Adolescent PrEP Delivery: Opportunities and Challenges in the World of HIV Prevention

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Diagnoses of HIV Infection Among Adolescents and Young Adults Aged 13-24 Years, by Race/Ethnicity, 2010–2014 United States and 6 Dependent Areas

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Hispanics/Latinos can be of any race.
Diagnoses of HIV Infection Among Adolescents and Young Adults Aged 13-24 Years, by Transmission Category, 2010–2014 United States and 6 Dependent Areas

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and incomplete reporting.

aHeterosexual contact with a person known to have, or to be at high risk for, HIV infection.
bIncludes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
Diagnoses of HIV Infection and Population Among Adolescents Aged 13–19 Years, by Race/Ethnicity 2014—United States

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

Hispanics/Latinos can be of any race.
PrEP and Youth

While uptake of PrEP is improving among the US population overall, young people – and particularly youth of color – are more hesitant.

Recent behavioral surveillance reports have not found differences in willingness to take PrEP by race/ethnicity (Hoots et al., CID, 2016)

- Black/AA and Latino YMSM are more likely to report concerns about PrEP efficacy as well as PrEP stigma (Lelutiu-Weinberger & Golub, JAIDS, 2016)
- However, prescriptions of PrEP for youth under age 25 and for black/AA YMSM are substantially lower than their white counterparts (Bush et al., ICAAC 2016)
New FTC/TDF for PrEP Starts by Race/Ethnicity and Age*

1 in 5 new HIV diagnosis occurs in those < 25 y/o:
56% AA (n=5,464), 22% Hispanic (n=2,108), and 17% white (n=1,644).

7.6% of those who initiated FTC/TDF for PrEP were under 25 y/o.
Racial demographics were similar, both below and above the age of 25 y/o.

*These data represent 43.7% (n=21,463) of unique individuals who have started FTC/TDF for PrEP from 2012-3Q2015.
Bush S, et al. ASM/ICAAC 2016; Boston, MA. #2651
Background on ATN 110/113

Blinded and open label studies among MSM support the efficacy of TDF/FTC for HIV prevention.

In the US, gay/bisexual/MSM ages 13-24 are hardest hit by HIV epidemic:
- 18-24 year old MSM not well-represented in PrEP safety or efficacy studies in US
- No PrEP data available on adolescent MSM to date

Additional safety and behavioral data, as well as implementation data, in youth are needed to support a PrEP indication.

Paired PrEP studies through the NIH-funded Adolescent Trials Network (ATN):
- **ATN 110** (ages 18-22); data presented IAS 2015/JAIDS 2016
- **ATN 113** (ages 15-17); data presented AIDS 2016
Primary Objectives

To provide additional safety data regarding TDF/FTC use among HIV-uninfected YMSM ages 15-17.

To examine acceptability, patterns of use, rates of adherence and measured levels of drug exposure when YMSM are provided open label TDF/FTC.

To examine patterns of sexual behavior when YMSM are provided a behavioral intervention as well as open label TDF/FTC.
Study Flow

1. **Pre-Screening Survey (venue-based or online)**
   - Ineligible or refuse survey

2. **In-person screening visit (IC and screening labs)**
   - Ineligible based on labs

3. **Baseline Visit (review labs & VL)**

4. **Behavioral Intervention (3MV or PCC)**

5. **Week 0 – Dispense PrEP**

6. **Follow-up Visits (weeks 4,8,12,24,36,48)**

7. **Week 48: Evaluate for EPH**

8. **HIV Seropositive Visits**

9. **Extension Phase Visits**
Baseline Demographics – ATN 110

- **Race/ethnicity distribution:**
  - Black: 53%
  - Hispanic/Latino: 17%
  - White: 21%
  - Other/Mixed: 7%
  - Asian/PI: 2%

- **Mean age:** 20.18

- **Sexual Identity:**
  - Gay: 77.8%
  - Bisexual: 13.7%

- **Highest grade completed:**
  - High School: 33.8%
  - Some college: 45.5%

- **Currently working:**
  - Not currently working: 30.1%

- **Other key statistics:**
  - Ever kicked out: 17.2%
  - Ever paid for sex: 28.6%
  - Partners in past 5 mo: 5
  - Condomless sex: 81%
  - CRAI w/last partner: 58%
  - Any positive STI test: 22%
### Baseline Demographics – ATN 113

#### Race
- Black: 33%
- Hispanic/Latino: 29%
- White: 21%
- Other/Mixed: 14%
- Asian/PI: 3%

#### Sex
- Male: 54%
- Female: 43%
- Gender Nonconforming: 3%

#### Mean Age
- 16.5

#### Sexual Identity
- Gay: 58%
- Bisexual: 28%
- Questioning and Other: 6%

#### Education
- Completed high school: 18.4%

#### Housing
- Living with parents/family: 88.5%

#### Public Aid
- Received public aid: 76.9%

#### Life Events
- Kicked out of house for being gay: 15%
- Ever been paid for sex: 17%

#### Sexual Behavior
- Partners in past month: 2
- CRAI with last partner: 60%
- Any positive STI test: 15.4%

![Pie chart showing race distribution with percentages]

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<tr>
<th>Description</th>
<th>Percentage</th>
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<tr>
<td>Mean age</td>
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Percent of Participants with STI Diagnoses

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<th>ATN 113</th>
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<td>Baseline</td>
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<td>Week 24</td>
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STI Incidence on Study:
- ATN 110 = 66.44/100 person years
- ATN 113 = 28.49/100 person years
HIV Incidence

**ATN 110**
- 4 seroconversions through week 48 (wks 4, 32, 40 & 48)
- HIV incidence = 3.29 per 100 person-years

**ATN 113**
- 3 seroconversions through week 48 (wks 32, 36 & 48)
- HIV incidence = 6.41 per 100 person-years

**ATN 110 Extension Phase**
- 5 seroconversions through 48 weeks on EPH
- HIV incidence = 7.2 per 100 person-years

No drug or very low levels at time of seroconversion in all cases
ATN 110 Adherence: TFV-DP (fmol/punch) via DBS and Dosing Estimates

- WK 4: 56.1%
- WK 8: 57.9%
- WK 12: 56%
- WK 24: 47.3%
- WK 36: 40.3%
- WK 48: 34.2%

Color codes:
- Green: >700 (4 or more days)
- Yellow: 350-699 (2-3 days)
- Blue: <350 (<2 days)
ATN 113 Adherence: TFV-DP (fmol/punch) via DBS and Dosing Estimates

- WK 4: 60% >700, 31% 350-699, 9% <350, 0% BLQ
- WK 8: 52.4% >700, 45.5% 350-699, 2% <350, 0% BLQ
- WK 12: 55% >700, 43.5% 350-699, 1.5% <350, 0% BLQ
- WK 24: 31.5% >700, 62.7% 350-699, 5.8% <350, 0% BLQ
- WK 36: 22.7% >700, 71.1% 350-699, 6.2% <350, 0% BLQ
- WK 48: 28.2% >700, 70.3% 350-699, 1.5% <350, 0% BLQ
Adherence: Median TFV-DP by Study

- ATN 110
- ATN 113

Week 4, Week 8, Week 12, Week 24, Week 36, Week 48

4+ doses
Adherence and Sexual Behavior

ATN 110
Participants that reported engaging in condomless sex had consistently higher levels of TFV-DP (p=0.005)
  - Remained consistent over course of the study.

Similarly, participants who reported CRAI with last partner demonstrated higher TFV-DP levels over course of the study
  - Trend not statistically significant

ATN 113
No statistically significant correlations between adherence and sexual behavior
In ATN 113, non-adherent participants were more likely to endorse the following beliefs than adherent participants:

- “I worry others will see me taking pills and think I am HIV-positive” (p=.03)
- “I am concerned people will know I have sex with other men because I’m taking PrEP” (p=.06)
- “I don’t like taking pills” (p=.06)
PrEP and Race

Recent research highlights lack of exposure to HIV prevention interventions by BYMSM, including lack of information about PrEP.
PrEP Beliefs and Race/Ethnicity

Black/AA participants in ATN 110 were more likely than white participants to endorse that they missed doses of medication because they:

- Had too many pills to take (p=0.02)
- Did not want others to notice them taking medication (p=0.01)
- Felt the study pill was toxic/harmful (p=0.02 at week 36)
- Felt sick or ill (p=0.004 at week 36)

Black/AA participants were less likely to endorse the belief that “PrEP is as effective at preventing HIV as condoms” than white or Latino participants (p=0.009)

No statistically significant differences by race in number of sexual partners, HIV+ partners, STIs or substance use
Secondary Objectives

To evaluate consent procedures and the acceptability/feasibility of allowing adolescents to consent for their own study participation.

To explore the discussions and recommendations of local IRBs on this approach to adolescent consent.
The purpose of our study was to describe participants’ lived experiences of research benefits and harms in the first youth-focused PrEP safety and effectiveness studies in the U.S. (ATN protocols 110/113).

Interviewed 25 participants, between 0-24 months after they completed the parent study

Participants were concerned about disclosing enrollment to significant others, including parents, immediate family, friends, and potential partners.

- 11 disclosed participation to parents – 2 prior to enrollment, 9 after enrollment
- 13 never disclosed to parents
- 1 participant did not have living parents

Concerns about disclosure were multi-layered:

- Being outed
- Admitting sexual activity, which is always awkward, but especially if frank discussion of sex with men
- Admitting concern about acquiring HIV and concern parents’ would think s/he was “irresponsible, promiscuous”
Was there anyone that you wish had been part of the consent process?

“"It was kind of cool just like with me and the doctor. At that time, I also wasn't out about my identity, so it was kind of like I didn't want to really talk about it to other parties.”

“I feel like my relationship with my dad isn’t the best. So I’m kind of like independent in that sense. I never discussed it with my dad so I wouldn’t say him. Like I said, my mom even since she was not knowledgeable in the area I didn’t really feel the need to inform her in the process.”
“No. No, not really. I feel like if I had to have a parent or guardian or someone there, it would have just been a little bit awkward, and it probably wouldn’t have happened because my mom doesn’t have time for all that.”

“I found it to be a really personal decision. I did discuss it with my mom but it wasn’t like she had a lot of input in it. It was more like I just let her know. She had never heard of PrEP. I told her the case study and that it was voluntary and she was fine with it. I discussed it with my partner as well. He was fine with it as well. I discussed it with people at [RESEARCH SITE]. I think a lot of it was just my own decision and me doing research online and like my prior knowledge.”
Adolescent Consent Laws

**Contraceptive Services:** 26 states and the District of Columbia allow all minors (12 and older) to consent to contraceptive services.

**STI Services:** All 50 states and the District of Columbia allow most minors to consent to testing and treatment for sexually transmitted infections (STIs). Many states, however, allow physicians to inform parents that the minor is seeking or receiving STI services when they deem it in the best interests of the minor.

- 32 states explicitly include HIV testing and treatment in the package of STI services to which minors may consent; many of these laws only apply to HIV testing.
Implementation Updates in the US

ATN 113 data will go to FDA in 2017


Specific provisions for PrEP to adolescents in New York

Sexuality Information and Education Council of the United States (SIECUS) PrEP toolkit for youth-serving providers

- Clinical tools, billing, youth laws and HIV policies

Multiple consultations, seminars, chat groups have occurred

Nationwide PrEP provider locator database launched in September 2016

- https://preplocator.org/
The Update allows for opportunities to refresh the ongoing work in HIV prevention, care, and research. Advances in four key areas are of critical focus for the next five years:

- **Widespread testing and linkage to care**, enabling people living with HIV to access treatment early.
- **Broad support for people living with HIV to remain engaged in comprehensive care**, including support for treatment adherence.
- **Universal viral suppression** among people living with HIV.
- **Full access to comprehensive PrEP services** for those whom it is appropriate and desired, with support for medication adherence for those using PrEP.
November 8th, 2016

I FELT A GREAT DISTURBANCE IN THE FORCE

IT'S AS IF MILLIONS OF VOICES WERE SUDDENLY SILENCED
The near future...

*Regarding HIV:* The 2016 Republican Platform discusses AIDS in a section on Africa, but does not specifically discuss the domestic HIV epidemic within the United States.

*Regarding LGBT rights:* In the platform, the Republican Party strongly affirms their belief that the institution of marriage should be between one man and one woman. Other Republican legislation prevents the Federal government from taking action against individuals and businesses that oppose same-sex marriage based on their religious beliefs.

Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone — Indiana, 2015

*Weekly*
May 1, 2015 / 64(16);443-444
Conclusions

ATN 110/113 successfully identified and engaged YMSM who would be appropriate for PrEP.

HIV incidence rate was high compared to PrEP arms in other open label trials
  ◦ Given high number of incident STIs, would likely be much higher in the absence of PrEP
  ◦ Those that seroconverted had undetectable drug levels

Adherence decreased for all participants as study visits decreased in frequency
  ◦ Youth may need enhanced visit schedules or more frequent interactions (in-person or via mobile technology)
  ◦ More work is needed to address traditional adherence barriers, plus additional stigma-related concerns

Adolescents need access to PrEP! We must decrease regulatory and financial barriers
  ◦ Most US states could interpret STI laws as permissive of PrEP without parental consent
  ◦ More specific guidance is needed
Acknowledgements

Most importantly, I would like to thank these brave adolescent participants for their willingness to share their lives and their time with us.

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Thank You!!