually transmitted infections
- D. Low libido

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HORMONAL MALE CONTRACEPTION UPDATE

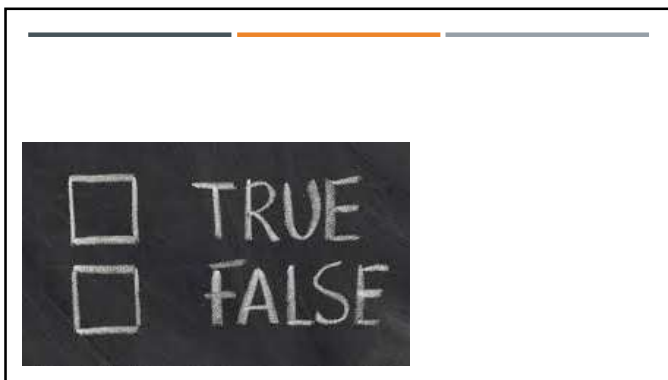


- Today there is no available and successful hormonal male contraception on the US market that is
 - Safe
 - Successful
 - Affordable

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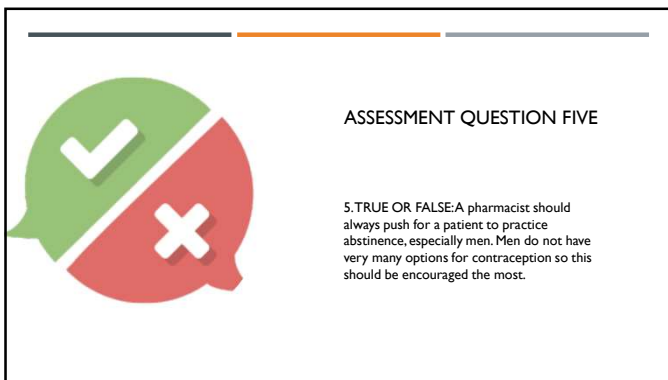
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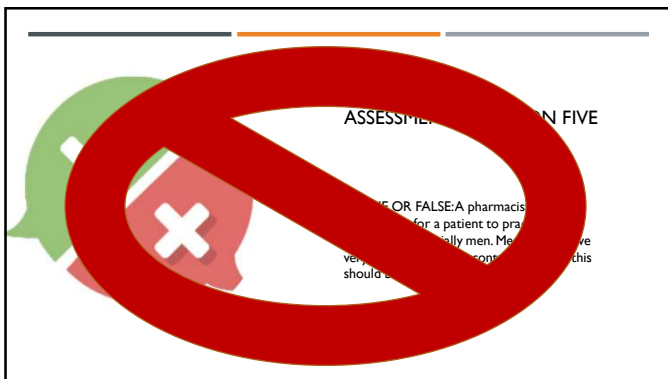
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PHARMACIST INTERVENTION

- What should the team know about contraception?
 - Develop an appropriate rapport with your male and female patients
 - Incorporate shared decision making and don't dismiss a patient's concerns
 - Efficacy is NOT always the most important factor
 - Always consider health literacy
 - Anticipate all adherence barriers before making any recommendation
 - Provide information on all emergency contraception
 - Stay abreast on all evidence-based updates



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