

Pilot program extends Hepatitis C care to an underserved population

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Hepatitis C is appropriately recognized as a serious liver disease with significant morbidity and mortality. Although it may manifest as an acute infection, roughly 75% of cases progress to a chronic disease that often requires tremendous use of healthcare resources for management and treatment.

In addition to its implications as a serious clinical condition, hepatitis C is also emerging as a potential public health crisis. Data from the Centers for Disease Control and Prevention suggest a potential rise in new cases, which may reflect an increase in new cases, better and improved disease surveillance or both.¹ It is estimated that as many as 3.5 million individuals are currently infected with Hepatitis C.²

In response to this threat, the CDC has launched efforts to encourage increased vigilance for Hepatitis C, including funding programs aimed at increasing diagnoses in underserved populations. These efforts are coincidental with (and perhaps spurred in part by) the availability of new treatments that are easier to administer by healthcare providers and easier to tolerate by patients. The overarching goal is to achieve earlier intervention so as to stave off later consequences that are associated with higher toxicity and are more costly to administer.

One crucial way to nurture earlier intervention is to enact strategies that facilitate the ability for patients to receive treatment in the same medical home where a diagnosis is made. One benefit of modern treatment strategies is that infectious disease specialists and primary care providers can often administer them, whereas in the past, consultation with a hepatologist or other specialist was often necessary to monitor for and treat associated toxicities.

Another critical barrier to hepatitis C management is the need for liver biopsies to gauge the level of fibrosis. However, again, the need for biopsy requires referral to a hospital or outpatient surgery center, taking the patient out of the medical home and requiring specialist care. Liver biopsy is also suboptimally specific and is associated with a not insignificant rate of complications.

The use of modern ultrasound technology obviates the need for biopsy. Because of this modality, patients may be evaluated and treated in the same medical home, thus lowering cost and reducing the potential for patients to be noncompliant with care. As well, ultrasonography may be repeated over time, opening the potential for serial evaluation to understand response to treatment and the need to titrate the intervention. Thus, the subtle change in how patients are evaluated for liver fibrosis has positive consequences for patients' outcomes, as well as important implications for serving high-risk yet underserved populations.

The FHSCD hepatitis C program

The Family Health Centers of San Diego received a funding grant from the CDC to initiate hepatitis C education in the community, inclusive of raising patients' awareness, fostering diligence with screening recommendations and educating providers about providing care. One important part of the CDC's efforts is to remove barriers to care, an especially important consideration among those populations with highest incidence of hepatitis C.

FHSCD serves a wide range of patients, including providing services to certain patient types that are at high risk for hepatitis C; in some of our clinics, upwards of 20% of patients are positive for the hepatitis C. Our system provides affordable, high-quality healthcare and support services to all people, with a special commitment to the uninsured, low-income and medically underserved. We offer a wide range of healthcare services throughout our region, including primary care clinics; six dental clinics; a teen health center; four behavioral health facilities; an

outpatient substance abuse treatment program; radiology, vision and physical therapy departments; three mobile medical units; and a pharmacy. In addition, FHCS D is also the largest healthcare safety-net provider, largest school-based healthcare provider and largest comprehensive HIV/AIDS services provider in the San Diego region. Roughly 30% to 40% of patients on our rosters are 200% below the poverty level.

Socioeconomic factors are a significant barrier to receiving hepatitis C services, although several others may contribute independently or in a confounding nature. For example, hepatitis C is generally an asymptomatic disease, and as many as half of all cases are undiagnosed. Therefore, the CDC strongly recommends screening members of populations at high risk for infection, including individuals born between 1945 and 1965, as well as anyone who had a blood transfusion, an unprofessional tattoo or who has ever injected drugs.

FHCS D has also received state and local grants that help underwrite the costs of our hepatitis C outreach. Some of these funds were used to purchase a shearwave ultrasound platform (Aixplorer, SuperSonic Imagine). This device received FDA clearance in 2013 for real-time quantification of tissue elasticity in kilopascals (kPa). It can acquire images 200 times faster than conventional ultrasound systems and generates a two-dimensional, color-coded map of tissue elasticity superimposed on a B-mode image of the same area for anatomical correlation. A report by the National Health Service Technology Adoption Centre estimated that wider adoption of this technology for liver staging in United Kingdom and Wales could yield \$20 million in savings.³ For our purposes, using this technology in our program has helped to eliminate several crucial barriers to care.

Role of ultrasound in liver staging

Liver biopsy has a controversial role in the management of hepatitis C. Serum testing, including HCV RNA testing, is sufficient for making a diagnosis, and even in absence of such testing, liver biopsy may not alter the diagnosis. However, liver biopsy is theoretically useful for staging severity, including the involvement and degree of liver fibrosis that may be present.

There are several shortcomings to liver biopsy, including patients' resistance to undergoing the procedure. It also requires referral and a separate visit to an outpatient surgery center or hospital; in our population of patients, where loss to follow up is likely and access to care is limited in the first place, referral for specialty services is less than ideal.

Moreover, biopsy is expensive. Costs can range from \$1,500 to \$2,000, and up to \$2,700 if there are complications.⁴ In the setting of limited resources, this option is largely unfeasible for our patients. On a clinical level, a liver biopsy only captures a small sample of the organ, heightening the possibility for an inaccurate or false reading. Liver biopsy may over- or underestimate pathology in as many as one-third of cases.⁵

The use of ShearWave Elastography, on the other hand, allows us to enter patients into hepatitis C management during the encounter when the diagnosis was made instead of referring them for a biopsy or second appointment. Patients can be diagnosed and begin the treatment phase in the same medical home, thus reducing the potential for loss to follow up within an indigent and sometimes transitory population.

Potential future directions

One of the things that use of ShearWave Elastography potentially adds to the management of patients with hepatitis C is the ability to repeat testing to glean response to treatment and to plot the future need for intervention. It adds the ability to follow patients after they are cured and to make management decisions about their long-term follow-up.

We are confident that the demonstration program we have undertaken at FHCS D is sustainable model of delivering needed hepatitis C services to a vastly underserved population. The role of ultrasound in the continuum of care is crucial for removing an important barrier to the staging of liver fibrosis. Whereas liver biopsy represents a costly and invasive measure, and one which often leads patients to discontinue care, ultrasound offers the ability to initiate treatment at the point of contact, thereby making it much more likely to capture the patient and direct him or her to needed services.

We hope to increase our capacity to extend this level of comprehensive hepatitis C care to all the patients in our network who need it. We currently are actively treating 80 patients for active hepatitis C, and in time, we hope to identify more patients and enroll them in services that will help save lives.

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