Serodiscordant Couple: Woman Pregnant
On-going Risks

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What would you do with this situation?

G6P2032 21 yo Hispanic female who is HIV negative presents to your office for prenatal care
Father of the baby is HIV positive
  We don’t have treatment details or viral load
She admits to on-going unprotected sexual intercourse during pregnancy
  “We have sex a lot, at least several times a week”
Additional History

- She has been tested twice during pregnancy for HIV and has been negative, most recently at ~ 1 month ago
- She is currently ~ 35 weeks pregnant
- History of intermittent prenatal care, presented at 12 weeks (with consideration for termination)
  - Used ED as primary OB care until recently
- Chlamydia + 1 month ago

Plan Discussed among Peds ID, High-risk OB and Adult ID

- Mom retested with VL and antibody
- Advised of the symptoms of acute HIV and for what symptoms to contact OB
- Recommended to use condoms for intercourse
- Plan to test mom with VL/4th generation tests at presentation in labor
- Plan to test baby at delivery with both viral load and HIV DNA PCR
  - AZT if any concern for transmission
- Mother offered pre-exposure prophylaxis with Truvada daily for duration of pregnancy
- Advised against breast-feeding after delivery
Pre-Exposure Prophylaxis (PrEP) – Ideal drug or Regimen

- Good tolerability and safety
- Low pill burden
- High potency
- Once-daily dosing
- Long half-life
- High barrier to resistance and lack of cross-resistance with other drugs


Relative Efficacy of PrEP and Other Prevention Strategies

<table>
<thead>
<tr>
<th>Study</th>
<th>Reduction in HIV Transmission</th>
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<tbody>
<tr>
<td>HPTN 052 (ARV treatment as prevention)¹</td>
<td>96%</td>
</tr>
<tr>
<td>IPrEx (FTC/TDF) in MSM¹</td>
<td>44%</td>
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<tr>
<td>Subjects with detectable drug levels²</td>
<td>94%</td>
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<tr>
<td>Partners PrEP (FTC/TDF) in discordant couples¹</td>
<td>75%</td>
</tr>
<tr>
<td>Subjects with detectable drug levels¹</td>
<td>90%</td>
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<tr>
<td>Condoms in heterosexuals⁴</td>
<td>80%</td>
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<tr>
<td>Condoms in US MSM⁵</td>
<td>70%</td>
</tr>
<tr>
<td>TDF2 (FTC/TDF) in men &amp; women¹</td>
<td>62%</td>
</tr>
<tr>
<td>Medical male circumcision¹</td>
<td>54%</td>
</tr>
<tr>
<td>STD treatment¹</td>
<td>42%</td>
</tr>
<tr>
<td>CAPRISA 004 (1% TFV vaginal gel) in women¹</td>
<td>39%</td>
</tr>
<tr>
<td>FEM-PrEP (FTC/TDF) in women⁶, VOICE (FTC/TDF, TDF, TFV vaginal gel) in women⁷</td>
<td>Not Significant</td>
</tr>
<tr>
<td>HIV vaccine (RV144)³</td>
<td></td>
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</tbody>
</table>

¹. Adapted from Abdool Karim S and QA. Lancet 2011;50140-6736/1142-7
⁵. Smith DK, et al. CROI 2013; Atlanta, GA. Oral #32
⁶. van Damme L, et al. NEJM 2012;367:411-422
⁷. Marrazzo JM, et al. CROI 2013; Atlanta, GA. Oral #26L8
CDC PrEP Guidelines
May 2014

- Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults.

- PrEP is recommended as one prevention option for sexually-active adult MSM (men who have sex with men) at substantial risk of HIV acquisition (IA).

- PrEP is recommended as one prevention option for adult heterosexually active men and women who are at substantial risk of HIV acquisition. (IA)

U.S. Public Health Service PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2014; A CLINICAL PRACTICE GUIDELINE May 2014

CDC PrEP Guidelines
May 2014

- PrEP is recommended as one prevention option for adult injection drug users (IDU) at substantial risk of HIV acquisition. (IA)

- PrEP should be discussed with heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) as one of several options to protect the uninfected partner during conception and pregnancy, so that an informed decision can be made in awareness of what is known and unknown about benefits and risks of PrEP for mother and fetus (IIB).

U.S. Public Health Service PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2014; A CLINICAL PRACTICE GUIDELINE May 2014
Fast forward to delivery.....

- Mom accepted tenofovir/emtricitabine (Truvada) once daily as prophylaxis
- Baby born by induction at 41 3/7 weeks
- Maternal VL and antibody/antigen testing done at presentation in labor—pending
- Last VL and Ab/ag tests at 35 weeks were negative
- Viral load and DNA PCR drawn and sent for baby—pending
- What next?? Treat or not to treat? Why?
- What else would you like to know?

What to do with the baby?

- What else would you like to know?
  - When was mother’s last sexual encounter with FOB?
    - She admitted to vaginal intercourse 7 days prior to delivery, without condoms. We pushed the lab to run the maternal and infant testing.
  - Does mom insist on breast-feeding, although she has been told the risks?
    - Addition risk with breastfeeding
      - 14% ↑ risk with established infection
      - 29% ↑ risk with primary infection
Further information...always useful

- Mother’s repeat VL and 4\textsuperscript{th} generation tests are negative
- Baby’s viral load is negative
  - DNA PCR sent to Wadsworth
- Mom said she did NOT want to breast feed

Interruption of Maternal–to–Child HIV Transmission: Take–Home Points

- Routine testing of all women during pregnancy
- If in labor with undocumented HIV status, rapid HIV testing should be done
- IV AZT for women with +HIV test at presentation in labor if previously unknown to be HIV +
  - C/S if before labor and rupture of membranes
- HIV testing of infant and infant prophylaxis with 6 weeks of AZT
- Avoidance of breast feeding in US (and other developed countries)

AAP policies; Red Book 2012, ACOG policies; Pediatrics 1999. 104: 128 (reaffirmed 2008)
What to do with this baby?

- Baby was not given AZT prophylaxis, as the tests on the mother and the baby were both negative.
- Baby was retested at 3 weeks of age by HIV DNA PCR and was still negative.
- No further testing of the baby is planned.
- Mom reminded not to breastfeed.
- She also agreed to frequent HIV testing while she remained with the current partner.

Optimal Management of HIV-exposed infant, 2014

- Diagnostic testing: PCR testing of infant starts day 1, then 2–3 weeks, 6–8 weeks, 4–6 months, & HIV Ab testing at 18 mos.
- Antiviral therapy**: ZDV PO X 6 weeks (dosage adjusted for gest age—may even be given to preemies by IV route if needed)
  - 4 mg/kg/dose q12h
  - RARELY if ever: TMP/SMZ po, (month 2–12 if infected or status uncertain) as PCP prophylaxis
- All routine immunizations.
- **Occasionally we will recommend a second drug if transmission risk is very high—generally nevirapine or 3TC (as these are the only “safe” drugs for neonates—PK often variable and side effects unsafe, such as heart block in use of lopinavir/ritonavir in preemies).