California Stories

New app to deliver HIV prevention meds without a doctor’s visit

Marisa Kendall, San Jose Mercury News | 3.29

[STD Update] FYI 3-30: New app to deliver HIV prevention meds without a doctor’s visit, First confirmed case of Zika acquired through sexual transmission in CA, Follow up studies on HIV-prevention vaginal ring announced, 5 papers, 1 webinar, more.

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It would have been unthinkable three decades ago, when San Francisco was in the grip of the AIDS epidemic and the city's gay community was living in terror of the mysterious, deadly virus. But now, preventing HIV may be as simple as pushing a few buttons on a smartphone.

That's the goal of San Francisco startup Nurx. On Tuesday the company rolled out an online service that allows healthy people to order a three-month supply of HIV prevention drugs called PrEP delivered to their door within 24 hours -- no visit to a doctor's office required.

Dr. Bradley Hare, director of HIV Care and Prevention at Kaiser Permanente San Francisco, said such a delivery service could increase patient access to the important medication.

"I think no one would try to argue in San Francisco that we've been able to get everyone on PrEP who should be on PrEP," he said.

Taken daily, pre-exposure prophylaxis or PrEP, medication can reduce a patient’s chance of contracting HIV by more than 90 percent. PrEP use already is so common among gay men in San Francisco that some list it on their online dating profiles, but Nurx's founders say many people who should be on the regimen still face obstacles when trying to get a prescription. Some primary care doctors don't know about PrEP or view it with suspicion, said Nurx co-founder and CEO Hans Gangeskar, and local clinics that offer the regimen are overcrowded.

"The current health care system has failed to get PrEP to the people who need it," Gangeskar said.

Nurx has been offering on-demand delivery of birth control pills in California since mid-December, and recently expanded to New York. The company also delivers emergency contraception.

Supporters say by eliminating time-consuming and potentially embarrassing face-to-face doctors visits for PrEP, Nurx may prompt more at-risk people to protect themselves from HIV. And as the rate of HIV diagnoses continues on a downward trend in San Francisco, Nurx could help bring the city one step closer to stopping new cases. But the service also raises the question of whether doctors can adequately treat patients they don't see.

"It's not a replacement for a visit," said Dr. Wanda Filer, president of the American Academy of Family Physicians, and a practicing physician in Pennsylvania. Filer supports getting patients access to PrEP as soon as possible, but says a prescription should be followed up with an in-person doctor visit -- which is not a requirement of Nurx.

"It's important that they have someone that they feel they have a medical relationship with," Filer said. She added an in-person visit lets the patient ask questions, and allows the doctor to provide information about vaccines, safe sex and healthy relationships.

PrEP also can have serious side effects, including kidney failure, and doctors recommend regularly monitoring users' kidney function and testing for HIV and other STDs.

Nurx was founded by Gangeskar and A. Edvard Engesaeth, former high school classmates from Oslo, Norway. Gangeskar has a legal background and used to practice intellectual property law in Washington, D.C. Engesaeth trained as a doctor in Norway. The team secured $120,000 in seed funding from
Mountain View incubator Y Combinator in November and also has some angel investors, Gangeskar said, but declined to disclose the total sum the company has raised.

To order PrEP, a user will log on to the app, answer a handful of questions about his or her sexual history and health, and visit a lab or community clinic for blood work to test for HIV, hepatitis and kidney problems. That information will be transmitted to a doctor, who may issue a prescription after evaluating the individual's health history. A Postmates courier or UberRush driver then steps in to deliver the pills to the patient's door.

For now, same-day service is available in San Francisco and the Peninsula, Gangeskar said, and only if users get their blood tests completed early in the day. In other parts of California, the pills will ship via the U.S. Postal Service. Nurx is hoping to further simplify the process by using mail-in blood test kits, or dispatching technicians to take blood samples at people's homes.

The doctor also has the option to contact patients via phone, video call or secure text message to ask additional questions and provide counseling.

Nurx usually charges about $15 for same-day delivery, Gangeskar said, but the cost depends on the distance traveled. Birth control and emergency contraception are free under the Affordable Care Act, and PrEP generally is covered by insurance.

Truvada, the drug that makes up the PrEP regimen, was approved by the U.S. Food and Drug Administration in 2012. In September, Kaiser Permanente reported it found no new HIV infections among 657 San Francisco PrEP patients treated over two and a half years.

Steve Gibson, director of sexual health services for the San Francisco AIDS Foundation, said it's not always easy to get a prescription.

"It was shocking to me to have people walk into the clinic here in the Castro and say, 'my doctor in San Francisco didn't know about it,'" Gibson said. "Or 'my doctor in San Francisco said no because my boyfriend's HIV negative. Or my doctor said no because he thinks I'm going to stop using condoms.'"

So patients flock to Strut, the foundation's sexual health clinic for gay, bisexual and transgender men. They come from the South and East Bay, as well as from all corners of San Francisco. It's not unusual to see 20 or 30 people waiting outside before the clinic opens, Gibson said, and there's a monthlong wait to book a PrEP appointment.

But not everyone wants front-door delivery.

PrEP user Phillip Babcock, a 50-year-old Castro resident, said he doesn't feel the need to disrupt his prescription refill experience.

"I'm not part of the new economy as much," he said, "so I'm not used to having everything delivered to my house."

View the story online: [Click here](#)
A San Francisco startup described as an “Uber for birth control” is expanding its services to offer Truvada for PrEP, a daily pill that has been shown to be more than 90% effective in reducing HIV infection from sex.

From Tuesday, Nurx will allow patients in California to obtain a prescription for PrEP (which stands for pre-exposure prophylaxis) through a mobile app without having to see a doctor.

“It’s really difficult for people who want PrEP to get PrEP,” said Hans Gangeskar, one of Nurx’s co-founder. He cited stigma and a lack of information as a reason for the lack of widespread adoption of PrEP, as well as a shortage of doctors who will prescribe the drug.

Nurx’s streamlines the process by allowing patients to request a prescription and fill out a health survey through the app. The information is then reviewed by a doctor, remotely, who will decide whether or not the patient is a good candidate for PrEP.

A patient must complete blood tests for HIV and renal function prior to receiving his prescription. But Nurx is experimenting with sending a phlebotomist in an Uber to the patient’s home to draw their blood, making the process as quick and easy as possible.

Gangeskar said: “PrEP has been available for three years, and the CDC [Center for Disease Control] says people should be taking it, but they aren’t.”

In November, the CDC issued a report finding that more than 1.2 million people in the US should be taking PrEP, whereas only about 21,000 people are currently taking it. The CDC recommends PrEP for people at “very high risk” of HIV infection, which includes about one in four men who have sex with men, one in five adults who inject drugs, and one in 200 sexually active heterosexual adults.

Ganeskar says the company has focused on PrEP and birth control because “these are both failures of the current healthcare system”: medications that are not as widely available as they should be to the populations who need them. According to the CDC, a third of primary care doctors and nurses have never even heard about PrEP.

Nurx’s doctors can communicate with patients, either by phone or text, but Gangeskar says that reducing the human interaction between doctor and patient can actually improve the standard of care, because people are more honest if they don’t feel judged.

“People have concerns about going to the doctor and talking about anal sex or having to justify not using condoms,” he said. “You’re able to ask questions that you wouldn’t ask face to face.”

Robert Grant, a professor of medicine at the University of California, San Francisco, who led the first clinical train for HIV PrEP, signed on as a volunteer adviser to Nurx when he learned about the startup. “I like that Nurx makes PrEP available to people who may be afraid of doctors or may be afraid of the
judgment that they’ve experienced from doctors,” he said. “We need to work to make medical services as friendly as possible and try to eliminate the shaming that comes with going to the doctor.”

View the story online: [Click here](#)

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**Public Health Reports First Confirmed Zika Virus Case Acquired Through Sexual Transmission in California**

Press Release, CDPH | 3.25

California Department of Public Health (CDPH) Director and State Public Health Officer Dr. Karen Smith today announced the first confirmed case of Zika virus acquired in California. This case involves transmission of Zika virus through sexual contact with a Zika infected partner who returned from a country where Zika virus was circulating, not from a mosquito bite. The woman who was infected was not pregnant and had not traveled out of the country. She and her partner have fully recovered.

“This is the first confirmed case in California where Zika virus was transmitted sexually,” said Dr. Smith. “If your partner has traveled to an area where Zika is present, protecting yourself by abstaining from sex or using condoms during sex is the best way to prevent sexual transmission of the Zika virus.”

A man infected with Zika virus can spread it to his sexual partners. It is not known how long after infection a man can spread Zika virus to sexual partners. At this time, there is no evidence that women can transmit Zika virus to their sexual partners.

CDPH recommends that if men have traveled to an area where Zika virus is circulating, they abstain from sex or diligently use condoms with a partner who is pregnant or trying to become pregnant for the duration of the pregnancy. These cautions apply to vaginal, anal or oral sex.

Women who want to get pregnant, whose partner has had exposure to Zika virus, should discuss with their health care provider any potential risk of Zika virus during pregnancy. The virus can spread from a woman to her child during pregnancy and the infection is believed to lead to neurologic complications in the infant, including microcephaly, which is a birth defect in which the baby is born with a smaller-than-normal head due to abnormal brain development.

Most people infected with Zika virus will not develop symptoms. If symptoms do develop, they are usually mild and include fever, rash, joint pain and eye redness. If you have returned from an affected country and you have fever with rash, joint pain, and eye redness within two weeks, or any other symptoms following your return, please contact your medical provider and tell the doctor where you have traveled. While there is no specific treatment for Zika virus disease, the best recommendations are supportive care, rest, fluids and medications for relief of fever.

Zika virus is primarily transmitted to people by mosquitoes known as Aedes aegypti (yellow fever mosquito) and Aedes albopictus (Asian tiger mosquito), which are the same type of mosquitoes that transmit dengue and chikungunya viruses. These types of mosquitoes have been detected in 12 California counties. To date, there have been 22 travel-associated cases of Zika virus reported in California in 2015-2016. There has been no local mosquito-borne transmission of Zika virus in California.
People who are traveling to areas with known Zika virus risk should take steps to avoid being bitten by mosquitoes, including:

- Use insect repellents containing DEET, picaridin, IR3535, oil of lemon eucalyptus or para-menthane-diol for long-lasting protection. If you use sunscreen and insect repellent, apply the sunscreen first and then the repellent. Pregnant women and women who are breastfeeding should choose an EPA-registered insect repellent and use it according to the product label.
- Wear long-sleeved shirts and long pants.
- Use air conditioning or window/door screens to keep mosquitoes outside. If you are not able to protect yourself from mosquitoes indoors, sleep under a mosquito bed net.
- Help reduce the number of mosquitoes outside by emptying standing water from containers, such as flowerpots or buckets.

For more information on Zika virus disease and other mosquito-borne illnesses, please visit the CDPH Zika virus information Web page.

View the story online: Click here

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**National Stories**

**PrEP's Arrival in San Francisco Coincided With Accelerated Increase in Sexual Risk Taking in Gay and Bi Men**

As reported by POZ | 3.18

The recent upswing in use of Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in San Francisco coincided with an acceleration in the already increasing rates of sexual risk taking and sexually transmitted infections (STIs) among this population. Whether PrEP’s uptake among local men has in fact influenced the change in these rates, however, remains unclear.

Publishing their findings in AIDS and Behavior, researchers analyzed data on HIV-negative men who have sex with men (MSM) in San Francisco from the National HIV Behavioral Surveillance (NHBS) study, which is conducted every three years in major U.S. cities. The study found that, overall, condom use has fallen in recent years among MSM across the country, but that use of condoms varies based on context.


None of the men reported any PrEP use until 2014, when 9.6 percent reported using Truvada for prevention.

The proportion of men who reported consistent condom use declined by more than half between 2004 and 2014, with an accelerated decline—a 40 percent drop—between 2011 and 2014, a period that overlaps with the uptake of PrEP among local MSM. The rates of consistent condom use were a respective 36.8 percent, 30.5 percent, 30.5 percent and 18.3 percent in 2004, 2008, 2011 and 2014. The
The proportion of men reporting no condomless anal sex partners was a respective 60.6 percent, 58.2 percent, 54.2 percent and 40.2 percent in those years.

The proportion of those who reported practicing what is known as pure serosorting, or having condomless anal sex with partners they presume are HIV-negative, increased sharply between 2011 and 2014.

The rate of those reporting multiple condomless anal sex partners more than doubled from 2004 to 2014.

San Francisco surveillance data shows that STI rates have increased among local MSM since 2004, and that the rates saw sharp increases in recent years.

San Francisco men at higher risk for HIV appear more likely to use PrEP. While 25.2 percent of non-PrEP-using men in 2014 said they were consistent condom users, only 10 percent of PrEP users said they always used condoms.

In 2014, 28.6 percent of the men with no harm reduction strategy for averting HIV were taking PrEP. Such strategies include not having anal intercourse; using condoms consistently; pure serosorting; condom serosorting, which means having at least one partner of unknown HIV status or who is HIV positive, while only having condomless sex with men presumed to be HIV negative; and seropositioning, in which men refrain from being the bottom, or receptive partner, with men in certain scenarios. The researchers argue that ideally all men with no prevention strategy should be taking PrEP, since they are likely at the highest risk for contracting the virus.

The researchers theorized that PrEP’s introduction may affect condom use rates among those not taking Truvada: Some MSM may have stopped using condoms consistently under the assumption that other men are taking PrEP.

View the story online: [Click here](#)

**HOPE for the Vaginal Ring: Follow-Up Studies on New HIV-Prevention Method for Women Announced**

Heather Boerner, The Body PRO | 3.25

More than 300 members of the Microbicide Trials Network (MTN) were gathered in a hotel conference room in Rockville, Maryland, earlier this month and, somewhat unexpectedly, the assembled scientists had something to celebrate. On March 13, four days after the National Institutes of Health (NIH) convened a stakeholder meeting of African women, researchers, advocates and statisticians, it announced that it would indeed fund follow-up studies to the ASPIRE dapivirine (TMC120) antiretroviral ring trial.

The results of ASPIRE and its sister trial, The Ring Study, were released during CROI 2016 at the end of February. Then, this month the NIH held its meeting. When Sharon Hillier, Ph.D., one of ASPIRE’s principal investigators, announced the results to MTN staff, "people literally cheered -- they just stood up and cheered," she said.
That's because, after many attempts and several disappointing trial results, this was one of the few microbicide trials -- and one of the fewer designed specifically for women -- to move on to open-label extension trials and potentially lead to availability for those women who need HIV prevention most.

"Everyone is so anxious to take this next step, to see -- can we realize the promise we think we have [with the ring]? And can we build on this to do even better?" she said. "No one is happy with 27% [overall effectiveness rate]. And we think we can do better than 27%.

ASPIRE and HOPE

When ASPIRE’s results came out at CROI 2016 last month for the dapivirine ring, the 27% reduction in HIV acquisition sounded modest to say the least.

But, when researchers parsed the data further, they discovered that efficacy went up with a woman's age. For women aged 21 and under, the ring provided no benefit. For women 21 to 25, effectiveness shot up to 56%. For women older than that, the rate was 61%.

That 61% was the foundation for moving forward with additional studies, said Anthony Fauci, M.D., director of the NIH's National Institute of Allergy and Infectious Disease.

"Everyone went in to the [NIH] meeting saying, 'We need to first examine the data -- is there really a pathway forward?'" he said. "It's clear there is, even though it's confusing when you look at the data. Twenty-seven percent is rather weak, but when you break it down by women older than 25 and women younger than 21, the 61 percent effectiveness is good enough to move forward. That's as good as circumcision in some respects."

Specifically, the NIH funded two follow up studies. One, ASPIRE's open-label extension trial, named HOPE, will seek to recreate the first study, but with some twists. Each of the 2,629 women in Malawi, South Africa, Zimbabwe and Uganda who participated in the original trial will be offered the dapivirine ring. The hope, said Fauci, is that if women know that they are getting a ring with active drug in it and that it's been proven to reduce HIV acquisition, then more women will use the ring, which may change overall protection rates. It's happened before.

However, the study will also tackle adherence another way: by asking the women to once again consent to the study, but this time also asking them candidly whether they're participating in the study because they really want to reduce their risk for HIV, or whether the study is the only way for them to get regular sexual and reproductive health care.

"By re-consenting them, we're saying, 'We get it,'" he said. "'So tell you what: Sign up for the study, but be honest, tell us if you have any intention or not of using the ring.' So then they'll be able to separate out the people who are really using it from those who aren't."

Study participants who say they don't intend to use the ring will still receive health care, but their intention not to adhere will be factored into results.

Then, the study will check in with participants every month for three months, changing out the ring and checking how much less dapivirine is in it after 30 days than when it was distributed -- a sign that
participants have actually used it. The idea is to remove the incentive to lie to get health care and use drug levels to test for adherence.

Finally, the study will have a divided design: In those first three months, participants will come to the clinic every month to get a new ring. For the second three months, participants will be given a pack of three rings and be instructed to change the ring out themselves. Then, participants will be asked to bring back the rings, and total drug depletion will be measured.

"It's clever," Fauci said. "It will give [researchers] a chance to compare a clinical trial setting, where [women] are seen every month, versus a real-world setting, where we give them three rings. The bottom line is to figure out what role adherence plays in efficacy and what are the motives to participate."

Robust Discussion

Dazon Dixon Diallo, president and founder of SisterLove, Inc., and convener of the U.S. Women and PrEP (Pre-Exposure Prophylaxis) Working Group, was at the NIH meeting and described it as a robust discussion of both the science and women's reproductive health needs.

Unlike the VOICE trial, which was designed to test the ability of combination tenofovir/emtricitabine (Truvada) to prevent HIV in women, but was stopped early due to lack of adherence, there was no effort to blame participants for not using the drug. The question was, "How do we design these trials in a way that does not design it to fit the research, but is also meant to fit into women's lives?"

"It was not about blaming them," Dixon Diallo said. "It was really looking at the full implications of a large clinical trial like this, and how nimble can it be to really understand and shift as needed to make sure that the trial itself is fitting into women's lives in such a way that makes them want to be more adherent and to participate."

In particular, she pointed to the comment of one 18-year-old participant, who had asked the ages of the counselors who worked with women during the trials. The implication, said Dixon Diallo, was that mixing peer support and relatable staff could improve social connections and change how younger women, especially, perceive the trials.

For her part, Hillier said that the NIH's decision to fund the studies was not just a win for ASPIRE, but also for the technology in general, which will receive follow up separately in The Ring Study.

"With these two positive results in two separate studies, if [the NIH] didn't move forward, it was really closing the book on this kind of research," Hillier said. But now, she said, everyone on the team is excited about next steps. "We're feeling like we have a ton of work to do, but we're really excited we get to do it."

View the story online: Click here

CDC Revises Sex Advice on Zika
More precautions urged
John Gever, MedPage Today | 3.25
Couples in which one partner may have been exposed to Zika virus should be even more careful than previously recommended about exposing each other and unborn children to the virus, the CDC said Friday.

Men with potential exposure -- because of travel to or residence in an active outbreak area -- should not engage in unprotected sex for at least 8 weeks after the exposure ends. Consequently, for couples residing in outbreak areas, couples should either use condoms or abstain completely from sex, the agency recommended.

Advice to use condoms or abstain from sex also applies to currently pregnant women with potential Zika exposure.

The CDC also recommended that healthcare providers caring for women who might become pregnant and may face Zika exposure counsel them on tactics for avoiding sexual exposures. They include:

- For women living in areas not affected by outbreaks and without symptoms but who might have been exposed, they should wait at least 8 weeks after the potential exposure to attempt conception;
- Women’s personal exposure can include having visited an outbreak area or having unprotected sex with a potentially exposed man within the past 6 months; and
- Women with a diagnosis of Zika infection should wait 8 weeks after symptom onset to attempt conception.

The CDC acknowledged that understanding of Zika virus is still evolving. These time periods are based on the best current information, the agency said, but could still change as more is learned.

Another concern raised by the CDC Friday was access to contraception in Puerto Rico, which is bracing for a surge in cases as mosquito season advances. The CDC estimated that 138,000 women of reproductive age in the island territory do not wish to become pregnant and are not using a contraceptive known to be effective.

"CDC and other federal and local partners are seeking to expand access to contraception for these persons," the agency said.

Among the estimated 1-year needs: 68,000 IUDs, 77,000 long-acting hormonal products, 36,000 contraceptive patches, 108,000 vaginal rings, and 168,000 oral contraceptives.

View the story online: [Click here](#)

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**Gene therapy snips HIV out of infected cells and makes uninfected cells resistant**

*First proof-of-concept of ‘targeting and editing’ approach to prevention and cure*

Gus Cairns, aidsmap | 3.30

For the first time, researchers have used a gene-editing technique already used to produce cells resistant to HIV infection to target HIV-infected cells. They have managed to remove HIV genes completely from infected cells, as shown by reductions in the cells' overall rate of HIV production. In
cells not already infected, the therapy has itself become part of their genome, producing cells that are resistant to infection for a prolonged period.

The therapy produced significant reductions in the ability of CD4 cells to be infected with HIV and to produce it. It produced positive results in a laboratory-generated CD4-cell analogue and in actual CD4 cells, both HIV-uninfected ones grown in the laboratory, and HIV-infected ones taken from four patients with HIV.

This gene-editing technique has so far only been used on cells in the laboratory dish, but this study takes us one step closer to a therapy that could be administered as an injection and work within the body.

**Background**

HIV is very difficult to cure because, as a retrovirus, it inserts its DNA – its genes, the ‘instructions’ for making more HIV – into our own DNA inside the cells of our immune system. The HIV infection within cells that are not actively producing HIV is invisible to the part of the immune system that would normally destroy virally-infected cells. It persists even when people take HIV treatment, and even on treatment, a smouldering infection continues from one cell to another that maintains the size of this so-called 'reservoir'.

Several ways of eliminating the viral reservoir have been suggested by scientists. The one most advanced in research has been the ‘shock and kill’ strategy; this involves using HDAC inhibitors, immune-stimulant drugs that reactivate the reservoir cells, making them visible to the immune system. There are several problems with this strategy; only a small proportion of all HIV-infected reservoir cells are activated and to activate more, a damaging amount of stimulus to the whole immune system might be required; the natural immune response does not seem to be strong enough to destroy the cells even when they are activated; and any reactivation runs the risk of setting off a renewed cycle of HIV infection that only ‘re-seeds’ the cellular reservoir.

Another method in early research is to do the opposite and try to maintain the immune system in a permanent state of lockdown, using PD-1 inhibitors, drugs that stall the development and maturation of immune cells. Until recently, however, it was thought these might have to be taken as a regular therapy and therefore could not be a cure, although one study suggested it might be possible to induce reservoir cells into a state of permanent quiescence with a novel tat inhibitor drug.

The third method, a therapy that actively penetrates the immune system and removes the HIV content of infected cells, has always been one of the most promising ideas but has appeared very technically difficult. It would need to be both highly specific (i.e. it only removes HIV material and not human genes) and highly sensitive (i.e. it is able to detect a high proportion of infected cells). With this current research, scientists have moved closer to developing such a specific and sensitive therapy.

**This study**

The scientists in this study used a genetic ‘missile’ that combined two different modules. The first is a probe consisting of two pieces of so-called ‘guide RNA’ (gRNA). Their job is to sensitively detect and home in on the two ends of the HIV genome, the so-called long terminal repeats (LTRs) that act as the viral genome’s ‘frame’.
The second is a nuclease, an enzyme called Cas9 that removes the viral genetic material and rejoins the two cut ends of the human DNA together. In the process, it adds some ‘filler’ DNA of its own.

Cas9 is a development of CRISPR, an enzyme already used in another HIV cure approach, to extract and ‘re-engineer’ CD4 cells outside the body to make them immune to HIV and then re-introduce them; continued research into this strategy is also underway, though so far it has proved difficult to turn the HIV-resistant cells into the majority of immune cells once they are re-introduced.

The present team used a lentiviral vector – the shell of a virus of the same family as HIV, containing the gRNA/Cas9 as a ring or plasmid of nucleic acid – to infect T-lymphocyte cells (of which CD4 cells are a subset) in the test tube.

In the first set of experiments they used 2D10 cells, laboratory-created immune cells containing a specially engineered ‘fake’ HIV genetic sequence consisting of the HIV genome with most of its replication genes removed and a fluorescence gene inserted. These cells therefore, instead of HIV viral particles, spit out green fluorescent protein (GFP) when stimulated, which shows up in microphotographs.

The 2D10 cells were infected with the vector and then stimulated with an HDAC inhibitor to see if they expressed GFP. Cells infected only with the Cas9 nuclease produced one unit of GFP unstimulated but 94 units of GFP when stimulated, while ones infected with the full gRNA/Cas9 probe produced less than one unit of GFP whether stimulated or not.

One of the issues with HIV infection is that the virus inserts its genome at random into the human genome, wherever it will fit, though some sites are more likely than others. Genetic analysis of cells used in the study found a complete HIV genome, consisting of 6130 base pairs (units of the DNA chain) on chromosome 1 of the cell's 23 chromosomes, and a near-complete genome of 5467 base pairs in chromosome 16. In the gRNA/Cas9-treated cells, these had been replaced by smaller DNA ‘fillers' consisting of 909 and 759 base pairs respectively.

These ‘fillers’ were not just inactive DNA: they acted as genes and actively expressed the gRNA and cas9 nucleic acid sequences.

The researchers then investigated whether the infection of the cells by the gRNA/Cas9 vector had any adverse effects on other genes in chromosomes 1 and 16 and on cellular health in general. They found no indication of significant mutations in other genes, or in the viability or lifespan of cells.

They next looked at whether it was possible to infect T-cells with HIV if they had already been infected with the gRNA/cas9 vector. They infected HIV-negative T-cells with the vector, and selected four clonal lines of T-cells. One line produced gRNA but not cas9, one cas9 but not gRNA, and two both, one of which expressed more cas9 than the other.

When these cells were cultivated with HIV, the cells expressing either gRNA or cas9 could be infected, with 20-50% infected in the lab dish, but cells expressing both were more resistant to infection, with 3-4% of cells with the lower level of cas9 infected and only 1% of cells with the higher level.

Two different strains of HIV were in fact used. With one the reduction in infections in cells expressing both gRNA and cas9 was 48%; but with the other strain the reduction was 100% and no HIV replication
was seen at all. The researchers found that the expression of the gRNA and cas9 products by cells diminished over time and eventually disappeared, but that as long as they were integrated within the cell, the cells were protected from infection.

The researchers then looked at the ability of the gRNA/cas9 vector to suppress replication in cells taken from people with HIV. They took T-cells from four patients who were all on antiretroviral therapy (ART) but had different responses: case one had a low viral load and high CD4 count but a low CD4 percentage (11%); cases two and three had undetectable viral loads and high CD4 counts, and case four a low but detectable viral load and a low CD4 count (53 cells/mm3).

Their CD4 cells were cultured in the test tube without ART and with the gRNA/cas9 vector. Four days after the vector was introduced, they tested lab dish fluid and individual cells for HIV viral loads. Cells cultured with the gRNA/cas9 vector had lower levels of the p24 HIV protein (71, 62, 39 and 54% less than control cells from the ofur patients respectively); cases one and two also had levels of the HIV gag protein measured too and this decreased by 92% and 56% respectively.

Implications and next steps

This is the first study to show that a combined HIV gene locator and remover removed HIV genes and repaired the genome of cells infected with HIV; inhibited HIV infection in treated laboratory cells; and reduced viral production by infected cells cells taken from people with HIV. It also shows that this gene therapy is safe and does not affect non-viral DNA.

Clearly not all HIV-infected cells were repaired, or completely repaired, by the gRNA/cas9 therapy, as although infection and replication was reduced, only in one case was it stopped completely. This may mean that the therapy did not get into all cells, but it may also mean that it did efficiently infect cells but may not have removed and replaced the DNA in different individuals exactly as predicted, and residual viral DNA may have been left.

The researchers also found that in cells taken from patients, the exact sequences removed and replaced in the DNA did not always match their expectations, showing that genetic variations between individuals and viral strains may influence the function and effect of the therapy. This suggests it may have to be individualised to match people’s genetic makeup.

This study looked at the effect of the gRNA/cas9 therapy on cells taken off antiretroviral therapy, in order to measure reductions in viral production. But given that the primary interest is to see if it can alter the genome and reduce the amount of HIV in non-productive reservoir cells, the researchers say that their next step will be to see if the gRNA/cas9 therapy directly reduces the amount of HIV DNA in cells treated with ART, taken from both ART-treated and drug-naïve patients.

The study does show that a genetic ‘probe’ is capable of targeting a high proportion of HIV-infected cells and efficiently and safely snipping out the entire HIV genome without damaging surrounding DNA. In addition, it integrates into non-infected cells, rendering them resistant to infection.

But, as the researchers note, “some formidable challenges remain before this type of strategy can be implemented.” The biggest barrier will be HIV’s genetic diversity, which will require a variety of different gRNAs and CRISPR nucleases to be devised, possibly down to the level of personalising them
individually. And secondly, although clearly high levels of cells were infected by the therapy vector, significant levels of viral replication remained, showing that some cells remained unaffected.

Animal studies will be required before the therapy is introduced into humans. Given its mode of action, however, it may eventually be possible with this combined therapy to clear HIV out of infected cells and make non-infected cells resistant by means of an injection rather than by cultivating cells in a lab dish and then re-introducing them.

We are a long way from that yet. Nonetheless, this study shows that a technical feat which a few years ago might have been thought impossible – the removal of proviral HIV DNA from the midst of a human cell’s genome – can be done efficiently, safely, and with significant positive effects on HIV infection and replication.

Reference


View the story online: Click here

How sperm are activated

As reported by NIH News | 3.29

Many different factors can affect a couple’s ability to conceive. Fertility issues can arise for men if there are problems with the number, shape, or movement of sperm. These glitches can make it hard for the sperm to fertilize an egg.

Once inside the female reproductive tract, sperm use their tail-like appendages to swim for the egg. A chemical signal around the egg called progesterone boosts the sperm’s movements into a “hypermotile” state. Tail movements become stronger and able to generate more swimming force. Sperm need this surge in activity to penetrate the tough outer layer of an egg.

To understand how this heightened activity is turned on, a team led by Dr. Polina V. Lishko at the University of California, Berkeley, searched for the sperm molecule that detects the egg’s chemical signal. The study was funded in part by NIH’s Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). Results were published online on March 17, 2016, in Science.

After the sperm detects progesterone, calcium rushes in through the tail’s outer membrane. A protein called CatSper sits in the membrane and acts as a gateway for calcium. The scientists investigated whether progesterone works directly through CatSper or if it opens the channel by working through another molecule. They measured CatSper activity in sperm cells treated with a drug that shuts down a class of enzymes they believed might be responsible for progesterone effects: metabolic serine hydrolases (mSH), which play a role in signaling pathways within lipid membranes.
Their hunch proved correct: the treated cells didn’t show progesterone-induced CatSper activity or change sperm motility. But the treatment didn’t affect baseline CatSper activity. The results suggested that progesterone works with a partner to open the way for calcium.

The group then searched for candidate partner proteins. They zeroed in on alpha/beta hydrolase domain-containing protein 2 (ABHD2). When the researchers blocked ABHD2 activity using specific antibodies, progesterone-induced CatSper activity and calcium entry decreased. The result confirmed that ABHD2 is the molecular target for progesterone.

The group showed that when progesterone is present, ABHD2 degrades endocannabinoid molecules in the plasma membrane. These keep CatSper closed, so their removal causes calcium to rush in and activate sperm.

“This is an important advance in explaining how sperm become hypermotile in the female reproductive tract,” explains Dr. Stuart Moss, director of the male reproductive health program at NICHD.

These findings may lead to new approaches for male contraception and treatments for infertility that result from problems with sperm mobility.

**Journal Reference:**
Unconventional endocannabinoid signaling governs sperm activation via sex hormone progesterone.

View the story online: [Click here](#)
circumstances, but the recent defunding bills prohibit state money for any services by an organization that also provides abortions.

During debate in Florida, state Sen. Aaron Bean offered this rationale: "We pay their light bill, we pay their salaries, we pay all kinds of things when the state contracts with these clinics... Let's get Florida out of the abortion business."

Many of the measures surfaced after anti-abortion activists began releasing secretly recorded videos last July alleging that Planned Parenthood sold fetal tissue to researchers for a profit in violation of federal law. Planned Parenthood denied any wrongdoing, and investigations by several congressional panels and states have produced no evidence that it acted illegally.

Despite that, some Republican governors and lawmakers have cited the videos as justification for defunding.

States where defunding has been blocked by litigation include Alabama, Louisiana and Utah. In some other states, the impact of defunding may be slight — Mississippi, for example, is pursuing that step even though Planned Parenthood received less than $1,000 in state money in each of the past five years.

However, Planned Parenthood says the cuts have had tangible impact in several states. It cites Indiana, saying funding cuts led to closure of a Planned Parenthood clinic that was the only HIV testing center in Scott County — the subsequent site of an HIV epidemic.

A look at some other states where defunding has had an impact:

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TEXAS

Texas was one of the first states to target Planned Parenthood’s funding, saying it would not send Medicaid funds to organizations that provided abortions. The Republican-led state government culminated a multiyear effort by ousting Planned Parenthood from the Texas Women's Health Program in 2013 and opting to fund the program entirely with state money so it would not run afoul of federal law.

Dr. Paul Fine, medical director of Planned Parenthood Gulf Coast, said the move affected health screenings and contraceptive services for more than 13,000 low-income women, many of them in areas with limited health care alternatives.

Charitable donations covered some of the lost funding, Fine said, but overall Planned Parenthood has seen a shift to more patients paying in cash or relying on commercial health insurance.

John Seago, legislative director of Texas Right To Life, acknowledged there was a dip in the number of women served after Planned Parenthood was defunded. However, he said Texas has made progress in rebuilding a network of facilities that provide women's health care, with more providers now than in 2010.
Seago said he's encouraged that numerous other states have sought to defund Planned Parenthood, but noted that some have struggled with their tactics.

"Defunding Planned Parenthood is not an easy public policy goal," he said. "There are limits on what states can do. Some states have crossed that line and made mistakes."

In February, a study in the New England Journal of Medicine asserted that fewer women in Texas had obtained long-acting birth control after Planned Parenthood was ousted from the health program.

The study fueled a backlash. State Sen. Jane Nelson called it biased and misleading, and one of the co-authors left his job with the Texas Health and Human Services Commission after incurring criticism for his role.

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WISCONSIN

In Wisconsin, Planned Parenthood has been the target of defunding efforts since Republican Gov. Scott Walker took office in 2011. Walker signed a bill that year eliminating all state funding for Planned Parenthood health centers, contributing to the closure of five rural clinics.

In February, Walker signed two bills that together are expected to cost Planned Parenthood $8 million per year in federal funds — including $3.5 million for family planning. The bills require state health officials to seek federal funding in the future on behalf of "less controversial providers."

Nicole Safar, government relations director for Planned Parenthood of Wisconsin, said her organization has not yet decided whether to challenge the bills in court.

If the cutbacks do take effect, Safar said, they would affect low-income women "who don't have anywhere else to go."

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OHIO

Amid his presidential campaign, Ohio's GOP Gov. John Kasich signed a bill in February designed to strip about $1.3 million in government money from the state's Planned Parenthood affiliates. The funds, mostly federal, have supported HIV testing, promoted teen pregnancy prevention, and assisted nearly 2,800 new or expectant mothers last year.

Diego Espino, a vice president of Planned Parenthood of Greater Ohio, said the cut would not force the organization to close any of its 28 health centers in the state.

"We're not going away," he said. "But this will deprive thousands of women of very essential services."

Stephanie Ranade Krider, who advocated for the funding cuts as executive director of Ohio Right to Life, said the political message was more important that the amount of the cutback.
"When we look at the whole picture, it's like a drop in the bucket," she said. "The public relations impact is much more significant — it makes a statement that Ohio will no longer be doing business with the abortion industry."

View the story online: [Click here]

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**Scientific Papers/Conference Abstracts**

**PrEP as Peri-conception HIV Prevention for Women and Men**

**Abstract:**
Daily oral tenofovir (TDF)-based pre-exposure prophylaxis (PrEP) is an effective HIV prevention strategy and recommended for men and women with substantial risk of HIV acquisition. The peri-conception period, the stage prior to pregnancy when condom use is necessarily reduced, has elevated HIV risk that can be mitigated by PrEP use. Data from a randomized trial suggest that peri-conception PrEP use by HIV-seronegative women does not increase the risk of pregnancy loss, birth defects or congenital anomalies, preterm birth, or infant growth faltering. Women considering PrEP use throughout pregnancy must weigh the known increased risk of HIV acquisition with unknown risks of drug effects on infant growth. PrEP has been used safely by HIV-seronegative men with HIV-seropositive female partners who have become pregnant. As an effective user-controlled HIV prevention strategy, PrEP offers autonomy and empowerment for HIV prevention and can be recommended alongside antiretroviral therapy, fertility screening, vaginal self-insemination, intercourse timed to peak fertility, medically assisted reproduction, and other safer conception strategies to provide multiple options. The integration of PrEP into safer conception programs is warranted and will safely reduce HIV transmission to women, men, and children during the peri-conception period.

View the paper online: [Abstract]

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**Background:**
Eliminating mother-to-child transmission (MTCT) of HIV has been one of New York State's public health priorities, and the goal has been virtually accomplished by meeting criteria established by the Centers for Disease Control and Prevention.

**Methods:**
We use a return on investment (ROI) approach, from the perspective of the state, to compare expenditures incurred to prevent MTCT of HIV in NYS during the period 1998–2013 to benefits realized, as expressed as HIV treatment costs saved from averting an estimated number of HIV infections among newborns. Extrapolating from the 11.5% incidence rate of HIV-infected newborns in 1997, we projected
the number of cases of MTCT of HIV that were averted over the 16-year period. A published estimate of lifetime HIV treatment costs was used to estimate HIV treatment costs saved from the averted infections; expenditures for clinical protocols and other services directly associated with preventing MTCT of HIV were also estimated. The ROI was then calculated by dividing program benefits by the expenditures incurred to achieve these benefits.

**Results:**
We estimate that 898 cases of MTCT of HIV were averted between 1998 and 2013, resulting in a savings of $321.03 million in HIV treatment costs. Expenditures to achieve these benefits totaled $81.07 million, yielding an ROI of $3.96.

**Conclusions:**
Aside from the human suffering from MTCT of HIV that is averted, expenditures for treatment protocols and interventions to prevent MTCT of HIV are relatively inexpensive and can result in almost 4 times their value in HIV treatment cost savings realized.

**View the paper online:** Abstract

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**Clear Links Between Starting Methamphetamine and Increasing Sexual Risk Behavior: A Cohort Study Among Men Who Have Sex With Men**

**Background:**
It remains unclear if methamphetamine is merely associated with high-risk behavior or if methamphetamine use causes high-risk behavior. Determining this would require a randomized controlled trial, which is clearly not ethical. A possible surrogate would be to investigate individuals before and after starting the use of methamphetamine.

**Methods:**
We performed a cohort study to analyze recent self-reported methamphetamine use and sexual risk behavior among 8905 men who have sex with men (MSM) receiving the “Early Test,” a community-based HIV screening program in San Diego, CA, between April 2008 and July 2014 (total 17,272 testing encounters). Sexual risk behavior was evaluated using a previously published risk behavior score [San Diego Early Test (SDET) score] that predicts risk of HIV acquisition.

**Results:**
Methamphetamine use during the last 12 months (hereafter, recent-meth) was reported by 754/8905 unique MSM (8.5%). SDET scores were significantly higher in the 754 MSM with recent-meth use compared with the 5922 MSM who reported that they have never used methamphetamine (P < 0.001). Eighty-two repeat testers initiated methamphetamine between testing encounter, with significantly higher SDET scores after starting methamphetamine [median 5 (interquartile range, 2–7) at recent-meth versus median 3 (interquartile range, 0–5) at never-meth; P < 0.001, respectively].

**Conclusions:**
Given the ethical impossibility of conducting a randomized controlled trial, the results presented here provide the strongest evidence yet that initiation of methamphetamine use increases sexual risk behavior among HIV-uninfected MSM. Until more effective prevention or treatment interventions are
available for methamphetamine users, HIV-uninfected MSM who use methamphetamine may represent ideal candidates for alternative effective prevention interventions (ie, preexposure prophylaxis).

View the paper online: Abstract

Correlates of recent HIV testing among substance-using men who have sex with men

Abstract:
Men who have sex with men are disproportionately impacted by HIV and substance use is a key driver of HIV risk and transmission among this population. We conducted a cross-sectional survey of 3242 HIV-negative substance-using men who have sex with men aged 18 + in the San Francisco Bay Area from March 2009 to May 2012. Demographic characteristics and sexual risk and substance use behaviors in the last six months were collected using structured telephone questionnaires. We used multivariable logistic regression to identify independent demographic and behavioral predictors of recent HIV testing. In all, 65% reported having an HIV test in the last six months. In multivariable analysis, increasing age (aOR = 0.87, 95% CI = 0.84–0.90) and drinking alcohol (<1 drink/day: 0.65, 0.46–0.92; 2–3 drinks/day: 0.64, 0.45–0.91; 4 + drinks/day: 0.52, 0.35–0.78) were negatively associated with recent HIV testing. Having two or more condomless anal intercourse partners (2.17, 1.69–2.79) was positively associated with having a recent HIV test, whereas condomless anal intercourse with serodiscordant partners was not significantly associated with testing. Older men who have sex with men and those who drink alcohol may benefit from specific targeting in efforts to expand HIV testing. Inherently riskier discordant serostatus of partners is not as significant a motivator of HIV testing as condomless anal intercourse in general.

View the paper online: Abstract

Pre-Exposure Prophylaxis (PrEP) for Safer Conception Among Serodifferent Couples: Findings from Healthcare Providers Serving Patients with HIV in Seven US Cities

Abstract:
Pre-exposure prophylaxis (PrEP) can reduce the risk of HIV transmission among serodifferent couples trying to conceive, yet provider knowledge, attitudes, and experience utilizing PrEP for this purpose are largely unexamined. Trained interviewers conducted phone interviews with healthcare providers treating patients with HIV in seven cities (Atlanta, Baltimore, Houston, Kansas City, Newark, Philadelphia, and San Francisco, N = 85 total). Quantitative and qualitative data were analyzed to describe experience, concerns, and perceived barriers to prescribing PrEP for safer conception. Providers (67.1% female, 43 mean years of age, 70.4% white, 10 mean years treating HIV+ patients, 56% in academic vs. community facilities, 62.2% MD) discussed both benefits and concerns of PrEP for safer conception among serodifferent couples. Only 18.8% of providers reported experience prescribing PrEP, 74.2% were willing to prescribe it under ideal circumstances, and 7.0% were not comfortable prescribing PrEP. Benefits included added protection and a greater sense of control for the HIV-negative partner. Concerns were categorized as clinical, system-level, cost, or behavioral. Significant differences in
provider characteristics existed across sites, but experience with PrEP for safer conception did not, p = 0.14. Despite limited experience, most providers were open to recommending PrEP for safer conception as long as patients understood the range of concerns and could make informed decisions. Strategies to identify and link serodifferent couples to PrEP services and clinical guidance specific to PrEP for safer conception are needed.

View the paper online: Abstract

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**Resources, Webinars, & Announcements**

**HRSA Calling for Abstracts for 2016 National Ryan White Conference on HIV Care & Treatment**
Blog.aids.gov | 3.28

The Health Resources and Services Administration’s HIV/AIDS Bureau is calling for abstracts for the 2016 National Ryan White Conference on HIV Care and Treatment, which will take place August 23-26, 2016 in Washington, DC. This year’s theme is *Forward Momentum: Accelerating Access. Optimizing Care. Transforming Public Health.*

The 2016 National Conference brings together HIV clinical decision makers and key HIV service delivery providers working in Ryan White HIV/AIDS Program-supported settings from across the country, as well as HIV health care providers, stakeholders, and people living with HIV. In keeping with the conference theme, six session tracks will serve as the basis for this year’s workshop and poster sessions: data to care, emerging issues, health care landscape, quality management, innovative practices, and clinical pathway.

To submit an abstract for a workshop or poster and register for the conference, visit [ryanwhite2016.org](http://ryanwhite2016.org). The deadline for submission is April 29, 2016. On the website, you can also register for the conference and view the continuously expanding conference agenda.

To stay on top of all 2016 National Conference news and important updates, please follow us on Twitter at [@RyanWhite2016](https://twitter.com/@RyanWhite2016).

**For more information:** [Click here](http://ryanwhite2016.org)

**HHS Releases Guidance for Syringe Services Programs**
Blog.aids.gov | 3.29

The United States is experiencing a growing opioid epidemic, which has made many communities vulnerable to outbreaks of HIV and viral hepatitis among people who inject drugs (PWID). To address this issue, Members of Congress worked together late last year on a broad, bipartisan basis to revise a longstanding ban on the use of federal funds for Syringe Services Programs (SSPs). President Obama signed the bipartisan budget agreement into law, which makes it possible for grantees to use federal funds to support operational components of SSPs under certain circumstances.
To support implementation of this change in law, the U.S. Department of Health and Human Services (HHS) has released new guidance [PDF 960 KB] for state, local, tribal, and territorial health departments that will allow them to request permission to use federal funds to support SSPs.

A large number of scientific studies have found that SSPs reduce HIV risk. In 2011, the U.S. Surgeon General determined that SSPs are an effective way of reducing HIV transmission among PWID and that there is ample evidence that SSPs promote entry to, and retention in, drug treatment and medical services, without increasing illegal drug use. Many national and community-based organizations worked for years to draw attention to the scientific evidence and to build support for SSPs. The change in the law would not have occurred without their sustained effort.

**Requesting Use of Federal Funds**

The HHS guidance describes how health departments can request to use federal funds to start or expand SSPs in order to prevent new HIV and viral hepatitis infections. Federal funds can now be used to support a comprehensive set of services, but they cannot be used to purchase sterile needles or syringes for illegal drug injection.

The guidance states that state, local, tribal, and territorial health departments must consult with the Centers for Disease Control and Prevention (CDC) and provide evidence that their jurisdiction is (1) experiencing, or (2) at risk for significant increases in viral hepatitis infections or an HIV outbreak due to injection drug use.

After receiving a request for determination of need, CDC will have 30 days to notify the requestor whether the evidence is sufficient to demonstrate a need for SSPs. When CDC finds there is sufficient evidence, state, local, tribal, and territorial health departments and other eligible HHS grant recipients may then apply to their respective federal agencies to direct funds to support approved SSP activities. Each funding agency will be providing specific SSP guidance to its grantees regarding which specific programs may apply and the application process for each agency.

**Lessons Learned**

The recent outbreak of HIV and hepatitis C virus (HCV) among persons who were injecting drugs in rural Indiana, and the steep rise nationally in new HCV infections, are powerful reminders that the hard-won gains of the past can be lost if we do not remain vigilant. The opioid epidemic is affecting many communities across the country, and these areas are vulnerable to future outbreaks of HIV and the continued spread of viral hepatitis if we do not work to ensure that robust SSPs and other critical prevention and treatment services are in place where they are needed. When the local opioid epidemic in Indiana fueled a dramatic increase in the number of new HIV cases, public health officials were able to halt the further spread of the virus by implementing a comprehensive response to identify and prevent new infections that included SSPs as a key component.

Expanding the reach of SSPs and the services that these programs provide is part of a comprehensive approach to addressing HIV and viral hepatitis among PWID that supports the goals of the updated National HIV/AIDS Strategy and the Viral Hepatitis Action Plan to reduce the number of new HIV and viral hepatitis infections. HHS is committed to supporting health departments and all of our partners in the field to conduct SSPs in a way that protects the lives and health of all those at risk for, and living with, HIV and viral hepatitis. In the weeks to come, HHS agencies will be offering additional information and technical assistance to federal grantees that may wish to use federal funds to support operational
components of SSPs. Together, our actions will play an important role in preventing new infections among PWID.

View the SSP guidelines here [PDF 960 KB].

View The White House Fact Sheet: Obama Administration Announces Additional Actions to Address the Prescription Opioid Abuse and Heroin Epidemic here.

For more information: Click here

WEBINAR: "Rjing" the Work: Bringing Reproductive Justice to What You Do

DATE: April 1
TIME: 2:00 PM

Meeting Description:
The Center for Strengthening Youth Prevention Paradigms (SYPP Center) invites you to participate in our quarterly webinar.

The reproductive justice (RJ) framework recognizes that people’s ability to exercise self-determination – over their bodies, gender and reproductive lives – is impacted by power inequities in our society’s public, private and cultural institutions. As such, RJ requires a comprehensive approach to analyze problems, develop strategies and envision solutions that affect sexuality and reproduction. During this webinar, Ena Suseth Valladares from California Latinas for Reproductive Justice, will lead us in exploring how/why the RJ framework came about; how/why it is necessary in addressing/reducing inequities and the critical role it can play in the work that we do.

By the end of the webinar, participants will be better able to:
1. Describe what the RJ framework is and how it can be used to address/reduce inequities; and
2. Identify tangible ways to incorporate the RJ framework in their work.

For more information and to register: Click here

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Archives of previous STD Updates can be found here. To unsubscribe or add colleagues’ names, email aaron.kavanaugh@cdph.ca.gov. If you have an item related to STD/HIV prevention which you would like included, please send. No bibliographic questions please; all materials are compiled from outside sources and links are provided. No endorsement should be implied! Note: Some words may have been placed in [brackets] or replaced with blanks (___) or asterisks (*) in order to avoid filtering by email inboxes.