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## Sharing the Cure: Building Primary Care and Public Health Infrastructure to Improve the Hepatitis C Care Continuum in Maryland

Risha Irvin<sup>1</sup>, Boatemaa Ntiri-Reid<sup>2</sup>, Mary Kleinman<sup>2</sup>, Tracy Agee<sup>1</sup>, Jeffrey Hitt<sup>2</sup>, Onyeka Anaedozie<sup>2</sup>, Tolu Arowolo<sup>2</sup>, Hope Cassidy-Stewart<sup>2</sup>, CaSaundra Bush<sup>2</sup>, Lucy E. Wilson<sup>2</sup>, Alexander J. Millman<sup>3</sup>, Noele P. Nelson<sup>3</sup>, Lauren Canary<sup>3</sup>, Sherilyn Brinkley<sup>1</sup>, Juhi Moon<sup>1</sup>, Oluwaseun Falade-Nwulia<sup>1</sup>, Mark S. Sulkowski<sup>1</sup>, David L. Thomas<sup>1</sup>, Michael T. Melia<sup>1</sup>

<sup>1</sup>Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, MD, United States

<sup>2</sup>Infectious Disease Prevention and Health Services Bureau, Maryland Department of Health, Baltimore, MD, United States

<sup>3</sup>Division of Viral Hepatitis, Centers for Disease Control and Prevention, Atlanta, GA, United States

### Abstract

In 2014, trained health care provider capacity was insufficient to deliver care to an estimated 70,000 persons in Maryland with chronic hepatitis C virus (HCV) infection. The goal of Maryland Community Based Programs to Test and Cure Hepatitis C, a public health implementation project, was to improve HCV treatment access by expanding the workforce. Sharing the Cure (STC) was a package of services deployed 10/1/14 to 9/30/18 that included enhanced information technology and public health infrastructure, primary care provider training, and practice transformation. Nine primary care sites enrolled. HCV clinical outcomes were documented among individuals who presented for care at sites and met criteria for HCV testing including risk factor or birth cohort (born between 1945 and 1965) based testing. Fifty-three providers completed the STC training. STC providers identified 3,237 HCV antibody positive patients of which 2,624 (81%) were RNA+. Of those HCV RNA+, 1,739 (66%) were staged, 932 (36%) were prescribed treatment, 838 (32%) started treatment, 721 (28%) completed treatment, and 543 (21%) achieved cure. Among 1,739 patients staged, 693 (40%) patients had a liver fibrosis assessment score < F2, rendering them ineligible for treatment under Maryland Medicaid guidelines. HCV RNA testing among HCV antibody positive people increased from 40% (baseline) to 95% amongst STC providers. Of 554 patients with virologic data reported, 543 (98%) achieved cure. Primary care practices can

**Corresponding author:** rirvin1@jhmi.edu.

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effectively serve as HCV treatment centers to expand treatment access. However, criteria by insurance providers in Maryland was a major barrier to treatment.

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## Introduction

In Maryland, approximately 70,000 persons are estimated to have chronic hepatitis C virus (HCV) infection and most are thought to be concentrated within Baltimore.<sup>1,2</sup> Baltimore's history as a heroin trafficking port city and present-day designation as a lucrative heroin market in the United States is intertwined with the hepatitis C epidemic as injection drug use remains the most common route of HCV transmission.<sup>3-6</sup> Moreover, as the opioid crisis continues to expand, hepatitis C incidence is now rising after declining for more than a decade.<sup>7,8</sup> These trends threaten public health since hepatitis C is a leading cause of liver cirrhosis and hepatocellular carcinoma.<sup>9-11</sup> Notably, human immunodeficiency virus (HIV) infection and alcohol misuse are also common in Baltimore and significantly increase the risk of liver related death from HCV infection.<sup>10,12-14</sup> The convergence of these epidemics has created a public health emergency and led to a prioritization among Maryland medical and public health professionals to reduce hepatitis C-related morbidity and mortality.

Hepatitis C-related morbidity and mortality is avoidable through prevention and treatment. With the emergence of short duration, non-toxic, highly effective, all-oral regimens known as direct-acting antivirals (DAAs), HCV infection can be cured, thereby reducing hepatitis C-related morbidity and mortality.<sup>3,15,16</sup> However, the population level effectiveness of DAAs has not been fully realized due to challenges associated with patients successfully progressing through the hepatitis C care continuum from identification (testing), linkage to care, treatment initiation, treatment adherence, to sustained virologic response (SVR)/cure.<sup>17-20</sup> For example, a community-academic testing initiative in Baltimore found that 42% of HCV antibody positive individuals were aware of their HCV infection but were not engaged in hepatitis C specialty care or treatment.<sup>18</sup> In order to improve the hepatitis C care continuum, the Maryland Department of Health (MDH) developed a plan along with the Johns Hopkins University School of Medicine (JHUSOM) Division of Infectious Diseases to expand identification of HCV infection and treatment access.

As a part of the MDH strategy to improve the hepatitis C care continuum, MDH was awarded CDC-RFA-PS14-1413, Community-based Programs to Test and Cure Hepatitis C, in 2014 by the Centers for Disease Control and Prevention (CDC). The program was designed as a 4-year cooperative agreement with the CDC to strengthen healthcare capacity to diagnose and cure HCV infection in a target population with hepatitis C-related health disparities through implementation of a package of services known as Sharing the Cure. The Maryland team developed Sharing the Cure to address key patient, provider, and structural barriers in the hepatitis C care continuum including low rates of linkage to specialty care, primary care provider hepatitis C knowledge deficits, limited accessibility of hepatitis C care locations, and an insufficient number of providers to treat HCV infection.<sup>17,18,21-23</sup> Expected outcomes included increased primary care provider capacity to diagnose and cure HCV infection (including increased use of the electronic medical record to enhance hepatitis C testing and management); increased availability of population-level data (for assessment

of community impact); and increased testing, diagnosis, and cure of persons impacted by HCV infection. This paper describes the public health implementation of Sharing the Cure to improve the hepatitis C care continuum and documents key program outcomes among Sharing the Cure providers, including SVR among patients.

## Methods

MDH assembled a coalition of key partners to implement the Sharing the Cure package of services with a concentration in Baltimore from 10/1/14–9/30/18. In consultation with partners, Maryland chose the birth cohort, individuals born from 1945 to 1965, as the primary focus of Sharing the Cure as they accounted for more than three-fourths of the total anti-HCV prevalence in the United States from 1999–2008.<sup>24</sup> Sharing the Cure providers were also trained to screen for hepatitis C risk factors.<sup>3</sup>

## Composition of Partnership

MDH and JHU identified primary care partners through community meetings. In order to become a partner in the program, clinical site leadership was required to support the implementation of a hepatitis C program and EMR improvements to enhance hepatitis C-related services (e.g., clinical alerts such as hepatitis C testing reminders), evaluate service outcomes (including quarterly data reporting to MDH and CDC), and inform quality improvement. Providers at each partner site were offered the opportunity to participate in the provider training program and self-identified their interest. Those who agreed to join Sharing the Cure, along with their clinic lead representative, signed a site agreement asserting they would participate in all components of the program. Partner sites were also provided funding to support their hepatitis C program (e.g., hiring of clinical coordinators, supplementing provider training time, EMR changes).

## Enhanced Information Technology

MDH worked with clinical partners to modify their EMR systems to inform and track hepatitis C service provision and outcomes, enhance hepatitis C-related services, and inform quality improvements. EMR modifications and development included:

- New data elements, flow sheets, and pre-visit planning reports for hepatitis C diagnostics and treatment;
- Alerts to recommend hepatitis C testing based on patient demographics and risk factors;
- Alerts or reports to flag HCV antibody or RNA positive patients who required additional testing or who had not been linked to or who have dropped out of care; and
- Quality assurance reports to measure compliance with screening recommendations, standards of care, and treatment adherence.

Development and functionality of the reports described above involved a combination of direct modifications to the clinic EMR system and utilization of analytics and reporting software that interfaced with EMR data.

## Primary Care Provider Training

The hepatitis C provider training and videoconference program (<https://sharingthecure.jhu.edu/>) was implemented by the JHUSOM Division of Infectious Diseases and deemed exempt by the JHUSOM Institutional Review Board. The program was developed through evaluation of best practices across the United States and a needs assessment amongst local primary care providers.<sup>25,26</sup> It was determined that the goal of the program would be to train primary care providers to test for HCV infection and offer appropriate treatment with the hopes of producing hepatitis C champions, advocates, and high volume treaters. The program provided clinical training and guidance related to public health implementation of a hepatitis C program, including overcoming patient, provider, and structural level barriers in the hepatitis C care continuum. Sharing the Cure also certified providers under Maryland Medicaid as a provider with expertise in hepatitis C management.<sup>27</sup>

Each provider, upon satisfactory completion of training, received certification. The following achievements were required prior to being awarded certification:

- Participation in a one-day conference on hepatitis C evaluation, treatment, and cure. The conference launched the training program for each cohort and included presentations and case discussions by leaders and experts in hepatitis C care. Additionally, each conference included a panel discussion focused on solutions to patient, provider, and structural level barriers to hepatitis C care.
- Participation in one half-day clinical preceptorship in the JHUSOM Viral Hepatitis Center. This included instruction on pre-treatment evaluation, treatment initiation, on-treatment monitoring, and post-treatment care, as well as program implementation instruction.
- Participation in weekly one-hour videoconferences. The videoconferences included a 10 – 15 minute didactic presentation by JHU experts followed by participant case presentations and group discussion. Attendance at 14 of the 20 sessions (70%) was required. The course curriculum covered core topics in management of HCV infection. Each provider was required to present a minimum of 10 cases with the understanding that the participant was co-managing their hepatitis C patients in conjunction with JHUSOM experts. Sharing the Cure also provided email and telephone consultation outside of the weekly videoconferences. Due to scheduling issues, 1 partner site which participated from year 2–4 instituted a separate training protocol which was composed of 6 two-hour in-person case conferences covering the same topics as the videoconferences. For this alternative training, attendance was required at all sessions.

- Achievement of a passing score (70%) on the certification exam developed by national experts in hepatitis C management. Those who did not pass on first attempt had the option of a review period followed by a second exam comprised of questions distinct from the initial examination.

## Practice Transformation

An additional key element of the program was to develop the clinical sites into hepatitis C treatment centers with high-quality, comprehensive, culturally competent, and efficient care. To achieve this goal, the practice transformation component was led by an experienced hepatitis C nurse practitioner through a lunch talk series on hepatitis C epidemiology, diagnosis, treatment, and the antiviral prior authorization process (insurance approval process). This component was focused on health professionals not enrolled in Sharing the Cure, such as nurses, medical assistants, and pharmacists at partner clinical sites at their request. Additional information was also provided on engaging patients with substance use and providing culturally competent care.

## Analysis

Clinical partner sites submitted quarterly reports to the MDH which included patient demographic data, HCV antibody/RNA data, and hepatitis C care continuum outcomes including treatment initiation, treatment completion, and achievement of SVR/cure. Descriptive statistics were used to characterize Sharing the Cure provider participants and hepatitis C care continuum outcomes. HCV RNA testing from baseline (10/1/13–9/30/14; prior to package of services) and during the project period (10/1/14–9/30/18) were compared using a chi-square. Sharing the Cure provider data is reported from 5/1/2015–9/30/18 based on reporting requirements and completion of the first participant cohort. Fibrosis scores were rounded down to reflect insurance policies where F1-F2 is treated as F1 and not eligible for treatment coverage under Maryland Medicaid (>F2 eligible for treatment during the project period).<sup>28</sup>

## Results

A total of nine clinical partner sites enrolled into Sharing the Cure. The program initially launched in 2014 with five clinical partner sites; four additional clinical partner sites were added over the course of the cooperative agreement period. The organizations enrolled included federally qualified health centers (FQHCs), city health department sexually transmitted disease clinics (STDs), academic center associated primary care practices, and a primary care practice with a Maryland Medicaid Managed Care Organization. Fifty-three primary care providers (physicians, nurse practitioners, and physician assistants) from the nine clinical partner sites completed Sharing the Cure in four sequential cohorts. Forty-five (85%) passed the Sharing the Cure certification exam on first attempt. Of the 8 providers who did not achieve a passing score, 3 passed on second attempt (91% cumulative pass rate). The others were not certified but offered additional training.

The Sharing the Cure primary care provider participants submitted a total of 3,250 patients who were screened for HCV infection to be included in the database, of whom 2,285 (70.3%) were in the birth cohort (born 1945–1965), 2,445 (75.2%) were Black/African American, and 2,181 (67.1%) were Medicaid enrollees (Table 1). Sites primarily reported HCV antibody positive/indeterminate and HCV RNA positive persons to the database and did not have the ability to report all HCV antibody negative persons due to EMR and lab reporting limitations. Of the 3,237 patients who were HCV antibody positive/indeterminate, 2,624 (81.0%) had a detectable HCV RNA.

The demographic breakdown of patients with chronic HCV infection reflected the demographic breakdown of those originally tested. Of the 2,624 HCV RNA+ patients, 1,481 (56.4%) had HIV test results available in the clinical database of which 130 (8.8%) were HIV infected. Additionally, of the 2,624 HCV RNA+ patients, 1,056 had prior or current intravenous drug use assessed and reported to the database of which 858 (81.2%) reported prior or current intravenous drug use. Furthermore, 1,739 of the 2,624 (66.3%) HCV RNA+ patients underwent a liver fibrosis assessment, which is required for Maryland Medicaid prescription coverage within the primary care home. Of these 1,739 individuals, 693 (39.9%) had a liver fibrosis assessment < 2. Treatment was documented as not initiated in 254 (14.6%) with no prescription written, initiated in 932 (53.6%) with a prescription written for treatment, and treatment initiation was not reported in 553 (31.8%). The reasons listed for not initiating treatment among the 254 patients captured included failure to meet prior authorization criteria as determined by provider assessment in 86 (33.9%), lack of patient follow-up in 50 (19.7%), and specialist referral in 38 (15.0%) (Table 2). Notably, the data reports generated by clinical sites were unable to capture specialty referrals unless specifically entered by the provider; many referrals may not have been captured along with clinical data outside of the primary care home.

Of the 932 patients for whom a prescription was written, 838 (89.9%) started treatment, treatment was pending in 28 (3.0%) (with additional follow up required before treatment initiation), and treatment was not started in 66 (7.1%). Documented reasons for not starting treatment despite a written prescription included denial by insurance (24/66, 36.4%), referral to a specialist (13/66, 19.7%), and the patient did not follow up with the provider (7/66, 10.6%).

The Sharing the Cure primary care providers started hepatitis C direct-acting antiviral treatment in 838 individuals with treatment ongoing (or no treatment end date reported) in 70 patients (8.4%), complete in 721 (86.0%), and discontinued or not completed in 26 (3.1%) (Table 1). At the end of treatment (N=721), post treatment HCV RNA levels were undetectable in 674 (93.5%) persons, detectable in 7 (1.0%), and missing in 40 (5.5%). Among the 554 individuals who completed treatment, were 12 weeks post-treatment, and for whom data was available, 543 (98.0%), achieved SVR. An additional 167 individuals completed treatment but have not yet returned for their SVR appointment and/or their information is not currently available in the data received from clinical partner sites.

At participating clinical partner sites, HCV RNA follow-up testing to positive antibody tests increased from 40.1% at baseline (year preceding Sharing the Cure) to 73.3% during

Sharing the Cure among all patients tested irrespective of provider training ( $p < 0.001$ ) (Figure 1). Among providers trained in the Sharing the Cure program, HCV RNA diagnostic testing was 94.9% during Sharing the Cure. Prior to Sharing the Cure, none of the sites were performing on-site hepatitis C work-up and treatment. The following were outcomes during the program period for patients evaluated by Sharing the Cure providers: 2,624 were identified with chronic HCV infection, 1,739 (66.3%) were staged, 932 (35.5%) were prescribed treatment, 838 (31.9%) started treatment, 721 (27.5%) completed treatment, and 543 (20.7%) achieved SVR/cure (Figure 2). While fibrosis scores were evenly distributed among the staging categories ( $N=1739$ ) with 367 (21.1%) F0, 326 (18.7%) F1, 354 (20.4%) F2, 342 (19.7%) F3, 350 (20.1%) F4, patients prescribed treatment ( $N=932$ ) were skewed to F2 and above with 66 (7.1%) F0, 125 (13.4%) F1, 268 (28.8%) F2, 252 (26.8%) F3, and 221 (23.7%) F4.

## Discussion

In this program, Sharing the Cure, primary care providers who practiced in settings with high hepatitis C prevalence but with no concerted hepatitis C care program and who had not been engaged prior in hepatitis C care were trained and given supportive services ranging from EMR to pharmacy assistance. As a consequence of Sharing the Cure, hepatitis C testing and treatment by these providers (and in these settings) increased sharply with over 500 persons documented as cured of HCV infection within their primary care home in Baltimore. These data highlight that primary care practices can effectively be transformed into hepatitis C treatment centers and provide one important approach to expanding hepatitis C treatment nationwide toward the WHO goal of elimination by 2030.<sup>29</sup>

Several studies have documented specialty provider shortages, a system level barrier to hepatitis C care, along with poor linkage to hepatitis C-related care rates, a patient-level barrier, among those most vulnerable and socially marginalized.<sup>17,18,21,22,30</sup> Thus, expanding hepatitis C care to the primary care home is a mechanism to alleviate workforce shortages and poor hepatitis C-related care linkage rates. Several hepatitis C provider training models have demonstrated the ability of primary care providers to effectively and safely treat HCV infection and achieve SVR/cure rates comparable with those of specialist care (gastroenterology, hepatology, and infectious disease).<sup>25,26,31,32</sup> Our model, Sharing the Cure, was developed through review of best practices, community collaboration, and provider needs assessment which identified our final components as a one-day conference, mini-clinical preceptorship, and ongoing videoconference (the videoconference series was modified for one provider site due to scheduling issues) to provide both clinical instruction and guidance related to public health implementation of an hepatitis C program. Sharing the Cure also reinforced the provider training components with practice transformation elements including development of hepatitis C treatment implementation plans, and education sessions focused on the extended health team at clinical sites. We believe that these combined elements maximized the likelihood of Sharing the Cure providers to become high volume hepatitis C treaters and champions within their primary care home and for their sites to implement and sustain a hepatitis C treatment program. All of the sites included in this public health implementation model continue to treat HCV infection.

The Sharing the Cure program data highlights the program's success in screening patients for HCV infection, making care accessible, and meeting patients where they are within their primary care home. While Sharing the Cure celebrated many successes, a critical barrier was also encountered, namely the inability to access DAAs for patients with a liver fibrosis assessment score < F2 due to Maryland Medicaid prior authorization criteria during the project period. The data also revealed that writing a prescription for DAAs was impacted by the Medicaid restrictions as patients with a liver fibrosis assessment score of < F2 accounted for 40% of those staged but only 20% of prescriptions written. Thus, many patients with a liver fibrosis assessment < F2 did not have a prescription written by a provider. Providers in Sharing the Cure were encouraged to write prescriptions for all patients staged to allow for accurate estimates to Medicaid of all those requiring treatment. However, the burden of submitting paperwork that would likely be denied was cumbersome for many providers and noted in videoconference discussions. Maryland Medicaid prior authorization criteria removed fibrosis restrictions as of January 1, 2020. Many individuals including those involved with Sharing the Cure advocated for the lifting of the fibrosis restrictions. The hope is that the remaining states with fibrosis restrictions will move to also lift them as we all work towards hepatitis C elimination efforts.

A second key barrier noted in Sharing the Cure was the inability to confirm SVR/cure in 167 patients due to their failure to return for their SVR visit. In this real-world setting where SVR is confirmed 12 weeks after treatment completion, many patients did not return to confirm cure, which is a finding consistent with other real-world DAA based treatment protocols.<sup>33,34</sup> As we continue to move towards a comprehensive hepatitis C elimination strategy, the Baltimore City Health Department has developed a hepatitis C plan which includes searching for patients to confirm hepatitis C cure. We are also working across clinical systems to streamline treatment data to catch patients at different clinical touch points across the city, but this is complicated by the many different computer operating systems used by our clinical partners.

Sharing the Cure aimed to transition from research-based hepatitis C training protocols to a full-scale public health implementation in conjunction with a package of services. This public health implementation project succeeded in transforming primary care practices into hepatitis C treatment centers which will be an important strategy as Maryland moves toward hepatitis C elimination. While this project was focused on Baltimore initially, it is now expanding throughout Maryland per the focus of the Maryland Department of Health to also include rural areas that have been impacted by the opioid crisis and hepatitis C. To achieve elimination goals, individuals not traditionally engaged in care will need to be identified and easily access multidisciplinary treatment through co-location of services, such as substance use treatment, syringe services, and HIV care with hepatitis C services.<sup>35</sup> Due to this, Sharing the Cure has expanded to train HIV and substance use providers and has further streamlined the curriculum in recognition of the development of pan-genotypic regimens.

As this was a public health implementation project and not a research protocol, there are limits to the data collected, including clinical sites not submitting comprehensive data for inclusion, clinical sites not having additional resources to locate individuals not returning for SVR/cure appointments, and not being able to capture information on patients referred to



specialty care. Providers were trained to refer any complex patients and/or patients with decompensated cirrhosis to specialty care and thus many F4 patients and/or patients with significant co-morbidities may not have been captured. Thus, the total number of patients linked to care by Sharing the Cure providers and ultimately treated/cured is likely underestimated by our data. Further, as the program is expanded across practices and with the lifting of fibrosis assessment restrictions in Maryland and new guidelines advising all individuals 18 or older to be screened for HCV infection, it is expected that the number of total patients treated, and the percentage of patients treated within their primary care home will increase substantially.

Primary care practices can be effectively transformed into hepatitis C treatment centers to expand hepatitis C treatment access and will be an important part of the care continuum in the context of HCV elimination plans. The Sharing the Cure model trained primary care providers and their practices to appropriately engage their primary care patients in hepatitis C testing, effectively work-up and treat HCV infection, and implement a hepatitis C program within their practice to increase hepatitis C-related care options in Maryland. In recognition of the success of the program, the model has been adopted by entities within Delaware and Louisiana as they aim to expand hepatitis C treatment access through public health focused efforts to reach hepatitis C elimination goals.

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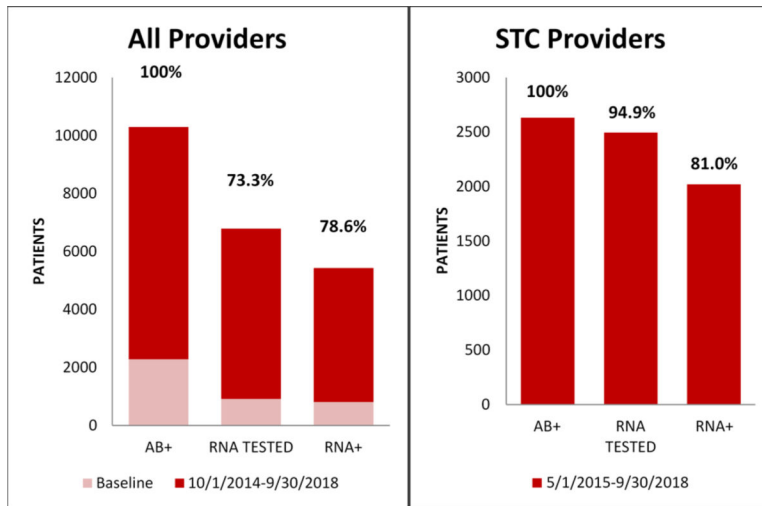
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## Citations

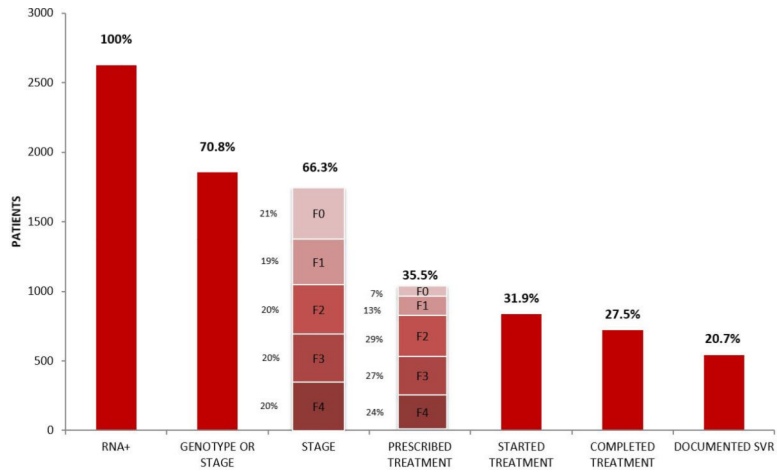
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**Figure 1:**  
\* Maryland; Baseline: 10/1/13–9/30/14  
AB: Antibody  
RNA: Ribonucleic acid



**Figure 2:**  
\*Maryland; 5/1/15–9/30/2018  
RNA: Ribonucleic acid  
SVR (Sustained Virologic Response): Negative HCV RNA 12 weeks after treatment completion

**Table 1.**

DEMOGRAPHIC AND HEPATITIS C CLINICAL CARE CONTINUUM CHARACTERISTICS OF PATIENTS SEEN BY SHARING THE CURE PROVIDERS AT COALITION PARTNER SITES \*

Characteristics (N=3,250)	N	Percent
Born 1945–1965	2285	70.3%
Male	2218	68.2%
Black/African American	2445	75.2%
Medicaid enrollee	2181	67.1%
<b>Diagnosis status for inclusion (N=3,237)</b>		
HCV RNA+	2624	81.1%
HCV Ab+ (or indeterminate)/RNA–	473	14.6%
HCV Ab+ (no RNA results)	136	4.2%
HCVAb indeterminate (no RNA results)	4	0.1%
<b>Among those HCV RNA+ (N=2,624)</b>		
Worked up for treatment with HIV results reported	1481	56.4%
HIV co-infected	130	8.8%
Prior/Current Intravenous Drug Use Assessed (Yes/No)	1056	40.2%
Confirmed prior/current intravenous drug use	858	81.2%
Worked up for treatment, with liver staging results	1739	66.3%
Metavir (liver fibrosis assessment) score below F2	693	39.9%
<b>Treatment Initiation decision* among those with liver staging results (N=1,739)</b>		
Treatment not initiated	254	14.6%
Treatment initiated	932	53.6%
Started treatment	838	89.9%
Pending	28	3.0%
Reason given for not starting treatment	66	7.1%
Treatment decision not reported	553	31.8%
<b>Among those who started treatment (N=838)</b>		
Completed	721	86.0%
Ongoing (or no treatment end date reported)	70	8.4%
Not completed	26	3.1%
Unknown	21	2.5%
<b>Among those who completed treatment (N=721)</b>		
Undetectable HCV RNA	674	94.3%
Detectable HCV RNA	7	1.0%
Missing RNA data	40	5.5%
<b>SVR/cure among those who completed treatment (12 weeks post treatment) (N=721)</b>		
SVR achieved	543	75.4%
SVR not achieved	11	1.5%
SVR results pending (missing)	167	23.2%

Characteristics (N=3,250)	N	Percent
<b>SVR/cure among those who completed treatment (12 weeks post treatment) and for whom SVR data is available (N=554)</b>		
SVR achieved	543	98.0%
SVR not achieved	11	2.0%

\* Maryland; 5/1/2015–9/30/18

HCV: Hepatitis C virus

Ab: Antibody

RNA: Ribonucleic acid

Treatment initiation decision: Documentation of a treatment initiation decision by the provider SVR (Sustained Virologic Response): Negative HCV RNA 12 weeks after treatment completion

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**Table 2.**

REASONS FOR NOT INITIATING TREATMENT AMONG PATIENTS WITH A TREATMENT INITIATION DECISION DOCUMENTED \*

Primary reason treatment not initiated among patients with treatment initiation decision recorded by clinical sites (N=254)	N	Percent
Prior authorization criteria not met by provider assessment (not submitted to insurance)	86	33.9%
Patient did not follow up with provider	50	19.7%
Referred to a specialist	38	15.0%
Patient not treated due to alcohol or injection drug use assessment by provider	6	2.4%
Provider deferred treatment due to clinical contraindication	4	1.6%
Patient declined therapy	4	1.6%
Provider did not start treatment for additional reason	4	1.6%
Patient cleared acute infection	1	0.4%
Other	53	20.9%
Unknown	8	3.1%

\* Maryland; 5/1/2015–9/30/18