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California Stories

Sex Ed Now Required in California Public Schools

Ana Tintocalis, KQED News | 1.13

A new state law in effect this year requires all California public school students to take sex education beginning in seventh grade.

Parents who don't want their kids to learn about issues like body image, contraception and HIV awareness and prevention will have to formally opt out by submitting a document to their school or district.

For years, sex education has been optional. If parents wanted their children to take a sexual health class, they had to sign up for the instruction.

The law, called the California Healthy Youth Act, attempts to standardize and update sex education in the state, which also now must include gender identity.

San Francisco Unified has one of the most comprehensive sex education curriculums in the state, covering everything from sexual orientation to abusive relationships.

Health educators in the district say seventh grade is the best time to start teaching students about sexual health.

“Their bodies are developing, and often young people start to develop crushes on other students,” says Christopher Pepper, a San Francisco Unified health teacher. “They’re dealing with effects of hormones in their body, and understanding all those things can be a little bit challenging.”

California is also the first state in the nation where high school students will now learn about affirmative consent, known as “Yes means Yes.”

Developing a more comprehensive sex education curriculum is expected to be challenging in more conservative areas like Clovis Unified, which was found to have violated the state’s pre-existing law on sex education by providing students with inaccurate and biased information about sexual health.

The big question is how the state will monitor school districts, and whether there will be an uptick in families opting out.

Camille Giglio, with the group California Right To Life, says this curriculum goes too far.

“This comes into a whole new category of being forced to listen for six years to one version of so-called sexual health,” Giglio said.

The California State PTA supports the new law, saying students should have medically accurate and unbiased information.

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

Easier access to birth control finally on its way

Ana B. Ibarra, Merced Sun-Star | 1.8

In what may seem like a long-overdue win for most women, birth control – including the pill, the ring and the patch – will be available without the need of a doctor’s prescription in Oregon, and California is set to follow soon.

This change can result in a number of benefits for communities where accessibility to health care services is known to be a concern, such as the Central Valley.

Instead of going through a physician, women in Oregon can fill out a questionnaire and meet with a pharmacist to determine which method will work best.

As explained by a Jan. 4 New York Times article, about 200 pharmacists of major chain pharmacies such as Rite-Aid, Walgreens and others have completed training and may prescribe appropriate contraception. California passed a similar law in 2013, but implementation has been delayed while authorities work to establish guidelines for pharmacists.

Pedro Elias, public affairs director at Planned Parenthood Mar Monte in Fresno, explained that easier access to contraception can help reduce unwanted pregnancies and abortions. That is because being able to obtain birth control with one stop to the pharmacy makes the process faster and easier, he said.

“It’s really going to make a significant difference,” Elias said. “This will help provide a positive lifestyle.”

Of the approximately 8 million women of reproductive age in California, Planned Parenthood provides contraception to about 800,000, Elias said. It also provides a number of other services, including screening for sexually transmitted infections.

Critics of the new law question whether women who choose to go straight to a pharmacist will overlook other basic medical care because they are forgoing a doctor’s visit.

According to text from the California bill, pharmacists are to provide a patient with referral or information to other health care professionals.

“We see it as win-win,” Elias said. “In order for pharmacists to dispense contraception, they must provide (the patient) with information to a health center or primary-care provider, if they don’t have one.”

Elias said Planned Parenthood is working to make sure pharmacists include Planned Parenthood in their list of community health centers available for referral.

The law is especially good news for women who face barriers such as transportation. Instead of going from a clinic or doctor’s office to a pharmacy, stopping only by the pharmacy will save time. This can also bring relief to areas with provider shortages, and areas where women may have to wait weeks to get a visit with their doctor.

As reported by Reuters Health, in 2012, the American College of Obstetricians and Gynecologists published a statement in which they recommended that birth control be available over the counter.

In a study by the nonprofit Ibis Reproductive Health, included in the Reuters report, researchers surveyed about 2,000 women ages 18 to 44. The study found that about two-thirds of women favored over-the-counter access to birth control.

However, it is important to note that the new laws do not make the pill or any other types of contraceptive an over-the-counter product. As the Times explained, making birth control available over the counter would require approval from the Food and Drug Administration, which could take a long time.

The law in Oregon requires women to be 18 or older to obtain birth control from a pharmacist. Women under 18 must still get their first prescription from their doctor. California's law does not have an age restriction.

In California, the new law will also allow pharmacists to prescribe nicotine patches and certain medications for travel abroad. An exact date on California's implementation of the law is not yet known.

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

National Stories

HIV subtypes may influence treatment failure

Jen Byrne, Healio Infectious Disease News | 1.4

Variations in drug-resistant mutations appeared to correspond with specific subtype designations in patients with HIV who failed first-line treatment, according to recent findings.

"Subtype designations are ... widely used to represent genetic background variation in HIV sequences," the researchers wrote. "While high viral genetic diversity and variable ART adherence is known to contribute to drug resistance and ART failure, subtype contributions to treatment outcomes remains actively researched through in vitro and surveillance methods."

The researchers evaluated a multicohort, multisubtype dataset of reverse transcriptase (RT) isolates from patients failing WHO-recommended first-line ART. The analysis included 1,425 sequences, including 202 subtype B sequences, 696 subtype C sequences, 44 subtype G sequences, 351 CRF01_AE sequences, 58 CRF02_AG sequences and 74 other subtypes. They used a hierarchical model to characterize resistance mutation variations as pertained to treatment histories and subtype genetic backgrounds.

Subtype B, predominately found in the United States and Western Europe, generally demonstrated lower resistance mutation frequencies. In contrast, subtype C, the most common subtype worldwide (largely found in South African and India), as well as subtype CRF01_AE, commonly found in Southeast Asia, demonstrated higher resistance mutation frequencies to both nucleoside reverse transcriptase inhibitors (NRTI) and non-nucleoside reverse transcriptase inhibitors (NNRTI).

Compared with subtype B, thymidine analogue mutation (TAM) frequency in subtype C and CRF01_AE increased by 9% to 20% at RT positions 41L (RR = 1.9-5.2), 67N (RR = 2.2-5.3), 70R/E (RR = 2.4-5.8), 184 V/I (RR = 1.2-1.6), 215 F/Y (RR = 1.9-4.3), and 219Q/E (RR = 1.8-5.6).

Furthermore, subtype C and CRF01_AE were projected to have greater cross-resistance to future treatment approaches vs. subtype B (42% and 48% vs. 60%, respectively).

"Given the higher levels of resistance observed in subtype C and CRF01_AE population, interventions that minimize ecological contributions to resistance such as increased monitoring, viral load testing or use of boosted [protease inhibitor-based] regimens may warrant consideration," the researchers wrote.

“Future studies should further disentangle the role of ecological and biological contributors for higher levels of resistance in subtype C and CRF01_AE. Identifying the correct causal explanations for the patterns of resistance characterized here is crucial to optimizing ART among populations infected with non-B HIV-1 subtypes.”

Journal Reference:

[Huang A, et al. *Open Forum Infect Dis.* 2015;doi:10.1093/ofid/ofv158.](https://doi.org/10.1093/ofid/ofv158)

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

A quarter of people with HCV initially refused access to sofosbuvir/ledipasvir, says US study, but most successfully appeal

Michael Carter, aidsmap.com | 12.29.15

Insurers deny almost a quarter of requests for sofosbuvir/ledipasvir (Harvoni) to treat people with chronic hepatitis C virus (HCV) infection, investigators from Yale Liver Center report in PLoS One. However, most of those who were initially refused subsequently gained access after appeal. Advanced liver disease and Medicare/Medicaid insurance were associated with earlier decision and approval times, whereas Medicare/Medicaid coverage and high viral load were significant predictors of initial approval.

“We found that nearly one in four were denied initial approval, although most patients eventually obtained drug authorization through the appeals process,” comment the authors. “Fewer than 10% of patients ultimately failed to obtain access to therapy, although the appeals process led to further delay in treatment initiation.”

Treatment of HCV infection has been revolutionised by the development of direct-acting antiviral (DDA) agents. Compared to traditional therapy with pegylated interferon/ribavirin, treatment with DDAs is associated with better tolerability, improved adherence and high cure rates. Because of its efficacy, the combination sofosbuvir/ledipasvir (SOF/LED) is recommended by professional organisations in the US for the treatment of HCV genotype-1 infection.

However, it is necessary for insurers to accept that treatment with DAAs is medically necessary and authorise access. A 12-week course of treatment with SOF/LED costs \$94,500, or \$1,125 per pill. Because of this high cost, insurer authorisation often requires that people have advanced fibrosis (F3 or above) or cirrhosis.

Investigators from Yale Liver Center wanted to see how many people with HCV were obtaining authorisation for therapy with SOF/LED in a “real world” setting, and also the factors associated with approval, time to decision, and time to approval. They therefore designed a retrospective study involving 129 people prescribed SOF/LED at the centre between October and December 2014.

Their mean age was 57 years, 61% were male and 61% had liver cirrhosis.

Over three-quarters (77.5%) received initial approval. A further 17 (14%) subsequently obtained access to the treatment on appeal. The average time to final appeal was 26 days, and for those who were approved, the average time to decision was 23 days.

Faster approval time was seen for people with Child-Pugh Class B disease (14 vs. 25 days, $p = 0.048$). People with Medicaid/Medicare coverage were more likely to be initially approved than those with private insurance (92% vs 71%, $p = 0.002$). A viral load above 6 million iu/ml was also associated with initial approval (84% vs. 63%, $p = 0.04$).

Factors associated with shorter decision and approval times were female gender, advanced fibrosis and higher MELD score. Psychiatric disease was a significant predictor of shorter time to approval.

“This is the first study to our knowledge assessing real-world access to interferon-free DAA regimens in established cohorts of patients with chronic HCV seeking antiviral therapy,” write the investigators. “These results contribute to the limited data available addressing the proportion of patients successfully obtaining drug authorization through public and private insurance carriers, time to approval, and predictors of approval.”

They emphasise, “most patients filing a pre-authorization request for SOF/LED are eventually approved, but nearly 1 in 4 were denied access upon initial request, which may represent a barrier within the HCV care cascade.”

A different study design, which looked at insurance approvals in patients presenting prescriptions at a specialty pharmacy chain in four US states, presented at the 2015 Liver Meeting, found that patients with Medicaid insurance were significantly more likely to be refused insurance coverage of their hepatitis C treatment.

Reference:

Do A et al. Drug authorization for sofosbuvir/ledipasvir (Harvoni) for chronic HCV in a real-world cohort: a new barrier in the HCV care cascade. PLoS ONE 10 (8): e0135645. [doi:10.1371/journal.pone.0135645](https://doi.org/10.1371/journal.pone.0135645).

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

FDA grants priority review of Sovaldi/velpatasvir for all HCV genotypes

As reported by Healio HCVnext | 1.6

Gilead Sciences announced the FDA has granted priority review designation of its new drug application for a fixed combination of Sovaldi and velpatasvir for the treatment of all genotypes of chronic hepatitis C virus infection.

The application consists of an all-oral, once daily combination regimen of Sovaldi (sofosbuvir, Gilead Sciences) and velpatasvir, a pan-genotypic NS5A inhibitor. Gilead submitted the application in October 2015, with the FDA granting breakthrough therapy designation shortly after, according to a previous press release.

Clinical results from the phase 3 ASTRAL trials showed high sustained virologic response rates after investigating the safety and efficacy of the combination among patients with HCV genotypes 1 through 6.

In the ASTRAL-1, ASTRAL-2 and ASTRAL-3 trials, 1,035 patients underwent therapy with the fixed combination regimen for 12 weeks. Of these patients, 98% achieved SVR at 12 weeks (1,015). In the ASTRAL-4 trial, 267 patients with decompensated cirrhosis were randomly assigned to receive either sofosbuvir/velpatasvir with or without ribavirin for 12 weeks or 24 weeks of sofosbuvir/velpatasvir. Ninety-four percent of patients who received sofosbuvir/velpatasvir plus ribavirin for 12 weeks achieved SVR12, whereas 83% of patients who received sofosbuvir/velpatasvir for 12 weeks achieved SVR12 and 86% of patients who received sofosbuvir/velpatasvir for 24 weeks achieved SVR.

Data from the ASTRAL-4 trial was presented as a Late Breaker highlight at The Liver Meeting 2015.

In a previous press release, Norbert Bischofberger, PhD, chief scientific officer at Gilead, stated: “The ASTRAL study results demonstrate that a 12-week course of therapy with the first fixed-dose combination of two pangenotypic compounds can provide high cure rates for patients with all HCV genotypes. We are pleased to have now brought forward our second single-tablet regimen for HCV infection that complements Harvoni, our first single-tablet regimen approved specifically for patients with genotype 1 infection, and which could eliminate the need for HCV genotype testing.”

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

New footage shows how AIDS vaccine candidate recruits immune cells to destroy infected cells

As reported by News Medical | 12.23

Using innovative technology, scientists from the Institut Pasteur and Inserm have filmed in vivo the process by which an AIDS vaccine candidate, developed by the French Vaccine Research Institute and the ANRS, triggers the immune response. This previously unseen footage clearly shows how the vaccine recruits the immune cells needed to destroy infected cells. These results, published in the journal *Nature Medicine* on December 21, 2015, shed new light on the mode of action and potential of this vaccine.

The aim of the study conducted by scientists from the Dynamics of Immune Responses Unit (Institut Pasteur / Inserm / VRI), directed by Inserm research director Philippe Bousso, was to observe the effect of the HIV/AIDS vaccine candidate MVA-HIV - currently undergoing clinical trials by the French Vaccine Research Institute (VRI) and the ANRS - on the immune response.

The scientists administered the vaccine to healthy mice, then observed in real time how cells from the immune system were mobilized to the lymph node, the organ where the vaccine response is developed, in just a few hours.

For the first time, using a powerful, non-invasive microscopic imaging technique, the scientists were able to watch in vivo and in real time as the vaccine induced the formation of the inflammasome, a complex assembly of proteins with a highly specific structure which appears in macrophages, the first immune cells targeted by the vaccine.

The inflammasome promotes the maturation of the chemical messenger interleukin (IL)-1 but also induces macrophage death, thereby releasing this inflammatory messenger in the lymph node. This

signal triggers a chain reaction which assembles several key players of the immune system in the lymph node, including killer cells, which are vital for the vaccine response.

These in vivo films have given the scientists a detailed picture of the main stages in the mechanistic action of this vaccine and highlighted an important pathway that orchestrates the effective mobilization of the immune response. "This is the first time that the formation of this original structure, the inflammasome, has been observed in vivo and in real time," commented Philippe Bousso. "Our research demonstrates the potential of the vaccine candidate MVA-HIV to trigger a significant, diverse immune response."

To view the film and for more information: [Click here](#)

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

Scientific Papers/Conference Abstracts

Sexual Behavior and Network Characteristics and Their Association with Bacterial Sexually Transmitted Infections among Black Men Who Have Sex with Men in the United States

Scott HM, Irvin R, Wilton L, et al. *PLOS One* 2015; DOI: 10.1371/journal.pone.0146025

Background:

Black men who have sex with men (MSM) have a high prevalence of bacterial sexually transmitted infections (STIs), and individual risk behavior does not fully explain the higher prevalence when compared with other MSM. Using the social-ecological framework, we evaluated individual, social and sexual network, and structural factors and their association with prevalent STIs among Black MSM.

Methods:

The HIV Prevention Trials Network 061 was a multi-site cohort study designed to determine the feasibility and acceptability of a multi-component intervention for Black MSM in six US cities. Baseline assessments included demographics, risk behavior, and social and sexual network questions collected information about the size, nature and connectedness of their sexual network. Logistic regression was used to estimate the odds of having any prevalent sexually transmitted infection (gonorrhea, chlamydia, or syphilis).

Results:

A total of 1,553 Black MSM were enrolled in this study. In multivariate analysis, older age (aOR = 0.57; 95% CI 0.49–0.66, $p < 0.001$) was associated with a lower odds of having a prevalent STI. Compared with reporting one male sexual partner, having 2–3 partners (aOR = 1.74; 95% CI 1.08–2.81, $p < 0.024$) or more than 4 partners (aOR = 2.29; 95% CI 1.43–3.66, $p < 0.001$) was associated with prevalent STIs. Having both Black and non-Black sexual partners (aOR = 0.67; 95% CI 0.45–0.99, $p = 0.042$) was the only sexual network factor associated with prevalent STIs.

Conclusions:

Age and the number and racial composition of sexual partners were associated with prevalent STIs among Black MSM, while other sexual network factors were not. Further studies are needed to evaluate the effects of the individual, network, and structural factors on prevalent STIs among Black MSM to inform combination interventions to reduce STIs among these men.

View the paper online: [Full paper](#)

HIV Testing among Outpatients with Medicaid and Commercial Insurance

Dietz PM, Van Handel M, Wang H, et al. *PLOS One* 2015; DOI: 10.1371/journal.pone.0144965

Objective:

To assess HIV testing and factors associated with receipt of testing among persons with Medicaid and commercial insurance during 2012.

Methods:

Outpatient and laboratory claims were analyzed from two databases: all Medicaid claims from six states and all claims from Medicaid health plans from four other states and a large national convenience sample of patients with commercial insurance in the United States. We excluded those aged <13 years and >64 years, enrolled <9 of the 12 months, pregnant females, and previously diagnosed with HIV. We identified patients with new HIV diagnoses that followed (did not precede) the HIV test, using HIV ICD-9 codes. HIV testing percentages were assessed by patient demographics and other tests or diagnoses that occurred during the same visit.

Results:

During 2012, 89,242 of 2,069,536 patients (4.3%) with Medicaid had at least one HIV test, and 850 (1.0%) of those tested received a new HIV diagnosis. Among 27,206,804 patients with commercial insurance, 757,646 (2.8%) had at least one HIV test, and 5,884 (0.8%) of those tested received a new HIV diagnosis. During visits that included an HIV test, 80.2% of Medicaid and 83.0% of commercial insurance claims also included a test or diagnosis for a sexually transmitted infection (STI), and/or Hepatitis B or C virus at the same visit.

Conclusions:

HIV testing primarily took place concurrently with screening or diagnoses for STIs or Hepatitis B or C. We found little evidence to suggest routine screening for HIV infection was widespread.

View the paper online: [Full paper](#)

How Different are Men Who Do Not Know Their HIV Status from Those Who Do? Results from an U.S. Online Study of Gay and Bisexual Men

Grov C, Rendina HJ, Parsons JT. *AIDS and Behavior* 2016; 10.1007/s10461-015-1284-7

Abstract:

We compared self-described HIV-positive (31.6 %, n = 445), HIV-negative (56.8 %, n = 801), and HIV-unknown (11.6 %, n = 164) gay and bisexual men on sociodemographic and behavioral characteristics. Participants from across the U.S. were enrolled via a popular sexual networking website to complete an online survey. In total, 44.8 % of HIV-negative and HIV-unknown men said they had not been tested for

HIV in the CDC-recommended last 6 months. HIV-unknown men significantly differed from HIV-negative and HIV-positive men in sexual behavior and HIV status disclosure patterns. HIV-unknown men were more willing than HIV-negative men to take PrEP; however, HIV-unknown men were significantly less likely than others to have health insurance or a primary care provider. Given the observed differences, researchers should consider analyzing men who are HIV-unknown distinctly from HIV-negative and HIV-positive men.

View the paper online: [Abstract](#)

Using Ecological Momentary Assessment (EMA) to Study Sex Events Among Very High-Risk Men Who Have Sex with Men (MSM)

Wray TB, Kahler CW, Monti PM. *AIDS and Behavior* 2016; [Epub ahead of print]

Abstract:

MSM continue to represent the largest share of new HIV infections in the United States each year due to high infectivity associated with unprotected anal sex. Ecological momentary assessment (EMA) has the potential to provide a unique view of how high-risk sexual events occur in the real world and can impart detailed information about aspects of decision-making, antecedents, and consequences that accompany these events. EMA may also produce more accurate data on sexual behavior by assessing it soon after its occurrence. We conducted a study involving 12 high-risk MSM to explore the acceptability and feasibility of a 30 day, intensive EMA procedure. Results suggest this intensive assessment strategy was both acceptable and feasible to participants. All participants provided response rates to various assessments that approached or were in excess of their targets: 81.0 % of experience sampling assessments and 93.1 % of daily diary assessments were completed. However, comparing EMA reports with a Timeline Followback (TLFB) of the same 30 day period suggested that participants reported fewer sexual risk events on the TLFB compared to EMA, and reported a number of discrepancies about specific behaviors and partner characteristics across the two methods. Overall, results support the acceptability, feasibility, and utility of using EMA to understand sexual risk events among high-risk MSM. Findings also suggest that EMA and other intensive longitudinal assessment approaches could yield more accurate data about sex events.

View the paper online: [Abstract](#)

Resources, Webinars, & Announcements

Map of the Day: Reproductive Rights In Your State

Courtesy of the Population Institute, here's a map and accompanying chart that tells you how your state is doing on reproductive rights. [More here.](#)

To see the maps: [Click here](#)

WEBINAR: LGBTQ Youth: Providing Care, Protecting Confidentiality

DATE: January 26

TIME: 1:00 PM

Lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth experience unique health and developmental challenges compared to their peers. In the first half of this webinar, participants will learn about ways in which school-based and other health care providers can support LGBTQ youth in navigating these challenges and improving their health outcomes. The second half will focus on consent and confidentiality issues related to sexual and reproductive health care, as well as to disclosure of sexual orientation and gender identity among LGBTQ minors and young adults. This webinar is a collaboration of the School-Based Health Alliance and the National LGBT Health Education Center.

For more information and to register: [Click here](#)

WEBINAR: Addressing Myths + Concerns About Contraceptive Method Risk

CFHC

DATE: January 25

TIME: 12:00 – 1:00 PM PST

Presenter:

Anita Nelson, MD, Medical Director, California Family Health Council Research Center; Chief of Women's Health Care Education Programs, Professor, Department of Obstetrics and Gynecology, UCLA

Overview:

Contraceptive method choice is affected by a variety of factors. Women may have concerns about contraceptive safety that may be fueled by the media, myths that are shared anecdotally or advertisements seeking to recruit plaintiffs in legal cases. This session will explore how to utilize and implement 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 that are attributable to contraceptive methods and compare contraceptive risks to those that may occur in daily life.

What Will You Learn?

After attending this training, participants will be able to:

- Describe women's concerns over time about the safety and side effects of different methods of contraception
- Explain why women may believe that there are serious health risks related to contraceptive use
- Discuss how you can approach a patient who only wants to use methods that they view as "natural"
- Quantify the known health risks attributable to contraception compared to risks in daily life
- Describe the nocebo effect

For more information and to register: [Click here](#)

Aaron Kavanaugh

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