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National Stories

Drug Resistance From Truvada as PrEP Does Not Last

As reported by aidsmeds.com | 12.21

Individuals who develop resistance to the components of Truvada (tenofovir/emtricitabine) after contracting HIV shortly before or while taking pre-exposure prophylaxis (PrEP) do not maintain such resistance for long, aidsmap reports. Researchers in the Partners PrEP trial conducted a small substudy of nine participants who showed signs of drug-resistant virus when they tested positive for the virus.

If people take PrEP while they are HIV positive, in rare cases they may develop drug resistance to either of the two antiretrovirals in Truvada. In clinical trials, this has typically happened when participants contracted HIV very shortly before starting PrEP. (Individuals are required to test HIV-negative before

starting PrEP. But if they were infected very recently the test may not detect the virus, resulting in a false negative test.) However, there have been rare documented cases of people receiving their PrEP prescription before contracting the virus who then develop drug resistance.

The researchers ran resistance tests on archived blood samples drawn 6, 12 and 24 months after the participants stopped PrEP. (The participants discontinued Truvada after testing positive.)

There were archived, pre-seroconversion blood samples available for four of the participants that showed a positive HIV RNA test result but a negative antibody result, indicating acute, or very early, infection. None of the virus in these samples was resistant to the components of Truvada, suggesting that these four individuals developed drug resistance while taking the tablet as PrEP.

Six months after discontinuing PrEP, all nine participants saw their resistant virus drop to undetectable levels, which persisted in the 12- and 24-month samples.

One of the participants started HIV treatment 33 months after contracting the virus, taking Viramune (nevirapine) and Truvada (tenofovir/emtricitabine). After three months of treatment this individual had an undetectable viral load.

To read the aidsmap article, click here.

To read the study abstract, click here.

View the story online: Click here

Single strategy not enough to curb HIV risk in young MSM

Jason Laday, Healio Infectious Disease News | 12.22

Targeted, multilevel strategies are needed to reduce risk behaviors among young men who have sex with men living with HIV, particularly among those with a detectable viral load, according to a study published in JAMA Pediatrics.

“Numerous studies have found that many HIV-infected [young men who have sex with men (YMSM)] engage in risky sexual behaviors after their diagnosis,” Patrick A. Wilson, PhD, associate professor of sociomedical sciences at Columbia University’s Mailman School of Public Health, and colleagues wrote. “YMSM who are not virally suppressed may be at particular risk to engage in sexual risk behaviors that serve to perpetuate HIV transmission.”

The researchers conducted a cross-sectional survey of 991 YMSM with HIV. Wilson and colleagues sought to analyze the differences between virologically suppressed participants and those with a detectable viral load, and to identify correlates of condomless anal intercourse and serodiscordant condomless anal intercourse among YMSM with a detectable viral load.

The survey participants, aged 15 to 26 years, were enrolled through 20 HIV clinics across the United States and provided demographic, behavioral and psychosocial assessments. The researchers obtained participants’ viral load information through blood testing or medical records. The survey was conducted from December 2009 through June 2012, with data analysis completed on July 31.

According to the researchers, 69.4% of the participants had detectable viral load, 46.2% reported having condomless anal intercourse, and 31.3% reported serodiscordant condomless anal intercourse within the past 3 months. YMSM with a detectable viral load were more likely than virologically suppressed YMSM to report condomless anal intercourse (54.7% vs. 44.4%) as well as serodiscordant condomless anal intercourse (34.9% vs. 25%). Problematic substance use, nonblack race and disclosure of HIV status to sexual partners were associated with condomless anal intercourse among YMSM with detectable virus, the researchers said.

Results also showed that transgender participants were less likely than their cisgender counterparts to report condomless anal intercourse (adjusted OR = 0.35; 95% CI, 0.14-0.85), and unemployed YMSM with detectable viral load were less likely to report serodiscordant condomless anal intercourse than employed participants (aOR = 0.74; 95% CI, 0.55-0.99).

More than half of YMSM in the study (52.1%) reported being currently prescribed ART.

"Our findings highlight the inadequacies of treatment as prevention as the sole risk reduction method among HIV-infected YMSM in the United States, and speak to a greater need for behavioral approaches to improve ART uptake and ultimately achieve higher rates of viral suppression in this population," Wilson and colleagues wrote. "Combination HIV prevention and treatment interventions, which include behavioral, biomedical and structural strategies to increase viral suppression and reduce HIV transmission risk behaviors, that target HIV-infected YMSM are needed."

Journal Reference:
Wilson PA, et al. *JAMA Pediatr*. 2015;doi:10.1001/jamapediatrics.2015.3333.

View the story online: Click here

Harvoni price 'maximizes' revenue, U.S. Senate Committee investigation concludes

Melinda Stevens, Healio Hepatology | 1.5

After an 18-month investigation into the pricing of Harvoni, members of the U.S. Senate Committee on Finance found that Gilead Sciences chose its price with a goal of maximizing revenue as opposed to treating as many patients with hepatitis C virus infection as possible.

"Using [Gilead Sciences'] own documents, the evidence shows that the company pursued a calculated scheme for pricing and marketing its hepatitis C drug based on one goal: maximizing revenue regardless of the human consequences," U.S. Sen. and finance committee member Ron Wyden, D-Ore., said at a press conference in December. "If Gilead's approach is the future of how blockbuster drugs are launched in America, it is going to cost billions and billions of dollars just to treat just a fraction of the health care patients in America."

Spearheaded by Wyden and U.S. Sen. Chuck Grassley, R-Iowa, the finance committee reviewed 20,000 pages of Gilead's documents, collected data from Medicaid programs and bureau of prisons among all 50 states and conducted a plethora of interviews with health care experts to determine how the company came to a price for the course of treatment and how it is affecting the health care industry.

“Our investigation focused on one drug, a specialty drug. We thought it was particularly important because if America is to cure Alzheimer’s, cancer, diabetes and HIV in the days ahead, these cures must not be unaffordable and beyond the reach of millions of Americans,” Wyden said at the conference. “Cures in America must not just be for the lucky few.”

Based on its investigation, Wyden said the committee found that Gilead’s own analyses show it was fully aware that as prices increased, the number of Americans treated and cured would go down.

“The company chose to put revenue ahead of affordability, of accessibility for millions of patients,” Wyden said. “The company knew that the prices would put treatment out of reach for millions of Americans and cause extraordinary problems for Medicare and Medicaid, yet the company went ahead and charged $1,000 a pill for Sovaldi, equal to $84,000 for a standard course of treatment.”

In addition, Wyden stated that the investigation showed that Gilead used the pricing of Sovaldi (sofosbuvir) to its advantage to serve as a platform to set an even higher price for Harvoni (ledipasvir/sofosbuvir) priced at more than $94,000 for one course of treatment. “They planned it from the beginning,” Wyden said at the press conference.

Gilead's Response

In a statement given to Healio.com/Hepatology from Gilead Sciences, the company maintains it was cooperative in the investigation and disagrees with the findings.

“We believe we were cooperative and transparent in our response to U.S. Sens. Wyden’s and Grassley’s inquiry, and we provided the senators with key internal documents and information so that they could understand all relevant details related to our pricing decisions,” the statement said. “While we appreciate the Senate Finance Committee’s attention to this issue, we respectfully disagree with the conclusions of their report.”

According to Gilead, the company sought to find a price that would be accepted with as little patient restriction as possible, a fact that is shown in the findings released by the Senate. The company also stated the price it chose for Sovaldi is under the price of the existing standard of care.

“In the U.S., the products were initially priced in line with the previous standards of care,” Gilead said in the statement. “With rebates and discounts now in place, the prices today are less than the cost of prior regimens, even though our therapies have significantly higher cure rates and very few side effects.”

The company added that shorter durations of therapy have also led to reduced pricing by one-third for many patients.

Wyden stated that Gilead is merely painting an “optimistic picture” about cost, when in fact Medicare has spent more on these drugs in the beginning of 2015 than it did for all of 2014.

“Since it was approved 18 months ago, Medicare has spent nearly $8.2 billion before rebates on Sovaldi and Harvoni and (that) total continues to grow. … Medicare spent more on these drugs in the first 6 months of 2015 than they did in all of 2014. Our report shows that Medicare now spends more on hepatitis C drugs in about 3 weeks than it did in all of 2013.”

Medicare is not the only program affected by the high costs, according to Wyden. Private insurers and state Medicaid programs have been forced to restrict patient access to control such high costs.

“Despite spending more than $1 billion on hepatitis C drugs last year, state Medicaid programs nationwide treated less than 2.4% of the patients who are known to have the disease,” Wyden said.

For example, state programs in Oklahoma spent approximately $18 million in 2014 to treat 220 people with HCV and Indiana spent more than $40 million to treat 462 people, according to Wyden.

In a press release, Grassley stated that the committee has a responsibility to properly oversee programs for prescription drug coverage.

“With that responsibility, the committee should know how the costs to the public programs and private insurance companies of a single innovative drug entering the market without competition can have major effects on which patients get the new drug and when,” Grassley said in the release. “This report sheds light on one example of the pricing decisions made by one company with a new prescription medicine that entered the market without competition in high demand. … I encourage everyone to read the report for the level of detail into pricing strategy that we don’t see often.”

Additional findings from the investigation mentioned in the release include: Gilead justifying sofosbuvir’s high price point based on price-per-cure; Gilead underestimated the degree of access restrictions that it expected would result from its pricing decision; and Gilead refusing to significantly lower the net price regardless of the access restrictions.

Wyden said Gilead agreed to some discounts. However, when the Medicaid programs asked for discounts to let them cure more patients, Gilead set a pre-condition that it would only agree to give a discount of a minimal 10% if the state dropped all access restrictions and states took on back-breaking costs.

“That’s not much of a choice at all. The Medicaid programs do not have unlimited resources to pour into Gilead’s bottom line,” Wyden said.

In addition, a number of Medicaid programs informed the committee in weeks leading up to the conference that the price remains a problem when factoring in the number of people who need treatment.

“Our report estimates that at the end of 2014, more than 97% of Medicaid patients diagnosed with hepatitis C remain untreated. More than 700,000 Medicaid enrollees are waiting in line,” Wyden said. “With Medicaid and private insurers struggling to offer access, Medicare could become the backstop that absorbs huge costs of Gilead’s drugs. People with hepatitis C might go without treatment until they quality for Medicare,” which may create problems for the Medicare D program.

According to Gilead, more than 600,000 people around the world have been treated with its HCV medications since they were approved in 2013 and 2014.

“Gilead appreciates the importance of making health care accessible for all,” the statement said. “Gilead responsibly and thoughtfully priced Sovaldi and Harvoni. We stand behind the pricing of our therapies

because of the benefit they bring to patients and the significant value they represent to payers, providers, and our entire health care system by reducing the long-term costs associated with managing chronic HCV," adding that there are multiple programs in the United States that can provide financial assistance for the therapies to uninsured people.

The press conference can be viewed here.

View the story online: Click here

Risk for HSV-2 transmission using condoms associated with gender

Jen Byrne, Healio Infectious Disease News | 1.2

The efficacy of male condom use in preventing herpes simplex virus-2 transmission among HIV-1 and herpes simplex virus-2 serodiscordant couples varied by gender, according to recent findings.

"We found condoms reduced the per-act risk of [HSV-2] transmission by 65% from women to men and by 96% from men to women," Helen Rees, MD, executive director of the Wits Reproductive Health and HIV Institute, University of Witwatersrand in Johannesburg, South Africa, and colleagues wrote. "The high estimated efficacy of male condoms in reducing HSV-2 transmission has important public health implications for this highly prevalent sexually transmitted infection for which there is not an effective preventive HSV-2 vaccine."

The researchers evaluated 911 HSV-2 and HIV-1 serodiscordant couples from East and Southeastern Africa who were enrolled in the Partners in Prevention HSV-2/HIV 1 Transmission Study. One partner in each couple was coinfected with HSV-2/HIV-1 (799 men); the other partner was HSV-HIV-1 seronegative. Participants were followed for a median of 18 months. The researchers evaluated the per-act rates of HSV-2 transmission with and without condoms, and utilized infectivity models to determine the effect of condom use on HSV-2 transmission.

HSV-2 transmission occurred in 68 couples, 17 of which included susceptible women and 51 with susceptible men.

The risk for HSV-2 transmission from men to women was 28.5 transmissions per 1,000 unprotected sex acts (95% CI, 10.8-74.1) and 1.3 male-to-female transmissions per 1,000 protected acts (95% CI, 0.4 to 4.5), yielding a 96% reduction in HSV-2 transmission with male condom use (95% CI, 84%-99%).

The risk for transmission from women to men was 1.7 transmissions per 1,000 unprotected sex acts (95% CI, 0.6-4.4) and 0.6 per 1,000 protected sex acts (95% CI, 0.2-1.7), or a 65% reduction in HSV-2 transmission with male condom use (95% CI, –5% to 88%).

According to the researchers, this difference in condom efficacy (P = .014) may be related to differences in the ability of condoms to minimize contact with the anatomic locations of virus shedding.

"Our findings suggest that male condoms are very effective in preventing HSV-2 transmission from men to women and are likely to provide some protection for susceptible men as well," Rees and colleagues concluded. "The mechanism of this sex difference may be related to the differing ability of the condom

to diminish contact with anatomic sites of viral replication, as men tend to shed HSV on the penile shaft, whereas HSV-2 shedding in women occurs on the wider area of the vulva and perineum."

Journal Reference:
Magaret AS, et al. *Clin Infect Dis*. 2015;doi:10.1093/cid/civ908.

View the story online: Click here

Birth Control Without Seeing a Doctor: Oregon Now, More States Later

Pam Belluck, The New York Times | 1.4

As of Jan. 1, women in Oregon can get hormonal contraceptives directly from a pharmacy, without having to go to a doctor for a prescription first. Here are answers to a few questions about the groundbreaking new law:

How does the new law change the way women can get contraceptives?
These birth control methods — which include pills, patches and rings — will still require prescriptions (so they are not technically over the counter), but now pharmacists who complete the Oregon training protocol can issue those prescriptions directly. At the pharmacy, women must complete a 20-question self-assessment so that pharmacists can determine which hormonal methods might be appropriate and safe. About 200 pharmacists in Oregon have completed the training so far and an aide to the bill's sponsor said that most of the major chain pharmacies, including Rite Aid, Costco and Walgreens, have signed agreements to train a significant number of pharmacists.

Will insurance cover birth control purchased this way?
Yes. Under the Affordable Care Act, all prescription birth control is covered by insurance. The only possible additional cost is a one-time or annual fee of $25 or so for the assessment services provided by the pharmacist. It is possible that insurers will cover that fee, but that is yet to be determined.

What is the goal of this law?
Supporters of the law, which was sponsored by a Republican and received bipartisan support, hope that by making birth control easier and more convenient to obtain, the law will encourage more women to use it and will reduce rates of unintended pregnancy and also abortion.

Are any other states planning to make the same change?
Yes. California has passed a similar law, which is expected to take effect in the coming months. Other states, so far mostly in the West, are considering similar legislation.

Do medical experts support the change?
Many reproductive health experts have long sought to make birth control more easily accessible, and there are studies showing that it is safe for women to obtain contraceptives without a doctor's prescription, and that women will still, for the most part, visit doctors for gynecological exams and screening for cervical cancer and sexually transmitted infections. Many experts say the ideal would be for contraceptives to be available with no prescription at all, but they acknowledge that the process of converting them into over-the-counter products –- which requires companies to apply for Food and Drug Administration approval –- could take a long time. Still, some, including the American Congress of

Obstetricians and Gynecologists, are concerned that laws like Oregon's could slow down the drive toward over-the-counter access.

Is there an age restriction?
Oregon's law requires teenagers under 18 to obtain their first contraceptive prescription from a doctor; after that they can go to a pharmacist. The law says that in five years, legislators will review that provision and decide whether to lift the age restriction. California's law includes no age restriction.

View the story online: Click here

The State of the HIV Epidemic

Following years of apparent stagnation in the U.S. fight against HIV, recent reports suggest that things are looking up. What's the full story?
Benjamin Ryan, POZ.com | 1.5

This summer will mark 35 years since the first reports of AIDS. Additionally, two decades have now passed since combination antiretroviral treatment began to transform a health crisis into a more manageable public health concern.

Anniversaries are time to take stock: to reflect on the lessons of the past, assess the status quo and make projections for the future. For many years now, the American HIV epidemic has appeared trapped in a protracted stagnation, paralyzed by the systemic flaws of the U.S. health care system, fueled by increases in sexual risk-taking among men who have sex with men (MSM) while new infections drop among other risk groups, and stymied by increased public apathy.

Recent reports, however, have given new reason for hope. In December, the Centers for Disease Control and Prevention (CDC) released data showing a 19 percent drop in HIV diagnoses over the past decade, as testing rates remained stable or rose among groups that saw a decline in diagnoses. The finer details of that report, as well as news of successes in the realms of prevention and treatment in major cities such as New York and San Francisco, suggest that the American HIV epidemic is finally charting a new course.

The state of the epidemic is improving. It is not really one epidemic, however, but a loose collection of smaller epidemics among various risk groups, including MSM and in particular black MSM, injection drug users (IDUs), and women of color. The epidemic also follows vastly different patterns in different metropolitan areas. So looking only at the big picture and not these finer details yields a particularly inadequate picture of HIV's present condition.

The promising news is that, between 2005 and 2014, HIV diagnoses fell 40 percent among women, including 42 percent among black women. The diagnosis rate also dropped 35 percent in heterosexuals and 63 percent among injection drug users (IDUs).

However, such progress has been uneven. While the rate of new diagnoses among MSM has finally leveled off, Latino MSM continue to see increases (although at a slower pace). And while the drumbeat about ending the epidemic grows ever louder from nonprofit and governmental agencies alike—San Francisco has its Getting to Zero initiative and New York State is gearing up to implement a Blueprint to End AIDS—crisis reigns in the South.

With a disproportionately high HIV prevalence rate, Southern states lag in the percentage of people living with the virus who have been diagnosed, and also have higher HIV-related death rates compared with the rest of the country..

Demetre Daskalakis, MD, MPH, the new assistant health commissioner in the Bureau of HIV/AIDS Prevention and Control in New York City, enjoys a robustly supportive cross-section of political, nonprofit and activist support for his team's efforts to battle the local epidemic. Reflecting on traveling to conferences to meet his counterparts from around the country, he says, "Getting on a plane sometimes feels like getting into a time machine." Coming from a state that has enthusiastically embraced the Affordable Care Act, he says of the conferences themselves, "I'm sitting next to departments of health from a state who literally are cheering because finally their governor will think about Medicaid expansion."

The Southern problem

HIV is fueled by the indignities of poverty, chief among them lack of access to health care; the stubborn refusal of Southern governors to expand Medicaid fuels the fire. An interactive map of uninsurance rates by county in The New York Times bears troubling similarities to the map of HIV prevalence in the United States.

"If you were to look at the states where Medicaid has not been expanded," says Eugene McCray, MD, director of the division of HIV prevention at the CDC, "those are the states that have the worst outcomes in terms of diagnoses, in terms of treatment outcomes, as well as in terms of late diagnoses. The other challenge is just poverty and other social determinants of health that are more prominent in the South."

In Georgia, AIDS has been among the top five causes of death for blacks between the ages of 20 and 54 for the past five years. And a shocking 11 percent of young black MSM living in Atlanta are estimated to contract the virus each year, with those who become sexually active at 18 projected to face perhaps a 60 percent chance of becoming HIV positive by age 30.

"We don't have the mature, nimble prevention systems that you see in San Francisco or Seattle," says Eli Rosenberg, PhD, an assistant professor of public health at Emory University in Atlanta, who was a coinvestigator of the Atlanta study. "We don't have the coordinated response. And we have a large population of minority MSM that you don't see in other cities. So in a sense it's a confluence of a large population center of diverse men in a Southern poor-resource environment. It's disheartening."

The treatment cascade

Nothing illuminates the United States' overall failure to diagnose and treat HIV like the so-called treatment cascade. Coined in 2010, the cascade, also known as the care continuum, charts a series of progressive milestones necessary before individuals living with the virus are on successful treatment. According to a 2011 estimate, out of 1.2 million HIV-positive Americans, 86 percent have been diagnosed, 40 percent are in regular medical care, 37 percent have been prescribed treatment, and just 30 percent have a fully suppressed viral load. The figures are considerably worse for HIV-positive 18-to-24-year-olds, among whom only an estimated 16 percent have an undetectable viral load.

From an HIV-prevention perspective, the end point of the treatment cascade is vital: Research increasingly suggests that transmitting the virus when an individual has an undetectable viral load is highly unlikely, and may be impossible. Earlier points in the continuum are important to prevention efforts as well, considering recent estimates that 23 percent of new HIV cases transmit from people who are undiagnosed and 69 percent do so from those who are not in regular medical care.

The U.S. cascade statistics, like the country's health care system, is an embarrassment compared to those of other Western nations. The viral suppression rates in France, the Netherlands, the United Kingdom, Denmark and Australia are all over 50 percent.

But for all the handwringing over the dismal U.S. cascade figures, there is reason to believe that the country has made progress. These figures have not been updated for several years, so they fail to account for recent improvements. Additionally, health officials believe that the figures underestimated reality to begin with.

The cascade statistics were already steadily improving during the early part of the century. In 2003, there were an estimated 250,000 Americans living with undiagnosed HIV, representing 25 percent of the total HIV population. That figure dropped by almost 40 percent, to about 156,000, in 2012.

Additionally, the CDC has been pushing local health departments to deduce whether people who have moved away have been wrongly counted as not being in care.

New York City's viral suppression rate, looking just at those who are indeed in care for HIV, rose from 72 percent in 2011 to 85 percent in 2014. San Francisco recently started a program of getting people on antiretrovirals immediately after diagnosis that has shown considerable success. New York City's comparable program is slated to launch this year.

"Closing the gaps in prevention and care is essential if we're going to really improve the health of our nation and get to where we want to be in HIV prevention," says McCray. "We have what I believe are the major prevention and treatment advances to help us get to where we need to be. The challenge we have today is making sure that everybody is benefitting from those advances."

Good news for gays

The prevention advances to which McCray refers are grounded in the increasing scientific understanding of the power of antiretrovirals to prevent transmission. First there is so-called treatment as prevention (TasP) among people living with HIV. In addition, Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) is available for HIV-negative people. Approved in 2012, PrEP is estimated to reduce the risk of acquiring the virus by more than 99 percent when taken daily.

The CDC recently estimated that 1.2 million Americans could benefit from PrEP, including 492,000 MSM, 115,000 injection drug users, and 624,000 heterosexuals.

A precise picture of how widespread PrEP use has become is hard to come by. But the combination of anecdotal evidence as well as data from Gilead Sciences, Truvada's manufacturer, suggests that the pill is becoming an increasingly popular form of HIV prevention. After prescriptions apparently tripled between 2014 and 2015, a very rough estimate of 22,000 Americans, primarily MSM, were on PrEP as of about a year ago.

Following several months of silence on the Truvada front, the dogged PrEP antagonist AIDS Healthcare Foundation recently ran an adin various gay newspapers titled "PrEP, the Revolution that Didn't Happen." Along with its president Michael Weinstein, AHF has been accused of "PrEP denialism. " By categorizing the 22,000 figure as a failure, AHF fails to account for the direction toward which PrEP-use trends are pointing, considering the rapid rate of change. For example, New York State Medicaid prescriptions for PrEP increased four-fold between 2014 and 2015.

"PrEP is launched," says Demetre Daskalakis, "and it's launching faster. I don't see it slowing down." Speaking of efforts to promote Truvada in New York City, he continues, "Frankly, I think we're going to set the place on PrEP fire."

How PrEP may actually affect HIV rates remains to be seen. Research has suggested that if PrEP is used among MSM at very high risk of HIV, only 13 men would need to take it for one year to prevent one HIV infection among them. Thus far, there have been no new cases of HIV in two groups totaling more than 1,000 generally high-risk individuals taking PrEP in San Francisco.

All this said, CDC officials aren't ready to project whether Truvada has already contributed to the leveling off of the rate of diagnoses seen among MSM between 2009 and 2014. After all, PrEP's use was much more limited before 2015. What is clearer is that PrEP has come along at a point when HIV rates are finally improving among MSM.

Looking more broadly at the past decade provides a discouraging picture of the epidemic among MSM. Comprising two-thirds of all new diagnoses in 2014, MSM experienced a 6 percent increase in the annual rate of HIV diagnoses between 2005 and 2014. Rates increased by 24 and 22 percent among Latino and black MSM, respectively, while dropping by 18 percent among white MSM. The rates have been particularly alarming among 13-to-24-year-old MSM, with young Latino and black MSM both seeing an 87 percent increase during this period while their white counterparts experienced a 56 percent increase.

Narrowing the focus to the diagnosis rates between 2010 and 2014 indicates that things may actually be looking up for MSM. During this period, diagnoses stabilized among the overall demographic, including among young white and black MSM. However, Latino MSM stand out with a 13 percent increase in diagnosis rates, with young Latino MSM experiencing a 16 percent increase.

Latinos—the forgotten demographic?

Much ink has spilled over HIV's disproportionate effects on African-Americans. Just 13 percent of the U.S. population, blacks made up 44 percent of new diagnoses in 2014. But Latinos are also more likely than the general population to contract HIV. Representing 17 percent of the population, they comprise 23 percent of new diagnoses. And while new diagnoses have fallen in blacks, Latinos and whites alike, such progress has stalled among Latinos in recent years.

Part of the problem lies in the very nature of racial categorization, which is particularly awkward where Latinos are concerned. Whites and blacks are more homogenous relative to Latinos. The latter category encompasses an array of dialects, cultures and countries of origin that are often quite dissimilar and which as a result have considerably different HIV prevention and care needs.

According to Susan P. Buchbinder, MD, director of Bridge HIV, an HIV prevention unit at the San Francisco Department of Public Health, “We need to be sure what we’re doing is culturally relevant for the populations we’re trying to reach. And we have to be really careful when we’re talking about Latinos that we are embracing the full range of Latino populations. Part of the challenge is that we call all of these groups ‘Latino’ and yet there may be very different identities within those various communities. If we do an initiative that’s targeted for Mexican-Americans, it may or may not speak to Central Americans or South Americans or people from different countries in the Caribbean.”

The CDC’s Eugene McCray argues that, compared with the Latino community, African-Americans have been more mobilized around fighting HIV. The machismo culture and its influence on homophobia and HIV stigma also play key roles in the HIV-related racial disparities seeing in Latinos, he says.

Guillermo Chacón, president of the Latino Commission on AIDS, says that nonprofits need to develop proven track records of working with any particular subset of the Latino population. “I am always shocked when I review an organization that receives a lot of funding, but no history of working with these communities,” he says.

Worries about rising injection drug use

After years of falling HIV incidence among the U.S. injection drug user (IDU) population, is the recent outbreak of HIV among individuals injecting prescription opiates in rural Indiana a harbinger of what’s to come elsewhere across the country? With over 180 cases diagnosed in 12 months in a community of just 4,300, Scott County, Indiana, has seen one of the highest HIV incidence rates ever documented in the United States.

The recent epidemic of prescription opiate addiction in the United States has led to a considerable rise in injection drug use, as addicts seek out cheaper or more readily available alternatives to pills. According to the CDC, heroin use among Americans ages 12 and older rose from 1.6 per 1,000 individuals in the beginning of the millennium to 2.6 per 1,000 in the early part of the current decade.

Currently, injection drug use fuels about 8 percent of new HIV infections per year in the United States. The CDC recently issued a warning to health departments to remain vigilant for overlapping epidemics of HIV and hepatitis C virus (HCV). (The latter virus is even more readily transmissible through the sharing of injection equipment than HIV.) The federal health agency recently identified a nearly four-fold increase in hep C incidence among IDUs in Appalachian states, a result of increasing rates of addiction to opioids and injection drug use. Massachusetts, Wisconsin and upstate New York have seen similar patterns.

Scott Country was particularly vulnerable to the outbreak because of the lack of local infrastructure already in place to respond to and contain the surge of new infections, most notably a syringe exchange program. Indiana Governor Mike Pence, a Republican, has granted a waiver to state law forbidding such programs, a move that has ultimately helped stem further transmissions of the virus.

The Indiana outbreak led to a surprising late-year move in Washington, DC, as senators all but ended the longstanding ban on federal funding for syringe exchange programs, according to Buzzfeed. The shift was tucked into an omnibus spending measure in December and will permit federal spending on program support for the progams, such as staff salaries, vans, gas and rent, but not for the syringes themselves.

The CDC is currently working with states to develop IDU-related HIV outbreak response programs and to assess their own vulnerability. Routine testing of IDUs in places such as jails and drug treatment centers is key to identifying problems early and mobilizing the response necessary to limit outbreaks, says McCray.

Diagnoses vs. estimated new infections

The CDC's diagnosis figures belie a longstanding, rarely questioned belief: that HIV incidence (the number of new annual infections) has for many years held stubbornly steady, at about 40,000 to 50,000. That claim relies on the CDC estimating the rate of new annual transmissions (there is no way to measure transmissions exactly). The last time the agency conducted such an estimate, a complex and expensive venture, was in 2010.

The new focus on diagnoses instead of estimated incidence represents a major shift in the way the CDC intends to identify trends in the epidemic.

"This doesn't mean we won't be putting out incidence data in the future," says McCray. "But we will probably be using it very differently, and it will probably just be used to give us snapshots of what's going on."

Recent improvements in HIV surveillance systems, McCray says, have allowed the CDC to have greater faith that diagnosis data provides a strong reflection of recent transmission trends. Diagnosis reports can provide a richer understanding of different demographic and regional patterns. Incidence estimates, on the other hand, are based on data from a limited number of locations.

As for the mood of public health officials around the country as they face the HIV future HIV fight, San Francisco's Susan Buchbinder says, "There's a great deal of optimism. Part of that comes from having really highly effective prevention and treatment now. And this idea that if we can synergize those two then we can really bring down new infections and keep people healthy in a way that we haven't been able to before."

View the story online: Click here

Scientific Papers/Conference Abstracts

Preexposure prophylaxis-selected drug resistance decays rapidly after drug cessation

Weis JF, Baeten JM, McCoy CO, et al. *AIDS* 2016;30(1):31-25

Objective:
Resistance to emtricitabine plus tenofovir disoproxil fumarate (FTC/TDF) or TDF alone used as preexposure prophylaxis (PrEP) has been detected in individuals who initiated PrEP during unrecognized acute HIV infection and, rarely, in PrEP breakthrough infections. PrEP-selected resistance could alter

future treatment options, and therefore we sought to determine how long resistance persisted after PrEP cessation.

Methods:
The Partners PrEP Study was a randomized placebo-controlled trial of FTC/TDF or TDF as PrEP for HIV prevention. We previously reported that PrEP-related mutations (K65R, K70E or M184IV) were detected by 454 sequencing following seroconversion in nine individuals who acquired HIV during the Partners PrEP Study. In the current study, we used 454 sequencing to detect and quantify PrEP-related mutations in HIV RNA-positive plasma samples prior to seroconversion, as well as in plasma from 6, 12, and 24 months after PrEP cessation from these nine individuals.

Results:
HIV RNA-positive, antibody-negative samples were available prior to seroconversion for four of nine individuals with resistance detected at seroconversion. In all four cases, K65R, K70E and M184IV were not detected prior to seroconversion, suggesting PrEP-related resistance was selected and not transmitted. All PrEP-selected mutations were no longer detectable by 6 months after PrEP cessation and remained undetectable at 12 and 24 months in the absence of antiretroviral therapy.

Conclusion:
Using highly sensitive assays, PrEP-selected resistance in plasma decays below detection by 6 months following drug cessation and remains undetectable for at least 24 months. Even high levels of resistance mutations during acute infection decay rapidly in the absence of ongoing PrEP exposure.

View the paper online: Abstract

Young Sexual Minority Males in the United States: Sociodemographic Characteristics And Sexual Attraction, Identity and Behavior

Fasula AM, Oraka E, Jeffries WL, et al. *Perspectives on Sexual and Reproductive Health* 2016;48(1): TK, doi: 10.1363/48e7016

CONTEXT:
HIV incidence is increasing among 13–24-year-old U.S. men who have sex with men, yet limited research is available to guide HIV prevention efforts for this population.

METHODS:
National Survey of Family Growth data collected in 2002, in 2006–2010 and in 2011–2013 from 8,068 males aged 15–24 were analyzed to describe the population of U.S. young sexual minority males (i.e., males reporting same-sex attraction, identity or behavior). Correlates of sexual minority classification were assessed in logistic regression models.

RESULTS:
An estimated 10% of young males, representing a population of 2.1 million, were sexual minorities. Males had an elevated likelihood of being sexual minorities if they were aged 18–19 or 20–24, rather than 15–17 (prevalence ratio, 1.7 for each); belonged to nonblack, non-Hispanic racial or ethnic minority groups (1.6); had no religious affiliation, rather than considering religion very important (1.9); or lived below the federal poverty level (1.3). They had a reduced likelihood of being sexual minorities if they lived in metropolitan areas outside of central cities (0.7). Among young sexual minority males, 44% were

15–19 years old, 29% were poor and 59% resided outside central cities. Forty-seven percent had engaged in same-sex behavior. Of those with data on all measured dimensions of sexuality, 24% reported same-sex attraction, identity and behavior; 22% considered themselves heterosexual, yet had had a male sex partner.

CONCLUSION:
Future investigations can further explore subpopulations of young sexual minority males and assess sexual trajectories, resilience and HIV risk.

View the paper online: Abstract

The Program Cost of a Brief Video Intervention Shown in Sexually Transmitted Disease Clinic Waiting Rooms

Gift TL, O'Donnell LN, Reitmeijer CA, et al. *Sex Transm Dis* 2016;43(1):61-64

Background:
Patients in sexually transmitted disease (STD) clinic waiting rooms represent a potential audience for delivering health messages via video-based interventions. A controlled trial at 3 sites found that patients exposed to one intervention, Safe in the City, had a significantly lower incidence of STDs compared with patients in the control condition. An evaluation of the intervention's cost could help determine whether such interventions are programmatically viable.

Materials and Methods:
The cost of producing the Safe in the City intervention was estimated using study records, including logs, calendars, and contract invoices. Production costs were divided by the 1650 digital video kits initially fabricated to get an estimated cost per digital video. Clinic costs for showing the video in waiting rooms included staff time costs for equipment operation and hardware depreciation and were estimated for the 21-month study observation period retrospectively.

Results:
The intervention cost an estimated $416,966 to develop, equaling $253 per digital video disk produced. Per-site costs to show the video intervention were estimated to be $2699 during the randomized trial.

Conclusions:
The cost of producing and implementing Safe in the City intervention suggests that similar interventions could potentially be produced and made available to end users at a price that would both cover production costs and be low enough that the end users could afford them.

View the paper online: Full paper

Time From HIV Diagnosis to Viral Load Suppression: 2007–2013

Toren KG, Buskin SE, Dombrowski JC, et al. *Sex Transm Dis* 2016;43(1):43040

Background:
US guidelines now recommend that all HIV-infected persons receive antiretroviral therapy). HIV prevention is increasingly focused on ensuring that infected persons are diagnosed soon after HIV

acquisition and quickly link to care and initiate antiretroviral therapy. We examined trends in time from HIV diagnosis to viral load suppression in King County, WA, to gauge improvement in our HIV care continuum over time.

Methods:
We used HIV surveillance data and Cox proportional hazards to evaluate how the time from diagnosis to viral suppression changed among persons newly diagnosed as having HIV in King County, WA, between 2007 and 2013.

Results:
A total of 1490 (84%) of 1766 newly diagnosed persons achieved viral suppression in a median time of 213 days (95% confidence interval, 203–229). Thirty-six percent of all persons diagnosed in 2007 and 77% in 2013 were virally suppressed within 12 months of HIV diagnosis ($P < 0.0001$). Differences in time to suppression by calendar year persisted when stratifying by CD4 count at diagnosis. Race was not significantly associated with time to viral suppression.

Conclusions:
Time from HIV diagnosis to viral suppression dramatically declined between 2007 and 2013, and more than three quarters of recently HIV-diagnosed individuals in King County, WA, now achieve viral suppression within a year of diagnosis. This improvement was evident among all persons newly diagnosed as having HIV, regardless of race/ethnicity or CD4 count at time of diagnosis.

View the paper online: Abstract

Resources, Webinars, & Announcements

Sexual Health Educator (S.H.E.) Training Program

CFHC

Program Overview:
This new Sexual Health Educator (S.H.E.) training program is for educators in school, community, and clinic settings who want to build their knowledge and capacity in sexual health and sexuality education. It includes in-person and online courses offered by California Family Health Council, the California STD Control Branch and partner organizations with expertise in the field. Once all course requirements have been fulfilled, participants will receive a Certificate of Completion as a Sexual Health Educator.

The mandatory and elective courses in the S.H.E. training program include up-to-date information on a variety of sexual and reproductive health topics. (CHES), Nursing and Social Work/LCSW continuing education credits will be included for free with most S.H.E. training courses.

California Healthy Youth Act, signed into law in October 2015, requires comprehensive sexual health education in public middle and high schools. The S.H.E. training program is an excellent way to ensure that school-based educators in California - and other states that allow or require comprehensive sex education in schools - are equipped with the information they need to provide medically accurate, age-appropriate and inclusive sex education.

Learn More and Register

Who Should Participate?

- Health + Sexuality Educators
- School + Community-Based Educators
- School Nurses + Teachers
- Counselors + Social Workers
- Youth Educators
- Family Planning Staff

S.H.E. Online Courses

- Best Practices in Birth Control Education. Learn More.
- Providing Age-Appropriate Sexual Health Education. Learn More.
- Encouraging Family Communication about Healthy Sexuality. Learn More.
- Helping Teens Access Sexual + Reproductive Health Services and Resources. Learn More.

See All S.H.E. Courses

STI Patient Education Tool for Clinicians

The Family Planning National Training Centers has created "Your Guide to Understanding the Most Common Sexually Transmitted Infections (STIs)." This two page patient education resource lists ten STIs, some basic information about transmission and prevention, and treatment for each infection.

County of San Mateo 2014 STD and HIV/AIDS Annual Report

Hello,

Happy New Year! The San Mateo County 2014 STD and HIV/AIDS Surveillance Annual Report is now available.

Thank you,
STD/HIV Program Staff

WEBINAR: Understanding Women's Sexuality at Mid Life and Beyond

OWH

DATE: January 13
TIME: 1:00 – 2:00 PM ET

Sex and sexuality are human needs that evolve and change over the life cycle and are contributing factors to our quality of life and sense of well-being. The need for intimacy is ageless, and there is an abundance of research showing the benefits of sexual activity in later years for women. However, the topic of intimacy and aging is often overlooked when working with women in midlife and beyond. This

webinar will inform public health professionals about how important intimacy and expressing sexuality are for older individuals, as well as how best to share this information with clients and patients. Presenters include:

- Ilene Warner-Maron, Philadelphia College of Osteopathic Medicine
- Terri Clark, ActionAIDS

For more information and to register: Click here

WEBINAR: Webinar Series Addresses Fears About HPV Vaccine

CDC

In observance of Cervical Health Awareness Month in January, CDC Adolescent Immunization Communications Team presents the "Taming Conversations Around HPV Vaccine and Other Immunizations in Social Media" webinar series. This weekly presentation will address various aspects of engaging with negative comments or safety concerns on social media platforms. Discussion will be mostly focused on HPV vaccine, and the unique challenges that come with it; however many principles that we will address are relevant to immunization overall. Each webinar will offer perspectives from experts in immunization, vaccine safety, vaccine acceptance, and social media.

Please register for one or more of the webinars listed below and share this announcement with your colleagues and partners.

- **Vaccine Hesitancy, Public Health, and Evidence Based Research**
  January 8 - 10:00 a.m. CT
  Presented by Seth Mnookin
  Webinar registration site

- **To Engage or Not to Engage: That is the question for social media comments**
  January 14 - 3:00 p.m. CT
  Presented by Julie Leask, PhD, MPH
  Webinar registration site

- **But I saw it on the internet! Addressing safety concerns that have gone viral**
  January 22 - 10:00 a.m. CT
  Presented by Cindy Weinbaum, MD, MPH and Melinda Wharton, MD, MPH
  Webinar registration site

- **Harnessing Enthusiasm: Real world examples of engaging partners in social media discussions**
  January 29 - 10:00 a.m. CT
  Presented by Karen Ernst and Christine Vara
  Webinar registration site

WEBINAR: Addressing Myths + Concerns About Contraceptive Method Risk

CFHC

DATE: January 25

TIME: 12:00 – 1:00 PM PST

Learn how to use a client-centered approach when discussing contraceptive safety and risk - both real and perceived - during a patient visit. Participants will learn how to differentiate between side effects and health risks and compare contraceptive risks to other life risks.

Course Fee: $40
(Includes FREE CEUs for CME, Nursing, CHES, Social Work)

For more information and to register: Click here

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