Meeting Agenda

VIRTUAL:
Wednesday, July 23rd, 2025
12 p.m. – 2:00 p.m.

- Call to Order
- Welcome/Introductions
- Approval of Agenda
- Approval of Minutes (June 25th, 2025)
- Report of Co-Chairs
- Report of Staff
- Discussion Items
  - Needs Assessment
- Other Business
- Announcements
- Adjournment

Please contact the office at least 5 days in advance if you require special assistance.
The next Comprehensive Planning Committee/Prevention Committee meeting is
TBD

Office of HIV Planning, 340 N. 12TH Street, Suite 320, Philadelphia, PA 19107 (215) 574-6760 • FAX (215) 574-6761 • www.hivphilly.org

Comprehensive Planning/Prevention Committee

VIRTUAL: Comprehensive Planning Committee/Prevention Committee
Meeting Minutes of
Wednesday, June 25th, 2025
2:30 p.m. – 4:30 p.m.
Office of HIV Planning, 340 N. 12th St., Suite 320, Philadelphia PA 19107

Present: Veronica Brisco, Keith Carter, Debra D'Alessandro (Co-Chair), James Ealy (Co-Chair), Gus Grannan (Co-Chair), Jeffery Haskins, Patrick Mukinay, Lorett Matus, Juju Myahwegi, Amy Onorato, AJ Scruggs, Clint Steib, Desiree Surplus (Co-Chair), Shakeera Wynne, Xandro Xu

Guests: Marina Leonardos (Gilead), Ernie White (Gilead), Jackson Suplita (DHH), Laura Silverman (DHH), Monique Howard, Cheryl Henne (PADOH)

Staff: Tiffany Dominique, Sofia Moletteri, Mari Ross-Russell, Kevin Trinh

Call to Order/Introductions: J. Ealy asked everyone to introduce themselves and called the meeting to order at 2:34 p.m.

Approval of Agenda:
J. Ealy referred to the June 2025 Comprehensive Planning Committee (CPC)/Prevention Committee agenda and asked for a motion to approve. **Motion:** K. Carter motioned; L. Matus seconded to approve the June 2025 CPC/Prevention Committee agenda via Zoom poll. **Motion passed:** 11 in favor. The June 2025 CPC/Prevention Committee agenda was approved.

Approval of Minutes (*May 15th & May 20th, 2025*):
J. Ealy referred to the May 2025 CPC & Prevention Committee Meeting minutes. **Motion:** K. Carter motioned; C. Steib seconded to approve the May 2025 CPC & Prevention Committee meeting minutes via a Zoom poll. **Motion passed:** 10 in favor. The May 2025 CPC & Prevention Committee meeting minutes were approved.

Report of Co-chairs:
S. Moletteri reminded the committees that G. Grannan's term was ending soon. They said a member could shadow G. Grannan to prepare themselves to become the next co-chair. They encouraged the members to ask S. Moletteri and the CPC co-chairs for more information if they were interested.

Report of Staff:
T. Dominique announced the CPC and Prevention Committee would be meeting in July as a combined meeting on July 23rd at 12pm. M. Ross-Russell explained that the meetings were taking place in July because they were still awaiting the Notice of Award and needed to postpone the allocations meetings. She hoped they would receive the award in July. They aimed to move quickly through the Allocations Process when they do receive the award.

Presentation:
-Twice Injectable PrEP-

M. Leonardos was a scientist representing Gilead and she had come to the committee to speak about the new pre-exposure prophylaxis (PrEP) medication, YEZTUGO. The medication had now been approved for HIV prevention on June 18th. YEZTUGO was innovative because it would only require two doses per year. She warned that YEZTUGO was not a complete treatment for HIV. If it was taken alone, the person may develop resistance to YEZTUGO.

All individuals initiating YEZTUGO, prior to each subsequent injection screen for HIV-1 using an antigen and antibody test. All individuals should confirm the test results using an RNA-specific assay. All individuals must have a negative test for HIV-1 prior to initiating YEZTUGO. M. Leonardos stated individuals had a 2-week period before and after to take their bi-annual injection. She stressed that it didn't matter if the person took the injection before or after but rather that they kept up adherence as a high concentration of the medicine determined the effectiveness of YEZTUGO.

A frequently asked question concerned the timing of when individuals taking YEZTUGO would begin to receive protection. M. Leonardos said a person should expect protection within 2 hours of taking their second "initiation" dose. K. Carter asked what would happen if the person missed their second "annual" dose. M. Leonardos recommended the person take the second "annual" dose as soon as possible. She said they had a solution for people who anticipate a gap in adherence. They would send the person pills the person would consume orally for up to six months. The pills would act as a bridge between doses until the person was able to receive the second dose. If a person had missed their dosage for more than 28 weeks, they were required to initiate YEZTUGO, including a screening to assess if they were still HIV- 1 negative. Certain medications could interfere with the effects of YEZTUGO. One such medication was Rifampin, which was used for the treatment of Tuberculosis. M. Leonardos explained they needed to increase the dosage of YEZTUGO if both medications were taken simultaneously.

YEZTUGO was injected in the abdomen or in the upper thigh. At the time, they didn't have approval for the patient to self-administer the treatment without assistance. The medication was a yellow fluid and contained no solids. M. Leonardos said if the medication was found otherwise as stated, the provider should contact Gilead for a replacement. G. Grannan asked how the medication had interacted with Grapefruit. M. Leonardos replied she had not heard about this interaction and would return with an answer in the future. T. Dominique would disseminate the information once she received the answer to this question. M. Leonardos described how to inject the treatment.

M. Leonardos warned that there was a potential risk of developing resistance to YEZTUGO if the individual acquired HIV-1 either before or when receiving YEZTUGO or following discontinuation of YEZTUGO. YEZTUGO resistance can develop in individuals. Healthcare providers should take the long-acting properties of YEZTUGO in consideration. Residual concentrations of LEN may remain in the systemic circulation of individuals for prolonged periods up to 12 months after the last dose. It was important to select individuals who agree to the required dosing schedule because nonadherence or missed doses could lead to HIV-1 acquisition and development of resistance. She warned that improper administration of LEN had been associated with serious adverse reactions including necrosis and ulcer. Other reactions included headache and nausea. M. Leonardos said the purpose 1 study had included pregnant

women and she wondered if this had contributed to the higher rate of nausea. She said she was awaiting more information from her leadership to answer this question.

K. Carter asked if the bump in medication was absorbed by the body. M. Leonardos confirmed that it was. She said this process may take six months.

In their purpose 1 portion of their study, cisgender women were given YEZTUGO. She reported none of the participants had acquiredHIV-1 under YEZTUGO. In the purpose 2 study which looked at the effects of YEZTUGO for self-identified men, two participants had contracted HIV-1 under YEZTUGO. The FDA had reviewed the study and their success rate had allowed them to bring the treatment to market early. A purpose 3 study was currently for cisgender women in the United States. A purpose 4 study was being conducted for people who inject drugs. In Europe, they would be conducting a purpose 5 study to learn how long people were willing to use YEZTUGO. T. Dominique said there was a question asking about the number of adolescents in the study. M. Leonardos answered that the women's study included people aged 16 to 25. For their purpose 2 study, they included people who were aged 16 to 74. She said they could not find enough senior participants and could not draw conclusions based on the small sample size of older adults 65 years old or older.

M. Leonardos listed drugs that did not have a clinically significant interaction with YEZTUGO. This had included Atorvastin, Famotidine, Pitavastin, Rosuvastin, Tenofovir alafenamide, and Voriconazole. In both studies, pregnant women were allowed in the sample population and they were allowed to breastfeed. M. Leonardos said they had detected only low levels of medication in the infants who were breastfed by mothers who were YEZTUGO. She concluded the medication was safe for women of childbearing age. YEZTUGO was not recommended in individuals with mild, moderate or severe renal impairment. YEZTUGO had not been studied for people who had a weight of less than 35 kilograms (77 lbs). YEZTUGO was not recommended for individuals with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) Hepatic impairment. YEZTUGO had not been studied in individuals with severe hepatic impairment (Child-Pugh Class C). G. Grannan wondered if the Purpose 4 study with people who injected drugs would be able to answer questions about the understudied populations mentioned above such as people who were less than 35 kilograms. M. Leonardos hoped purpose 4 study would answer those questions and more.

The Purpose 1 study was conducted in South Africa and Uganda with cisgender girls and young women between ages 16-25 years old. About 99.9% of participants were Black. Participants who tested negative for HIV-1 were randomized to receive YEZTUGO or DESCOVY. M. Leonardos emphasized that they had not given a placebo to the study population. The use of DESCOVY (F/TAF) for prevention of HIV in cisgender women was investigational and the safety and efficacy of this use had not been established. M. Leonardos stated not enough women took DESCOVY and the FDA would not give them approval based on this additional data. The HIV incidence per 100/PY was compared between participants receiving YEZTUGO and TRUVADA. YEZTUGO demonstrated superiority over TRUVADA with a 100% reduction in the risk of incident HIV-1 transmission. YEZTUGO also demonstrated superiority in the risk of incident HIV-1 transmission over background HIV (bHIV). M. Leonardos explained bHIV who had not completed an HIV test in the last 3 months and did not know their HIV status. She said

they had wanted to prevent people who knew their HIV status from skewing the data. K. Carter asked if they were going to test DESCOVY on women in their Purpose 4 study. M. Leonardos replied she did not have access to that knowledge.

J. Myahwegi, as an HIV pharmacist, asked how they would achieve worldwide distribution. M. Leonardos referred to her colleague, E. White, who could answer all questions regarding distribution.

During the Purpose 1 study, there were two incident transmissions among participants in the YEZTUGO arm of the trial. One incident had occurred in a participant after LEN exposures had fell below the target concentration following discontinuation of YEZTUGO and the virus from this participant had no LEN resistance-associated capsid substitutions. The other incident had occurred in a participant with viral loads that were too low for genotyping. M. Leonardos explained that this had meant they did not know if the person had resistance or not.

Purpose 2 Study was in cisgender men, transgender women, transgender men and gender-nonbinary individuals over age 16 with an unknown HIV-1 status at screening and at risk of HIV. The study had enrolled participants in Argentina, Brazil, Mexico, Peru, South Africa, Thailand and the United States. The median age of the participants was 29 years old. 67% of participants were Non-White. 63% of participants were Hispanic/Latino. 22% of participants were reported as gender diverse.

Participants in this study who tested negative for HIV-1 were randomized to receive YEZTUGO or daily TRUVADA in a 2 to 1 ratio. For every person on YEZTUGO, there was a person on TRUVADA. YEZTUGO demonstrated superiority over TRUVADA with an 89% reduction in the risk of incident HIV transmission. YEZTUGO also demonstrated superiority in the risk of incident HIV transmission over bHIV. G. Grannan asked if there were plans to distribute naloxone with YEZTUGO. M. Leonardos said she would find the answer and relay the answer back to T. Dominique. During the trials, there were 3 incidents among participants in the YEZTUGO arm. One incident had occurred after the time of primary analysis. Resistance was associated with all three participants. M. Leonardos said the reason why the 2 participants who acquired HIV during the primary analysis was still being examined. K. Carter asked what was the sample size of the Purpose 2 study. M. Leonardos replied 2,179 were on YEZTUGO and 1,086 people were on TRUVADA. K. Carter asked if the study was scientifically significant. M. Leonardos replied that YEZTUGO was 89% more effective compared to no treatment.

M. Leonardos noted that the participants in the Purpose 2 study had more baseline knowledge about PrEP than those in Purpose 1. She noted that this contributed to an easier process of encouraging Purpose 2 participants to take the preventive medication.

At the end of the presentation, J. Ealy encouraged people to contact E. White if they had any questions. He could be reached at this email address: Ernie.white6@gilead.com. He hailed the treatment as a significant achievement with a promising future in eliminating the epidemic. K. Carter asked E. White about a patient assistance program to aid in purchasing what was likely an expensive treatment to pay out of pocket. E. White explained that if they contacted him individually, he could connect them to their Medicine-Assisted Treatment Program. The

treatment could be acquired from a list of 8 special pharmacies in the network. C. Steib asked if most insurances would cover the treat with a copay plan. E. White replied that it was not covered by those plans at the moment. He said they did have a co-pay program through their portal and estimated the cost would be $8,200 per year.

Action items:

-Priority Setting Review-

Over the past three to four months, the Comprehensive Planning Committee had been ranking service categories and ranking them from a score of 1 to 8. S. Moletteri explained the scoring system to describe how important the service category was to care. The higher the score, the more crucial it was to care. They had previously completed the Priority Setting in the last CPC meeting and the committees would review the Priority Setting for approval to forward it to HIPC. S. Moletteri revealed they would now complete Priority Setting yearly instead of every three years like they had before.

S. Moletteri presented the committees with a chart comparing the Priority Setting from 2022 and 2025. The top 12 service categories in 2022 had consistently remained important to the committee members in 2025. With the exception of Direct Emergency Assistance Services (DEFA), service categories like Housing Assistance, Food Bank Services, Nutritional Services continued to be regarded as critical to care in the community. D. D'Alessandro asked the committee if they had wanted to review the services that were not highlighted. With no objections, the committee agreed they would focus on service categories whose ranking had changed significantly between 2022 and 2025.

Looking at the service category rankings, S. Moletteri noted that there were more repeat rankings in 2022 due to the fact that the number of members for each meeting had fluctuated. They said this didn't happen in 2025 where they had more diverse attendance.

DEFA had ranked as #2 in the 2022 Priority Setting and was ranked #7 in 2025. While 85% of members ranked this service as a critical priority, it wasn't rated as highly as other services. The decline in ranking was due to less reported need in the Client Services Unit (CSU) than other services. DEFA was also not mentioned in the Medical Monitoring Project (MMP). S. Moletteri added that clients often reported they had never heard of the service on the Consumer Reports. On spending reports, the service was often underspent due to being underutilized. L. Matus said the committee should consider that service utilization was affected by case managers who recommended services based on the needs of the client.

Information and Referral Services was ranked #22 in 2022 and was ranked #13 in 2025. The committee members voting for the service believed the service category was critical to navigation, linkage, and retention to care. 56% of voting members rated the service as an 8 because it offered connection to other services.

The AIDS Drug Assistance Program (ADAP) was ranked #8 in 2022 and #15 in 2025. The committee members saw the value of the service but noted the service category's lower usage with insurance/Medicaid. Cost and access issues were noted but were not seen as urgent since other mechanisms were covering those people.

Home and Community-Based Health Services was ranked #23 in 2022 and #16 in 2025.

Home and community service was a service category providing care for people with HIV over age 50 and those with disabilities. Many of the committee members viewed the service as important for helping the aging PLWH population and supporting social integration for seniors through day treatment.

Legal Services was rated highly in 2022 at #5. In 2025, the rating had dropped to #17. 75% of members ranked this service as a low service as a 1 in service priority. This was despite acknowledgement of future discrimination threats. Committee members felt that this service was limited in addressing immigration or minority discrimination.

Translation and Interpretation Services was ranked #12 in 2022 and #17 in 2025. The service was ranked low in CSU, MMP and the Consumer Survey. The committee acknowledged the demand for the service may not be reflected in the data due to language barriers. For example, only seven people had finished and returned the Spanish surveys for the Consumer Survey. During the Priority Setting Process, the committee members discussed language access apps and their limitations.

Home Health Care was ranked #22 in 2022 and was ranked #18 in 2025. The committee recognized the service had low utilization but they highlighted the burgeoning need for this service as the aging PLWH population grew. During the process, committee members discussed how limitations for coverage under Medicaid had made this service more important in the future.

Health Education/ Risk Reduction had ranked #13 in 2022 and had dropped to #19 in 2025. Most committee members had rated the service as a 5, indicating a middle of the road in importance to engagement and care. The service had ranked low in CSU and the Consumer Survey.
Home health and the votes had reflected the data.

Substance Use Residential was ranked #6 in 2022 and fell to #20 in 2025. During the discussion of the service, committee members acknowledged the service was needed but questioned the service's low efficacy and high readmission. Overall, the committee members favored outpatient models.

Care Outreach Services had ranked #8 in 2022 and the service's rank had dropped to #22 in 2025. Most of the committee members had rated the service as a 5 (80% of votes). While committee members had felt the service was essential to engagement in care, CSU, MMP and the Consumer Survey had ranked the service low and consequently affected the overall ranking.

The Local Pharmaceutical Assistance Program (LPAP) was ranked #14 in 2022 and had dropped to #23 in 2025. The service was recently defunded in the Philadelphia EMA because it was deemed duplicative of ADAP and Emergency Financial Assistance (EFA) Pharma. Members felt that other pharmaceutical services were more effective.

Child Care Services had dropped from rank #18 in 2022 to #24 in 2025. The committee members felt that the service may not reflect the demographics of the EMA's PLWH needs. Additionally, the committee members discussed how the program guidance may make receiving child care services from a trusted neighbor or friend more difficult. The program guidance had prohibited direct cash payments to the caretaker.

Non-Medical Case Management was ranked #20 in 2022 and had dropped to #25 in 2025. The service was seen as a "Light touch" support for those not needing intensive help. The members discussed how it was not currently being funded by RW Part A and how Medical Case Management had priority over Non-Medical Case Management. They had also discussed other avenues such as PhillyKeepOnLoving and CSU.

Rehabilitation Care was ranked in #21 in 2022 and had dropped in rank to #26 in 2025. The committee members felt the service was helpful for aging adults but limited funding and competing needs for the service had dissuaded the members from rating the service as a higher priority.

Day or Respite Care was ranked #17 in 2022 and was ranked #27. The service was underutilized in the Consumer Survey and was ranked low in CSU and MMP. Similarly, the committee members didn't have much discussion around how this service was essential for PLWH's engagement in care.

K. Carter expressed his concern about potential reductions in funding and how it would impact services. D. D'Alessandro said her organization had already experienced a cut in their funding. S. Moletteri cautioned that they should wait to see how the situation would resolve before deciding how they would move forward. They said the Priority Setting rankings would stay the same until they had more information.

Motion: K. Carter motioned; D. D'Alessandro seconded to forward the Priority Setting forward to the HIV Integrated Planning Council.

J. Ealy: In Favor
K. Carter: In Favor
C. Steib: In Favor
J. Haskins: In Favor
L. Matus: In Favor
J. Myahwegi: In Favor
V. Brisco: In Favor
P. Mukinay: In Favor
S. Wynne: In Favor
X. Xu: In Favor
A. Scruggs: In Favor
G. Grannan: In Favor
D. Surplus: In Favor
D. D'Alessandro: In Favor

Motion Passed: 14 in Favor. The motion to forward the Priority Setting forward to the HIV Integrated Planning Council was passed

-Needs Assessment-
M. Ross-Russell said they were planning what they needed to do to complete the Needs Assessment in a timely fashion as part of the Integrated Plan. After reviewing the Consumer Survey, they were considering town halls and focus groups. Town halls were to be the initial step and the information gleaned from these meetings would be incorporated into the focus groups.

S. Moletteri presented the committee with a list of the top 10 service category rankings. The list had questions. They encouraged the members to read the questions and answer them after the meeting.

The first question asked about major challenges PLWH faced when seeking access to services. The second question asked what priority services they wanted to explore in depth at the town hall. The third question stated that DEFA was a lower priority and asked the person to assess the current community needs and the potential financial hardship for PLWH based on this information. The fourth question asked if the person felt there were populations particularly underserved by the priority services.

Other questions on the list asked if there were any other services not listed in the top 10 services. Committee members were also asked about the effects of social determinants of health on health outcomes of PLWH. Additional questions were asked about the structure of the town hall such as tone, the shape and goal of the meeting. S. Moletteri suggested answering these questions and they would discuss the results at their next meeting.

D. D'Alessandro asked what was the timeline of the town hall. S. Moletteri answered that they didn't have a timeline yet. M. Ross-Russell said they should aim to start the process towards the end of the year. D. D'Alessandro suggested they should have co-facilitators to guide the town hall. M. Ross-Russell said she was unsure who would facilitate the town hall.

C. Henne said the PA Department of Health was also looking to have their own needs assessment. She said they would delay their needs assessment by two weeks to prevent confusion with HIPC's needs assessment.

Any Other Business:
None.

Announcements:
A. Scruggs said they were given a grant to hold a day symposium and a ball during OURfest. The symposium would be on Assigned Female at Birth (AFAB) and HIV criminalization.

L. Matus announced that Friday was National Testing Day.

J. Haskins announced Chris Bartlett was resigning as director of the William Way Center and there would be a brunch on Saturday to honor him.

V. Brisco announced the AIDS Healthcare Foundation would be hosting their HIV testing tomorrow.

Adjournment:
J. Ealy called for a motion to adjourn. **Motion:** K. Carter motioned, D. D'Alessandro seconded to adjourn the June 2025 CPC/Prevention Committee meeting. **Motion passed:** Meeting adjourned at 4:33 p.m.

Respectfully submitted,

Kevin Trinh, staff

Handouts distributed at the meeting:

- June 2025 Prevention Committee Meeting Agenda
- May 2025 Prevention Committee Meeting Minutes
- June 2025 CPC Meeting Agenda
- May 2025 CPC Meeting Minutes

Planning a Needs Assessment/Town Hall

The CPC recently ranked service categories. Please review the Top 10 priorities below and use them as a guide in answering the following questions.

1. **Housing Assistance**
2. **Medical Case Management**
3. **Mental Health Services**
4. **Transportation**
5. **Food Bank**
6. **Dental Care**
7. **Direct Emergency Financial Assistance (DEFA)**
8. **Ambulatory Care**
9. **Psychosocial Support Services**
10. **Benefits Assistance**

DEFA saw the biggest decrease in ranking (-5). Food Bank and Housing Assistance also rose (+2) since 2022.

Looking at the Priority Services:

1. What major challenges or barriers do you think People Living with HIV (PLWH) are currently facing when trying to access the services listed above (stigma, access, quality, wait times, etc.)?

2. Which of the priority services would you most want to explore in depth at a town hall? Why (growing need, service barriers, etc.)?

3. DEFA moved down 5 spots. What do you think this says about current community needs or potential financial hardship for PLWH?

4. Do you think any populations are particularly underserved within each of the priority services (e.g., youth, trans people, immigrants, People who Use Drugs (PWUD), etc.)?

Anything Missed:

1. Are there services not listed in the Top 10 that you believe should still be explored in a needs assessment / town hall?

2. What role do social determinants of health (e.g., housing/neighborhood, food security, transportation, employment, stigma) play in shaping health outcomes for PLWH in our EMA?

Structure:

1. How do we make the town hall interactive and engaging (e.g., small group discussions, anonymous cards, breakout groups by topic, etc.)?

2. What tone / shape do you think the town hall should take on (e.g., community healing, issue-focused, open forum, structured listening session, etc.)?

3. What information do we hope to walk away with after the town hall?