# Panel #2

## Pre-Exposure Prophylaxis (PrEP) and Non-Occupational Post-Exposure Prophylaxis (nPEP)

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Mara Michniewicz, M.P.H.</td>
<td>Prevention Program Manager</td>
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<tr>
<td>Brandon Moton, M.P.H.</td>
<td>PrEP/nPEP Coordinator</td>
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<td>Gay Koehler-Sides, M.P.H., C.P.H.</td>
<td>Area 3/13 HIV/AIDS Program Coordinator</td>
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<td>Michael Alonso, M.S.</td>
<td>Area 10 PrEP Coordinator</td>
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<td>Joey Wynn</td>
<td>Community Relations Director, Empower-U</td>
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</tbody>
</table>

- **HIV/AIDS Section Statewide Initiatives and PrEP Materials**
- **Local Area Highlight: PrEP Clinic Implementation Process from Alachua County (Area 3/13)**
- **Local Area Highlight: The Role of Public Health Detailing and PrEP Navigators in Broward County (Area 10)**
- **Future Biomedical Interventions and Latest Research**
State of Florida Integrated Plan: Objectives and Strategies

• Objectives: 1.2, 3.1, 3.2, 3.3, and 3.4

Statewide Initiatives:
Pre-Exposure Prophylaxis (PrEP) and Non-Occupational Post-Exposure Prophylaxis (nPEP)

Florida HIV/AIDS Comprehensive Planning Network (FCPN) Meeting
May 17–18, 2017
Kissimmee, FL

Mara Michniewicz, MPH
Prevention Manager
Florida Department of Health
Bureau of Communicable Diseases
HIV/AIDS Section

Brandon Moton, MPH
PrEP Coordinator
Florida Department of Health
Bureau of Communicable Diseases
HIV/AIDS Section
Florida’s Plan to Eliminate HIV Transmission and Reduce HIV-related Deaths

Four Key Components

• Test and rapid access to treatment (Test and Treat)
• **Antiretroviral pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) initiatives**
• Routine HIV and sexually transmitted disease (STD) screening in health care settings/targeted testing in non-health care settings
• Community outreach, engagement, and messaging
Infrastructure, Inventory, and Evaluation

• PrEP Navigators/Coordinators within county health departments (CHDs) and local community-based organizations (CBOs)

• State health office exploring ways to purchase PrEP medications for distribution to CHDs (coverage for uninsured)

• PrEP/nPEP modules added to HIV 500/501 training curriculum

• Statewide PrEP provider inventory and survey
Infrastructure, Inventory, and Evaluation, continued

• Role of Disease Intervention Specialists (DIS) with regard to PrEP

• PrEP Monitoring and Evaluation
  • STD Data System (PRISM) modifications
  • Health Management System (HMS) modifications
  • DH1628 HIV testing data collection form
Infrastructure, Inventory, and Evaluation, *continued*

- Role of CHDs with regard to nPEP
  - Agreements with local pharmacies
  - Coordination with sexual assault nurses, child protection teams, rape crisis centers
  - Collaborations with and education for Emergency Departments (EDs), urgent care clinics, county medical associations, hospital grand rounds
  - AETC exposure risk algorithm distribution and education

- Other staff needed to assist in prevention continuum?
Training and Capacity Building

• PrEP technical assistance and capacity building for health departments and community-based providers
  • New York City and San Francisco Departments of Health, AIDS Education and Training Center (AETC)

• Provider education and detailing
  • HIV/AIDS Medical Director detailing; PrEP/nPEP Toolkits; local PrEP Coordinators
Social Marketing, Media, and Educational Materials

**Available**
- HIV/AIDS Section PrEP/nPEP Toolkits
- Billing Guides (HIV/AIDS Section and NASTAD)
- HIV/AIDS Section PrEP/nPEP referral cards for DIS field services
- Centers for Disease Control and Prevention (CDC) materials

**Under Development**
- Statewide Minority Media Campaign (PrEP/nPEP-specific)
- PrEP/nPEP resources folders
  - Billing one-pagers
  - Pocket cards
  - Exam room posters
  - Patient information tear-off sheets
Social Marketing, Media, and Educational Materials, continued

get PrEPared, and stay protected.

Early, when it comes to HIV detection, that’s what matters most. And if you’re negative, PrEP is just one of many new ways to keep you and your loved ones safe. For good.

Get tested. Know your status. Learn what’s next.

having unprotected sex? it’s time for a PEP talk.

If you’ve had unprotected sex and think you might have been exposed to HIV within the past 72 hours, you need to learn about PEP now. It’s just one of many new options available to keep you safe. For good.

Protect yourself. Know your status. Learn what’s next.

Be part of the movement, spread the word not the virus.

www.KnowYourHIVstatus.com

Be part of the movement, spread the word not the virus.

www.KnowYourHIVstatus.com
Contact Information

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HIV Prevention Program
(850) 245-4336
Alachua County PrEP Program

Gay Koehler-Sides, MPH, CPH
Area 3/13

- 15 counties:
  - Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee and Union

- Program housed in Alachua county
Funding

• Creative budgeting to fund the PrEP clinic
  • Used existing program funds
  • Bill clients who have insurance to help cover the costs for those who do not have insurance

• Make sure everyone is on board including CHD administrator and business manager
Staffing

- MD/ARNP
- Nurse
- Tech/lab staff
- Peers (appointments, prior authorizations)
- Front desk staff
- Billing staff
PrEP Education for All Staff

- April 8, 2016 at DOH - Alachua
- Provided by North Florida AIDS Education and Training Center (AETC)
  - Jennifer Janelle, MD
  - NF AETC Principal Investigator
Pre-Exposure Prophylaxis for Prevention of HIV infection
Clinical guidelines

Key Principles for Prescribing PrEP
The following information is from New York State Department of Health AIDS Institute: Guidance for the use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV transmission. [www.hivguidelines.org](http://www.hivguidelines.org)

- PrEP should not be offered as a sole intervention for HIV prevention. PrEP should only be prescribed as part of a comprehensive prevention plan.
- PrEP may help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive.
- PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available.
- Efficacy of PrEP is dependent on adherence. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.
- Although consistent condom use is a critical part of a prevention plan, lack of use of barrier protection is not a contraindication to PrEP.
- PrEP is contraindicated in individuals with documented HIV infection or creatinine clearance <60 mL/min, and in those who are not ready to adhere to daily PrEP.
- The first prescription of PrEP (Truvada 1 tablet PO daily) should only be for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the patient should then return for 3-month HIV testing and other assessments. After that visit, prescriptions can be given for 90 days, provided that the patient is adherent.
- Patients receiving PrEP require regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.
- For patients who receive a reactive HIV screening test result or for whom acute infection is suspected, initiate fully active ART.

Potential Candidates for PrEP
PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given.
Clinic Officially Opens!

- First patients seen on April 20, 2016!
- 44 clients currently enrolled
- Trying to engage more minorities
HIV Negative?

PrEP Can Help You Stay That Way

PrEP is a new HIV prevention method in which people who don’t have HIV infection take a pill daily to reduce their risk of becoming infected.

NEW!

PrEP Clinic
Florida Department of Health in Alachua County

Call 352-334-7969 for information and appointments
Daily pill decreases HIV-infection risk

By Cleveland Tinker
Special to the Guardian

People at high risk of contracting HIV are encouraged to take advantage of a new program that will drastically reduce their chances of becoming infected with the dreadful virus.

The Pre-Exposure Prophylaxis (PrEP) Clinic at the Alachua County Health Department is designed to prevent people from contracting the virus by taking a Truvada pill once a day.

When taken as prescribed, Truvada has been shown to reduce the risk of HIV infection by up to 92 percent.

April is STD Awareness Month, and Gay Koehler-Sides, health department program manager, said the health department is trying to educate and inform people about how they can protect themselves from contracting STDs.

“The PrEP Clinic can help people keep from becoming infected with HIV,” Koehler-Sides said. “We just opened it late last year, and it is available for people with or without insurance.”

Koehler-Sides said those interested should call the health department at 352-334-7969 for more information or to make an appointment.

“Our STD and HIV programs remind clients to reduce their risk of STDs by using condoms correctly, limiting sexual partners and engaging in routine testing,” Koehler-Sides said.

According to the Florida Department of Health, the number and rate of syphilis cases is higher than it has been in more than 20 years in the U.S. To prevent the spread of all STDs, including syphilis, health departments provide screening, counseling, treatment and partner notification services to people infected or suspected of being infected with STDs.

The FDOH reports that syphilis is on the rise across the country and with almost every ethnic and age groups, and babies born with the disease is also increasing at an alarming rate.

A report found on www.flhealthcharts.com shows there were 28 reported cases of syphilis between 2010-12 and 85 between 2013-15 in Alachua County. Also, the rate of reported syphilis infections in Alachua County was 3.8 between 2010-12, compared with a state of Florida rate of 6.7. From 2013-15, the rate in Alachua County was 11.3, compared to 9.1 for the state.

The only way to avoid getting syphilis and other STDs is to not have sex, according to the FDOH. However, if you are sexually active, you can do the following things to lower your chances of infection:

■ Be in a long-term, monogamous relationship with a partner who has tested negative for syphilis and other STDs.
■ Use condoms the right way.
■ Get tested by your health-care provider for syphilis and other STDs, or locate a clinic near you for free, fast and confidential testing.
■ Get treated right away and be sure your sexual partner is treated as well to reduce the risk of re-infection if you test positive for syphilis or other STDs.

STD Awareness Month provides the opportunity to remind individuals to take control of their health and assist health-care providers in educating their patients,” said Paul Myers, health department administrator.

—Cleveland Tinker is a Gainesville Sun staff writer.
Challenges

• Getting the word out
• Clients with health insurance who don’t want others to find out they are on PrEP, such as college students on their parents’ insurance plan
• PrEP not approved for those under 18 y/o- would need parent/guardian permission
Questions? Comments? Concerns?
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Area 3/13 HIV/AIDS Program Coordinator
Florida Department of Health in Alachua County
352-334-7965
Gay.Koehler-Sides@flhealth.gov
STATEWIDE INITIATIVES: PRE-EXPOSURE PROPHYLAXIS (PREP)

FUTURE BIOMEDICAL INTERVENTIONS AND LATEST RESEARCH

Florida HIV/AIDS Comprehensive Planning Network (FCPN) Meeting
May 17–18, 2017
Kissimmee, FL

Joey Wynn
Community Relations Director / PrEP Coordinator
Empower U Community Health Center
Within the HIV/AIDS research mission of the NIH, what are the 3 most important and/or promising scientific developments in the HIV/AIDS field for NIH funding? Reducing the incidence of HIV/AIDS in fiscal year 2019

Novel technologies and additional combined long-acting biomedical agents for HIV prevention, such as injections, implants and vaginal rings;

ALVAC/gp 120 protein vaccines for HIV prevention in all high risk populations;

Emerging behavioral, social science and implementation research that promotes PrEP initiation, adherence, and successful prevention of infection,

STI testing, acceptance of and linkage to care and adherence to biomedical prevention.
Over the next three to five years (fiscal years 2019 – 2023)

Novel technologies that allow for **extended release** of antiretroviral drug products emerging as significant scientific advances in the field of biomedical HIV prevention domestically and globally. Technologies include **insertable vaginal rings, vaginal and rectal tablets, nanofibers, and implantable devices**. (The NIH has the opportunity to conduct or support research and development of technologies that are capable of administering highly effective antiretrovirals, like tenofovir disoproxil fumarate, for biomedical prevention for licensing of technologies to non-profit entities that will effectively circumvent market exclusivity protections, thereby greatly increasing access and deceasing HIV incidence.)

**Nanosuspensions** and related formulations that allow for long-acting antiretroviral efficacy that demonstrate the potential for significant uptake and effectiveness in key vulnerable populations. (The NIH has the opportunity to conduct or support research and development of nanoformulations of poorly soluble antiretrovirals for biomedical prevention that will effectively circumvent market exclusivity protections, thereby greatly increasing access and deceasing HIV incidence.)
BIOMEDICAL INTERVENTIONS = PREP  
BUT PREP DOES NOT EQUAL TRUVADA

ARV-Based Prevention Pipeline

The pipeline of ARV-based prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable ARVs. Not pictured are a range of multipurpose technologies in development that aim to reduce women's risk of HIV and STIs, and provide effective contraception.

For up-to-date information on the ARV-based prevention pipeline, visit the HIV Prevention Research Database at www.avac.org/pard.
An Advocate’s Guide to Research Terms in the Post-Placebo Era

HIV Prevention Trial Lexicon

- **Active arm (of a trial)** is the group of participants receiving a proven or experimental strategy. There can be one or more active arms in a trial. There can be an “active control” arm (see below) or an “active experimental arm.” This difference is whether the efficacy of the active strategy is known or not. Outcomes (like rates of HIV or rates of pregnancy) in people in the experimental active arm are compared to outcomes in people in the control arm.

- **Active control arm (of a trial)** is usually a group of trial participants who are receiving a known effective strategy or intervention that participants in the experimental arm are not receiving. For example, in trials of long-acting injectable PrEP, in people in the active control arm are receiving daily oral PrEP, a known effective strategy.

- **Blinded trials** are ones in which the participants don’t know what they are receiving. A double-blinded trial is one in which neither the participants nor the trial team know which participants are receiving the experimental product and which ones are receiving something else—either a placebo or another product. Blinding protects against bias. If participants or trial staff know who is getting the active experimental product they might act differently. Participants who know they got the experimental product might take more risks if they believe the experimental product protects them. This might lead the placebo group to use more condoms.

- **Control arm (of a trial)** is the group of participants that are not receiving the experimental product or strategy. This group receives the same prevention package (see below) as the experimental arm.

- **Double-dummy double-blind trials** are a way to compare two strategies that can’t be made to look identical, without revealing who’s receiving what. Imagine a trial seeking to compare an injection and a pill. They don’t look alike, right? In a double-dummy double-blind trial design, all of the participants would get both a pill and an injection. One group of participants would get an active pill and a dummy injection, the others would get an active injection and a dummy pill. Neither the staff nor the participants would know who had which active strategy.

- **Dummies** are the same thing as placebo. A dummy version of an experimental product looks exactly like that product (e.g., vaccine, injection, infusion, pill or ring) except that it doesn’t have any active ingredient. Examples include a sugar pill or a saline injection or a ring without any drug inside it.

- **Non-inferiority trials** are trials that are designed to show that a new method (Product A) works as well as a method that has previously been shown to work (Product B). If it doesn’t meet or exceed B’s effectiveness, it is considered inferior. This doesn’t mean it isn’t effective, just that it is not better than the existing product.

- **Open-label (trial)** is a trial in which both participants and trial staff know who is receiving what. Trials of voluntary medical male circumcision were open-label in that trial. Staff and participants knew who had undergone the procedure immediately and who had been assigned to the delayed surgery arm.

- **Open-label extension (OLE) trial** is a study that usually follows directly from an efficacy trial that showed the product was successful in reducing HIV risk. In OLEs, trial participants from both the active and placebo arm and, sometimes, members of their communities, get the chance to use the active product. Everyone knows who they are receiving and that the product worked in the efficacy trial.

- **Placebo** is a group of people in whom the prevention package (see below) is used, but they do not receive the active product. Why? Because some prevention methods (e.g., HIV testing and treatment) may provide other services (like harm reduction, referrals for voluntary medical male circumcision, PrEP, etc.)

- **Placebo-controlled trials** are trials that are designed to show that a method (Product A) is more effective than placebo, or sometimes, to show that a new method (product A) is more effective than an already-existing method (Product B). A superiority trial is designed to find out whether product A is more effective than placebo or (Product B) in enrolled participants, and the trial makes every effort to ensure the products are used correctly and consistently.

PaWine: A Quarterly Update on HIV Prevention Research | Volume 10 | No. 2 | April–June 2017
2016-17: A Percolating Pipeline — While scaling up access to all treatment and prevention options that currently exist is essential, it is not sufficient. There remains a critical need for additional options. In addition to the introduction of oral TDF-based PrEP and the open-label extension studies of the vaginal dapivirine ring, there are a number of efficacy trials planned or underway (noted below). They’re tackling virtually every intervention — from next-generation PrEP in the form of F/TAF, a drug that will soon be tested for efficacy as daily oral PrEP, to long-acting injectables, vaccines and antibody-mediated prevention.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Trial</th>
<th>Product</th>
<th>Number participants</th>
<th>Population</th>
<th>Status start–end</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody</td>
<td>HVN 704/</td>
<td>VRC01 antibody, infused every two months</td>
<td>2,700</td>
<td>Men and transgender persons who have sex with men</td>
<td>Enrolling Apr 2016–Sept 2020</td>
<td>Brazil, Peru, US</td>
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<tr>
<td></td>
<td>HPTN 085</td>
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<tr>
<td>Antibody</td>
<td>HVN 703/</td>
<td>ALVAC/gp120 MF59 adenoviral vector vaccine,</td>
<td>1,500</td>
<td>Sexually active women</td>
<td>Enrolling May 2016–Jul 2020</td>
<td>Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe</td>
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<tr>
<td>Preventive HIV vaccine</td>
<td>HPTN 702</td>
<td>low-dose adjuvant boost, five doses over 12 months</td>
<td>5,400</td>
<td>Sexually active heterosexual women and men</td>
<td>Planned Nov 2016–End 2020</td>
<td>South Africa</td>
</tr>
<tr>
<td>Long-acting injectable</td>
<td>HPTN 083</td>
<td>Cabotegravir injections every two months</td>
<td>4,500</td>
<td>Men and transgender persons who have sex with men</td>
<td>Planned Q4 2016–June 2020</td>
<td>~40 sites in North and South America, South Africa and Asia</td>
</tr>
<tr>
<td>Oral PrEP</td>
<td>Discover</td>
<td>Daily F/TAF</td>
<td>5,000</td>
<td>Men and transgender women who have sex with men</td>
<td>Planned Q4 2016–End 2020</td>
<td>Over 90 sites in Canada, Europe and the US</td>
</tr>
<tr>
<td>Long-acting injectable</td>
<td>HPTN 084</td>
<td>Cabotegravir injections; schedule to be</td>
<td>TBD</td>
<td>Sexually active women</td>
<td>Potential start in 2017</td>
<td>Southern and East African countries TBD</td>
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<tr>
<td></td>
<td></td>
<td>confirmed, either every two or three months</td>
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<tr>
<td>Preventive HIV vaccine</td>
<td>TBD</td>
<td>Ad26/MVA boost</td>
<td>TBD</td>
<td>TBD</td>
<td>Potential start in 2017</td>
<td>US, Latin American, Southern and East African countries TBD</td>
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In a patient survey, participants reported higher rates of satisfaction with injections compared to oral drugs and higher preference for continuing with current combination.

Even with the potential obstacles and disadvantages of intramuscular injections with very long half-lives, the option to not take daily pills has always been seen as exciting by many people – even now once-daily single pill formulations are available.
FTC/TAF PREP PROTECTS MACAQUES FROM RECTAL SHIV INFECTION

- FTC/TAF prevents rectal SHIV infection in macaques to a degree similar to that previously found with FTC/TDF but with a substantially reduced TFV dose\(^1\)
  - FTC/TAF protected 100% of macaques (N=6) challenged with SHIV in a similar, pre-clinical trial\(^2\)

**FTC/TAF should not** be used for PrEP in humans until a planned clinical study is completed

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Outcome</th>
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| **Dapivirine**<sup>1</sup>  
Vaginal ring  
*Phase 3 (MTN020 Aspire)* | - 27% reduction in HIV acquisition risk  
- Efficacy correlated with age (0% protection below age 21; 56% age 21-26) |
| **Dapivirine**<sup>2</sup>  
Vaginal ring  
*Phase 3 (Ring Study)* | - 31% reduction in HIV acquisition risk  
- Good adherence results in further reduction in HIV acquisition risk |
| **TFV**<sup>3</sup>  
Rectal gel  
*Phase 2 (MTN017)* | - Use of the gel in pre- and post-receptive anal sex (RAI) preferred over daily use and resulted in better adherence  
- Adherence to RAI schedule was similar to adherence in oral FTC/TDF arm |
| **TFV**<sup>4</sup>  
Vaginal film  
*Phase 1* | - Well tolerated  
- Decreased HIV p24 antigen expression in explants |

1. BAETEN J, ET AL. CROI 2016. BOSTON, MA. #109LB  
2. NEL A, ET AL. CROI 2016. BOSTON, MA. #110LB  
3. CRANSTON R, ET AL. CROI 2016. BOSTON, MA. #108LB  
4. BUNGE K, ET AL. CROI 2016. BOSTON, MA. #871
# HIV PREP RESEARCH PIPELINE: CANDIDATES FOR SYSTEMIC DELIVERY

<table>
<thead>
<tr>
<th>Medication</th>
<th>Outcome</th>
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</table>
| Maraviroc$^5$ Oral Phase 2 (HPTN069) | ▪ AEs similar among 4 arms  
▪ 5 sero-conversions:  
  --1 in MVC+TDF arm (no drug at seroconversion)  
  --4 in MVC arm (1 with higher than expected steady-state MVC level) |
| TAF$^6$ Biodegradable implant (Preclinical) | ▪ Thin-film polycaprolactone delivery device releases drug over 3 months  
▪ Stable release rate moderated by size and film thickness |

CABOTEGRAVIR IS LONG ACTING, FORMULATED AS A 200 MG/ML NANO-SUSPENSION
**PHARMACOKINETIC EVALUATION OF A SINGLE INTRAMUSCULAR GSK744 LA INJECTION IN HUMAN VOLUNTEERS (CABOTERGRAVIR)**

- **Other Names:** 744 LA, CAB, GSK-1265744, GSK1265744, GSK744, GSK744 LA, GSK744 LAP, S-265744, S/GSK1265744, cabotegravir LA, cabotegravir sodium
- **Drug Class:** Integrase Inhibitors
- **Molecular Formula:** C19 H17 F2 N3 O5
- **Registry Number:** 1051375-10-0 (CAS)
- **Chemical Name:** (3S,11aR)-N-((2,4-difluorophenyl)methyl)-6-hydroxy-3-methyl-5,7-dioxo-2,3,5,7,11,11a-hexahydrooxazolo(3,2-a)pyrido(1,2-d)pyrazine-8-carboxamide
- **Company:** ViiV Healthcare
- **Phase of Development:** Cabotegravir is in Phase IIb development for HIV treatment and Phase IIb/III development for HIV prevention.

*Andrews et al. CROI 2014; Boston, MA. Abstract 39.*
A huge Phase III trial of a long-acting injectable form of the experimental antiretroviral cabotegravir for use as PrEP against HIV has begun.

The randomized, double-blind HPTN 083 trial will enroll 4,500 HIV-negative transgender women and cisgender men who have sex with men. The trial, to be conducted at 45 sites in eight countries in the Americas, Asia and Africa, will determine whether long-acting cabotegravir injected every eight weeks protects against HIV as well as daily oral Truvada among the high-risk participants.

Members will be randomly assigned to receive one drug or the other and will remain in the trial for an average of four and a half years. Results are expected in 2021.

Another study, HPTN 084, will test the safety and efficacy of long-acting injectable cabotegravir as PrEP among young women in sub-Saharan Africa starting this year.

(Poz Magazine April 3rd, 2017)
## The Years Ahead in Biomedical HIV Prevention Research

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<thead>
<tr>
<th>Efficacy Trial</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
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<tr>
<td><strong>Vaginal Ring</strong></td>
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<td>Dapivirine Ring</td>
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<td>HOPE (MTN 025)</td>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 2,500 women in Malawi, South Africa, Uganda, Zimbabwe</td>
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<td>DREAM (IPM 032)</td>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 1,400 women in South Africa and Uganda</td>
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<td><strong>Antibody</strong></td>
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<td>VRC01</td>
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<tr>
<td>AMP (HVTN 704/ HPTN 085)</td>
<td>Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 2,700 MSM and transgender persons in Brazil, Peru, Switzerland and US</td>
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<tr>
<td>AMP (HVTN 703/ HPTN 081)</td>
<td>Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 1,500 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe</td>
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<td><strong>Oral PrEP</strong></td>
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<td>F/TAF (Descovy)</td>
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<td>DISCOVER</td>
<td>Randomized controlled trial of once-daily F/TAF as PrEP; ongoing in 5,000 MSM and transgender women at approximately 90 sites in Europe and the Americas</td>
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<td><strong>Long-acting Injectable</strong></td>
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<td>Cabotegravir</td>
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<tr>
<td>HPTN 065</td>
<td>Randomized controlled trial of injectable cabotegravir every two months; ongoing in 4,500 MSM and transgender persons in Argentina, Brazil, India, Peru, South Africa, Thailand, US, Vietnam</td>
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<tr>
<td>HPTN 084</td>
<td>Randomized unblinded trial of injectable cabotegravir every two months; planned for women in Southern and East African countries</td>
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<td><strong>Preventive HIV Vaccine</strong></td>
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<td>ALVAC/gp120 w/MF59</td>
<td>Randomized controlled trial of ALVAC/gp120 prime-boost with MF59 adjuvant, five doses over 12 months; ongoing in 3,400 men and women in South Africa</td>
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<td>HVTN 702</td>
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<td>Ad26/MVA boost</td>
<td>Randomized controlled trial of Ad26 prime and MVA boost, planned for men and women in the Americas and Southern and East Africa</td>
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<td>HVTN 705/HIPX2008</td>
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*Pr* *W* *E* *H* *I* *V* *P* *R* *E* *A* *C* *H*. A Quarterly Update on HIV Prevention Research | Volume 10 | Issue 1 | January-March 2017
QUESTIONS????

I can be reached at:

JWynn@Empower-U-Miami.org or
WonkaBear@aol.com
Preparation for Detailing:

- Surveillance Data
  - Prioritization of zip-codes
  - Campaigns (private physicians, academic institutions, when to follow-up)

- Make No Assumptions
  - Purview paradox (from data through billing/coding)
- Provider Surveys
  - Measuring: Attitudes, Beliefs, Readiness
- Toolkits
- Educational Material (leverage BRTA)
- Drop-ins versus appointments/follow-ups
- Staff in-services (lunch & learns)
Limitations/Lessons Learned

- Staff (need for training throughout)
- HIV Docs/agencies primary providers (increase reach into other specialties)
- Myths (use of surveillance data)
- Infectious Disease Group in Hollywood, FL (egregious breach of Hippocratic Oath)
- Results: 19 recruited out of 78 detailed
PrEP Navigation

• Program Collaboration and Service Integration (PCSI)
  – STD Department Referrals
  – Broward Wellness Center
  – Prevention Training Consultants and Outreach

• Continuum
Broward nPEP Continuum

1. **PEP Eligibility**
2. **HIV Testing**
3. **PEP Medication Prescription**
4. **PEP Navigation Referral**
5. **PEP Medication Started**
6. **PrEP Medication Completed**
7. **PEP Follow-up (Clinical Services)**

*Individuals testing HIV negative at PEP Follow-up will be considered for PrEP eligibility. If deemed eligible, individual will continue through PrEP Continuum.
HIV Testing
nPEP Medication
Follow-up Services
PrEP Assessment
Referrals to Services
Tracking of Clients Referred to nPEP Services
HIV Testing
nPEP Medication
Follow-up Services
PrEP Assessment
Referrals to Services
PrEP Navigation Cont’d

- Navigator Training
- Monitoring and Evaluation
  - Over 13 indicators
- Limitations/Lessons Learned
  - 3 Types of Clients
    - Insured, Uninsured, Undocumented
That’s all folks!

THANKS FOR PAYING ATTENTION

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