

## Testing and Treating (and Preventing) STIs in People Living with HIV

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### Financial Relationships With Ineligible Companies (Formerly Described as Commercial Interests by the ACCME) Within the Last 2 Years:

Dr Clement reports research grants paid to her institution from Gilead Sciences, Inc., ViiV Healthcare, and Janssen. She has been on Advisory Boards for ViiV Healthcare. She receives royalties from UpToDate, Inc. (Updated 03/17/23).

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### Learning Objectives

After attending this presentation, learners will be able to:

- Manage and treat STIs in People with HIV
- Describe recent updates to CDC guidelines
- Weigh risks and benefits of antibiotic prophylaxis for STIs

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## Outline

- STI Epi Overview
- Testing and Treatment Updates
- Recent data on STI Prevention
- Mpox

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## Outline

- **STI Epi Overview**
- Testing and Treatment Updates
- Recent data on STI Prevention
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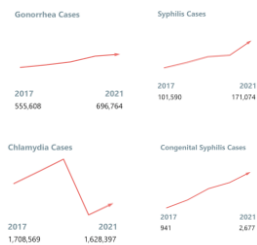
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## 2021 STI Surveillance – Preliminary Data

2.5 million cases

Preliminary data show 2.5 million reported cases of chlamydia, gonorrhea, and syphilis in 2021.



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<https://www.cdc.gov/std/statistics/2021/default.htm>

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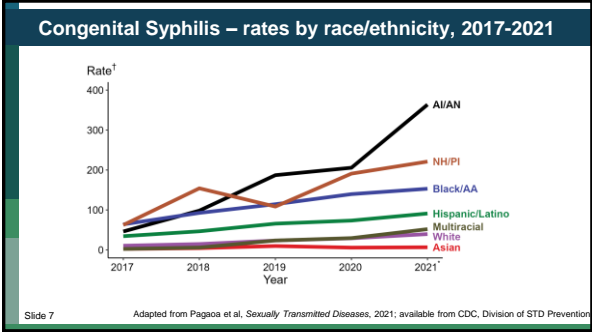
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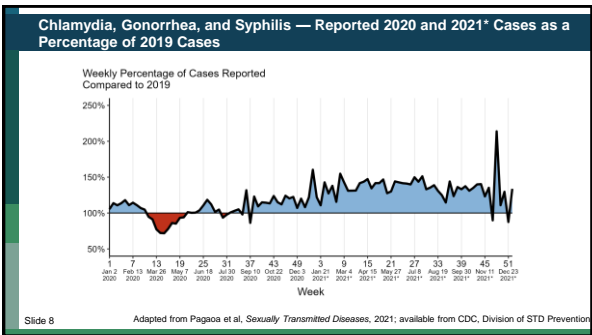
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## Outline

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### STI Prevention – Home Testing

**Home Testing:**

- Mail-in Testing Kits – available and generally reliable
- 2015 Cochrane Review: Clients participating in home-based testing prefer the simplicity, security, and privacy of self-collected specimens
- CDC: Molecular Testing Labs - CLIA licensed, ordered by physicians, covered by most insurance



**National Coalition  
of STD Directors**  
At-home Self-collection Lab Testing  
for Sexually Transmitted Infections  
Technical Assistance Brief  
Updated May 20, 2020

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Fajardo-Bernal et al. Cochrane Database Syst Rev. 2015 Sep 29;(9):CD011317.

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### STI Prevention – Home Testing



**STATE SPECIFIC SELF-TESTING SERVICES**

■ Local Jurisdiction Self-Testing Service Available ■ Self-Testing Service Available ■ No Information

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<https://www.nacstd.org/images/state-specific-self-testing-services>

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### STI Treatment- 2021 Recommendations

## Sexually Transmitted Infections

#### Summary of CDC Treatment Guidelines—2021

Updates for the following STIs:

- *Gonorrhea*
- *Chlamydia*
- *Trichomonas vaginalis*
- PID

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# STI Treatment – 2021 Recommendations

## Regimen for Uncomplicated Gonococcal Infections of the Cervix, Urethra, or Rectum

**Gonorrhea** should be treated with a **single 500 mg injection of ceftriaxone**

CDC no longer recommends a 2-drug approach.

- Ceftriaxone 500mg IM as a single dose for those weighing <150 kg (or 300 lb)
- If weight ≥ 150 kg (300 lb) → Ceftriaxone 1000mg IM

- If chlamydia infection has not been excluded, treat with doxy 100 mg BID for 7 days
- During pregnancy, still use azithromycin 1 g to treat chlamydia
- For pharyngeal GC, TOC needed at 7-14 days

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# STI Treatment – 2021 Recommendations

**Graph 1: Free CRO in Plasma (μg/mL) vs Time (h)**

**Graph 2: CRO Dose (mg/kg) vs Gc Clearance (%) at 48 h Post-treatment**

**Graph 3: CRO Dose (mg/kg) vs T<sub>max</sub> (h)**

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# STI Treatment- 2021 Recommendations

**Percentage of STI cases by year (2009-2018)**

Legend: Ceftriaxone, Cefixime, Azithromycin

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# Chlamydia

IN NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

## Azithromycin Versus Doxycycline for Urogenital Chlamydia trachomatis Infection

Robert A. Anderson, M.D., M.P.H., Elizabeth A. Jensen, M.D., M.P.H., Shelly Y. Leung, M.D., Elizabeth K. Foreman, D.D.V.M., Kenneth A. Douglas, Jr., M.D., M.P.H., Lawrence H. Harrison, M.D., and Bruce R. Brown, D.D., M.P.H.

Clinical Infectious Diseases  
**MAJOR ARTICLE**

AIDS

## Treatment Effectiveness of Azithromycin and Doxycycline in Uncomplicated Rectal and Vaginal Chlamydia trachomatis Infections in Women: A Multicenter Observational Study (FemCure)

David A. Hays, M.D., M.P.H., Robert L. Cook, M.D., M.P.H., Elizabeth A. Jensen, M.D., M.P.H., Robert A. Anderson, M.D., M.P.H., and Bruce R. Brown, D.D., M.P.H.

### RCT: UGC infection in participants from young commercial facilities

- 155 pills in per-protocol analysis
- 0 failures in azithromycin group; 5 failures in doxycylin
- Non-inferiority of azithromycin not established

### RCT – MSM with rectal chlamydia

- 177 infections, cure rate 91% (80/88) with doxy and 71% (63/89) with azithromycin, absolute difference 20%, P<0.001

Clinical Infectious Diseases  
**MAJOR ARTICLE**

AIDS

### Doxycycline Versus Azithromycin for the Treatment of Rectal Chlamydia in Men Who Have Sex With Men: A Randomized Controlled Trial

Elizabeth A. Jensen, M.D., M.P.H., Robert A. Anderson, M.D., M.P.H., Shelly Y. Leung, M.D., M.P.H., Kenneth A. Douglas, Jr., M.D., M.P.H., Lawrence H. Harrison, M.D., and Bruce R. Brown, D.D., M.P.H.

### Prospective cohort study of cisgender women:

- 341 rectal infections
- Microbiological cure in azithro-treated group was 78.5% (164/209) and 95.5% (126/132) in doxy-treated group
- Difference, 17.0%, P<.001.

[illegible]

# Chlamydia

- Treat uncomplicated pharyngeal, rectal, or urogenital infections with doxycycline 100mg BID x 7 days
- Alternative: Azithromycin 1 g x one dose
- Azithromycin for pregnant women
- Don't forget LGV: extend course to 21 days if bloody discharge, perianal or mucosal ulcers, or tenesmus with positive chlamydia test

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## ARS Question 1

A 43-yo cisgender woman with HIV presents to your HIV clinic for routine care. She takes bicittegravir/emtricitabine/tenofovir alafenamide with good adherence. She has had two sexual partners in the past year. She has always had normal Pap smears and is on a schedule of receiving them every three years; her last Pap two years ago was normal. She has not had STI screening in recent years and requests testing today. In addition to ordering tests for syphilis, gonorrhea, and chlamydia, what other testing should be ordered?

- a. HPV testing
- b. Vaginal gram stain
- c. Vaginal culture
- d. NAAT for *T. vaginalis*

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- b. Vaginal gram stain
- c. Vaginal culture
- d. **NAAT for *T. vaginalis***

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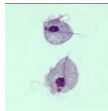
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### Trichomonas

- Screen women with HIV upon entry to care and annually with NAAT
- Test women with discharge
- Treatment:
- Clearance can take up to 3 weeks (with NAAT)
  - Metronidazole 500 mg BID x 7 days for vaginal infections
  - Tinidazole 2g one time as alternative
  - 2g dose for men
- If persistent infection, perform resistance testing, consider combination treatment



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<https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm>

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### Pelvic Inflammatory Disease

- IM/oral (outpatient) treatment:
  - Ceftriaxone 500 mg PLUS doxy 100 mg q12h x 14 days PLUS metronidazole 500 mg q12h x 14 days
- Clindamycin + gentamicin is alternative



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<https://www.cdc.gov/std/pid/stdfact-pid.htm>

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## STI Prevention – Antibiotic Prophylaxis

### iPERGAY OLE: Doxycycline Post-Exposure Prophylaxis Study

Randomized Open-Label Trial (July 2015- July 2016)

- HIV-negative high risk MSM
- Enrolled in the ANRS iPERGAY Open-label extension study
- No contraindication to Doxy

On Demand PEP with Doxycycline  
(200 mg ~ 24h after sex, up to 72h)\*

No PEP

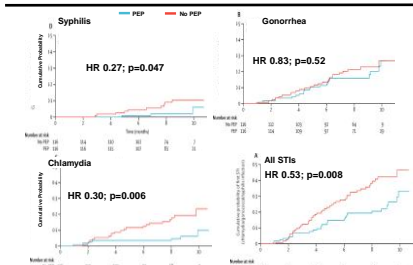
- 232 Participants
- Follow-up: median of 8.7 months

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Molina JM et al. Lancet ID 2018

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### iPERGAY OLE: PEP with Doxycycline and Incidence of Bacterial STIs



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Molina JM et al. Lancet ID 2018

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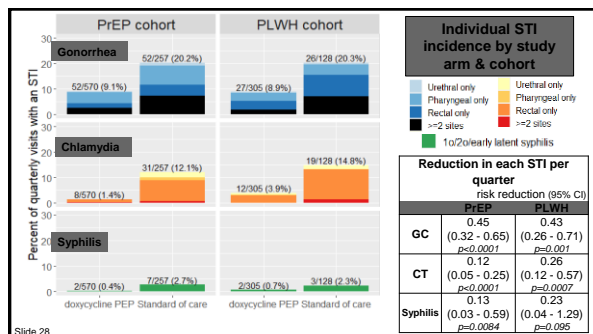
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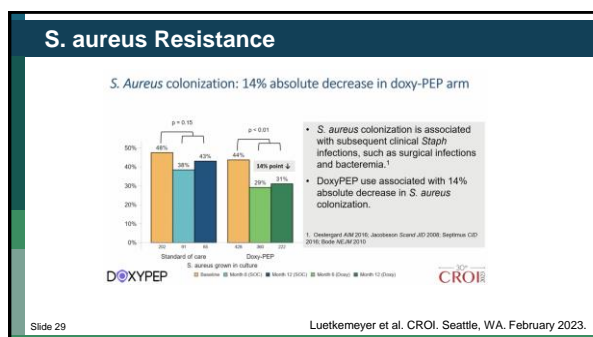
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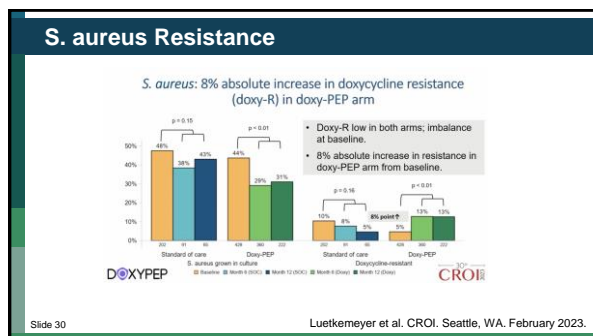
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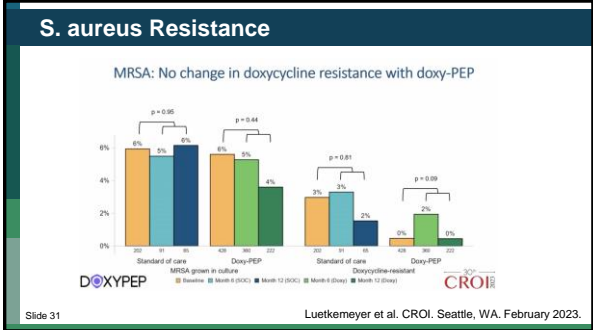
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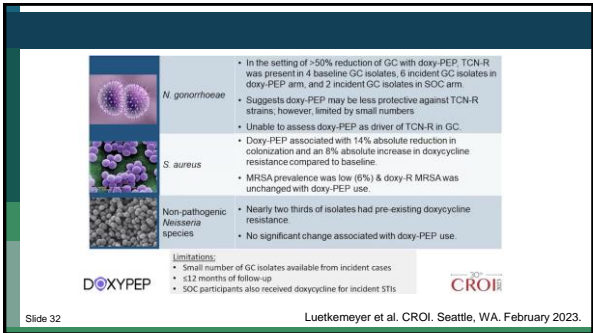
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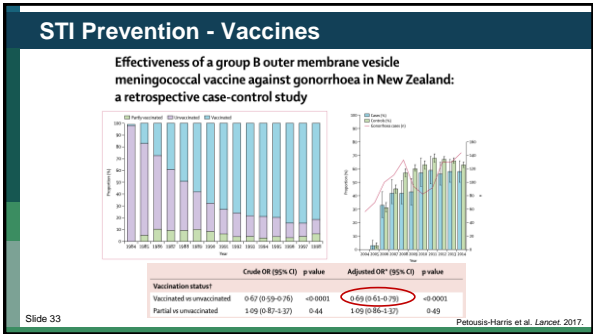
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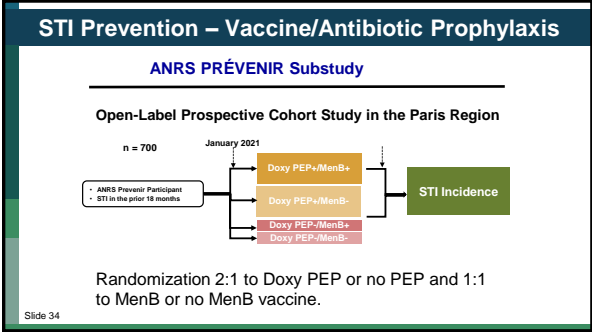
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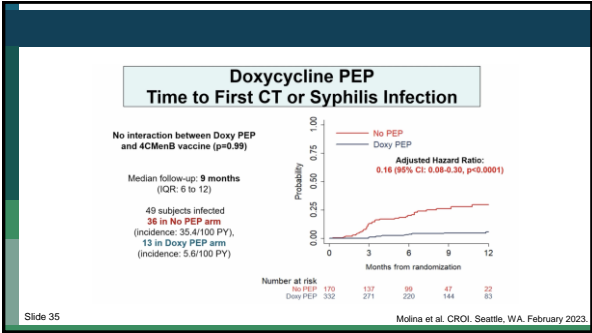
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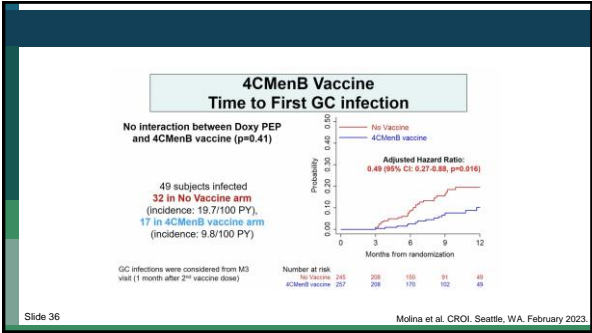
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## DOXYCYCLINE POSTEXPOSURE PROPHYLAXIS FOR PREVENTION OF STIs AMONG CISGENDER WOMEN

Cisgender women bear the highest burden of morbidity and mortality from bacterial STIs (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Treponema pallidum*)<sup>1,2</sup>.

We conducted the first trial of doxycycline PEP among cisgender women.

### STI sequelae

- PID
- chronic pain
- infertility
- pregnancy complications
- HIV acquisition

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Stewart et al. CROI 2023.

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## Results

### Results – Incident STIs

Analyze	Endpoint	Total	PEP (n=224)	DOC (n=225)	RR	95% CI	P-value
Intention to Treat	All STIs	109	50	59	0.88	0.60-1.29	0.51
	Chlamydia	85	35	50	0.73	0.47-1.13	0.18
	Gonorrhea	31	19	12	1.84	0.79-5.47	0.19

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### Doxycycline as STI PEP: Considerations for Individuals and Healthcare Providers of Gay or Bisexual Men or Transgender Women

As CDC and others work quickly to evaluate data to inform clinical guidance on the safe and effective use of post-exposure prophylaxis with doxycycline (also called doxy as PEP) to prevent gonorrhea, chlamydia, and syphilis, we acknowledge there are individuals and clinicians who are already engaged in the off-label use of doxycycline as bacterial STI post-exposure prophylaxis or considering it. As such, we are providing the following considerations to inform those decisions:

- Current efficacy data only applies to gay and bisexual men and transgender women. Studies among heterosexual cis-gender women are ongoing.
- Doxycycline 200 mg administered within 24-72 hours of condomless sex was the regimen evaluated in this study. Other antibiotics should not be considered for PEP.
- In addition to informing patients about the potential STI prevention benefits of doxy as PEP, providers should also counsel patients about potential adverse side effects of doxycycline including phototoxicity, gastrointestinal symptoms, and more rarely esophageal ulceration.
- Providers should continue to screen, test, and treat for bacterial STIs in accordance with CDC's STI Treatment Guidelines and CDC's PrEP for the Prevention of HIV guidelines , even among people who may be using doxycycline as PEP or PrEP.

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<https://www.cdc.gov/std/treatment-guidelines/clinical-primary.html#CautionsForDoxPEP>

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## Antibiotic Prophylaxis for STI Prevention

Considering Risks/Benefits

- Resistance implications
- Changes in microbiome
- Side effects
- Cost?
- Risk Compensation

Figure: Recommendations for research activities

- Clinical efficacy:** Quantifying clinical efficacy in a variety of populations is needed.
- Dosing strategies:** Daily and post-exposure/event-driven dosing is being studied. Other options, such as weekly dosing, should be investigated.
- Coin group focused intervention:** Modeling and analyses of pooled study data are needed to identify the populations most suitable for maximizing the impact of doxycycline prophylaxis.
- Formulation:** Clear information on the frequency of side effects for different doxycycline formulations is needed. Direct comparisons using randomized clinical trials may be appropriate. Further long-term studies on side effects are also needed.
- Educational efforts:** Prior to broad implementation, effective educational campaigns are needed to ensure that high-risk populations clearly understand the difference between HIV PrEP and Doxy PEP/PEP.
- Risk compensation:** Ongoing monitoring for risk compensation in all trials is critical.
- Resistance monitoring:** All studies should robustly investigate development of resistance in bacterial STIs as well as commensal organisms. Standardized laboratory methods for defining and monitoring doxycycline resistance in STIs are needed.
- Cost-effectiveness:** Cost-effectiveness analyses are needed to better understand the utility of Doxy PEP/PEP.

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Grant et al. Clin Infect Dis. 2019

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## Mpox in the United States

U.S. Cases

Total Cases: 30,225

U.S. Deaths

Total Deaths: 38

Legend

- 0 to 10
- 11 to 50
- 51 to 100
- 101 to 500
- 500+

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<https://www.cdc.gov/poxvirus/mpox/response/2022/us-map.html>

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## ARS Question 2

A 55-yo cisgender man with HIV well-known to your HIV clinic presents with painful vesicular anorectal lesions. His last CD4 count from 18 months ago was 74 (8%) with a viral load of 22,000. HSV testing is negative but his Polymerase chain reaction (PCR) testing for orthopoxvirus DNA is positive. You are concerned for Mpox and you initiate treatment with tecovirimat. All of the following populations should be prioritized for treatment except:

- a. People age 65 years and older
- b. Pregnant or breastfeeding people
- c. People with skin conditions such as psoriasis
- d. People with severe immune compromise (e.g. advanced HIV, leukemia, SOT)

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## Mpox Outcomes – CD4 $\leq$ 350



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Orkin C, et al. Mpox in People Living with HIV and CD4  $<350$  cells/mm<sup>3</sup>: A global case series. CROI 2023.

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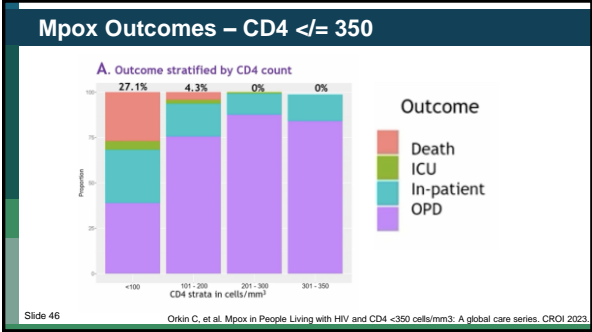
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**Mpox**

DEATHS	TOTAL: n (%) N = 27/382 (7.1%)
CD4 count (cells/mm <sup>3</sup> ) - median (IQR)	35 (24-100)
Deaths with CD4 count $\geq$ 200	0
Death rate with CD4 $\geq$ 200	15% (27/179)
Death rate with CD4 $\leq$ 100	27%
Viral Load (log copies/mL) - median (IQR)	5 (4-9)
Complications	
Severe coalescing or necrotising skin lesions	25 (93%)
Blood stream or 2 <sup>o</sup> bacterial infections	24 (89%)
Respiratory symptoms and respiratory failure	23 (85.0%)
Rectal complications	21 (78%)
Oropharyngeal	18 (78%)
Ocular	13 (48.5%)
CNS	8 (30%)
Cause of death	
Septic shock and multiorgan failure	20 (74.1%)
Respiratory failure	4 (14.8%)
Disseminated mpox	2 (7.4%)
Cardiac arrest	1 (3.7%)

Slide 47 Orkin C, et al. Mpox in People Living with HIV and CD4  $\leq$ 350 cells/mm<sup>3</sup>: A global care series. CROI 2023.

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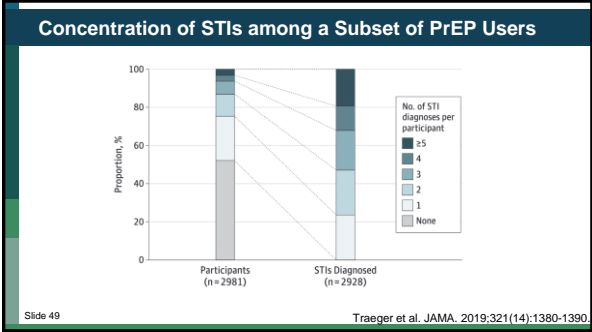
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