



August 24, 2016

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Dear Ms. Ross:

The California Department of Public Health (CDPH), Office of AIDS submitted a determination of need request to the Centers for Disease Control and Prevention (CDC) with data examining whether the jurisdiction is experiencing or at risk for an increase in viral hepatitis or HIV infection due to injection drug use. Consulting with CDC is a requirement in the process of seeking approval to use federal funds to support syringe services programs (SSPs). All such requests are reviewed by a panel of CDC subject matter experts who evaluate submitted data in accordance with the *U.S. Department of Health and Human Services (HHS) Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016*.

After careful review of the CDPH's submission, CDC concurs that California is at risk for an increase in viral hepatitis or HIV infections due to injection drug use. The submitted data provide sufficient evidence to establish a need for SSPs within the jurisdiction.

Specifically, the requestor presents statewide data and data from select urban and rural counties to characterize illicit drug use in California, particularly with regard to heroin, which is frequently injected. Although drug overdose mortality in California has been lower than overall U.S. rates, the requestor sufficiently demonstrated increases in heroin overdose mortality, particularly among 15-29 year olds. ED admissions for heroin poisoning similarly increased from 2012 to 2014 as did all opioid-related ED admissions among those aged 20-34.

Data on treatment admissions where heroin was listed as the primary drug are provided for Los Angeles and San Diego counties. Both of these urban counties experienced increases in admissions from 2008 to 2011/2012. The narrative cites successes of urban SSPs in reducing HIV and hepatitis transmission; it is concerning that increases in heroin use, as indicated by heroin admissions, could overwhelm the current SSP capacity, even in urban communities.

The requestor shared survey results from 37 SSP directors in the state. These directors reported increases in the number of clients (about a 200% increase in average number of new clients, 2014 to 2015), the number of younger clients, visits, supplies provided, and syringes exchanged. The increased demand for services reflects an increase in injection drug use and infectious disease risks associated therewith.

This submission appropriately focuses heavily on heroin, which is frequently injected, and on younger populations with known riskier injection practices. Taken together, the increases in heroin overdose deaths, treatment admissions for heroin abuse, ED visits related to heroin and other opioids, as well as increased demand for services in SSPs, make a compelling case that California is at risk for increases in HIV and hepatitis related to injection drug use and could benefit from SSPs, particularly in less urban areas.

This notice may be used by state, local, territorial, or tribal health departments or eligible HHS-funded recipients to apply to direct federal funds to support SSPs. As there is no expiration date for this notice, California may elect to either (1) immediately request to direct FY 2016 funds to support SSPs or (2) delay requests to direct funds to support SSPs until a subsequent fiscal year. California is strongly encouraged to discuss their plans to direct funds for SSPs with their respective federal funding agency.

Only CDC directly-funded, eligible awardees should submit a request to CDC to direct funding for SSP activities.

Thank you for your interest in the public health implications of injection drug use in California. If you have any questions or require further technical assistance, please do not hesitate to send an email to SSPCoordinator@cdc.gov.

Sincerely,

CDC SSP Determination Panel

REQUEST FOR DETERMINATION OF NEED

Requesting jurisdiction: State of California

We are submitting evidence to demonstrate our jurisdiction is AT RISK FOR significant increases in viral hepatitis or HIV infections due to injection drug use.

Data Sources Table

Outcomes	Data Source	Geographic Area	Assessment Period Beginning Year and # or Rate	Assessment Period Ending Year and # or Rate	% Increase
1. Increase in Heroin-Related Deaths Among CA Residents Aged 15-64 years	<i>CDPH Vital Statistics Death Statistical Master and Multiple Cause of Death files</i>	Statewide	Month: Jan – Dec Year: 2012 Value: 0.92 per 100,000 California Residents Unit: Rate	Month: Jan – Dec Year: 2013 Value: 1.22 per 100,000 California Residents Unit: Rate	32.6%
2. Increase in Heroin-Related Deaths Among CA Residents Aged 15-29 years	<i>CDPH Vital Statistics Death Statistical Master and Multiple Cause of Death files</i>	Statewide	Month: Jan – Dec Year: 2012 Value: 1.1 per 100,000 California Residents Unit: Rate	Month: Jan – Dec Year: 2013 Value: 1.7 per 100,000 California Residents Unit: Rate	54.5%
3. Increase in Substance Use Disorder Treatment Program Admissions Where Heroin was Listed as the Primary Drug	<i>National Institute on Drug Abuse (NIDA)</i>	Sample Urban County: Los Angeles	Month: Jan – Jun Year: 2008 Value: 5,208 Units: Number per Year	Month: Jan – Dec Year: 2012 Value: 9,122 Units: Number per Year	75.2%
		Sample Urban County: San Diego	Month: Jan – Jun Year: 2008 Value: 1,425 Units: Number per Year	Month: Jan – Dec Year: 2011 Value: 3,019 Units: Number per Year	111.9%

Outcomes

4. Increase in Emergency Department Admissions for Heroin Poisoning	<i>Office of Statewide Health Planning and Development (OSHPD)</i>	Statewide	Month: Jan – Dec Year: 2012 Value: 2,130 Unit: Number per Year	Month: Jan – Dec Year: 2014 Value: 2,838 Unit: Number per Year	33.2%
5. Increase in New Clients Registered per Month at a Rural Syringe Exchange Program	<i>Shasta County HHSA -Outcomes, Planning & Evaluation Revised 4/19/2016</i>	Sample Rural County: Shasta	Month: Jan – Dec Year: 2014 Value: 9.7 Units: Average Number per Month	Month: Jan – Dec Year: 2015 Value: 29.2 Units: Average Number per Month	201.0%
6. Increase in Chronic HCV Infections Among Males Aged 18-24 Incarcerated in State Prisons.	<i>Office of Viral Hepatitis Prevention – CDPH, STD Branch</i>	Statewide	Month: Jan – Dec Year: 2009 Value 2,024.4 per 100,000 Unit: Rate	Month: Jan – Dec Year: 2013 Value: 2,555.1 per 100,000 Unit: Rate	26.2%
7. Increase in Non-Fatal Opioid-Related ED Visits Among CA Residents Aged 20-34 (Prescription and Non-Prescription Opiates)	<i>CDPH Vital Statistics Death Statistical Master and Multiple Cause of Death files.</i>	Statewide	Month: Jan – Dec Year: 2012 Value: 47.7 per 100,000 California Residents Unit: Rate	Month: Jan – Dec Year: 2014 Value: 59.3 per 100,000 California Residents Unit: Rate	24.3%

Request for Determination of Need: Summary of Evidence - California

Overview

The State of California is submitting evidence to demonstrate that our jurisdiction is at risk for increases in viral hepatitis and/or HIV infections due to injection drug use. In California, HIV and chronic hepatitis C virus (HCV) infection rates are currently relatively stable; in several areas of the state where a small rise in these two rates have been observed, it is difficult to determine whether the increase is real or is due to improved surveillance data. Importantly, though, the number of individuals contracting HIV or HCV through injection drug use remains high compared to other states. The California Request for Determination of Need narrative demonstrates California's risk for significant increases in viral hepatitis and/or HIV infections due to intravenous drug use using data from morbidity statistics, substance use disorder treatment centers, emergency department admissions, and reports from syringe services programs. Using these data, the California Request for Determination of Need narrative will briefly describe the generally stable HIV and HCV rates, making note of one sentinel statistic from the California prison system that shows an increase in HCV infection in one subpopulation, followed by evidence showing an increase in injection drug use that puts California at risk for increase in HCV and HIV infections, particularly among young people, ages 15-34.

HCV and HIV State-wide Incidence Rates Have Stabilized

In 2013, the rate of notifiable chronic hepatitis C in California decreased when compared to the prior four years though the number of newly identified infections continued to be substantial, with 24,268 newly reported cases.¹ Recent trends in chronic hepatitis C case reports may be indicative of demographic shifts in the epidemiology of HCV in California. Between 2009 and 2013, rates of newly reported chronic hepatitis C infection decreased consistently across all age groups except for persons ages 18-24; rates in this age group remained relatively stable, showing a 1-2 percent increase since 2009.

HCV Rates among Incarcerated Males ages 18-24: The increase in chronic hepatitis C infections among persons younger than 30 years is most likely due to injection drug use behaviors. Among males ages 18-24 incarcerated in state prisons, the rate of newly reported chronic hepatitis C infections increased 26 percent between 2009 and 2013, from 2,024.4 to 2,555.1 per 100,000 population. The monitoring of chronic hepatitis C infection among persons incarcerated in state prisons may provide sentinel surveillance data for the rest of the state.

¹ Chronic Hepatitis C Infections in California: Cases Newly Reported through 2013 (in press). California Department of Public Health, Sexually Transmitted Diseases (STD) Control Branch.

The rate of new HIV infection among all individuals in California has remained steady at approximately 5,000 – 6,000 new diagnoses each year since 2001, while the number of people living with HIV has continued to increase as people with HIV live longer and healthier lives. California is similar to other states in that the number of cases of HIV that may be attributed to injection drug use appears to have diminished, and the percentage of individuals living and diagnosed with HIV statewide who list injection drug use as a risk factor has dropped from 19% of the total in 2004 to 14% in 2013. However, this statewide decrease masks important differences by county. The percentage of persons living with HIV (PLWH) whose HIV infection is attributable to injection drug use is slightly lower and rates of new infections have decreased in areas with longstanding syringe services programs, such as Los Angeles and San Francisco. Other locations, such as Orange, San Bernardino and Riverside counties, that have no or limited access to syringe services programs have a percentage of injection drug use-related HIV cases that is higher than the state's average.

Evidence of State-Wide Increase in Injection Drug Use

While the rates of HIV and HCV infections have stabilized, the number of infections remains substantial and, California is at risk for increased HCV and HIV infections due to an increase in injection drug use. This is evidenced by a rise in heroin-related deaths; increases in substance use disorder treatment admissions, emergency department visits, and HCV rates among incarcerated young people; and increased demand for syringe services programs.

Increase in Heroin-Related Death Rates: California as a whole has seen an increase in heroin-related deaths (CDPH Vital Records). In a one-year period (from 2012 to 2013), the heroin-related death rate increased by more than 30%, going from 0.92 to 1.22 per 100,000 California residents. When viewing these figures over the same time period by age group, the rate of heroin-related deaths among California residents aged 15-29 increased by 55%. Additionally, San Diego County is experiencing an increase in overdose deaths involving heroin/morphine. In the first half of 2013 there were 4.5 deaths per 100,000 population compared to 4.1 per 100,000 the year before, continuing a gradually increasing trend since 2010.

Increase Substance Use Disorder Treatment Admissions: According to the National Institute on Drug Abuse (NIDA), two large metropolitan areas in California, San Diego and Los Angeles, have experienced a very large increase in substance use disorder treatment program admissions where heroin was listed as the primary drug over the one-year period from 2012 to 2013 (Los Angeles, 75% increase; San Diego, 112% increase). Among people who use heroin, injection is the primary route of administration. The level of increase in Los Angeles County is particularly significant since it is the most populous county in California, with one out of every four California residents living there.

Increase in Emergency Department Admissions for Heroin Poisoning: The California Office of Statewide Health Planning and Development (OSHPD) data indicate there has been an overall increase of 33.2% in emergency department admissions for heroin poisoning between 2012 and

2014. Of these admissions, the increase since 2012 among the 20-29 year-old group was 32.0% (1,296 cases in 2014) and the 30-39 year-old group has increased 61.2% (598 cases in 2014).

Increase in Syringe Services Program Demand for Services: In informal surveys conducted by the California Department of Public Health, Office of AIDS (OA) over the past five years, syringe service programs (SSPs) have consistently reported increases in demand for services. To gauge the extent of recent changes, the Office of AIDS conducted a survey of the 37 SSPs in the state. Directors of the SSPs were asked to report on the type of changes that had occurred between 2014 and 2015 in the demand for SSP services. With a 62% response rate, the majority of respondents saw an increase in the following areas: the number of unique SSP clients (94.5% of respondents), the number of unique clients that were age 25 or younger (88.3% of respondents), the number of new clients (83.3% of respondents), the number of total visits (94.5% of respondents), the number of other supplies provided (88.9% of respondents), and the number of syringes exchanged (100% of respondents).

An additional seven program directors indicated that they had reduced the number of supplies distributed per client to prevent their supplies from depleting. Additionally, over half of the programs (n=14; 60.9%) indicated that their program had provided supplies to another syringe services program that had run out. Although several providers noted the increase in demand may be due in part to an increase in outreach activities and public awareness, the majority pointed toward increased injection drug use as the primary factor, with a particular spike in the number of clients who are 25 years old and younger.

In Shasta, a rural county with one of the highest overdose rates in the state, the syringe services program (SSP) has experienced increases in the number of syringes dispensed and returned, the number of clients, and the number of visits per month. As noted in the accompanying table, new client registrations per month increased by over 200 percent between 2014 and 2015. The local report also noted a change in drug of choice, with an increase in heroin as primary drug of choice. Shasta County has numerous parallels with Scott County, Indiana which experienced a large HIV outbreak in 2015. The county is rural and under-resourced, and local elected leaders in Shasta County have traditionally favored a law enforcement approach to problems associated with drug use, rather than medical or public health approaches.

Increase in Non-Fatal Opioid-Related ED Visits: Increased injection drug use is evidenced also in the significant increase in non-fatal opioid-related emergency room visits among California residents aged 20-34 years; the rate of non-fatal opioid-related emergency department visits increased 24 percent between 2012 and 2014, from 47.7 to 59.3 per 100,000 California residents.

The availability of Medication-assisted Treatment (MAT): Medication-assisted treatment (MAT) is one countermeasure used to reduce the incidence of injection drug use and reduce the risk of both HCV and HIV transmission. MAT is inconsistently available in California. A 2016 analysis of buprenorphine availability conducted by the Pew Charitable Trusts ranked California 30th in the

U.S., behind Tennessee and on par with Mississippi and Louisiana.² California Department of Health Care Services data indicate that among the 2,525 California prescribers listed as DATA-waived³ in 2013, 42% had issued no prescriptions for buprenorphine that year.⁴

Additionally, although the number of treatment admissions for both heroin and prescription opiate dependence has increased, the availability of methadone remains limited. The National Survey of Substance Abuse Treatment Services (N-SSATS) single-day count conducted in 2002 found 30,023 clients enrolled in California facilities that offered methadone.⁵ The 2013 N-SSATS single-day count found that number had increased by only 2.8% (to 30,872).⁶

The two figures below serve as a visual indicator of the potential relationship between HCV rates and the lack of methadone availability. The more rural and northern California counties have no licensed narcotic treatment programs (methadone clinics) (Figure 1). A majority of these same northern and rural counties have seen rates of chronic HCV infections rise by at least one "level." (Figure 2)

² Vestal, Christine. "Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs." *Stateline*. The Pew Charitable Trusts, 15 Jan. 2016. Web. 12 May 2016. <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/15/few-doctors-are-willing-able-to-prescribe-powerful-anti-addiction-drugs>

³ Only physicians waived under the Drug Addiction Treatment Act (DATA) are permitted to dispense or prescribe buprenorphine.

⁴ James J. Gasper, PharmD, BCPP. California Buprenorphine Report, 2015. California Department of Health Care Services, Pharmacy Benefits Division

⁵ 2002 State Profile – California. National Survey of Substance Abuse Treatment Services. Substance Abuse and Mental Health Services Administration. Center for Behavioral Health Statistics and Quality. http://www.dasis.samhsa.gov/webt/state_data/CA02.pdf

⁶ 2013 State Profile – California. National Survey of Substance Abuse Treatment Services. Substance Abuse and Mental Health Services Administration. http://www.dasis.samhsa.gov/webt/state_data/CA13.pdf

Figure 1: Narcotic Treatment Programs County Participation Map

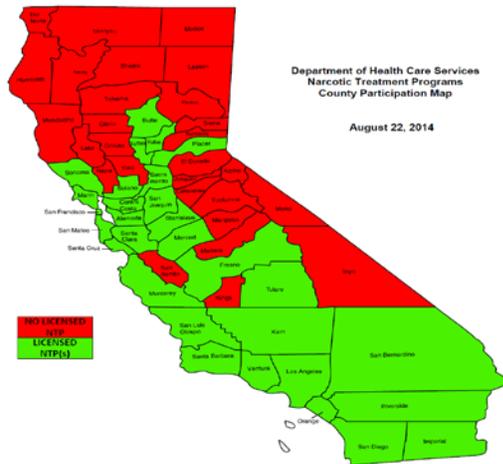
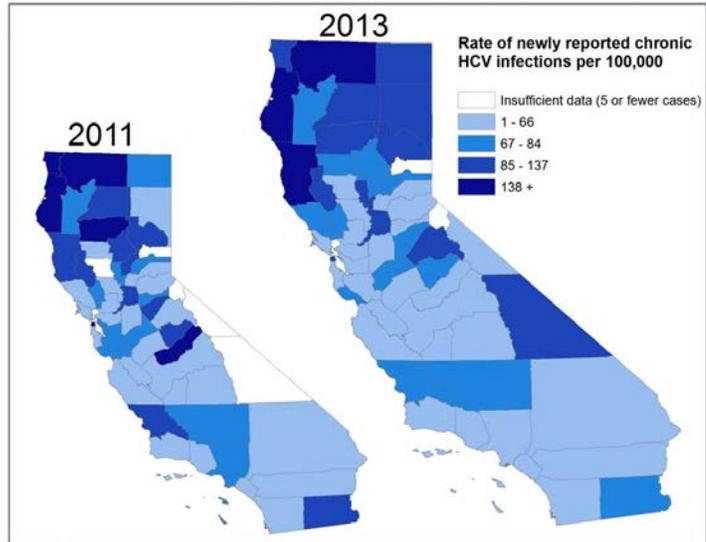


Figure 2: Rate of newly reported chronic HCV infections per 100,000



Conclusion

The numbers of HCV and HIV infections in this highly populous state are a cause for concern. The number of individuals contracting HIV or HCV through injection drug use remains high, compared to other state jurisdictions, fueled by a state population that accounts for nearly 12% of all US residents. As evidenced by the multiple indicators delineated above, injection drug use has increased substantially in California, suggesting that the state is at risk for increased HCV and HIV infections and outbreaks, and meets the requirements for a CDC Determination of Need.