

Localized US Efforts to Eliminate Hepatitis C



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KEYWORDS

- Hepatitis C virus • Elimination • Coalition • Advocacy • Legal
- People who inject drugs • Continuum of care

KEY POINTS

- Local strategies must be developed to implement hepatitis C elimination programs.
- Coalitions of community advocates, health and social service providers, researchers, legal experts, and government representatives have come together in New York State, San Francisco, California, and Massachusetts to create hepatitis C virus elimination plans.
- Barriers to the hepatitis C care continuum can be addressed on a local level using new and existing resources.
- Funding remains a challenge and focus of advocacy.

Disclosure Statement: End Hep C SF has received a charitable donation from Abbvie Pharmaceuticals and a grant from the Gilead Foundation (K. Burk). Research grant support to UCSF related to HCV from AbbVie (32175), Gilead and Merck (A. Luetkemeyer). Nothing to disclose (A. Gaudino, B. Gay, C. Garmon, M. Selick, R. Vreeland, E. Hurliaux, S.N. Facente, P. Waters, C.S. Graham).

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Infect Dis Clin N Am 32 (2018) 293–311

<https://doi.org/10.1016/j.idc.2018.02.009>

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INTRODUCTION

We have now reached a sentinel point in addressing the scourge of hepatitis C virus (HCV) infection. Interferon, with its difficult side effects, is no longer used in the United States for HCV infection, we have tests to determine liver damage that do not require liver biopsy, and previously “difficult-to-cure” patient groups have a greater than 95% cure rate with 8 to 12 weeks of well-tolerated all-oral medications. These advances have led the National Academies of Medicine, Engineering and Science to declare that hepatitis C can be eliminated in the United States.¹

The National Viral Hepatitis Action Plan details actions that agencies within the federal government can take to facilitate improvements in diagnosing patients, linking them to care, and supporting their successful completion of curative treatments.² Many of the systemic challenges facing us as a nation benefit from large-scale coordination of policies and actions at the federal level. However, much of our health care is organized on a state level, including departments of public health-sponsored surveillance, health insurance, and certain policies. Coalitions are emerging to address city and state-level elimination strategies, and these have several initiatives in common. This review discusses examples of programs from 2 states—New York and Massachusetts—and 1 city-wide effort, in San Francisco. Our goal is to facilitate the creation of HCV elimination campaigns in every state.

BACKGROUND: HEPATITIS C VIRUS IN NEW YORK STATE

Since 2001, more than 254,200 chronic HCV cases have been reported in New York state. In 2014, there were 16,169 chronic HCV cases and 127 acute cases reported. The statewide HCV case rate in 2014 was 83.4 per 100,000. The rate was higher in New York City (94.1 per 100,000) than outside of New York City (75.7 per 100,000). Although New York City has historically been the epicenter of the state’s HCV epidemic, in 2014 more than one-half (51.2%) of new chronic hepatitis C cases were diagnosed outside of New York City.³

Since 2004, in New York state there has been a shift in the age distribution of reported HCV cases from being primarily among persons aged 40 to 60 years to being reported among a growing cohort of persons aged 20 to 40 years. This shift is especially striking outside of New York City. Recent increases of HCV are occurring outside of New York City among young people who inject drugs (PWID), which parallels the growing epidemic of prescription opioid misuse seen in suburban and rural areas. There has also been a shift in the distribution of cases by sex. In 2005, females aged 15 to 44 accounted for 35.7% of HCV cases reported outside of New York City. This proportion increased to 56.5% in 2015.⁴

Hepatitis C Virus Services in New York State

Although New York state faces concerning gaps in its HCV continuum of care caused by ongoing barriers to HCV prevention and treatment, the state has built a strong foundation for an HCV elimination plan. New York state has one of that largest concentrations of skilled medical providers, prevention and harm reduction specialists, researchers, hepatitis C-focused coalitions, such as the New York City Hepatitis C Task Force, and public health officials in the nation, combined with a vibrant network of community outreach workers and community-based health activists throughout the state. There are several initiatives that build HCV clinical capacity and expand access to HCV treatment. The New York State Department of Health’s AIDS Institute Hepatitis C Care and Treatment Initiative aims to increase the number of people with HCV who get linked to care and initiate and complete treatment. Each funded program provides

linkage to care activities and on-site HCV medical care, care coordination, treatment, and supportive services in a clinical setting (ie, community health centers, drug treatment programs, and hospital-based clinics). The New York City Department of Health and Mental Hygiene (DOHMH) Project INSPIRE adapted the evidenced-based New York City HIV Care Coordination Program for HCV patients, and built capacity at 2 major medical centers by funding a multidisciplinary team including care coordinators and peer navigators to provide services, as well as supported clinical telementoring to build primary care provider capacity to deliver HCV care and treatment. Project INSPIRE aimed to improve patient outcomes and quality of care while reducing costs and proposed a payment model for sustained funding for these services. The New York City DOHMH Check Hep C Patient Navigation Program builds community health organization capacity and trains navigators to conduct effective HCV outreach, prevention, linkage to care, and clinical care coordination services to support complete HCV treatment and reinfection prevention after cure. Check Hep C is a flexible low-cost and low-threshold model for delivering patient navigation services that has been implemented at more than 45 community health organizations, including syringe exchange programs, community health centers, and hospitals, and has trained more than 100 peer and patient navigators in HCV patient navigation. New York State's more than 20-year history of support for syringe exchange and harm reduction services, and its role in originating and expanding medication-assisted treatment for opioid dependence, have informed human immunodeficiency virus (HIV), hepatitis, and substance use services worldwide. New York State has also been on the vanguard of successful and ongoing Medicaid reform that provides further support for new efforts to fill the gaps in the HCV care continuum.

The Catalyst for the Elimination of Hepatitis C Virus in New York State: The Human Immunodeficiency Virus Elimination Initiative “Ending the Epidemic”

The call to eliminate HIV first came in May 2013, when New York-based advocacy organizations convened community leaders, advocates, health and social service providers, researchers, and government representatives to assess the adequacy of New York's response to the HIV/AIDS epidemic and to discuss developing an action plan that would bring about the end of the epidemic in New York State. Community leaders partnered with the AIDS Institute and the DOHMH to convene key stakeholders who were tasked to identify priorities through a statewide community engagement process. These stakeholders held various town halls, rallies, actions, public lectures, and social media campaigns to raise awareness and pinpoint statewide priorities. Priority areas included policy, prevention, biomedical interventions, surveillance, access to care, messaging, and resources.

This first effort was the foundation for the Ending the Epidemic (EtE) initiative and informed a historic June 29, 2014, announcement from then-Governor Cuomo about his 3-point plan to end AIDS in New York State by the end of 2020—the first pledge of its kind in the United States.⁵ The goal is to reduce the number of new HIV infections from an estimated 3000 to 750 by 2020 to reduce the prevalence of HIV in New York State. That same year, the governor appointed an “Ending the Epidemic Task Force” to create a blueprint to implement this plan. New York state's pioneering plan to end its HIV/AIDS epidemic by the end of 2020, and the recommendations made by the Governor's EtE Task Force also provide an example of how state, city, county, and community experts can set long-term goals and work toward achieving elimination targets.

The EtE initiative has already improved health outcomes across the HIV continuum of care, and New York state has begun meeting its EtE goals. These include (1)

changing the HIV testing law, (2) gaining insurance coverage for health care specifically for transgender people, (3) the legal prohibition of using condoms as evidence for the two lowest levels of misdemeanor criminal charges for sex work, (4) enabling medical providers to access surveillance data to retain patients in care and help them to achieve viral suppression, and (5) allowing pharmacists to dispense starter kits for preexposure prophylaxis to prevent HIV transmission, among other adopted recommendations.

Developing an Initiative to Eliminate Hepatitis C in New York State

In Spring 2015, after meetings with community advocates who were intimately involved in the EtE campaign that was so successful the year before, community leadership invited the New York State Department of Health's AIDS Institute and New York City DOHMH into initial discussions to support a parallel initiative to eliminate hepatitis C in New York City and New York state. Many of the same advocacy organizations that were involved with EtE were reconvened with the stewardship of the New York state Hep C Elimination Campaign, and asked to develop a strategy for New York state to end hepatitis C. The response was unanimous and by Fall 2015, formation of a statewide Campaign to Eliminate HCV had begun.

Before the first steering committee meeting in March of 2016, the coalition leadership was composed of community-based HIV organizations and multiservice providers, harm reduction and treatment advocacy organizations, and multi-issue membership organizations that represented PWID. Leaders from these organizations wrote a discussion paper that served as an initial call to action for the rest of the state's HCV advocates that outlined the committee's vision for the work that lay ahead. This paper was the foundation for the coalition-building work that took place throughout the rest of 2015 and culminated in a statewide Summit for HCV Elimination in New York State.

The March 2016 meeting of the steering committee saw the development of a process for pursuing the vision, and a structure was created to carry it out. A group of 94 stakeholders from across the state, including state and local government representatives, epidemiologists, physicians, harm reduction and social service providers, and community advocates, formed the core coalition. It was to be guided by an advisory board that included the leading government agencies and the original members of the coalition. However, the steering committee had the authority to act for the campaign.

The steering committee decided to follow a path similarly taken by the EtE leadership and created 5 working groups that developed recommendations to inform the overall elimination strategy that would be presented to the New York state Governor. The groups were called Prevention/Harm Reduction/Prevention of Reinfection, Testing and Linkage to Care, Clinical Care/Treatment Access/Supportive Services, Surveillance and Data Metrics, and Social Determinants (Fig. 1).

Work group members were recruited from various institutions and fields, representing different geographic areas, experiences, expertise, work and community settings, and genders, and included professionals and people living with HIV, HCV, those who have used harm reduction services, and others disproportionately affected by HCV. Throughout the process, members were requested to consult other people in their networks, particularly to ensure the inclusion of practitioners and community representatives in the areas most affected by HCV. Each group was given a directive along with a set of questions to answer that were specific to the purpose of their group, and they were given 6 weeks to report back to the steering committee with their findings in the form of draft recommendations.

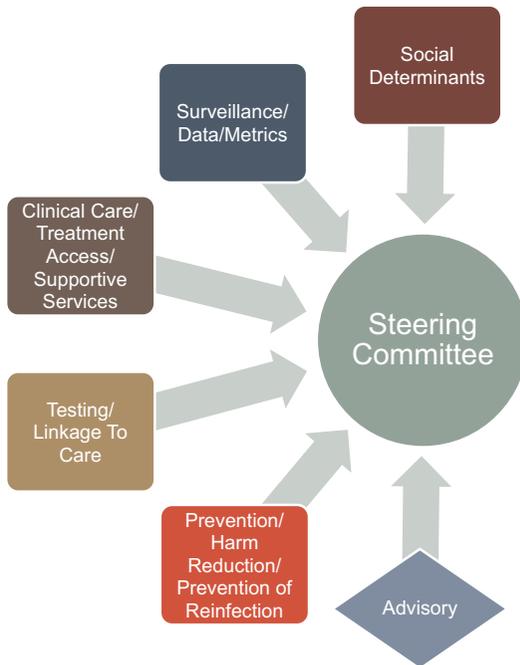


Fig. 1. New York work group structure.

Despite the extensive outreach to recruit a diverse membership, there were some limitations in the work groups' composition. This could be attributed to insufficient time and resources to announce the HCV elimination process or a lack of strong relationships within the more remote communities. There were gaps in participation by key impacted populations, especially people who inject or use drugs, Native and homeless populations, and those who were formerly incarcerated or who worked with people reintegrating into society. Ongoing efforts to engage the upstate, rural communities most impacted by the HCV and opioid epidemics in the statewide elimination campaign are needed. Stronger community voices and active participation would ensure a balance among the researchers, social service providers, and physicians.

The work group chairs reported their findings to the steering committee at a meeting held on November 28, 2016. Their analysis included gaps in services related to their area of focus, populations at risk, best practices, potential policy changes, and a list of their recommendations prioritized in order of need to achieve elimination (Box 1).

Establishing Elimination Targets

An important discussion arose around the establishment of elimination targets and the accompanying metrics with which to measure progress toward achievement. This work was done within the Data, Surveillance and Metrics work group, but the actual targets could not be determined until better estimates of the prevalence of people infected with chronic HCV are calculated, which the New York State Department of Health and the New York City DOHMH are coordinating efforts to complete in the near future. This work group has been trying to set elimination targets based on a prevalence estimate and consistent with the World Health Organization and National

Box 1**New York work group recommendations***Prevention*

1. Health literacy and education.
2. HCV prevention services in correctional settings.
3. Prevent the onset of drug injection and HCV infection among young opioid users.
4. Access to medication-assisted therapy (buprenorphine).
5. Enhancing syringe exchange programs.
6. Safer injection/consumption facilities.

Testing/linkage to care

1. Facilitate and/or ensure confirmatory testing.
2. Expand patient and peer navigation programs.
3. Expand training and other educational opportunities for medical providers, testing and linkage to care staff, and the public.

Care and treatment access

1. Eliminate remaining restrictions on DAAs for all payers.
2. Address patient barriers to treatment.
3. Increase transparency about negotiated drug costs by payers.
4. Special attention should be given to incarcerated populations.

Data and metrics

1. Set realistic but ambitious targets for elimination.
2. Systematically track and disseminate information on progress toward achieving the goals of the initiative.
3. Strengthen surveillance systems.

Social determinants

1. Eliminate legal barriers for people who inject drugs.
2. Increase funding for discharge planning and care coordination services after release from correctional settings.
3. Implement culturally appropriate messaging to the multiple populations with higher HCV risk or prevalence.

Abbreviations: DAA, direct-acting antivirals; HCV, hepatitis C virus.

Academies of Sciences, Engineering, and Medicine targets. However, setting elimination targets tends to be a political decision, and depends on which stakeholders have the leverage to determine the appropriate target, the dynamics of the decision-making process, which stakeholder is responsible to monitor progress, and how accountability is implemented during the process.

In contrast, the elimination target of a decrease of new HIV infections to 750 by 2020 was easier to determine for EtE owing to the decades of surveillance systems in place for HIV, which could be attributed to greater resources and funding. For HCV, once a statewide prevalence estimate for New York state is in place, the 2 health departments will work with a consultant to model an elimination scenario and metrics.

New York State Hepatitis C Elimination Summit

After the Joint Steering Committee/Work Group Meeting in November 2016, plans were underway for the next major milestone: the statewide Hepatitis C Elimination Summit. This followed similar tactics of the EtE leadership, which were successful in engaging stakeholders, building consensus recommendations, developing a shared knowledge base, and creating a transparent process for going forward. It was held in Albany on February 7, 2017, and in the time leading up to that culminating event, the steering committee was tasked with reviewing the work group recommendations and refining and abridging them into a concise set of core positions that would be presented to those at the summit, agreed upon by consensus, and then advanced for gubernatorial support.

The New York State Summit was the first statewide elimination effort in the United States, drawing national attention. There were 252 state and local officials, elected representatives, medical and social service providers, and community stakeholders, including people living with HIV, HCV, who have used harm reduction services or others disproportionately affected by HCV, who participated in the meeting in person or online. Presentations described the impact of HCV on people across the state, their most urgent needs, and the pathway to elimination. Participants had the opportunity to respond to and endorse the community consensus statement. This was presented as a call to action for New York state elected officials, the goal for whom was the establishment of a formal Task Force to support the Five Pillars into which the work group recommendations had been adapted (**Box 2**).

The Consensus Statement was ratified unanimously, and following the meeting, the steering committee gathered endorsements from community organizations, medical providers and facilities, policymakers, and local governments. In all, 134 organizations have endorsed the statement and, in May of 2017, the document was sent the New York state governor with a request to advance the recommendations.

Stakeholder Listening Sessions

Ratification by the 252 people who attended or viewed the summit, followed by the written endorsement of the community organizations, was only the first step toward

Box 2

Five pillars for New York statewide HCV elimination

1. Enhance HCV prevention, testing, and linkage to care services for people who inject drugs, people who are incarcerated, men who have sex with men, and other populations disproportionately impacted by HCV infection.
2. Expand HCV screening and testing to identify people living with HCV who are unaware of their status and link them to care.
3. Provide access to clinically appropriate medical care and affordable HCV treatment without restrictions and ensure the availability of necessary supportive services for all New Yorkers living with HCV infection.
4. Enhance New York state HCV surveillance, set and track HCV elimination targets and make this information available to the public.
5. Commit New York state government and elected officials, public health professionals, HCV experts, and industry partners to leadership and ownership of the New York State Plan to Eliminate HCV alongside community members living with and affected by HCV.

Abbreviation: HCV, hepatitis C virus.

statewide consensus. The steering committee spent the next 6 months (February to August 2017) holding listening sessions in every part of New York state to ensure that stakeholders who had not been able to attend the summit could review the recommendations and provide feedback to the organizers that would further inform the document. From Buffalo to Staten Island, 20 sessions have been held so far, with more than 228 total attendees.

Conclusions from the New York State Elimination Program

New York State is the first state in the United States to create a set of recommendations to eliminate HCV, which can inform the gubernatorial task force's statewide strategy. New York state can be a model for other states because many of the same problems addressed during New York State's HCV Elimination Summit are being felt across the country: rural and suburban regions of the state face an epidemic of young opioid users; urban populations face poverty and limited access to services; the insurance industry faces ever-rising drug prices; patients face rising drug costs that outpace inflation; and no generic competition of the direct-acting antivirals (DAAs) exists in the United States.

We are now on firm ground to call for eliminating HCV in New York by treating as many patients as possible and curbing new transmissions, given the effectiveness and tolerability of current DAA regimens. We need to increase the number of people who know they have HCV by increasing public and health provider education, strengthening our testing law, and encouraging routine testing in clinical settings and increased targeted testing in drug treatment programs, syringe programs, and other places likely to serve people who may have been exposed to HCV. We can build a robust hepatitis C treatment infrastructure in New York state to care for all those previously and newly diagnosed by repurposing the very successful HIV treatment infrastructure and expanding hepatitis C treatment capacity within primary care, licensed drug treatments programs, and corrections facilities. Drug manufacturers and government must find a solution for high HCV drug prices that addresses the inherent budgetary strain of treating a high volume of patients. In the call to action emphasized in the consensus statement that was endorsed by community advocates across the state, the coalition requested a joint commitment by the Governor, the New York state Legislature and industry partners to find a viable, cost-effective solution that will expedite people's access to HCV testing, treatment, and care. On March 16, 2018, Governor Cuomo announced the State's commitment to eliminate HCV. Community leaders cheered, then set to work to make his pledge a reality.

SAN FRANCISCO HEPATITIS C VIRUS ELIMINATION INITIATIVE: *END HEP C SF*

San Francisco is profoundly impacted by HCV. An estimated 22,000 San Franciscans have HCV antibodies, and of those, approximately 12,000 are estimated to have current HCV infection.⁶ As in many other communities, in San Francisco, HCV disproportionately impacts Baby Boomers (people born between 1945 and 1965) and some of our most vulnerable and stigmatized people, including PWID and men who have sex with men (Fig. 2).⁷ In addition, San Francisco has the highest rate of hepatocellular carcinoma of any city in the United States, driven by both hepatitis B virus and HCV.⁸

Recognizing that San Francisco had been hit hard by the HCV epidemic, in 2008 representatives of public health organizations, research institutions, and civic groups convened to discuss and craft a local response. In May 2009, Mayor Gavin Newsom appointed a panel to serve on the Mayor's San Francisco Hepatitis C Task Force and charged the group with developing a comprehensive set of recommendations to



Fig. 2. Disproportionate burden of hepatitis C virus (HCV) in San Francisco, 2015. Although transgender women make up a small percentage of the total population of San Francisco (0.1%), End Hep C SF estimates that more than 1 of every 6 transgender women is currently living with HCV. Note that the above groups do not add up to 100%; it is possible for a person to be in more than one group.

address the HCV epidemic. The task force's initial recommendations were published in 2010 and are updated annually (available: <http://sfhepc.org/recommendations/>). The Hepatitis C Task Force successfully advocated for the creation of a viral hepatitis prevention coordinator position with the San Francisco Department of Public Health (SFDPH), as well as for allocation of local funds to broaden HCV testing and linkage to care efforts. With this proactive public health engagement on HCV and the advent of highly effective oral DAA therapy, San Francisco now has the tools necessary to greatly reduce HCV related morbidity and mortality, break the cycle of forward transmission, and ultimately eliminate HCV. To that end, in 2016 SFDPH, University of California, San Francisco, and other community partners established the *End Hep C SF* initiative to lay the groundwork for HCV elimination (available: www.EndHepCSF.org).

Several conditions make San Francisco an ideal place for a groundbreaking HCV elimination effort. Access to HCV prevention, testing, and treatment in San Francisco is strong compared with much of the greater United States, and San Francisco has a history of implementing cutting-edge, evidence-based public health interventions such as syringe access, opiate agonist therapy, health coverage for uninsured individuals, overdose prevention programs, rapid initiation of HIV treatment immediately after diagnosis, and early adoption of universal HIV treatment regardless of CD4 cell count.⁹ In 2015, San Francisco became one of the first cities in the world to commit to achieving the UNAIDS vision of "Getting to Zero" for HIV (zero new HIV infections, zero HIV deaths, and zero HIV stigma by 2020).¹⁰ San Francisco's Getting to Zero initiative provided inspiration for a similar elimination initiative focused on HCV.

End Hep C SF is a multisector independent consortium operating under the principles of collective impact. Collective impact involves people working together on a complex issue under 5 conditions: common agenda, shared measurement, mutually reinforcing activities, continuous communications, and backbone support.¹¹ The *End Hep C SF* founders recruited members for what was initially called the Steering Committee. This group met biweekly in the first quarter of 2016, learning about collective impact while laying the foundation for the initiative. After deliberation as to the best structure for the initiative, the Steering Committee formed 4 workgroups—(1)Research and Surveillance, (2)Prevention and Education, (3)Testing and Linkage, and (4)Treatment Access, then reached out to those working in HCV across the city in a variety of settings and requested their participation in the initiative. Since its inception, *End Hep C SF* has strived to uphold the principles of collective impact and align with the framework's 5 conditions (available: <http://www.fsg.org/approach-areas/collective-impact>). To this end, we emphasize collective decision making, data sharing, and evaluation as key components of the initiative's process and diffused leadership model; we have also conducted structured evaluations to assess adherence to collective impact principles and will continue to do so at regular intervals.

As of the end of 2017, 32 organizations and more than 100 individuals had signed on as *End Hep C SF* partners, with representation from sectors including academia, local government, drug treatment programs, syringe access programs, homeless service organizations, pharmacies, private medical systems, HIV/AIDS service organizations, and advocacy groups. *End Hep C SF*'s organizational representatives participate in various ways, including membership on the Coordinating Committee or the 4 workgroups, guidance through the Executive Advisory Committee, or participation in semi-annual community-wide meetings. Many of our most actively involved stakeholders are staff of community-based organizations, committed to one or more key aspects of HCV elimination: diagnosis, treatment, prevention, and education. *End Hep C SF* has explicitly created opportunities for participation at varied levels of commitment to encourage broad-based representation in the initiative across San Francisco.

Vision and Priority Setting

End Hep C SF envisions a San Francisco where HCV is no longer a public health threat, and HCV-related health inequities have been eliminated. The initiative's mission is to support all San Franciscans living with and at risk for HCV to maximize their health and wellness. The initiative defined this vision, mission, corresponding values, and short-term goals in its first 3-year strategic plan published in March of 2017.¹² These priorities were established over a period of 4 months with the help of an external consultant who led workgroup members through a series of discussions related to available risk data, analysis of the existing landscape of interventions, and stakeholder wisdom about gaps and areas of potential high impact. Initial priority interventions were refined into measurable, achievable, time-based priorities for action both in 2017 and in 2018/2019 to move closer to elimination. A corresponding list of budget requests was simultaneously developed by the workgroups, identifying which priorities could not be achieved without additional funding and how much would be required. This list of funding needs was used to inform the San Francisco Hepatitis C Task Force's official request for the mayor's budget in 2017, as well as requests for funding from research institutions, private foundations, and corporate giving programs.

Core Strategies

In our first 2 years, *End Hep C SF* has focused on several key strategies: addressing data gaps, reaching people living with HCV "where they are," developing models of HCV care and treatment outside of specialty care, and seeking innovative partnerships with insurers to support elimination.

Strategy: addressing data gaps

One of *End Hep C SF*'s core strategies is a focus on data, improving and aligning research and surveillance of HCV, and making better use of existing data to guide programs and policies. To understand the potential effect of *End Hep C SF* interventions, it is critical to have a strong estimate of citywide HCV prevalence, including in key populations with programmatic significance. However, despite the implementation of HCV surveillance systems and the inclusion of HCV measures in national health surveys, accurate estimates of total active HCV infections at the local level, including breakdown by key populations, are lacking. To address this data need, epidemiologists in the Research and Surveillance workgroup developed a process to triangulate surveillance, research, and local health systems data to produce a baseline estimate of the number of people in San Francisco with anti-HCV antibodies, as well as active HCV infection (detectable HCV RNA), with findings released in June 2017.⁶ San Francisco's

prevalence estimate is the result of an innovative, collaborative process made possible by the existence of *End Hep C SF*. Data regarding disparities among certain key populations will guide future efforts of the other workgroups, which will prioritize these populations for prevention, testing, linkage, and treatment interventions. Annual assessment of citywide HCV treatment starts as well as revised estimates of active HCV prevalence will be conducted to track progress toward HCV elimination.

Strategy: reaching people living with hepatitis C virus where they are

Education and outreach for key populations *End Hep C SF* maintains an explicit commitment to prioritizing marginalized populations for HCV interventions. In 2016, *End Hep C SF* launched the “New Treatments Have Changed the Game” HCV education initiative based on feedback from PWID during focus groups conducted by *End Hep C SF* partner GLIDE. GLIDE provides HCV testing, syringe access, and naloxone distribution services primarily to people who are homeless in San Francisco’s Tenderloin neighborhood. Focus groups had the dual purpose of assessing clients’ baseline knowledge of new developments in HCV treatment, and testing messages about HCV prevention, testing, and treatment. Three overarching messages for and by PWID resulted from the process: (1) “Sharing equipment spreads hep C. Come get sterile stuff.” (2) “We can’t treat hep C if we don’t know we have it.” (3) “Living with hep C? New treatments have changed the game.” These messages were featured on posters with pictures of HCV service providers from 7 different *End Hep C SF* partner agencies (Fig. 3), viewable at <http://www.endhepcsf.org/campaigns/>.

Increased community-based testing *End Hep C SF*’s Testing and Linkage workgroup meets regularly to discuss community-based HCV testing practices and develop standards and protocols for testing in nonclinical settings. In the first year of *End Hep C SF*, this workgroup examined SFPD surveillance data alongside community-based testing data and literature estimating the number of PWID citywide. The group set a target to increase community-based testing rates 4-fold over 3 years and have already increased testing rates by 18%, despite no significant increase in resources. This was done by programs integrating point-of-care rapid HCV testing with existing HIV testing services and reaching PWID and other key populations at syringe access programs, drug treatment programs, in residential hotels, on the street, in shelters, and other relevant settings.

Hepatitis C virus navigation services In 2016, *End Hep C SF* partners SFPD, GLIDE, HealthRIGHT360, and the San Francisco AIDS Foundation launched HCV navigation services. These services support linkages to an HCV treatment provider for community members newly diagnosed with HCV, or those who have been living with HCV but are disconnected from care. The programs are specifically designed for people who are actively using drugs, homeless or marginally housed, and/or have cooccurring mental illness. The navigators educate clients about HCV, ensure their insurance status is up to date, connect them with appropriate providers, facilitate support groups, and help them to track appointments and medications. In the first year, 252 people connected to primary care, the majority of which included HCV treatment capability and at least 89 people achieved sustained virologic response at 12 weeks. These numbers have continually improved in the second year of programming as linkage strategies and data collection processes evolve.

Community engagement *End Hep C SF* is committed to hosting evening meetings twice annually for members of the larger community to learn more about local

Living with Hep C? New treatments have changed the game



There is new hope for people with Hep C
Come visit us to talk about the new cure

Fig. 3. Sample poster from the “New Treatments Have Changed the Game” campaign, a social marketing effort to boost hepatitis C virus testing and treatment rates among San Francisco people who inject drugs. (Courtesy of Glide Harm Reduction Program, San Francisco, CA; with permission.)

HCV services, and provide feedback to *End Hep C SF* about potential gaps in services and/or what should be scaled up. In August 2017, *End Hep C SF* hosted the first consumer advisory meeting entitled “Tales from the Cured.” This meeting featured an explanation of *End Hep C SF*, a discussion of the HCV prevalence estimate, and an “Ask the Doctor” segment about new HCV treatments and interventions. A panel of 4 former clients of the HCV navigation programs discussed their experience being cured of HCV and the wide-reaching positive impact being cured has had on their lives. Meeting participants offered feedback on potential service locations and suggestions for peer-driven HCV linkage services.

Strategy: Developing Models of Hepatitis C Virus Care and Treatment Outside of Specialty Care

Primary care-based hepatitis C virus treatment

Providing HCV treatment in primary care is crucial given high need and the limited number of hepatology, gastroenterology, and infectious disease specialists treating HCV; the fact that many specialists lack experience working with PWID, people who are homeless, and others disproportionately impacted by HCV may also affect their ability to provide culturally competent care.¹³ Further, referring a primary care patient to specialty care for treatment is an additional step that may hinder treatment initiation. In 2015, before the genesis of *End Hep C SF*, efforts began within the SFDPH's network of 19 clinical locations largely serving low-income San Franciscans, to train primary care providers to manage and treat HCV. Concurrently, efforts were underway at a local federally qualified health center (Tenderloin Health Services, part of Health-RIGHT360) to provide HCV treatment as part of primary care in a community clinic serving largely homeless and marginally housed patients. Through these efforts, dozens of primary care providers are newly treating HCV, and hundreds of patients have been cured in the primary care setting as a direct result (see Shelley N. Facente and colleagues' article, "[New Treatments Have Changed the Game: Hepatitis C Treatment in Primary Care](#)," in this issue).

Hepatitis C virus treatment outside of primary care

To further enhance access to HCV care and treatment, *End Hep C SF* has also focused on establishing innovative models for care in nonclinical settings frequented by many of the most stigmatized people living with HCV. These settings include residential drug treatment programs, methadone clinics, the street (via medical outreach to people who are homeless), the San Francisco jail, a sexual health clinic for men who have sex with men, and syringe access programs. Within opiate agonist therapy settings, 2 innovative HCV care and treatment programs launched by *End Hep C SF* partners are at the Opioid Treatment Outpatient Program (OTOP) at Zuckerberg San Francisco General Hospital and the Bayview Hunters Point Foundation. Both organizations are outpatient medication-assisted treatment clinics serving people with opioid use disorders, and both now provide DAAs via directly observed therapy for individuals who come in daily for methadone. OTOP has a history of serving people living with HIV who access methadone and other medication-assisted treatment for opioid dependence, and OTOP staff have years of experience providing HIV treatment and adherence support. Given this, OTOP clinicians, nurses, and counselors were well-positioned to start prescribing HCV DAAs and to support patient adherence to DAA regimens. OTOP implemented this model by hiring a full-time nurse through a grant from the California Department of Public Health. In the first year of OTOP's HCV treatment program, they have treated 68 patients. Bayview Hunters Point Foundation's methadone clinic does not have a history of treating HIV and worked closely with a primary care clinician and HCV treatment champion located at a neighboring SFDPH clinic to build capacity for HCV directly observed therapy and adherence support. To reach others who may not access health services in a primary care setting, the San Francisco AIDS Foundation is beginning to provide HCV treatment at its gay men's sexual health clinic and at one of its syringe access locations. Additionally, the SFDPH has begun treating people who are homeless through its Street Medicine team, and treating individuals incarcerated in the county jail through the SFDPH-run Jail Health Services. Funding the HCV treatment effort in the county jail is a unique challenge given the suspension of Medicaid and private

insurance benefits when people are incarcerated; there is a critical need for sustainable funding mechanisms for treatment in this highly impacted population.

Strategy: Seeking Innovative Partnerships with Insurers to Support Elimination

A unique partnership between *End Hep C SF* and the San Francisco Health Plan—the managed care plan for 87% of Medicaid enrollees in San Francisco—has helped facilitate many of these innovative approaches to HCV treatment. The San Francisco Health Plan participates regularly in *End Hep C SF*'s Treatment Access workgroup meetings and provides data about monthly HCV treatment uptake among Plan members. These data help the workgroup to monitor trends (ie, treatment compliance and completion rates, retreatment rates, prescriber trends) and strategize about ways to improve treatment uptake. The plan's workgroup participation has also offered clinicians the opportunity to understand the plan's process for determining preferred DAA regimens, alleviating clinicians' frustrations during the prior authorization process and motivating them to use preferred regimens when appropriate. The workgroup meetings have provided a forum for clinicians to give input into the plan formulary decisions, share the testing or treatment challenges with each medication, and work collaboratively to address barriers to effective care. For example, clinician feedback on treatment challenges introduced by a remote specialty pharmacy facilitated quality improvement efforts to simplify the ordering, refill, and delivery processes. The plan has been able to advocate effectively for funding support from the state with this detailed provider input. Additionally, the plan has provided technical assistance to clinics regarding prior authorizations and use of specialty pharmacies, and has provided financial support for innovative efforts, such as HealthRIGHT360's project to initiate HCV treatment in residential drug treatment facilities.

Future Directions

Data gaps

We still do not have comprehensive data on the number of individuals successfully treated for HCV in San Francisco. Instead, we have relied on available survey and surveillance data, modeling, and shared data on treatment from health systems. The Research and Surveillance workgroup continues to build on their initial prevalence estimation work, gathering data to create a cascade of HCV care in San Francisco. This will provide a better picture of HCV diagnosis, confirmation, and treatment rates. It will also inform forecast modeling, to determine the optimal combination of HCV treatment and prevention interventions within subpopulations to shorten HCV elimination timelines and improve cost feasibility.

Building capacity for hepatitis C virus interventions

The Prevention and Education workgroup is planning to use a widely distributed survey to measure the capacity of San Francisco organizations to integrate HCV interventions into their work, so targeted capacity-building efforts can begin. This group also plans to expand on the "New Treatments Have Changed the Game" campaign by creating a video featuring the stories of clients who have been cured of HCV. The Testing and Linkage workgroup continually works on scaling up HCV testing, and aims to develop peer-based HCV linkage services.

Expanding hepatitis C virus treatment access

The Treatment Access workgroup plans to continue to expand HCV treatment in nontraditional settings and seek funding to support HCV-dedicated nursing, as well as creating an academic detailing program. Academic detailing is an outreach education technique that helps clinicians provide evidence-based care to their patients

through 1-on-1 conversations.¹⁴ We plan to use academic detailing to improve screening and linkage to care in primary care settings, particularly in private health care settings outside the SFDPH. We are in the process of developing detailing materials and plan to begin the academic detailing program in 2018. Further, we plan to build on the success of the staff-based navigator program by building a cadre of peer navigators, training those with lived HCV treatment experience to support those living in their communities to be tested, linked to care, and treated for HCV.

Through our collective efforts to treat people living with HCV in both primary care and community-based settings, it has become evident that dedicated resources for HCV care and treatment are vital to their success. For example, SFDPH's efforts to treat people in the homeless shelter system were successful, with 6 people treated over 6 months of the program; however, the shelter treatment program has been paused because the provision of HCV treatment in this setting pulled limited nursing resources from the acute care services nursing staff must provide in the shelters. *End Hep C SF* will be working on strategies to overcome this barrier, which will likely include advocating for funds to support dedicated nursing staff.

Taken together, these planned initiatives will significantly scale up testing and treatment in San Francisco and move the needle closer to HCV elimination. *End Hep C SF* remains committed to broad representation of community members, service providers, and organizations disproportionately impacted by HCV, and to continually refining strategies through formal evaluation to maximize efficiency and effectiveness.

COALITION TO ELIMINATE HEPATITIS C VIRUS IN MASSACHUSETTS

The Massachusetts End Hep C-MA coalition grew out of a long-standing organization called the Massachusetts Viral Hepatitis Coalition. With the recognition that challenges facing people living with HCV infection and strategies for elimination were quite different from those needed to control or eliminate hepatitis B virus infection, it was decided to reorganize and create an organization that explicitly focused on the mission of HCV elimination. *End Hep C MA* was adopted from the San Francisco coalition's name, *End Hep C SF*. Activities described herein included work from both groups (termed the MA Coalition).

The MA Coalition has a similar structure to the New York State and San Francisco initiatives. It consists of a large coalition including health advocates from the fields of health access and health disparities, substance use services, housing, mental health, legal advocacy, poverty programs, health professionals including hepatitis C treaters from academic and community health centers, and people living with HCV. Members of the Massachusetts Department of Public Health provide information and advice but do not vote on decisions. Industry partners participate in open forums but do not vote on decisions. Subcommittees are where the bulk of the work is done, and include (1) awareness, engagement, and empowerment, (2) screening, services and case management, (3) insurance access, (4) corrections, and (5) harm reduction and prevention. The steering committee ensures that subcommittee work is on track, endorses other organizations' work, and provides input into state and national policies.

The MA Coalition is primarily an advocacy group that works to increase awareness about barriers to HCV care and treatment and identify and execute on strategies to reduce those barriers. Work done to remove restrictions on reimbursement of HCV treatment by Massachusetts Medicaid, which had national implications, and addressing the increased rate of HCV cases in younger people in Massachusetts is described.

Removing Insurance Restrictions

When the first all-oral DAA regimens were approved in 2013, there were wide variations in restrictions on access to these treatments by the various public and private insurance plans in Massachusetts. The fee-for-service (FFS) program of the Massachusetts Medicaid program, called MassHealth, approved coverage for the (at that time) off-label combination of sofosbuvir plus simeprevir for genotype 1 infection, or sofosbuvir plus ribavirin for other genotypes, without any patient restrictions. Prescribers had to seek prior authorization to ensure the appropriate selection of treatment based on patient characteristics. MassHealth collected data on which patients were receiving treatment and health outcomes including completion of treatment and sustained viral response rates. Despite the lack of restrictions, in the first year after DAAs were approved, less than 15% of eligible patients in FFS Medicaid had been treated.

In contrast, all 6 of the Medicaid managed care organizations (MCOs) in Massachusetts, which covered more than one-half of MassHealth recipients, had policies that restricted treatment to patients with advanced liver fibrosis (F3 to F4 stage liver disease), who had at least 6 months sobriety from substance use, and were receiving care or consultation from a specialist. The MA Coalition, led by members of the Center for Health Law and Policy Innovation of Harvard Law School, determined that the treatment restrictions being imposed by MCOs were contrary to Medicaid law.

Regulations set forth by the Centers for Medicare and Medicaid Services seek to ensure that Medicaid beneficiaries served by MCOs receive a comparable level of benefits and services as beneficiaries participating in the FFS system. These regulations state that MCOs must offer services “in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid.”¹⁵ Owing to the treatment restrictions being imposed by MassHealth MCOs where the FFS program offered open access, MCOs were not meeting their obligations under the law to provide the same level of coverage.

Acting on this knowledge, the MA Coalition pressured MassHealth officials to eliminate this treatment access disparity within MassHealth. This effort was bolstered when the Centers for Medicare and Medicaid Services, because of persistent efforts of advocates nationwide, released guidance to state Medicaid programs that explicitly called out these practices as inconsistent with the law.¹⁶ Despite multiple meetings with MassHealth officials, MassHealth officials continued to identify contractual and financial barriers to implementing this change. The MA Coalition wrote to Massachusetts Attorney General Maura Healey outlining these concerns and threatening legal action to hold the Commonwealth accountable should the situation remain unchanged.

This effort did not prove directly successful, although it did serve to bring more attention to the issue, brought drug manufacturers to the discussion, and ultimately was a stepping stone for the MA Coalition’s success. In January 2016, Attorney General Healey wrote to the leading manufacturer of HCV medications at the time, Gilead Sciences, warning the company that it could face legal action unless it acted to lower the price of its treatments. This threat received Gilead’s attention, and they requested a meeting with Healey’s office to discuss the issue. However, no action was taken by MassHealth. The MA Coalition continued to press MassHealth officials to solve the disparate treatment access issues between the FFS and MCO programs. This continued pressure, in combination with the public attention drawn to the problem

as a result of Attorney General Healey's action, culminated in MassHealth finally taking action to hold its MCOs accountable. In July 2016, Daniel Tsai, Assistant Secretary for MassHealth, issued a bulletin to all MCOs providing services to MassHealth beneficiaries. The bulletin directed MCOs to cover HCV medications for all MassHealth members with no restrictions related to fibrosis score, substance use abstinence, or prescriber specialty, effective August 1, 2016.¹⁷ As a result, all restrictions were lifted by all MCOs and MassHealth beneficiaries now enjoy the same open access policy, regardless of if they are enrolled in the FFS program or receive their services from an MCO. Commercial insurance plans operating in Massachusetts followed the lead of MassHealth and most plans have lifted restrictions on reimbursing DAAs, although there are formulary restrictions. The MA Coalition is working to ensure that all restrictions are removed for all plans.

Identifying Previously Undiagnosed Patients with Hepatitis C Virus Infection

The MA Coalition had supported legislation requiring that primary care centers offer HCV antibody testing to all patients born from 1945 through 1965, although there were no penalties attached to noncompliance with the law, nor additional funds to survey for compliance with the law. An informal survey conducted in the spring of 2017 showed that several major health systems still had no programs in place to facilitate testing of this birth cohort. Most of the health systems that did have programs in place relied on electronic medical record prompts. However, recent data in Massachusetts also demonstrate that nearly two-thirds of new cases of hepatitis C are in people born after 1965.¹⁸ Cases of hepatitis C in this younger cohort are likely being driven by the youth opioid epidemic. The MA Coalition is now advocating that all adults age 18 and older in Massachusetts be offered an HCV test as a state-wide pilot program.

SUMMARY

These 3 examples of US state and local HCV elimination initiatives have common elements. All have diverse coalitions composed of community-based organizations, academic and community health centers, and public health officials. In each model, relationships with public health officials are handled similarly; the public health officials provide data and assistance, but are also the recipients of policy initiatives. Each has created working groups to define and execute on coalition goals. There are also common challenges, including ensuring that the many diverse groups of people impacted by HCV are fairly represented in the coalition. A lack of funding for HCV-specific programs and insufficient access to HCV medications are both a challenge and a focus of advocacy for all 3 coalitions.

We are proposing that each state create an End Hep C XX coalition to facilitate joint advocacy on national level initiatives and Federal policy. An annual day of educating congress and other government agencies on the personal and economic impact of HCV could be tied to state-level efforts. Our nation has all the tools needed to eliminate HCV and now requires the focus and funding to make this a reality.

ACKNOWLEDGMENTS

The authors thank all members of the HCV elimination coalitions in New York, San Francisco, and Massachusetts for the work they do to make eliminating HCV a reality.

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