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# *Use of HIV pre-exposure prophylaxis during conception, pregnancy and lactation at 2 U.S. medical centers*

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# Considerations for PrEP use in and around pregnancy

## BENEFITS

- Prevent maternal HIV acquisition
- Prevent neonatal transmission

## RISKS

- Maternal toxicity/side effects
- Potential teratogenicity
- Potential infant toxicity



# Rationale for PrEP during pregnancy & lactation

- **Pregnancy is associated with ~2X increased risk of HIV acquisition**
- **Acute HIV during pregnancy associated with ~8X increased risk of perinatal transmission**
- **Acute HIV during breastfeeding associated with ~4X increased risk of neonatal transmission**

# Risks of PrEP?

- **Preconception**

- signal towards association with pregnancy loss?
  - 42.5% for FTC+TDF vs. 32.3% for placebo (difference 10.2%; 95% CI, -5.3% to 25.7%;  $p = 0.16$ )

- **Pregnancy**

- APR: adequate 1<sup>st</sup> trimesters exposures to detect 1.5X risk of overall birth defects
- No impact on in utero growth; conflicting post-natal growth data
- Possible effect on infant bone mineral content

- **Postpartum & lactation**

- TDF/FTC secreted in breast milk, but infant levels <2% proposed infant doses
- No difference in contraceptive efficacy or efficacy of PrEP in setting of contraception

Mugo JAMA 2014; Antiretroviral Pregnancy Registry 1989 –2015; Siberry AIDS 2012; Ransom JAIDS 2013; Gibb PLoS Med 2012; Siberry CID 2015; Himes J Pediatric Infect Dis 2015; Benaboud Antimicrobial agents and Chemotherapy 2011; Heffron AIDS 2014; Murnane AIDS 2014.

# Guideline recommendations



- *PrEP-ception is one of many options*
- *“Pregnancy & breastfeeding are not contraindications to PrEP”*



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- *Limited data, but TDF/FTC commonly used in pregnancy and has “reassuring” safety profile*
- *Practice vigilance for new HIV infections in lactating women*



- *Discuss risks/benefits/alternatives of PrEP with pregnant & breastfeeding women*



# Objective

***Describe offering PrEP to women at substantial risk of HIV in and around pregnancy at 2 medical centers in the United States***

# Methods

- **Retrospective chart review at 2 medical centers in San Francisco and New York**
- **Subjects**
  - Women identified as at substantial risk of HIV preconception, during pregnancy and lactation
  - Referred to specialty clinics for women living with or at substantial risk of HIV
- **Time period: 2010 - 2015**
- **IRB approved**

# Results

- **Who identified women?**
  - Obstetricians, midwives, general practitioners, partners' providers, health educators, & health departments
- **When were women identified?**
  - 27% preconception (8/30)
  - 70% during pregnancy (21/30)
    - Median gestational age 20 weeks, range 7 – 32
    - None received safer conception counseling
  - 3% postpartum (1/30)
- **When were women offered PrEP?**
  - Median time to consultation: 30 days (IQR 2-62)
  - Two women lost to follow-up before consultation



# Demographics

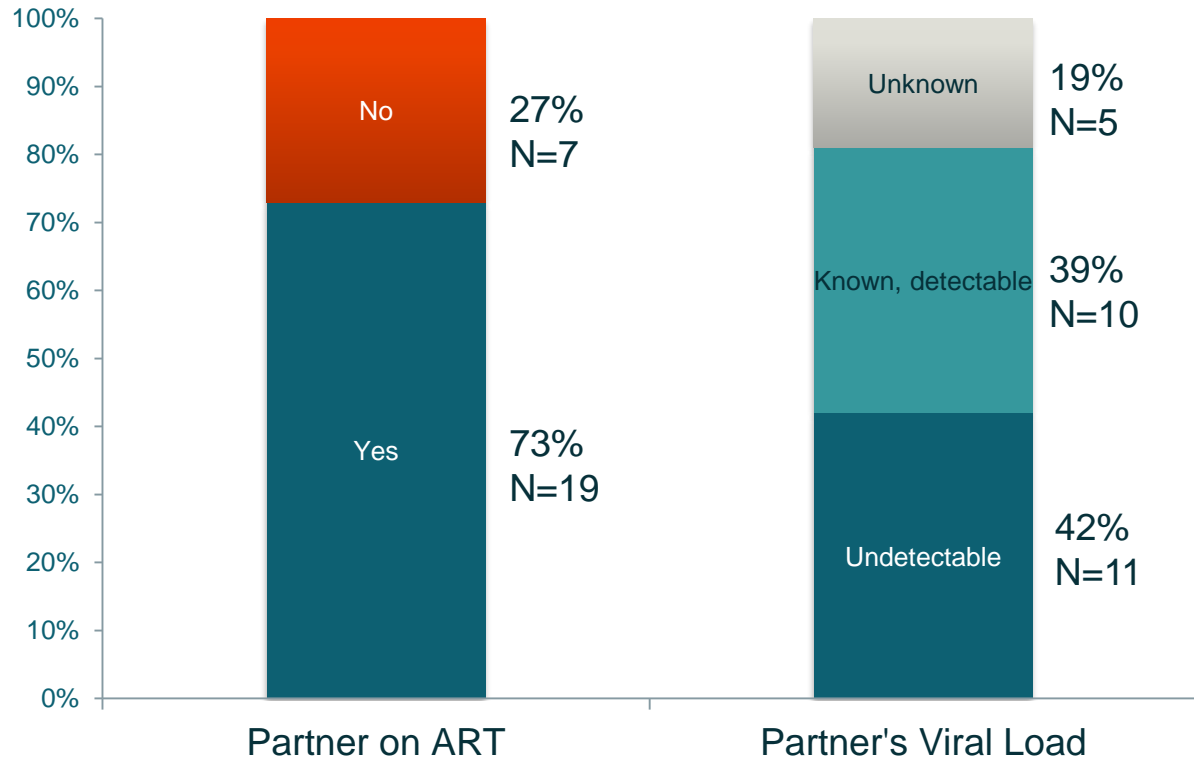
	N=27 (%)
Age, years (median, range)	27 (18 – 43)
Race	
Black	5 (19)
White	4 (15)
Latino	12 (44)
Asian	2 (7)
Other	4 (14)
Graduated high school	9 (26)
Unstable housing or homeless	14 (52)
Current IPV	6 (22)
Current substance use	6 (22)
History of mental health disorder	12 (44)
Parity (median, range)	1 (0-4)



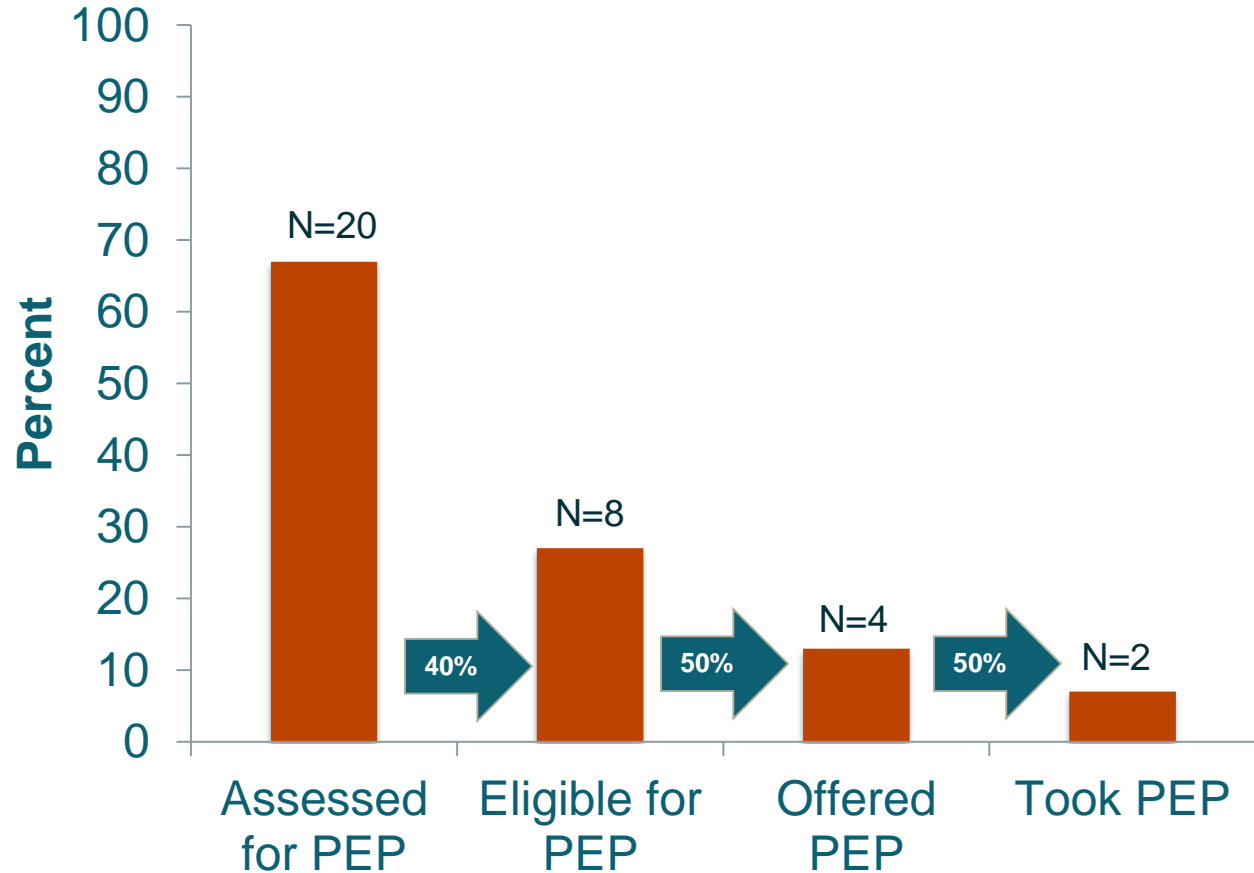
# Risk factors for HIV

- 26/27 women had partner who was a man living with HIV
- 1/27 women had partner who was MSM

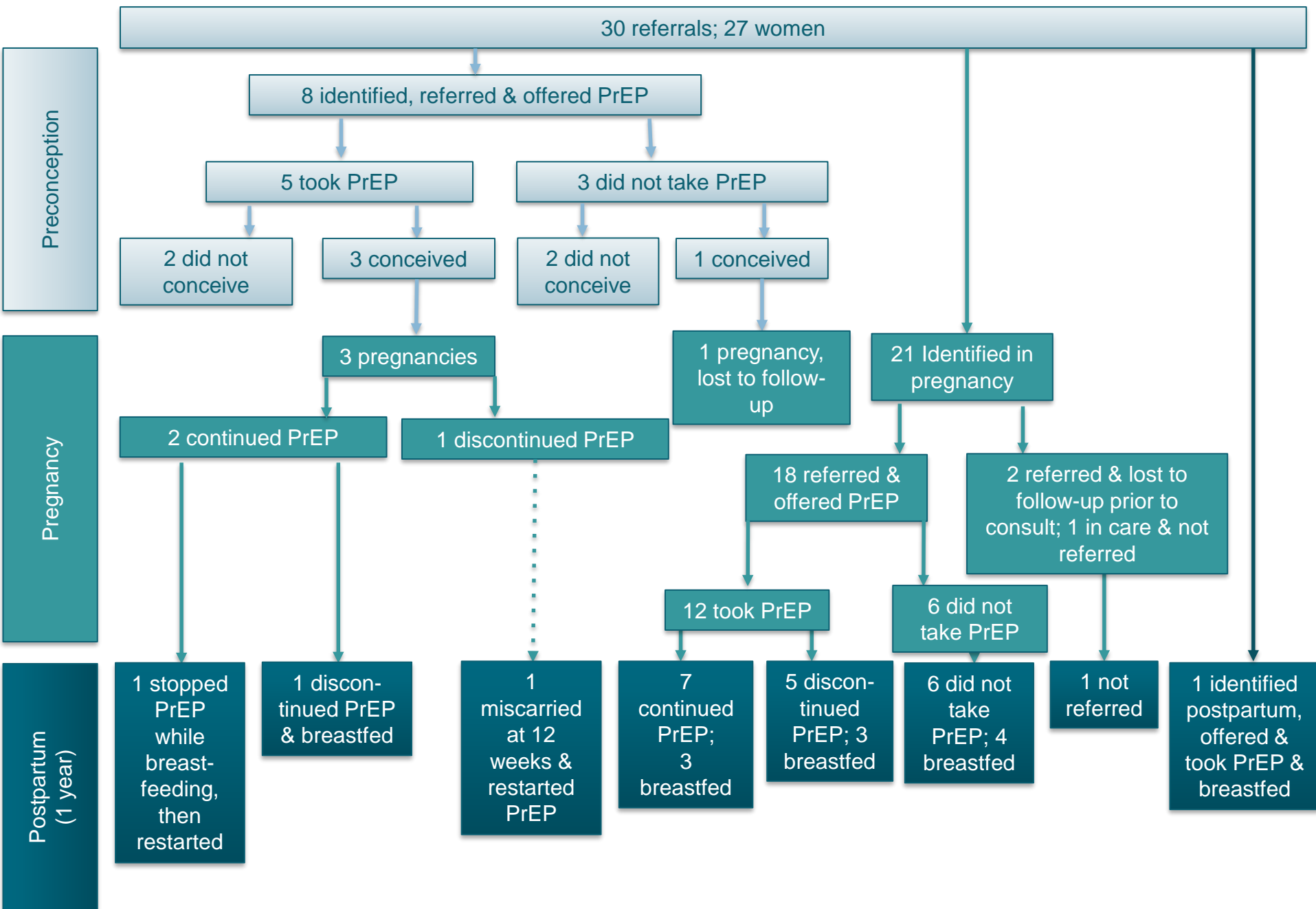
Partner's treatment status and viral load



# PEP evaluation & provision at presentation



# Women identified as at substantial risk of HIV acquisition pre-conception, during pregnancy and postpartum at 2 U.S. centers



# HIV prevention methods used

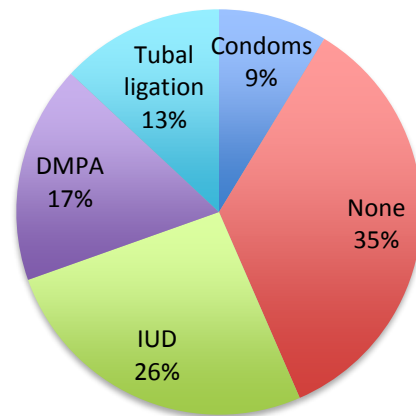
- **67% (18/27) of referrals offered PrEP chose to use PrEP**
  - 63% (5/8) preconception patients
  - 67% (12/18) pregnant patients
  - 100% (1/1) postpartum patients
- **33% (9/27) of referrals offered PrEP chose not to use PrEP**
  - 67% (6/9) chose condoms
  - 56% (5/9) chose treatment as prevention
  - 22% (2/9) chose abstinence

# PrEP use

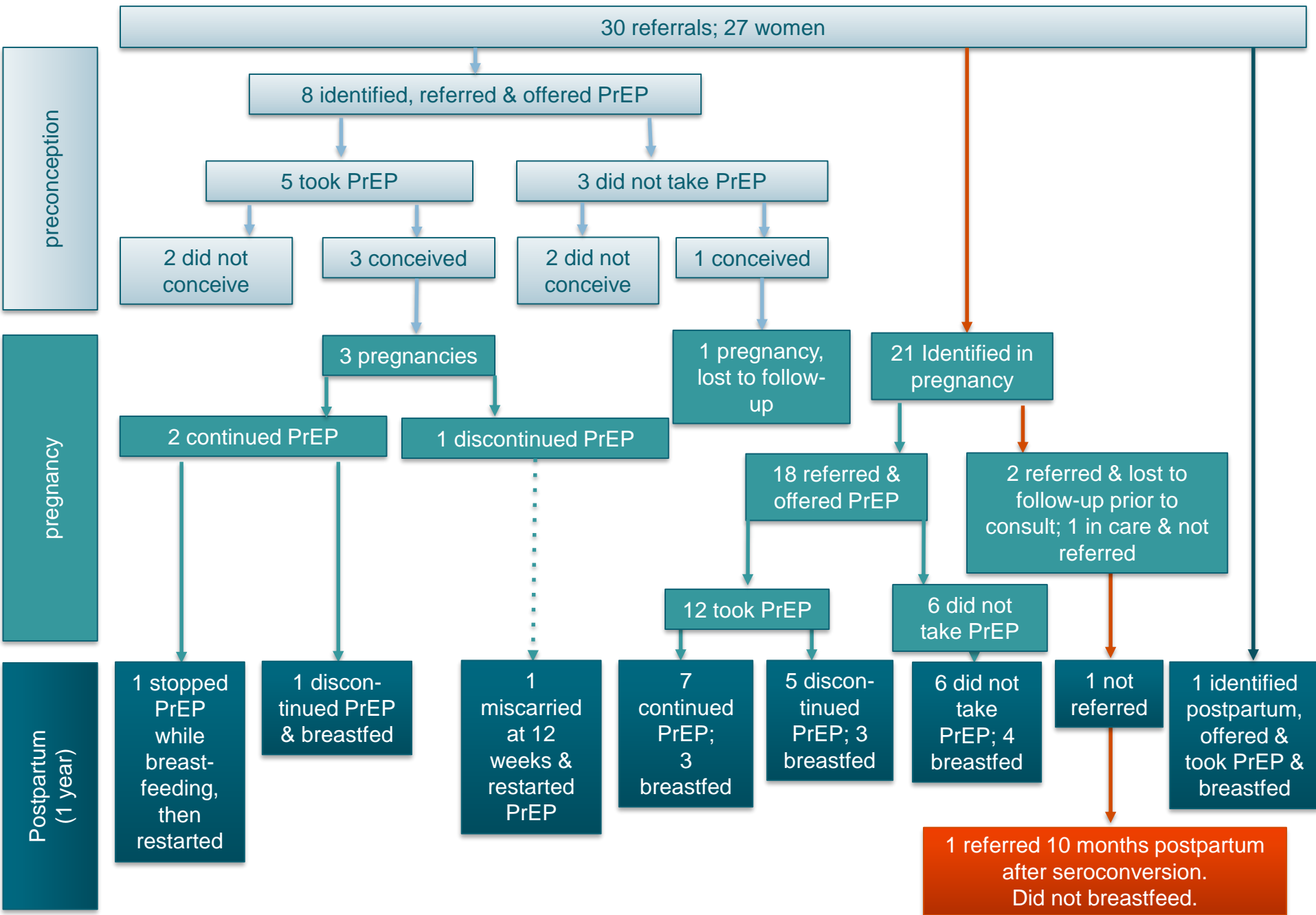
- **Median time on PrEP: 30 weeks (range 4 - 74)**
- **50% (9/18) reported any adherence challenge**
  - 33% due to side effects (3/9)
  - 33% due to social stressor(s) (3/9)
  - 33% due to difficulty with a daily pill (3/9)
- **Pregnancy complications related to PrEP use: none identified**

# Postpartum

- **57% (13/23) of women in care at delivery did *not* follow up postpartum**
- **Breastfeeding**
  - 50% (4/8) of women who took PrEP postpartum breastfed
  - 53% (8/15) of women who did not take PrEP postpartum breastfed
- **Contraception (N=23)**



# Who was missed?





## 3 women not offered PrEP

Presented to ED s/p assault, 27 weeks pregnant. Disclosed partner living with HIV and not on meds. Not offered PEP or PrEP. Lost to follow-up.

Diagnosed with syphilis, 32 weeks pregnant. Reported many partners, some of whom living with HIV. Homeless, engaging in exchange sex, active meth use. Treated for syphilis, multiple brief OB triage visits, never offered PEP/PrEP & lost to follow-up.

Late presentation to care, diagnosed with significant fetal anomalies at 30 weeks. Disclosed partner living with HIV at first visit. Seen twice weekly until delivery. Never referred for consult but had frequent HIV testing. Viral load negative at delivery. Infant died postpartum and patient lost to follow-up. Represented 10 months postpartum, positive HIV test, referred for care.



# Discussion

- **When offered pre-conception, during pregnancy and lactation, women at 2 U.S. centers frequently chose to use PrEP**
- **Identification of women at substantial risk may occur at multiple points in the healthcare system requiring multidisciplinary trainings on screening, referral, PEP & PrEP**
- **The postpartum period is particularly vulnerable to loss to follow-up**

# Limitations

- **Retrospective chart review**
- **2 U.S. centers - limited generalizability**
- **Practice changed over time**
- **Sampling limited to women who were referred to clinics**

# Future directions

- **Further research is needed**
  - Safety, efficacy and acceptability of PrEP in & around pregnancy
  - Best practices for implementation & dissemination
  - Strategies to reach women most vulnerable to HIV & engage them in care

# Acknowledgements

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- **Women & HIV Workshop**
- **Clinic patients and staff**

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