

Clinical Updates: Sexual & Reproductive Health

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Outline

Sexually transmitted infections

- STD incidence rates & screening recommendations
- Pre Exposure Prophylaxis for HIV (PrEP)

Contraceptives

- Extended use of IUS/IUD
- Drospirenone (Slynd) progestin-only pill
- Nesterone + EE (Annovera) vaginal ring
- Cost-effectiveness of providing 12-13 OC cycles

Cancer screening and prevention

- HBOC
- Cervical Cancer

STIs are on the Rise in the United States

The STATE of STDs in the United States



in 2017

STDs TIGHTEN THEIR GRIP
ON THE NATION'S HEALTH
AS RATES INCREASE FOR A
THIRD YEAR



1.69 million
CASES OF CHLAMYDIA

5% increase since 2016



548,678
CASES OF GONORRHEA

17% increase since 2016



98,437
CASES OF SYPHILIS

12% increase since 2016

LEARN MORE AT: www.cdc.gov/std/

more than **900** Congenital Syphilis Cases in 2017 **44%** ↑

*Data are preliminary as of April 12, 2018; congenital syphilis data are preliminary as of July 10, 2018

Syphilis Screening



USPSTF: Persons at increased risk for syphilis [A]

- MSM (61% of syphilis diagnoses)
- Men and women living with HIV
- History of incarceration
- History of commercial sex work
- Certain racial/ethnic groups (AA > Hispanic > white)
- Being a male younger than 29 years
- Regional variations (hot spots)

Implications for Family Planning Clinics

- Are you in a “hot spot” area??
- In-service clinicians re: syphilis screening guidelines
- Offer screening: based on risk factors or other clinical indications
 - Seeking pregnancy
 - Other STI testing requested/positive
 - IUC/EC visits
 - New partners
- Offer treatment for confirmed syphilis cases

PrEP is

- Short for pre-exposure prophylaxis
- A pill taken once a day to prevent HIV
- Safe
- Over 90% effective when taken daily

LEARN MORE AT



FOR ASSISTANCE FINDING PREP OR TO CHAT WITH US
VISIT [PLEASEPREPME.ORG](https://pleaseprepme.org) OR CALL/TEXT 707.820.7737.
EMAIL US AT CONTACT@PLEASEPREPME.ORG.



AS WOMEN, IT IS IMPORTANT TO HAVE AN HIV PREVENTION METHOD THAT IS IN OUR HANDS.

Consider PrEP if you are a woman who:

- Worries about her HIV risk
- Has condomless sex with partners of unknown HIV status
- Recently had gonorrhea or syphilis
- Wants to have a baby with a man living with HIV
- Injects drugs
- Exchanges sex for \$/food/housing/drugs

has a male sex partner who:

- Has condomless sex with others
- Has sex with men
- Injects drugs
- Has HIV or sexually transmitted infections

contact@pleaseprepme.org



PrEP vs. PEP

- PrEP = *Pre-exposure* prophylaxis for HIV prevention

HIV-negative individuals take antiretroviral medications before and after exposure for an *indefinite* amount of time

- PEP = *Post-exposure* prophylaxis

HIV-negative individuals take antiretroviral medications after exposure *for 28 days*

Why Offer PrEP?



- *Patients* want integrated sexual & repro healthcare
- *Providers* are uniquely qualified to offer comprehensive sexual & reproductive healthcare
- Prevention of other STI's (e.g., HPV vaccine, genital herpes prophylaxis) already offered
- Many individuals access healthcare only through FP visits
- Offering PrEP is a way to promote health equity



Offer PrEP to persons at high risk of HIV acquisition

Grade [A] recommendation

- Unusual, since most are Grade [B]
- All non-grandfathered health plans must cover PrEP without cost-sharing no later than 2021

Indications for PrEP

- A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
- Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk
- Inconsistent use of condoms during anal sex (MSM)
- Syphilis or GC within the past 6 months

Indications for PrEP

- Persons who inject drugs with shared use of drug injection equipment
- Persons who engage in transactional sex
 - Sex for money, drugs, or housing
 - commercial sex workers
 - persons trafficked for sex work

How Is PrEP Given?

PrEP is currently only available as Truvada®...but new formulations are coming soon

- Tenofovir/emtricitabine 300/200 mg: 1 tab orally / day
- Prescribe < 90-day supply
- Refill after confirming patient remains HIV-negative

GileadAdvancingAccess.com program

- Insured: co-payment assistance to \$7,200 per year
- Uninsured: Gilead Medication Assistance Program

Monitoring PrEP patients

The CDC guidelines recommend that people taking PrEP be seen every 2-3 months in order to:

- Test for HIV infection
- Check for side effects of Truvada
- Check for problems taking PrEP every day
- Reinforce condom use and other prevention messages
- Check for side effects: (common initially: headache, nausea, vomiting, rash and loss of appetite; infrequent intermediate: increased creatinine and transaminases; rare long term: decreased bone mineral density, kidney failure)



Newly FDA-Approved Methods of Contraception

Liletta extension

28 OCT 2019

PRESS RELEASES

FDA Approves Medicines360's LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg to Prevent Pregnancy for up to Six Years, the Longest Approved Duration of Use of Any Hormonal IUDs

SAN FRANCISCO and DUBLIN – Medicines360, a global nonprofit organization with a mission to expand women's access to quality medicines, and Allergan plc (NYSE: AGN), a leading global pharmaceutical company, announced that the U.S. Food and Drug Administration (FDA) approved Medicines360's Supplemental New Drug Application (sNDA) to extend the duration of use of LILETTA®

“Extended use” review



- Among parous women ≥ 25 yo at IUD insertion:
 - TCu380A (Paraguard®) and the TCu220 for **12 years**
 - Levonorgestrel Intrauterine System (Mirena® or Liletta®) 52 mg for **7 years**
- Women 35 yo at insertion of TCu380A IUD can continue use until menopause with a negligible risk of pregnancy
- No data to support use of the LNG-IUS 13.5 mg (Skyla®) beyond 3 years

Slynd™ (Drospirenone 4 mg) POP (progestin only pill)

DRSP is 4th gen progestin in some COCs: Yaz, Yazmin, Ocella

- Diuretic effect like spironolactone; may help PMDD

24/4 Dosing Regimen

- 24-hour missed pill window

No thromboembolic risk (vs. increased risk with COC)

- No black box warning, unlike other COCs

Annovera Contraceptive Vaginal Ring (CVR)



The Basics: Annovera CVR

Single ring prevents ovulation for one year (13 cycles)

- Segesterone acetate (Nestorone®) + ethinyl estradiol
- Used in 28-day cycle; monthly withdrawal (menses)
- Side effect and bleeding profile similar to NuvaRing
- Same diameter as NuvaRing, but twice as thick

FDA approval on August 10, 2018

Use of the Annovera CVR

- In for 21 days, then removed for 7 days to induce a scheduled bleed
- Can remove for up to 2 hours for intercourse or cleaning
- Can use water-based creams and lubricants
- Can *not* use oil and silicone-based lubricants due to altered exposure to EE and segesterone

Comparison of CVRs

	NuvaRing	Annovera
Lifespan	30 days	1 year
Progestin release rate	Etonogestrel 120 mcg/day	Segesterone 150 mcg/day
EE release rate	15 mcg/day	13 mcg/day
Diameter	54 mm	56 mm
Thickness	4 mm	<u>8.4 mm</u>

Dispense More Pills, Patches, & Rings

- Provision of 12 or 13 cycles of OCs
- Halves pregnancy and abortion rates
- Decreases coverage gaps
- Improves continuation of use
- “Wastage” is minimal (8-10 % of cycles)
- Is cost effective

HBOCS Counseling and Testing



Women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or an ancestry associated with *BRCA1/2* gene mutation

The USPSTF recommends that primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with breast cancer susceptibility 1 and 2 (*BRCA1/2*) gene mutations with an appropriate brief familial risk assessment tool. Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing.

B

Tools show who *should receive counseling*, not testing

ACA requires *no cost sharing* for counseling and testing for women who have not been diagnosed previously with a cancer

Breast Cancer Chemoprevention

Recommends that clinicians *offer to prescribe* risk-reducing medications to women who are at increased risk for breast cancer and at low risk for adverse effects

Cost of prescription on GoodRx.com

- Letrozole 2.5 mg: \$12-13/ month
- Tamoxifen 20 mg: \$20-23/month
- Raloxifene 60 mg: \$26-28/ month

Why Does This Affect Family Planning Clinics?

- Breast cancer risk assessment recommended in the QFP as a core family planning service
- Intervention
 - Give up routine screening clinical breast exams
 - Replace with genetic risk assessment and consider offering of prescription of chemoprevention drugs

2018 Cervical Cancer Screening Guidelines

	< 21	21-29 y.o.	30-65 y.o.
USPSTF 2018	[D]	Cytology every 3 yrs	Co-test: every 5 years or Cytology: every 3 yrs or hrHPV alone: every 5 yrs
Triple A 2012	None	Cytology every 3 yrs	Co-test: every 5 or Cytology: every 3 yrs
ACOG 2016	Avoid	Cytology every 3 yrs	Co-test: every 5 or Cytology: every 3 yrs

Coming Soon! ASCCP 2020 Consensus Guidelines

Focus on finding CIN 3

Prior history critical re: “persistent HPV infection”

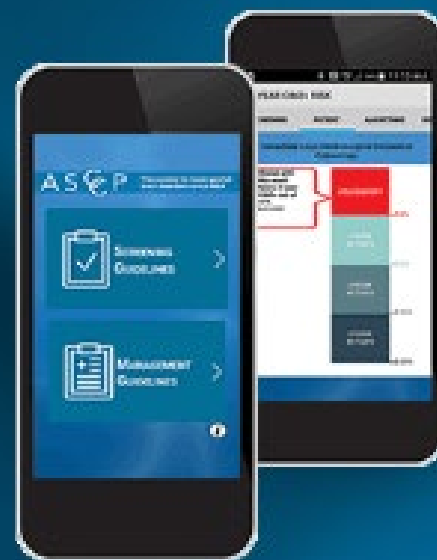
Figure 1. Summary of Risk-based Clinical Action Thresholds

CIN3+ risk Risk	Surveillance		Colposcopy		Treatment	
	Return in 5 years equivalent to general population with one negative HPV or co-test	Return in 3 years similar to a negative screening cervical cytology	Return in 1 year between colposcopy and 3-year return thresholds	Colposcopy Approximate risk of low-grade to moderately abnormal results in a screening population (e.g. LSIL)	Colposcopy or Treatment Approximate risk of moderate to high risk results in a screening population (e.g. ASC-H)	Treatment preferred* Very high risk results (e.g. HSIL/ HPV 16+)
	≤0.1% at 5 years	0.2% -0.5% at 5 years	0.6% at 5 years to <4% immediate risk	4%-24% immediate	25%-49% immediate	≥50% immediate



UPDATED CONSENSUS GUIDELINES

ASCCP Mobile App



Download

Android, iPhone, iPad, Spanish
Language

FDA Approves Gardasil 9 (27-45 year olds)

October 2018

9vHPV studied in 3,200 women 27-45 followed for 3.5 yrs

- 88% decrease in persistent infection, genital warts, precancerous cervical, vaginal, vulvar lesions (covered types)

In men 27-45 years, approval was based upon

- Efficacy data in women for this age group
- Earlier trials in boys and younger men
- Immunogenicity data from 150 men in older age group

FDA Approval: Gardasil 9 for 27-45 year olds

Why does it work in older individuals?

- Even if previously exposed to a few types, can gain protection against HPV types not yet encountered

CDC ACIP does not recommend the initiation of vaccination in this age group.

“Engage in shared decision-making about catch-up series for those incompletely vaccinated as adolescents”

Reproductive Health Apps

Medical Eligibility Criteria for Contraceptive Use &
Selective Practice Recommendations

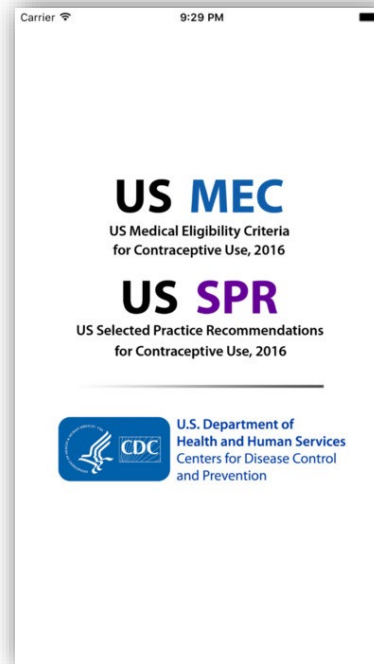
2020

STD Treatment Guidelines



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

STD Tx Guidelines



2020



ASCCP: Cervical cancer screening

Questions?

Keep up the good work of meeting the sexual
and reproductive health needs of Californians

Thank you!!