

Information, inspiration and advocacy for people living with HIV/AIDS, since 1985

TOP STORIES FROM 2010, LOOKING FORWARD

## Finding health care; preparing for the future

*Julie Cross, Health & Disability Policy Consultant*

As a longtime HIV benefits counselor and policy advocate, I have spent many years helping to link individuals with their health and disability benefits. Over the years, I have witnessed dramatic changes in the benefits needs of people living with HIV/AIDS.

In the late 80s and early 90s, accessing benefits was fairly direct as most individuals automatically qualified for disability benefits. Things changed dramatically in the late 1990s when there was a sudden need for return-to-work benefits following the introduction of HAART. In recent years, there has been a more troubling trend with regard to benefits, as we now see an unprecedented number of individuals unable to find needed benefits due to their inability to meet outdated disability standards.

Fortunately, we are very close to seeing this barrier eliminated through the passage of the Patient Protection and Affordable Care Act, also known as health care reform. For example, many people who would not qualify for health care under the current criteria will be eligible for either subsidized insurance or for Medicaid under health care reform. Getting coverage will no longer be exclusively linked to disability; it will instead be based on need alone. If implemented correctly, health care reform will illuminate the way to create the improved access to health coverage that the HIV community has long fought for.

While health care reform stands to make dramatic improvements for persons with HIV, it is important to recognize that these changes can feel overwhelming to almost everyone. Leaving familiar health programs to access new ones can be confusing and stressful. The good news is that many new resources are currently being developed to help you navigate this new health system. While health care reform's full implementation is not expected until 2014, it is not too soon to engage in the reform effort.

Here are three important actions that you can take this year to begin the process:

### 1. Understand your current benefits

While this might seem simplistic, I can't stress how important it is to understand which programs are currently paying your health care bills. Benefits are confusing to most people. For example, people often confuse their Medicare and Medicaid benefits. And individuals getting care under the Ryan White system or ADAP don't always understand that they are technically uninsured.

Try to understand as much of your personal benefits profile as you can. These are complicated systems, so don't be afraid to ask for help. Ask your case manager, doctor's office, or pharmacist

#### CONTENTS

- 1-5 Top stories
- 5-7 Hepatitis update
- 7-12 Positive changes in HIV news
- 12-13 New HIV drugs
- 13-14 Disappointing HIV news
- 14-18 Project Informs policy work
- 18 HIV and aging
- 18-20 Editorial

for assistance. Keep copies of all your important benefits paperwork in a safe place. Understanding your current benefits is more important than ever because this will be the information you need to find your new benefits through health care reform.

## 2. Identify health care reform facts vs. fiction

Over the next few years we will see major attempts throughout the country to derail the health care reform effort. While it will be important to pay attention to these repeal attempts, we can't let this interfere with our efforts to do the work needed to get ready for health care reform.

Project Inform is collaborating with several community partners to embark on an important project that will pull together resources to help you sort out health care reform fact from fiction. This resource will also give you tools to help you understand what health care reform means for you in the coming years. These web-based resources will be available in the next few months. Check [www.projectinform.org](http://www.projectinform.org) for more information.

## 3. Share your personal health care stories

Some of the most powerful tools we have to fight the repeal of health care reform and to ensure that health care reform is designed to meet the needs of people living with HIV/AIDS are personal stories from individuals detailing how the current health care system is failing them. Are you having trouble getting a certain medication? Are you experiencing difficulty accessing a specific type of medical care? How has your lack of health coverage impacted your life?

We definitely want to hear from you. Sharing your personal stories helps to influence policy makers to make critical decisions about fixing our broken health care system. If you have a story that you would like to share, please email Project Inform at [support@projectinform.org](mailto:support@projectinform.org) or Julie Cross at [cross\\_jl@msn.com](mailto:cross_jl@msn.com).



For more  
treatment and  
health care  
information, call  
Project Inform's  
toll-free  
HIV  
Health  
Infoline at  
1-800-822-7422.  
HOURS:  
10a-4p, M-F

## In conclusion ...

It is important to be aware of the upcoming implementation of the biggest overhaul our health care system has ever experienced. But it is important to not let the magnitude of this change, political rhetoric or media "noise" scare you away. Begin with the three simple steps listed above in the upcoming months. And remember that HIV activists are mobilizing to get you the information and support you need to insure that the promise of health care reform becomes a reality for all people living with HIV/AIDS.

## Well implemented, President Obama's National HIV/AIDS Strategy is precisely what is needed to further control HIV/AIDS

During the 2008 campaign, a coalition of AIDS service organizations and advocates called upon all candidates for the Presidency to develop a National HIV/AIDS Strategy to address serious gaps in progress against HIV/AIDS. As a candidate, the future President Obama pledged that his administration would develop a Strategy and, since his election, the White House has actively solicited advice from people living with HIV and community groups on what should be contained in the Strategy. Project Inform has served as a member of the Steering Committee of the Coalition for a National AIDS Strategy and has provided significant advice as to what we believe this much needed document should contain.

In December 2009, Project Inform and the Community HIV/AIDS Mobilization Project co-hosted a meeting of leading HIV experts who recommended that the Strategy include an initiative called Testing & Linkage to Care Plus (TLC+). TLC+ proposes that by greatly increasing HIV testing nationally and quickly linking newly diagnosed HIV-positive people to primary medical care, social services, prevention counseling, plus treatment, the US could greatly increase the percentage of HIV-positive people adhering to care and treatment, improve their health outcomes, prevent new infections, and reduce health disparities suffered by women and people of color.

On July 13, President Barack Obama released the National HIV/AIDS Strategy and warmly welcomed HIV advocates to a White House reception to mark this important development in the epidemic. Project Inform was honored to be in attendance at that historic event. The Strategy was prepared in close coordination between the President's Office of National AIDS Policy (ONAP) and an Inter-Agency Work Group made up of representatives of all Federal agencies involved in the nation's response to HIV/AIDS. It was reviewed before being released by the President's Advisory Committee on HIV/AIDS (PACHA), which includes people living with HIV and representatives of AIDS service organizations.

The Strategy is almost entirely what Project Inform hoped for. It sets assertive but achievable goals for improving the health of HIV-positive people and reducing new infections. It is deliberately and thoughtfully focused on a limited set of goals and activities that are most likely to have significant impact on the epidemic. ONAP, the Inter-Agency Work Group and PACHA deserve enormous credit both for the plan itself and the inclusive process used to develop it. Project Inform's summary of the Strategy can be seen here [[www.projectinform.org/nhas/NHAS\\_summary.pdf](http://www.projectinform.org/nhas/NHAS_summary.pdf)]. President Obama's remarks about its release are available at [AIDS.gov](http://aids.gov/federal-resources/policies/national-hiv-aids-strategy/) [<http://aids.gov/federal-resources/policies/national-hiv-aids-strategy/>].

First and foremost, the Strategy takes a well-reasoned and thoughtful public health approach previously missing in the epidemic. HIV treatment has historically been focused on improving the health of the individual, as well it should be. However, just as TLC+ does, the Strategy is focused on making certain that more HIV-positive people know their status and are linked quickly to care and social services that will prepare them to take HIV medications early in infection and remain adherent to treatment. It asserts that doing so will help to meet the important goals of increasing the percentage of HIV-positive individuals engaged in care and treatment that prolongs and improves quality of life, as well as reducing new HIV infections. The Strategy also makes clear that effective HIV prevention requires combining different proven methods, including promotion of condoms, availability of sterile syringes for injection drug users and supporting HIV-positive people to avoid transmitting the virus to others.

With regard to prevention, the Strategy courageously promotes two additional actions. First, it asserts that the focus of prevention programs and funding should be on those geographic areas and risk groups that are actually suffering the greatest burden of new infections. Those include urban areas and gay and bisexual men, particularly gay and bisexual men of color, transgenders and injection drug users. It notes that most, though certainly not all, HIV cases among people of color occur in gay and bisexual men. Second, the Strategy supports the development of prevention interventions that are likely to have community-wide impact, not just individual impact.

While both the HIV care and prevention provisions of the Strategy have a decidedly medical focus, the document correctly asserts that successfully engaging HIV-positive people in care and treatment, as well as preventing HIV, requires an increased focus on the enormous needs of people

living with and at high risk for HIV for basic social services including housing, mental health and substance abuse treatment. It also asserts the importance of reducing stigma and discrimination against people with and at risk for HIV — including among medical providers— in order to increase chances that individuals will obtain HIV testing, medical care and treatment.

Importantly, the Strategy contains a discussion about the need for much greater coordination of the work of Federal agencies involved in the nation's response to HIV/AIDS, and for improved coordination and streamlining of programs among Federal, State and local government agencies. The President has directed the Office of the Assistant Secretary of Health & Human Services (HHS) to coordinate the efforts not just of the many agencies involved in HIV/AIDS within HHS, but of all Federal agencies.

The document does not discuss financing of new directions in the fight against HIV at great length, a point that many HIV advocates have noted with concern. It correctly argues for the more effective use of existing funding, particularly for HIV prevention programs. It notes that recently adopted national health care reform will provide the means by which most HIV-positive Americans will be able to access primary medical care and treatment. And it asserts that the Ryan White Program, which currently provides over \$2 billion in Federal funding for care, treatment and social services programs for people with HIV, needs to be extended and reconfigured to support this new direction in the fight against HIV/AIDS. It does not, however, commit to whether all of those \$2 billion should be preserved.

Project Inform agrees with all of these points regarding financing of HIV/AIDS services. But we believe that all of the \$2 billion appropriated to the Ryan White Program — and perhaps more — will need to be appropriated to fill in for gaps in health care reform and assure the level of social services and linkage of HIV-positive people to care and treatment that are called for in the Strategy. We also believe that HIV research, particularly cure-related research at the National Institutes of Health, and HIV prevention programs of the Centers for Disease Control & Prevention (CDC), will need funding increases in coming years. And we are alarmed that the Obama administration and the Congress are currently placing insufficient funding into the AIDS Drug Assistance Program (ADAP) as a bridge to health care reform, which is to be fully implemented in 2014.

An otherwise visionary and thorough document, the Strategy's main weakness appears to be in the area of expanded HIV testing. This is particularly disappointing in that the fundamental goal of increasing participation in care and treatment is predicated on greater awareness of HIV status. The CDC has previously been cited as making some progress on its goal of assuring that all Americans aged 13 to 64 know their HIV status, but inadequate progress. And while the Strategy does encourage greater cooperation from major national medical groups in assuring that medical providers routinely offer testing to their patients, it does little else to make clear how the nation will increase the percentage of HIV-positive Americans who know their serostatus. Project Inform will press to assure that the detailed implementation plan that is to follow the release of the Strategy by December 13, 2010 corrects this problem.

This is an extremely encouraging and opportune time in the domestic fight against HIV and AIDS. The National HIV/AIDS Strategy sets the proper course for improving the health of HIV-positive individuals, reducing new HIV infections, and reducing great disparities in the HIV health now experienced by women and people of color. National health care reform will greatly help us to assure access to care and treatment for most, though not all people living with HIV. The current arsenal of HIV medications, while not perfect, is capable of greatly prolonging the length and qual-

Go online and  
get connected  
to treatment  
information  
around the  
clock and in  
the privacy of  
your home!

ity of life of HIV-positive people when taken early in infection and preventing new infections. It is vital that the nation seize on this set of advances and fund them adequately in order to achieve the vision of President Obama's Strategy: that "The US will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination."

Project Inform is proud to have played a part in the development of the Strategy and will remain heavily engaged both in informing the details of its implementation and monitoring its results. We will regularly update our constituents about progress in this regard.

#### HEPATITIS UPDATE

## Hepatitis C advocacy ramped up in 2010

2010 was a significant year in hepatitis C advocacy that saw increased attention to the impact of the epidemic in the United States and a more aggressive community response to the failure of government at all levels to provide adequate funding and attention.

In January 2010, the Institute of Medicine released a report highlighting the severity of the chronic hepatitis B and C epidemics and the inadequate response by the federal government. Nearly 5 million Americans are living with chronic hepatitis B and/or C and the overwhelming majority is not aware of their status. An estimated 25–30% of people with HIV are co-infected with hepatitis C, and end stage liver disease is now a leading cause of death among people with HIV.

However, the response by elected officials continues to be abysmal. The federal government provides less than \$20 million per year for viral hepatitis prevention services, and there is no effort to establish programs to provide access to care and treatment for uninsured people living with hepatitis C. Meanwhile, most states and localities lack resources or a plan to offer adequate screening, testing, care and prevention services.

Project Inform continued our leadership role in hepatitis C advocacy at the national and local levels in 2010 by working in coalition with partners to secure a comprehensive strategy to address the epidemic. At the national level, we advocated for increased federal funding through our participation in the Hepatitis C Appropriations Partnership, led by the National Alliance of State and Territorial AIDS Directors. This advocacy led to the first funding increase proposal from President Obama and a commitment from Leader Nancy Pelosi to prioritize additional funding for viral hepatitis programs. We also led the organizing of the first major hepatitis B and C rally at the United States Capitol. Held on May 19, 2010 (World Hepatitis Day), this rally brought hundreds of hepatitis advocates to the nation's capitol to demand leadership from Congress.

In San Francisco, we played a significant role in developing the San Francisco Mayor's Hepatitis C Task Force's report, "Recommendations for Strategically Addressing Hepatitis C in San Francisco." This document, released in January 2011, resulted from a year-long process by the Task Force researching and identifying gaps and needs in hepatitis C services and makes several key recommendations to ensure that San Francisco has a comprehensive plan to address the growing epidemic. Project Inform chairs the Task Force's Public Policy Committee and is organizing an advocacy campaign to make sure the recommendations are implemented.

2011 brings even more opportunities for hepatitis C advocates around the country. Project Inform, along with the Association of Asian Pacific Community Health Organizations and the Harm Reduction Coalition, has recently launched a national campaign called “Hepatitis Health Action: The Hepatitis Community Responds to Health Care Reform.” This coalition will monitor implementation of health care reform legislation and advocate on behalf of people living with and at risk for hepatitis B and C throughout the process.

For information about our hepatitis C advocacy, contact Ryan Clary at [rclary@projectinform.org](mailto:rclary@projectinform.org).

## Two promising drugs for hepatitis C arrive in 2011

In 2010, two new drugs to treat hepatitis C (HCV) were submitted to the FDA for approval as well as requests for expedited reviews. The shortened review period has been granted to both telaprevir and boceprevir because they represent a significant improvement over current standard care (interferon + ribavirin). The approvals will hopefully happen by mid-summer.

These new HCV protease inhibitors are promising because the cure rate has shifted from about 40% on standard treatment up to around 75% by adding of one of these drugs. People new to treatment and those who stopped treatment before or whose HCV wasn't cured benefited from these new regimens. What's also encouraging is that treatment can be cut from 48 weeks to 24 for most people.

Although the course of treatment has shortened and the cure rate greatly improved, the main concern with HCV treatment is being able to manage its sometimes considerable side effects. The most common mild-to-moderate side effects were rash, itchiness, fever, tiredness, headache, nausea, trouble sleeping, anemia and diarrhea. With careful planning, most people can manage them. Beyond this year's considerable advance, there are dozens of other experimental drugs in the pipeline that hopefully will do away with the need for standard therapy, which includes injecting one of the drugs.

What these new drugs mean for HIV-positive people who live with hepatitis C is not so clear. For these approvals, the studies were done in mono-infected individuals, although clinical studies have now started in co-infected people. Since nearly 1 out of 4 HIV-positive people also live with HCV, it's important to know how successful these new drugs will be for them.

It's likely that the companies will help individuals with payment for the drug through new PAPs. For current PAP and co-pay program information, go to <http://fairpricingcoalition.org/projects>. Call the HIV Health InfoLine for more information on HCV, or go to [www.hcvadvocate.org](http://www.hcvadvocate.org) and [www.hivandhepatitis.org](http://www.hivandhepatitis.org).

## Booster dose of hep A vaccine needed in HIV+ men

At the 2010 ICAAC, it was reported that an extra “booster” dose of the hepatitis A virus (HAV) vaccine may be needed for HIV-positive men who have sex with men (MSM). This is to get a vaccine antibody response equal to what was seen in HIV-negative MSM.

HIV-positive MSM are generally 3 times more likely to get hepatitis A than their HIV-negative counterparts. It's currently recommended that all HIV-positive people get the HAV (and HBV) vaccine to protect them from serious illness. However, it's known that people with CD4 counts below 200 have poorer responses to vaccines in general. A study in Taiwan studied giving a booster dose of HAV vaccine to 476 MSM.

World  
Hepatitis  
Day  
July 28, 2011

Check  
[www.projectinform.org](http://www.projectinform.org)  
for more  
information on  
Project Inform's  
activities for  
World Hepatitis Day,  
or go to  
[www.worldhepatitisalliance.org](http://www.worldhepatitisalliance.org)

A total of 187 HIV-negative men got two doses of the vaccine at 0 and 6 months, as did 135 HIV-positive men. Another 154 HIV-positive men got three doses, at 0, 1 and 6 months. Levels of antibodies were checked at the study start, just before the 6-month dose and then 6 months after that.

Results showed that the levels of antibodies just before the 6-month dose were significantly lower in HIV-positive men. Only 39% of the HIV-positive men who took two doses compared to 63% of the negative men showed an antibody response by 6 months. However, those HIV-positive men who took the booster dose at 1 month had a similar response rate to HIV-negatives at 65%. Those men with CD4s below 200 who got 2 shots showed very poor response rates.

However, somewhat at odds with the results, the researchers didn't also report on the response rates of the men with CD4s below 200 who got 3 shots nor on the response rates that were seen 6 months after all the doses were given compared across all groups.

#### POSITIVE CHANGES IN HIV NEWS FROM 2010

## US Guidelines for treating HIV get updated

The US Department of Health & Human Services announced an update to the federal Guidelines for treating HIV on January 10, 2011. The revisions are mostly small changes to using certain HIV meds, CD4 counts and viral load test results. Other changes include treating people co-infected with hepatitis B or tuberculosis.

### What to Start: changes for people going on treatment for the first time

The Guidelines describe several groups of regimens when starting HIV treatment: “preferred”, “alternative”, “acceptable/may be acceptable” and “may be acceptable but used with caution”. The first group includes regimens that generally are more tolerable and the most potent. Each group after begin to have increasingly more disadvantages than the one before it. The new recommendations highlight three changes in first line treatment:

- A regimen with Selzentry + Combivir has been upgraded to “acceptable” because of stronger data from a randomized study.
- “Selzentry + Truvada” and “Selzentry + Epzicom” have been added as “may be acceptable”.
- In response to a recent product label change to saquinavir (Invirase),
- Regimens with Invirase + ritonavir have been downgraded from “alternative” to “may be acceptable but used with caution” due to increased risk for heart rhythm problems.

### CD4 counts

A small change was made in recommending how often CD4 counts are done. The new recommendation is that the CD4 count may be monitored less often, for example every 6–12 months (instead of every 3–6 months). This applies to those who are on treatment and remain undetectable with no new changes in their general health, such as new HIV symptoms or having to start medicines that affect the immune system (interferon, corticosteroids, etc.)

Questions about  
hepatitis C?  
Or the new drugs  
for it  
this year?  
Call  
1-800-822-7422.  
M–F,  
10a–4pm, PST.

### **Viral load tests**

Low-level results (typically <200) are commonly reported from some viral load tests. These results tend to be caused more by isolated “blips” due to the test’s variability rather than being an actual increase in viral load. The new recommendation cautions providers not to use “detectable” viral load below 200 as a reason to switch treatment. Trends over time, such as a continually increasing viral load with two or more tests, are more accurate predictors of treatment success or failure.

### **Drug-resistance testing for integrase inhibitors (INSTIs)**

HIV resistance is a concern for any HIV drug, including the newest class of integrase inhibitors. However, standard genotypic tests only check for mutations for the NRTIs and protease inhibitors. The new recommendations encourage providers to order genotypic tests specifically for integrase inhibitors in addition to other genotypic tests done.

### **Tuberculosis disease with HIV co-infection**

All HIV-positive people with active TB should be treated with HIV treatment. For patients with <200 CD4s, HIV treatment should be started within 2–4 weeks of starting TB treatment. For patients with 200–500 CD4s, the Guidelines Panel recommends starting HIV treatment within 2–4 weeks, or at least within 8 weeks, after starting TB treatment. For patients with >500 CD4s, most Panel members also recommend starting HIV treatment within 8 weeks of TB treatment.

### **Hepatitis B disease with HIV co-infection**

This section has been revised to provide recommendations for managing co-infected people, including those with HBV infection resistant to 3TC or FTC and for patients who cannot tolerate tenofovir (Viread).

## **For some, taking Prezista once a day is enough**

In 2010, the FDA approved a change in the dosing for Prezista (darunavir) for people who have been on HIV treatment before. This could possibly help people take their regimens on schedule every day. However, the dosing change should not be attempted in people with known resistance mutations to Prezista.

The current dosing of Prezista for treatment experienced people is twice a day. In the ODIN study, one group continued to take Prezista twice a day for 48 weeks while a second group changed their dose to once a day.

In those whose HIV showed no resistance to Prezista, the drug controlled HIV to undetectable levels for the 48 weeks. Although this is an improvement in dosing and convenience, and will hopefully suppress HIV for more than a year, more attention may need to be paid to monitoring resistance and viral load while on once a day Prezista for treatment experienced.

## **Switching to Viramune is possible at higher CD4s**

Current US Guidelines state that Viramune (nevirapine) should not be started in women with CD4s above 250 and in men with CD4s above 400. This is due to potentially severe allergic reactions found mostly at higher CD4 counts. However, there’s no guidance around switching someone to a regimen with Viramune after already having been on treatment for awhile.

In 2010, the European Medicines Agency, who reviewed data from more than 12,000 patients in several large studies such as EuroSIDA, ATHENA and others, now recommends that women and men can switch to Viramune regardless of their CD4 counts provided that their viral loads are undetectable. Sometimes Viramune may be a better choice for certain individuals due to the side effects, drug interactions or resistance with other drugs.

People who wish to switch to Viramune should consult their doctors and weigh the pros and cons with this information. This change was not incorporated into the latest update to the US Guidelines in January 2011.

## Once a day Kaletra gets approved for treatment experienced, but with caution

In April 2010, the FDA approved the once-a-day dosing of Kaletra (lopinavir + ritonavir) for adults who have taken HIV therapy before but with two or less lopinavir mutations. This new dose is not recommended for those with 3 or more of the following mutations: L10F/I/R/V, K20M/N/R, L24I, L33F, M36I, I47V, G48V, I54L/T/V, V82A/C/F/S/T, and I84V.

Results from the M06-802 study of nearly 600 people compared Kaletra taken once a day to twice a day. All participants had never taken lopinavir before, and all had viral loads of at least 1,000 before starting Kaletra. (Viral loads of 1,000 or more are necessary to run resistance tests to identify mutations.) About 1/3 were women. All took two NRTIs in addition to Kaletra.

However, taking Kaletra twice a day may still be a better choice for some individuals. Results from another study, ACTG 5076, followed 321 people who took Kaletra either once or twice a day with 2 NRTIs. Although adherence was better in those taking Kaletra once a day, for those with viral loads above 100,000, their HIV levels weren't as well controlled. 89% on twice a day Kaletra were undetectable at 48 weeks, while only 76% of those on once a day were undetectable.

In the end, once a day dosing can improve adherence rates in general, and once-a-day Kaletra seems to be safe and effective in people with lower viral loads. However, for those whose viral loads are above 100,000, they may want to take Kaletra twice a day to more fully control HIV.

## Stopping PCP prevention is possible at lower CD4s

In September 2010, study results from the European COHERE study were published showing that some people could stop taking preventive treatment for PCP (*Pneumocystis jiroveci* pneumonia) provided that their viral loads were under control by a potent HIV regimen. Earlier in the epidemic, PCP quickly became an AIDS-defining illness and a leading cause of death for people living with HIV. It most often appeared when CD4 counts fell below 200.

In response, PCP preventive treatment (usually Bactrim) was recommended for anyone with CD4s in this range and certain others whose health warranted it. Many new cases of PCP were avoided because of this new standard of care, but also because of many improvements HIV therapy over the years. Taking Bactrim can be an added burden for some, so being able to stop it safely would be welcome news.

COHERE did two analyses by examining the medical files of HIV-positive people across Europe. Their first analysis looked at more than 23,000 people and their risk factors for PCP. Their second one of about 5,000 people focused on issues related to stopping PCP preventive treatment.

Of the 5,000 studied, 24 cases of PCP occurred after stopping their preventive therapy. Most cases were in people with CD4s below 100. When they looked at those in the range of 101–200 CD4s, there was no difference in the rate of cases in those on and those not on preventive treatment. In fact, no one who took HIV drugs with CD4s in this range and whose viral load was undetectable developed PCP.

Still, anyone whose CD4 count is below 100 should continue taking PCP preventive therapy, regardless of their viral load. The US Guidelines still recommend taking PCP preventive therapy until the CD4 count rises above 200 for at least three months, which may change in the next revision. In light of this new information, people may want to consult their doctors and weigh the pros and cons of stopping PCP preventive treatment between 101–200 CD4s.

## “Berlin Patient” continues to point to an HIV cure

In 2007, an HIV-positive man from the US faced a leukemia diagnosis while living in Berlin. He underwent a bone marrow transplant to try to cure his leukemia. However, this was also an opportunity for him and his doctors to better control, or even cure, his HIV. A bone marrow donor was found who had HIV-resistant stem cells. Due to a genetic mutation called delta-32, these cells did not produce the R5 co-receptor found on immune cells, which HIV uses to get in and reproduce.

In late 2010, an article appeared in the journal, *Blood*, and reported on this patient’s progress now nearly 4 years after the operation. Initially, some thought HIV would reappear given that the virus is present in resting cells which eventually become reactivated and start producing HIV again. However, he continues to have normal CD4s and undetectable viral load while having been off HIV treatment for nearly 3.5 years now.

About a year after his first transplant, his leukemia returned and so another transplant was done with the same type of stem cells. His leukemia is now in remission. And although tests previously found some HIV that uses another co-receptor, called X4, his HIV has not converted to using that co-receptor and has indeed not been found in recent testing of his blood. Researchers have also found that CD4s have come back in various parts of his body including gut lymph tissue ... a very strong sign of immune reconstitution.

For more information on this fascinating development in HIV research, go to [www.aidsmeds.com/articles/hiv\\_berlin\\_cure\\_1667\\_19563.shtml](http://www.aidsmeds.com/articles/hiv_berlin_cure_1667_19563.shtml).

## New treatment for excess deep belly fat approved

In November 2010, a new drug called tesamorelin (Egrifta) was approved by the FDA to treat excess deep belly fat in HIV-positive people. The drug is a synthetic human growth hormone releasing factor that stimulates the pituitary gland to make growth hormone. Although it may help some people trim down a portion of their deep belly or visceral fat found under the stomach muscles, it should not be viewed as a weight control product.

A 52-week study followed 816 people: 2/3 started on tesamorelin while the other 1/3 used placebo. At 24 weeks, everyone on placebo was switched to tesamorelin while half the original tesamorelin group continued on the drug as the other half went on placebo. At the end of the study, people who took tesamorelin for the full 52 weeks showed 18% less deep belly fat than placebo.

**Become  
a fan of  
Project Inform  
on Facebook!**

Simply go to  
[www.facebook.com/  
ProjectInform](http://www.facebook.com/ProjectInform)  
to become a fan.

*Project Inform  
posts important HIV  
news several days each  
week to help you stay  
informed!*

Some people may find using tesamorelin difficult. First, it's injected once a day into the stomach below the belly button. Second, once the drug is stopped, the belly fat returns within a few months. And, the mixing process before injection can be confusing.

EMD Serono, who makes tesamorelin, helps with this by offering patients a one-on-one injection trainer to show how to mix the drug and inject it properly. The cost is high as well, though the company has both a patient assistance program and co-pay program to help with drug costs. Call 877-714-2947 for details, or go to [www.egrifta.com](http://www.egrifta.com).

For more information on tesamorelin, read Project Inform's publication at [www.projectinform.org/info/tesamorelin/](http://www.projectinform.org/info/tesamorelin/).

## Gardasil approved to prevent anal cancer

In the US more than 5,000 people are diagnosed with anal cancer each year. More women than men are diagnosed with it, and people living with HIV experience higher rates of the cancer, especially gay and bisexual men who have had anal sex. Treatment is challenging and can include surgery, radiation or chemotherapy.

The Gardasil vaccine is currently used to prevent certain diseases caused by the human papillomavirus (HPV) in women, such as genital warts, abnormal skin cells of the cervix and cervical cancer. With this recent change, the vaccine has now been approved by the FDA to prevent abnormal skin cells of the anus and anal cancer in men and women. This applies to people 9–26 years of age before sexual activity has started.

Gardasil was studied in a large international study of gay men, who have high rates of anal cancer. Results showed a 78% reduction in cases of HPV-related abnormal skin cells of the anus. Although only men were studied, women are included in the change since the disease is the same in both sexes. Both men and women who are at higher risk for anal cancer, including gay men and HIV-positive men and women, should continue routine screening even after getting the vaccine.

However, despite this change by the FDA, the CDC still states the vaccine as being optional for boys and young men, which means that the vaccine cost will likely not be covered by public or private health insurance. More advocacy is taking place to encourage the CDC to change its position.

## HRA screening is most cost-effective for HIV-positive men

In late 2010, results from a Canadian study showed that using HRA, or high resolution anoscopy, is the most cost-effective way to screen for anal cancer. With HRA, a doctor uses a small camera called an anoscope to look at and take a tissue sample from the anus to later screen for cancerous cells.

HIV-positive people in general have higher rates of abnormal cells of the anus (called *dysplasia*) and anal cancer than HIV-negative people. This is due to infection with HPV, or the human papillomavirus. As well, HIV-positive men who have sex with men (MSM) have much higher rates of anal cancer ... up to 160 times higher. Although standard procedures are not in place for screening anal dysplasia and cancer, many experts believe yearly screening is wise in HIV-positive MSM, and perhaps all people living with HIV.

The study compared the accuracy, cost and ability to distinguish high-grade anal dysplasia between HRA and the two other, less expensive screening methods: the HPV genotype test and the anal Pap smear (swabbing the anus for tissue). Just over 400 HIV-positive MSM were screened in three groups (of whom HRA results were already available): one with HRA only, one with HRA only after a Pap smear showed cancer-causing strains, and one with all three screenings.

The results found 98 cases of grades 2/3 dysplasia and showed HRA was better able to detect these cases than Pap smear or Pap smear + HPV genotype. Many cases of grades 2/3 were missed by the Pap smears, and sometimes the cost of several Pap smears with HPV tests was eventually more costly than HRA only.

HRA may not be available to everyone who wishes to be screened in this way. Additionally, the procedure requires more training than the other two methods, which may make it difficult for some to make this screening method a part of their routine HIV care.

#### NEW HIV DRUG DEVELOPMENT IN 2010

## New combo pill submitted to FDA

In November 2010, a new combo pill was submitted to the FDA for approval. If approved, this would be the second full-regimen pill on the market next to Atripla. The pill combines the new NNRTI rilpivirine with a standard NRTI combination of Truvada (tenofovir + emtricitabine) and may be approved before the end of 2011 for people new to HIV treatment.

In studies comparing the new combo pill to Atripla [Sustiva (efavirenz) + Truvada], the new combo pill appears to be as potent as Atripla, though with fewer side effects. Many have difficulty tolerating some of the potential side effects from the Sustiva in Atripla, such as vivid or disturbing dreams. Studies showed that nausea was common among both regimens. However, rash and central nervous system side effects were much less likely to occur with the new combo pill.

## “Quad pill” continues to do well in early study

A new competitor to the only full-regimen pill on the market (Atripla) may emerge within another year or two with the continued development of the “quad pill”. This combo pill includes three HIV drugs (the new integrase inhibitor elvitegravir + tenofovir + emtricitabine) and one non-HIV booster drug called cobicistat.

Two 48-week studies included about 150 people who had never been on HIV treatment. The first study compared the quad pill to Atripla, while the second evaluated cobicistat as a booster and compared cobicistat + Reyataz + Truvada to ritonavir + Reyataz + Truvada. CD4 counts ranged 341–436, viral loads were around 45,000, and no one had resistance to NRTIs, NNRTIs or protease inhibitors. Average age was about 35, and 9 out of 10 participants were men.

In the quad vs. Atripla study, higher CD4 count increases occurred with the quad pill (240 vs. 162). Also, side effects occurred less often (about 10%) in those taking the quad pill, and included nausea, vomiting and rash. In the cobicistat vs. ritonavir study, higher CD4 count increases occurred with cobicistat (230 vs. 206). Side effects also occurred less often with the cobicistat regimen, although more severe ones occurred with that regimen. Similar decreases in viral load to below 50 copies were seen in all four groups.

It appears that the new quad pill able to suppress HIV to undetectable levels equally as Atripla, perhaps without the side effects that many experience on Atripla due to Sustiva. It also appears that cobicistat is equal to ritonavir in boosting the protease inhibitor Reyataz.

However, an ongoing concern with cobicistat is its effect on kidney function. At 24 weeks, the drug caused a higher rate of abnormal kidney function in the quad pill study. Over the next 24 weeks, that change in function appeared to level off. Phase 3 study will help to distinguish this concern further.

## Development of new NRTI festinavir continues

Promising news about a new NRTI called festinavir (OBP-601) continued through its Phase 1 and 2 studies. The HIV drug is chemically similar to an earlier NRTI called d4T (stavudine), although it doesn't appear to cause the same disruption of mitochondria, or the "power centers" inside cells. This disruption led to a serious condition called mitochondrial toxicity and contributed to significant body shape changes that many experienced earlier in the epidemic.

Early results so far suggest the drug is well tolerated and is effective against strains of HIV resistant to current NRTIs on the market. It may work better in those with resistance to lamivudine (Epivir), emtricitabine (Emtriva) and efavirenz (Sustiva). The drug is dosed once a day. More study is obviously needed in larger numbers of individuals, but hopefully within a couple of years festinavir can be shown to add some unique benefit to current treatments.

### DISAPPOINTING HIV NEWS IN 2010

## Cautionary recall of swabs used for Fuzeon and Pegasys announced

A voluntary and cautionary recall of sterile and non-sterile alcohol swabs manufactured by the Triad Group was announced in January 2011. The swabs include alcohol prep pads, alcohol swabs and alcohol swabsticks manufactured for various brand names. The pads may be contaminated with *Bacillus cereus*, which could lead to life-threatening infections.

Some swabs are sold in their own boxes, available through many drugstores, while some are packaged with injected prescriptions. People living with HIV and/or HCV should examine swabs that are packaged with their prescription HIV drug Fuzeon or with the HCV drug Pegasys. The swabs packaged with other injected drugs, such as Boniva and Nutropin, are also affected.

To identify which swabs should be discarded or returned to the store, people should look at the label for "manufactured by Triad Group". The swabs packaged under other brand names may not be marked like that and include: Boca/ Ultilet, Cardinal Health, Conzellan, CVS, Moore Medical, PSS Select, VersaPro and Walgreens. People can call with questions at 262-538-2900, M-F.

## Switching Isentress to once a day is less effective

Although the integrase inhibitor Isentress (raltegravir) is recommended for people going on treatment for the first time, it's the only first line drug that's taken twice, not once, a day. In an effort to simplify the dosing, a study compared taking Isentress twice a day vs. once a day.

Unfortunately, the 48-week results showed that fewer people who took Isentress once a day (83%) had undetectable viral loads below 50 copies compared to those who took it twice a day (89%). The reason for

this is likely because the drug is quickly processed out of the body. Although this difference appears slight it was statistically significant, thereby showing once a day does not provide an equal level of HIV suppression that twice a day does, especially in people who started treatment at viral loads over 100,000.

### **Vicriviroc fails for the treatment experienced**

Merck announced in 2010 that its experimental entry inhibitor, vicriviroc, would not move forward for FDA approval, given the disappointing results from two large studies in people with treatment experience as well as another study in individuals new to treatment. A similar drug, Selzentry (maraviroc), is currently the only R5-inhibitor drug on the market.

## **Patients face more complications with facial filler, Bio-Alcamid**

At a London conference in November 2010, a Canadian study reported that about 1 out of 5 people who got the facial filler called Bio-Alcamid experienced infections at the site of injections. The filler is often used to treat the loss of fat in the face, called lipoatrophy, most often in HIV-positive people outside the US. Lipoatrophy can result from various reasons, including HIV itself and certain drugs used to treat HIV disease.

As a polymer gel, Bio-Alcamid works by making the body produce natural collagen that eventually enwraps the gel to keep it intact in the face. Many doctors use the gel because it lasts longer than other facial fillers and perhaps in larger quantities.

The medical files of 263 HIV-positive people were reviewed, all of whom were treated with an antibiotic during and after treatment. Despite the antibiotics, 19% had an infection at the injection site some time after the procedure. The reasons for infections were “clearly due” to the Bio-Alcamid in 5% of patients and “probably due” in 14% of others, while many were due to trauma near the site, such as getting dental work.

Given these results and growing concerns over the past few years about infections with Bio-Alcamid, people may want to explore using other types of facial fillers. Moreover, people may want to be more diligent on noticing any symptoms of infection, especially when dental work is done sometime after getting the filler. For more information on facial fillers, go to [www.aidsmeds.com/articles/Lipoatrophy\\_4798.shtml](http://www.aidsmeds.com/articles/Lipoatrophy_4798.shtml).

#### PROJECT INFORM'S POLICY WORK

## **Health care reform provides quality care for many more; still needs our support**

The Patient Protection and Affordable Care Act (ACA), or health care reform, was signed into law March 2010. This milestone represents the most important advance in secure, quality health care for people with HIV since the start of the Ryan White Program. However, this historic health care expansion is now under serious attack by those who would roll it back by taking advantage of misunderstandings and negative propaganda about reform. We cannot afford to let this hard-won

victory be dismantled or underfunded. Each of us has an important role to play in defending health care reform and ensuring a successful implementation.

Most people still don't understand the ACA even as it is already making a dramatic improvement in many people's lives and health. Significant activity is already underway to allow expanded insurance coverage to upwards of 32 million uninsured Americans. By 2014 people will be guaranteed access to quality insurance regardless of their health status, a required package of essential benefits, significant assistance to low-income people to get insurance, and caps on the out-of-pocket costs most Americans pay.

You can help defend health care reform by educating yourself and your loved ones about the benefits of the ACA already in place and those to come in 2014. You can also contact your elected officials in Congress and let them know why you support the ACA and how it will make a difference in your life and your health.

Already, health care reform has ensured that:

- Health plans can no longer impose lifetime or annual limits on coverage. Many people with HIV suffered with plans that did not cover the cost of their care due to caps and limitations.
- Health plans must cover children (under 19) with pre-existing conditions.
- All young adults are allowed to stay on their parents' insurance policies until they are 26, giving them time to finish schooling and establish insurance through their employer.
- Insurance companies must justify their premium rates and increases.
- All newly sold insurance plans are required to cover certain prevention and wellness benefits with no deductibles or cost-sharing.
- Insurance companies are required to spend 80–85% of the premiums they collect on health care services and improvements in the quality of care or they must provide refunds to beneficiaries. Many companies are considering expanding their benefits and possibly providing refunds to meet the requirements.
- Insurance companies are no longer able to take away policies when people get sick.
- Certain people with pre-existing conditions, including HIV, have access to a temporary insurance program (Pre-existing Condition Insurance Programs or PCIPs) with premium rates that are consistent with rates for those without pre-existing conditions. This program will remain intact until 2014 when the expansion of Medicaid and the establishment of Health Insurance Exchanges will provide much more coverage.
- Medicare beneficiaries who reached the coverage gap in 2010, almost all people with HIV who depend on Medicare, received a \$250 rebate.
- As of January 2011, Medicare beneficiaries will receive a 50% discount on brand name drugs in the coverage gap. This is significant for people with HIV who typically reach the coverage gap in the second or third month of coverage.
- As of January 2011, AIDS Drug Assistance Program (ADAP) payments for Medicare prescription drugs will begin to count toward allowing a beneficiary to move through the coverage gap to meaningful drug coverage. People with HIV who rely on Medicare and ADAP will, for the first time, be able to take advantage of their full Medicare benefit rather than relying entirely on ADAP for most of the plan year.
- Small businesses receive tax credits to provide health insurance to their employees.

### Become a fan of Project Inform on Twitter!

Simply go to  
[www.twittwer.com/  
ProjectInform](http://www.twittwer.com/ProjectInform)  
to become a fan.

*Project Inform  
posts important HIV  
news several days each  
week to help you stay  
informed!*

In 2014, many significant protections and expansions in coverage will be enacted:

- Medicaid will be expanded to serve all low income individuals at 133% of the FPL regardless of disability status. For the first time most low-income people with HIV will be able to get Medicaid coverage before they become sick. The asset test for Medicaid will also be eliminated and a new package of essential benefits, including prescription drugs, will be mandatory for new beneficiaries.
- Medicare drugs will continue to become more affordable until the coverage gap is eliminated in 2020.
- Health exchanges, regulated marketplaces for purchasing insurance, will be enacted at the state level. Insurance companies will be required to have a much greater level of transparency with their benefits and will have to provide at a minimum an essential package of benefits. States will have new authority to regulate plans in their exchanges. All of these provisions could ensure more competition among insurers and give people the opportunity to purchase better plans at the better prices.
- Out-of-pocket expenses related to health care coverage will be capped, providing peace of mind for people with HIV and others with extensive medical needs. Subsidies will be provided for people with incomes up to 400% of the Federal Poverty Level (FPL).
- Insurance companies will be required to provide coverage to people who have pre-existing conditions at rates that are the same as others in the community.
- Insurance companies will not be able to discriminate or charge higher rates based on gender and will be limited in charging more for age or geographic location.

People who currently have insurance sometimes find it hard to see how health reform will help them. However, health care reform not only provides new coverage for people who are uninsured, it also provides much needed security for those who are already insured.

For the first time, people will not be tied to their jobs for fear of losing health insurance coverage for themselves or a family member and for their families. Many people currently stay in jobs or fear lay-offs and company closures primarily because they will be unable to get insurance for themselves or their family.

Insurance companies can no longer take away your coverage if you get sick. The elimination of discrimination against those with pre-existing conditions (which can include such seemingly inconsequential conditions as varicose veins as well as more serious conditions such as HIV), subsidies in exchanges, and Medicaid expansion should mean that people who lose or change jobs will, at a minimum, keep their health insurance.

The cap on out-of-pocket expenses and the prohibition on lifetime and annual caps will provide much needed security to Americans with high medical costs. Currently excessive medical costs are the leading reason for bankruptcy in the United States.

Now is the time to understand and take advantage of the benefits of health reform that have already been enacted. It is also critical to defend health care reform against attempts in Congress to repeal, defend and/or dismantle health care reform. Contact your elected officials and tell them how health care reform will improve your life and your health and that of those you love. If health care reform is fully implemented all of us will benefit from the same access to secure affordable health insurance enjoyed by members of Congress and their families.

For an up-to-date listing of Congressional addresses, go to [www.contactingthecongress.org](http://www.contactingthecongress.org).

## National ADAP crisis

The AIDS Drug Assistance Program (ADAP), part of the Ryan White program, provides prescription assistance to low-income individuals living with HIV. ADAP helps over 165,000 HIV positive Americans maintain their health by providing access to life-prolonging drugs.

ADAP is now in the most serious crisis since its inception, with over 6,000 individuals on waiting lists for their life-saving medications in 10 states: Arkansas, Florida, Georgia, Louisiana, Montana, North Carolina, Ohio, South Carolina, Virginia and Wyoming. Many more states have been forced to implement cost-containment measures that further restrict treatment access. While the crisis varies state to state, federal and state funding has not kept up with the financial needs of the program. In addition, the economic environment has caused unusually high unemployment. Many people have lost their health insurance and are forced to rely on ADAP and other public health programs.

In response to the government's inadequate response to this crisis, advocates from across the country are working tirelessly at the state and federal levels to increase funding and avoid more cuts. Two innovative actions have helped to alleviate the crisis. The first is the development of the Welvista program ([www.welvista.org](http://www.welvista.org)). The second is the recent successful advocacy effort to ensure treatment access for those who will be removed from Florida's ADAP for a two-month period.

Last year, advocates from the Fair Pricing Coalition (FPC), co-founded by Project Inform, worked with the Heinz Family Foundation, Welvista and the pharmaceutical industry to develop a program to ensure that people on ADAP waiting lists would automatically qualify to get their HIV meds from a central location rather than having to apply to each company patient assistance program separately. This new program is run by Welvista, a non-profit mail-order pharmacy based in South Carolina. While this program allows people to easily access some meds, it falls far short of filling the ADAP funding gaps left by federal and state governments.

Most recently, the FPC also worked with the state of Florida, Welvista and industry to avoid a major crisis in that state that would have doubled the overall number of people affected by the ADAP crisis. Florida planned on removing 6,500 people from its ADAP for a two-month period, due to a program funding shortfall. Advocates negotiated a temporary program through Welvista to provide medicines to all 6,500 Floridians affected. The process aims to be seamless for recipients, with all information transferred from Florida's ADAP to Welvista. Local social workers will be trained in how to transition clients to Welvista and then back onto Florida's ADAP in April when it expects to receive the necessary federal funding.

Project Inform continues to prioritize ADAP advocacy at the national and California state levels so that people with HIV/AIDS have stable access to treatment as we move towards health care reform implementation. As a co-founder of the grassroots Save America's ADAPs, a national citizen response to the ADAP crisis, we also mobilize constituents to tell their elected officials to fully fund America's ADAPs. For more information on what you can do to help solve the ADAP crisis, contact Michael Friedman: [michael@projectinform.org](mailto:michael@projectinform.org).

## CHARPA scores victory on HIV and aging research

In 2010, several HIV activist organizations, including Project Inform, and individuals formed the new advocacy group CHARPA, or the Coalition for HIV and Aging Research and Policy Advocacy.

In September, CHARPA sent a letter to Dr. Anthony Fauci calling for the prioritization of research into HIV and aging at the National Institutes of Health (NIH). The letter was endorsed by 113 organizations and 396 individuals and led to a meeting between CHARPA and the Office of AIDS Research (OAR), Division of AIDS (DAIDS), and the National Institute on Aging (NIA) at the NIH in December. According to an update sent to CHARPA members, as the result of the meeting, OAR has agreed to the following:

- 1) OAR will set up a Special Initiative Working Group on HIV and Aging consisting of leading researchers and community representatives and which is slated to meet in early 2011. Members will investigate ways to advance the research, such as “issuing RFAs (Request For Applications) with set aside funding for FY2012 to look at specific research questions, and convening a meeting in 2011 with researchers running large cohorts to pool samples for analysis on HIV and aging issues. The group will make their recommendations to OAR’s advisory committee.”
- 2) OAR has also pledged to set up an internal committee, with participation from other relevant NIH Institutes and Centers, to better coordinate multi-disciplinary research across NIH on HIV and Aging.
- 3) The NIH will set up a separate tracking code for HIV and Aging grants, so that it’s easier to assess ongoing research and funding levels, and to project future funding needs.
- 4) OAR will work with the Center for Scientific Review (CSR) to determine whether it is feasible to set up a review section devoted to evaluating grant proposals on HIV and aging.

CHARPA noted that they’ve “succeeded in elevating HIV and Aging to a research priority at the NIH. Given the ominous budget environment with the new Congress, increasing funding for HIV and aging research will likely be an uphill battle. But with the establishment of the Special Initiative Working Group, we hope to see the start of better coordinated and prioritized research into this important area.”

### EDITORIAL

## Is a generation without HIV within our grasp?

*(Originally published in the December 31, 2010 issue of the Bay Area Reporter.)*

Exciting developments in HIV prevention research, combined with a renewed commitment on the part of gay and bisexual men and transfemales to collective action against HIV, could make 2011 a turning point in the steady march of new infections that looms over our communities.

In November, the iPrEx study showed that, overall, 44 percent fewer infections occurred among 1,248 high-risk gay men and transfemales who took the daily HIV pill Truvada and were counseled to consistently use condoms. Among study participants who took Truvada 90 percent of the time, new infections fell by a stunning 73 percent. Participants reported that their condom use increased

and number of sex partners decreased, enhancing the preventive benefits of PrEP. Side effects and development of drug resistance were not problems.

In July, the CAPRISA study showed that women who applied a gel containing the HIV drug Tenofovir before and after sex were 39 percent less likely to become HIV-positive. Effectiveness increased to 54 percent among those who consistently used this “microbicide” gel.

It is now understood that HIV-positive people effectively treated with antiretroviral medications can be up to 92 percent less likely to transmit the virus to their partners. San Francisco’s model programs to encourage gay and bisexual men and transfemales to know their status and enter care and treatment early if positive are helping to slow new HIV infections.

PrEP and microbicides require additional research before they become widely available. Project Inform is currently advocating with Federal officials for funding of demonstration projects in several US cities to determine whether iPrEx’s thrilling results, along with increased adherence to daily pill taking, can be achieved outside the confines of a rigorous, placebo-controlled study. In separate research, PrEP will be examined to see whether taking Truvada less frequently is as effective as daily dosing. And microbicides are being studied to assess their effectiveness in the rectum — an environment in which it is more difficult to achieve protection than in the vagina.

The US Centers for Disease Control & Prevention issued guidance to physicians in late January describing how they can deliver PrEP to patients who want to consider it now. It may be several years, however, before public and private insurers actually pay for this costly intervention. In the meantime, it is extremely important to remember that PrEP should not be tried at home because it requires the advice and active clinical supervision of a doctor. It is critical that HIV-positive people not share their meds with HIV-negative people wanting to try PrEP, thereby threatening the health of both individuals. And there is currently no evidence suggesting that taking HIV medications less often than daily is effective in reducing one’s chances of becoming infected.

Many issues have been raised about widespread use of PrEP. In addition to concerns that it may backfire by further reducing condom use, many wonder how we could even consider delivering expensive HIV medications to HIV-negative people when waiting lists for meds for HIV-positive people are growing nationally. One answer, of course, is that we cannot possibly hope to keep pace with the cost of care and treatment for HIV-positive people if we do not invest more money in slowing the rate of new infections. Spending on prevention currently represents only 4 percent of overall HIV expenditures. Additionally, unless the current Congress unravels health care reform, both PrEP and the cost of care and treatment of people with HIV are likely to shift from discretionary programs subject to annual budget-making whims to better guaranteed funding sources.

PrEP has been met by concerns that only the worried well will seek it out rather than people who are at highest risk for infection. Clinical guidelines and outreach for PrEP should favor people at highest risk for infection, particularly those who have genuinely tried other forms of prevention but are nevertheless vulnerable to engaging in receptive anal intercourse without condoms. Concern has also been expressed that only those who can afford PrEP will get it, further exacerbating disparities in the health of youths, low-income people and people of color. Advocacy for payment for PrEP in those groups that most need it must be strong. At the same time, everyone who wants to remain HIV-negative deserves support to do so, and PrEP should not be denied to anyone who can benefit from it.

PrEP will be met by great moralizing among conservatives who wonder why taxpayers should be asked to pay for something that, never mind the evidence, may increase promiscuity or risk-

taking. The fact is that gay men and others at risk for HIV are hardly the only people who engage in behaviors they know can result in disease, but to which they are still susceptible. Taxpayers are paying dearly for the cost of prevention, care and treatment of heart disease, hypertension, diabetes and smoking — far more than for HIV. Finally, the high cost of PrEP causes many to ask an obvious and fair question. Why pay for a prevention intervention that may cost \$10,000 to \$20,000 per year when a condom costs 10 cents?

It is easy to see that community norms of safe sex and condom use are not as strong as they once were among gay and bisexual men. Saving PrEP as a prevention intervention only for those who truly need it, our community already has significant power to usher in the first generation of gay and bisexual men and transfemales who can live without the fear of HIV. Five things would help. We need to rededicate ourselves to using condoms when we have sex with partners whose HIV status is different from our own or whose status we are not sure of. We need to continue to build a culture in which we value protecting one another from HIV. Each of us can commit to knowing our HIV status and being re-tested regularly. And those of us who learn we are positive can enter care immediately and carefully consider early treatment. And finally, we can dedicate ourselves to participating in ongoing research on PrEP, microbicides and vaccines that offer hope of eliminating new cases of HIV once and for all.

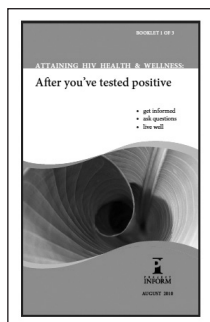
For more information about PrEP and HIV treatment as prevention, visit [www.projectinform.org/info/prep/](http://www.projectinform.org/info/prep/).

## Interim PrEP Guidelines announced by the CDC

Following on the footsteps of the iPrEx study data released late last year, the CDC issued their guidelines January 2011 for using PrEP in high-risk gay men. The new Guidelines are found at [www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm?s\\_cid=mm6003a1\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm?s_cid=mm6003a1_w). Project Inform's publication on PrEP can be found at [www.projectinform.org/prep/prep.shtml](http://www.projectinform.org/prep/prep.shtml), and in Spanish at [www.projectinform.org/prep/prep\\_sp.shtml](http://www.projectinform.org/prep/prep_sp.shtml).

## ATTAINING HIV HEALTH & WELLNESS

Project Inform created this series of three publications to address commonly asked questions and issues that people face as they come to terms with their HIV status and begin addressing their health care needs.



- *After you've tested positive*
- *Considering treatment & your health care*
- *What you should know about when to start & what to use*

The full series is currently available in both English and Spanish. These booklets are free to individuals and service providers alike. To request a set of booklets to review, or to order multiple copies:

- **CALL** the the toll-free HIV Health InfoLine at 1-866-HIV-INFO
- **EMAIL** [questions@projectinform.org](mailto:questions@projectinform.org)