NYSDOH AIDS Institute: PrEP Implementation Forum

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90 Church St
New York, NY

New York State Department of Health
AIDS Institute

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Executive Summary

This report outlines key recommendations made at the first statewide New York State Department of Health (NYSDOH) PrEP Implementation Forum on August 26th, 2015. It is divided into three parts. Part one is an overview of panel presentations given by providers in different health care settings currently implementing Pre-Exposure Prophylaxis (PrEP) in pilot programs. Part two summarizes recommendations provided by participants on four key topics related to PrEP implementation at the forum: quality metrics, implementation, policy, and the intersection of PrEP and sexually transmitted infections (STIs). Part three discusses the next steps that will be executed to implement the recommendations outlined in this report.

On June 29, 2014, Governor Andrew Cuomo announced a three-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 persons engaging in high risk behaviors to keep them HIV negative. The PrEP Implementation Forum hosted by NYSDOH AIDS Institute (AI) was attended by healthcare providers, consumers, community stakeholders, and state and local health officials, to discuss the use of PrEP and PrEP care in NYS.

This report summarizes panel presentations from eight different clinical sites showcasing their respective PrEP programs. The objective of these panels was to learn how PrEP services are being implemented in the State, what populations are being served, and both the policy and programmatic issues that need to be considered and addressed as New York State moves forward with PrEP implementation.

Panelists represented community health centers, Designated AIDS Centers, and hospitals from various locations throughout New York State. Presenters were asked to focus on the patient population being served, the service model being used, performance metrics used, and their program successes and challenges.

Themes from panel presentations

Key themes

- All sites currently have a PrEP coordinator as a full-time employee
- All sites utilize a multidisciplinary team approach to providing PrEP services
- Over half of the sites host recurring outreach events in the community to raise awareness and increase PrEP uptake
- Half of the sites face challenges to provide care to uninsured and underinsured patients
- Half of the sites want PrEP navigation training for the entire clinic staff
- Half of the sites are unable to meet demands for PrEP services due to limited staffing capacity issues

The second part of the report outlines key recommendations suggested by participants during "World Café" style breakout groups which focused on: 1) defining quality measures for PrEP services; 2) reviewing the status of currently implemented PrEP programs and identifying further areas for implementation knowledge and research; 3) advising the state on policy issues related to PrEP implementation; and 4) discussing the intersection of PrEP services with STIs.

Summary of recommendations from breakout discussions

Quality Metrics

- Clinical metrics include comprehensive STI testing every 4 months, risk assessments, and annual counseling and assessment for mental health, substance abuse, and domestic violence
- Population metrics include STI incidence rates and linkage to care rates for PrEP patients to primary care
- Assessments of patient experience that include stigma and reasons for stopping PrEP
- Organizational level metrics include ongoing training for all staff, referrals and linkage policies for primary care, and rates of access to medications for the site

Implementation

- Increase uptake of PrEP through the integration of PrEP care into primary care and other non-HIV specific clinical settings
- Tailor future PrEP messages to promote and encourage PrEP uptake in target populations
- Develop a system-based framework to quantitatively and qualitatively evaluate PrEP implementation programs
- Create a best practices toolkit for providers to demonstrate successful clinical practices and PrEP service models
- Address stigma by partnering with nontraditional, community venues such as churches and family planning centers

Policy

- Increase PrEP uptake and implementation beyond the HIV community in settings such as STI, urgent care, and family planning clinics
- Provide multiple types of educational resources for providers
- Develop a guide for pharmacies to facilitate PrEP services at the pharmacist level
- Navigate insurance roadblocks to PrEP related to confidentiality, eligibility, and coverage
- Collect surveillance and patient registry data to measure implementation needs and effect

STIs and Prep

- Implement 'bundled screening', which would include comprehensive STI testing, renal and other metabolic tests, and psychosocial screening with PrEP care
- Identify appropriate resources to cover the increase in STI screenings as part of PrEP care
- Encourage providers to offer PrEP to patients with a history of STIs and/or other factors that would benefit from PrEP
- Raise awareness about the importance of 3-site testing for providers
- Create comprehensive clinical 'hubs of care' at STI clinics that include linkage to PrEP care

The third part of the report outlines follow-up initiatives currently implemented by NYSDOH AI Office of the Medical Director (OMD) and post-Forum follow-up strategies. NYSDOH AI OMD plans on launching a website to continue the exchange of ideas and conversations initiated at the Forum and developing a set of quality metrics to measure the quality of PrEP services.

Summary of PrEP Program Panel Presentations

Key themes

1. All sites currently have a PrEP coordinator as a full-time employee
2. All sites utilize a multidisciplinary team approach to provide PrEP services
3. Over half of the sites host recurring outreach events in the community to raise awareness and increase PrEP uptake
4. Half of the sites face challenges with insurance for under-insured and uninsured patients
5. Half of the sites want all clinic staff to be trained in PrEP navigation
6. Half of the sites are unable to meet demands for PrEP services due to limited capacity issues

Eight panelists were invited to present at the PrEP Implementation Forum on their respective PrEP programs. The panelists represented eight PrEP programs from across New York State, which included community health centers, hospitals, and other clinical settings. The purpose of the panel presentations was to showcase how PrEP services are currently being implemented in the State, who is currently utilizing PrEP, and what remains to be learned about the implementation of PrEP in New York State. The represented PrEP programs on the panel included:

- Trillium Health
- Albany Medical Center
- Evergreen Health Services
- APICHA
- SUNY Downstate Medical Center
- Callen-Lorde
- Mount Sinai Hospital
- Community Healthcare Network NYC

The following questions helped frame each presentation:

Questions for Panelists

1.1 How is PrEP being utilized at your site? What are the demographics of your patient population and are there any unique characteristics in your recruitment model?
1.2 What service model is being implemented at your site?
1.3 Are there any data metrics in place to measure performance, quality of services, and outcomes of your PrEP programs?
1.4 What have been successes of the PrEP program? What is unique about your program?
1.5 What challenges does your program face as you implement PrEP?

The PrEP programs represented sites from Buffalo, Rochester, Albany, and New York City. Most of the sites noted that the demographics of their PrEP patients mirrored the overall demographics of the sites' general patients.

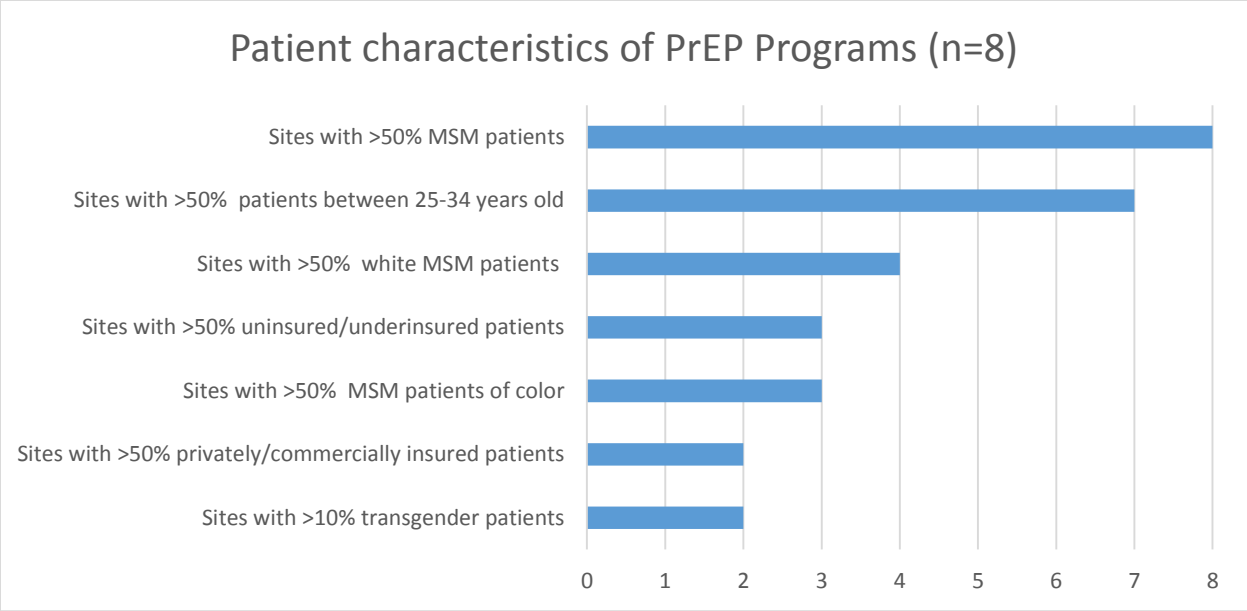


Table 1: Common characteristics of PrEP patients from the eight PrEP programs.

All of the programs noted that a full-time PrEP specialist dedicated to navigating PrEP insurance and services was an integral part of each program's success. Common responsibilities for the PrEP specialist position include insurance navigation, case management, and patient counseling. All of the programs used a multidisciplinary team approach to provide PrEP services, involving clinical providers, a PrEP specialist, prevention educator, and a clinical pharmacist, among others. Some programs had success with PrEP outreach and education at community events such as a ball in the vogue ballroom scene. Some programs also noted success with special initiatives such as using a PrEP mobile app to increase medication adherence and PrEP starter packs when initiating PrEP to mitigate insurance issues affecting access to medication.

The most common barriers to implementing PrEP from the eight programs were roadblocks with insurance coverage, limited understanding by staff members on how to address insurance issues, and insufficient resources. Common insurance challenges include prior-authorization for PrEP prescriptions and coverage for medical visits. Patients with high-deductible insurance plans face the most insurance challenges. At least half of the programs specifically mentioned the need to train and educate all staff members about navigating insurance for PrEP services. Lastly, half of the programs face limited capacity and human resources, an issue resulting from an unanticipated increase in PrEP patients for some programs.

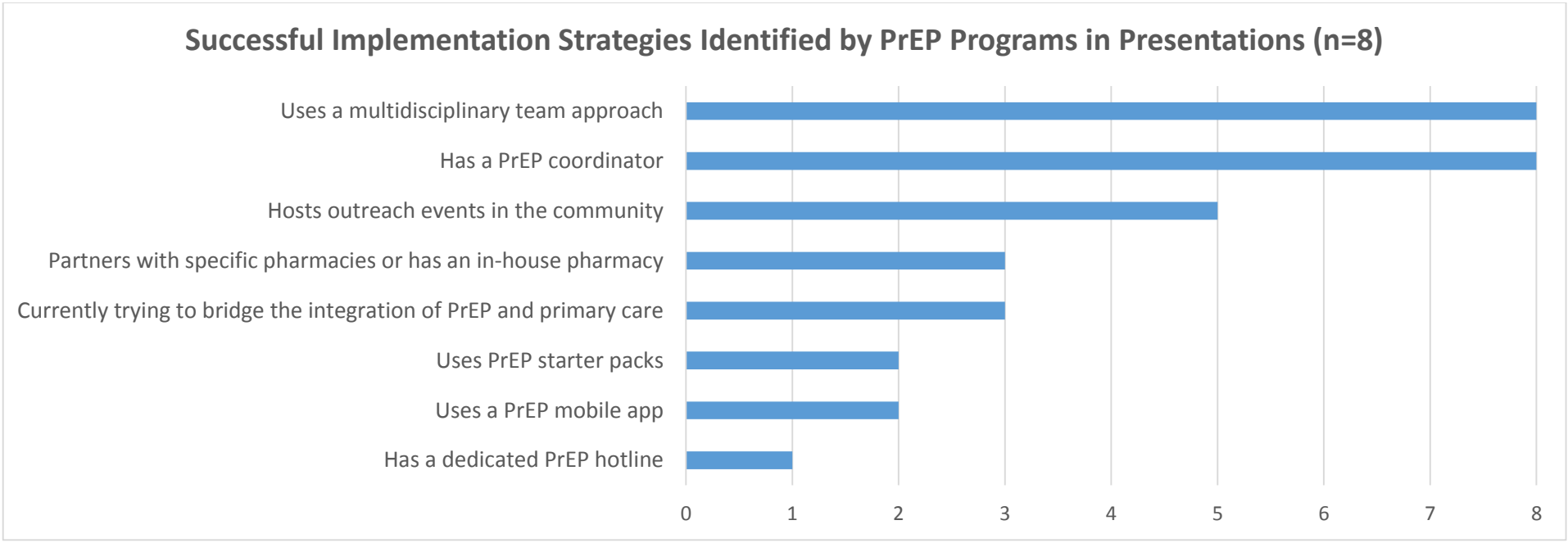


Table 2: Key successes of each PrEP program.

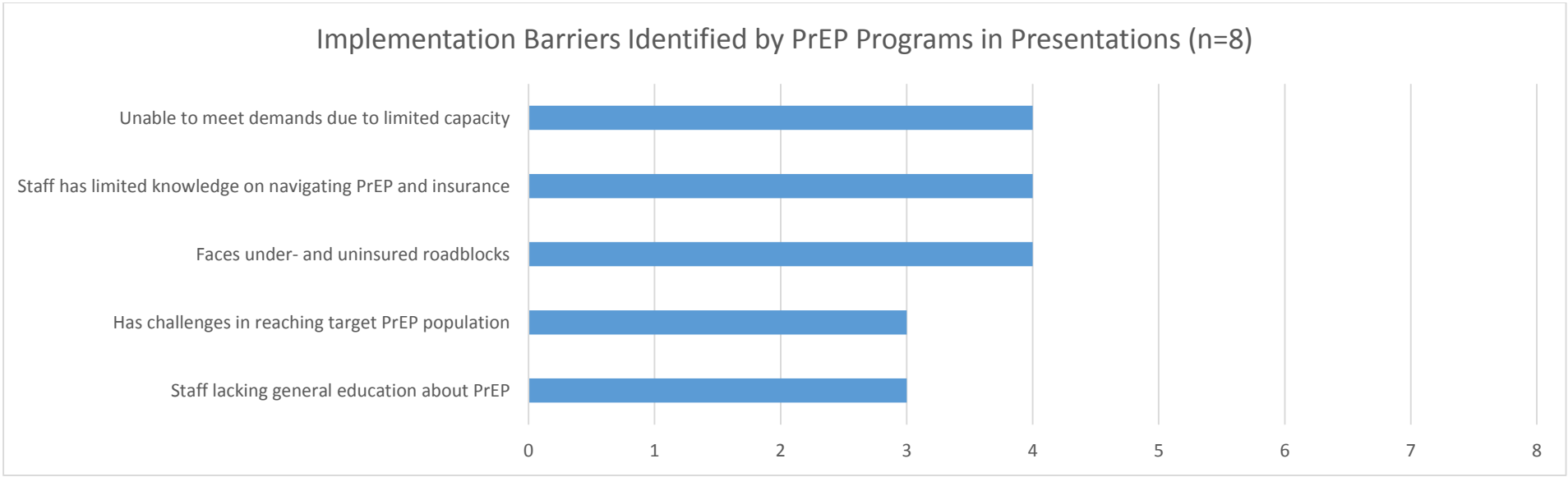


Table 3: Key barriers of each PrEP program.

Quality Metrics

Key Themes

1. Clinical metrics include comprehensive STI testing every 4 months, risk assessments, annual counseling and assessment for mental health, substance abuse, and domestic violence
2. Population metrics include STI incidence rates and linkage to care rates
3. Experience metrics include assessing patient experience, stigma, and reasons for stopping PrEP
4. Organizational level metrics include ongoing training for all staff, referrals and linkage policies to primary care from PrEP, and access to medications for the site

The main goal of the quality metrics discussion was to generate measures to accurately gauge the success and track the progress of each individual PrEP program. While general quality of care metrics have been studied and used extensively in all health care settings, quality metrics specific to PrEP have not yet been created and widely used. Recommendations from participants were grouped into four major domains: clinical metrics, public health metrics, patient experience assessments, and organizational level metrics.

Participants centered their recommendations around quarterly, bundled HIV and STI testing at each medical visit. Participants recommended that providers should conduct HIV, STI, and renal function testing at least every four months (with testing for renal functioning every six months after the initial test). Along with testing metrics, participants emphasized the need to measure PrEP retention rates, specifically, how many patients discontinue PrEP for reasons other than decreased risk perception or side effects, but remain in care. Participants stated that it is important to measure both retention in care and adherence to medication, and less important to measure the actual number of patients on PrEP at a given time as a marker of quality.

Participants agreed that both organization level metrics and patient experience assessments should be developed to evaluate PrEP programs. Participants wanted to prioritize the development of patient experience assessments which would include the patient's experience with any stigma associated with onsite PrEP and HIV services and organizational metrics should address staff training and education, referral and linkage rates to primary care, and access to medications. Lastly, participants suggested population-based metrics such as STI incidence rates to measure the success of PrEP implementation as a public health initiative.

Participants voiced concern about defining a denominator for some quality metrics. Some participants suggested that a denominator could be every patient seen by the provider, regardless of whether the patients have stopped using PrEP; others felt that only those who remained in care with that provider should be included.

The following diagram depicts the quality metrics recommended provided by participants at the Forum. Recommendations in **bold text** signify key topics identified during the discussions.

Quality Metrics

Clinical metrics:

-**HIV and STI testing** at least every four months

-Renal, urinalysis and metabolic function testing at three months after initiation of PrEP and then every six months

-Linkage to care rates within 5 days of seroconversion

-Fill time rates for medications or prescription monitoring

-**HIV seroconversion rates** for patients on PrEP and not on PrEP

-**Retention rates** with frequency based on risk assessment at either three or six months

-Annual comprehensive counseling and assessment for mental health, substance use, and domestic violence

-Adherence assessment at every medical visit

-Routine offering of PrEP to eligible patients

-Risk assessment at every medical visit

Population and State metrics:

-STI incidence rates

-Linkage to care rates for PrEP services

Patience Experience Assessments:

-Stigma encountered during PrEP services

-**Patient experience surveys** on PrEP services

Organization level metrics:

-Ongoing training of staff

-Access to medications at the program

-**Referral and linkage policies** to primary care from PrEP care

-Reengaging patients who were lost to care

Implementation

Key themes and recommendations

1. Integrating PrEP care into primary care and other clinical settings
2. Tailoring PrEP messaging to reduce PrEP stigma in target populations
3. Developing evaluation systems to accurately measure the success of implementation programs
4. Creating a best practices toolkit on PrEP for providers
5. Utilizing nontraditional venues to address stigma surrounding PrEP

Key questions

2.1 How can PrEP services be integrated into primary care?
2.2 How can clinics reduce stigma or discomfort about PrEP services?
2.3 What clinical models would be best for implementing PrEP?
2.4 How should success be measured?
2.5 What would be most helpful for providers looking to implement PrEP?
2.6 What are the areas that should be prioritized to learning more about implementation of PrEP services?

The main goals of these discussions were to review current implementation and evaluation methodologies, identify challenges providers and consumers are currently facing, and develop new strategies for PrEP implementation. Discussion topics included: strategies to increase PrEP uptake across different clinical settings, developing different service models for PrEP programs, and addressing funding concerns with the scaling up of PrEP.

To increase PrEP uptake across the state, participants provided recommendations for providers currently engaged with HIV care and providers outside of the HIV clinical setting. For programs currently providing PrEP services participants recommended that the sites start building capacity in anticipation for the increase in PrEP patients as PrEP awareness and implementation becomes more widespread. Participants identified Community Based Organizations (CBOs) as important sites for identifying eligible PrEP candidates and linking them to PrEP services.

To help facilitate PrEP uptake in a variety of settings, participants suggested different service models that could be used for PrEP programs. Participants recommended creating a PrEP 'gatekeeper' position to streamline PrEP services by pre-screening patients for eligibility and linking eligible patients to services. Gatekeepers would be staff members, like PrEP coordinators, to help alleviate provider workload. Participants also suggested implementing a PrEP 'champion', a provider knowledgeable and dedicated to providing PrEP care who would serve as a clinical resource for the facility.

Many providers at the Forum expressed concerns that the lack of, or limited resources available at their facility would hinder PrEP implementation. Participants wanted to be informed about available sources of funding for PrEP implementation and identified the PrEP coordinator position as a priority for funds.

The following questions were posed to the breakout groups by facilitators to guide discussions regarding the process of implementing PrEP. Following each question are participants' key recommendations. Recommendations in **bold text** signify key topics identified during the discussions.

2.1: How can PrEP services be integrated into primary care?

STI clinics

- Normalize the process of offering PrEP in STI clinics
- Offer PrEP starter packs at STI clinics to help bridge the linkage between STI clinics and PrEP care

Scaling up PrEP uptake

- Ensure that HIV providers are all currently offering PrEP or referring to PrEP programs
- **Increase capacity within general clinical settings** to allow for future scale up of PrEP implementation
- Incorporate and implement PrEP into general primary care
- Suggest that Ryan White providers have a memorandum of understanding (MOU) with PrEP providers if not offering it directly

Private providers

- Use private practitioner referral networks to facilitate linkage of PrEP
- Consider developing a rate system for different levels of complexities to involve private physicians

Community Based Organizations (CBOs)

- **Recommend that CBOs integrate PrEP** into their work by identifying and linking PrEP eligible candidates to PrEP services
- Develop partnerships between CBOs, providers and other collaborative partners.
- Leverage outreach programs at CBOs to reach target populations in the community
- Develop an Ambassador Program for the community with the goal of educating, raising awareness, and reducing stigma

2.2: How can clinics reduce stigma or discomfort about PrEP services?

PrEP language and messaging

- Use social media to advertise PrEP to 15-30 year olds
- Clarify and provide clear message of the 'what' and 'why' of PrEP for patients and providers
- Emphasize wellness and dissociate PrEP from being only for MSM
- **Tailor PrEP messages** to address specific concerns affecting different groups

Stigma

- Normalize sexuality in the healthcare setting by providing provider trainings and education, particularly on taking patients' sexual history.
- Reframe HIV and prevention to equate the messaging to sexual health overall while avoiding language such as 'high' and 'low' risk
- **Educate consumers about basic HIV information** including transmission and prevention methods to decrease stigma

2.3: What clinical models would be best for implementing PrEP?

PrEP 'Gatekeeper'

- Create a 'gatekeeper' position responsible for pre-screening patients for PrEP eligibility and linking eligible patients with appropriate services
- Gatekeeper should be able to effectively communicate with the served community and have a social

awareness of the community's needs
- Choose gatekeepers that can build the most rapport with the communities served, Eg. peers and immigrants

PrEP 'Champion'
- Identify specific providers responsible for immediate linkage and transition of PrEP patients to general providers over time
- Support a PrEP 'champion' at each facility to be the point-person for PrEP care and internal education

General facility level recommendations
- **Develop buy-in from all staff and providers** for PrEP care
- Prioritize staffing patterns depending on program size and scope of services for PrEP
- Combine primary care and supportive services into HIV care
- Build PrEP workforce capacity for HIV providers

2.4: How should success be measured?

Consumer experience
- Request and **document patient experience** by conducting feedback surveys, personal and group interviews and other qualitative methods to evaluate quality of PrEP services

Evaluation systems
- Develop an evaluation framework that can examine systems and organization factors, qualitatively and quantitatively, and on both consumer and provider levels
- Examine data from the statewide and local level to compare successes for upstate vs. downstate
- Evaluate whether interventions target the intended population to measure success

2.5: What would be most helpful for providers looking to implement PrEP?

Best practices guides
- Clarify what is expected from each type of provider
- **Develop a best practices toolkit** detailing PrEP implementation successes from a variety of clinical settings and how to take a comprehensive sexual history to determine PrEP candidacy
- Create a 'harm reduction' model related to PrEP

Provider education
- **Provide basic PrEP training on implementation and uptake** for primary care providers
- Educate primary care physicians on STI testing
- Provide facilities with 'detailing packages' modeled after the NYCDOHMH's public health detailing campaign
- Create peer-to-peer learning networks for primary care providers
- Incorporate PrEP into residency programs and medical school curricula to train future providers
- Utilize Gilead, Academy of Medicine, and CEI as potential venues for provider education

2.6: What are the areas that should be prioritized for learning more about the implementation of PrEP services?

Insurance

- Involve insurance companies in future stakeholder meetings
- **Provide guidance on navigation of private and public health insurance** and deductibles for consumers and providers
- Identify uninsured patients to gauge who is not getting medical care
- Establish an 'Insurance Exchange' line for potential PrEP patients to call and quickly obtain insurance

Funding and resources

- Identify available sources of funding for PrEP services
- Create specific investments for practitioners who need resources to implement PrEP
- Identify primary barriers to provider uptake of PrEP including specific resources and access to resources
- Prioritize funding for a PrEP coordinator position to facilitate navigation of PrEP services

Policy

Key Themes

1. Advancing PrEP beyond HIV-specific settings
2. Providing multiple types of educational resources on PrEP for providers
3. Developing a PrEP best practices guide for providers and pharmacists
4. Navigating PrEP-specific insurance roadblocks
5. Collecting PrEP surveillance and patient registry data for quality measurements

Key Questions

3.1 What are some of the priority insurance issues that should be addressed?
3.2 What role should pharmacies play in PrEP implementation?
3.3 What are some strategies that can facilitate bringing people into PrEP care?
3.4 How should the state and city develop standards for PrEP implementation programs?

This section discusses policy and regulatory issues related to access to care, medication access, patient education, prevention, and eligibility for PrEP care. Topics discussed by participants included: removing barriers to insurance; incorporating pharmacies into the PrEP services model; and strategies to increase PrEP uptake in all clinical settings.

Participants offered a number of recommendations to address reimbursement barriers to PrEP care. Participants suggested supplying patients with PrEP 'starter packs', or a set amount of PrEP medication, to provide uninterrupted service if they are experiencing delays in medication access due to insurance issues like prior-authorization. Participants recommended that future PrEP messaging should raise awareness that getting tested and using PrEP would not be considered as a pre-existing condition and would have no impact on insurance premiums or other costs. Participants also found it imperative to identify which insurance plans are available for undocumented immigrants.

Participants wanted pharmacies to play a larger role with PrEP. Pharmacists could assist patients with lapses in medication and help navigate prior authorization issues. Participants recommended creating a best practices guide for pharmacists outlining general information about Truvada as both pre- and post-exposure prophylaxis, linkage and referral policies to PrEP services, and insurance navigation. In order to create buy-in from pharmacists, participants recommended that PrEP education for pharmacies emphasize the potential financial benefits for providing PrEP, especially for local pharmacies.

Participants provided a number of recommendations to increase PrEP uptake in all clinical settings. To increase linkages of PrEP eligible patients to care, participants recommended partnering with CBOs and using internal partner identification programs to link potential PrEP users. Private providers should also be encouraged to refer and link patients to PrEP as part of a multi-pronged strategy for increasing PrEP uptake. Participants recommended broadening PrEP messages to include populations other than MSM in order to standardize PrEP as a general health prevention measure for eligible patients.

The following questions were posed to the breakout groups by facilitators to guide discussions regarding the development of PrEP policy. Following each question are key recommendations provided by participants at the forum. Recommendations in **bold text** signify key topics identified during the discussions.

3.1: What are some of the priority insurance issues that should be addressed?

Insurance issues

- Identify insurance plans that cover undocumented immigrants
- **Create PrEP starter packs** to provide patients with care should insurance issues arise when PrEP is initiated
- Raise awareness that getting tested and using PrEP will not be considered as a pre-existing condition
- Suggestion for insurance cooperation: the state should declare that prior authorization is not acceptable because of the public health emergency of HIV
- Standardize insurance codes for PrEP to increase confidentiality

Confidentiality

- Expand policy to protect confidentiality of PrEP patients under 26 on their parents' insurance
- Work towards allowing minors to get PrEP without parental consent
- Address confidentiality issues regarding the need to send an EOB about medical visits and lab details to insurance holder

Medicaid reform

- Create a financial incentive for providers and other implementers to provide PrEP services
- Create a PrEP services bundle for payment based on value-based outcomes

3.2: What role should pharmacies play in PrEP implementation?

Pharmacies

- Local pharmacies can help patients with lapses in prescriptions and prior authorization issues
- Utilize pharmacists as case managers and start encouraging HIV testing at pharmacies
- Create a list of pharmacies specializing in HIV care for patients
- **Develop a best practices guidelines book for pharmacies** to cover general information about PrEP, referral and linkage policies to PrEP services, and insurance navigation
- Educate pharmacies on potential financial benefits that PrEP can provide

3.3: What are some strategies that can facilitate bringing people into PrEP care?

Capacity building

- Give providers the tools to talk about PrEP
- Develop capacity building initiatives at sites to accommodate future PrEP implementation
- Set standards of service and follow up with technical assistance for implementation

Extending PrEP services outside of HIV care

- Expand PrEP to providers outside of HIV care
- License healthcare providers in PrEP training (to be combined with STI and sexual health training)
- **Incorporate PrEP services into broader plans** as part of general prevention strategies
- Utilize family planning coverage as an outreach opportunity for youth and young adults to access PrEP
- Consider having everyone with patient contact in primary care to start addressing PrEP

Linkage to care

- **Link HIV-negative patients with STIs** to PrEP care
- Establish a partner identification program to link the partners of HIV-positive patients to PrEP services
- Create grant requirements for PrEP linkages to demonstrate effective linkages between medical providers and CBOs
- Consider using an incentive program based on frequency of physicals and screenings to encourage patients to attend medical PrEP visits
- Link youths and older patients on PrEP to primary care
- Include PrEP as a routine part of the post-counseling session for HIV negative test results
- Ensure that providers are aware of risk factors not identified with sexual behavior, such as recreational usage of inhalants for MSM, when determining PrEP eligibility

PrEP messaging

- **Deliver PrEP message and education that is applicable to all groups**, making sure to include older adults
- Couple HIV care with primary care to combat stigma by standardizing preventative health
- Establish a clear baseline for the definition of 'high-risk' patients

PrEP programs

- Develop flexible PrEP programs at CBOs and primary care settings to provide accommodated services based on a sliding scale of need
- Consider the development of publically known PrEP specific centers in each area of the state

3.4: How should the state and city develop standards for PrEP implementation programs?

PrEP eligibility measures

- Define the denominator for PrEP eligible patients
- Use a proxy to represent denominator for PrEP eligible patients until a definition is agreed upon

PrEP registries

- **Create a PrEP patient registry** using Medicaid claims, refill rates, and pharmaceutical claims data
- Use community mapping as a first step towards creating a PrEP provider registry

STIs and PrEP

Key themes

1. The intersection between STIs and PrEP care needs to be further studied
2. Lack of insurance coverage for STI screenings in PrEP service settings
3. Providers should offer PrEP to patients with a history of STIs and/or other factors that would benefit from PrEP
4. Providers should be sensitized on the importance of 3-site testing routinely for at-risk patients
5. Creating comprehensive clinical hubs of care at STI clinics

Key Questions

4.1 What are the priority issues related to the intersection between STIs and PrEP?
4.2 Are there policy issues that need to be addressed?
4.3 How can state and city websites and media campaigns be tailored to illuminate the intersection between STIs and PrEP?
4.4 How can we better educate providers and consumers?
4.5 What are the clinical concerns related to these issues?

As New York State begins to implement PrEP statewide, addressing the intersection between STIs and PrEP has become a top priority for NYSDOH AIDS Institute. Participants generated a number of recommendations for the following five domains: intersection between STIs and PrEP, policy, PrEP messaging in STI media campaigns, and clinical level concerns.

The discussions about the intersection between STIs and PrEP focused on implementing appropriate STI screening for patients on PrEP. Participants recommended that the frequency for STI screenings should be a minimum of four months for PrEP patients. Participants strongly recommended practicing 'bundled testing' should be part of a comprehensive screening process that includes STI, HIV, and other metabolic processes testing such as renal testing. Additionally, for those looking to start PrEP, participants recommended nucleic acid amplification tests (NAAT) for STI testing due to its higher sensitivity compared to traditional serological methods.

Policy recommendations focused on identifying the appropriate payer to cover the costs of increased STI screening and PrEP visits. Additional recommendations include incorporating HPV vaccinations into PrEP care and extending coverage for vaccinations to adults over 26 years old.

Addressing the stigma surrounding PrEP usage and STIs was another area of focus during the discussion. Participants stressed the importance of delivering sex-positive messaging in future media campaigns run by the state and city on STIs and PrEP. For providers, participants recommended that providers avoid moralizing 'safe' sex practices when talking with patients and, instead, tailor harm reduction messages to the individual.

Other clinical recommendations included the incorporation of mental health, substance use, and domestic violence screening as part of the standard STI care. Patients would be screened for these issues during regularly scheduled visits, allowing providers to further connect them to supportive services, if needed, as a means to provide comprehensive psychosocial care in addition to standard

clinical care. Some participants noted the potential for PrEP services in STI clinics to be a portal for patients to transition into primary care.

The following questions were posed to the breakout groups by facilitators to guide discussions regarding the intersection between STI and PrEP. Following each question are key recommendations provided by participants at the forum. Recommendations in **bold text** signify key topics identified during the discussions.

4.1: What are the priority issues related to the intersection between STIs and PrEP?

Bundled screening

- **Bundle comprehensive STI and HIV screening** while on PrEP
- Promote a policy to recommend STI screening recommendations for MSM
- Change PrEP-AP recommendation for STI screening from 6 months to a minimum of 4 months
- Develop a more comprehensive **PrEP screening regimen to include STIs such as herpes and syphilis**
- Address the concordance between future NYS and CDC PrEP screening guidelines

Extragenital testing

- Educate providers and administration about the importance of **implementing 3-site screenings** for PrEP patients
- Consider standardizing NAAT and rectal screening for gonorrhea and chlamydia
- Follow up with policies and FDA approval on 3-site testing

HPV and PrEP

- Connect HPV vaccinations with PrEP, focusing on adolescent care

4.2: Are there policy issues that need to be addressed?

Policy

- **Address lack of insurance coverage** for the high volume of bundled STI screening involved with PrEP services
- Advocate for insurance coverage of HPV vaccines for adults over 26
- Allow informed consent for minors for PrEP and HPV vaccine

4.3: How can state and city websites and media campaigns be tailored to illuminate intersection between STIs and PrEP?

PrEP messaging

- Deliver sex-positive messages about PrEP
- Create simplified palm cards for PrEP

Stigma

- Educate providers to avoid the moralization of ‘safe sex’ when counseling potential PrEP patients
- **Address PrEP stigma in general populations** such as heterosexual women

4.4: How can we better educate providers and patients?

Patient education

- Educate consumers by **emphasizing that PrEP (HIV prevention) is an additional prevention intervention** rather than a replacement for condoms (prevention of STIs)

Medical school curriculum and ongoing training

- Incorporate STI care in relation to PrEP as part of an ongoing component of medical school curricula

Provider education

- Focus efforts on **educating primary care providers** who care for patients with a high volume of STIs to provide appropriate PrEP services to patients
- Develop PrEP and STI educational components specific to transgender women and MSM
- Develop a Clinical Education Initiative module to provide PrEP guidance for providers, especially general primary care physicians
- Disseminate UCSF PrEP hotline number to all primary care physicians
- Address providers' personal inhibitions and cultural barriers regarding general sexual health, patient sexual behaviors, MSM issues, and trans issues to reduce stigma when prescribing PrEP

4.5: What are the clinical concerns related to these issues?

Clinical 'hubs of care'

- Use STI clinics as linkage sites to primary care through PrEP services
- **Create clinical 'hubs of care'** by integrating mental health and partner services at testing sites
- Provide culturally appropriate behavioral health services and clinically appropriate services to create a stigma free environment and encourage PrEP uptake

Provider practices

- Determine explicit goals of PrEP with the patient
- **Tailor risks and harm-reduction messages** to each patient
- Require providers to document patient gender identity and the gender identity of their partner in records to ensure the appropriate screening regimens are delivered to patients

Next Steps

Follow-up initiatives

1. Launch the PrEP forum website for providers, consumers, and other stakeholders to continue engaging with the topics discussed at the Forum.
2. Create quality metrics to develop standards for PrEP services.

This section discusses the steps NYSDOH AI OMD will be taking in order to implement the recommendations outlined in this report:

- The first step will be launching the NYPrEPForum.org website to serve as a platform for providers, consumers, and other stakeholders to continue the conversations initiated at the PrEP Forum. The website will offer regular updates on the literature regarding the state of the art on PrEP implementation, a blog series with guest posts from consumers, providers, and non-clinical staff involved with PrEP on their experiences with either providing or receiving PrEP care, and will be using social media platforms such as Twitter© to provide updates on PrEP implementation in NYS.

- The second step will be developing quality metrics to measure the quality of PrEP services. The recommendations summarized in the first part of this report will be used to guide the development of the PrEP quality metrics. NYSDOH AI OMD will define the scope of the numerators and denominators for each PrEP quality metric created.

Appendix 1: Agenda

PrEP Implementation Forum
90 Church Street, 4th floor
August 26th, 2015 – 8:30 AM – 5:00PM

Breakfast and Registration	8:30 – 9:00 AM
Welcome and Review of Agenda *Bruce Agins*	9:00 – 9:10 AM
Opening Remarks *Dan O'Connell and Demetre Daskalakis*	9:10 – 9:30 AM
Keynote Speaker[1] *Ken Mayer*	9:30 – 10:20 AM
Break	10:20 – 10:30 AM
NYS Provider Presentations[2] *Panel #1 – Moderator: Lyn Stevens* *Shona Ruggeri (Albany Medical Center)* *Michael Lee (Evergreen Health Services)* *Jeffrey Birnbaum (SUNY Downstate Medical Center)* *Robert Murayama (APICHA)*	10:30 – 11:35 AM
Panel #2 – Moderator: James Tesoriero *Freddy Molano (Community Healthcare Network NYC)* *Michel Ng and Joaquin Aracena (Mt. Sinai Health System)* *William Valenti (Trillium Health)* *Peter Meacher (Callen-Lorde CHC)*	11:40 – 12:45 PM
Introduction to Breakout Sessions	12:45 – 1:00 PM
Lunch	1:00 – 1:30 PM
World Café – Break out discussion groups *Room assignments:* *Group 1 – Room A/B (Quality Metrics)* *Group 2 – Conference Room C (Implementation)* *Group 3 – Conference Room D (Policy)* *Group 4 – Conference Room E (STIs and PrEP)*	1:30 – 4:15 PM
Break	4:15 – 4:30 PM
World Café – Debrief *Room A/B*	4:30 – 5:00 PM
Closing Remarks	5:00 PM

[1] [3] For full PowerPoint presentations from the Keynote speaker and panel presentations, please visit: http://www.hivguidelines.org/quality-of-care/prep-forum/adults/presentations/

Appendix 2: Summary table of PrEP programs from panel presentations

Themes	Albany Medical Center	APICHA	Callen-Lorde	Community Health Network NYC	Evergreen Medical Group	Mount Sinai Hospital	SUNY Downstate Medical Center	Trillium Health	Total
Has a PrEP coordinator	X	X	X	X	X	X	X	X	**8**
Uses a multidisciplinary team approach	X	X	X	X	X	X	X	X	**8**
Hosts outreach events in the community	X	X	X			X	X		**5**
Currently trying to bridge the integration of PrEP and primary care			X	X				X	**3**
Partners with specific pharmacies or has an in-house pharmacy	X				X		X		**3**
Uses a PrEP mobile app						X		X	**2**
Uses PrEP starter packs		X		X					**2**
Has a dedicated PrEP hotline					X				**1**

Appendix 2.1: Table summarizing the successful practices of each PrEP program.

Themes	Albany Medical Center	APICHA	Callen-Lorde	Community Health Network NYC	Evergreen Medical Group	Mount Sinai Hospital	SUNY Downstate Medical Center	Trillium Health	Total
Faces under- and uninsured roadblocks				X	X	X		X	**4**
Staff has limited understanding about PrEP and insurance navigation		X	X	X				X	**4**
Unable to meet demands due to limited capacity	X		X			X		X	**4**
Staff lacking general education about PrEP				X		X		X	**3**
Has challenges in reaching target PrEP population			X		X			X	**3**

Appendix 2.2: Table summarizing the barriers faced by each PrEP program.

Themes	Albany Medical Center	APICHA	Callen-Lorde	Community Health Network NYC	Evergreen Medical Group	Mount Sinai Hospital	SUNY Downstate Medical Center	Trillium Health	Total
Has over 50% MSM patients	X	X	X	X	X	X	X	X	**8**
Has over 50% patients between 25-34 years old	X	X	X	X	X	X		X	**7**
Has over 50% white MSM patients	X		X		X			X	**4**
Has over 50% MSM of color patients		X		X		X			**3**
Has over 50% uninsured/underinsured patients		X		X		X			**3**
Has over 50% privately/commercially insured patients	X		X						**2**
Has over 10% transgender patients		X		X					**2**

Appendix 2.3: Table summarizing patient characteristics from PrEP programs.

Appendix 3: Ken Mayer – Keynote Presentation

THE FENWAY INSTITUTE

PREP UPDATE

NY STATE AIDS INSTITUTE, AUGUST 26TH, 2015

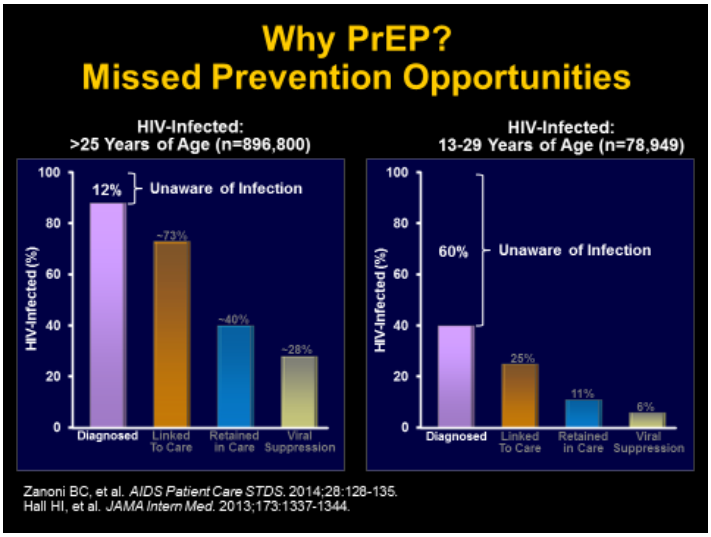
KENNETH H. MAYER, M.D.

Disclosures: Unrestricted Research Grants from Gilead Sciences and ViiV

thefenwayinstitute.org

Slide 1

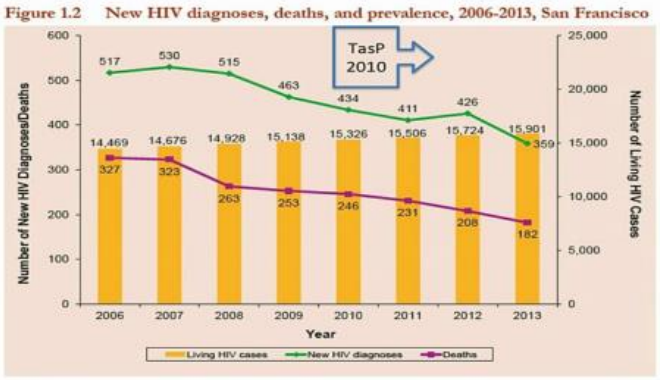
Why PrEP? Missed Prevention Opportunities



Zanoni BC, et al. *AIDS Patient Care STDS*. 2014;28:128-135.
Hall HI, et al. *JAMA Intern Med*. 2013;173:1337-1344.

Slide 2

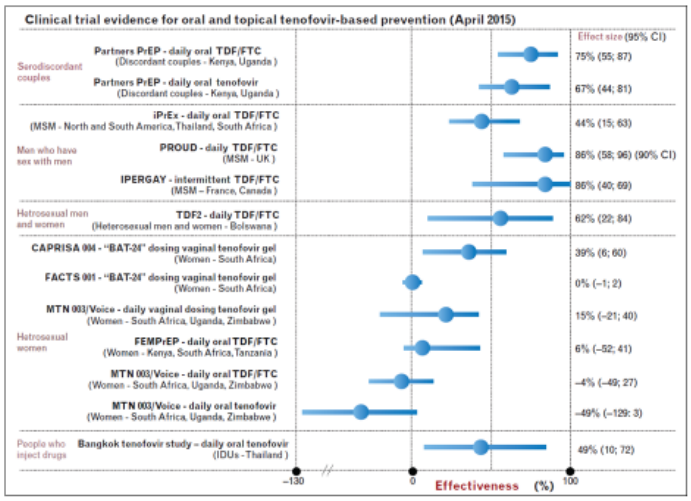
Leaks in the cascade may reduce TasP effectiveness: SF example (and Australian paradox, De Wit, AIDS Impact, 2015)



Adapted from SF DPH, *2013 HIV/AIDS Epidemiology Annual Report*, August 2014.

Slide 3

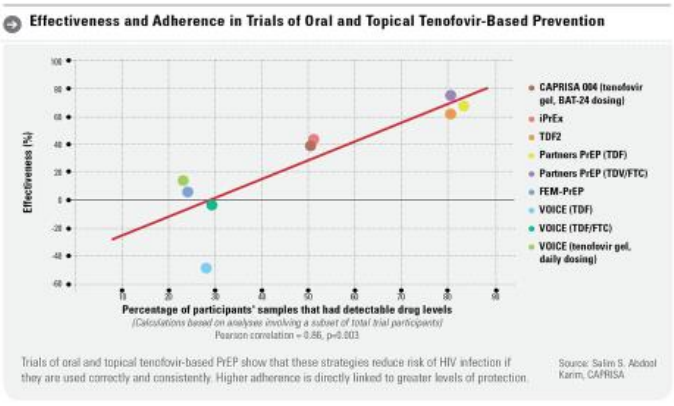
Clinical trial evidence for oral and topical tenofovir-based prevention (April 2015)



Mayer et, et al. *Curr Opinion HIVAIDS*, 2015, modified from Abdool Karim et al, *AVAC Report*, 2014

Slide 4

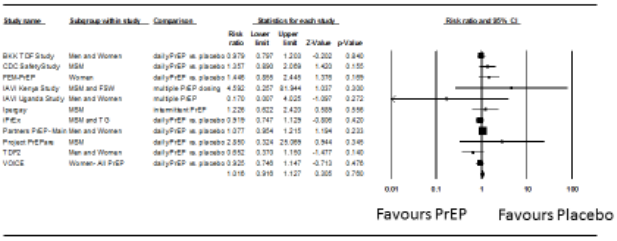
PrEP works, but adherence is key



AVAC Report 2013: Research & Reality
www.avac.org/report2013

Slide 5

PrEP is well-tolerated, discontinuations rare (WHO Guidelines, 2015)



- No difference in proportion of participants reporting any adverse event (RR=1.01, 95% CI: 0.99-1.03, p=0.27)or any grade 3 or 4 adverse event comparing PrEP to placebo study arms.
- Several studies noted subclinical declines in renal functioning and bone mineral density among PrEP users.

Slide 6

Influences on PrEP Adherence and Protection

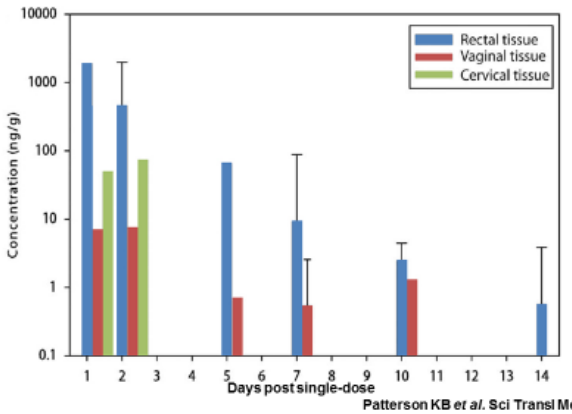
- Trial (lots of stated negatives) vs. real world
- Self-perception of risk
- Medical trust/mistrust
- Biology ("forgiveness" when missing doses)
- Support for adherence
- Integrating behavioral health with PrEP
- Modality (Next Gen PreP)

(Auerbach, Marrazzo, VanDamme, Van der Straten, Stadler, Tolley, Hendrix, Abdool Karim, Saethre, Corneli)

Slide 7

"Forgiveness"

Tenofovir Concentration: Rectal>Cervical>Vaginal



Patterson KB *et al.* Sci Transl Med. 2011.

Slide 8

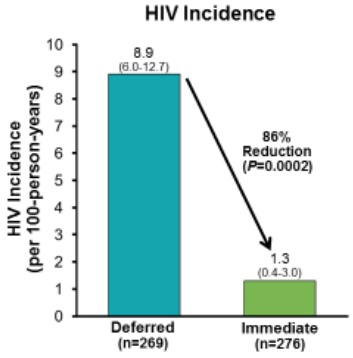
PrEP: Risk, Compensation, Adherence, Coverage

• Best Case: "risky" person is highly adherent (good coverage)	→→	No HIV transmission
• Worst case: "risky" person is not adherent (poor coverage)	→→	HIV Transmission; selection for resistance
• Risk compensation? Not often relevant • Possible, not often seen in studies to date • But what if condoms are never used?		
• Match counseling messages and prevention intervention to risk	→→	Requires discussion with clinician

Slide 9

UK GU Med Clinics: PROUD Study

- Significantly fewer new HIV infections with immediate versus deferred PrEP (3 versus 19 cases)
  - 86% reduction (*P*=0.0002)
  - Number needed to treat to prevent 1 infection: 13
- PEP used by 31% in deferred arm
- Preliminary analysis found that risk behaviors were similar between the 2 arms



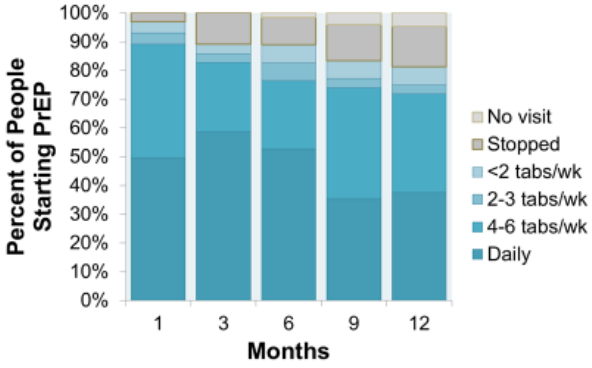
PEP: post-exposure prophylaxis.

McCormack S, et al. 22nd CROI. Seattle, 2015. Abstract 22LB.

Slide 10

iPrEx Open Label PrEP in San Francisco:

81% still on PrEP at 12 months,[1]
92% on PrEP use 4+ tablets per week.[2]



1. Grant *Lancet ID* 2014 14(9):820-9;
2. Estimated from dried blood spots in iPrEx OLE in San Francisco.

Grant CROI Abstract 25 Seattle 2015.

Slide 11

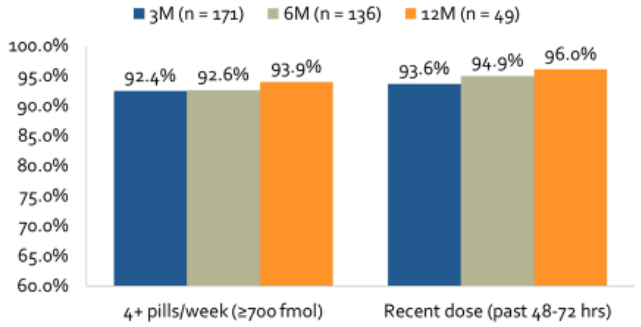
New technologies and PrEP adherence

- ↑ treatment adherence with text messaging (Lester, Lancet, 2010)
- Wisepill: modified Life-Steps HAART adherence intervention, including daily SMS with pts→84% had levels c/w daily used at 6 months (Mayer/Safren)
- Next step counseling in iPrEX Ole, augmented by electronic diary in SF and Chicago was associated with ↑ adherence (Amico/Hosek)
- Feedback on drug levels been studied as adjunct to counseling (Landovitz)
- SexPro App including diary features and adherence support, tested in NYC, SF, Lima and Rio (Buchbinder)

Slide 12

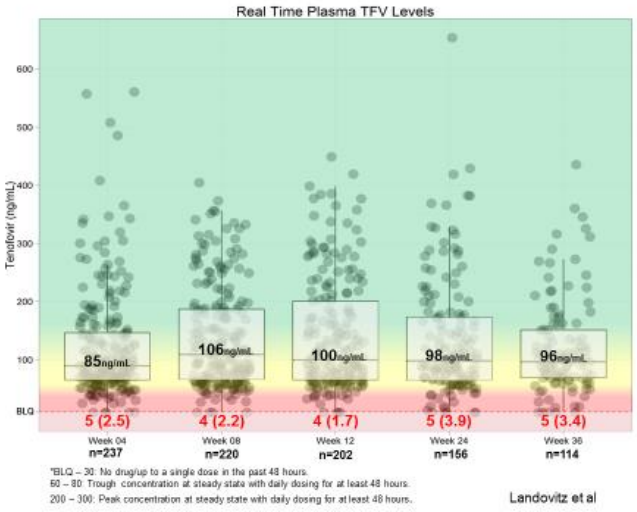
SPARK
YOUR HEALTH + YOUR CHOICE

Preliminary DBS Adherence Data (06/15/15)



R01AA022067 (Golub, PI)

Slide 13



Slide 14

Tailoring PrEP for Key Populations

HPTN 073 Black MSM

Client-centered care coordination (C4)
(Wheeler/Fields)

ATN 110/113

- YMSM 15-22 y.o.
- PreP + Individual vs. group EBI behavioral intervention (Hosek et al)

Slide 15

Impact of age on adherence

- iPrEX sub-study *(Liu, JAIDS, 2014)*

TABLE 4. Proportion and Factors Associated With Sometimes and Always (vs. Never) Drug Detection Over Time*

Characteristics	Never Detected, %	Sometimes Detected, %	Always Detected, %	OR (Some vs. Never) (95% CI)	P	OR (Always vs. Never) (95% CI)	P
Age							
≤20	58	29	13	Ref		Ref	
21–25	28	45	27	4.04 (1.66 to 9.85)	**0.002**	6.32 (2.09 to 19.09)	**0.001**
26–30	32	44	24	3.42 (1.21 to 9.67)	**0.02**	4.74 (1.26 to 17.76)	**0.021**
>30	16	29	55	5.13 (1.87 to 14.07)	**0.001**	33.24 (9.91 to 111.45)	**<0.001**

- Partners PrEP sub-study
  - AOR 1.7 (1.3–2.1, p=0.01) for <80% MEMS adherence *(Haberer, PLoS Med, 2013)*

Slide 16

ATN 110: PrEP Demonstration Project and Safety Study for Young MSMs in the US

- Phase 2, open-label study
  - 18 to 22 years old
  - Self reports evidence of high risk for acquiring HIV
  - HIV negative
- Primary objectives
  - Safety data on emtricitabine/tenofovir DF
  - Acceptability, patterns of use, rates of adherence, drug exposure
  - Patterns of sexual behavior

Baseline Characteristics

	Enrolled (n=200)
Mean age (years)	20.2
White/black/Hispanic/Asian (%)	21/53/17/2
Gay/bisexual (%)	78/14
Completed high school/ some college (%)	34/45
Not currently working (%)	30.2
Partners in past month (number)	5
Condomless sex (%)	81
Condomless receptive anal intercourse with last partner (%)	58
Any positive STI test (%)	22

High risk for HIV: condomless anal intercourse with an HIV-infected male partner or a male partner of unknown HIV status; anal intercourse with ≥3 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 STI; sexual partner of an HIV-infected male with whom condoms were not consistently used; or at least one episode of anal intercourse where the condom broke or slipped off

Hosek S, et al. *J Int AIDS Soc.* 2015;18(suppl 4):48. Abstract TUAC0204LB.

Slide 17

ATN 110: Main Outcomes of PrEP Demonstration Project and Safety Study for Young MSM

- Safety
  - Discontinued (n=25)
  - Treatment-related adverse events (n=3)
    - Nausea, weight loss, headache (all grade 3)
- HIV seroconversions (n=4)
  - HIV incidence: 3.29/100 person-years
  - No drug resistance
- Sexual behavior and adherence
  - STI diagnoses remained constant over time
  - Higher adherence and tenofovir diphosphate levels among those participating in condomless sex and condomless receptive anal intercourse
  - Adherence decreased for all participants over time

Hosek S, et al. *J Int AIDS Soc.* 2015;18(suppl 4):48. Abstract TUAC0204LB.

Slide 18

How To Improve Chemoprophylaxis Effectiveness?

Slide 19

CORRELATES OF PREP PROTECTION (GRANT ET AL, LANCET ID, 2014)

TABLE 2

	BLQ	LLOQ to <350 fmol per punch	350-699 fmol per punch	700-1249 fmol per punch	≥1250 fmol per punch
Estimated dose (tablets per week)	None	<2	2-3	4-6	7
Follow-up (% of visits)	25%	26%	12%	21%	12%
HIV infections (n)	18	9	1	0	0
Person-years per infection	384	399	179	316	181
HIV incidence (95% CI)	4·70 (2·99–7·76)	2·25 (1·19–4·79)	0·56 (0·00–2·50)	0·00 (0·00–0·61)	0·00 (0·00–1·06)
HR vs previous placebo (95% CI)*	1·55 (0·88–2·56)	0·69 (0·32–1·32)	0·19 (0·01–0·88)	0·00 (0·00–0·25)	0·00 (0·00–0·50)
HR vs concurrent off-PrEP (95% CI)†	1·25 (0·60–2·64)	0·56 (0·23–1·31)	0·16 (0·01–0·79)	0·00 (0·00–0·21)	0·00 (0·00–0·43)

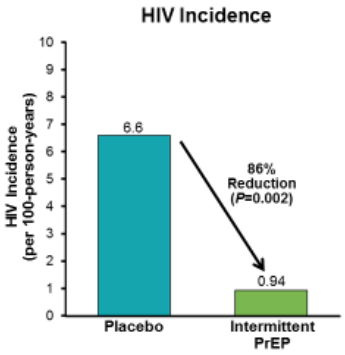
HR=hazard ratio. PrEP=pre-exposure prophylaxis. BLQ=below limit of quantification. LLOQ=lower limit of quantification. *Adjusted for study site. †Adjusted for study site, age, number of sexual partners, non-condom receptive anal intercourse, and syphilis. Drug concentration measurements were not available for 5% of visits.

Table 2: Effect of tenofovir diphosphate in dried blood spots on HIV infection

Slide 20

ANRS Ipergay Trial: Event-Driven PrEP

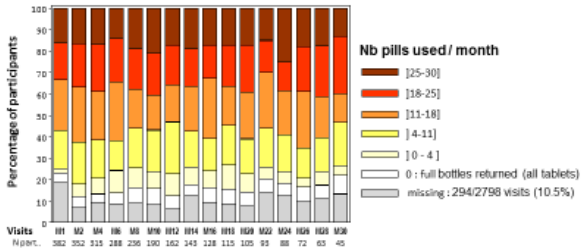
- Significantly fewer new HIV infections with intermittent PrEP versus placebo (2 versus 14 cases)
  - 86% reduction after a mean follow-up of 13 months (P=0.002)
- Safety of on-demand PrEP was similar to placebo except for GI adverse events
- Adherence to PrEP was good, supporting the acceptability of on-demand PrEP



Molina JM, et al. 22nd CROI. Seattle. 2015. Abstract 23LB.

Slide 21

iPERGAY TDF/FTC Usage

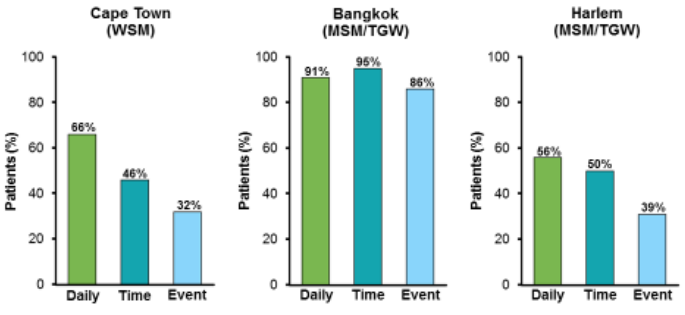


- **Median number of pills/month (IQR):** 16 pills (10-23) in the placebo arm and 16 pills (12-24) in the TDF/FTC arm (p=0.84)
- **48 participants (12%) received PEP**
  25 (13%) in the TDF/FTC arm and 23 (11%) in the placebo arm (p=0.73)

Molina JM, CROI 2015, Abstract 23LB

Slide 22

HPTN 067/ADAPT Study: Proportion Achieving Detectable Tenofovir Concentrations at Week 30



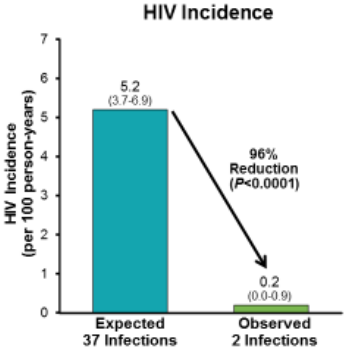
With sex in the past 7 days.
Cape Town and Bangkok (tenofovir diphosphate >9.1 fmol/M PBMC).
Harlem (tenofovir ≥5 ng/mL plasma).

Bekker LG, et al. 8th IAS Conference. Vancouver, 2015. Abstract MOSY0103.
Holtz TH, et al. *J Int AIDS Soc*. 2015;18(suppl 4):24-25. Abstract MOAC0306LB.
Mannheimer S, et al. *J Int AIDS Soc*. 2015;18(suppl 4):24-25. Abstract MOAC0305LB.

Slide 23

Partners Demonstration Project: TasP and PrEP

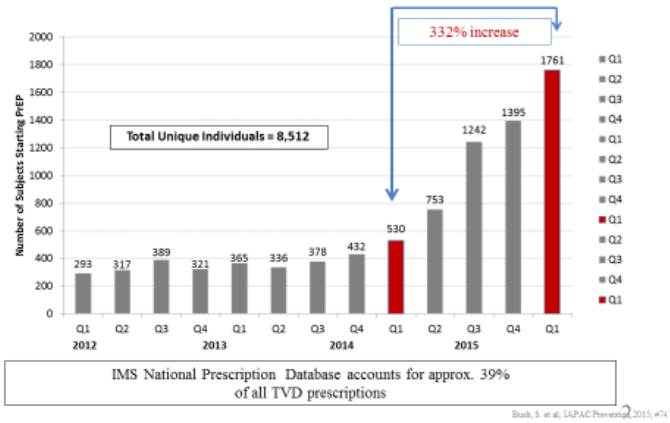
- Open-label prospective study
  - Heterosexual discordant couples not using ART or PrEP in Kenya & Uganda
  - At high risk for HIV transmission based on risk scoring tool
  - ART per national guidelines (treat all seropositive partners in a discordant relationship)
  - PrEP (open-label emtricitabine/tenofovir DF) until HIV-positive partner is on therapy for 6 months as a 'bridge' to ART
- 858 person-years of follow-up
- 95% uptake of PrEP and 80% on ART



Baeten J, et al. 22nd CROI. Seattle. 2015. Abstract 24.

Slide 24

New PrEP Starts per Quarter



Slide 25

PrEP Eligibility and Use in SF

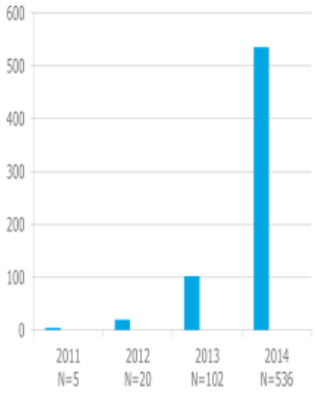
Group	People
HIV negative at substantial risk:	
MSM with 2+ non-condom anal sex (ncAI) partners[1]	12,589
MSM with 0 ncAI and an STI in the last year[2]	2,325
Female partners of HIV+ MSM[3]	653
Trans women[4]	522
TOTAL estimated PrEP eligibility	**16,089**
TOTAL reporting any PrEP in past year[5]	5,059
Percent of eligible people using PrEP in the past year	31%

1. SF City Clinic 2014 survey x HIV negative MSM population of 50,000;
2. SF NHBS self report of STI among MSM with 0 ncAI in 2014 x HIV negative MSM population of 50,000;
3. SF NHBS MSM reporting female partners in 2014 x HIV positive MSM population of 14638.
4. IDU and ncRAI in est. 923 HIV negative trans women in SF, adapted from Wilson *BMCID* 2014 14:430.
5. SF NHBS 2014, data on file.

Grant CROI Abstract 25 Seattle 2015.

Slide 26

Fenway Health: PrEP Experience



- 85.5% of initiators still on PrEP; Longest: 3.8 years
- 79.7% White; 8% Black; 12.3% Latino
- 95.1% identified as gay
- 158 zip codes
- "Gayborhood" <10%
- Private Ins: 80.7%; Medicare: 9%; Medicaid: 8.7%
- 25.9% who d/c'ed PrEP, initiated again
- More than 30 prescribers

Slide 27

Factors Associated with PrEP Use among US MSM Multivariable Model, Manhunt Survey, 1/14

(under review)

Characteristic	Multivariable OR (95% CI)
College graduate or above (vs. less than college education)	5.33 (1.25 to 22.7)
Ever diagnosed with an STI	2.74 (1.36 to 5.52)
Used PEP	16.0 (8.24 to 31.2)
Comfortable talking with provider about MSM sex	4.19 (1.51 to 11.6)

MSM in states that were more LGBT supportive were more likely to use PrEP, be out to their providers, and less likely to engage in condomless sex
(Oldenburg et al, AIDS, in press, 2015)

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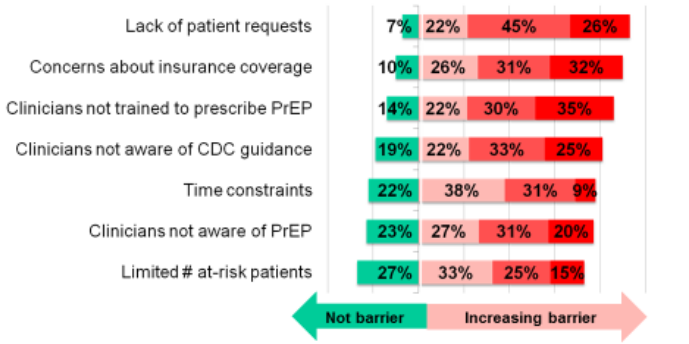
New England providers perceived numerous barriers to prescribing PrEP

(Krakower, PLOS ONE, in press 2015)



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Numbers represent percentage for each response category: not a barrier, minor barrier, moderate barrier, major barrier. Bars total to 100%

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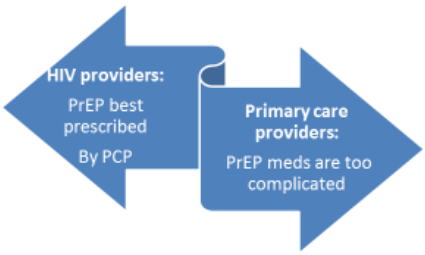
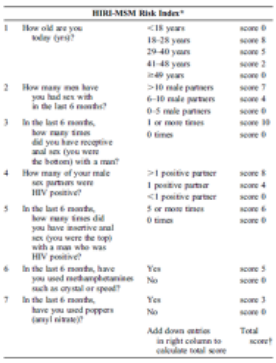
Purview paradox: contradictory beliefs about who should prescribe PrEP

(Krakower D, AIDS and Behavior, 2014; Smith D, JAIDS, 2014)





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Conclusions

- Oral PrEP works, if used
- Adherence is the 1^0 issue to ensure success
- Behavioral interventions may ↑ adherence
- New technologies to measure adherence are being developed
- New technologies to enhance adherence are also being developed
- New delivery systems for PrEP may obviate some challenges for PrEP (e.g. quarterly injections)
- Providers need to be engaged
- PrEP is a work in progress

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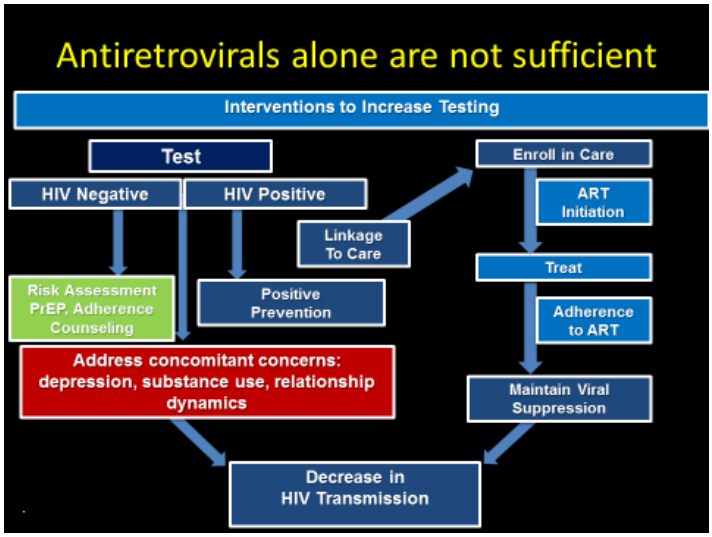

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Many thanks

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