HIV Integrated Planning Council
PrEP Work Group
Wednesday, April 18, 2018
2-4pm
Office of HIV Planning, 340 N. 12th Street, Suite 320, Philadelphia, PA 19107

Present: Erika Aaron, Michael Cappuccilli, Chet Carter, Meg Carter, Caitlin Conyngham, Annet Davis, Dave Gana, André Guedes, Shalik Howson, Kailah King, Najia Luqman, Laura Martindale, Mudhillun MuQaribu, Allison Myers, Nhakia Outland, Eran Sargent, Julian Serrings, Zsofi Szep, Tahira Tyler, Roberta Vena, Kristin Walker, Katie Wooten-Brielski

Guests: Dr. William Short

OHP Staff: Briana Morgan**,** Stephen Budhu

Call to Order: C. Steib called the meeting to order at 2:05 pm. Those present then introduced themselves.

Approval of Agenda: C. Steib presented the agenda for approval**. Motion:** D. Gana moved, M. Carter seconded to approve the agenda. **Motion Passed:** All in favor.

Approval of Minutes: C. Steib presented the minutes for approval. **Motion:** L. Martindale moved, D. Gana seconded to approve the minutes. **Motion Passed:** All in favor.

Report of Chair: C. Steib introduced the CROI update to the work group and welcomed Dr. Short.

Special Presentation: CROI Update ─ *Dr. William Short, Perelman School of Medicine, University of Pennsylvania*

W. Short greeted the group and provided a brief review of CROI (Conference on Retroviruses and Opportunistic Infections), they last met in March 2018. He explained to join the conference you must apply and be recommended by a current member.

W. Short reviewed utilization of PrEP by race/ethnicity. In 2015, 1.1 million adults were estimated to benefit from PrEP. Of that 1.1 million, 71% of them were MSM, 23% were heterosexual, and 6% were injection drug users. A. Myers asked if transgender individuals were included in the estimates. W. Short replied yes, the estimates accounts for male, female, and transgender. W. Short stated of that 1.1 million, 44% were African American, 31% were white, and 25% were Hispanic.

In response to demographic data presented, E. Sargent noted that often people do not discuss PrEP due to cultural stigma. Women especially do not seek PrEP and it is not necessarily marketed towards women. E. Aaron noted this data has been presented to pharmacies around the Philadelphia. At CROI there were also studies that looked into the use of PrEP, PrEP prescriptions, and HIV incidence. E. Aaron added since 2015 PrEP prescriptions have increased, while the incidence of HIV has decreased. A. Davis stated that the numbers from CROI focus on new prescriptions of PrEP not necessarily PrEP prescription refills.

W. Short presented data from partner studies that were discussed at CROI. 2751 HIV-negative pregnant women were observed who were in relationship with an HIV positive "ART-naïve" male. Participants were observed until the first evidence of HIV infection linked to male partners. From the cohort 78 incidences

of HIV infections were observed over the 9-month gestational period. W. Short explained as pregnancy progresses HIV risk increases due to changes. HIV acquisition risk per sex act was increased 3-fold in late pregnancy and 4-fold postpartum. He noted perinatal HIV transmission was rare but there has been a case in the Philadelphia area this year.

W. Short discussed the racial disparity of PrEP access and PrEP coverage in the United States. He discussed access by region and ethnicity. The regions presented were the northeast, midwest, south, and west. In all regions white/Caucasians were more likely to have access compared to those who were black or Hispanic. W. Short introduced the phrase "PrEP desert" which is defined as an area where someone would have to drive in excess of 30 miles to get PrEP. The south had the highest percentage of PrEP deserts compared to other regions.

W. Short reviewed PrEP data from an NYC PrEP clinic that was presented at CROI. In 2017, 2925 MSM were identified as a priority population. Of the 2925, 97% were offered PrEP navigation services, and 64% who were offered services accepted them. Of the 64%, 1136 were deemed PrEP eligible, and 647 were referred to a PrEP provider. Of the 647, 298 were linked to a PrEP provider and 222 of them received PrEP prescriptions.

W. Short reviewed disparities in PrEP uptake among primary care patients in San Francisco. From this data it was observed that women, specifically those who are African American, have a difficult time linking to PrEP. In total 2510 cases were reviewed and 451 were on PrEP. After presenting the San Francisco data, W. Short stated the common theme is African Americans and women have more difficulty linking to PrEP and if they do link to PrEP they also have a higher rate of discontinuation.

W. Short presented these key points from major US cities:

- PrEP uptake in NYC-PrEP navigator effectively resulted in improved referrals (uninsured persons were less likely to be linked to a PReP clinician) (*statistically significant odds ratio*)
- Atlanta: 41% did not return to start PrEP after screening.
- Chicago: PrEP use increased from 6.6% in visit one to 17.5%. 33% of participants discontinued PrEP: trouble getting a provider appointment (21.5%), or health coverage or loss of it (20%) were most commonly given reasons.

M. Cappuccilli asked if Philadelphia has PrEP navigators. C. Conyngham replied the city does, there are navigators who are funded through the 1509 grant. These navigators work with PrEP but also offer other services.

M. MuQaribu stated Chicago has been dedicated to working on racial and gender inequity in the medical sector. He asked if any major cities did not observe racial and gender disparities that were seen in PrEP surveillance. W. Short replied there are cities that are good at linking to care or retaining to care however there are no cities that the do not follow the racial and gender disparity trend. Z. Szep asked who normally prescribes PrEP. W. Short stated usually it is a combination of both primary care providers and PrEP navigators. He noted in some EMAs like New York City it is not necessary to see a primary care provider to receive a PrEP prescription. K. Walker stated it was difficult to find appointments for a PrEP provider after business hours and on the weekends. E. Aaron noted from survey analysis she has observed that primary care providers who have a large amount of the HIV+ clients also prescribe PrEP. In many cases PrEP clinics often provide primary care services for clients as well.

W. Short reviewed seroconversion on PrEP. From this case the MSM was actively on PrEP but the degree of rectal inflammation caused HIV infection. From this case the takeaway is people on PrEP need to see their physician 4 times a year. Generally medical guidelines are good to follow, but those who are more sexually active may need to seek more frequent medical visits.

W. Short reviewed the role of the vaginal microbiome in preventing HIV infection. The healthy vaginal microbiome contains primarily lactobacillis bacteria that is important for preventing HIV infection. Vaginal dybiosis[1] is a key factor in vaginal inflammation; the epithelial barrier loses its integrity and there is an elevated risk of HIV infection.

W. Short reviewed at study by Beer, et al. CROI 2018, "PrEP use amigo[2] HIV-negative partners of US MSM receiving medical care". From the study the reported PrEP use from partners of MSM HIV+ individuals were low, and estimated figures are about 1 in 4. Black partners were less likely to use PrEP compared to white partners.

W. Short concluded his presentation with the review of new HIV drugs. He explained Gilead created Descovy and it was widely viewed as the replacement for Truvada in PrEP use. Descovy is a pill that contains two drugs used to fight HIV: tenofovir alafenamide (TAF) and emtricitabine. TAF has less risk of kidney or bone side effects than older versions of tenofovir (TDF) that are used in Truvada. Descovy is not yet approved for PrEP use.

M. MuQaribu asked if studies have looked at the effect on TAF or TDF on trans-men. W. Short replied, not as yet, the surveillance for transgender persons is not yet adequate from an epidemiological standpoint.

M. Cappuccilli asked if there are other drugs in the HIV pipeline. W. Short replied yes, there's talk of a drug that's similar to a Listerine strip that can be used as a weekly vaginal insertion. The drug would contain either TAF or TDF, and studies in macaques have shown high efficacy. He added there is also a drug in production, Cabotegravir, that is a penile injection. Injection would be monthly, and efficacy is around 93%.

E. Sargent stated drugs that required genital injectables or require genital touching may present a barrier for some people.

N. Outland asked was there data on the effectiveness of vaginal rings or vaginal inserts for HIV treatment. W. Short replied there are many iterations of the treatment, and when treatment is adhered to, efficacy is usually high; however, he did not have any study examples on him at the moment.

C. Conyngham explained CROI offers scholarships and aid to applicants. To receive an award candidates must attend the full conference, including the Program Committee Workshop for New Investigators and Trainees, attend the opening session and reception, and complete daily and overall conference evaluations. [3] C. Steib added CROI, is housed in Massachusetts, but there are many international travel opportunities.

Report of OHP Staff: B. Morgan stated in reference to K. Walker's comment about services, the OHP has a new website with a searchable resource inventory. The inventory has 427 providers.

Action Items: None

1. Vaginal dybiosis is common disease in reproductive-age women were the vaginal flora is reduced or altered. Commonly observed in vaginal dybiosis is a vaginal microbiome that is nor predominantly laxctobacillus bacteria, common infections may be able to metabolize HIV medications such at TDF
2. Amigo is short for Advanced Model identification using Global Optimization.
3. For more information visit http://www.croiconference.org/scholarships/scholarship-information

Discussion Items:

- **Hard to link PrEP cases**

E. Sargent presented a hard to link case. The person was a trans-masculine HIV-negative person who recently had a HIV+ partner. She reviewed the barriers/difficulty this case had with linking to care; e.g., stigma.

She explained the case was seronegative, and initially had two preliminary 4th generation HIV tests after possible HIV exposure. Both tests were negative. After the 2nd test, the case was advised to wait another 30 days and after that period they would need to take another HIV test; that test would have to be negative before the case could be prescribed PrEP.

E. Aaron asked if the provider did not initially prescribe him PrEP due to the fact the provider was concerned the case could be HIV positive. E. Sargent replied yes. M. Cappuccilli stated in this case, the provider created anxiety for the case and the main barrier to care was created by the provider. M. MuQaribu stated since the case went through two 4th generation tests, there was no need to wait an additional 30 days before linking the case to case to PrEP. E. Sargent stated her team were not privy to the medical aspects of the case. There are protocols that are followed and each medical provider may have different ones. N. Outland discussed her experience with hard to link cases. She explained in this example she may have insisted the case be placed on PEP within the 30-day waiting period. For clarity, E. Aaron explained the difference between PrEP and PEP. PrEP is an abbreviation for Pre-Exposure Prophylaxis, and it's the use of anti-HIV medications to keep HIV negative people from becoming infected. PrEP contains emtricitabine and tenofovir disoproxil fumarate (TDF). Truvada has been approved for PrEP use by the FDA in 2012. PEP is an abbreviation for Post-Exposure Prophylaxis, where an HIV negative person is given anti-HIV medication after a possible exposure to HIV. PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. Like PrEP, PEP uses emtricitabine and TDF but also has raltegravir, an integrase inhibitor.

In reference to the case, C. Conyngham asked if the case was uninsured. E. Sargent replied the case did have insurance. L. Martindale stated within her agency the only thing that may present a barrier to care would have been insurance status. Her agency likely would have offered a same day start of PrEP. N. Outland explained there are some providers that do use same day start, but it is on a case to case basis. It is not applicable in every case, and usually it is only given to clients the same day who have a pre-existing relationship with the clinic in her experience.

E. Aaron stated PrEP and PEP are still available to those who are uninsured. E. Sargent stated in the situation that someone is uninsured the agency will try to go through Medicaid or use the Gilead co-pay assistance services. The process is online and quite easy. C. Steib stated the Gilead services are not available to those under 18, in the case of uninsured minors, there may be difficulty linking them to care. Fortunately, many persons under 18 are under their parents' insurance, but there may be confidentiality issues. C. Steib noted the provider could ask for a privacy block for the minor, this block is at the discretion if the insurance provider.

C. Conyngham explained Gilead offers assistance with PEP copays. Unlike PrEP assistance though, Gilead will only offer assistance for PEP once per person. For PrEP there is no limit. E. Sargent stated in her experience Gilead is super helpful with approving applications for its services.

M. Cappuccilli asked how 15-09 programs are funded. C. Conyngham replied 15-09 programs are funded by the CDC, currently the funding is from a 3-year demonstrative grant. E. Aaron added 1802 is another CDC grant, that is focused on expanding PrEP clinics and navigators.

Old Business: None

New Business: E. Aaron stated the PrEP work group will begin having its clinical providers' meeting on May 3, 2018 at 8 am, more information will be sent out via email. The PrEP work group will meet next Wednesday, May 16, 2018 from 2-4pm, after that the work group will meet every other month.

C. Conyngham stated the PrEP work group is looking for a permanent co-chair. She noted co-chairs would have to be HIPC members, and she encouraged all work group members to apply for HIPC membership.

Announcements: D. Gana announced on Friday, April 20, 2018, Hahnemann University Hospital is hosting an Anal Health Symposium. The event starts at 8:30am, food and refreshments will be provided.

Adjournment: Adjourned by consensus at 3:45pm, after a short networking period.

Respectfully submitted by,

Stephen Budhu, staff

Handouts distributed at the meeting:

- Meeting Agenda
- Meeting Minutes
- OHP Calendar