Practical Contraception UPDATE – CASE STUDIES

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Disclosure

I have no financial interests or relationships to disclose.

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Additional Disclosure

Also, for this topic, the terms "woman" refers to any patient who has female reproductive organs and the potential to become pregnant. We also need to consider the contraceptive needs of transgender men and gender nonbinary persons.

Learning Objectives

- **Review and update the various contraceptives: currently available, the latest, and soon-to-come**
- **Augment one's patient-centered approach to counseling and prescribing contraception**
- **Remove unconscious barriers to access to contra-ception; facilitate easier access**
- **Incorporate the U.S. MEC guidelines to empower women with preexisting medical conditions to feel comfortable with contraception**

Reproductive Justice

- The human right to determine one's
  - Sexuality
  - Gender and identity
  - Bodily autonomy
  - Right to have children
  - Right to not have children (for a time, or forever)

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Sexual History – More Inclusive Verbiage for 2024

- OLD: "Do you have sex with men, women, or both?"
- NEW: "Are you currently having sex of any kind, oral, vaginal, and/or anal, with anyone?"
- The "6 P's" of the sexual history:
  - Partner(s)
  - Protection
  - Prior STI Hx
  - Preexposure prevention (HPV vaccine)
  - Planning on pregnancy?
  - Pleasure ("Are you satisfied with your current sexual relationship(s)?")

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Contraception
2024

Empowering Women in Making Reproductive Choices

David M. Plourd, M.D.

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What We Could Learn from COVID in Providing Contraception

- Nearly 1 in 5 (18%) women were not using their preferred method of contraception because…
  - Cost
  - It would require an office visit
  - Medical condition(s)
  - Partner's preference

A Call To ACTION

Ranji U. Kaiser Family Foundation webinar. April 21, 2021

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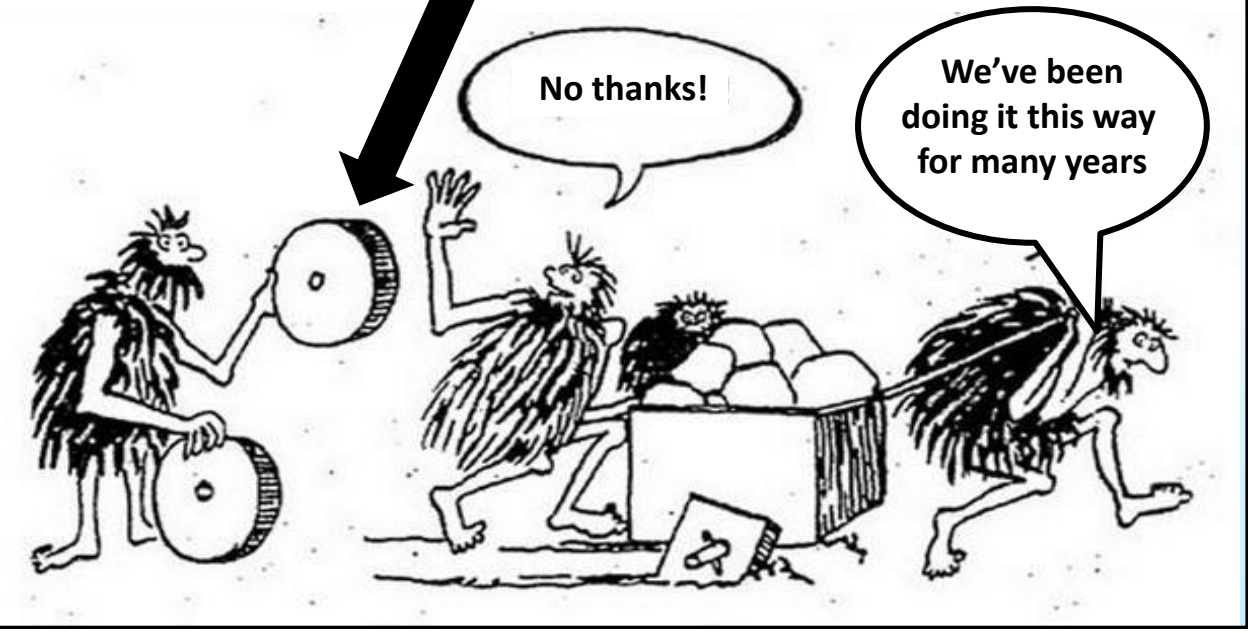
What's New …



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Question the Status Quo

- Ask WHY have we been doing things a certain way for all this time
- Ask WHAT "unconscious barriers" access-to-contraception have we imposed by our old practice patterns?
- Most of this information I'll be presenting today was already evidence-based PRE-pandemic, but was not implemented until the pandemic forced it to be

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What's New …

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Forms of Contraception (16)

Hormonal >90% eff'v.

- Birth control pills
- Transdermal patches
- Vaginal rings (monthly; yearly)
- Injectable
- Implant (subdermal rod)
- Hormonal IUD (4 FDA-approved)

>99% actual use efficacy

Non-hormonal 70-85% eff'v.

- Condoms (male and female)
- Diaphragm
- Cervical cap
- Vaginal spermicidal sponge
- Vaginal spermicidal gels
- Copper IUD >99% actual use efficacy
- Fertility awareness methods
- Withdrawal method
- Breastfeeding
- Abstinence

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LARC Methods
"Long-Acting Reversible Contraceptives" (Reliable)

Implantable etonogestrel rod (3 years)
5 Currently available FDA-approved IUD's
- **Copper (10 years)**
- **L-norgestrel (3--8 years)**
  - **Skyla® (3 yrs)**
  - **Kyleena® (5 yrs)**
  - **Liletta® (8 yrs)**
  - **Mirena® (8 yrs)**

All are >99%* effective

***Actual use effectiveness**

"Set it, and forget it"

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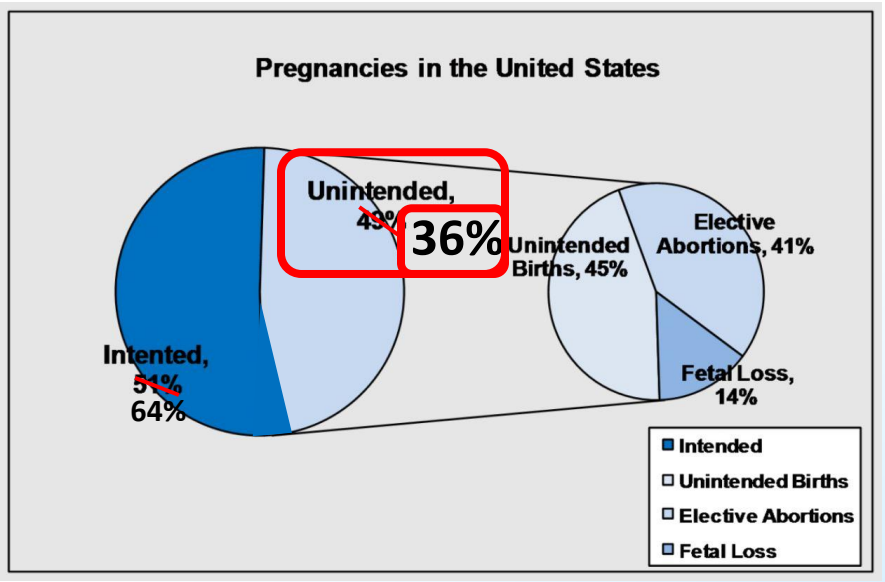
Unintended Pregnancies in the U.S.



U.S. National Center for Health Statistics. April 12, 2023

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Highly Effective Methods Available

> 90% actual-use effectiveness

- Hormonal
  - OCP's 92.4%
  - Patch 94.5%
  - Monthly Ring 95.2%
  - Yearly Ring 96-98%
  - Depot Injection 96.4%
  - Implantable Rod 99.994%
- Intrauterine
  - Copper-based 99.6%
  - L-norgestrel based 99.8 %

LARC's

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So, Why Is the U.S. Unintended Pregnancy Rate So HIGH?

- **Among 15—44 y/o women who wish NOT to become pregnant – only 11 % do not use contraception**
  - **Yet that 11% contribute to HALF of all unintended pregs**
  - **More distressing: Those USING contraception contribute to the other half**
    - »**BUT, those using contraception CORRECTLY account for only 5% of all unintended pregnancies**

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Every Night in America ...

- 16 million couples have intercourse
- 36 thousand condoms break

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The Perceived vs. Real Safety of Hormonal Contraceptives

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Women's Perceived Safety

In a public survey of 1,839 women…

56% of women believed that OCP's were MORE RISKY than pregnancy

Kakaiya R. Contracept & Repro Med. 2017; doi 10.1186/s40834-017-0046-5

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Then There's ACOG Perceived Safety

- **"ACOG supports OTC [some: BTC] access to hormonal contraception without age restrictions". 2019**
  - **OCP's, vaginal rings, contraceptive patch, and DMPA injections (SubQ can be done by patient)**
    - »**Eliminates the need for prescriptions**
    - »**Relies on the woman to self-screen for eligibility**
      - A simple matter of one's personal medical history
    - »**Pharmacist-provided contraception & counseling for adolescents < 18 y/o, & for injections (in some states)**
      - Refc: ACOG Committee Opinion. #788, October, 2019 (OB & GYN. 2019; 134(4): e96-105

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- **"ACOG supports OTC [some: BTC] access to hormonal contraception without age restrictions". 2019**
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Patient Self-Screening Tool

1. **Have you had a DVT or PE**
2. **Could you be pregnant**
3. **Have you had a baby in the past 3 weeks**
4. **Are you currently breast-feeding; baby <6mos old**
5. **Do you have high B/P**
6. **Are you a smoker >35 y/o**
7. **Do you have diabetes**
8. **Do you have migraine HA's**
9. **Do you have liver disease or a hx of liver CA**
10. **Do you have GB disease**
11. **Hx of breast CA**
12. **Do you take a statin**
13. **Do you take Rx for seizures or TB**

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Initiation and Continuation of Contraception Through Telemedicine

1. Questionnaire for contraindications to hormonal contraceptives
2. But what about the blood pressure and physical exam/pelvic exam ?

Assessment	In Office	At Home
Blood pressure	In-person measurement	• Home BP cuff • Self-report of normal BP in last year • Risk-benefit conversation
Physical exam	Not routinely indicated	N/A
Urine pregnancy test (UPT)	Point-of-care UPT	• Reasonably certain not pregnant questions from CDC • Home UPT comparable to office UPT

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As of Nov., 2024: 29** States & D.C. Allow Pharmacists to Prescribe Contraceptives

Arizona
Arkansas
California
Colorado
Connecticut
Delaware
Dist. of Columbia
Hawaii
Idaho
Illinois
Indiana
Massachusetts
Maine
Maryland
Michigan
Minnesota
Nevada
New Hampshire
Nevada
New Mexico
New Hampshire
New York
N & S Carolina
Oregon
Rhode Island
Tennessee
Utah
Vermont
Virginia
West Virginia

** Was only 19 prior to 2020

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What's New …

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What's New … August, 2018
EE/ Segesterone Acetate

- a **yearly** vaginal contraceptive ring
- 3 weeks in / 1 week out
- (rinse & store in a case at room temp),
  - then replace the same ring x 13 cycles
- 3 weeks x 13 cycles = 39 weeks (?? Would it work continuously for 39 weeks??) Off-label use
- 96-98 % efficacy [Pearl index of 2.98]
  - May be removed for up to 2 hours for intercourse
- Does NOT require refrigeration prior to dispensing
- COUNSELING POINT: ring turns dark brown over time of use

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FDA-approved Dec. 11, 2019

- The first generic equivalent to the NuvaRing ® (EluRyng)
- Delivers 0.120 mg etonogestrel / 0.0015mg EE/day

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What's New: FDA-approved June 2019 Drospirenone-only OCP

- Formulation: 4.0 mg DRSP in a 24 + 4 cyclic regimen
- Efficacy (1st year): 93.3-96% (reliable ovulation suppression)
- Amenorrhea occurred in 74% of users, by 1 year
- Lower breakthrough bleeding rate
  - 40.3% vs ~65-70% for most other OCP's
- Long-acting progestin – allows for greater latitude in the tight timing of daily dosing for all other POP's

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Contraindications to Progestin-only Contraceptives

- MEC Category 4 conditions
  - Breast CA in the past 5 years
  - Renal impairment
  - Adrenal insufficiency

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FDA-approved March, 2020 A New Contraceptive PATCH

- Formulation:
  - Ethinyl estradiol 30 mcg
  - Levonorgestrel 120 mcg

} release / day

- N = 1,736 women < 35 y/o; 15,165 evaluable cycles
- Pearl Index 5.83 across all BMI's
  - 3.5 in BMI<25 kg/m^2; 5.7 in BMI 25-30kg/m^2

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May 22, 2020: 1st Non-Hormonal Contraceptive FDA-Approved in Decades

- A novel intravaginal gel
  - NOT Nonoxynol-9 (like all other spermicidals) which works by disrupting sperm cell membranes)… BUT ➡ leads to increased STI's
  - Instead, Phexxi is an acidic intravaginal gel
    - » BUT only 86.3% eff'v @ 6 mos = other OTC intravaginal spermicides)
  - **Phexxi**® (lactic acid, citric acid, & potassium bitartrate)
  - Requires a PRESCRIPTION ($$, access)

MAY ⬇ the risk of STI's (chlamydia & GC by 50% & 78% respect'ly)

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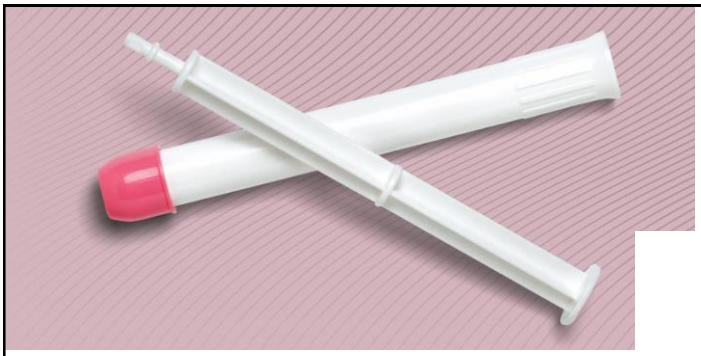

Must be applied <60 minutes prior to intercourse

Packaged as 12 prefilled applicators

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Both Copper AND Hormonal IUD's Are Very Effective as E.C. (Jan. 2021)

Off-label use

- Randomized trial: 638 women received either IUD within 5 days (<120 hours)* of unprotected sex
- Pregnancy test done at 1 month F/U visit

	# of "sexposures"	# of pregnancies	
Hormonal IUD/IUS	317	1	Off-label use
Copper-IUD	321	0	Off-label use

*Copper-IUD >99% effective in women 6-14 days after UPI

Turok D. NEJM. 2021; 384:335-344
DOI: 10.1056/NEJMoa2022141
BakenRa A. Obstet Gynecol 2021

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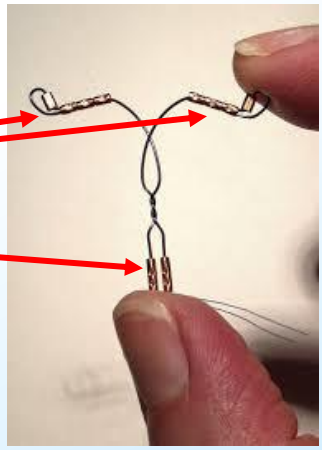
Coming Soon: A New Copper IUD

- Copper 170mm^2 IUD
- VeraCept Copper IUD (nitinol frame)
  - 170 mm^2 of copper
    - »Copper where you need it
      - At the tubal ostia
      - At the internal cervical os
  - Small & flexible – 32 x 30 mm
  - Lighter bleeding
    - »(related to Cu++ content)
- Highly eff'v: 99.54% [98.33--99.94]
  - » Turok D. Obstet Gynecol. 2020; 135: 840-4



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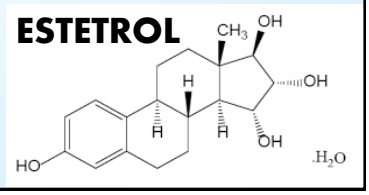
FDA-approved April, 2021
A New OCP with a Novel Estrogen

- a 24/4 regimen
  - Not good old ethinyl estradiol – found in ALL other CHC's
    - » THE FIRST NOVEL ESTROGEN in >50 YEARS
  - 14.2 mg Estetrol (E_4) – a natural estrogen produced by the fetal liver in pregnancy (10-20% the potency of E_2) long $T^{1/2}$
    - » Less adverse impacts on coagulation, lipids, B/P than EE
  - 3 mg Drospirenone (DRSP) – progestin with a long $T^{1/2}$
  - 97.4% efficacy
    - » 97.1% in BMI>30 kg/m2



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Advantages of Estetrol Over Ethinyl Estradiol

- Neutral impact on liver – not prothrombotic
  - Lower VTE-risk (theoretic) – awaits clinical experience
  - VTE is the principal health risk of combination OCP's
- Beneficial on bone
- Beneficial on heart
- Beneficial on vaginal epithelium
- Antagonistic on mammary tissue
- Excreted in urine (no increased risk of gallstones)

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"NEWS FLASH": July 13, 2023: The FDA Approved the First OTC Oral Contraceptive Pill

- Norgestrel 0.075 mg
- Not REALLY the 1st OTC OC- since the "morning after pill" was FDA-approved OTC ~ a decade prior in June, 2013
- 98% effective with perfect use; 91% with typical use

Allen RH. Obstet & Gynecol. 2024; 143: 184-8

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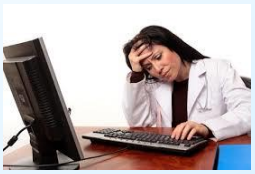

Isn't There a Reasonably Quick and Easy App/Way to Look Up the Safety of Various Contraceptive Methods in Women with Specific Medical Conditions?

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CDC's Updated (Aug 8, 2024) U.S. Medical Eligibility Criteria (MEC)

Category 1	No restriction for use of the contraceptive method
Category 2	Advantages of using the method generally outweigh the risks
Category 3	Risks usually outweigh the advantages of using the method
Category 4	Unacceptable health risk if the method is used

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Which Best Describes Your Current Practice?

A. I am familiar with, and regularly refer to, the U.S. MEC App for contraception
B. I have the U.S. MEC free App, but only use it only occasionally
C. I have heard of, but rarely if ever use, the U.S. MEC
D. I am not familiar with the U.S. MEC for contraception

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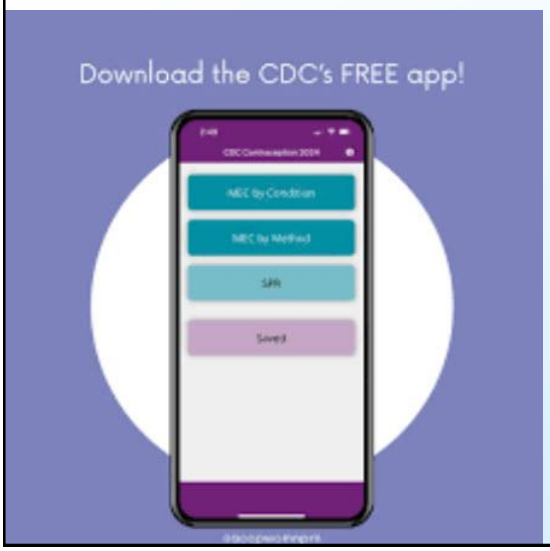
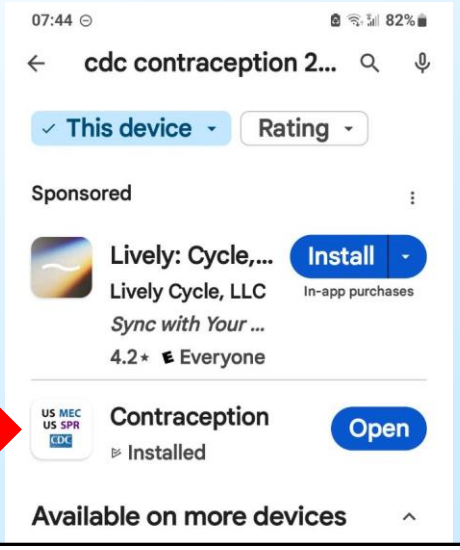
U.S. Medical Eligibility Criteria ("M.E.C.") 2024 Update





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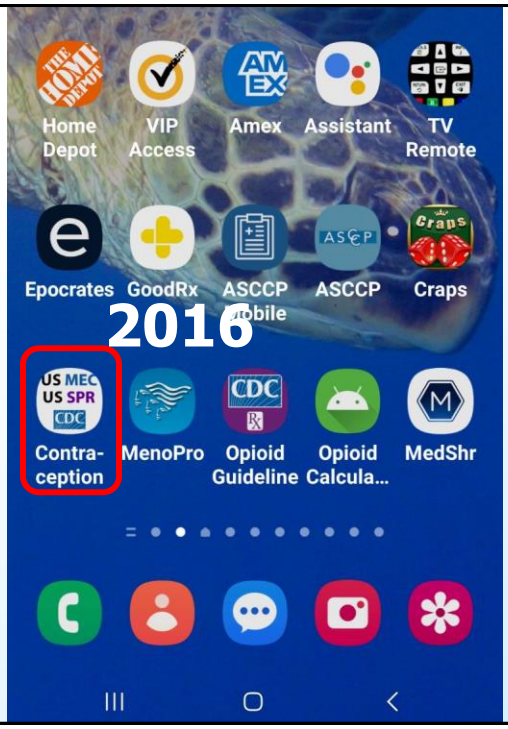

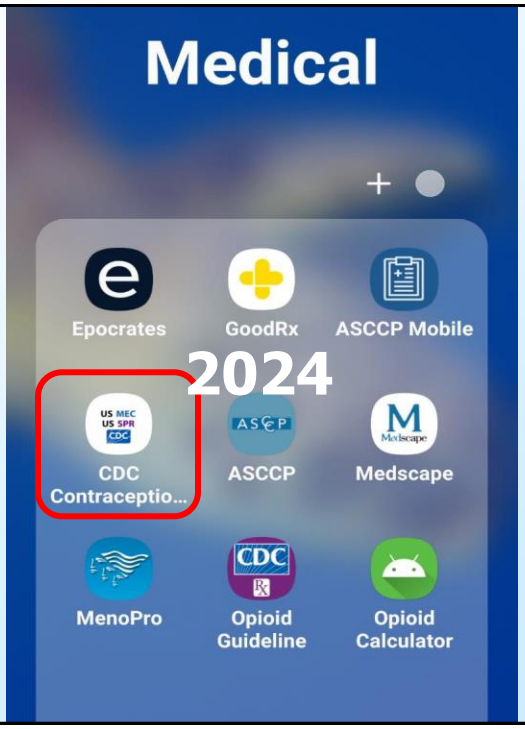

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CDC's Mission Statement Regarding the 2024 M.E.C.

The 2024 U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) comprises recommendations for the use of specific contraceptive methods by persons who have certain characteristics or medical conditions. The goals of these recommendations are to remove unnecessary medical barriers to accessing and using contraception and to support person-centered contraceptive counseling and services in a noncoercive manner. The information in this report replaces the 2016 U.S. MEC (CDC. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR 2016:65[No. RR-3]:1–103).

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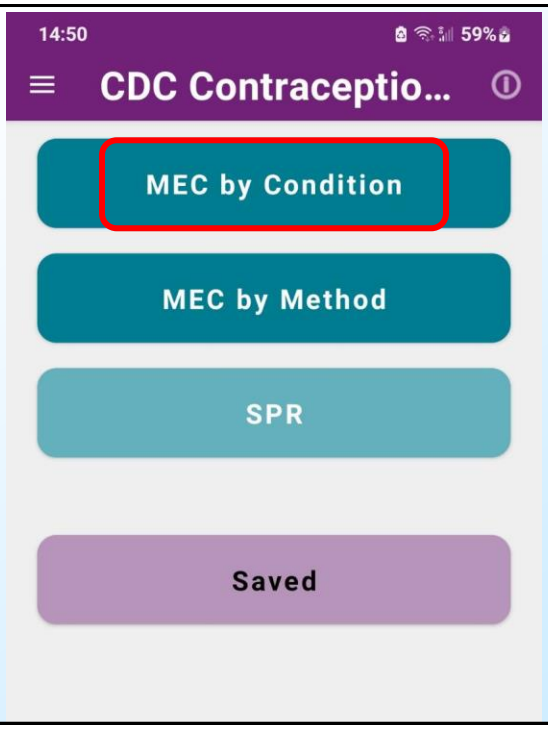

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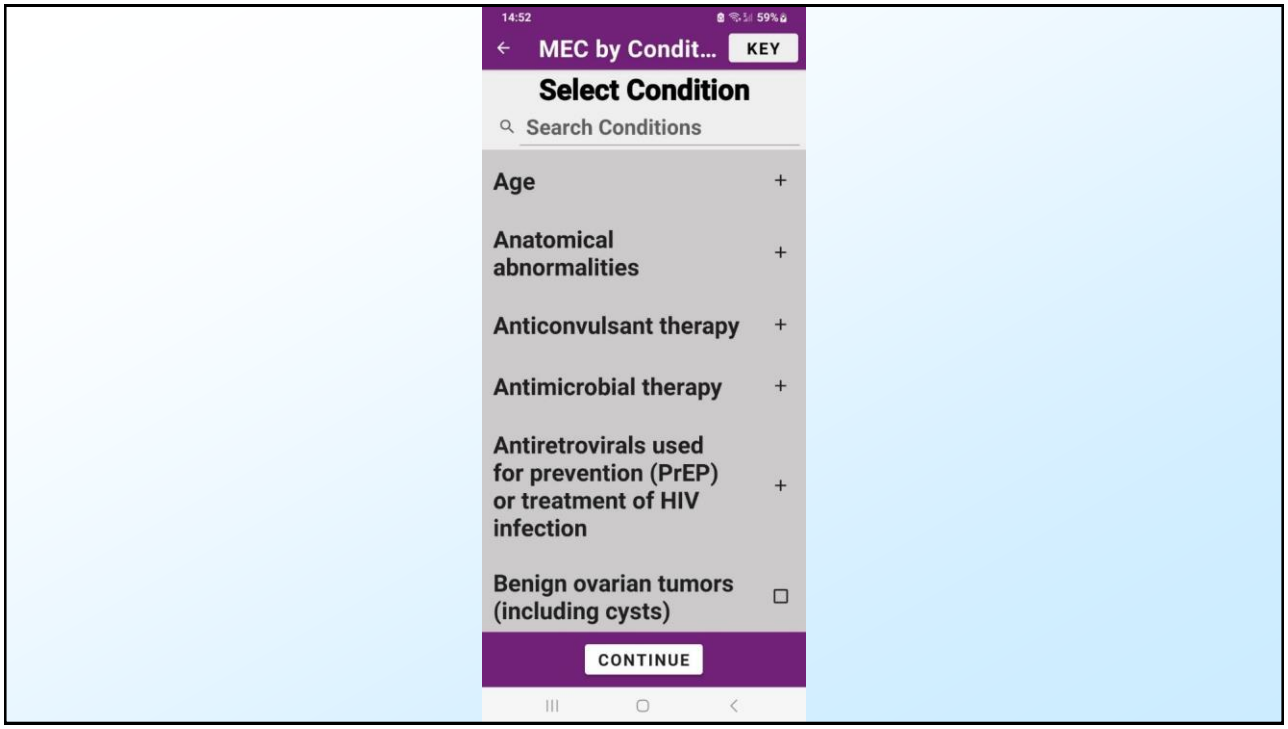
14:52
59%
MEC by Condit...
KEY
Select Condition
Search Conditions
Age
Anatomical abnormalities
Anticonvulsant therapy
Antimicrobial therapy
Antiretrovirals used for prevention (PrEP) or treatment of HIV infection
Benign ovarian tumors (including cysts)
CONTINUE

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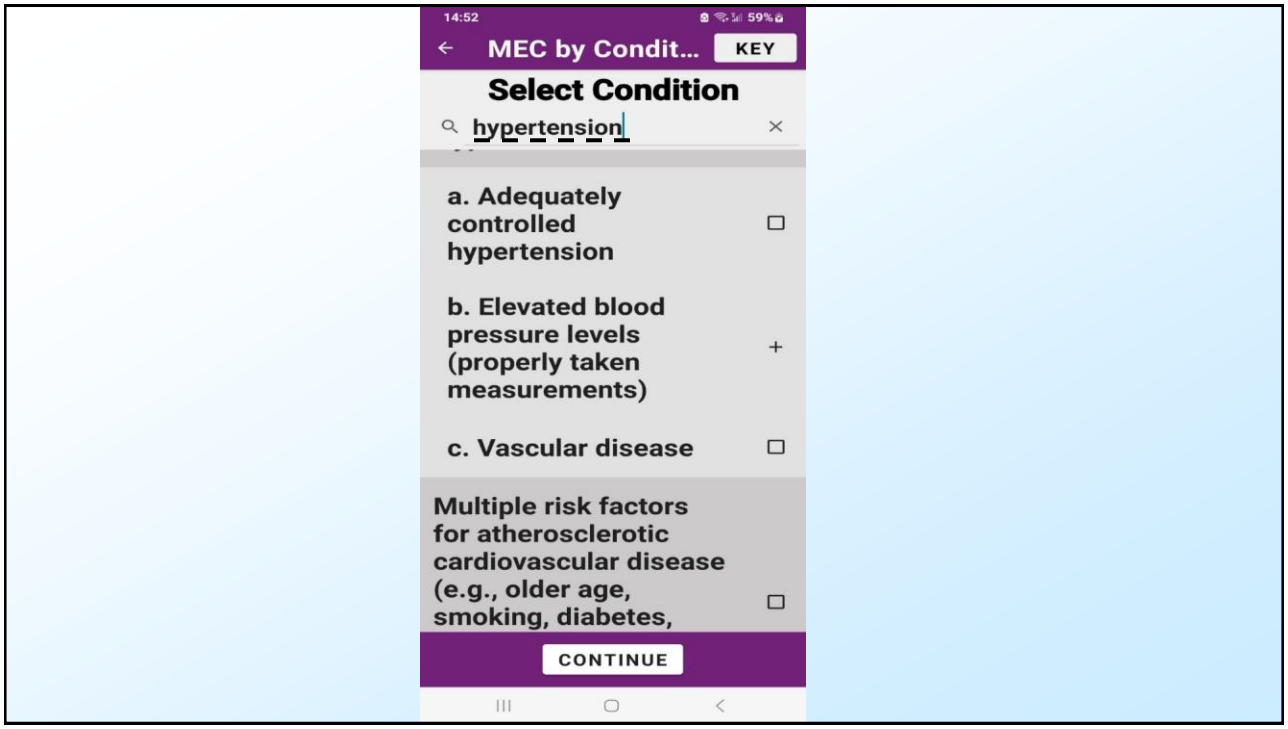
14:52
59%
MEC by Condit...
KEY
Select Condition
hypertension
a. Adequately controlled hypertension
b. Elevated blood pressure levels (properly taken measurements)
c. Vascular disease
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes,
CONTINUE

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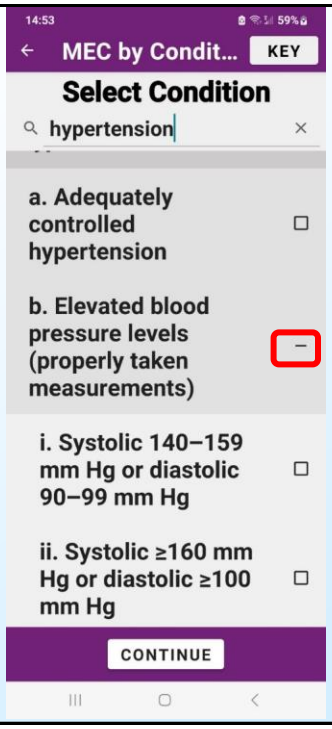
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59%
MEC by Condit...
KEY
Select Condition
hypertension
a. Adequately controlled hypertension
b. Elevated blood pressure levels (properly taken measurements)
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg
CONTINUE

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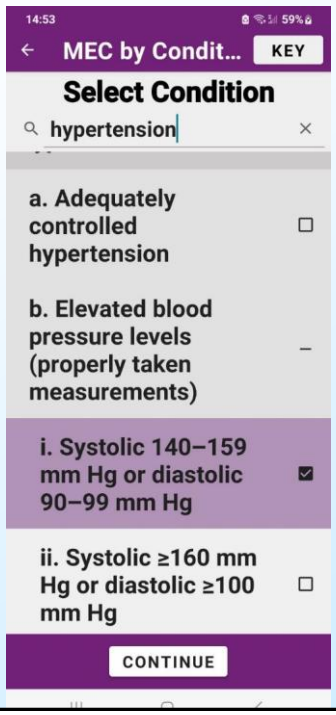
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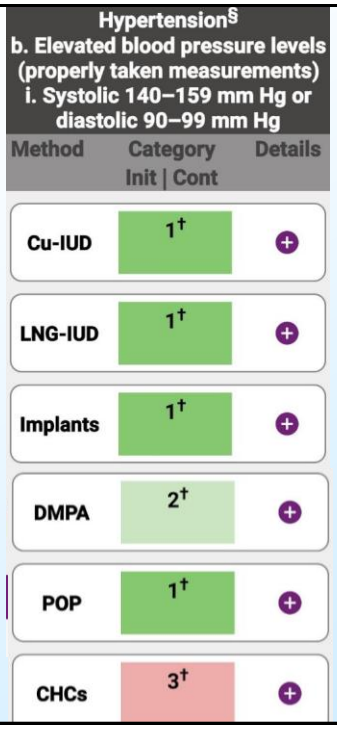

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Case #1

A 25-year-old law student presents requesting birth control pills as she has recently become sexually active. She has not been seen for any healthcare for over 5 years, and has never had a Pap smear

What Would You Advise Her, Regarding Her Contraception Options, If She Has SLE with + Antiphospholipid AB's?

A. All of the LARC methods are "acceptable without restriction" (MEC category 1)
B. Only the copper-IUD is "acceptable without restriction" (MEC category 1)
C. She may safely use any hormonal contraceptive (they are all MEC category 1 or 2)
D. She should first have a pelvic exam and cervical cytology before you can prescribe any contraceptive

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CDC's U.S. MEC App (Free) UPDATED: Aug 8, 2024

1018040456

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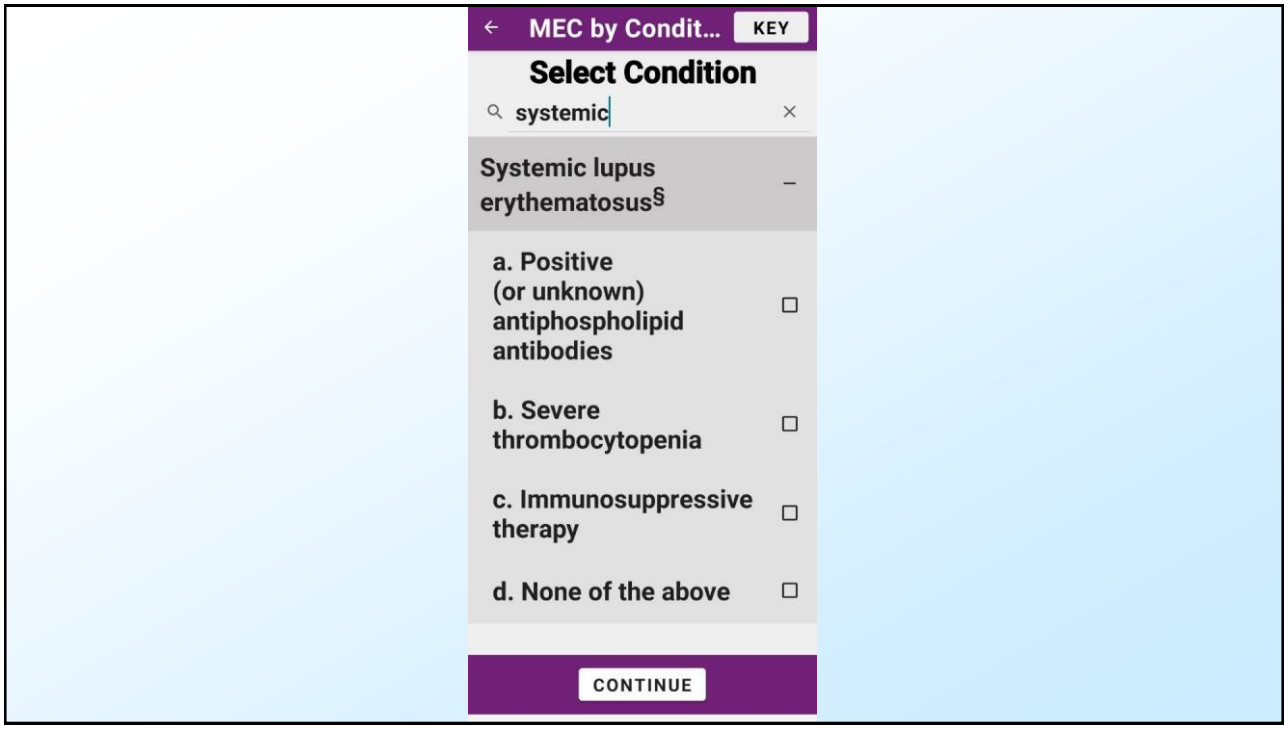
MEC by Condit...
KEY
Select Condition
systemic
Systemic lupus erythematosus§
a. Positive (or unknown) antiphospholipid antibodies
b. Severe thrombocytopenia
c. Immunosuppressive therapy
d. None of the above
CONTINUE

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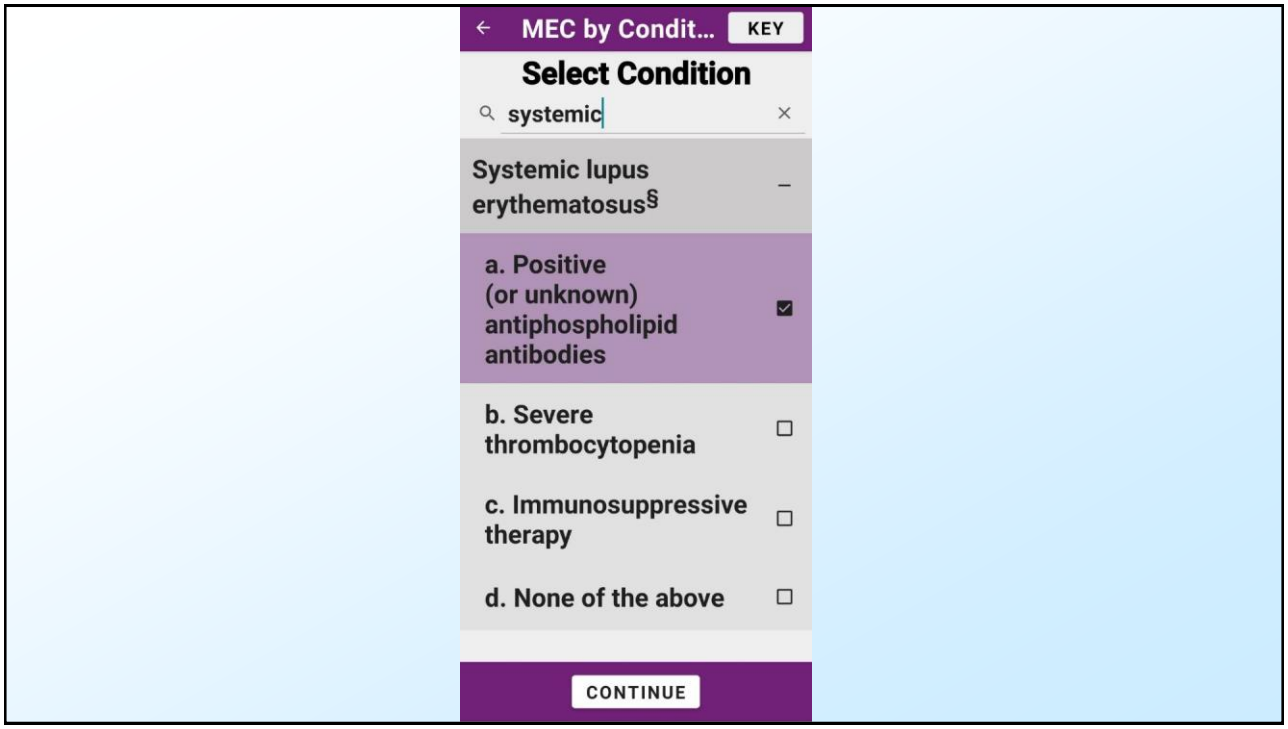
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Systemic lupus erythematosus§
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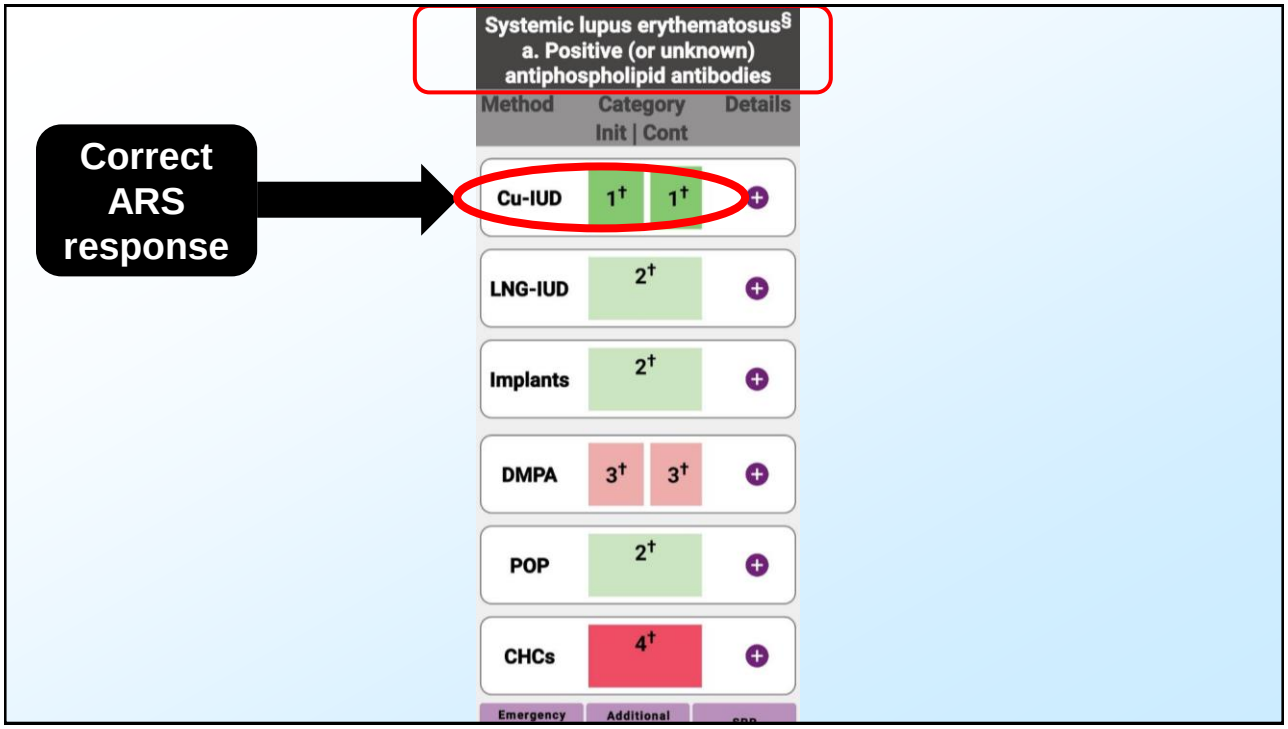

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Which of the Following Conditions Is MEC Category 1 (No Restriction On Use) for Combined Hormonal Contraceptives (e.g. Birth Control Pills, Patches, Rings)?

A. Migraine headaches without aura
B. 2 weeks post-partum, not breastfeeding
C. BMI > 30
D. Varicose veins of the lower extremities

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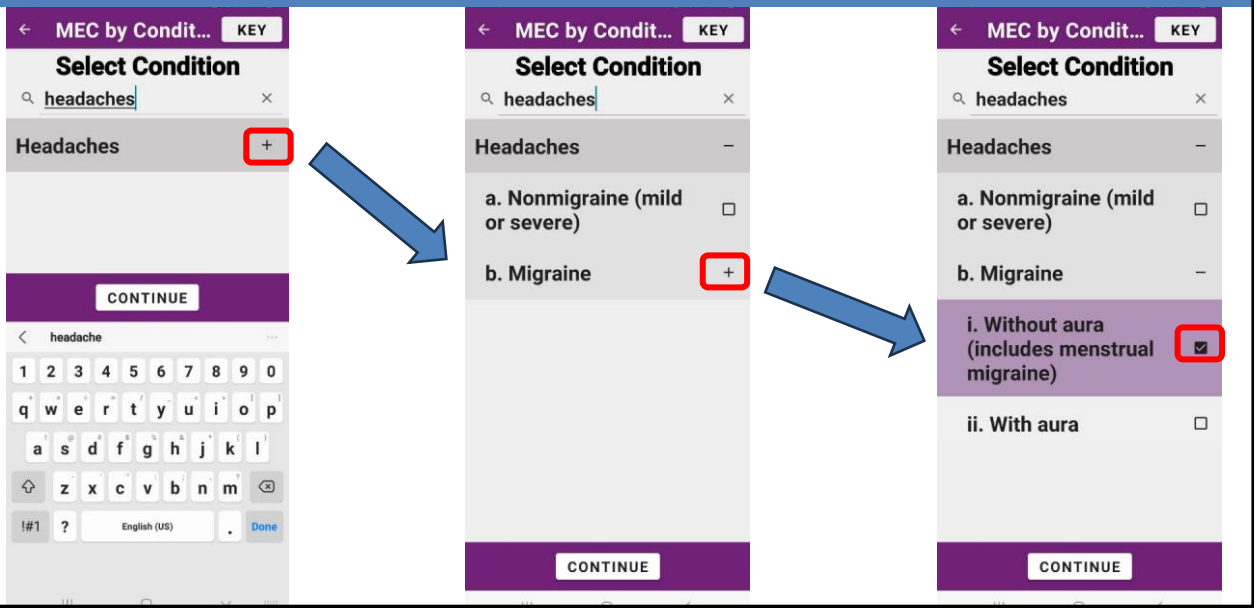
A. Migraines without Aura?



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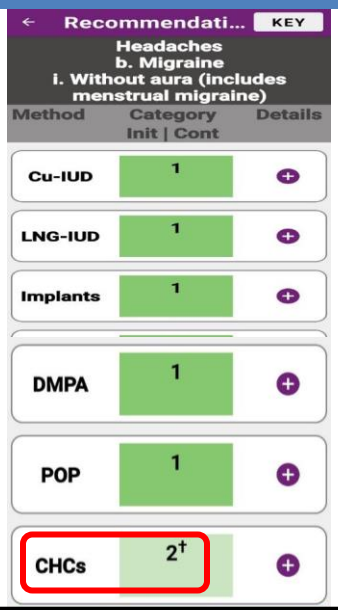
A. Migraines without Aura?



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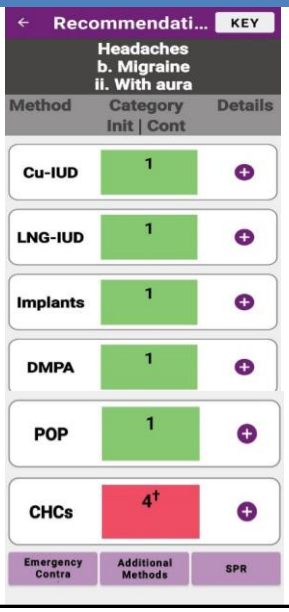
A2. Migraines with Aura?



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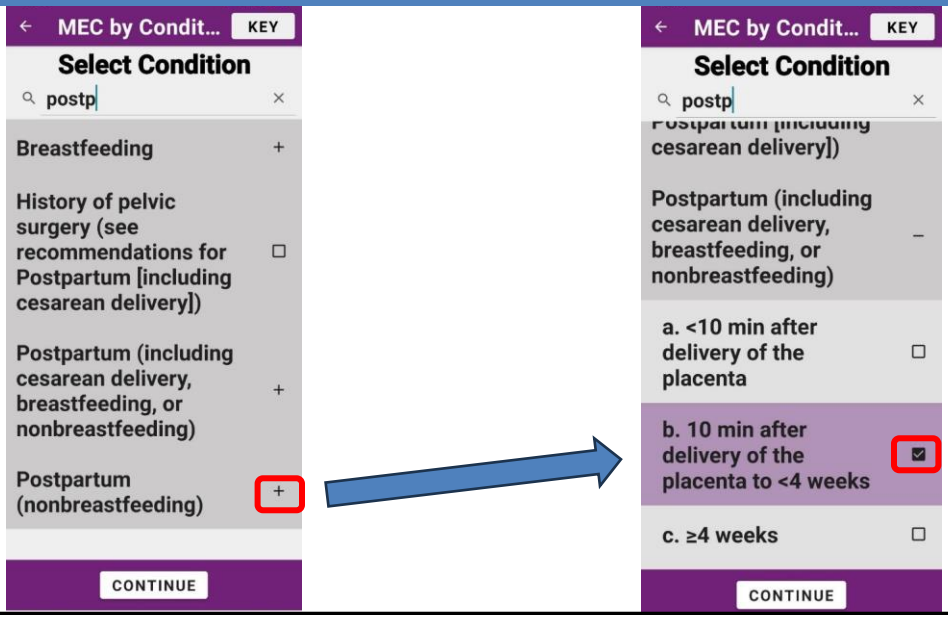
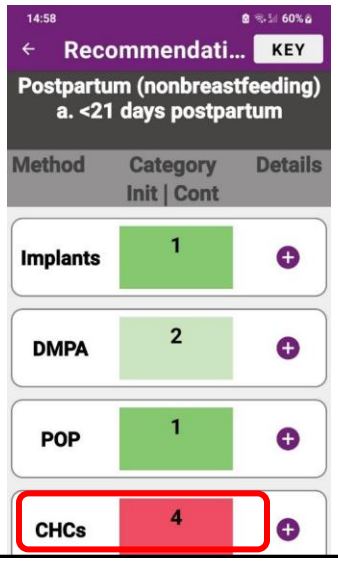
B. 2 Weeks Postpartum, Not BF'ing



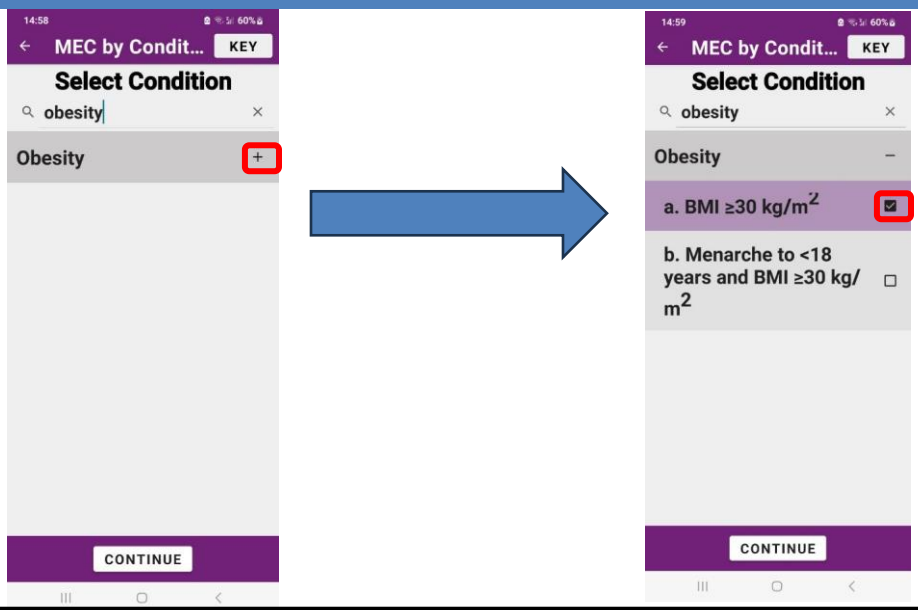
60

B. Two Week Postpartum?



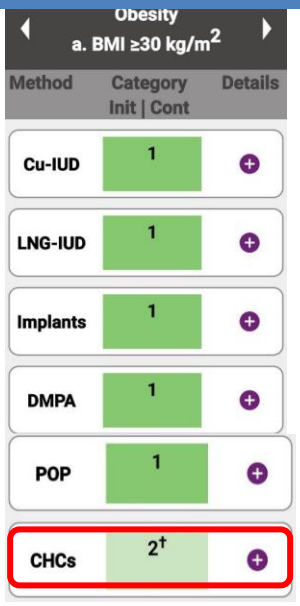
61

C. Obesity?



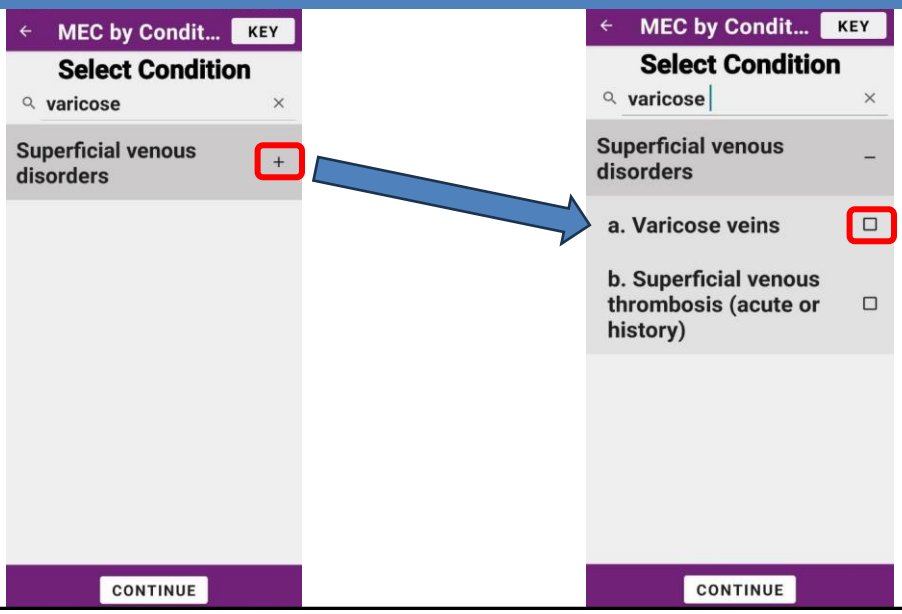
62

C. Obesity?



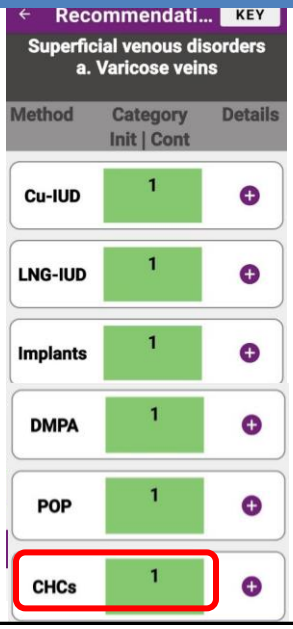
63

D. Varicose Veins?



64

D. Varicose Veins?



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A Source of Confusion Regarding the 4 MEC Categories

Occasionally, the recommendation will be different for INITIATING vs CONTINUING a contraceptive method in the face of a particular medical condition

e.g. SLE with severe thrombocytopenia

Condition	Sub-Condition	CHC	POP	Injection		Implant	LNG-IUD	Cu-IUD	
Systemic lupus erythematosus[†]	a) Positive (*or unknown*) antiphospholipid antibodies	4	3	3	3	3	3	1	1
	b) Severe thrombocytopenia	2	2	3	2	2	2*	3*	2*
	c) Immunosuppressive treatment	2	2	2	2	2	2	2	1
	d) None of the above	2	2	2	2	2	2	1	1

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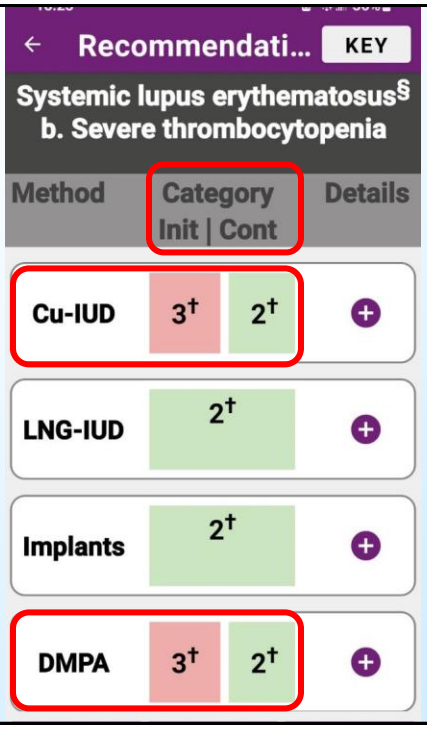

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Background Information Regarding the U.S. Medical Eligibility Criteria (MEC)

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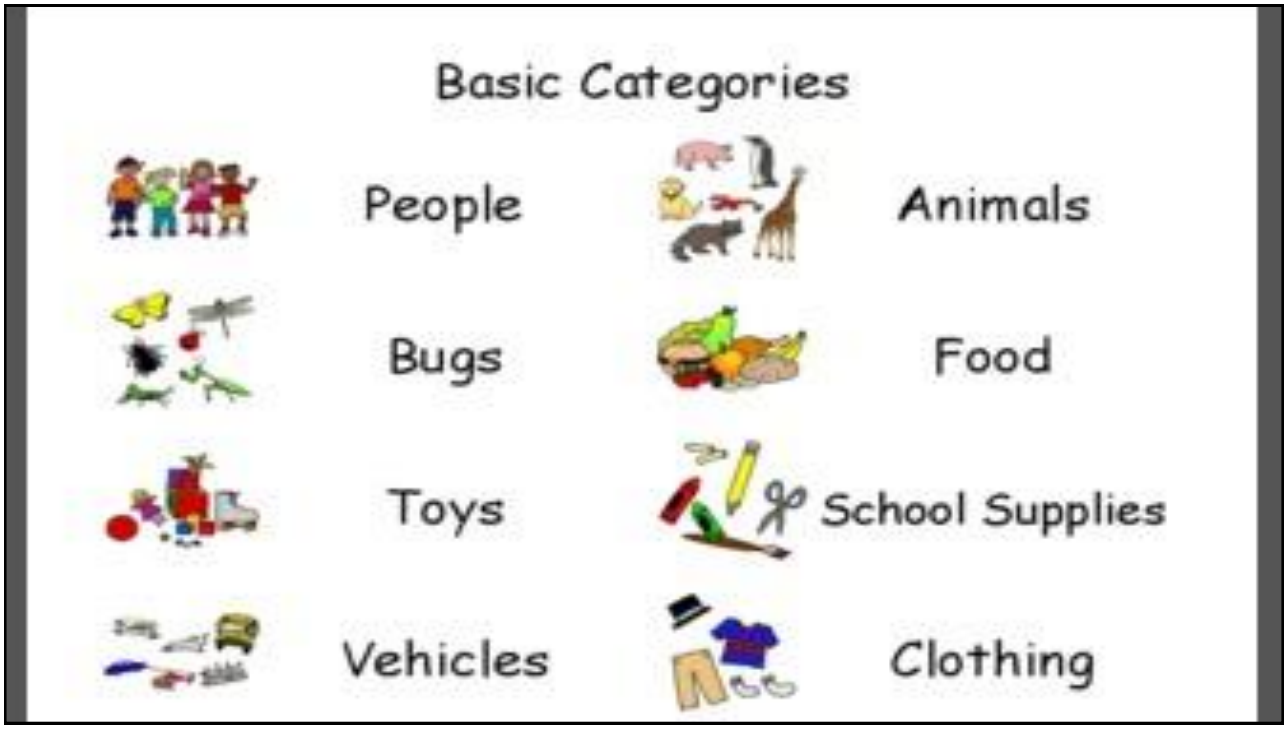
Basic Categories
People
Animals
Bugs
Food
Toys
School Supplies
Vehicles
Clothing

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A QUICK REFERENCE FOR HURRICANE CATEGORIES
CAT 1
CAT 2
CAT 3
CAT 4
CAT 5

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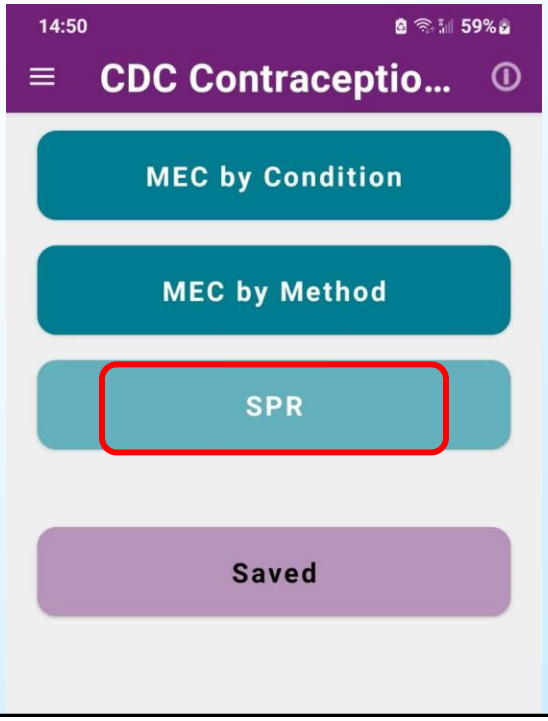

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The Expert Panel Made Four Major Changes/Additions to the 2016 SPR

- Updated recommendations for the provision of analgesia during IUD placement
- During recommendations for managing irregular bleeding during implant use
- New recommendation regarding testosterone and the risk of pregnancy
- New recommendation for self-administration of injectable contraception

CDC MMWR. Aug 8, 2024. 73(3);1–77

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1. Analgesia for IUD Placement

- Misoprostol is not recommended for routine use for IUD placement
  - Misoprostol might be useful in selected circumstances (e.g., in patients with a recent failed placement).
- Lidocaine (paracervical block or topical) for IUD placement might be useful

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2. Bleeding Irregularities During Implant Use

- Pre-insertion counseling is the BEST approach
  - Set expectations
  - "The most cited reason for a woman to seek early removal is bothersome unscheduled bleeding"
- Reassurance that irregular light bleeding is normal
  - Many (34%) will have infrequent bleeding (<3 episodes/ 90 days)
  - amenorrhea may occur (in 13-22% of women by 12 mos.)

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Bleeding Irregularities During Implant Use

- Hormonal treatment
  - 20–30 µg ethinyl estradiol [EE]
  - Combined oral contraceptives [COCs]
  - Menopausal estrogens
- Antifibrinolytic agents (e.g., tranexamic acid)x 5 days
  - For heavy bleeding
- Nonsteroidal anti-inflammatory drugs
  - e.g. celecoxib, ibuprofen, or mefenamic acid) x 5–7 days
- Selective estrogen receptor modulators (SERMs)
  - e.g. tamoxifen x 7–10 days

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3. Testosterone in Transgender Patients

- Counsel that testosterone use might not prevent pregnancy among transgender, gender diverse, and nonbinary persons with a uterus who are using testosterone.
- Offer contraceptive counseling and services to those who are at risk for and do not desire pregnancy

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4th SPR: A Simple Way to Empower Our Patients to Reduce Their Risk of Unintended Pregnancy

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4. Sub-Q Injectable DMPA

Self-administered subcutaneous depot medroxyprogesterone acetate (DMPA-SC) should be made available as an additional approach to deliver injectable contraception

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Self-Administered Sub-Q DMPA: A Viable Solution in 2024

- Sub-Q DMPA has been FDA-approved since 2004
- Averts needs for medical-setting encounters/risks
  - Perfect when access to care is restricted
- 20% higher continuation rates (at 1 year) compared to in-clinic administration of IM DMPA
- Mitigates racial disparities in access to contraception
- Same efficacy for 150 mg IM and 104 mg sub-Q

Burlando A. Obstet & Gynecol. 2021; 138(4): 674-7

81

Self-Administered Sub-Q DMPA in 2024, Continued

HOW TO:

At initial office visit:

- Educate patient on contraceptive options
- Office staff educate and rehearse the patient on proper self-injection technique
- Give the patient DMPA 150 mg IM – to give her and the pharmacy a 3-month lead time in getting DMPA sub-Q
- Promote local pharmacy awareness and uptake
- Prescribe to a cooperative phcy, and provide alcohol wipes

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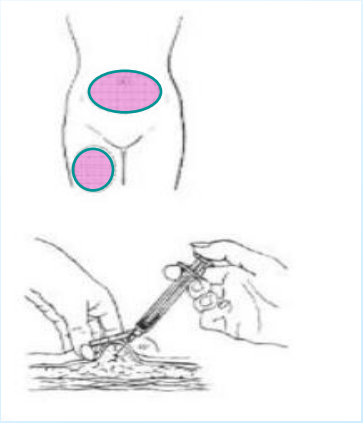
At-Home Self-Administration of SubQ Depo Provera



- **Prefilled syringe with 26 gauge needle**
  - **104mg/0.65 mL**
- **Inject in anterior thigh or abdomen**
  - **DON'T RUB injection site**
- **Every 12-14 weeks**
- **If she forgets - at >15 weeks and 0 days:**
  - **Evaluate her individual pregnancy risk (shared decision making)**
  - **She can self-administer; consider BUMBC for 1 week**

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When Does a Urine Pregnancy Test Become Positive?

A. Within 12-24 hours after fertilization
B. Within 3-5 days after fertilization
C. Within 7-10 days after fertilization
D. Not enough information to answer the question

CONTINUING EDUCATION COMPANY

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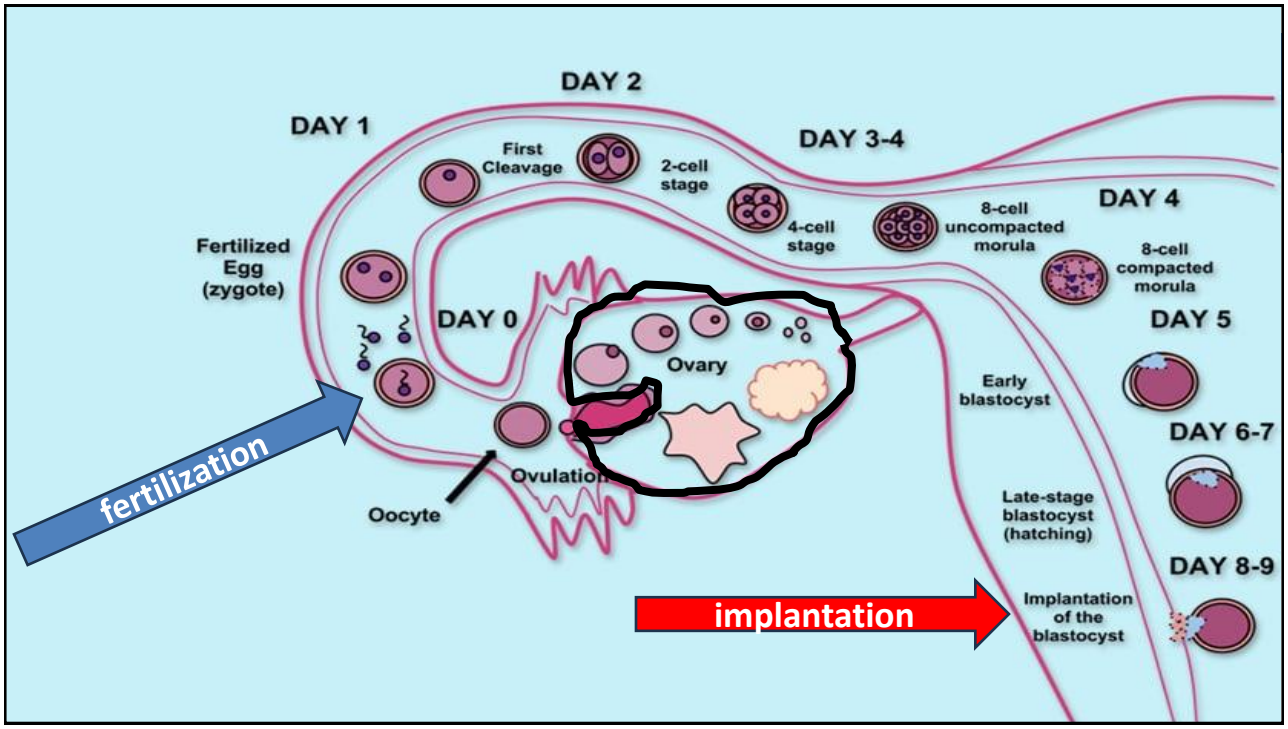

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Excluding Pregnancy with Certainty: An Illusion and a Barrier to Access

- ILLUSION- a serum or urine ß-hCG can miss an early pregnancy in the luteal phase
- BARRIERS to CARE-
  - Requiring a point-of-care hCG and/or
  - Requiring abstinence for >10 days and/or
  - Requiring a second visit after abstinence and/or
  - Requiring that she's menstruating at the visit

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"PREG" Pregnancy Reasonably Excluded Guidelines

1. Is ≤7 days after the start of normal menses
2. Has not had sexual intercourse since the start of last normal menses
3. Has been correctly and consistently using a reliable method of contraception
4. Is ≤7 days after spontaneous or induced abortion
5. Is within 4 weeks postpartum
6. Is fully or nearly fully breastfeeding, amenorrheic, and <6 months postpartum

Stanback J. Checklist for ruling out pregnancy among family-planning clients in primary care. *Lancet.* 1999;354:566.

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Effect of Implementing PREG

- 96% (974 of 1012) women could have their contraception initiated same-day
  - vs. 58% prior to implementing PREG
- Only 24% (244 of 1012) needed a B-hCG
- Only 3.8% (38 of 1012) needed a 2nd appt.

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Employ LARC Methods for Their Evidence-Based Duration (Do Not Consider FDA-labeling as Restrictive)

METHOD	TRADE NAME	FDA Label	EVIDENCE-BASED
Subdermal Implant	Nexplanon	3 years	4—5 years
52-mg LNG-IUD's	Mirena & Liletta	8 years	8 years
13.5 & 19.5 mg LNG-IUD's	Skyla & Kyleena	3 years	3 years
Copper IUD T-380A	Paragard	10 years	12 (?15) years

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SUMMARY: Replace Traditional Practices With More Recent Evidence-Based Practices Remove "Unconscious Barriers"

- Counsel: in a PATIENT-centered approach
- Implement: easier access to contraception:
  - R/O pregnancy with "reasonable certainty"
  - Utilize telemedicine to initiate/continue contraception
  - Drive-up contraception
  - At home self-administered SubQ injectable Depo-Provera
  - Dispense a 1-YEAR supply of pills, patches, rings
  - Extended-use LARC methods

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