On Beyond Condoms: PreExposure Prophylaxis for Women

Maria Teresa Timoney CNM
Bronx Lebanon Hospital Center
June 8, 2017
HIV diagnosis rate per 100,000 population by UHF among females

- 0.0 - 2.5
- 2.6 - 8.4
- 8.5 - 13.3
- 13.4 - 30.4
- Non-residential Zones

Rates of new HIV diagnoses among females were highest in Hunts Point-Mott Haven, East New York, and Crotona-Tremont.

1Rates calculated using the intercensal 2015 NYC population.
Female includes transgender women.
As reported to the New York City Department of Health and Mental Hygiene by June 30, 2016.
NEW HIV DIAGNOSES BY TRANSMISSION RISK AND GENDER IN NYC, 2015

MSM and those with heterosexual contact risk accounted for the majority of new HIV diagnoses among males and females, respectively, in NYC in 2015.

Female includes transgender women and male includes transgender men.
As reported to the New York City Department of Health and Mental Hygiene by June 30, 2016.
Gender Disparities in Heterosexual HIV Transmission in New York City

- NYC Pop. (2010 Census): 47% Male, 53% Female
- All PLWHA as of 2012: 74% Male, 26% Female
- Het. PLWHA as of 2012: 26% Male, 74% Female
- New Het. Diagnoses in 2012: 22% Male, 78% Female

Heterosexual PLWHA and new heterosexual diagnoses are disproportionately female.
The number of HIV-infected infants born to HIV-infected mothers in NYC each year decreased dramatically from the peak in 1990. This decline followed the introduction of intensive perinatal prevention programs in NYC. During 2009-2014, there were 24 perinatally-infected infants born in NYC. In 2015, there were no reported infections among children born in NYC.
In 2015, for the first time since the epidemic began, there were no reported mother to child HIV transmissions among children born in NYC, reflecting the success of interventions to prevent perinatal HIV infection.

1Includes data collected at high-volume NYC medical facilities that care for the majority of HIV-exposed and infected children. Children born outside of NYC are not included in this figure.

2Children born to HIV-infected mothers are followed for 2 years after birth to determine HIV status. HIV status is indeterminate if child is lost to follow-up. As reported to the New York City Department of Health and Mental Hygiene by June 30, 2016.
New HIV Diagnostic Testing Algorithm

1. HIV-1/2 Ag/Ab combo immunoassay (4th generation)
   - (+) Negative for HIV-1 and HIV-2 antibodies and p24 Ag
   - (-) HIV-1/HIV-2 antibody differentiation immunoassay

2. HIV-1/HIV-2 antibody differentiation immunoassay
   - HIV-1 (+) HIV-2 (-) Positive for HIV-1 antibodies
     - Initiate care
   - HIV-1 (-) HIV-2 (+) Positive for HIV-2 antibodies
     - Initiate care
   - HIV-1 (+) HIV-2 (+) Positive for HIV antibodies
     - Initiate care
   - HIV-1 (-) or indeterminate HIV-2 (-) HIV-1 RNA assay
     - RNA (+) Positive for HIV-1
       - Initiate care
     - RNA (-) Negative for HIV-1
Reduction of Window Period

Viral and antibody levels

- P24 antigen
- HIV RNA
- Antibodies

Symptoms

$0$  $7$  $14$  $21$  $28$  $35$  $42$  $49$  $56$  $63$  $70$

$4^{th}$ Gen  $3^{rd}$ Gen  $2^{nd}$ Gen  $1^{st}$ Gen

Das G et al. BMJ 2010;341:bmj.c4583
E.B.

- 16 yo G1P0 39 6/7 admitted to L&D in active labor on 6/28/12
  - Complete PNC at Tremont
  - HIV negative at initial prenatal visit
  - HIV negative on 5/14/12
  - NSVD live baby boy, breastfed
- Alert from NYS DOH Newborn Screening of positive on 7/9/12
  - Mother and baby brought to Peds ID
  - FOB perinatally infected, off HAART
  - Stop Breastfeeding
  - AZT/NVP as post exposure prophylaxis for BF
- Baby boy HIV negative
Seroconversion in Pregnancy

Acquisition and transmission of HIV by women is higher during pregnancy

Studies of acute infection during pregnancy in the US include:
Birkhead et al (2010)\textsuperscript{2} reported 13.8\% (9/65) in New York City of perinatal infections occurred in maternal primary infection
Patterson et al (2007)\textsuperscript{3} reported 50\% (3/6) in North Carolina of perinatal infections occurred in maternal primary infection

Acute infection during pregnancy can lead to higher MCT due to increased viral load during acute infection\textsuperscript{4}

\textsuperscript{1}Mugo NR et al. AIDS 2011;25:1887-1895.
\textsuperscript{3}Patterson KB et al. AIDS 2007;21:2303-2308.
HIV Seroconversions During Pregnancy and Prior-to-Pregnancy, EPS, 2005-2010

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</thead>
<tbody>
<tr>
<td>All Pregnancies</td>
<td>2,064 (100)</td>
<td>1,975 (96.4)</td>
<td>1,814 (99.0)</td>
<td>1,720 (100)</td>
<td>1,543 (100)</td>
<td>1,192 (100)</td>
<td>10,308 (100)</td>
</tr>
<tr>
<td>During Pregnancy</td>
<td>8 (0.4)</td>
<td>26 (1.3)</td>
<td>14 (0.8)</td>
<td>28 (1.6)</td>
<td>26 (1.7)</td>
<td>22 (1.9)</td>
<td>124 (1.2)*</td>
</tr>
<tr>
<td>Prior-to-Pregnancy</td>
<td>1,470 (71.2)</td>
<td>1,381 (69.9)</td>
<td>1,283 (70.7)</td>
<td>1,204 (70.0)</td>
<td>1,061 (68.8)</td>
<td>836 (70.1)</td>
<td>7,235 (70.2)</td>
</tr>
<tr>
<td>Unclassifiable</td>
<td>586 (28.4)</td>
<td>568 (28.8)</td>
<td>517 (28.5)</td>
<td>488 (28.4)</td>
<td>456 (29.6)</td>
<td>334 (28.0)</td>
<td>2,949 (28.6)</td>
</tr>
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</table>

*Estimated Annual Percent Change p<0.0001*
### Perinatal HIV Transmission Among DP and PTP Seroconverting Women, EPS, 2005-2010

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</thead>
<tbody>
<tr>
<td><strong>Perinatal HIV Transmission Among All Deliveries</strong></td>
<td>56 (2.7)</td>
<td>35 (1.8)</td>
<td>42 (2.3)</td>
<td>29 (1.7)</td>
<td>26 (1.7)</td>
<td>22 (1.9)</td>
<td>210 (2.0)</td>
</tr>
<tr>
<td><strong>Perinatal HIV Transmission Among DP Seroconverters</strong></td>
<td>2 (25.0)</td>
<td>3 (11.5)</td>
<td>2 (14.3)</td>
<td>3 (10.7)</td>
<td>2 (7.7)</td>
<td>4 (18.2)</td>
<td>16 (12.9)</td>
</tr>
<tr>
<td><strong>Perinatal HIV Transmission Among PTP Seroconverters</strong></td>
<td>32 (2.2)</td>
<td>22 (1.6)</td>
<td>21 (1.6)</td>
<td>17 (1.4)</td>
<td>14 (1.3)</td>
<td>12 (1.4)</td>
<td>118 (1.6)</td>
</tr>
</tbody>
</table>
Rationale for PrEP during preconception, 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

PrEP Studies:
HIV transmission risk lowest when participants took PrEP consistently

<table>
<thead>
<tr>
<th>STUDY</th>
<th>OVERALL Reduction in risk of HIV infection</th>
<th>Detectable level of medication in the blood Reduction in risk of HIV infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>44%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>TDF2</td>
<td>62%</td>
<td>---</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>75%</td>
<td>90%</td>
</tr>
<tr>
<td>BTS</td>
<td>49%</td>
<td>74%</td>
</tr>
</tbody>
</table>

Adapted from summary of research at http://www.cdc.gov/hiv/prevention/research/prep/
PROUD

- An open-label randomized trial done at 13 sexual health clinics in England
- 544 HIV-negative gay and other men who have sex with men who had had anal intercourse without a condom in the previous 90 days.
- Participants were randomly assigned (1:1) to receive daily combined tenofovir disoproxil fumarate (245 mg) and emtricitabine (200 mg) either immediately or after a deferral period of 1 year
- 3 HIV infections occurred in the immediate group (1.2/100 person-years) versus 20 in the deferred group (9.0/100 person-years) despite 174 prescriptions of post-exposure prophylaxis in the deferred group
- Based on early evidence of effectiveness, the trial steering committee recommended on Oct 13, 2014, that all deferred participants be offered PrEP.
Daily oral PrEP with TDF/FTC is recommended as one HIV prevention option for heterosexually-active men and women at substantial risk of HIV acquisition because these trials present evidence of its safety and 2 present evidence of efficacy in these populations, especially when medication adherence is high. (IA).
National HIV Behavioral Surveillance (NHBS)

- 25 cities throughout the United States
- Funded by CDC, designed collaboratively
- Ongoing, cyclical study of three risk groups: MSM, IDU, and high-risk heterosexuals (HET)
- NHBS-HET data collection in 2006-7
- Cross-sectional study design
- Interviewer-administered quantitative survey & HIV test
- Anonymous recruitment, survey & test
What is a High-Risk Heterosexual?

**Past Definitions**
- Multiple sexual partners
  - But most women and many men recently infected report 1 sexual partner in past year
- Sexual partners’ risks
  - But most did not accurately know partners’ risks

**Newer Ideas**
- Geography
  - Heterosexual HIV is clustered in high-poverty neighborhoods
- Social networks
  - Some social and sexual networks have high HIV levels despite equal individual risks
  - Greater inter-network mixing may drive infections
High-Risk Areas

1. Created high-risk area (HRA) index with:
   - New HIV diagnoses, 2001-6, NYC HIV surveillance
   - Household poverty, 2000, census

2. Explored index to identify:
   - Geographic clustering
   - Non-residential zip codes (for exclusion)

3. Selected top 30 zip codes as HRAs (top 20%)
High-Risk Heterosexual Definition

- Has a geographic or social connection to an HRA
  - Lives in HRA (geographic connection)
  - Recruited by someone who lives in HRA (social connection)
- A man or woman between 18-50 years old
- Vaginal or anal sex with opposite-sex partner in the past year
- Resident of NYC
- Speaks English or Spanish
Ms N.K.

- 35 yo G2P1001, American of Guinean descent, at 8 6/7 by LMP and sono. HIV negative on 11/25/12
- Did not return for new OB because of travel. Returns with husband and 2 yo daughter in 3/2013
- On 3/14/13 FOB admitted to BLHC with fever, diffuse vesicular rash.
  - HIV positive. VL>500k, CD4 23
- Alert from ER counseling team to PRSW re pregnant wife
- NK is HIV negative w pcr <20
- Counseled abstinence, rx Truvada 1 tab po daily
- Adherence, repeated testing
- 7/8/13 C/S baby girl, HIV negative
- After extensive counseling, breastfeeding
- 10/2014 HIV ab negative pcr <20 intermittent PrEP
- 11/15/14 FOB VL 179, cd4 260 on HAART
FOR AN HIV-NEGATIVE WOMAN PLANNING PREGNANCY WITH AN HIV-POSITIVE MALE PARTNER

- Options Reducing the risk of HIV acquisition by an HIV-negative woman during conception can be achieved by use of the following, singly or ideally in combination
- Antiretroviral treatment of the HIV-positive male partner to achieve an undetectable viral load
- STI diagnosis and any indicated treatment for both partners before conception attempts
- Daily, oral doses of TDF/FTC beginning 1 month before a conception attempt and continuing for 1 month after a conception attempt
- Intravaginal or intrauterine insemination, or intracytoplasmic sperm injection with a semen sample processed by “sperm washing” and confirmed to have a negative test result for the presence of remnant HIV
- Limit sex without a condom (natural conception) to peak fertility times identified by home or laboratory tests for ovulation in the female partner.
Breastfeeding

• The safety of PrEP with TDF/FTC or TDF alone for infants exposed during lactation has not been adequately studied. However, data from studies of infants born to HIV-infected mothers and exposed to TDF or FTC through breast milk suggest limited drug exposure.

• Additionally, the World Health Organization has recommended the use of TDF/FTC or 3TC/efavirenz for all pregnant and breastfeeding women for the prevention of perinatal and postpartum mother-to-child transmission of HIV.

• Therefore, providers should discuss current evidence about the potential risks and benefits of beginning or continuing PrEP during breastfeeding so that an informed decision can be made.
Past partner with HIV: yes
Electronic Signatures:
- Referred for PrEP counseling: accepted by patient
LABOR AND DELIVERY

What is your partner's HIV Status?

- **POSITIVE**
  - HIV AB Expeditend
    - HIV RT PCR (viral load - acute *seroconversion*)
    - HIV AB POSITIVE
      - AZT
      - Cesarean Delivery
      - ALERT Peds ID
    - HIV AB negative
      - Educate patient re risk of acute *seroconversion*
      - ALERT Peds ID
      - *Expectant management* of labor and delivery
      - *MONITOR PENDING VL RESULT* (OB and Peds teams)
        - Infant receives PO AZT until VL confirms status
  - VL PCR
    - <20 is negative
    - >1000 considered positive
    - >20 but <1000 is indeterminate
    - Repeat VL, Peds ID to determine treatment

- **Negative**
  - No further action

- **I don’t know**
  - All HIV infected women admitted to OB GYN Service need an ID consult
  - OB/HIV team should be immediately informed of any newly identified HIV infected woman admitted to Labor and Delivery
Ms CS

• 32 yo Caucasian G7P2 admitted on 2/18/14, 30 3/7 EGA febrile, PPROM x3 d
  – Hepatitis C, polysubstance abuse: cocaine, marijuana, etoh
  – Prior admission at Lincoln for pyelo 1/2014
  – 1/24/14 HIV negative Lincoln, 2/5/14 HIV negative BOOM
  – Incarceration 9/2-10/8/13
  – Records from FLA show 2 ER evaluations after assaults

  – C/S 2/21/14 baby girl 840 g LBW, respiratory distress, suspect sepsis
  – ACS: baby to foster care
Baby S

• Born 2/21/14
• Peds ID consult for Hep C exposure
• Discharged from NICU on 4/28/14, 65 days, 39 2/7
• 5/1/14 evaluated CCC for Hep C exposure
• 5/6/14 call from Newborn Screening “specimen problem”
  – 4 newborn screens sent, 3/4 negative, 4 is positive
• 5/7/14 Rapid test positive, EIA positive, VL sent
  – Too late for prophylaxis
  – ZDV, Epivir, Kaletra
• 5/29/14 Reevaluation at Wadsworth of 3 initial blood spots
  – Birth negative pcr
  – Day 5 positive pcr
  – 1 month positive pcr
• Baby adopted, in care at CCC, doing well.
Reduction of Window Period

Viral and antibody levels

- **P24 antigen**
- **HIV RNA**
- **Antibodies**

Symptoms

- 4th Gen
- 3rd Gen
- 2nd Gen
- 1st Gen

Das G et al. BMJ 2010;341:bmj.c4583
<table>
<thead>
<tr>
<th><strong>Detecting substantial risk of acquiring HIV infection</strong></th>
<th><strong>Men Who Have Sex with Men</strong></th>
<th><strong>Heterosexual Women and Men</strong></th>
<th><strong>Injection Drug Users</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive sexual partner</td>
<td>HIV-positive sexual partner</td>
<td>HIV-positive injecting partner</td>
<td>HIV-positive injecting partner</td>
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<tr>
<td>Recent bacterial STI</td>
<td>Recent bacterial STI</td>
<td>Sharing injection equipment</td>
<td>Sharing injection equipment</td>
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<tr>
<td>High number of sex partners</td>
<td>High number of sex partners</td>
<td>Recent drug treatment (but currently injecting)</td>
<td>Recent drug treatment (but currently injecting)</td>
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<tr>
<td>History of inconsistent or no condom use</td>
<td>History of inconsistent or no condoms use</td>
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<tr>
<td>Commercial sex work</td>
<td>Commercial sex work</td>
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<tr>
<td>In high-prevalence area or network</td>
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<thead>
<tr>
<th><strong>Clinically eligible</strong></th>
<th>Documented negative HIV test result before prescribing PrEP</th>
<th>Documented negative HIV test result before prescribing PrEP</th>
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</thead>
<tbody>
<tr>
<td>HIV-positive sexual partner</td>
<td>No signs/symptoms of acute HIV infection</td>
<td>No signs/symptoms of acute HIV infection</td>
</tr>
<tr>
<td>Recent bacterial STI</td>
<td>Normal renal function, no contraindications</td>
<td>Normal renal function, no contraindications</td>
</tr>
<tr>
<td>High number of sex partners</td>
<td>Documented hepatitis B virus infection and vaccination status</td>
<td>Documented hepatitis B virus infection and vaccination status</td>
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| **Prescription**                                         | Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply | Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply |

<table>
<thead>
<tr>
<th><strong>Other services</strong></th>
<th>Follow-up visits at least every 3 months to provide the following:</th>
<th>Follow-up visits at least every 3 months to provide the following:</th>
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<tr>
<td>HIV test, medication adherence counseling, behavioral risk reduction support,</td>
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<tr>
<td>side effect assessment, STI symptom assessment</td>
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<tr>
<td>At 3 months and every 6 months thereafter, assess renal function</td>
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<tr>
<td>Every 6 months, test for bacterial STIs</td>
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<tr>
<td>Do oral/rectal STI testing</td>
<td>Assess pregnancy intent</td>
<td>Access to clean needles/syringes and drug treatment services</td>
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<tr>
<td></td>
<td>Pregnancy test every 3 months</td>
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</tbody>
</table>

STI: sexually transmitted infection
TDF Concentrates 10-100x More in Rectal Tissue than in Cervico-vaginal Tissues

Slide courtesy Landovitz

Patterson KB et al. Sci Transl Med. 2011.
Maximizing the Potential Effectiveness

TDF/FTC (7x/week)
CI: 96 - 99
Some adherence forgiveness with retained protection

TDF/FTC (~1x/24°)
CI: -17 - 100
6-7 doses per week likely required

Slide courtesy: Landovitz
March 23, 2016

Dear New York City and New York State PrEP Providers,

Last month, the first reported case of a breakthrough HIV infection in a patient consistently taking oral tenofovir disoproxil fumarate and emtricitabine (TDF/FTC, or Truvada®) as pre-exposure prophylaxis (PrEP) to prevent HIV was reported at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston [1]. The patient was infected with a strain of HIV resistant to both TDF and FTC. While such viruses are extremely rare, the case demonstrates that PrEP, like other preventive medications and behavioral interventions, does not provide 100% protection against HIV infection. Nevertheless, the body of scientific and clinical data previously presented about the efficacy of PrEP confirms the critical role of this intervention in reducing new HIV infections in New York City (NYC), and New York State (NYS).

As such, the New York City and New York State Departments of Health (DOH) continue to fully support the use of TDF/FTC as PrEP for individuals at risk of HIV infection. The rare event reported at this conference provides an opportunity to revisit NYSDOH AIDS Institute guidance for PrEP and to clarify the importance of communicating with patients about PrEP and the risk of HIV and other sexually transmitted infections (STIs).

We urge providers to adhere to CDC and NYSDOH AIDS Institute PrEP guidance with their patients on PrEP by:
1. Testing for HIV every three months using a laboratory-based, ideally 4th generation, HIV test;
2. Assessing for signs of acute HIV infection at every visit;
3. Having a low threshold for testing for acute HIV and other STIs; and
4. Encouraging patients on PrEP (or on HIV treatment) to use condoms as often as possible.

THE CASE REPORTED AT CROI 2016
A 43-year-old man in Toronto, Canada, was diagnosed with acute HIV infection after taking PrEP for 24 months, during which time he tested negative for HIV 7 times. Patient self-report, pharmacy data and laboratory analyses indicated the patient had long-term adherence to PrEP and a high concentration of TDF/FTC in his blood at the time of seroconversion. The patient was diagnosed with acute HIV infection when visiting an emergency room with severe abdominal pain and a high fever; he reported receptive anal sex without condoms with multiple male partners in the 2 to 6 weeks before diagnosis. Subsequent viral sequencing determined that the patient was infected with a strain of HIV-1 that demonstrated genotypic evidence of high-level resistance to emtricitabine and low-level resistance to tenofovir disoproxil fumarate, the two antiretroviral (ART) drugs in PrEP. The transmitted virus also demonstrated resistance to integrase inhibitors, medications used in first-line HIV treatment and post-exposure prophylaxis (PEP) regimens. The patient immediately began HIV treatment and achieved an undetectable viral load by taking a combination of dolutegravir (Tivicay®), darunavir/ritonavir (Prezista®) and rilpivirine (Edurant®).
Women identified as at substantial risk of HIV acquisition pre-conception, during pregnancy and postpartum at 2 U.S. centers

Preconception

30 referrals; 27 women

- 8 identified, referred & offered PrEP
  - 5 took PrEP
    - 2 did not conceive
    - 3 conceived
  - 3 did not take PrEP
    - 2 did not conceive
    - 1 conceived

Pregnancy

- 21 identified in pregnancy
  - 3 pregnancies
    - 2 continued PrEP
    - 1 discontinued PrEP

- 1 pregnancy, lost to follow-up

Postpartum (1 year)

- 1 stopped PrEP while breastfeeding, then restarted
- 1 discontinued PrEP & breastfed
- 1 miscarried at 12 weeks & restarted PrEP
- 7 continued PrEP; 3 breastfed
- 5 discontinued PrEP; 3 breastfed
- 6 did not take PrEP; 4 breastfed
- 1 not referred
- 1 identified postpartum, offered & took PrEP & breastfed

Who was missed?

30 referrals; 27 women

8 identified, referred & offered PrEP

5 took PrEP

3 did not take PrEP

2 did not conceive

3 conceived

2 did not conceive

1 conceived

3 pregnancies

1 pregnancy, lost to follow-up

21 Identified in pregnancy

18 referred & offered PrEP

2 referred & lost to follow-up prior to consult; 1 in care & not referred

1 referred 10 months postpartum after seroconversion. Did not breastfeed.

Postpartum (1 year)

1 stopped PrEP while breastfeeding, then restarted

1 discontinued PrEP & breastfed

1 miscarried at 12 weeks & restarted PrEP

7 continued PrEP; 3 breastfed

5 discontinued PrEP; 3 breastfed

6 did not take PrEP; 4 breastfed

1 not referred

1 identified postpartum, offered & took PrEP & breastfed

Preconception

Use of HIV Pre-Exposure Prophylaxis During Conception Pregnancy and Lactation at 2 US Centers. Seidman, Weber, Timoney, Oza, Mullins, Wright
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, treated at same institution, 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.

LC

• 27 yo G3P2012 HIV negative w positive partner who is in care, adherent to atripla
  – Planned pregnancy (PrEP prior to IUD removal)
  – Repeated negative Ab and pcr, weekly pcr before delivery.
  – Planned breastfeeding, endorsed by Peds ID
  – NSVD, no need for NN AZT, stopped truvada after delivery
  – Breastfed 1 month
  – Restarted PrEP prior to mirena and resumption of sexual activity
Assess risk in ALL women, not just pregnant women.

Thank you!

mtimoney@bronxleb.org