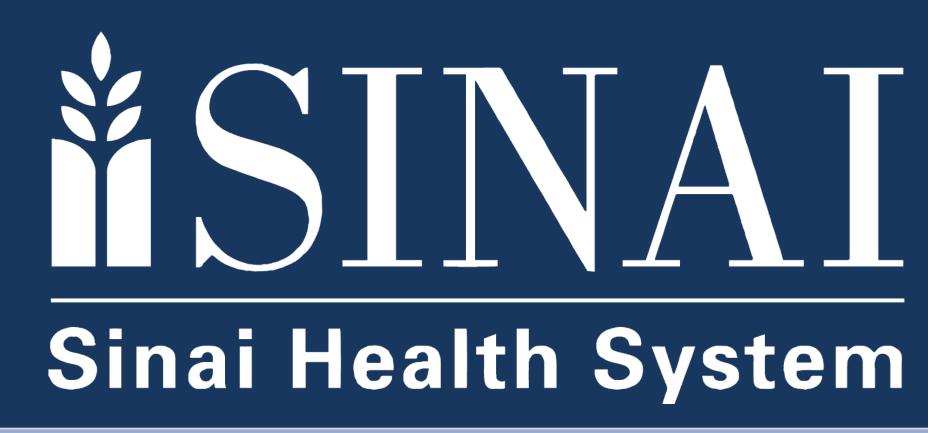
Implementation of an HCV linkage-to-cure program at an urban safety-net hospital



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OBJECTIVE

Mount Sinai Hospital, part of Sinai Health System (SHS), is a 319-bed safety net hospital in Chicago, IL. Sinai serves some of Chicago's most marginalized communities, which are affected by high rates of poverty and the associated health conditions that stem from economic hardship. In 2011, Sinai was funded to implement routine HIV screening as part of FOCUS (Frontlines of Communities in the United States, a partnership with Gilead Sciences). The success of Sinai's HIV FOCUS project encouraged Sinai to initiate a pilot HCV linkage-to-care program.

Nationwide gaps in diagnosing and linking persons with hepatitis C to treatment suggest a need for programs and system changes to address these issues. Of those with chronic hepatitis C, it is estimated that 50% have been diagnosed and are aware of their infection, 43% have access to outpatient medical care and 27% have been HCV RNA confirmed (1). In 2013, new interferon-free breakthrough therapies for HCV changed the prospects for treating and curing people with chronic hepatitis C.

Sinai's HCV pilot program began in August 2014. Funding for the pilot allowed for a patient navigator to be hired who was dedicated to ensuring that patients who screen reactive for HCV antibodies in the hospital have proper follow-up testing, disease staging, and are linked to outpatient providers for consideration and receipt of HCV treatment.

METHODS

Sinai Health System initiated an HCV linkage to care pilot in Mount Sinai Hospital (MSH). Patients tested on the inpatient floors were eligible for navigation. The HCV navigator conducted a retrospective review of the electronic medical record (EMR) to identify patients who had screened reactive for HCV antibodies from July — October 13, 2014 to determine their status, and began a daily review of HCV antibody test results from October 14, 2014 to determine patients who would require real time navigation while they were still hospitalized.

Retrospective navigation consisted of the HCV navigator (1) calling patients up to three times to notify them of their HCV antibody screening results (if patient was not reachable, an EMR bulletin was posted for the HCV navigator to be paged if the patient returned to MSH); (2) scheduling appointments for labs, FibroScan, or medical appointments; (3) coordinating follow up, and (4) meeting patients at subsequent appointments.

In-hospital navigation was provided to persons (1) identified with HCV antibody reactive test results from the EMR, and (2) referred to the patient navigator by a nurse, physician, social worker or HIV team member. Patients with poor prognosis as determined by the Medical Director were not medically eligible for patient navigation.

For patients in the hospital, physicians were contacted to order hepatitis C RNA Quantitative PCR for confirmatory testing (HCV RNA PCR). In December 2014 Sinai began reflexing the HCV RNA PCR test for HCV antibody reactive results to increase confirmed HCV diagnoses. The existing relationship with Sinai's laboratory facilitated switching to a reflexed test effortless. Patients were provided with available HCV antibody and HCV RNA test results. Navigated patients were offered HCV education, liver disease staging using FibroScan at a partner agency, and follow-up clinic visits for evaluation and treatment at Sinai or other clinics treating patients with HCV.

HCV treatment was established in two existing infectious disease (ID) clinics at Sinai. The HCV navigator assisted patients with transportation to appointments, navigating health insurance, obtaining medical referrals, and establishing a primary care physician. The Medical Director and HCV navigator gave presentations to medical staff, residents, and social workers to increase HCV testing and medical follow up. The HCV navigator and ID physicians assisted patients recommended for treatment by submitting treatment authorization applications to a specialty pharmacy, appealing authorization denials, and providing follow-up to help achieve treatment approval.

RESULTS

- **Retrospective navigation:** From July to October 13, 2014, 8.12% (67/825) of patients screened reactive for hepatitis C antibodies, of which 59.7% (40/67) received an HCV RNA test. 29% (9/31) of those chronically infected received a FibroScan for liver staging.
- In-hospital HCV testing and linkage: From October 14, 2014 to April 2015, 1,509 patients were screened for hepatitis C with a 9.61% (N=145) anti-HCV sero-prevalence rate. 52% (76/145) of individuals reactive for hepatitis C antibodies were screened in the hospital. Of note, 13% (10/76) of persons were tested in the Psychiatry department with a 27% (10/37) prevalence. 77.63% (59/76) of patients received an HCV RNA test of which 75% (44/59) were confirmed with chronic hepatitis C. 43% (19/44) of those chronically infected received FibroScan, 44.45% (20/44) received medical evaluations for hepatitis C treatment and 11.36% (5/44) have submitted applications for HCV therapy. HCV screening and notification of results has increased, along with referrals for patient navigation, FibroScan, and subspecialty HCV care.
- **Patient navigation case load:** Since the start of the pilot, Sinai has extended patient navigation services to its Infectious Disease clinic patients along with in-hospital navigated patients. From October 2014 to April 2015, navigation services have been accepted by 113 persons. 93% (106/113) received HCV RNA confirmatory tests, 84.91% (90/106) were confirmed with chronic hepatitis C and 79% (61/90) attended at least one medical visit for HCV. Of the 67% (61/90) of patients who received FibroScan, 35% (21/60) were staged with a >F3 Metavir score. 19% (17/90) of chronically infected persons applied for HCV therapy, of which 58.8% (10/17) initiated therapy.

CONCLUSIONS

Sinai's model has shown that in-hospital patient navigation services are an effective way to link and retain individuals who screen for HCV in-hospital and in outpatient HCV medical care. Utilization of EMR systems with patient navigation can identify HCV screening results while patients are in the hospital, and ensure both proper lab follow-up and receipt of test results. Repeated physician education on HCV testing, linkage procedures, and new therapies can improve HCV diagnosis and referrals for medical management. Working with a partner agency to obtain FibroScans can increase capacity for disease staging and treatment preparation.

A patient navigator's ability to schedule FibroScan appointments directly with patients and attend visits offered consistency and ease traversing multiple health systems. Obtaining HCV therapy for patients required more time and coordination between staff, pharmacies and patients than anticipated. Differences in treatment criteria and requisite lab workups among insurances inspired multiple changes in work flow and staff responsibilities. Treatment for hepatitis C can be obtained and initiated with real-time changes and coordination to reflect the changing landscape of hepatitis C treatment. Patient navigation can improve patients' involvement, trust, and stress level throughout the process of obtaining therapy by serving as the primary contact and liaison between medical staff and patient.

As many insurances restrict HCV treatment to persons with liver disease staging of F3 or F4 and to those who are substance-use free, disease management efforts using harm reduction philosophies can be utilized to slow disease progression and continue engagement in medical care. An understanding of harm reduction philosophies can be beneficial in providing patient-centered and culturally tailored education. Scale up of HCV screening, with successful linkage of patients to outpatient HCV care and HCV treatment, is feasible in this setting.

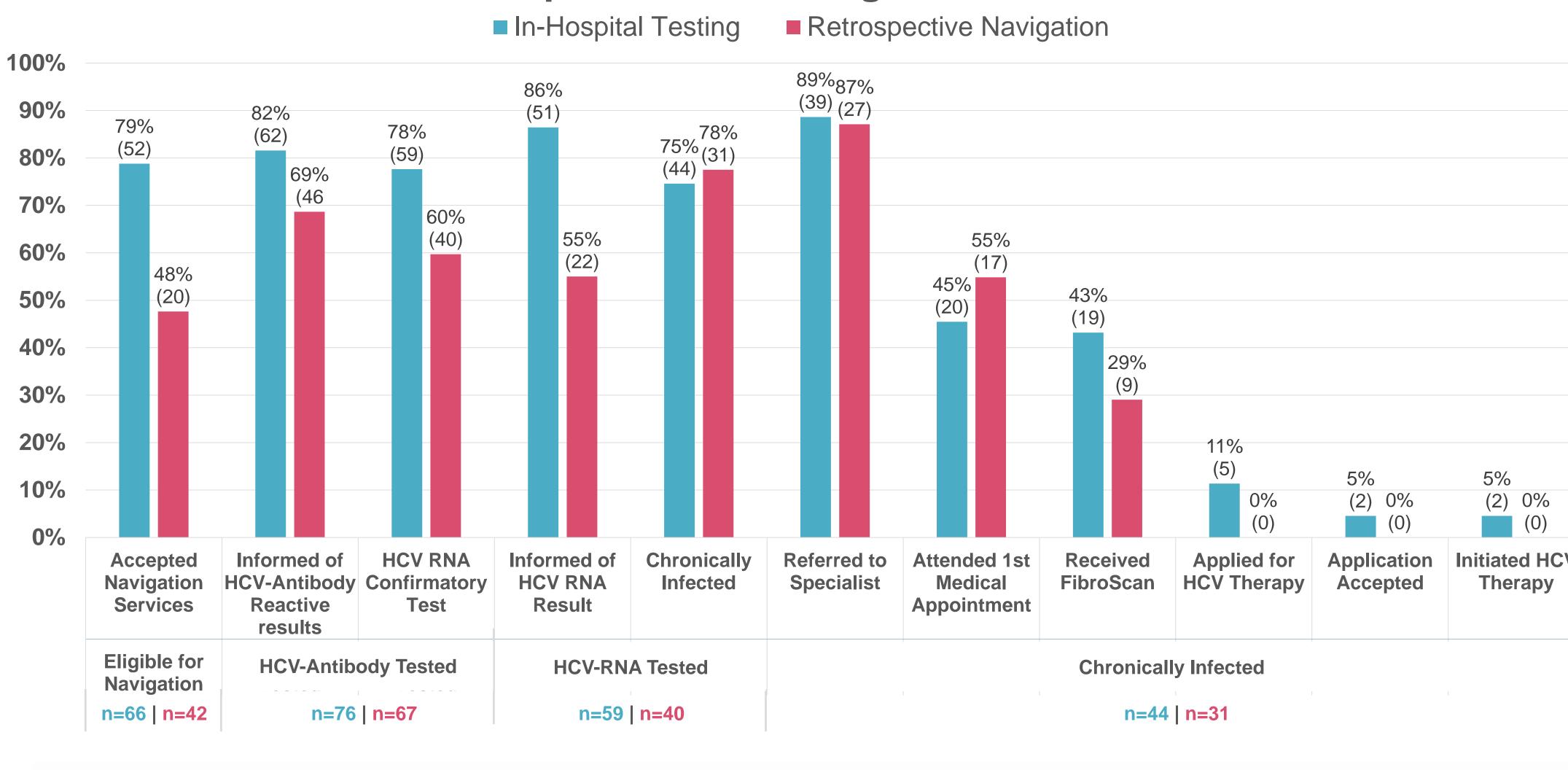
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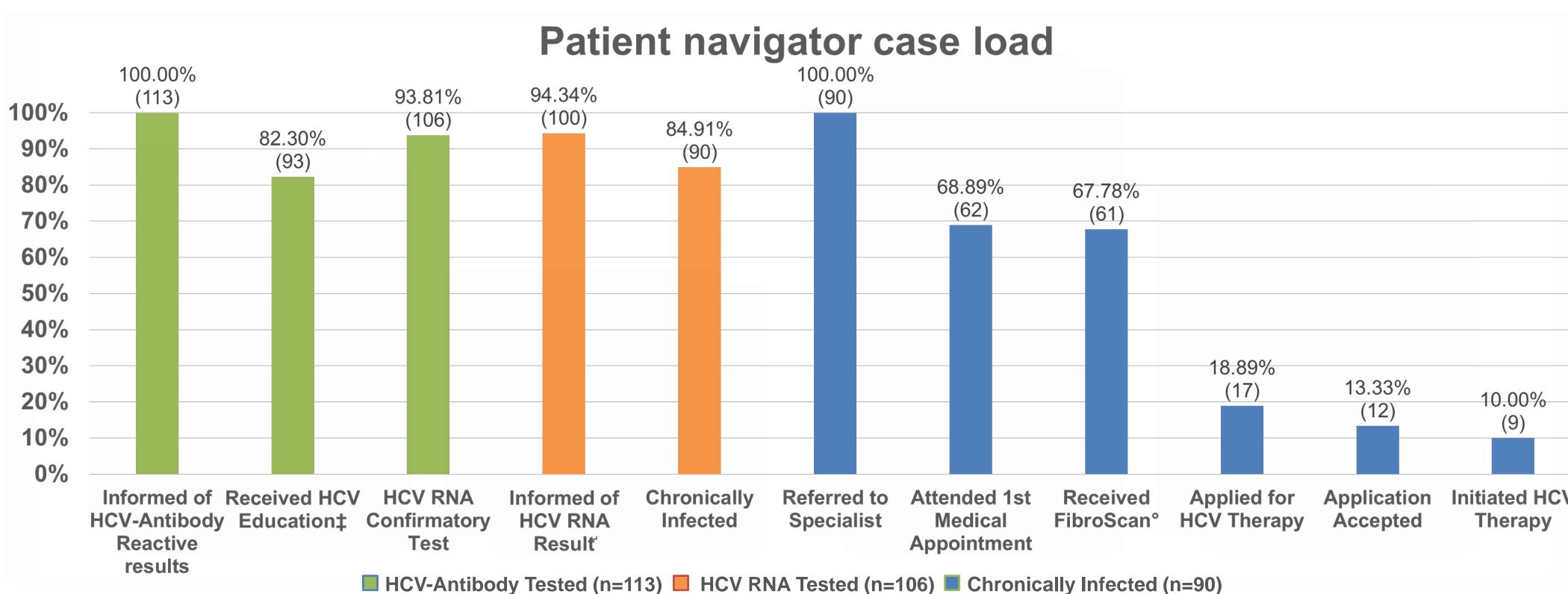
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In-hospital HCV testing & linkage-to-care and retrospective HCV navigation cascades





HCV prevalence by race and age

Overall HCV prevalence 9.61%

Prevalence		Race/Ethnicity	Prevalence
6.15%		Caucasian	7.28%
15.59%		African American	11.98%
4.96%		Latino(a)	7.16%
9.61%		Asian	5.26%
	6.15% 15.59% 4.96%	6.15% 15.59% 4.96%	6.15% Caucasian African American Latino(a)

FOCUS approached Sinai to initiate a pilot HCV program

Sinai received funding for HCV program. Met with specialty pharmacies for assistance obtaining HCV Therapy

HCV patient navigator
was hired

Agreement with The Ruth M. Rothstein CORE Center for FibroScan referrals for Sinai patients

initiated in-hospital patient navigation and retrospective navigation

1st ID provider
dedicated
appointment slots to
HCV patients.
Initiated outpatient
patient navigation.

reflexed to HCV RNA
PCR for confirmatory
testing. GI provider
dedicated
appointment slots to
HCV patients for
cirrhosis
management.

2nd ID provider
dedicated
appointment slots to
HCV patients

FibroScan referrals
and results can be
uploaded into EMR

1st patient initiated
HCV therapy. The
patient navigator's
caseload reaches 100
clients.

Sinai's request for more funding was accepted. Funding reaches 100

Sinai's request for more funding was accepted. Funding received for 2nd patient navigator.

Coordinated process for obtaining HCV therapy. HCV-Antibody testing rate increased 21% from start of HCV program