

MEETING AGENDA

HYBRID:

Wednesday, September 23rd, 2026

2:30 p.m. – 4:30 p.m.

- ◆ Call to Order
- ◆ Welcome/Introductions
- ◆ Approval of Agenda
- ◆ Approval of Minutes (August 26th, 2026)
- ◆ Report of Co-Chairs
- ◆ Report of Staff
- ◆ Presentation Item
 - ExIS & C-Core
- ◆ Discussion Item
 - Co-Chair Nomination
- ◆ Other Business
- ◆ Announcements
- ◆ Adjournment

Please contact the office at least 5 days in advance if you require special assistance.

The next Prevention Committee Meeting
is October 28th, 2026.

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**HYBRID: Prevention Committee
Meeting Minutes of
Wednesday, August 26th, 2026
2:30 p.m. - 4:30 p.m.**

Office of HIV Planning, 340 N. 12th St., Suite 320, Philadelphia, PA 19107

Present: K. Carter, S. DiBianca, J. Ealy (Co-Chair), S. Jacinto, A. Onorato

Excused: C. Johnson

Guests: Saira Chaudhry (Merck), Evan Harbaugh, Brian Hernandez, J. Staley, Karri Sutter (Merck), Michele Houpp (Merck), Scott Hawkins (Merck), Brent Drollette (Merck)

Staff: Tiffany Dominique, Elizabeth Fischer, Debbie Law, Sofia Moletteri, Kevin Trinh, Kristin Wilson

Call to Order/Introduction: J. Ealy called the meeting to order at 2:41 p.m. K. Trinh asked for introductions. People introduced themselves in the room and through Zoom.

Approval of Agenda:

J. Ealy referred to the August 2026 Prevention Committee agenda and asked for a motion to approve. **Motion:** J. Ealy motioned; K. Carter seconded to approve the August 2026 Prevention Committee agenda. Members voted vocally in the room and through Zoom. **Motion passed:** All in Favor. The August 2026 Prevention Committee agenda was approved.

Approval of Minutes (June 24th, 2026):

J. Ealy referred to the June 2026 CPC/Prevention Committee Meeting minutes. **Motion:** S. DiBianca motioned; J. Ealy seconded to approve the June CPC/Prevention Committee meeting minutes. Members voted vocally in the room and through Zoom. **Motion Passed:** All in Favor. The June 2026 CPC/Prevention meeting minutes were approved.

Report of Co-chairs:

None.

Report of Staff:

K. Trinh said that Office of HIV Planning (OHP) staff tabled at a Mazzoni Center event on August 22nd. S. Moletteri added the event was “Take Back Your Health.” She said staff aimed to recruit new members and connect with other organizations, and she felt they were successful.

S. Moletteri reported that CPC and Prevention would have a combined meeting on November 19th due to the Thanksgiving holiday.

T. Dominique reported attending the Ryan White (RW) Conference in Washington, D.C. She said the OHP staff had been meeting with other eligible metropolitan areas (EMA) to compare processes, exchange ideas, and look for opportunities to improve their operations.

T. Dominique thanked those who attended the Allocations process in July. She mentioned a preliminary financial report with a funding cut, though the amount was currently unknown. She said the funding amount would be released in 2027.

T. Dominique said one notable presentation was on HIV & Aging by Evan Thornburg. She noted that there were three sessions that were focused on just Planning Councils. She said there was a Planning Council Manual that was expected to be disseminated by the end of the year.

K. Trinh said OHP would be tabling at the New Jersey Gay Pride event on September 6th from 12 p.m. to 6 p.m. at Cooper River Park in Cherry Hill, NJ.

Presentation Items:

~Merck Presentation~

S. Chaudhry introduced herself as the Regional Medical Scientific Director, and K. Sutter introduced herself as the US Director of Medical Affairs. K. Sutter said Merck had many assets within the HIV space. She noted that the new drug was Doravirine/Islatravir (IDVYNZO).

K. Sutter said Doravirine (DOR) had been around for 8 years and has been shown to be effective against wild-type viruses that were commonly associated with NNRTI-associated mutants. It also has a low potential for DDI interactions and can be taken with or without food.

K. Sutter said Islatravir (ISL) had important attributes that made it important in a two-drug ART regimen. ISL also had a low DDI potential and can be co-administered with several co-medications. ISL development was paused at a 0.75 mg dose, which affected CD4 and lymphocyte counts. She noted that the dose that moved forward and had been approved was a .25mg dose, which did not see an impact on CD4 and lymphocyte counts.

K. Sutter explained that ISL had multiple mechanisms of action. Most notably, it had a translocation inhibitor and resulted in delayed chain termination.

K. Sutter said the Phase 3 Clinical Development Program evaluated the .25mg dose of ISL and 100mg of DOR. The combination was compared with baseline Anti-Retroviral Treatment (ART) in an open-label randomized design among individuals who were virologically suppressed. It was also compared to BIC/FTC/TAF in a blinded randomized design with individuals virologically suppressed. They also completed a study comparing it with BIC/FTC/TAF in a blinded randomized design with ART-naïve individuals. The final study was an open extension study with individuals on 100 mg of DOR and .75mg of ISL.

K. Sutter introduced the first study, which compared DOR/ISL (100/.25mg) to BIC/FTC/TAF. This was known as protocol 52, but was completed in virally suppressed people with HIV (PWH). K. Carter asked which studies were discontinued. K. Sutter said the studies that used .75mg of ISL did not move forward, but the studies with .25mg continued. K. Carter asked if they did any dose reduction to .25mg. K. Sutter said .25mg was found efficacious in covering the strings with mutations but not impacting CD4 or lymphocyte counts. At 48-weeks, the DOR/ISL group was at 1.5% of participants who had HIV-1 RNA ≥ 50 copies/mL compared to .6% of participants on BIC/FTC/TAF.

K. Sutter moved on to discuss findings from Week 96. K. Sutter noted that resistance analysis was also part of the trials completed. Study participants had no known resistance to DOR/ISL, nor did they actively have Hepatitis B. She said patients were randomized 2 to 1. She shared the definition of CD4 counts and lymphocytes.

K. Sutter said baseline characteristics were comparable between both groups. The median age was 47 years old, 25% were assigned female at birth, the median years since HIV diagnosis was 11 years, and the median years of prior BIC/FTC/TAF was 3 years. She also highlighted that the population was racially and ethnically diverse.

K. Sutter said that at Week 96, confirmed HIV-1 RNA ≥ 50 copies/mL occurred in 1.5% of participants in the DOR/ISL compared with 1.2% of participants in the BIC/FTC/TAF group. HIV-1 RNA < 50 copies/mL was maintained in 88.9% in the DOR/ISL and 90.1% in the BIC/FTC/TAF group, and < 200 copies/mL in 88.9% and 91.2%, respectively. Through Week 96, .6% of participants in the DOR/ISL and 0% in the BIC/FTC/TAF group discontinued due to lack of efficacy.

K. Sutter explained that through 96 weeks, treatment-emergent resistance was not detected in the BIC/FTC/TAF group versus .3% in the DOR/ISL group. She noted additional details about the one patient in whom they detected treatment-emergent resistance. The virus remained sensitive to DOR/ISL at Week 24.

K. Sutter said the mean percent changes in CD4+ T-cell counts were comparable between both groups. In both groups, .6% discontinued due to protocol-specified decreases in CD4 count.

K. Sutter explained that proportions of participants with adverse events through Week 96 were similar between groups. The most common drug-related adverse events were diarrhea, flatulence, lymphocyte count, and pruritus with DOR/ISL, and sleep disorder, osteopenia, decreased weight, and decreased appetite with BIC/FTC/TAF.

K. Sutter added that no cases of clinical Hepatitis B reactivation were observed, though transient low-level Hepatitis B viremia was detected in 3 DOR/ISL participants who reported Hepatitis B at the start of the study; none had symptoms, surface antigenemia, or transaminase elevation. She added that four DOR/ISL participants developed new Hepatitis B infections, all of whom remained asymptomatic. She noted that the participants were offered vaccination as part of the study.

With the first study, K. Sutter noted that the measurement parameters were consistent within the two groups. The main findings were that switching to DOR/ISL from BIC/FTC/TAF maintained a high rate of virologic suppression and had similar efficacy to continuing BIC/FTC/TAF at Week 96; DOR/ISL was generally well tolerated over 96 weeks, and the adverse effects were comparable; a switch to DOR/ISL had no adverse effects on total lymphocyte and CD4+ T-cell counts through Week 96. Ultimately, these findings were consistent with the study's primary Week 48 results.

T. Dominique asked for clarification on wild-type and on the eligibility criteria of participants. K. Sutter said the studies were conducted in adult participants, but there was ongoing work to complete studies in adolescents. S. Chaudhry said wild-type HIV refers to a form of the virus that did not have mutations associated with resistance to HIV medications. In resistance testing, wild-type HIV means they have not detected mutations that make the virus resistant to certain medications. Generally, it was the form of HIV before exposure to treatment. K. Carter asked if that would be considered naive patients. S. Chaudhry said it would not be considered naive.

K. Sutter moved on to the second study, which was conducted in virally suppressed individuals. This study was presented at Week 48 and would continue through Week 144. This presentation was reflective of Week 96. The second study differed from the first because it was open-label, and DOR/ISL was compared with participants on their baseline ART. She noted that participants could switch from their baseline therapy to DOR/ISL. The population was similar to the first study, but this study was open-label. It consisted of adults with HIV-1 RNA <50 copies/mL for ≥ 3 months on stable, oral 2- or 3-drug ART. The participants had no known resistance to DOR and no active Hepatitis B.

K. Sutter noted that on Day 1, 366 participants switched to DOR/ISL and 185 continued their baseline ART regimen. She explained that 40% were assigned female at birth, 45% identified as Black, and 14.5% identified as Hispanic or Latinx. Most participants were on an integrase strand transfer inhibitor (INSTI)-based regimen and 30% on a protease inhibitor (PI)-based regimen.

In Group 1 DOR/ISL, viral suppression was maintained in 92.6% of participants at Week 96. 2% of participants in this group had HIV-1 RNA ≥ 50 copies/mL at Week 96. In Group 2 DOR/ISL, virologic suppression was maintained in 96.6% of participants at Week 96.

K. Sutter continued that the mean percent changes in total lymphocyte count and CD4+ T cell count remained comparable between treatment groups. No participants met discontinuation criteria or had a decrease in total lymphocyte count or CD4+ T-cell count.

K. Sutter said adverse event rates during the first 48 weeks on DOR/ISL were similar in Group 1 from Week 0-48 and Group 2 from Week 48-96. In Group 1, fewer participants reported drug-related adverse events during Week 48-96 compared to Week 0-48. The most common drug-related adverse events were diarrhea and weight increase in Group 1 and weight increase and abnormal dreams in Group 2. There were no cases of clinical Hepatitis B reactivation, and 3 participants had transient Hepatitis B viremia that resolved on DOR/ISL. All were asymptomatic with no surface antigenemia or elevated transaminases. She noted that the participants were offered vaccination as part of the study. No clinically relevant changes were observed in LDL-cholesterol, non-HDL-cholesterol, or insulin resistance.

K. Carter asked how many men were included in the sample size. S. Chaudhry said the sex assigned at birth was broken down into subgroups in a different study. She noted that they focused on including more women in the study because they've been underrepresented. She noted that the study included around 300 participants. K. Sutter added that the slide did not include every demographic.

K. Sutter concluded that switching to DOR/ISL maintained high rates of virologic suppression through 96 weeks of treatment. There was no treatment-emergent resistance to DOR or ISL observed through Week 96. She added that switching to DOR/ISL had no adverse effects on total lymphocyte or CD4+ T-cell counts through Week 96 and overall, DOR/ISL maintained a favorable safety and tolerability profile over 96 weeks.

K. Sutter continued with the 3rd study, which had results from Week 48. She highlighted that the participants were adults with plasma HIV-1 RNA ≥ 500 copies/mL at screening, treatment-naïve, had no documented or known resistance, and had no active Hepatitis B. She noted 116 study sites across 20 countries worldwide.

K. Sutter explained that the demographics were similar between the two treatment groups. She noted that 10% of participants in each group had an HIV-1 RNA $> 500,000$ copies/mL and 35% of participants had HIV-1 RNA $> 100,000$ copies/mL. At Week 48, DOR/ISL was not inferior compared to BIC/FTC/TAF. She noted that 2 participants who experienced treatment-emergent resistance were randomized to the DOR/ISL group. No participants in the BIC/FTC/TAF group developed treatment-emergent resistance.

K. Sutter noted that there was similar efficacy for both treatment groups depending on CD4 count, high viral loads, and HIV subtype. Similar immune reconstitution for DOR/ISL was comparable, and the DOR/ISL safety profile was comparable to BIC/FTC/TAF. There were 2 serious adverse events in the DOR/ISL group, including a drug reaction with eosinophilia and system symptoms as well as drug-induced liver injury. There were 3 reported Hepatitis B infections in the DOR/ISL group. Increase in weight was similar between DOR/ISL and BIC/FTC/TAF.

In conclusion, K. Sutter noted that DOR/ISL had comparable efficacy to BIC/FTC/TAF for the initiation treatment of HIV-1 at Week 48. Immune reconstitution with DOR/ISL was similar to BIC/FTC/TAF, and DOR/ISL was generally well-tolerated.

K. Sutter summarized that DOR/ISL was non-inferior to comparators in both treatment naïve and virologically suppressed persons living with HIV, including patients with advanced disease at Week 48 & 96, respectively. DOR/ISL also had a safety profile similar to comparators and was not associated with clinically relevant metabolic or renal adverse events. DOR/ISL was approved a couple of months before.

Regarding sex assigned at birth, S. Chaudhry said there were no combined data across both studies, but they could report sex assigned male at birth in the first study. She said 214 were assigned male at birth in the DOR/ISL group and 118 were assigned male at birth in the baseline ART group. She emphasized that they prioritized inclusivity in the studies, specifically with sex and race. K. Carter asked if they had any participants who identified as transgender. S. Chaudhry confirmed that the study included transgender participants, though she did not have the exact number.

T. Dominique asked if the first two studies were only conducted in the United States. S. Chaudhry said all the studies were conducted globally. She noted that the participants had

extremely low CD4 counts and extremely high viral loads. They wanted to show that DOR/ISL could be just as efficacious given to somebody with those extremely high viral loads.

T. Dominique asked if they studied any metabolic changes that could impact someone 50+ or using Hormone Replacement Therapy (HRT). S. Chaudhry said they found no differences in the lipid changes or in weight. She said many factors could have affected the results and that they would look into it further as they collect more data.

~Mental Health~

E. Harbaugh presented “On the Mend-tal Health: A Mental Health Literacy Training”.

E. Harbaugh said the requirements for a mental health diagnosis included distress or poor functioning and impact on one of the following: cognition, emotions, mood, and behavior. The distress or poor functioning cannot be better explained by another medical diagnosis or substance use.

E. Harbaugh continued that three main factors that can cause mental illness were biology, life events, and lifestyle. Major types of mental illness include mood disorders, psychotic disorders, anxiety disorders, trauma-related disorders, obsessive-compulsive disorders, eating disorders, dissociative disorders, personality disorders, and neurodevelopmental disorders.

E. Harbaugh said a mood disorder was anything that impacted a person’s mood by causing distress. Major Depressive Disorder (MDD), Dysthymia, Seasonal Affective Disorder (SAD), Bipolar Disorder, and Cyclothymia were all examples of mood disorders. For diagnosis, depression was categorized by 2 - 4 weeks of symptoms, whereas dysthymia was categorized by months to years of symptoms. SAD occurs when people experience depressive symptoms during the winter due to the lack of sunlight. J. Ealy asked if SAD was treated with light therapy. E. Harbaugh confirmed that light therapy was used to treat SAD. He continued that bipolar disorder occurs when someone feels intense depression and manic at opposing times. Symptoms of a manic episode include feeling euphoric, becoming easily irritable, loss of sleep, and having a hard time focusing. Mania was more severe in Bipolar 1, and depression was severe in Bipolar 2. Cyclothymia occurred when someone experienced hypomania and low-grade depression.

E. Harbaugh asked if anyone knew how to treat mood disorders. J. Staley said therapy was an option to treat mood disorders. T. Dominique said Selective Serotonic Reuptake Inhibitors (SSRIs). E. Harbaugh explained that SSRIs increase serotonin between cells, making it more likely the next cell can absorb it. E. Harbaugh added that SSRIs were most helpful for people with depression.

E. Harbaugh said medication was a component to overcome mood disorders. He said that therapy, such as Cognitive Behavioral Therapy, and lifestyle changes like increasing exercise. J. Ealy noted that alcohol was a depressant. E. Harbaugh noted that mood stabilizers impact mania and depression to balance mood. T. Dominique asked for examples of mood stabilizers. E. Harbaugh said lithium was the first introduced mood stabilizer and was still frequently used. He noted that it can cause thyroid issues. T. Dominique asked if a patient can be diagnosed with multiple disorders. E. Harbaugh said that many mainframes don’t allow a provider to take away a

diagnosis. He said that symptoms can overlap, so it may just be a different disorder with the same symptoms.

E. Harbaugh described psychotic disorders. He described psychosis as a disconnect between an individual and reality. He said Schizophrenia occurred when someone experiences psychosis, specifically delusions and hallucinations. The individual would have hallucinations and develop delusions based on the hallucinations. Schizoaffective disorder had psychotic elements and mood elements such as depression. Brief psychotic disorder was a one-time or several-time event when someone lost touch with reality, but bounced back by themselves or with treatment. Delusional disorder occurred when someone functioned well, but they had one thing that they believed that may cause issues in their life.

E. Harbaugh listed the four A's of schizophrenia as affect, autism, associations, and ambivalence. Autism manifested as being focused inwardly, which made it hard to empathize. Associations involve observing other people's behavior and interpreting it accordingly. Ambivalence referred to a state where an individual knew a belief was not rationally true, but it felt completely true to them.

E. Harbaugh said the treatment for psychotic disorders was antipsychotic medication, which was used to address the hallucinations. If the delusions weren't reinforced by the hallucinations, the delusions would eventually fade. E. Harbaugh said antipsychotic medications trigger drowsiness. J. Ealy asked how long the medication takes to take effect. E. Harbaugh responded that it would take about 4-6 weeks. T. Dominique asked if psychotic disorders were tied to age or gender identity compared to others. E. Harbaugh said these disorders typically stem from a traumatic event. He said therapy could be useful, but in some cases it did not help.

Next, E. Harbaugh described anxiety disorders. E. Harbaugh described Generalized Anxiety Disorder as a persistent feeling of anxiety during multiple parts of life. The difference between worry and anxiety was that worry was about a specific thing, but anxiety wasn't about something specific. Panic disorder occurs when an individual experiences panic attacks. He noted that fear of having a panic disorder was a symptom of a panic disorder. Phobias occur when an individual feels fear of a particular thing. An example of a phobia was agoraphobia—the fear of leaving the house. Social anxiety disorder was typically experienced in younger individuals. Separation anxiety disorder can occur in parents, children, or spouses. Selective mutism was also considered an anxiety disorder. E. Harbaugh said treatments for anxiety disorders included SSRIs and anti-anxiety medications such as benzodiazepines (Benzos), which were highly addictive. CBT therapy could also be used to treat anxiety disorders. Exercise can also help alleviate anxiety disorders.

K. Carter asked if there were more people with anxiety disorders due to the COVID pandemic. E. Harbaugh said there were higher rates of mental health disorders due to the pandemic, but in his field, he hadn't seen much.

E. Harbaugh described trauma-related disorders. Acute stress disorder occurs when an individual experiences symptoms 2-6 weeks after the traumatic event, but after 6 weeks, it becomes post-traumatic stress disorder (PTSD). After a year, it would become complex PTSD. One of the

most prevalent symptoms was a lot of anxiety that reminded the person of the trauma or hypervigilance. He clarified that trauma could be anything that resulted in serious bodily harm or other types of serious events that happened to a person, or that they witnessed. Prolonged Grief Disorder was controversial because it puts a timeline for grief. K. Carter said that grief disorders weren't always just caused by death; it could be the loss of anything. Another trauma-related disorder was adjustment disorder. Treatments include CBT and dialectical behavior therapy (DBT). Antianxiety medication can help, but cannot cure a person.

E. Harbaugh said obsessive-compulsive disorder occurs when someone has obsessive thoughts and compulsive behaviors. J. Staley shared his experience with mental health. Hoarding disorder occurs when an individual doesn't want to let go of things. Body dysmorphic disorder occurred when people were obsessed with how their body looked. Other compulsions include trichotillomania and excoriation disorder. Treatments include therapy with exposure treatment and anti-anxiety medications. With psychotic and OCD disorders, lifestyle changes were often not effective unless they reduced stress.

E. Harbaugh discussed the various eating disorders. Anorexia occurred when a person restricted calories to an extreme amount. They often had poor body image. Bulimia involved binge eating and purging, such as vomiting, extreme exercise, or diuretics. Binge-eating disorder was another example. Avoidant/Restrictive Food Intake Disorder (ARFID) occurred when children were very particular with what they eat. Treatment includes CBT therapy and lifestyle changes to help recovery.

E. Harbaugh discussed dissociative disorders. Dissociative amnesia happens when an individual has a gap in their memory, leading them to feel that portion of their day was missing. Dissociative fugue or highway hypnosis occur when traveling. Dissociative Identity Disorder was defined as when someone had multiple personalities.

E. Harbaugh said that to debunk common myths, he reminded members that mental illnesses can affect everyone, early onset can occur, the body-mind connection was important, it was treatable, it was not violent, early help was important, and there were barriers and stigma.

E. Harbaugh said that depression and anxiety can be a barrier to taking HIV medication, trauma & PTSD can impact someone's trust of providers, there were cognitive changes, and treatment barriers. He said PWH need access to integrated care, peer support, and professional treatment.

E. Harbaugh said OHP could send the presentation out to members. K. Trinh said it would be posted on the website.

Other Business:

None.

Announcements:

L. Fischer would email out the events that A. Onorato shared. K. Trinh read through the announcements from A. Onorato. There would be an HIV Cure Research Education Webinar on September 15th, a Penn Centers for AIDS Research (CFAR) session on September 22nd, and the

2026 Penn CFAR Research Symposium on September 30th. K. Trinh reminded members of the Narcan training on September 30th at 10:00 AM.

Adjournment

J. Ealy called for a motion to adjourn. Motion: J. Ealy motioned, K. Carter seconded to adjourn the August 2026 Prevention Committee meeting. Members voted vocally in the room and through Zoom. Motion passed: All in favor. The meeting adjourned at 4:35 p.m.

Respectfully submitted,
Elizabeth Fischer

Handouts distributed at the meeting:

- August 2026 Prevention Committee Agenda
- June 2026 CPC/Prevention Committee Meeting Minutes