



PrEP in Minors An Uphill Battle Worth Fighting

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Objectives

- HIV Prevention and Adolescents
- PrEP safety in adolescents: It's complicated
- Barriers to PrEP for adolescents
- Legal issues regarding PrEP and Adolescents

The Numbers

HIV Diagnoses

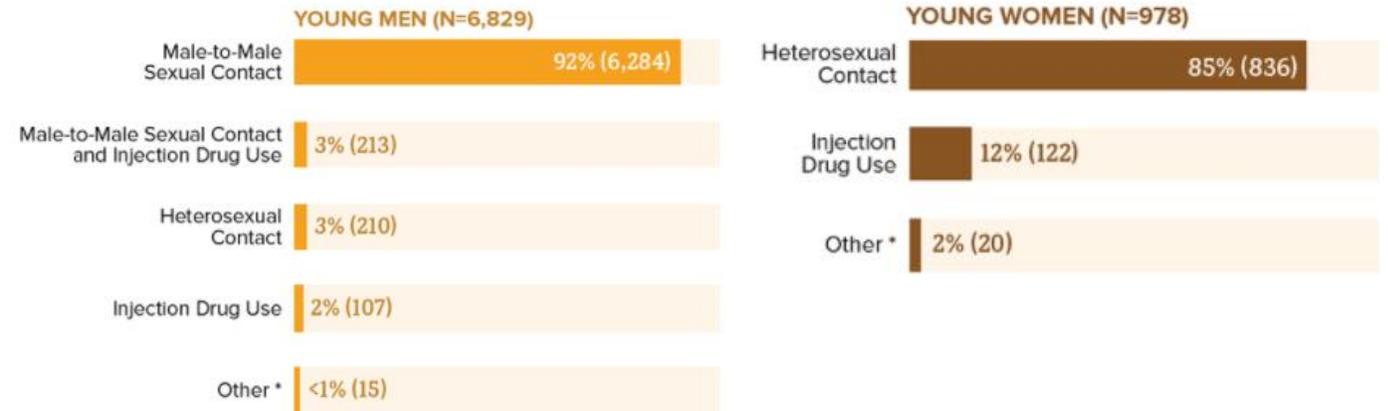


Of the **37,832 NEW HIV DIAGNOSES** in the US and dependent areas in 2018, 21% were among youth.

(Ages 13-24)

New HIV Diagnoses Among Youth by Transmission Category and Sex in the US and Dependent Areas, 2018

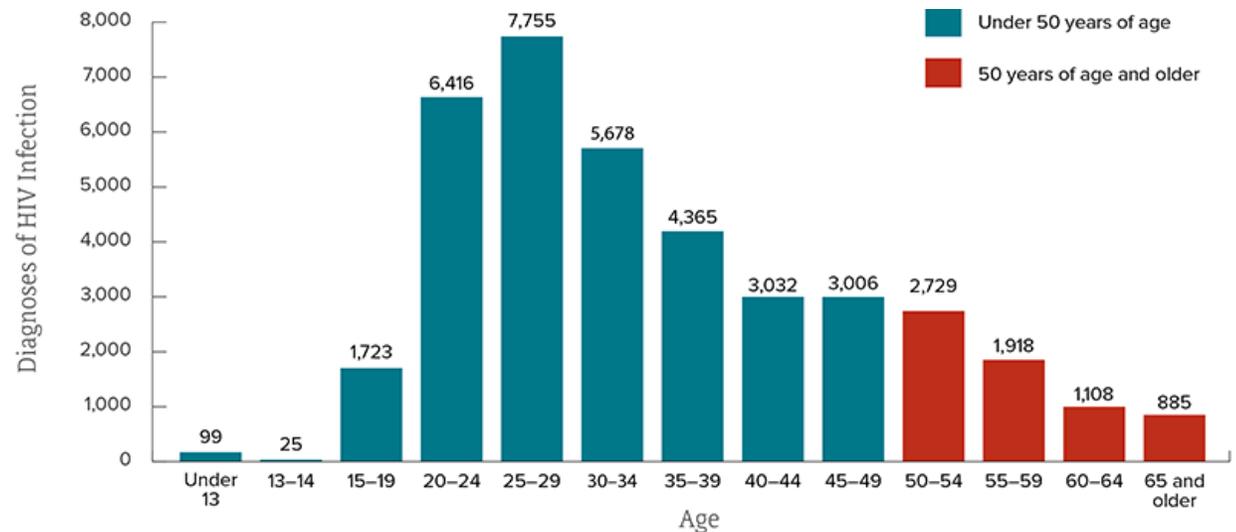
Most new HIV diagnoses among youth were among young gay and bisexual men.



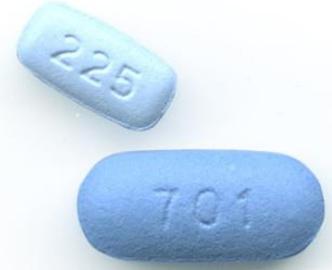
Importance of HIV Prevention in Adolescents

- Adolescents in the United States remain at risk for acquiring HIV
- Study of young men sex with men (MSM) in Chicago - HIV incidence in MSM aged 16–17 years not significantly different than MSM aged 18–20 years
- Preventing HIV among adolescents is particularly important
 - poor adherence
 - failure to achieve viral suppression, viral rebound
 - greater loss to follow-up than adults with HIV

New HIV Diagnoses in the US and Dependent Areas by Age, 2017



PrEP



- Strategy of using medication PRIOR to HIV exposure in an uninfected person
- Daily Truvada (FTC/TDF) approved as PrEP in July 2012
- Daily Descovy (FTC/TAF) approved as PrEP in Oct 2019 (excluding individuals whose primary risk factor is receptive vaginal sex)

Side Effects

Truvada (FTC/TDF)

- Nausea (other GI side effects)
- Weight loss
- Fanconi Syndrome
 - Loss of kidney function, sugar and protein in urine
 - Case series of HIV+ pt on TDF– 1/1000 person years (Medland et al Int J STD AIDS 2018)
- Loss of bone mineral density
 - ~1-2%
 - Studies have not demonstrated increased fracture risk)

Descovy (FTC/TAF)

- Nausea (other GI side effects)
- Weight gain (in some individuals)
- Possible lipid abnormalities

May 25, 2018 - PrEP Now Approved by FDA for Adolescents at Risk for HIV

After being first approved in 2012 for adults, on May 15, 2018, the FDA approved the use of the medication Truvada for Pre-Exposure Prophylaxis, or PrEP, for adolescents at risk for HIV infection.

This FDA approval was partially based on ATN 113, a study of HIV-negative adolescent boys aged 15-17, which showed that adolescents tolerated PrEP usage. Adherence to the daily PrEP regimen, however, markedly declined when office visits decreased from a monthly to quarterly visit schedule.



“Study ATN 113 provided supportive safety and adherence information from a cohort of U.S. adolescents at risk of acquiring HIV,” the FDA’s Division of Antiviral Products within the Office of Antimicrobial Products said in a statement to the ATN. “The adherence data from ATN 113 specifically helped inform Truvada labeling with respect to adolescent PrEP monitoring, by suggesting that adolescents may benefit from more frequent visits and counseling to maintain proper adherence to the drug.” ATN 113 was a 48-week study that also concluded that adolescents may need more frequent clinical visits to ensure they are adherent to taking PrEP.

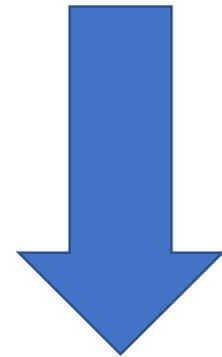
Bone Density in Adolescents in ATN 113

- Dual-energy x-ray absorptiometry (DXA) tests, used to assess BMD, indicated substantial increases from baseline BMD in the spine, hip, and total body at 48 weeks (expected)
- BMD Z-scores in the hip and spine did not change from baseline to 48 weeks
- Total body Z-score decreased (-0.20; interquartile range: -0.3 to 0.0; $p < 0.001$)
- Interpretation of these safety results might be affected by the overall low adherence

Bone Toxicity

ATN 117 evaluated the association of serum 25-hydroxy vitamin D insufficiency and TDF exposure with bone toxicity, as defined by age-specific DXA criteria

- 1) vitamin D replete with poor TDF exposure
- 2) vitamin D replete with high TDF exposure
- 3) vitamin D insufficient with low TDF exposure
- 4) vitamin D insufficient with high TDF exposure



Increasing bone toxicity

The study also reported a higher rate of bone toxicity in black persons, independent of vitamin D or TDF levels

HIV DRUG INJURIES



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Truvada Lawsuit Information
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👤 👤 Truvada linked to bone density and kidney side effects.
Anyone who experienced severe negative side effects due to the medication called Truvada may be eligible for significant compensation.
We help those affected get every dollar they deserve. There is limited time to file a claim. Click below to get a FREE claim evaluation. It only takes one minute.




BREAKING NEWS

TRUVADA SIDE EFFECTS

TRUVADA.LAWSUITSCOUT.COM
Compensation for Truvada Victims Sign Up

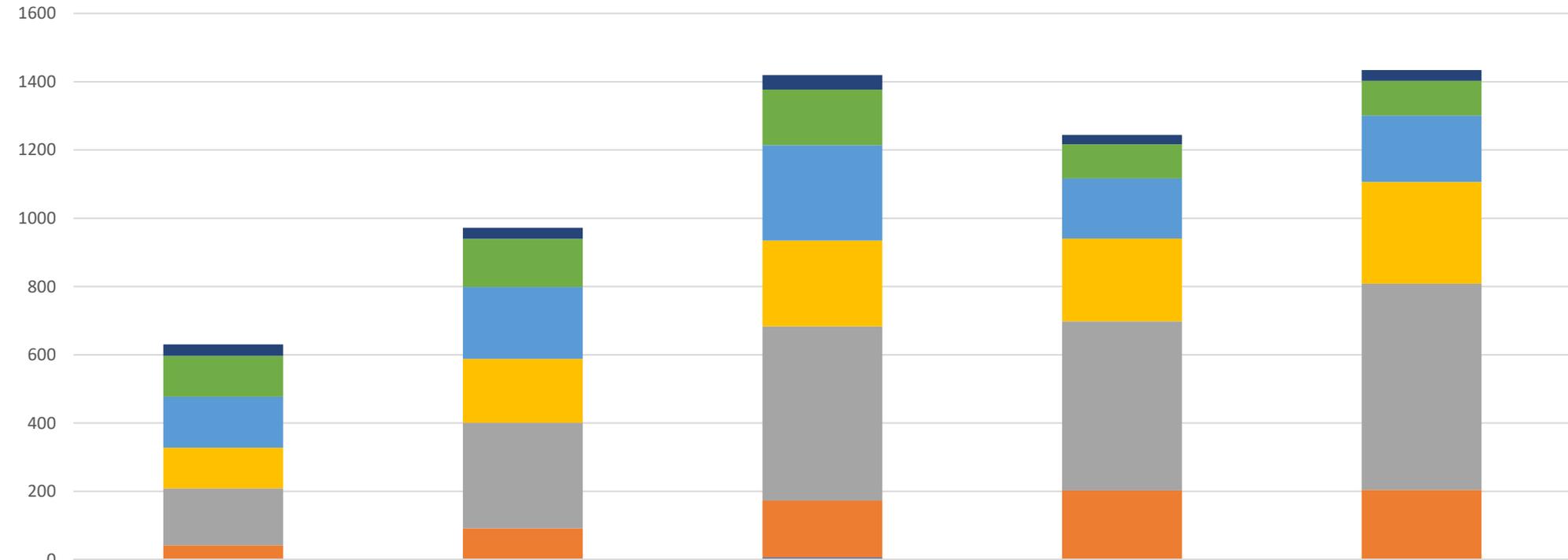
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My Take

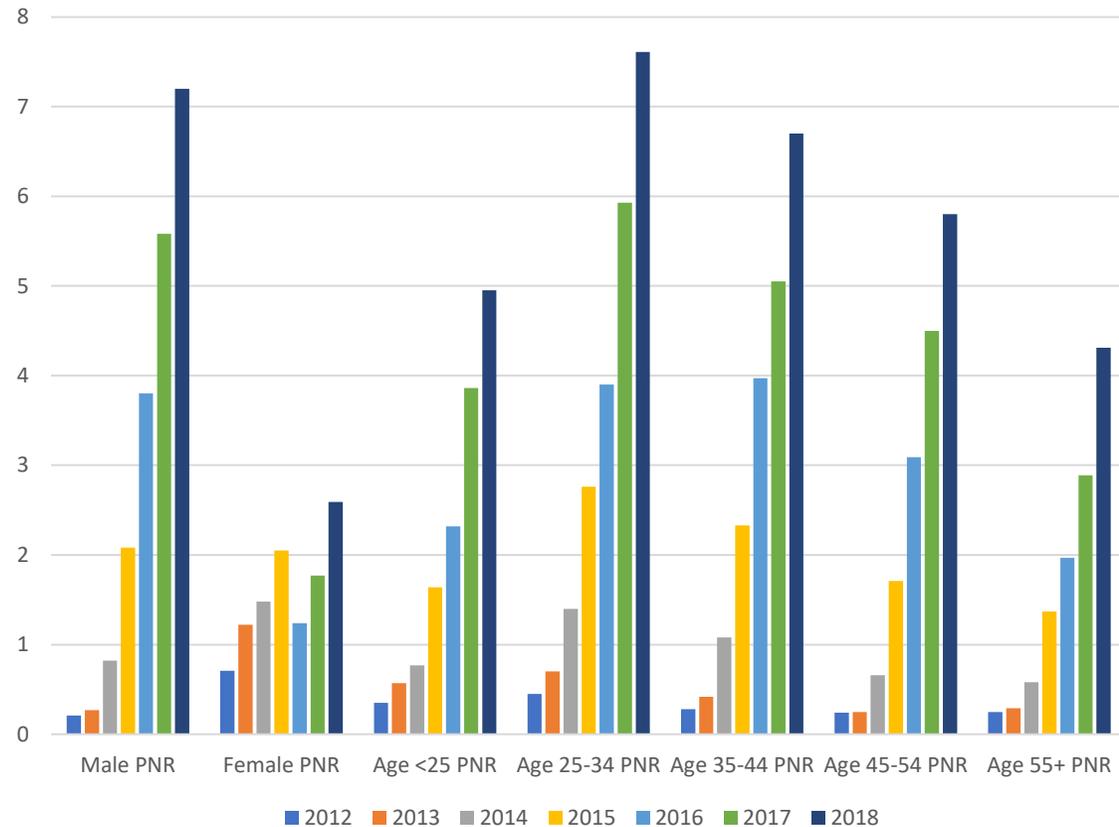
- Truvada and Descovy are both considered safe with appropriate monitoring and approved for adolescents > 35 kg
- Bone toxicity data suggests that for adolescents, Descovy may be a more beneficial option although no formal guidelines exist
- Long term data not available at this time
- Importance of community and provider education (and also dispelling myths, misleading/damaging messaging)

of Health Plan Members in Allegheny County with at least one PrEP prescription in the calendar year, 2015-2019, by age



	2015	2016	2017	2018	2019
65+	34	32	43	27	31
55-64	120	141	163	100	102
45-54	149	211	279	176	194
35-44	119	187	252	243	299
25-34	167	309	510	495	604
15-24	41	90	167	202	204
0-14	1	2	6	1	0

Pennsylvania-Specific PrEP-to-Need Ratios By Gender & Age (2012-2018)



- A PrEP-to-Need Ratio (PNR) represents the ratio of the number of PrEP users per year over the number of people newly diagnosed with HIV in each respective year. It is used to describe the distribution of prescriptions relative to the epidemic need.
- **A lower PNR indicates more unmet need.**

Provider's Perspective:

- Many providers in Allegheny County and statewide have acknowledged that they are hesitant/uncomfortable or unwilling altogether to consider prescribing PrEP to minors
- In Allegheny County, at least two organizations (e.g. Adagio Health + CVS Minute Clinic) have decided not to provide PrEP to minors (those under the age of 18) to avoid any concerns around liability and parental consent.
- The providers who do prescribe PrEP to minors often require parental consent before starting the medication. In very few cases, PrEP Navigators have been able to work with parents to educate them on the benefits of PrEP and its safety to support PrEP access for a minor.
- Some providers do prescribe PrEP to minors without parental consent (e.g. Philly FIGHT). They recommend ordering a HIPAA block (to hide what services the minor is receiving) and declination of benefits (so mail about services received is either not sent to the parents or is sent to the minor specifically). Some providers still cite concerns about liability in this instance, but feel like it is within their rights as a medical provider to do so.

PrEP Barriers: Patient Perspective

- Confidentiality: Minors may not want to discuss their sexual practices with their parents, especially if they are uncertain about how their parents will react with regard to being sexually active in general and/or the gender of their sexual partners.
- Safety: Minors may be concerned about their physical or emotional safety upon sharing this information with their parents (e.g. may be physically hurt, verbally harassed, or kicked out altogether).
- Cost: Even if a HIPAA block and/or declination of benefits are in place, parents may see that their child is using their insurance by way of financial changes on their account (e.g. changes in deductible amount). This may prompt parents to question their children about what they are using their insurance for, which in turn could challenge their safety.

Legal Issues

- As of a broad legal review in 2017, no states specifically prohibit minors' autonomous consent to PrEP.
- All states have statutes, regulations, or both that explicitly allow certain minors to consent to STI diagnosis and treatment.
- Allowing minors to autonomously consent to PrEP does not necessarily mean that care will remain confidential. Potential limitations to confidentiality include billing documentation, mandated reporting laws for child abuse and neglect, and others depending on the state.
- PrEP providers have to be familiar with the statutes and regulations regarding the provision of health care to minors in their jurisdictions.

Current PA Statute

- 35 P.S. §10103 states the following

“Any minor may give effective consent for medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases reportable...”

A Legal Question

NOT

If without a healthcare provider's prescription & supervision.

Q: Can A Minor Access PrEP Without Parental Consent In Pennsylvania ?

NOT

If it is unclear whether the law allows a minor to do so.

What Does The PA Minors Consent Act Say?

"Any minor may give effective consent for medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases..."

--35 P.S. § 10103

Should We Amend The PA Minors Consent Act?

PrEP can be considered a "treatment" under the PA Minors Consent Act based on the statutory intent and the absurdity doctrine. Thus, the Act already allows minors to access PrEP without parental consent.

-- Parents United (3rd. Cir. 1998)



Change ● Keep

- Accessing PrEP is not a right.
- The text's ordinary meaning does not include PrEP.
- Unlike the use of condoms, PrEP needs physician supervision and could be more invasive.
- Why not change the law to provide minors and healthcare providers clarity, uniformity, and certainty?

How Should PA Amend The Law?

States	Prior Laws	Current Laws/Suggested Language for PA
MD	A minor has the same capacity as an adult to consent to only treatment for or advice about venereal disease. --Md. Code Ann. §20-102 (2015).	"A minor has the same capacity as an adult to consent to: TREATMENT FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV)." --Md. S.B. 251 §1 (c)(9) (2019).
CT	"Any licensed physician or advanced practice registered nurse may examine and provide treatment for human immunodeficiency virus infection..." without parental consent if the physician or RN considers it necessary. -- Conn. Gen. Stat. §19a-592.	"Any licensed physician or advanced practice registered nurse may examine and provide prophylaxis or treatment for human immunodeficiency virus infection..." without parental consent if the physician or RN considers it necessary. --Public Act No. 19-109.
PA	"Any minor may give effective consent for medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases ..."	Add "Any minor may give effective consent for the treatment for the prevention of human immunodeficiency virus (HIV)." as section (b).

Find PrEP near you at: <https://npin.cdc.gov/DynCombinedWidgets/#/>

Proposed modification

“Any minor may give effective consent for medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases reportable...”

Addendum: “and for the treatment for the prevention of HIV”

The Road Ahead

- Do we opt for changing the language of the statutes to allow minors to be able to consent for PrEP use
- Do we pursue an “executive order” from the governor’s office to “mandate” that minor’s can give consent for treatment for prevention of HIV?
- Do we pursue other modalities to advocate for PrEP in adolescents and to reduce barriers?