

PrEP for Adolescents: Successes, Challenges & Opportunities

A Statewide Forum Hosted by the New York State Department of Health AIDS Institute **NOVEMBER 18, 2015**



MEETING REPORT

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FOREWORD

Lyn Stevens, MS, NP, ACRN

Deputy Director, Office of the Medical Director, AIDS Institute, and Forum Director

In November 2015, the New York State Department of Health AIDS Institute convened the first forum to bring together stakeholders from across the state to discuss the unique issues associated with providing PrEP for adolescents engaged in high-risk behaviors.

We invited PrEP providers, public health officials, and community members representing a wide variety of perspectives to contribute insights gleaned from their experiences with delivering PrEP services to adolescents in diverse settings. The day's discussion focused on identifying successes to date, policy issues, and clinical practice challenges in delivering PrEP to adolescents, and on opportunities to expand PrEP for adolescents statewide in support of the *NYS End the Epidemic* by 2020 initiative.

Invited speakers, who included researchers, clinicians, and service delivery providers, presented background on the clinical, psychological, and social service evidence supporting adolescent PrEP and shared data and lessons learned from their experience. Attendees then participated in each of 3 breakout sessions to address issues they identified in advance as key to implementation of adolescent PrEP statewide: 1) consent, payment, and access; 2) linkage to care and retention; and 3) clinical care.

First noted by AIDS Institute Director Dan O'Connell in his opening remarks, those themes dominated the day's discussions, and all agreed that consent, payment, and access to care must be addressed in tandem to ensure New York State's success in delivering PrEP to high-risk adolescents over the next 5 years.

Successes realized to date were acknowledged as well. Providers reported steadily increasing numbers of patients on PrEP who stay on PrEP. Clinical trials have indicated that PrEP is effective and safe and that adolescents are good candidates for PrEP. AIDS Institute funding to support PrEP specialists has been a resounding success. The greatest opportunities for change identified by participants were in the realms of policy and regulations; funding; and education for young people, community members, and clinical practitioners.

The day's discussion identified an immediate need for dissemination of information on payment options, as it was made clear that many attendees believe that private and public PrEP payment options are not readily available for adolescents. However, this is not the case. Though Gilead's payment assistance program is not open to minors, other options are available and accessible.

The success of events like this forum always depends on the time, thought, and effort of many. The people responsible for planning, logistics, materials design and production, venue coordination, registration, note-taking, facilitation of and reports on breakout sessions, and transcription of notes included Mary Ellen Reo, Jen O'Connor, the Johns Hopkins University Clinical Guidelines team, Marcia Kindlon, Toan Nguyen, Tracy Hatton, Donna Parisi, Kraig Pannell, Dora Swan, Carmen Vasquez, Laura Duggan Russell, Felicia Schady, Dan Tietz, and Beth Yurchak. Thank you all for making the day a great success.

This is an exciting time. We now have a proven method for preventing new HIV infections in some of the most vulnerable people in New York State. Identifying our successes to date, the challenges to ongoing success, and priorities for change in delivering PrEP to high-risk adolescents throughout New York is an important step in the right direction.

EXECUTIVE SUMMARY

FORUM ON ADOLESCENT PREP: SUCCESSES, CHALLENGES & OPPORTUNITIES

This report summarizes speaker presentations and the panel and participant discussions at the first statewide forum on implementation of pre-exposure prophylaxis (PrEP) for adolescents, which was hosted by the New York State Department of Health AIDS Institute (NYSDOH AI) on November 18, 2015.

On June 29, 2014, Governor Andrew Cuomo announced a 3-point plan to accelerate the end of the HIV/AIDS epidemic in New York State. A key component of this plan is to increase the accessibility and uptake of PrEP for high-risk HIV-uninfected individuals. PrEP implementation for adults was addressed on August 26, 2015, when the NYSDOH AI convened a forum, attended by healthcare providers, consumers, community stakeholders, and state and local health officials, to discuss the use of PrEP and PrEP quality of care for adults in New York State. The November 18, 2015, forum on adolescent PrEP was designed as a companion event to address challenges and opportunities specific to the adolescent population.

Presentations and discussions focused on 5 key areas:

1. Issues and challenges unique to PrEP implementation for adolescents
2. Keys to success, including best practices for engaging adolescents
3. Policies needed to increase adolescent access to PrEP statewide
4. Priorities for change to guarantee success in the next 3 years

There was near unanimity regarding the most important issues and challenges and equal agreement on top priorities for change to ensure success in expanding PrEP implementation in the next 3-5 years:

1. Update Public Health Law/Regulations

- Older adolescents can consent to PrEP; younger adolescents/minors should be granted the legal right to consent to PrEP.
- Regulatory relief should be provided to protect minors from unwanted disclosure to parents by insurance companies that insist on mailing preauthorization and explanation of benefits (EOB) documents to parents' address.

2. Increase Funding and Raise Awareness of Available Payment Options

- Expand PrEP-AP to include coverage for medications. *Editor's note: PrEP-AP currently covers the cost of clinic visits and laboratory tests but does not pay for medications.*
- Ensure that care providers are aware of and able to access all available options for payment.
- Increase public funding for PrEP implementation and access.

3. Frame Key Issues More Effectively

- Consent and payment are health issues, not civil rights issues—the ability to consent to PrEP is necessary to protect the health of and avoid harm to minors.
- PrEP is a public health issue—the inability to access PrEP is a threat to the health of those at risk of acquiring HIV, which may, in turn, pose a threat to the public's health.
- HIV prevention is analogous to pregnancy prevention.

4. Expand Training and Education

- For care providers—to ensure adequate numbers and geographic distribution of pediatricians and primary care physicians with the knowledge and willingness to prescribe PrEP, and to ensure that emergency physicians have the knowledge necessary to prescribe post-exposure prophylaxis (PEP) when it is indicated.
- Among young people—to reduce stigma, encourage concern for sexual health and engagement in care, and build knowledge of options for engaging in healthy sex.
- Throughout communities—to encourage support of PrEP and to normalize discussions of sex, sexual identity, and sexual health.

5. Expand Outreach to Youth

- Use a wide variety of outreach approaches to greatly expand efforts to identify youth who could benefit from PrEP, including younger adolescents/minors.
- Engage community partners and resources to reach and support young people.
- Create innovative programs and messaging to reach adolescents and customize messaging and outreach efforts for the different age groups within adolescence. Younger adolescents and older minors are developmentally different from each other and from older adolescents/young adults.
- Employ mobile and new technologies to engage and assist adolescents with adherence to PrEP treatment and associated clinic visits.

SUMMARY OF SPEAKER PRESENTATIONS

OPENING REMARKS

Dan O'Connell

Director, New York State Department of Health AIDS Institute

The AIDS Institute Director opened the forum by linking PrEP to prevent HIV infection to Governor Cuomo's 3-point plan to end the AIDS epidemic by 2020. The State has set the goal of reducing new infections from 3,000 to 750 annually by the end of 2020. The number of new infections has declined steadily, and now the availability of an effective, safe, and manageable biomedical intervention offers great hope for achieving the goal for 2020.

Providing PrEP to persons who engage in high-risk behaviors to prevent them from acquiring HIV is one of the 3 pillars of the State's initiative. Toward that end, the State's blueprint recommendations for PrEP and for post-exposure prophylaxis (PEP) call for a state-wide education campaign, increased distribution and access statewide, and statewide mechanisms to track and measure uptake.

O'Connell acknowledged the policy challenges to increasing minors' access to PrEP, highlighted the issues of consent and confidentiality, and stressed that efforts are underway to identify regulatory changes to allow minors to consent to their own care and prevention services. The issues of consent to care, access, payment, and education were the primary themes of the day's discussions.

Demetre Daskalakis, MD, MPH

Assistant Commissioner, Bureau of HIV Prevention and Control, New York City Department of Health and Mental Hygiene

Dr. Daskalakis stressed the importance of applying lessons learned in providing antiretroviral therapy for adolescents to implementing PrEP for adolescents and emphasized that New York City and New York State have forged a strong, complementary working relationship that has greatly expanded access to HIV care. Daskalakis described New York State as fertile ground for providing biomedical interventions and social services to prevent HIV. He asserted that care should be status neutral and that the goals of care, for people who are and are not HIV-infected, should be to test more, treat more, and engage youth in care, ideally, before they start taking risks.

Engage youth in care *before* they have engaged in risky behaviors.

With that, Daskalakis pointed out that guidelines and clinical studies, with their emphasis on youth who have already engaged in high-risk behavior, focus on the past-on behavior that has already occurred. He proposed looking forward to anticipate the activity of adolescents and empower them to make choices in advance. Accomplishing that, Daskalakis urged, requires early, unconstrained, and continuous dialogue with adolescents about life changes, sexuality, sexual health, and options, especially because it can be very difficult for adolescents to anticipate behavior that they have never engaged in or been close to. Daskalakis encouraged educating adolescents in advance so they know the options available to them when needed – not because they are planning to put themselves in harm's way, but so they can protect themselves if and when protection may be needed. He ultimately observed that youth is itself a health disparity deserving of careful consideration. The ultimate goal, said Daskalakis, should not be making sure that adolescents take pills; instead, the goals should be to engage adolescents in caring for their bodies, increase their awareness of risk, and provide them with the means to protect themselves when they are at risk and the ability to recognize when their season of risk is over and they no longer need PrEP.

INVITED SPEAKER PRESENTATIONS

Bill Kapogiannis, MD

Adolescent Medicine Trials Network for HIV/AIDS Interventions, National Institutes of Health (NIH), Bethesda, MD

PrEP adherence was greater among YMSM who were most susceptible to HIV infection.

An HIV PrEP Demonstration Project and Phase II Safety Study for Young MSM in the US: Noting that the NIH recognizes the dearth of PrEP safety and efficacy data for young men who have sex with men (YMSM), Dr. Kapogiannis discussed the results of ATN 110, a trial that included 200 US adolescents (18 to 22 years) who, as YMSM, were appropriate candidates for PrEP. All were HIV antibody-negative at the time of screening and all self-reported high-risk for acquiring HIV in the previous 6 months. Evidence of high-risk included the following:

- Condomless anal intercourse with an HIV-infected male partner or with a male partner of unknown status
- Anal intercourse with 3 or more male sex partners
- Exchange of money, gifts, shelter, or drugs for anal sex with a male partner
- Sex with a male partner and has had a sexually transmitted infection (STI)
- Sexual partner of an HIV-infected male with whom condoms were not consistently used
- At least one episode of anal intercourse during which the condom broke or slipped off



The majority of participants were Black (53%); 21% were White, 17% Hispanic/Latino, 2% Asian/Pacific Islander, and 7% were other/mixed race. The mean age was 20.18 years. Most (77%) of the participants identified as gay; 13.7% identified as bisexual.

After PrEP was dispensed, follow-up visits occurred at weeks 4, 8, 12, 24, 36, and 48, at 12 study sites located throughout the US.

Kapogiannis reported that PrEP was well-tolerated, with minimal adverse events. The number of STI diagnoses was high to start and remained so throughout the study. With 4 seroconversions through week 48, HIV incidence was high, but the researchers posit that, given the high rate of STIs, the seroconversion rate likely would have been higher in the absence of PrEP. Participants who seroconverted had undetectable drug levels, indicating lack of adherence with the

PrEP regimen. However, participants who engaged in condomless sex had higher drug levels, indicating that adherence was greater among the participants who were most susceptible to HIV infection.

Though generally good, adherence varied by race/ethnicity, with the lowest levels occurring among Black YMSM (BYMSM). Among all participants, adherence declined as the interval between study visits increased, with a notable drop after week 12, when the interval between visits increased from 4 weeks to 12. This finding suggests that youth may need more frequent or longer visits with providers, with in-person meetings augmented by contact via mobile technologies. The researchers also called for more research and greater understanding of barriers to PrEP access and adherence, particularly among BYMSM and other high-risk populations.

Kapogiannis also reported on bone changes among the study participants, noting that bone loss is the primary toxicity of the combination tenofovir/emtricitabine (TDF/FTC; brand name Truvada), which is used for PrEP. Results indicated that bone mass was lower at baseline than expected among study participants, and bone loss was modest. The effects of bone mass loss in adolescents, before peak bone density is achieved, is a concern. Additional research is needed to determine if bone mass losses reverse once PrEP is discontinued.

Susan Rosenthal, PhD, ABPP*Director, Division of Child and Adolescent Health, Columbia University, New York, NY***The most significant difference between adolescents and adults is legal status.**

Adolescent Autonomy and Decision-Making: Implications for Prescribing PrEP: Dr. Rosenthal opened her presentation by acknowledging that the prospect of prescribing PrEP for adolescents may inspire fear among care providers. She recommended cultivating a sense of excitement (rather than fear) because of the opportunity PrEP offers, and she provided insights into characteristics of adolescents and their behavior to help alleviate providers' fears.

Rosenthal stressed that adolescent autonomy “includes the right to give another person decision-making responsibilities.” Treating adolescents as if they have diminished autonomy and reflexively deferring to parents or surrogates assumes, perhaps incorrectly, that others have cognitive abilities to make decisions and the desire to act in adolescents' best interests. Because adolescents' abilities to make autonomous decisions are individual and situation-specific, some adolescents are capable of consenting to PrEP.

NY State law grants the right to consent to any type of health care to some minors, including those who are emancipated, married, have children, or are assessed to be “mature,” as designated and documented by a health care provider. All minors have the right to consent to reproductive health care, testing and treatment for STIs, and testing for HIV. But all minors do not currently have the right to consent to HIV treatment, PrEP, and other health and prevention care.

Rosenthal emphasized that “adolescence” is not a uniform state. It covers a wide range of ages, with dramatic variances in maturity within and among age groups. In general, mature judgment appears to develop between the ages of 16 and 19 years, and impulsivity declines between the ages of 15 and 30 years. Adolescents may be more vulnerable to risk-taking, but, she explained, research does not suggest great differences between adolescents and other age groups.

Practical Suggestions to Support Adolescents in Accessing PrEP:

Setting: Provide a space that is welcoming and comfortable for adolescents and that is safe for young people who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ). Ensure that staff and care providers are trained to work with and are comfortable with adolescents, have positive attitudes, clear boundaries, and understand their roles. Providers should avoid adopting the role of either parent or peer. Extra time should be accommodated in scheduled appointments for adolescents.

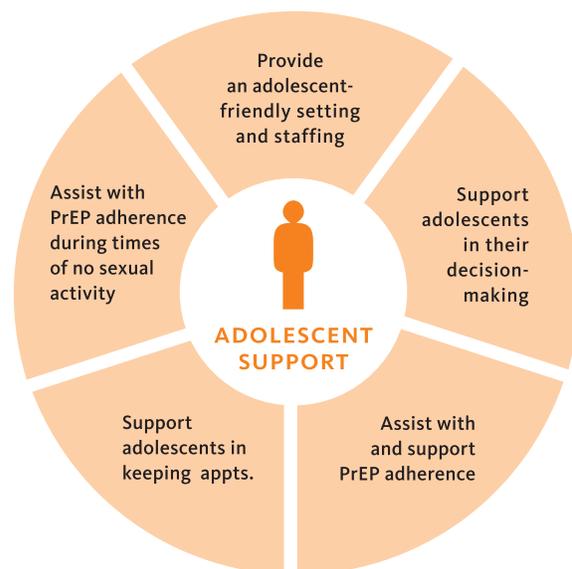
Decision-making: Support adolescents in their decision-making by addressing such questions as: Do they see PrEP as appropriate? Does it match their behavior? Do they see themselves as being at risk? Do they have an HIV-infected partner? Do they admit to injection drug use? Do they believe that PrEP works and is a good option for them? Do they believe they can remember to take the medication every day and keep their appointments?

PrEP adherence: This is especially important if adolescents do not wish to disclose that they are taking PrEP. When this is the case, adolescents may need help planning how to store and access their medications while maintaining their confidentiality. Providers should help adolescents identify ways to remember PrEP every day, such as tying it to showering, teeth brushing, or other daily routines.

Also important is helping adolescents maintain adherence between times of sexual activity. Unlike condoms, PrEP is not linked to having sex per se, so adolescents may need help and support in maintaining adherence even when they are not sexually active.

Keeping appointments: Support adherence to PrEP-related medical appointments by addressing and troubleshooting reasons for missing clinic appointments, and assist in planning to keep appointments.

In closing, Rosenthal emphasized that the most significant difference between adolescents and adults with regard to PrEP is their legal status (not, as many believe, developmental or social factors) because legal status impedes access, consent, and payment.



Lillian Rivera, MPH

The Center for LGBTQ Youth Advocacy and Capacity Building, Hetrick-Martin Institute, New York, NY

Create political will by demonstrating the cost-effectiveness of PrEP vs. a lifetime of HIV care

Imagining a Tomorrow with Choices: Mapping a Trajectory for YMSM Access to PrEP Based on the History of Reproductive Justice: In describing the approach to youth and sexual health taken by the Hetrick-Martin Institute, Ms. Rivera stressed the importance of context, and in so doing, encouraged a sharp focus on the needs of youth. Specifically, she urged a holistic approach that provides access to high-quality sexual health care and helps youth develop a healthy sense of their sexuality. She stressed that doing so will encourage young people to recognize the importance of sexual health.

Rivera described an approach focused on creating access to choices for youth, with no barriers, by providing accurate, youth-targeted information, public education, and advocacy. She emphasized the need to create political will by, for instance, demonstrating the cost-effectiveness of PrEP versus a lifetime of HIV care. Rivera also encouraged a focus on health promotion, rather than risk and harm prevention. This idea was underscored during the question-and-answer session when all 3 presenters confirmed the difficulty of asking adolescents to predict their behavior, which is often not possible because sexual behavior may be new.

Payment Options Are Available for PrEP for Adolescents

Throughout the day's discussions, many participants reported that they find it difficult, if not impossible, to secure payment for PrEP for adolescents. There are private and public payment options available, and there are some common misperceptions about coverage. This shared difficulty points to the need to educate providers about payment options, which is a priority for the AIDS Institute. We strongly encourage care providers to consult with colleagues, with the AI, and with other public resources when assistance is needed to secure payment for adolescents.

PANEL DISCUSSION:

EXPERIENCES IMPLEMENTING PREP IN ADOLESCENT CLINICS

PANELISTS:

- **Donna Futterman, MD**, Director, Adolescent AIDS Program, Children's Hospital at Montefiore, Bronx, NY
- **Jeffrey M. Birnbaum, MD, MPH**, Executive Director, HEAT Program, SUNY Downstate Medical Center, Brooklyn, NY
- **David Rosenthal, DO, PhD**, Medical Director, Northwell Center for Young Adult, Adolescent and Pediatric HIV, Great Neck, NY
- **Uri Belkind, MD, MS**, Clinical Director of Health Outreach to Teens (HOTT), Callen-Lorde Community Health Center, New York, NY

Panelists were invited to discuss their experiences in implementing PrEP for adolescents in 4 different clinical settings and were asked to describe the following aspects of their programs:

- Utilization: Number of patients served, demographics, unique characteristics, and recruitment
- Service model: Support team, providers, special training, linkages, funding, and unique issues (e.g., adherence, social services, medical services)
- Metrics: Performance data, quality measures, and outcomes
- Successes: Key achievements and unique aspects of the program
- Challenges: Key challenges to PrEP implementation

An overview of panelists' presentations is presented in Table 1.

Table 1: Overview of Panelists' Adolescent PrEP Program Implementation

ADOLESCENT AIDS PROGRAM, CHILDREN'S HOSPITAL AT MONTEFIORE, BRONX, NY PRESENTER: DONNA FUTTERMAN, MD, DIRECTOR	
Utilization	<ul style="list-style-type: none"> • 7/2014-11/2015: 31 screened; 14 clinically assessed; 7 prescribed PrEP; 3 waiting for PrEP • 58% Black; 33% Latino; 10% White • 52% male; 13% female; 35% transgender • 35% gay; 26% straight; 13% pansexual; 13% bisexual; and 13% other
Service Model	<ul style="list-style-type: none"> • Policy and procedure based on Centers for Disease Control and Prevention (CDC) and NYSDOH guidance • Attending physician, NPs, 2 PrEP specialists (social worker and LPN); all staff received CME training • Clinical referrals from medical providers; linkage agreements with CBOs; word-of-mouth; partner referrals; packaged with other clinical services, such as hormones and STI screening • Payment: private insurance, Medicaid, Gilead patient assist, NYS PrEP-AP, private fund for minor and uninsured; to date, no denials from private insurers
Metrics	<ul style="list-style-type: none"> • Percentage screened, assessed, and prescribed • Retention in care • Adherence self-report • Seroconversions • Patient satisfaction • Qualitative assessment of facilitators and barriers
Successes	<ul style="list-style-type: none"> • Dedicated PrEP specialists • Primary care as gateway to PrEP • Continued engagement of patients not initially interested • Flexibility with visits • Improved psychosexual health
Challenges	<ul style="list-style-type: none"> • Barriers to uptake: low perception of risk, adherence, parental disclosure, other medical priorities, not ready • Private insurance: prior authorization, high co-pays, required mail-order pharmacy, EOBs that threaten confidentiality • Multiple follow-up visits
Priorities for Change	<ul style="list-style-type: none"> • Insurance coverage for minors • Parental consent waiver • Increased access in primary care settings • Scaled up routine HIV testing • Greater understanding of how to motivate and communicate with youth about PrEP

Table 1: Overview of Panelists' Adolescent PrEP Program Implementation, continued

HEAT PROGRAM, SUNY DOWNSTATE MEDICAL CENTER, BROOKLYN, NY PRESENTER: JEFFREY M. BIRNBAUM, MD, MPH, EXECUTIVE DIRECTOR	
Utilization	<ul style="list-style-type: none"> • ~125 HIV-infected youth, aged 13-24 years; much larger number of non-HIV-infected youth for HIV and STD screening • 28 assessed for PrEP; 8 initiated; 6 continued on PrEP; 1 lost to follow-up; 1 unable to start due to insurance/confidentiality issues • Youth who are insured by parents and related issues of consent and confidentiality are issues unique to this population • PrEP target population includes partners of HIV-infected youth • Broad recruitment among all HIV-infected clinic patients and targeted outreach to YMSM and transgendered youth in community settings, including house ball community • Principles of adherence same as for HIV care for adolescents
Service Model	<ul style="list-style-type: none"> • Team includes PrEP specialist, peer outreach staff, 3 medical providers, case management and mental health services • Community outreach to LGBTQ youth organizations; in-reach and training provided to hospital medical staff • AI-funded PrEP specialist makes direct contact with youth, schedules appointments, reminds, and assesses insurance status • Population is generally high-risk youth, often homeless, often difficult to engage in care, unmet mental health needs
Metrics	<ul style="list-style-type: none"> • Began measuring performance in AIRS 2/2015 • Medical encounter forms for medical services related to PrEP • Adherence to quarterly visit schedule • Considering use of quarterly lab measures • No seroconversions to date • Keeping any patient on PrEP protocol for 6 months
Successes	<ul style="list-style-type: none"> • Program is up and running (with AI support) • Patients who are started on PrEP are adherent with regimen and visits • External referrals • Buy-in from house ball community
Challenges	<ul style="list-style-type: none"> • Uninsured youth and difficulty with securing payment for adolescents. Youth unable to access their insurance information from parents (confidentiality and sensitivity issues) • Loss of confidentiality due to EOB letters • High-risk minors cannot consent to treatment in New York • Lack of information about PrEP among some of the highest-risk youth • Stigma about HIV among youth, especially in house ball community
Priorities for Change	<ul style="list-style-type: none"> • Access • Payment

Table 1: Overview of Panelists' Adolescent PrEP Program Implementation, continued

NORTHWELL CENTER FOR YOUNG ADULT, ADOLESCENT AND PEDIATRIC HIV, GREAT NECK, NY PRESENTER: DAVID ROSENTHAL, DO, PHD, MEDICAL DIRECTOR	
Utilization	<ul style="list-style-type: none"> • New PrEP referrals are increasing: 2 in 2013, 13 in 2014, 25 as of September 2015 • Overwhelming majority of PrEP patients are MSM, with small numbers of heterosexual and transgender youth • 62% of referrals are from community partners; 15% from the community van; 10% from patients' partners; small numbers from the internet, physician referral, schools, etc. • Wide variety of community partners in Queens and Nassau • College and public health outreach were not high-yield, nor was advertising—need to target message better • Social media and apps are crucial
Successes	<ul style="list-style-type: none"> • Steady increase in referrals • HIV testing van with AI-funded PrEP specialist—"talking about PrEP every possible way" • Community partnerships, which are key for referrals • Training care providers about PrEP
Challenges	<ul style="list-style-type: none"> • Care provider training broadly—not just for people who take care of patients with HIV infection • Funding continuity and sustainability: start-up grants are great, but once funding priorities shift, there is no way to maintain programs • Not doing great with PrEP among adolescents—much more energy and resources are needed • Young men under 20 are not very willing to engage with PrEP; their good intentions get in the way (e.g., "I am going to start using condoms every time I have sex") • Great need for new working relationships/collaborations with different sectors of healthcare system and within healthcare systems (i.e., in-patient service often is disconnected/unaware of out-patient service)
Priorities for Change	<ul style="list-style-type: none"> • Direction needed from the State on EMR carve-out for sexual health information for 13- to 17-year-old patients; access to information blocked to care providers • Expanded funding for PrEP • Make linkage to PEP for emergencies much easier and less cumbersome; PEP for emergencies is crucial—true harm reduction; initiate PEP starter packs; PEP needs to be seen as equally important as PrEP

Table 1: Overview of Panelists’ Adolescent PrEP Program Implementation, continued

CALLEN-LORDE COMMUNITY HEALTH CENTER, MANHATTAN, NY PRESENTER: URI BELKIND, MD, MS, CLINICAL DIRECTOR OF HEALTH OUTREACH TO TEENS (HOTT)	
Utilization	<ul style="list-style-type: none"> • 148 PrEP patients: 91 from HOTT; 57 adults • 55% White; 13% Black; 10% other; 22% no response; 32% Hispanic • 87% male; 11% transgender; 2% other
Service Model	<ul style="list-style-type: none"> • 3 PrEP specialists who are part of the HIV prevention and outreach team; they handle HIV counseling and testing, PrEP outreach and counseling, staff training, PrEP-AP applications, and Gilead MAP applications • HOTT medical providers, triage nurse, sexual health clinic, SPARK project • PrEP protocol: 1) initial visit (history, labs, STI screening, counseling); 2) adherence assessment; 3) first follow-up; 4) every 3 months follow-up • PrEP support services: HOTT triage nurse, case managers, and PrEP specialists • Funding: Insurance, PrEP-AP, grants (AI, NYSDOH, SPARK-NIH)
Successes	<ul style="list-style-type: none"> • PrEP is viable option for older adolescents and young adults • Participation is similar to that of other groups • Multiple options for accessing and obtaining PrEP • Multidisciplinary teams with cross-training and collaboration • Community outreach, including in house ball community
Challenges	<ul style="list-style-type: none"> • Equal access to services across racial and gender barriers • Younger patients more likely to be uninsured and have confidentiality issues • Consent: law is not clear regarding minors’ ability to consent to prevention

PANELISTS' SHARED SUCSESSES, CHALLENGES, AND PRIORITIES

From the panel discussion, a clear picture of shared successes, challenges, and priorities for change emerged. Shared successes included the addition of AI-funded PrEP specialists, who all panelists agreed were instrumental in program implementation. All reported steadily increasing numbers of patients on PrEP and reported that those who have started PrEP have, for the most part, stayed with it. Training for care providers was also reported as a success, as was increasing external referrals and expanding community partnerships for outreach and referrals.

Three dominant themes emerged as challenges and priorities for change:

Consent: Older adolescents/young adults are able to consent to PrEP, but many minors (age 17 and younger) cannot. Regulatory change is needed to allow minors to consent.

Limited payment options: Panelists reported that payment options are limited, particularly because adolescents often cannot readily access parents' insurance coverage. When they can, doing so may jeopardize their confidentiality if insurance companies insist on mailing documentation, such as EOBs, to policy holders' (i.e., parents) homes.

Limited access: Youth access to PrEP is limited because of consent and payment issues, because there are not enough providers who can prescribe PrEP, and because there are not enough resources to reach youth who need PrEP and engage them in care.

In addition, conference participants stressed the following: 1) concern that a relatively small number of adolescents girls are receiving PrEP when there are many who are having sex with YMSM; 2) the ongoing need for education because many adolescents do not know how HIV is transmitted and acquired.



SUMMARY OF BREAKOUT SESSIONS AND REPORT OUT

Meeting participants were divided into 3 groups and invited to rotate through 3 breakout sessions, each of which addressed topics identified in advance as important to any discussion of adolescent PrEP implementation. Groups were facilitated by AIDS Institute staff, who then reported on the groups' responses when asked to identify the following:

- Issues and challenges unique to PrEP implementation for adolescents
- Keys to success, including best practices for engaging adolescents
- Policies needed to increase adolescent access to PrEP statewide
- Priorities for change to guarantee success in the next 3 years

The ideas expressed and the conclusions drawn in the group discussions largely echoed the concerns and conclusions of all speakers and presenters.

SESSION I: CONSENT, PAYMENT, AND ACCESS TO CARE

PrEP is a public health issue, not a civil rights issue.

Issues and Challenges Identified by Participants:

- Most minors (age 17 and younger) are not able to consent to PrEP. Emancipated minors, minors with children, and minors assessed as being "mature" by care providers are the exceptions. If a care provider documents in his/her assessment that a minor is "mature," then the minor can consent to PrEP.
- The legal definition of "adult" is not clear and should be clarified from the top down, i.e., in guidance from the CDC and the Food and Drug Administration (FDA).
- A mechanism for waiving parental consent is needed; requiring parental consent for PrEP (and HIV treatment) may violate adolescents' confidentiality and prevent them from seeking PrEP.
- Private insurance companies and mail-in prescription services may not be willing to refrain from delivering documents that may violate adolescents' confidentiality to parents (e.g., EOBs, preauthorization forms, and prescription order receipts).
- Payment options and access are limited. Adolescents may have difficulty accessing their insurance coverage without disclosing to their parents.
- More resources and support are needed. Much time and effort is required in working with adolescents to arrange payment, to negotiate with insurance companies to take steps to protect adolescents' confidentiality, and to support adherence. Navigating the labyrinthine logistics of payment/coverage can be time consuming, and negotiations are not always successful.

Participants' Proposed Solutions and Changes:

- Take action now for the future by revising regulations to allow minors to consent to PrEP and to other prevention measures, such as the human papillomavirus (HPV) vaccine, and to HIV treatment. There is precedent: minors are able to consent to treatment of STIs and to family planning.
- Revise Article 23 to include HIV among STIs, but exempt HIV from the statute that criminalizes transmission of STIs.
- Make broader use of the "mature minor" provision to prescribe PrEP for minors.
- Increase public funding to pay for PrEP for adolescents.
- Accommodate longer clinic visits and provide more resources and support to address all of the issues that attend PrEP for adolescents.
- Lobby to change insurance company rules regarding home delivery of coverage-related materials for adolescents; establish easier mechanisms for requesting that insurance companies deliver materials to alternate addresses.
- Expand efforts to identify young people who are in need of PrEP. Doing so requires avoiding common and stereotypical conceptions of risk and expanding education and outreach throughout the community, most especially in schools, pharmacies, and healthcare systems.
- Establish a risk stratification strategy in guidelines to help identify those with whom PrEP should be discussed.
- The AIDS Institute should take the lead in promoting use of PrEP and making clear that the benefits outweigh any risks.

Participants' Top Priorities for Next 3-5 Years to Improve Consent, Payment, and Access to Care for Adolescent PrEP:

- Change the language of Article 23 to include HIV as an STI, but exempt HIV from statutes that criminalize transmission. Build community support for these changes.
- Expand PrEP-AP to cover adolescents. *Editor's note: Although PrEP-AP does not cover the cost of medications, the program does cover the cost of clinic visits and laboratory tests.*
- Grant adolescents the ability to consent to care and expand coverage of PrEP for adolescents at the same time. Consent without access to payment will not be helpful.
- Conduct more clinical trials to push the FDA toward approval of FTC/TDF for use as PrEP in individuals under 18 years of age.
- Reframe the key issues: 1) PrEP is to protect health; therefore, the ability to consent to PrEP is required to protect adolescents' health and to avoid harm to minors; 2) PrEP is a public health issue, not a civil rights issue; therefore, the health of those unable to access PrEP is threatened, which may, in turn, threaten the public's health; 3) prevention of HIV is analogous to prevention of pregnancy.

SESSION II: LINKAGE TO CARE AND RETENTION

PrEP is a public health issue, not a civil rights issue.

Issues and Challenges Identified by Participants:

- Our culture prioritizes health care for sickness, not for prevention to stay healthy. Adolescence is not generally a time of illness, and adolescents do not see themselves as in need of health care.
- Our culture also does not support or encourage open discussion of sex, sexuality, and sexual health. As a result, discussions of prevention are focused on risk, and discussions of sex are medicalized, which may not be an effective approach for youth.
- Issues of access, consent, payment, and confidentiality pose barriers to PrEP for adolescents.
- Public health messaging and the current public health approach to PrEP for adolescents reflects ambivalence. The message needs to be clear and unambivalent: PrEP is for healthy sex.
- There are not enough care providers who are knowledgeable about, able, and willing to prescribe PrEP, particularly in rural areas.

Participants' Proposed Solutions and Changes:

- Widespread training of pediatricians and primary care providers to expand awareness of PrEP and access issues. One approach may be to make PrEP training and competency a requirement for licensure.
- Make starter packs available that provide a 14- or 30-day supply of FTC/TDF to ensure that patients return for follow-up care.
- Expand and enhance the use of digital technologies to create multiple channels for reaching, engaging, and retaining youth in care.
- Create innovative adherence tools.
- Adopt new, clear approaches to messaging for youth (e.g., PrEP is for healthy sex)
- Expand the capacity of healthcare facilities to welcome and accommodate young people. Going to a clinic, especially a clinic in a hospital, is an adult activity that many adolescents are not prepared to do on their own.
- Expand sensitivity training to improve clinical environments for LGBTQ youth.
- Expand and support partnerships between and among health system entities, community-based organizations, and other community partners.
- Involve schools to a much greater degree for education and health service delivery.
- Improve access to city and state data to help care providers locate patients in need of PrEP and to locate patients for follow-up.
- The AI should identify ways to use its data system to close loopholes in the referral/appointment/attendance process.

Participants' Top Priorities for Next 3-5 Years to Improve Linkage to Care and Retention for Adolescent PrEP:

- Revise public health laws to address consent, access, and payment barriers.
- Educate healthcare providers to expand their awareness and knowledge of PrEP; ensure training across multiple specialties (e.g., pediatrics, primary care, emergency medicine), not just among HIV care providers. Consider a mechanism to tie PrEP training and competency to licensure.
- In the approach to adolescents, focus on sexual health.
- Pilot-test innovative programs, including expanded use of peers and peer navigators.
- Implement school-based clinics.

SESSION III: CLINICAL CARE**Addressing consent and payment issues is labor-intensive and time-consuming.****Issues and Challenges Identified by Participants:**

- Issues of consent, confidentiality, access, and payment pose barriers to PrEP for adolescents.
- HIV is not, but should be, considered an STI for regulatory purposes.
- Adolescents need extraordinary support for successful adherence, including more frequent and longer visits with care providers, incentives to keep appointments, novel approaches to reminding youth to take medications, and sensitivity to special circumstances, such as a need to maintain confidentiality.
- It is labor-intensive and time-consuming to navigate issues of consent and payment for adolescents.
- Adolescents often lack the health and sexual health literacy necessary to demand PrEP and/or to understand the requirements associated with PrEP, such as screening and lab testing.
- Healthcare providers' discomfort with discussing sex and sexuality with adolescents may lead them to avoid the ongoing dialogue necessary to promote adolescent sexual health.
- There are not enough care providers with the knowledge and willingness to prescribe PrEP.

Participants' Proposed Solutions and Changes:

- Expand training to ensure adequate numbers of care providers who are knowledgeable, able, and willing to prescribe PrEP for adolescents; there is a great need for PrEP providers in rural areas in particular.
- Tailor PrEP clinic settings, hours, and approaches to the needs of adolescents by: 1) expanding clinic hours; 2) providing sensitivity training to all staff—not just clinical staff; 3) making effective use of mobile technologies to reach and engage young people through multiple channels; 4) lengthening and increasing the frequency of visits as individual needs dictate; and 5) expanding community partnerships and settings in which PrEP can be accessed.
- Tailor PrEP-related messaging to adolescents of various ages and to delivery in a wide variety of settings; create effective campaigns to increase health literacy among youth.
- Provide support and training for care providers to increase their comfort in addressing sex, sexuality, and healthy sex with youth.
- Develop incentives that are meaningful to adolescents to support and reinforce their engagement with care and adherence.
- Make starter packs available to provide a 14- or 30-day supply of FTC/TDF and ensure that patients return for follow-up care.
- Address regulatory issues that impede prescribing PrEP for minors and expand PrEP-AP to cover PrEP and vaccinations for minors.
- Update guidelines to include adolescent-specific recommendations that address the following: 1) identification of candidates for PrEP through risk stratification; 2) more frequent (every 3 months) STI screening; 3) increased frequency of PrEP follow-up visits to ensure coverage for monthly visits if they are needed; and 4) lab work, routine health maintenance, and mental health and substance use screening.

Participants' Top Priorities for Next 3-5 Years to Improve Clinical Care for Adolescent PrEP:

- PrEP and sexual health training for care providers, beginning in medical school.
- Revise public health law to address issues of consent, payment, and access.
- Update guidelines to address adolescent-specific key issues (specifics noted above).
- Expand health education for youth, and include education tailored specifically to younger adolescents.
- Use multiple channels and innovative approaches to engage and retain young people in care.

CONCLUSIONS:

KEY ISSUES AND PRIORITIES FOR CHANGE TO EXPAND ACCESS TO AND IMPLEMENTATION OF PREP FOR HIGH-RISK ADOLESCENTS IN NEW YORK STATE

The 3 dominant themes that emerged as challenges and priorities for change during the panel discussion were also emphasized by participants during the breakout session discussions: 1) minors are not able to consent to PrEP and NYS regulatory change is needed to allow minor consent; 2) payment options are limited because adolescents cannot readily access insurance, and payment programs such as Gilead assistance do not cover prescriptions for minors; and 3) access is limited by consent and payment issues, by the small numbers and limited geographic distribution of providers who will/can prescribe PrEP, and by insufficient resources to reach the youth who need PrEP and to engage them in care.

Attendees were in broad agreement that the top priorities for change to ensure success in expanding PrEP implementation in the next 3-5 years should be:

1. Update Public Health Law/Regulations

- Grant minors the legal right to consent to PrEP.
- Provide regulatory relief to protect minors from unwanted disclosure to parents by insurance companies that insist on mailing preauthorization and EOB documents to parents' address.

2. Increase Funding and Expand Payment Options

- Expand PrEP-AP to include coverage for medications in addition to current coverage of cost of clinic visits and laboratory tests for minors and clarify language.
- Increase care providers' knowledge of and ability to access all available options to pay for PrEP for adolescents.
- Increase public funding for PrEP implementation and access.

3. Frame Key Issues More Effectively

- Consent and payment are health issues, not civil rights issues—the ability to consent to PrEP is necessary to protect adolescents' health and to avoid harm to minors.
- PrEP is a public health issue—the inability to access PrEP is a threat to the health of those at risk of acquiring HIV, which may, in turn, pose a threat to the public's health.
- HIV prevention is analogous to pregnancy prevention.

4. Expand Training and Education

- Train care providers, to ensure adequate numbers and geographic distribution of pediatricians, primary care physicians, and emergency physicians with the knowledge and willingness to prescribe PrEP.
- Educate young people, to reduce stigma, encourage concern for sexual health and engagement in care, and to build knowledge of options for engaging in healthy sex.
- Educate community members, to encourage support of PrEP and to normalize discussions of sex, sexual identity, and sexual health.

5. Expand Outreach to Youth

- Use a wide variety of outreach approaches to greatly expand efforts to identify youth who could benefit from PrEP.
- Engage community partners and resources to reach and support young people.
- Create innovative programs and messaging to reach youth.
- Employ mobile and new technologies to engage and assist adolescents with adherence to PrEP treatment and associated clinic visits.

APPENDIX A: MEETING AGENDA

9:00 AM–9:30 AM	Registration, Continental Breakfast, Networking
9:30 AM–9:40 AM	Welcome and Introductions: Lyn Stevens, MS, NP, ACRN, Deputy Director, Office of the Medical Director, NYSDOH AIDS Institute
9:40 AM–9:50 AM	Opening Remarks: Dan O’Connell, Director, NYSDOH AIDS Institute
9:50 AM–10:00 AM	Opening Remarks: Demetre Daskalakis, MD, Assistant Commissioner of the Bureau of HIV Prevention and Control, NYC DOHMH

PART I: INVITED SPEAKERS

10:00 AM–10:30 AM	ATN 110: An HIV PrEP Demonstration Project and Phase II Safety Study for Young MSM in the US Bill Kapogiannis, MD, Adolescent Medicine Trials Network for HIV/AIDS Interventions, NIH
10:30 AM–11:00 AM	Adolescent Autonomy and Decision-Making: Implications for Prescribing PrEP Susan Rosenthal, PhD, ABPP, Director, Division of Child and Adolescent Health, Columbia University
11:00 AM–11:30 AM	Imagining a Tomorrow with Choices: Mapping a Trajectory for YMSM Access to PrEP Based on the History of Reproductive Justice Lillian Rivera, MPH, The Center for LGBTQ Youth Advocacy and Capacity Building, Hetrick-Martin Institute
11:30 AM–12:00 PM	Questions and Answers
12:00 PM–12:15 PM	Break: Pick up lunch and return for panel discussion

PART II: WORKING LUNCH WITH PANEL DISCUSSION

12:15 PM–1:00 PM	PrEP Implementation in an Adolescent PrEP Clinic <ul style="list-style-type: none"> • Donna Futterman, MD, Adolescent AIDS Program, Children’s Hospital at Montefiore • Jeff Birnbaum, MD, Heat Program, SUNY Downstate • David Rosenthal, DO, PhD, Northwell Center for Young Adult, Adolescent and Pediatric HIV • Uri Belkind, MD, MS, Health Outreach to Teens (HOTT), Callen-Lorde
1:00 PM–1:15 PM	Questions and Answers

PART III: ROUND-ROBIN BREAKOUT SESSIONS

1:15 PM–2:45 PM	Participant Discussions: Attendees will circulate through three 25-minute breakout sessions to discuss their experiences with the following key topics in adolescent PrEP implementation: consent, payment, retention, adherence, sexual health, and clinical care. After 25 minutes of discussion in one session, participants will be directed to the next session until everyone has had the opportunity to participate in each of the 3 sessions. After a short break, we will gather to report out and identify priorities for policy and change.
2:45 PM–3:00 PM	Break

PART IV: PRIORITIES FOR POLICY AND CHANGE: REPORTS FROM BREAKOUT SESSIONS

3:00 PM–3:45 PM	Report Out: Successes, Challenges and Priorities for Change: Session leaders will report out to the whole group with the goal of identifying the top 3-5 items in each of the following areas: <ul style="list-style-type: none"> • Issues and challenges unique to PrEP implementation for adolescents • Keys to success, including best practices for engaging adolescents • Policies needed to increase adolescent access to PrEP statewide • Priorities for change to guarantee success in the next 3 years
3:45 PM–4:00 PM	Next Steps and Closing Remarks: Lyn Stevens

APPENDIX B: LAWS CONCERNING MEDICAL TREATMENT OF MINORS AND CONSENT IN NEW YORK STATE

TOPIC	NEW YORK PUBLIC HEALTH LAWS AND DESCRIPTION
<p>Consent for Medical Treatment in General, Including HIV Treatment</p>	<p>PHL § 2504 provides that parental or guardian consent is generally required for a physician to treat a person who is under 18, including for HIV/AIDS. However, there are exceptions:</p> <p>§ 2504(1): A person who is a) 18 or older; b) the parent of a child; or c) has married may give consent for medical, dental, health and hospital services for himself or herself, and the consent of no other person shall be necessary;</p> <p>§ 2504(3): A person who is pregnant may give consent for medical, dental, health and hospital expenses relating to prenatal care;</p> <p>§ 2504(4): Medical, dental health and hospital services may be rendered to persons of any age without the consent of a parent or legal guardian when in the physicians judgment an emergency exists and the person is in immediate need of medical attention and an attempt to secure consent would result in delay of treatment which would increase the risk to the person's life or health.</p> <p>§ 2504(6): Anyone who acts in good faith based on the representation by a person that he or she is eligible to consent pursuant to the terms of this section shall be deemed to have received effective consent.</p>
<p>HIV Screening</p>	<p>§ 2781: An HIV-related test may not be ordered without the informed consent of the subject, if the subject has the capacity to consent, or, if he/she does not, the consent of a person authorized to consent to health care for the subject.</p> <p>However, PHL § 2780 provides that the “capacity to consent” to HIV testing means an individual’s ability, determined without regard to the individual’s age, to understand and appreciate the nature and consequences of a proposed health care service, treatment, or procedure, or of a proposed disclosure of confidential HIV related information, and to make an informed decision.</p>
<p>HIV Treatment of Survivors of a Sexual Offense</p>	<p>§ 2805 i(1)(c): Every hospital providing treatment to alleged victims of a sexual offense is responsible for offering and making available appropriate post HIV-exposure treatment therapies in cases where it is determined, in accordance with guidelines issue by the commissioner that significant exposure to HIV has occurred.</p>
<p>STD Screening and Treatment</p>	<p>§ 2305: A licensed physician may diagnose, treat or prescribe for a person under 21 without the consent or knowledge of the parents or guardian of said person, where such person is infected with a sexually transmitted disease, or has been exposed to infection with a sexually transmitted disease.</p> <p>§ 2311: Requires the Commissioner of DOH to promulgate a sexually transmitted disease list. HIV is not on the list.</p> <p>§ 17: Records concerning the treatment of a minor for a sexually transmitted disease or the performance of an abortion upon such minor patient shall not be released or made available to the parent or guardian of such minor.</p>

APPENDIX C: MEETING PARTICIPANTS

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