San Francisco Department of Public Health Responds to Hepatitis C

Strategic Directions for 2015 and Beyond

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6/1/2015

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Overview

The hepatitis C virus (HCV) is the most common blood-borne disease, a major cause of liver cancer, and the leading cause of liver transplants in the United States. Nationwide it is estimated that there are at least 3.2 million people infected with HCV,[1] and in California it is estimated that there are 750,000 people living with HCV.[2] Because people living with HCV are often asymptomatic, 45-85% of HCV-infected patients do not know they are infected,[3] and may unknowingly be experiencing liver damage and passing HCV to others. Unless current trends are reversed, the deaths due to HCV will double or even triple in the next 20 years.[4]

Despite the extremely high disease burden of HCV, there is no ongoing federal or state-specific funding stream available to the San Francisco Department of Public Health (SFDPH) that is dedicated to HCV prevention, testing, linkage to care, or treatment activities.

In San Francisco, preliminary analysis of HCV data indicates that the city's HCV burden mirrors that of the United States in terms of its disproportionate impact amongst people who inject drugs (PWIDs), Blacks/African Americans, and baby boomers (people born during or between 1945 and 1965).[5] San Francisco also has the highest rate of liver cancer in the nation, much of it attributable to HCV.[6] Community-based antibody screening amongst high-risk populations in San Francisco has yielded an antibody positivity rate of 5.4%,[7] and HCV antibody screening in San Francisco jails has yielded an antibody positivity rate of 10%.[8] As of 2014, there were nearly 3,000 San Francisco Health Network (SFHN) patients with a HCV viral load in their medical record, indicating a chronic HCV infection.[9]

In the United States, HCV prevalence is approximately five times greater than HIV prevalence,[10] and approximately 25% of HIV-positive individuals are co-infected with HCV.[11] Since 2007, more people die of HCV than HIV each year.[12] Despite the extremely high disease burden of HCV, there is no ongoing federal or state-specific funding stream available to the San Francisco Department of Public Health (SFDPH) that is dedicated to HCV prevention, testing, linkage to care, or treatment activities. The existing HCV community-based screening and treatment initiatives at SFDPH are the result of the department's creative leveraging of existing resources to address community HCV-related needs.

Current HCV Activities at SFDPH

SFDPH conducts core as well as enhanced surveillance.

Since 2005, the SFDPH has received funding from the CDC to develop and maintain a population-based registry of persons in San Francisco with past or present HCV infection. With this funding, the SFDPH has conducted core surveillance (ie: tracking state-mandated lab reports) on cases with past or present HCV infection, as well as enhanced surveillance on a random sample of newly reported cases (currently 20% based on current funding) to the SFDPH each year. Enhanced surveillance activities include interviewing cases and faxing or mailing follow-up surveys to the provider who ordered the case's HCV tests. This enhanced surveillance allows the SFDPH to acquire information unavailable through routine public health reporting to better characterize the population of San Franciscans who are infected with HCV, including detailed demographics, risk factors for infection, and reason(s) that the provider ordered HCV testing for the case. Through these enhanced surveillance activities, SFDPH educates persons with HCV infection about HCV and how to prevent transmission of the infection to their close contacts, and sends educational materials and community resources for testing and vaccination in the desired language.

In the absence of a dedicated funding stream, SFDPH leverages existing resources to address HCV.

SFDPH has also demonstrated commitment to HCV by creatively leveraging existing resources dedicated to HIV and substance use prevention. For example, SFDPH integrated HCV screening and counseling services into HIV prevention programs and offers trainings to community providers around HCV prevention counseling and screening administration. SFDPH's Program Coordination and Service Integration (PCSI) grant supported community-based HCV screening, as well as a process by which a multi-disciplinary team established HCV screening recommendations for various populations. The existing HCV screening pilot will also be temporarily expanded to additional sites in 2015. SFDPH has continually partnered with affected community members on the HCV Task Force and maintained a presence in their monthly meetings. In Spring of 2015, SFDPH funded Glide Health Services to conduct focus groups, education, and testing amongst its highly impacted client population to develop updated population-specific HCV counseling messages. In addition, physicians at the SFGH Liver Clinic and in community clinics such as Tom Waddell Urban Health Clinic, the Positive Health Program at SFGH, and Castro Mission Clinic have treated and cured hundreds of patients living with HCV.

Leveraged funding is currently being used to support SFDPH-wide coordination of viral hepatitis efforts.

In November 2014, the Community Health Equity and Promotion (CHE&P) branch hired Katie Burk, Viral Hepatitis and HIV Set-Aside Coordinator, to review and coordinate SFDPH's activities related to

viral hepatitis, and to determine how SFDPH could be most impactful in preventing, screening, and treating and/or curing HCV. This needs assessment involved key informant interviews with SFDPH staff in both the Population Health Division and SFHN, attendance at community support and education groups, and conversations with providers in SFDPH-funded organizations. In March 2015, the Viral Hepatitis Coordinator conducted two focus groups to gain a better sense of hepatitis-related programmatic needs—one with a group of medical providers who treat HCV, and the other with community-based HIV/HCV test counselors. Also in March 2015, an SFDPH Hepatitis Planning Group convened to identify goals related to both hepatitis B and HCV.

Limitations in SFDPH's Ability to Address HCV

Surveillance data have notable constraints.

Existing surveillance data do not enable estimation of incidence and/or prevalence in San Francisco. Prevalence cannot be calculated because some persons infected with HCV have not been tested, and others were tested before consistent laboratory reporting to SFDPH was established in 2007. In addition, some persons who were tested anonymously may not have been reported to SFDPH, and people who were included in this registry may not live in San Francisco, either because their address information was not provided or because they have moved. While SFDPH does identify the first date an HCV case was reported, this date is not necessarily the date of infection or initial diagnosis, meaning that incidence cannot be calculated. Also, in many cases labs do not report simple demographic information such as race and ethnicity.

Given these limitations, SFDPH cannot ascertain how many people are living with HCV or acquiring HCV each year, and the case reports that SFDPH does track through core surveillance contain very little information about the patients or how they acquired HCV. It is also important to note that the current CDC surveillance grant funding will end in 2015 (with the possibility of a one-year extension), and in the absence of a new funded award there will be no resources for viral hepatitis surveillance in SFDPH.

Current community and clinic-based screening efforts are not sufficient to optimize HCV response.

Ongoing and robust HCV screening must be prioritized in order to identify San Franciscans who may be unknowingly living with HCV (and potentially transmitting the virus to others) so that they can be linked to health education, counseling around alcohol use reduction or cessation, clinical management, care, and treatment.

In 2012, the CDC issued a recommendation of one-time HCV screening for all individuals born during or between 1945 and 1965 ("baby boomers"). Preliminary analysis of SFDPH clinical data indicate

that **only about 65% active baby boomer SFDPH primary care patients (defined as having been to an SFDPH patient at least twice in the past two years) have been screened for HCV**, and it is likely that SFDPH clinicians fare better with HCV screening rates than their counterparts who treat the privately insured population.

Current SFDPH-supported community-based HCV screening programs are targeted to PWIDs, a high-risk group, but are usually non-sustainable pilot or one-time projects, due to lack of ongoing funding. Current projects have yielded a significant antibody positivity rate of 6%, yet community-based HCV screening occurs on a much smaller scale than community-based HIV testing, despite the prevalence of HCV being five times higher nationally than that of HIV. Further, temporary pilot programs produce snapshots of HCV impact among certain populations, which can be helpful in informing SFDPH's understanding of HCV impact in San Francisco, but due to small scale cannot help assess prevalence.

There is no systematic mechanism to support patients who learn their HCV status in a community setting to connect to medical care.

HCV disproportionately impacts marginalized populations such as homeless, substance using, and incarcerated people.[13] As these populations tend to be less well-connected to primary care, the process of identifying HCV cases among them may be more likely to occur in community (i.e., non-clinical) settings. When one learns he or she has an active HCV infection, this knowledge often creates a window of opportunity in which the patient is motivated to address their HCV. However, if one is not currently connected to medical services, the prospect of registering for insurance coverage and connecting with a clinician for care may prove too overwhelming for those patients who need medical care the most. Similarly, there are numerous community members who may have known they are living with HCV for years but feel powerless to address their HCV or are unaware of recent developments in HCV treatment. HCV-specific linkage-to-care services, which SFDPH currently does not offer, are needed to support HCV patients in connecting with appropriate care. Linkage-to-care programs in Alameda County, New York City, Chicago, Baltimore, and Seattle have been successful in connecting HCV patients who have multiple and complex needs to culturally competent medical care and support. Adapting successful models from HIV linkage programs could ensure the effectiveness of an HCV linkage-to-care program.

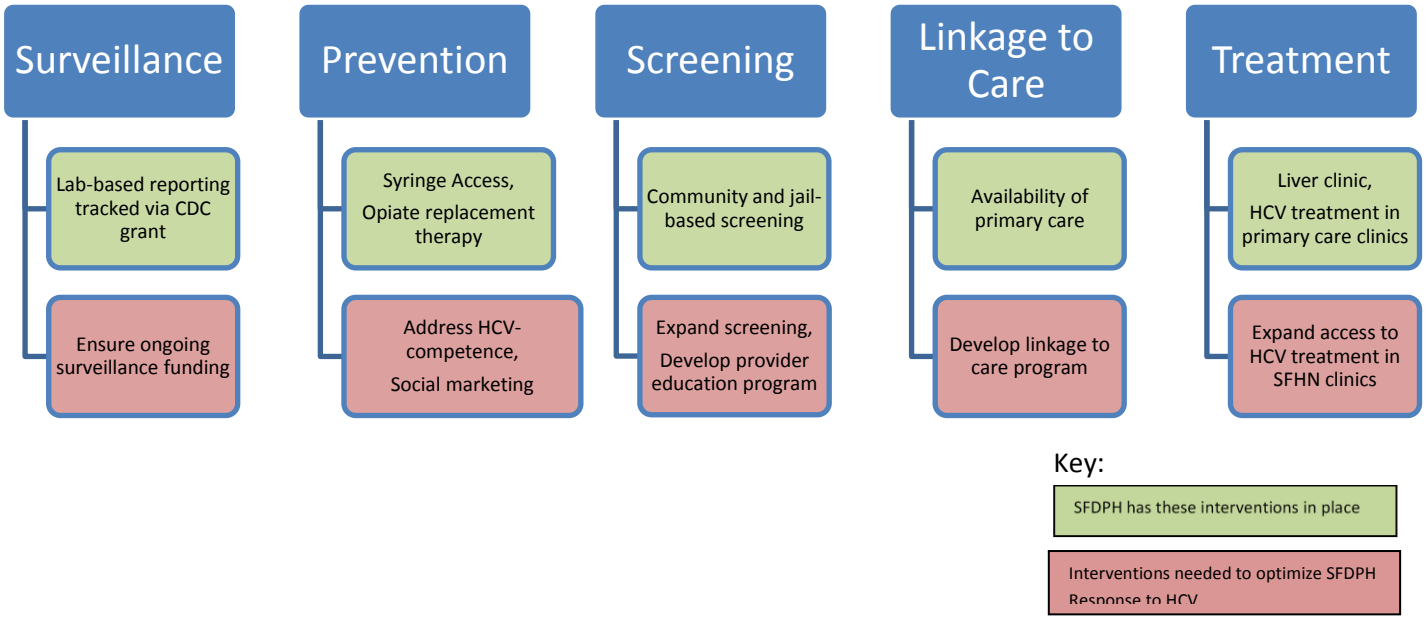
Many primary care providers need more support to provide primary care-based HCV treatment.

Patients served by the SFHN can seek HCV treatment through the SFGH Liver Clinic and at a limited number of SFDPH primary care clinics. The advent of new HCV direct-acting antiviral agents (DAAs) has made treating HCV easier in terms of medication tolerability, risk for adverse events, and efficacy or higher cure rates. A small number of primary care providers in the SFHN treat HCV within the primary care setting, but there are not enough providers with this specialty knowledge to serve the number of patients with chronic infection, particularly those at the highest risk for sequelae of

advanced disease who would most benefit from HCV curative treatments. **Provider education could expand the number of HCV-competent clinicians to provide treatment and therefore increase access to HCV services.**

For those providers who do treat HCV, they have been able to access the DAAs via public and private insurance benefits and, more typically, patient assistance programs. Due to restrictions on access to these costly yet cost-effective medications, obtaining the medications is a time-consuming, multi-phase paperwork process. Specialty pharmacy support at community pharmacies and through the SFGH pharmacy has been helpful with prior authorizations and patient assistance program paperwork. Some primary care clinics use nursing support for this process and to support the clinician during the treatment process by monitoring adherence, adverse events and confirming virologic response or cure rates. **The nursing and clinician resources dedicated to HCV treatment are currently inadequate to optimize efficiency and maximize the number of patients being treated and cured.**

Strengths and Proposed Interventions in SFDPH HCV-Programming Along the Continuum of HCV Services



Why Act Now to Scale up HCV-Related Services and Treatment?

A number of factors have converged to make now a crucial time to direct resources toward preventing, managing, and curing hepatitis C.

The success of existing SFDPH initiatives relies on addressing HCV.

SFDPH launched its Black/African American Health Initiative (BAAHI) in April 2014 to address the health disparities seen in San Francisco's Black/African American population. Addressing HCV is a vital component to this initiative, as surveillance data indicate that although this group represents only 6.6% of San Francisco's general population, they account for approximately 33% of San Francisco's HCV cases and 23.5% of the population of people who are co-infected with HIV and HCV.[14]

In January 2015 SFDPH collaborated with a consortium of community agencies to launch its "Getting to Zero" Initiative with the goal of San Francisco becoming the first city to get to zero new HIV infections, zero HIV-related deaths, and zero HIV-related stigma. Preventing HIV transmission is a crucial component in the HCV prevention toolbox—it is known that being co-infected with HIV and HCV increases the likelihood of a person transmitting HCV, and also speeds up the progression of HCV in co-infected people. Co-infection with HIV and HCV can also limit possible HIV treatment options for the co-infected person, and high community uptake of HIV antiretrovirals is a vital component of the "Getting to Zero" strategy.

Curative treatments can be accessed at no cost for eligible patients via patient assistance programs.

The recent availability of direct-acting antiviral agents as curative treatments for HCV has revolutionized the field of HCV treatment. The former standard-of-care for treating HCV involved a regimen of pegylated interferon and ribavirin, a grueling 24- to 48-week treatment with debilitating side effects that only cured approximately 45% of patients. **The new medications, by contrast, cure upwards of 95% of patients in 8-24 weeks with no or mild side effects.** These medications, along with expanded Medi-Cal coverage via the Affordable Care Act, present a unique convergence of factors that combine to increase incentives for disengaged, high-need patients to engage in care, and the ability of the medical system to bill for treating this population.

While the cost of these medications have posed significant barriers to access, including care rationing by insurance companies, **the pharmaceutical companies that created the new HCV medications have developed generous patient assistance programs that provide the drugs at no cost to patients** making less than $100,000/year. Given the income requirement, the vast majority of SFDPH patients living with HCV would qualify for patient assistance if the status of their liver disease alone does not qualify them for coverage via standard insurance benefits. SFDPH providers have become remarkably efficient in accessing this resource, and the vast majority of SFHN patients who have been treated and cured obtained their medications free of charge via the patient assistance programs following Medi-Cal or Healthy San Francisco denials of prior authorization requests.[15] At present, Medi-Cal only covers new HCV medications for patients whose liver damage

is advanced (staged at F3-F4), but this may change over time. In the meantime, there is no guarantee that the patient assistance programs will last indefinitely, so it is crucial to take full advantage of the programs while they exist in their current form.

Curing HCV is likely cost-effective.

The California Technology Assessment Forum announced in February of 2015 that Gilead Science's provision of an average discount of 46% for its HCV-treatment drugs Sovaldi and Harvoni renders the medications of high value for most health systems.[16] Untreated/uncured SFDPH patients with HCV are far more likely to strain the SFDPH system financially and logistically by requiring hospitalizations, multiple appointments with specialists, and frequent clinic visits.

"Cure as Prevention" will reduce community-level HCV viral load.

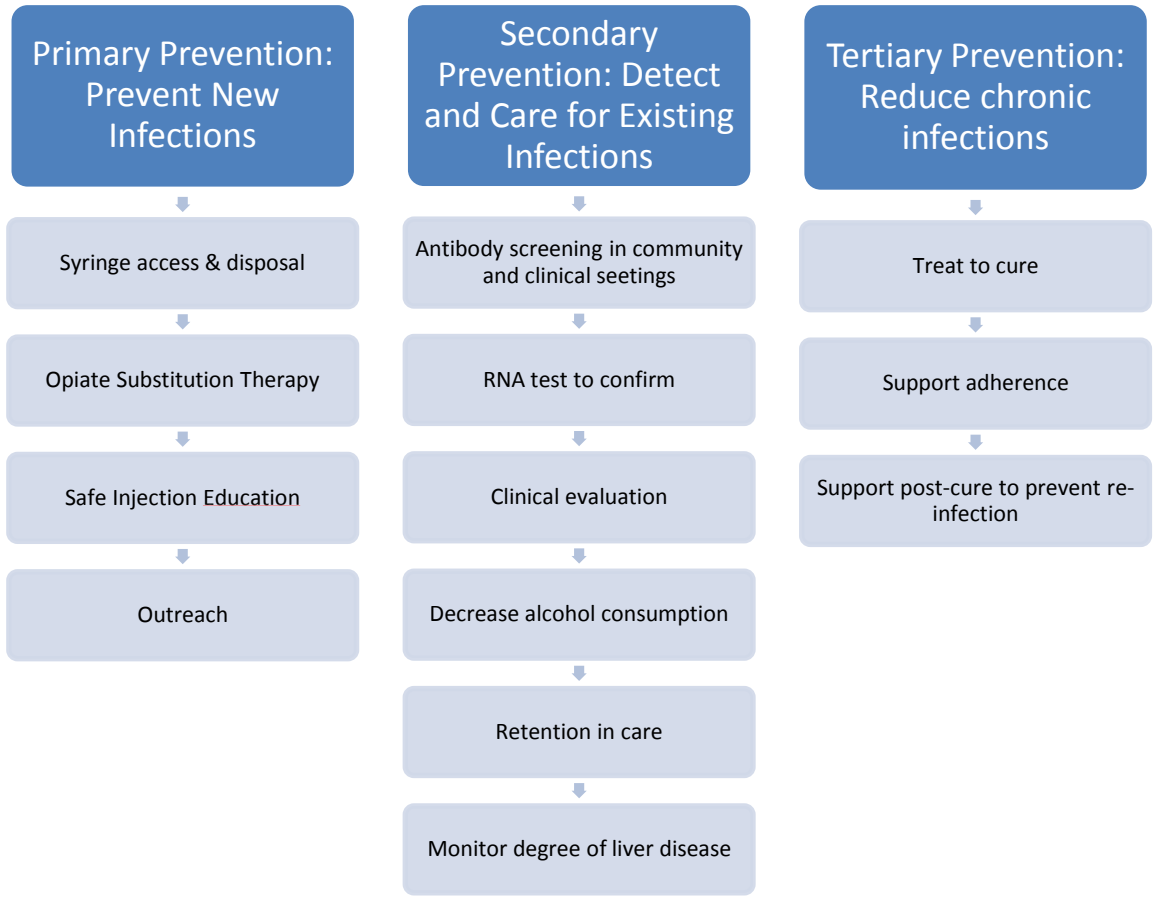
Taking cues from SFDPH's impressive success in implementing a treatment as prevention (TasP) framework for HIV, people who have been cured of HCV and remain uninfected can no longer infect others. Given the improved treatment regimens, traditionally challenging-to-treat populations such as marginally housed individuals and people actively using substances can be successfully cured, as has been demonstrated in SFDPH clinics.[17] Small investments in treating PWIDs, for example, can have tremendous impact—according to one study, treating just 8% of active injectors per year would reduce HCV prevalence by 50-90% in 15 years.[18]

SFDPH Strategic Directions in Addressing to HCV

SFDPH's strategic directions in addressing HCV are rooted in national[19] and local HCV data and national research, and they are closely aligned with existing SFDPH BAAHI and Getting to Zero initiatives, as well as the California Department of Public Health's viral hepatitis strategic plan. Every opportunity to co-locate the interventions and services described below will increase the impact of the SFDPH response to HCV .[20]

Key Recommendations in Responding to HCV:

- *Increase HCV awareness among affected populations.*
- *Increase community and clinic-based screening.*
- *Develop a linkage-to-care program.*
- *Increase primary care provider capacity to treat HCV.*
- *Increase patient uptake of curative therapies.*



Primary Prevention

San Francisco was an early adopter of syringe access and disposal services in order to reduce HIV transmission among PWIDs, and this program is credited with the low HIV transmission rate of 6% among PWIDs.[21] Today SFDPH funds a sophisticated network of organizations that offer culturally competent services to an array of subpopulations within the PWID community. Ensuring primary HCV prevention for PWIDs is challenging due to HCV's virulence compared to HIV. Syringe access and disposal services are a vital intervention in the fight against HCV, and research demonstrates that offering syringe access and disposal services in combination with opiate substitution therapy are effective in preventing transmission of HCV. SFDPH must continually appropriately invest in these life-saving interventions to ensure that every PWID has access to opiate replacement therapy as well as "a new kit for every hit."[22]

It is important to note that community-based assessment in San Francisco has indicated a significant amount of misinformation and confusion among PWIDs about how HCV is contracted, what antibody versus viral load test results indicate, and what treatment for HCV entails. SFDPH should prioritize efforts to support SFDPH-funded agencies that work directly with San Franciscans who are at high risk of HCV transmission and/or heavily affected by HCV in providing updated and accurate

information to their program participants. This can be done through staff trainings and supporting culturally relevant social marketing campaigns.

Secondary Prevention

Knowing one's HCV status is the first step to getting treated, cured, and avoiding infecting others. It is vital to improve upon SFDPH's 65% rate of baby boomer HCV screening, and a provider education program and electronic health record prompt coupled with general population social marketing campaigns could help address the gap between screening recommendations and practice. Community and jail-based screening for high-risk populations should be supported and expanded. Perhaps most importantly, SFDPH should investigate opportunities to support linkage-to-care services for those San Franciscans who learn they have chronic HCV infection in a community-based setting, but who are disconnected to medical care. Culturally competent eligibility workers and patient navigators are critical support these efforts.

Tertiary Prevention

SFDPH physicians at the Liver Clinic and some SFDPH primary care clinics have had great success in treating and curing patients with HCV. Given the simplicity of most new HCV treatment regimens, some primary care physicians have been curing uncomplicated cases of chronic HCV infection within the primary care settings, a development that has been successful in treating those patients who otherwise have difficulty traveling to the Liver Clinic. Increasing the capacity of other primary care clinic providers to treat uncomplicated HCV infection onsite will have tremendous impact in opening up treatment access for those patients who will be more successful undergoing treatment in their medical homes and would be consistent with the principles of patient-centered care. This can be accomplished in a variety of ways, including but not limited to setting up physician education and mentorships, budgeting for HCV-specific clinic hours within primary care, offering conferences and HCV-related CEU opportunities, and supporting the provision of additional nursing and specialty pharmacy staff to assist in the process of accessing medications.

Conclusion

SFDPH's mission to protect and promote the health of all San Franciscans serves as a reminder of the importance of addressing the significant HCV burden among its population. Implementing a comprehensive HCV-response with a focus on disproportionately impacted populations will improve the health and quality of life of thousands of affected San Franciscans while also protecting the health of the population. Making relatively small investments related to the key recommendations outlined in this document (i.e., developing linkage-to-care services and increasing HCV awareness, screening rates, primary care provider capacity, and access to curative treatments) can yield significant impacts in identifying San Franciscans who may be unknowingly living with HCV and connecting them to treatment. **San Francisco has led the nation in innovative and evidence-based**

response to the HIV epidemic, and now has the opportunity to take a similar leadership role in its response to HCV.

Acknowledgements

Several key partners contributed to the development of this report and its recommendations:
Kelly Eagan, MD offered feedback on community treatment of HCV.
Melissa Sanchez, PhD, MA, Supervising Epidemiologist and Project Director of Viral Hepatitis Surveillance at SFDPH contributed the description and explanation of viral hepatitis surveillance activities.

Additional input was provided by:
Rachel McLean, Viral Hepatitis Coordinator at CDPH
Chris Taylor, Viral Hepatitis Director at NASTAD
Emalie Huriaux, Director of Federal and State Affairs at Project Inform,
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Dara Geckeler, Integration Manager, SFDPH Community Health Equity and Promotion branch

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The Hepatitis C Task Force of San Francisco
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- Dara Geckeler, Integration Manager, Community Health Equity & Promotion
- Jose-Luis Guzman, Program Liaison, Community Health Equity & Promotion
- Thomas Knoble, Capacity Building Program Manager, Community Health Equity & Promotion
- Noah Carraher, Quality Improvement Manager, Office of Equity and Quality Improvement
- Arcadi Kolchak, Executive Director of Hep B Free
- Kate Monico Klein, Director, HIV & Integrated Services (HIV&IS) a Program of Jail Health Services
- David Leiva, Prevention Services Coordinator, HIV & Integrated Services (HIV&IS) a Program of Jail Health Services
- Trang Nguyen, Epidemiologist, Applied Research, Community Health Epidemiology, and Surveillance Branch

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