



➤ Addressing Comorbidities: The Hepatitis C Treatment Expansion Initiative

Since the advent of highly active antiretroviral therapy (HAART), the mortality associated with HIV infection has been markedly reduced. In parallel, liver disease caused by chronic hepatitis C (HCV) infection—and exacerbated by the presence of HIV disease—has emerged as a leading cause of hospitalization among people living with HIV/AIDS (PLWHA)^{1,2} and as the most common cause of non-AIDS-related death among people who are HIV positive.^{3,4}

HIV/HCV coinfecting patients are more than 3 times as likely to develop an HIV-related bacterial or mycotic infection and twice as likely to experience stroke as the HIV-monoinfected population.^{5,6} Approximately 50 percent of all deaths of PLWHA in the United States are the result of HCV-related liver diseases.⁷

It has always been the mission of the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance (SPNS) Program to respond to the emerging needs of the Nation's HIV-positive population through the development and evaluation of innovative models of HIV care. Because of the mounting challenges posed by HIV/HCV coinfection and requests from providers for assistance in establishing HCV treatment, the SPNS Program has launched the Hepatitis C Treatment Expansion Initiative.

The goal of the initiative is to develop innovative, replicable models for HCV treatment within the context of HIV primary care funded by the Ryan White HIV/AIDS Program. Because of the vast interest in implementing this treatment, the initiative will provide two rounds of funding, each for 2 years (up to \$80,000 per site per year). The first round of funding was awarded in September 2010 to 15 demonstration programs across the country. The University of South Florida in Tampa is the evaluation and technical assistance center for the initiative, providing technical assistance, both clinical and evaluation, to grantees in the implementation of their treatment models.

This issue of *What's Going on @ SPNS* describes the treatment models being implemented at three grantee sites: the Kansas City Free Health Clinic (Kansas City, Missouri), Inova Health Care Services (Springfield, Virginia), and the University of California, San Francisco (UCSF). It also examines the evaluation methods the University of South Florida is using to examine the models.

Kansas City Free Health Clinic

Treatment Model: Primary Care Management With Expert Backup

The Kansas City Free Health Clinic has created a collaborative agreement between its multidisciplinary primary care team (consisting of a physician, three registered nurses, a medical assistant, and a clinical pharmacist) and a board-certified gastroenterologist/hepatologist experienced in HCV treatment. The gastroenterologist/hepatologist will provide consultation services to the multidisciplinary team regarding HCV treatment decisions—a treatment model typically established in clinics with a lower volume of coinfecting patients undergoing treatment.

HCV treatment will be administered—and monitored—by the HIV primary care team onsite at the clinic, where it will be fully integrated with other care services. “Before, we had to refer patients out for treatment,” says Craig Dietz, the clinic medical director. “This helps bring us to a one-stop-shop.” Multidisciplinary support at the clinic already includes psychiatry, mental health and substance abuse counseling, HIV case management, peer treatment adherence educators, evidence-based prevention interventions, and an onsite pharmacy.

“We knew from internal reviews and pressure from the community, due to the local hospital being overwhelmed and a lot of HCV clinical studies closing, that something needed to be done,” explains Dietz. “We also saw the struggles that our patients experienced with HCV treatment, so when we saw the RFP for this initiative, it just made sense,” adds Sally Neville, project director.

The Kansas City Free Health Clinic screens all new patients for HCV. If a patient tests positive for HCV but is deemed ineligible for treatment because of mental health, substance abuse, or other barriers, a plan is established to address the patient's barriers to treatment initiation. The plan is then revisited on a regular basis until the barriers are resolved. Patients eligible for HCV treatment are educated about HCV disease, medication side effects, treatment monitoring, and the larger SPNS initiative. The multidisciplinary team discusses each eligible patient by case conference to ensure client readiness before treatment initiation. "One of the biggest challenges," says Dietz, "is finding patients who are really ready for treatment and keeping these patients going once they've started, similar to initiating HIV treatment," because patients often struggle with toxicity and side effects. Dietz advises clinicians to "be realistic about the number of patients you can treat . . . because coinfecting patients are likely to be higher needs patients [than monoinfected patients]."

To provide additional client support, and in light of the vast success Kansas City Free Health Clinic has had with HIV peer support groups, a similar HCV treatment support group is planned. The HCV support group will be open to patients who are HCV positive but not yet eligible for treatment, those about to initiate treatment, and those actively engaged in treatment. Because of the adverse side effects associated with HCV treatment, patients will also have access to the same medical adherence support programs for HCV as they do for HIV.

The clinic is working with the gastroenterologist/hepatologist consultant to talk them through initial treatment options and provide ongoing support as necessary. To increase efficacy, the clinic selected a consultant within the community with whom clinic staff had an ongoing relationship and who accepts Medicaid. The consultant reports directly to Dietz, who treats the patients. This methodology will further strengthen the ability of core staff to administer and manage HCV treatment and create a greater ability to sustain the initiative's efforts after the grant funding period.

Although only some patients and staff will be engaged in this particular SPNS initiative, Neville explains, "We're doing a series of educational sessions for peers and staff on HCV and HCV treatment so everyone has at least a basic working knowledge, understands the screening process, and . . . the decisions regarding starting or delaying treatment."

As part of the initiative's reporting requirements, the clinic will track patient outcomes, receipt of care and treatment, and rates of suppressed HCV. It will also compare the number of patients who started treatment with the number who finished and identify reasons for patient retention.

Dietz emphasizes the cost-effectiveness of the approach. "Because we're integrating it into an existing, long-standing HIV clinic, we'll become experts on HCV as well. We're not using

SPNS HCV Treatment Expansion Initiative Grantees

- AIDS Resource Center of Wisconsin, Milwaukee, WI
- Bexar County Hospital District, San Antonio, TX
- Bronx-Lebanon Hospital Center, Bronx, NY
- Cambridge Health Alliance, Cambridge, MS
- Carilion Medical Center, Roanoke, VA
- Clarion University of Pennsylvania, Clarion, PA
- East Bay AIDS Center, Oakland, CA
- Harlem United Community AIDS Center, New York, NY
- Inova Health Care Services, Springfield, VA
- Kansas City Free Health Clinic, Kansas City, MO
- Research Foundation of the State University of New York, Brooklyn, NY
- St. Mary Medical Center Foundation, Long Beach, CA
- The Regents of the University of California, San Francisco
- University of South Florida, Tampa (evaluation and technical assistance center)
- Washington University, St. Louis, MO
- William F. Ryan Community Health Center, New York, NY

funding to fully support new positions but to provide bits and pieces of support as needed. . . . When the initiative is done, we'll be in a good position to apply for clinical trials, and we'll have established ourselves as experts in HCV and HIV/HCV coinfection care management."

Neville adds, "This particular grant fits so well with what we already do and fits with what our mission is. All we needed was a little help to get started, and that's what SPNS has offered us."

Inova Health Care Services

Treatment Model: Integrated Care With HCV Management by Providers Without Designated HCV Clinic

Unlike the Kansas City Free Health Clinic, Inova Health Care Services already had in-house HCV expertise. In fact, Leigh Guarinello, the initiative's project coordinator, had been hired in 2004 under a viral hepatitis C education grant, which funded her to educate providers about HCV throughout the State of Virginia. Even after that grant's completion, Guarinello kept hearing about the increased need for continued HCV treatment and education. This gap in resources spurred Inova to develop a protocol to help doctors and mid-level providers (physician assistants and nurse practitioners) become more knowledgeable and comfortable prescribing—and overseeing—HCV treatment. In Inova's role as a HRSA AIDS Education and Training Center (AETC) local perfor-

Developing a Successful HIV Program

The SPNS Hepatitis C Treatment Expansion Initiative grantee guidance outlined a set of recommended integrated strategies for co-located HIV/HCV treatment. The recommendations drew on the successes other Ryan White HIV/AIDS Program providers have had in addressing coinfection and initiating HCV treatment.

1. *A medical director dedicated to treating HCV.* Clinics that have a successful record of managing coinfection have a dedicated lead medical provider responsible for overseeing the treatment of HCV. Medical directors have often been instrumental in establishing their clinic's HCV treatment program and intimately involved in the clinical management of their coinfecting patients.
2. *An HCV program started to address unmet patient treatment need.* The impetus for launching coinfection treatment programs is centered on a key observation: Since the advent of antiretroviral therapy, medical providers are noticing a decline in AIDS-related complications but a rise in patient deaths related to chronic HCV and liver disease.
3. *A key medical provider for treatment and monitoring.* A core provider—a nurse, nurse practitioner, or pharmacist—is critical in coordinating treatment and monitoring patients. This provider is highly involved in the day-to-day aspects of treatment, including patient education, treatment adherence, monitoring and managing side effects, and checking lab results.
4. *Ongoing evaluation of candidates for possible HCV treatment.* The integration of HCV screening practices is essential in identifying and tracking coinfecting patients. Patients are regularly evaluated as possible candidates for HCV treatment. Providers also made a dedicated effort to address and resolve barriers to treatment.
5. *Development of treatment protocols.* Treatment protocols related to HCV screening, indications for treatment, medication dosing, duration of therapy, and clinical and laboratory monitoring for medication-related toxicity are developed and implemented.
6. *Patient education.* Before therapy, a designated core provider, whether a nurse, nurse practitioner, pharmacist, or patient educator, is responsible for educating patients about the natural history of HCV and the importance of therapy.
7. *Client support.* Many clinics reported that support groups served as a critical component of their coinfection treatment program. Clinics that did not host support groups noted that the close relationships patients had with their providers served as their primary support mechanisms.
8. *Access to psychiatry and mental health services.* Evaluation and management by a psychiatrist or other mental health professional are other critical components of clinics' treatment programs, because HCV medication has the potential for severe adverse psychiatric manifestations.
9. *Access to substance abuse counseling and treatment.* For the management of substance abuse, many clinics provide on-site evaluation and counseling. These services are often used before initiating HCV therapy. Active drug use is viewed by many clinics to be a direct contraindication to continued therapy, but others have made allowances for mild to moderate drug use on a case-by-case basis.
10. *Medication access and payment.* Eligible patients have access to pegylated interferon/ribavirin treatment, even if they do not have the ability to pay. Most clinics are reimbursed through Medicare, Medicaid, or ADAP. If no payment mechanism is available, a medical provider is able to use pharmaceutical drug assistance programs.
11. *Availability of clinic administration of pegylated interferon injections.* All clinics offer clients the choice to receive pegylated interferon injections at the clinic rather than give themselves injections at home. The person administering the injections is usually a nurse or pharmacist. This approach is particularly valuable for former injection drug users.
12. *Access to liver biopsy.* The option to undergo a liver biopsy, when clinically indicated, for evaluating the stage of HCV-related liver disease is also available. Most clinics refer patients to interventional radiology for liver biopsy, although some are referred to hepatologists. No grantee performs liver biopsies as part of primary care services, but all clinics have access to reading of liver biopsies by pathologists.

mance site, clinic staff have conducted numerous trainings on the topic. Financial constraints, however, impeded implementation of HCV protocols on a broader scale within Inova's primary HIV care clinic. "We had everything in place, but we didn't have the money to fully implement the protocols and training we wanted to until now," explains Guarinello. Because the groundwork had been set in place years earlier, buy-in within the clinic for both HCV treatment and this particular treatment model were already well

underway. "It's to our advantage to embrace this approach, plus it's easier, in my opinion, to train HIV doctors to do HCV treatment than the other way around. We're also moving toward a medical home model, so it made [more] sense to add HCV treatment here than [to] refer patients elsewhere," adds Guarinello.

Inova recognizes that as the initiative gets further underway, a patient may present with a particularly complicated case of HCV, necessitating referral to a local hepatologist—someone with whom

clinic staff are already familiar. Nearly all other cases, however, can be handled in house. Guarinello explains that allowing patients to be seen any time they are in the clinic rather than having particular clinic days devoted to HCV has created maximum flexibility for their patients.

Similar to the Kansas City Free Health Clinic, Inova will be educating patients about HCV and associated treatment; conducting HCV viral load testing, HCV genotype testing, and liver biopsies; and assessing mental health and substance abuse status. Inova will also be conducting clinical meetings to discuss patient progress. HCV patients who are formally enrolled in the initiative will be assigned a case manager and a nurse, who will see the patients regularly. This aspect of the program will be evaluated to see whether a more intensive approach affects patient retention in care.

Regarding sustainability, Guarinello explains that treating HCV-infected patients in bulk with this project will enable them to wipe out much of the HCV in their coinfecting clinic population.

Although the SPNS initiative is in its infancy, Guarinello offers some advice to other clinics considering implementing HCV treatment within an HIV or primary care practice:

- Engage the AETCs, because they are well connected when it comes to identifying HCV providers and training staff in coinfection.
- Engage core staff to develop forms and procedures and to envision what HCV treatment could look like within the clinic.

“That’s what we did,” says Guarinello, “and now we have a grant to see it through.”

University of California, San Francisco

Treatment Model: Integrated Care With Designated HCV Clinic

Similar to Inova, UCSF already has staff experienced with HCV treatment. As Val Robb, project coordinator, data manager, and clinical nurse for this initiative, explains, “We developed an initiative to start treating coinfecting patients in our clinic in 2004, as we have over 800 coinfecting patients and were seeing increased numbers of liver-related deaths. The unique barriers that our patients face in getting HCV treatment caused us to explore treatment within our primary care clinic. To date, we have treated over 100 patients for HCV but needed to increase our treatment capacity to better serve our remaining coinfecting population.” The SPNS initiative is helping the clinic fill that need.

Because UCSF had initiated HCV treatment for a large proportion of its coinfecting population, buy-in was already in place. In fact, Brad Hare, the clinic’s medical director, is a clinician and principal investigator on the initiative and serves with Robb as part of the local and State hepatitis task force.

For More Information . . .

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Unlike Inova, UCSF will hold a specific coinfection clinic at a designated time for initiative enrollees. The benefit to this approach is to allow more concentrated time for HCV-related issues. As with any new initiative, however, some obstacles exist.

“Our biggest challenges remain having staff capacity and providing enough motivation and support for patients to initiate and maintain a year-long challenging treatment,” explains Robb. “Specifically, we continue to struggle with having enough psychiatry and nurse time available for the volume of patients we intend to treat.” To help address this challenge, the second year of UCSF’s initiative will include training more providers on HCV treatment management.

Similar to Kansas City Free Health Clinic, UCSF has strong support group networks in place. “Our patient support network functions beyond the weekly support group by participating in community forums, educational events at drug treatment programs, and has even participated in the making of a film [entitled] *Coinfection* in collaboration with the Oasis Clinic in Oakland, [California],” explains Robb.

UCSF staff are confident that, given their past performance in addressing coinfection, coupled with the work underway for the SPNS initiative, the clinic will be able to garner further funding to sustain its HCV treatment work at the end of the grant cycle. “Last year we lost a 42-year-old mother of three to end-stage liver disease and a Latina transgender patient to hepatocellular carcinoma. Combining scientific breakthroughs with innovative treatment programs could reduce or eliminate such heartbreaking losses and provide increased quality of life to more than one-third of our patients,” says Robb. She adds, “With new medications in the treatment pipeline, this is an exciting time to be part of this SPNS initiative.”

University of South Florida

Technical Assistance and Evaluation Center

The University of South Florida is responsible for providing technical assistance to all 15 SPNS grantee sites, as well as evaluating

HHS Takes Action Against Hepatitis

On May 12, 2011, the U.S. Department of Health and Human Services (HHS) launched its action plan to prevent and treat viral hepatitis (hepatitis B and C), a silent epidemic affecting 3.5 to 5.3 million Americans. HHS is committed to ensuring that new cases of viral hepatitis are prevented and that people who are already infected are tested; informed about their infection; and provided with optimal counseling, care, and treatment. This increasing commitment is evidenced in the new *Healthy People 2020* plan, the first Healthy People publication to document increasing viral hepatitis awareness among people who are infected as a formal HHS objective. To read the plan, see <http://www.hhs.gov/ash/initiatives/hepatitis>. For more information on viral hepatitis, see <http://www.cdc.gov/hepatitis/>.

grantee treatment models and methodologies for cost-effectiveness and overall efficacy.

Todd Wills, co-investigator and infectious disease specialist at the University of South Florida, explains that several themes have already emerged among grantees. One theme is the challenges of dealing with patient-specific barriers to initiating treatment, particularly because many coinfecting patients have a higher likelihood of ongoing substance abuse (generally injection drug use and alcohol dependency) and weaker support networks than do mono-infected patients.

In addition, psychosocial challenges are already high within this population. “This can be tricky,” explains Wills, “as HCV treatment is riskier if people have severe depression, so sites are trying to look at how readily accessible mental health services need to be; for instance, is an in-house psychiatrist necessary, or can the clinic perform screenings and involve mental health services as necessary?”

As part of its general assessment, the University of South Florida will be examining core measures such as clinic size, number of HIV patients, number of coinfecting patients, and demographic information. More specifically, evaluators will examine information on coinfecting patient enrollees, patient treatment successes, associated lab data, medication safety, and price of treatment models. Wills emphasizes that economic cost, coupled with treatment model success, will be a big indicator of a project’s replicability.

Grantee sites are also asked to track their own challenges and work to create effective solutions. Ensuring their ability to do so, however, involves helping grantees in their endeavors. The University of South Florida’s technical assistance is designed to provide this support.

Staff from the University of Florida will conduct visits to each grantee site to verify that the data grantees are being asked to collect can, in fact, be gathered at their sites in a way that meets the requirements of the evaluation. Martha Friedrich, project evalu-

ator at the University of South Florida, will work with grantees on data-related challenges, and Wills and other clinical staff will address grantees’ clinical concerns and needs.

To share lessons learned, the University of South Florida has developed multiple forums. Evaluators will conduct an annual meeting with demonstration sites to discuss clinical issues and participate in activities that are best done or discussed face-to-face. The evaluation center has also embraced video conferencing to conduct multisite calls. Says Wills, “This allows didactic training to move the learning curve more quickly and enables us to present visual material. . . . In addition, some sites have more HCV experience than others, and by doing case-based discussions in this way, they can further help one another and foster joint learning.”

Conclusion

Integrating the delivery of HCV care into existing Ryan White HIV/AIDS Program clinic infrastructure is advantageous because patients are familiar and comfortable with the clinic setting and staff. This approach may also foster engagement and retention in care as well as enhance communication and collaboration among providers.

In coinfecting patients, potential benefits to treating HCV include eradicating the virus, delaying or reversing fibrosis, preventing disease progression, boosting the tolerance and effectiveness of HAART, improving extrahepatic manifestations of HIV, and improving quality of life and health outcomes.⁸ Initiative results from the first round of grantees sites are slated for release at the end of 2012.

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