Research Update

HIV Vaccine Trial Halted

An HIV vaccine trial underway in 19 U.S. cities halted immunizations in late April after a review revealed that the shots neither prevented HIV infection nor lowered HIV viral load in those who became infected.

HVTN 505 was designed to evaluate whether a series of injections with two different vaccines was safe and worked against HIV. The series was meant to “prime” the immune system to produce antibodies (molecules that help the body identify viruses and other invaders) against HIV and also “boost” the immune system’s response.

The study had enrolled 2,504 HIV-negative volunteers. Participants in the HVTN 505 trial will continue to be monitored but will not receive further injections.

Pharmaceutical Update

Approval of Elvitegravir and Cobicistat on Hold

Gilead Sciences announced April 29 that the U.S. Food and Drug Administration (FDA) has denied—at least for now—their application to market the HIV drugs elvitegravir and cobicistat as individual medications. Both drugs are part of the single-pill, once-daily Stribild regimen (also known as the “Quad” pill), which the FDA approved in August 2012.

“[The] FDA states that it cannot approve the applications in their current forms,” explained a Gilead press release. “The letters state that during recent inspections, deficiencies in documentation and validation of certain quality testing procedures and methods were observed.”

The company is working with the FDA to address these issues and move the New Drug Applications forward. In the meantime, “[t]his regulatory action does not affect the marketing authorization or continued use of Stribild,” the press release emphasizes.

Health Care Reform Update

Covered California Reveals Insurance Plans and Premiums

This October, people whose HIV counted as a “pre-existing condition” and excluded them from health insurance will be able to enroll in health care plans through the new insurance marketplaces (formerly known as “exchanges”) created in each state under the Affordable Care Act.

Covered California, the state’s health insurance marketplace, announced May 23 the selection of 13 health plans that will be available to residents, including tens of thousands who are living with HIV. The selected plans, which must be approved by state regulators, include Alameda Alliance for Health, Anthem Blue Cross of California, Blue Shield of California, Chinese Community Health Plan, Contra Costa Health Plan, Health Net, Kaiser Permanente, L.A. Care Health Plan, Molina Healthcare, Sharp Health Plan, Valley Health Plan, Ventura County Health Care Plan, and Western Health Advantage.

Under these plans, the average premium (the amount individuals must pay for health insurance) is roughly $300 per month. “Although that premium does represent a significant monthly cost for many people, it’s actually lower than advocates had feared,” observed Courtney Mulhern-Pearson, state and local affairs director for San Francisco AIDS Foundation.

In addition, Mulhern-Pearson explained, individuals with incomes below 400% of the federal poverty limit (approximately $45,000 per year) will be eligible for subsidies to help make these plans more affordable. And as indicated in the May 2013 revised budget for California, the State Office of AIDS is working to create a payment program that would cover insurance premiums and HIV drug co-pays for people who qualify.

“This will mark the first time many people living with HIV, in California and beyond, have been able to purchase private insurance,” added Mulhern-Pearson. To learn more, visit www.CoveredCA.com.
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
www.altabates.com/clinical/aids_scvs.html

- GS-US-292-0102: A phase 2, randomized, double-blind study of the safety and efficacy of the elvitegravir/cobicistat/emtricitabine/tenofovir single-tablet regimen compared with the elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate single-tablet regimen in HIV-positive, treatment-naïve adults. Must be 18 years or older and have had no prior ART. Compensation is $35 per study visit. **NS**

- 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 study visit.

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

- GS-US-292-0104: A phase 3, placebo-controlled study to evaluate the safety and efficacy of single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide vs. single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate in HIV-positive adults. Must have had no prior ART.

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

- GS-US-292-0104: A phase 3, placebo-controlled study to evaluate the safety and efficacy of single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide vs. single-tablet elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate in HIV-positive adults. Must have had no prior ART.

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

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

- GS-US-292-0109: A phase 3, open-label switch study of the safety, antiviral activity, and pharmacokinetics of the elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide single-tablet regimen in HIV-positive adolescents. Must have undetectable viral load on current HIV regimen. Compensation is $75 per study visit. **NS**

- GS-US-292-0112: 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 alafenamide single-tablet regimen in HIV-positive adolescents. Must have had no prior ART or have undetectable viral load on current regimen and have compromised kidney function. Compensation is $75 per study visit. **NS**

- **ABBVIE M14-004 (PEARL) HIV/hepatitis C coinfection treatment study:** A three-month study of hepatitis C (HCV) treatment with an interferon-free regimen of ABT-450/ritab-267 and ABT-333, with or without ribavirin (RBV). Must have had no prior HCV treatment or be an HCV treatment-failure candidate. Must have only genotype 1a HCV and have well-controlled HIV. **NS**

- **MK-1439:** A study comparing once-daily MK-1439 (an investigational NNRTI) plus Truvada vs. efavirenz plus Truvada. Must have had no prior ART. Compensation is $75 per study visit.

**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>GENERIC NAME</th>
<th>BRAND NAME</th>
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<tr>
<td>Protease Inhibitors (PIs)</td>
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<tr>
<td>atazanavir</td>
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<td>tipranavir</td>
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<td>Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)</td>
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<td>Complera</td>
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<td>Combivir</td>
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<td>zidovudine/lamivudine/ abacavir</td>
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• M14-004: A phase 2/3 study for the treatment of genotype-1 hepatitis C in patients also coinfected with HIV. Subjects will be treated with three direct-acting antiviral agents (DAAs), ABT-450/rr/ABT-267 + ABT-333, plus ribavirin for either 12 or 24 weeks; there is no placebo. Open to adults with or without prior exposure to pegylated interferon and ribavirin, but not to those with prior exposure to DAAs, including telaprevir and boceprevir. Patients with compensated cirrhosis are also eligible. Compensation is $50 per visit. NS

• HIV gene therapy study of modified stem cells. Must be HIV positive and age 18–65, with a history of ART and a CD4 count >600 cells/mm³. Sponsored by Calimmune, Inc.

  • “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 the 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

• M2.0: A study testing whether taking a medication (mirtazapine) reduces methamphetamine use in men who have sex with men. Study includes weekly substance use counseling. Compensation is $5 to $45 per visit (15 visits over 3 years). 415-694-1547.

• HIV clinical trial for men who have sex with men testing whether taking a medication (oral 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, www.trexsf.com.

San Francisco Veterans Affairs Medical Center
4150 Clement Street
San Francisco, CA 94121

• A prospective, randomized, placebo-controlled, double-blind clinical trial to evaluate whether injected tesamorelin (Egrifta), 2 mg once daily, increases the risk of development or progression of diabetic retinopathy in HIV-positive people with abdominal lipohypertrophy (excess deep-belly fat) and type-2 diabetes. Compensation is $50 per study visit (15 visits over 3 years). 415-683-9895. NS

Stanford AIDS Clinical Trials Unit
1000 Welch Road, Suite 202
Palo Alto, CA 94304
650-723-2804
http://actu.stanford.edu

Compensation is provided for travel and meals for most studies.

• ACTG 5298: A placebo-controlled, phase 3 trial of the quadrivalent human papillomavirus vaccine (qHPV) to prevent anal HPV infection. 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. Study currently open only to women with no history of anal, vulvar, vaginal, cervical, or oropharyngeal cancer.

• Stanford HIV Aging Cohort Study: A five-year observational study in patients with HIV and undetectable viral load on ART. Visits are yearly and include neurocognitive testing, psychosocial questionnaires, and heart disease risk assessment. Also recruiting an HIV-negative control group.

• 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 be on ART.

• A5303: A study evaluating a standard HIV medication combination compared with an experimental combination containing maraviroc. Must have a viral load <1,000, be hepatitis B negative, and have had no prior ART.

• POEM Study: A five-year study to monitor the safety of long-term use of maraviroc in a large and diverse patient population. Those without R5 tropism will not be given maraviroc but will be observed in the study.

UCSF/SFISReady.org
415-554-9013
www.sfhiv.ucsf.edu

San Francisco General Hospital.

PhD levels in African-American men age 50 and older: A study to compare phDHL 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.

UCSF/Adult AIDS Clinical Trials Unit
995 Potrero Avenue, Building 80, Ward 84
San Francisco, CA 94110
415-476-4082, ext. 358
http://php.ucsf.edu/rsrch_trials.shtml

All studies provide compensation.

• A5279: A study comparing two treatment methods to keep latent tuberculosis (TB) from becoming active in HIV-positive individuals. Must have a TB-positive skin or blood test, and be on an efavirenz- or nevirapine-based regimen or not taking ART. Each participant will be followed for at least three years. All study visits take place at San Francisco General Hospital. NS

• A5298: A placebo-controlled, phase 3 trial of the quadrivalent human papillomavirus vaccine (qHPV) to prevent anal HPV infection. 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. Study currently open only to women with no history.
of anal, vaginal, cervical, or oropharyngeal cancer.  

- A5294: 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 and be on stable ART (specific drugs only) for more than eight weeks before study start, or not currently be on ART.  

- A5303: A study evaluating a standard HIV medication combination compared with an experimental combination containing maraviroc. Must have a viral load ≥1,000 copies/mL, be hepatitis B negative, and have had no prior ART.

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**UCSF/San Francisco General Hospital**  
1001 Potrero Avenue, Ward 5B  
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 and CD4 count <350. 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-naïve 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.

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**Other UCSF Studies**

- A study looking at cerebrospinal fluid (fluid surrounding the brain and spinal cord) in HIV-positive individuals. Must be on stable, standard ART for >1 year with documented undetectable viral load. Participants will undergo a blood draw, spinal tap, and extensive neuropsychological testing. Compensation is $125. 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 <300 cells/mm³. Must be about to start ART under the supervision of a physician. Study includes spinal taps, blood draws, and extensive neuropsychological testing over a one-year period. Participants receive up to $415 over the course of the year. 415-206-4328.

- PISCES Study: A study looking at changes in the brain and nervous system. Must have been diagnosed as recently infected with HIV (less than one year ago). Must be willing to undergo three MRI scans, spinal taps, blood draws, physical exams, and neuropsychological testing over one year with the possibility of follow-up study visits. Compensation is $415 over the course of the first year. 415-206-4328.

- IR1SS 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.

- 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.

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**Veterans Affairs Palo Alto Health Care System**  
3801 Miranda Avenue, Suite 132  
Palo Alto, CA 94304  
650-496-2510

- HIV & Hepatitis C or Hepatitis C Study: A one-time blood draw for those who have cleared hepatitis C virus, either spontaneously or with treatment.

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**NEW ON THE BETA BLOG**

Are you reading the BETA blog? It’s your bright and brainy source on new developments in HIV prevention, evolving approaches to HIV treatment, strategies for living well with the virus, and prospects for an HIV cure.

Contributing writers include researchers, clinicians, and advocates—smart folks with a passion for turning science and jargon into something everyone can understand and use to improve their own health and well-being.

Recent columns and stories include:

- Ask a Guinea Pig: Gene Therapy Clinical trials  
- More Good News from Stem Cell Research  
- Promiscuous Gay Nerd: Is It Time to Abandon Serosorting?  
- Ask A Lawyer: The Injustice of HIV Criminalization  
- HIV & Aging: Do Drug Concentrations Change With Age?  
- Ask a Pharmacist: Attacking Your Allergies  
- Expert Q&A: What is “Harm Reduction”?  
- First Glimpse of a Pediatric HIV Cure?  
- Non-AIDS-Defining Cancers: Five Ways to Reduce Your Risk  
- Viral Load, “Leaky Guts,” and Inflammation: Connecting the Dots  
- A “Birthday” Gift: The Story of a Cure  
- Making the Most of Your Medical Visits  
- Alcohol and HIV Meds: Dispelling the Myths  
- Resource Round-Up: Starting Meds for the First Time  
- HIV and “Accelerated Aging”  
- Smoking and Your HIV Health

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The BETA blog builds on a long history of HIV treatment and prevention education and advocacy. BETA’s mission today is all about health literacy—providing tools to help you ask smarter questions, understand meaningful developments in HIV research, and get the most from your medical care.

Visit www.betablog.org today, and switch on your HIV smarts.