Treatment and Prevention Updates

FDA Approves Stribild, the Once-Daily “Quad” Pill

People starting HIV treatment for the first time have a new simplified treatment option: On August 27, the U.S. Food and Drug Administration (FDA) approved Gilead Sciences’ combination pill Stribild, formerly known as the “Quad” pill.

Like Atripla and Complera, Stribild is a complete HIV treatment regimen in a single pill taken once daily. It combines the new integrase inhibitor elvitegravir and the “boosting” agent cobicistat with the HIV meds tenofovir and emtricitabine (the drugs already combined in Truvada).

The new combination pill comes with safety warnings about buildup of lactic acid in the blood, as well as kidney and liver complications experienced by some tenofovir users. People coinfected with hepatitis B virus are advised not to use Stribild.

Gilead is reportedly working out discounts for AIDS Drug Assistance Programs (ADAPs) to help people access the new combination pill, which costs more than $28,000 yearly. The company’s patient assistance program also helps people pay for the drug; call 1-800-226-2056, 9 a.m.–8 p.m. EST, for information.

Truvada Approved as PrEP to Prevent HIV Infection

The FDA on July 16 approved the antiretroviral drug Truvada to be taken by HIV-negative people to prevent HIV infection—a strategy known as pre-exposure prophylaxis, or PrEP.

In clinical trials of PrEP to date, the drug was linked with up to 92% lower HIV infection risk when taken as directed and as part of a comprehensive HIV-prevention package that included condoms, safer sex counseling, and HIV testing.

With an estimated 50,000 people newly infected with HIV every year nationwide, safe and effective new HIV prevention approaches are vital to ending the epidemic. Studies of PrEP are ongoing, and demonstration projects in U.S. cities hope to illuminate how best to use this new HIV prevention tool in the “real world,” outside of controlled clinical trials.

Research Update

AIDS 2012: Closing in on a Cure

Promising findings in the search for a cure were announced at the 19th International AIDS conference (nicknamed “AIDS 2012”), held last July in Washington, DC.

Researchers reported on two HIV-positive men who underwent chemotherapy and bone marrow stem cell transplants as treatment for lymphoma (a type of cancer), in a procedure similar to the one that appears to have cured another man, “Berlin Patient” Timothy Brown. The donor cells replaced the men’s HIV-infected immune system cells, and sensitive tests have found no traces of the virus in their blood or CD4 cells up to three and a half years later. Levels of antibodies to HIV also continue to drop, as would be expected with fewer copies of the virus in the body.

Scientists also described using the chemotherapy drug vorinostat to reach “reservoirs” of hidden HIV, a major obstacle to a cure. Eight people took one dose of vorinostat in addition to their HIV meds; blood tests showed that signs of hidden virus increased, suggesting this drug can “force the virus out into the open” where it can be targeted by antiretroviral drugs and other therapies.

A third study led researchers to suggest that very early antiretroviral treatment might create a “functional cure,” in which the virus is not eradicated entirely but the body keeps HIV in check without medications. Fourteen people in France started treatment very soon after becoming infected (most within 40 days), took HIV meds for about three years, and are now off treatment and healthy. The researchers propose that very early treatment altered the individuals’ viral reservoirs, resulting in far less virus present in the body even after treatment was stopped.

In a July 26 press conference, leading cure researcher Steven Deeks of the University of California, San Francisco, said these studies “provide reason for enthusiasm that ultimately we’re going to get to where we need to go, which is a way to cure people with HIV infection.”
Clinical Research Opportunities

Studies are listed with brief descriptions only; additional inclusion and exclusion criteria may apply. For more information, please contact the study site directly.

East Bay AIDS Center (EBAC)
3100 Summit Street, 2nd Floor
Oakland, CA 94609
510-869-8490
http://altabates.com/clinical/aids_scvs.html

- GS-US-236-0112: A Phase 2/3, open-label study of the safety, antiviral activity, and pharmacokinetics (how the body processes drugs) of the elvitegravir/cobicistat/emtricitabine/tenofovir single-tablet regimen in HIV-infected adolescents. Must have had no prior ART. Compensation is $50 per visit. NS

Kaiser Permanente Clinical Trials Unit
4141 Geary Boulevard, Suite 219
San Francisco, CA 94118
415-833-3487

- GS-US-334-0123: A Phase 3, open-label study to investigate the efficacy and safety of GS-7977 plus ribavirin for 12 weeks in people with both HIV and chronic genotype-1, 2, and 3 hepatitis C virus (HCV). NS

- GS-US-236-0115: A study to evaluate switching from a ritonavir-boosted PI plus tenofovir/emtricitabine to single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir in people with well-controlled HIV. NS

- GS-US-236-0121: A study to evaluate switching from an NNRTI plus tenofovir/emtricitabine to the single-tablet regimen elvitegravir/cobicistat/emtricitabine/tenofovir in people with well-controlled HIV. NS

Kaiser Permanente Department of Infectious Diseases
27400 Hesperian Boulevard
Hayward, CA 94545
510-784-6499

- GS-US-236-0115: A study to evaluate switching from a ritonavir-boosted PI plus tenofovir/emtricitabine to single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir in adults with well-controlled HIV. NS

- GS-US-236-0121: A study to evaluate switching from an NNRTI plus tenofovir/emtricitabine to single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir in adults with well-controlled HIV. NS

Metropolis Medical Group
815 Hyde Street, Suite 301
San Francisco, CA 94109
415-292-5477 ext. 487
http://metropolismedical.net

All studies provide free labwork, study drugs, and compensation between $500 and $750.

- MK-1439: A study comparing once-daily MK-1439 (an investigational integrase inhibitor) plus Truvada vs. efavirenz plus Truvada. Must have had no prior ART. NS

- BMS A1467003: A Phase 2b trial to investigate BMS-986001 (an investigational NRTI) plus efavirenz/tenofovir vs. tenofovir/emtricitabine, all once daily. Must have had no prior ART. NS

- BMS A1442493: Participants with detectable viral load on their first regimen will receive either atazanavir/ritonavir or darunavir/ritonavir plus an optimized NRTI backbone. Must have detectable HIV on first-time therapy with an NNRTI or integrase inhibitor. NS

- BMS A1442494: A study to compare the efficacy of atazanavir/ritonavir/ lamivudine vs. atazanavir/ritonavir/ tenofovir/emtricitabine. Must have had no prior ART. NS

- HIV Vaccine trial (SAV): A Phase 1, randomized, observer-blinded, placebo-controlled clinical study to assess the safety and tolerability of a killed-whole-HIV vaccine (SAV001-H) administered intramuscularly. Must have chronic HIV infection and be on ART. NS

- Gilead 118: A 96-week study of the safety of the single-tablet Quad formulation (elvitegravir/cobicistat/emtricitabine/tenofovir). Must have borderline kidney function (GFR 50–75) and have had no prior ART.

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Quest Clinical Research
2300 Sutter Street, Suite 202
San Francisco, CA 94115
415-353-0800

- A double-blind study of a once-daily CCR5 inhibitor drug (TBR-652) or once-daily efavirenz, each with Truvada. Must have had no prior ART and have a CD4 count >250 cells/mm³ and a viral load >1,000 copies/mL. Compensation is $50 per visit and $300 if selected to undergo a single-day pharmacokinetic analysis (to understand how the body processes the drugs).

ABBREVIATIONS

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<thead>
<tr>
<th>BRAND NAME</th>
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<tr>
<td>atazanavir</td>
<td>Protease Inhibitors (PIs)</td>
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<td>darunavir</td>
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<td>Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)</td>
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<td>emtricitabine (FTC)</td>
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<td>Other Classes</td>
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<td>enfuvirtide (T-20)</td>
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<td>maraviroc</td>
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<td>raltegravir</td>
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Fixed-Dose Combinations

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<thead>
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<tr>
<td>elvitegravir/cobicistat/emtricitabine/tenofovir</td>
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<td>lamivudine/abacavir</td>
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<td>tenofovir/emtricitabine</td>
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<td>tenofovir/emtricitabine/ rilpivirine</td>
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<td>zidovudine/lamivudine</td>
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<tr>
<td>zidovudine/lamivudine/ abacavir</td>
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http://questclinical.com
• A trial to investigate the safety, efficacy, and dose response of an investigational attachment inhibitor drug (BMS-663068), followed by an open-label period of taking a recommended dose. Must be HIV positive and have used ARVs before, with a CD4 count >50 cells/mm³ and viral load >1,000 copies/mL. Compensation is $50 per visit and $500 for each pharmacokinetic analysis performed (for participants who qualify).

• “Zinc finger nuclease” (ZFN) study: CD4 cells are extracted from participants’ blood and genetically modified by ZFNs to resist HIV infection. More modified cells are then made and re-infused back into participants. Researchers hope these genetically modified cells will make more HIV-resistant CD4 cells in the body. Must have a viral load >1,000 copies/mL. Must have had no prior ART and have a current CD4 count >500 cells/mm³ or have experienced ART “failure” and have a current CD4 count >250 cells/mm³.

San Francisco Department of Public Health AIDS Office
25 Van Ness, Suite 500
San Francisco, CA 94102

• HPTN 069: A Phase 2, randomized, double-blind study testing the safety and tolerability of the anti-HIV medications maraviroc, emtricitabine, and tenofovir for use as pre-exposure prophylaxis (PrEP). Behavioral risk and adherence to study drugs will also be assessed. Must be HIV negative, male or transgender female, and have sex with men. Compensation is $50 per study visit. 415-437-7485, http://www.JoinPrep.org.

• HVTN 505: A double-blind, Phase 2 trial evaluating the safety and efficacy of a preventative HIV vaccine in HIV-negative individuals. A prime-boost regimen aims to protect against HIV infection, or significantly reduce viral load in individuals who become infected. No live or attenuated (weakened) HIV is used in the vaccine. Must be HIV negative, age 18–50, male or transgender female, circumcised, and have sex with men. Compensation is $50–$75 per visit. 415-437-7485, www.SFisReady.org.

• Phase I Vaccine Studies: Phase 1 trials evaluating the safety and dosage regimens of HIV vaccines in HIV-negative individuals. No live or attenuated (weakened) HIV is used in the vaccines. Must be HIV negative, healthy, and age 18–50. May be male, female, or transgender. Compensation is $50–$75 for study visits. 415-437-7485, www.SFisReady.org.

• TREx: A study testing whether a monthly injectable medication (naltrexone) reduces methamphetamine use among men who have sex with men. Study includes weekly substance-use counseling. Compensation is $10–$50 per visit. 415-554-9013, http://trexsf.com.

• ACTG 5294: A study adding boceprevir to standard HCV treatment for HIV/HCV coinfected adults. May have had prior HCV treatment or be new to HCV treatment. Must have had a liver biopsy within the last two years or confirmed cirrhosis. Must have a CD4 count >200 cells/mm³ and be on stable ART for more than eight weeks before study start, or not currently on ART.

• ACTG 5298: A study to determine if the human papillomavirus (HPV) vaccine, Gardasil, prevents anal HPV infection in HIV-positive men who have sex with men. Participants will be followed for three to four years and will undergo anal HPV testing along with high-resolution anoscopy. Must be over the age of 27 years.

• Gilead 236-0115: A study for people with undetectable viral load who want to switch from a ritonavir-boosted PI and tenofovir/emtricitabine to the once-a-day, four-in-one Quad pill (elvitegravir/cobicistat/tenofovir/emtricitabine).

• Vertex VX11-950: A hepatitis C virus (HCV) treatment study for those with both HIV and genotype-1 HCV infection. Must be on stable ART with either efavirenz, raltegravir, or atazanavir and have undetectable viral load. Treatment consists of telaprevir/pegylated interferon and ribavirin.

• A5303: A study evaluating a standard HIV medication combination compared with an experimental combination containing maraviroc. Must have a viral load ≤200 cells/mm³; may be male or female. Must not have used a systemic antifungal in the past 60 days. Study takes 90 minutes. Compensation is $20. 415-353-2463, option #2.

Stanford AIDS Clinical Trials Unit
1000 Welch Road, Suite 202
Palo Alto, CA 94304
415-723-2804
http://actu.stanford.edu/

Compensation is provided for travel and meals for most studies.

• ACTG 5292: A study of the prevention of human papilloma virus (HPV) in saliva after ART initiation and the association of oral sex practices and any changes in the presence of oral warts. Must have had no prior ART. Compensation is $20 per study visit (except screening visit). 415-353-2463, option #1.

• PiHDL levels in African-American men age 50 and older: A study to compare PiHDL serum levels in older African-American men with and without HIV. Must be African-American, male, and 50 or older; may be HIV positive or negative. Must not be using a lipid-lowering agent. If HIV positive, viral load must be undetectable. Study takes 75 minutes. Compensation is $35.

• OHARA ACTG 5254: A study to assess the accuracy of clinical diagnoses of HIV-related mouth diseases made by clinical researchers compared with those made by oral-medicine-trained dentists, describe the relationship between HIV viral load in blood and HIV viral load in saliva, and assess the relationship between Candida levels in the mouth and clinical diagnosis of oral candidiasis. Must be 18 or older and HIV positive with a CD4 count ≥200 cells/mm³; may be male or female. Must not have used a systemic antifungal in the past 60 days. Study takes 90 minutes. Compensation is $20. 415-353-2463, option #2.

UCSF/Adult AIDS Clinical Trials Unit
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
650-723-2804
http://php.ucsf.edu/rsrch_trials.shtml

All studies provide compensation.

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HIV

- A5254: A study evaluating the ability of trained staff to conduct an effective oral exam. For individuals with <200 CD4 cells/mm³.

- A5275: A study to see whether the cholesterol-lowering drug atorvastatin can reduce inflammation in HIV-positive individuals who have an undetectable viral load and normal LDL cholesterol levels and are on a boosted-PI-containing ARV regimen.

UCSF/San Francisco General Hospital
1001 Potrero Avenue, Ward 4C
San Francisco, CA 94110

- ACE Inhibitor Study: A randomized, controlled study assessing the effect of adding the blood pressure medicine lisinopril to current ART for 24 weeks in participants with an undetectable viral load. The study will assess whether lisinopril decreases fibrosis in the gut, improves immune function, and decreases the size of the viral reservoir. Compensation provided. 415-476-4082, ext. 341.

- SCOPE Study: An observational study recruiting: (1) “elite controllers” (HIV positive with viral load <2,000 copies/mL and not taking ARVs), (2) antiretroviral-naive individuals (those with no prior ART), (3) long-term non-progressors (HIV positive for more than ten years and with a CD4 count >500 cells/mm³ without taking ARV drugs), and (4) HIV-negative “control” participants. Study involves an interview and blood draw every two to four months. Compensation is provided. 415-476-4082, ext. 155 or 139.

- Mesalamine Study: A randomized, controlled trial adding the anti-inflammatory drug mesalamine to current ART in people with a low CD4 cell count despite undetectable viral load. Study will assess whether decreasing inflammation in the gut improves immune function. Compensation is provided. 415-476-4082, ext. 104 or 139.

Other UCSF Studies

- IRISS Study: A study exploring ways to help people cope with a new HIV diagnosis. Includes nine interviews over a year and a half. Must speak English or Spanish and have been recently diagnosed with HIV. Sites in San Francisco and Oakland. Compensation is $20–$50 per visit. 415-353-4299.

- A study looking at cerebrospinal fluid (fluid surrounding the brain and spinal cord) in HIV-positive individuals. Must be on stable, standard ART for ≥2 years with documented undetectable viral load for the past year. Participants will undergo a blood draw, spinal tap, and neuropsychological testing every four months for one year. 415-206-4328.

- Another study evaluating the contents of and changes in cerebrospinal fluid related to HIV infection. Must have had no prior ART or be off ART for at least one year, with a CD4 count <400 cells/mm³. Must be about to start ART under the supervision of a physician. Study includes spinal taps, blood draws, and neuropsychological testing over a one-year period. 415-206-4328.

- OPTIONS Project: A study for individuals recently exposed to HIV and experiencing acute retroviral syndrome (e.g., flu-like symptoms), those who became infected with HIV within the past six months, and those who are HIV negative and having unprotected sex with men. Compensation and counseling are provided. 415-502-8100, www.ucsf.edu/options

- HIV Negatives Study: A study examining how some men can be exposed to HIV yet not become infected with the virus. For men who have unprotected sex with men and are currently HIV negative or untested. Compensation and counseling are provided. 415-502-8100, http://labs.ucsf.edu/options/negstudy.html.

- A blood-draw study to find the CD8 cell anti-HIV factor (CAF) that naturally protects HIV-infected people from disease. Must not be on ART or must have been on ART less than one year. 415-476-4071.

- The DUO Project seeks gay male couples for interviews about HIV-related issues. One or both partners must be on ART. Compensation up to $120 per couple. 877-386-6292 or 415-597-9322.

- A study of the interaction of alcohol and ARVs, for people about to start or restart HIV medications. Compensation up to $575. 415-206-3364.

REAL TALK FORUM SERIES

San Francisco AIDS Foundation and STOP AIDS Project are excited to announce the second event in our new Real Talk public forum series. The goal of this series is to host timely, interactive dialogs and exchange knowledge and resources around topics at the forefront of discussions in our community.

Our next Real Talk forum will focus on sexual decision-making. Gay or straight, single or married, poz or not—there have been times when most of us have had sex without a condom. Let’s talk about it.

Why do you f**k without condoms? What informs your decisions? Are you confident you’re protecting your health?

Join us for a free community forum to explore serosorting—making choices about sex and risk based on HIV status. Share your stories and your strategies, hear from other members of our community, and learn risk-reduction approaches to help keep you and your partners safer.

September 12, 6:00–8:00 p.m.
San Francisco LGBT Community Center
1800 Market Street, San Francisco

Can’t make it to the forum? Keep an eye out for a written summary, available soon after the event at www.betablog.org.