Legal Issues Raised by PrEP for Youth
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Introduction
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PrEP Generally

PrEP, or “Pre-Exposure Prophylaxis,” is an antiretroviral drug commonly used to treat HIV infection – actually a pill that combines two separate drugs, Emtricitabine and Tenofovir – which has been proven to be extremely effective in preventing HIV infection through sexual activity, including condom-less anal and vaginal intercourse. The drug, manufactured by Gilead and marketed under the brand name Truvada, is approved by the FDA for adults who are at risk of HIV transmission.

Studies have demonstrated that when taken daily, PrEP is upwards of 99% effective. The drug takes somewhat longer to become concentrated, and fully effective, in vaginal tissue than in anal tissue. PrEP also appears to be quite effective – more than 95% - when taken 4 times per week. The evidence of effectiveness is more mixed when the drug is taken episodically – shortly before and shortly after unprotected anal or vaginal sex.

Side effects in adults are infrequent and generally mild – headache, nausea and diarrhea, which usually disappear after a few days, and infrequent, mild effects on kidney function and bone density. The major challenge is adherence – studies have demonstrated that the drug’s effectiveness is much lower in persons who take it infrequently or sporadically.

Individuals on PrEP must test HIV-negative prior to taking the drug and should be medically monitored at least every 3 months to check for side effects and to verify that they remain HIV-negative. PrEP is not recommended, and can be dangerous, if an individual is HIV-positive – Truvada alone is not a recommended therapy for persons living with HIV, and if used alone can result in mutation of the virus to become drug-resistant.

References

Information on PrEP is on the CDC’s web site:
https://www.cdc.gov/hiv/basics/prep.html

and on the web site of the San Francisco AIDS Foundation:
http://men.prepfacts.org
Information on PrEP for women:

Some of the recent scientific literature is discussed on the NIH web site:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4949005/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5125131/

Covering the Costs of PrEP (Including the Indicated Medical Checkups as Well as the Drug Itself)

After some uncertainty, PrEP is generally covered by many if not most private health plans, by Medicaid in most states, and by Medicare. Gilead administers an assistance program that will cover the costs of the drug itself up to $3,600. However, Gilead’s assistance program will not cover the costs of the required periodic checkups – and under many health plans the co-pays of medical visits and tests can be significant. Moreover, persons under 18 are not currently eligible for Gilead’s assistance plan.

As PrEP usage increases, there are reports of increasing problems with at least some insurers. For instance:

- There are a number of reports that people on PrEP have been denied other types of insurance. GLAD Legal Advocates and Defenders currently has a case in federal court against Mutual of Omaha for denying long-term care insurance to a gay man because of PrEP. https://www.glad.org/cases/doe-v-mutual-of-omaha. See also Donald C. McNeil Jr., He Took a Drug to Prevent AIDS. Then He Couldn’t Get Disability Insurance, New York Times (Feb. 12, 2018), https://www.nytimes.com/2018/02/12/health/truvada-hiv-insurance.html?utm_campaign=KHN-%20Daily%20Health%20Policy%20Report&utm_source=hs_email&utm_medium=email&utm_content=60643268&_hsenc=p2ANqtz-98OToClpMX3bBwi1n0ordG3XNPv8BY7OMcwcRJMUbOYe6ELqnC9HrnVb08rqBeeG0uXE-TMKWioNYfw_ztNagPBE-DWBFrBqQt8ovsrYGyJlprnKX0&_hsmi=60643268.

- Last summer, UnitedHealthcare denied coverage of a man’s PrEP prescription on the grounds that he was engaged in “high risk homosexual behavior.” After public outcry, the insurance company reversed its policy and apologized. UHC also reversed its policies of requiring pre-approval for PrEP and requiring covered individuals to use its mail-order pharmacy (policies also imposed by many other insurers). https://www.nbcnews.com/feature/nbc-out/united-apologizes-reverses-truvada-policy-after-hiv-activists-push-back-n789801.

- UnitedHealthcare, and other insurers, recently announced that amounts received under Gilead’s patient assistance program would not be counted towards the insured person’s annual deductible or out-of-pocket maximum. http://www.newnownext.com/united-healthcare-truvada-coverage/12/2017. It should be noted that a number of insurance companies are adopting similar policies towards co-pay assistance programs operated by pharmaceutical companies (“co-pay cards”), motivated by a concern that these programs...
are encouraging over-use of prescription drugs.\(^1\) Whatever the merits of such an approach generally, it appears to conflict with the public health goal of encouraging wider use of PrEP. *See, e.g.*, a recent study that concluded that current CDC-issued indications for PrEP are inadequate to protect young Black gay and bisexual men. Nicola Lanckia, Ellen Almirola, Leigh Alona, *et al.*, *Preexposure Prophylaxis Guidelines Have Low Sensitivity for Identifying Seroconverters in a Sample of Young Black MSM in Chicago*, 32 AIDS 383-92 (2018).

- Publix, a large grocery store chain in Florida and 6 other states in the South, was reported to have notified employees on its health plan that it did not cover PrEP. After public criticism, Publix announced that it was reversing its policy. [http://www.miamiherald.com/news/politics-government/article198652559.html](http://www.miamiherald.com/news/politics-government/article198652559.html)

### Evidence of PrEP Safety and Effectiveness for Youth

The FDA has not yet formally approved PrEP for persons younger than 18, but many FDA-approved drugs, including PrEP, are frequently prescribed for “off-label” uses.

A recent study of young men who have sex with me, between the ages of 15 and 17, concluded that PrEP was highly effective in the young men who adhered to treatment.

Concerns have been expressed about potential side effects in adolescents – particularly effects on bone density at ages when full physical growth has not yet been reached. Recent studies suggest that there is an occasional, small but measurable, reduction in bone density, which is reversed when Truvada stops, and can be reduced or counteracted by other therapies. In young people who are sexually active and do not use condoms or use them sporadically, any risk of future harm to bone density must be weighed against the risk of contracting HIV at a young age.

A major issue highlighted by PrEP studies of youth is adherence. For many if not most study participants, adherence has dropped sharply after several months – and rates of HIV seroconversion increase correspondingly.

### References


Renata Arrington-Sanders, *Human Immunodeficiency Virus Preexposure Prophylaxis for Adolescent Men: How Do We Ensure Health Equity for At-Risk Young Men?*, 171 JAMA

Challenges and Concerns Regarding PrEP for Youth

Health care providers and health centers that prescribe PrEP for young persons whose sex lives put them at significant risk of HIV, or who are considering policies to expand their services to include minors, face a number of challenges and have a number of questions, including:

- Can we legally prescribe PrEP for minors without parental knowledge and consent? What if our state’s laws allow minors to consent to diagnosis and treatment of STIs but do not expressly include “prevention”?

- Even if the law allows minors to consent to services that are focused on HIV prevention, PrEP in my adult patients is frequently a way to get the patients engaged in primary care. Can I approach minors in the same way, or do I need parental consent for primary care?

- How can I best encourage my young patients to take PrEP as recommended? Should I see them more often than my adult patients? How can I incorporate the flexibility I need to work with young people, into a medical practice that emphasizes maximizing patient encounters and billing?

- Will the insurance that covers a young patient cover PrEP?

- Can I assume my young patients that their information will remain completely confidential, or should I advise them of risks that their parents will learn that they are taking PrEP – and therefore, that they are sexually active/gay/bisexual? If the young patient is covered under their parent’s plan, will the parents learn about it?