Evaluations of the ADAP Program for HCV Treatment

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Abstract

Background: Hepatitis C (HCV) is a viral infection that causes severe liver disease, including hepatocellular carcinoma and cirrhosis. Among people living with HIV, there are high rates of co-infection with HCV, particularly among people who inject drugs. While highly effective HCV medications have been developed in the past decade, they remain extremely expensive and their approval by insurance companies and Illinois Medicaid is often contingent on a patient's degree of liver damage, making them largely inaccessible for many patients. In 2016, the AIDS Drug Assistance Program, funded by the Illinois Department of Public Health, added HCV medications to their formulary, allowing low-income patients who are co-infected with HIV and HCV to access HCV treatment. This study aimed to evaluate the ADAP HCV Treatment Program for barriers faced by patients and providers to utilizing the program, as well as treatment outcomes for enrollees.

Methods: This study utilized both qualitative and quantitative methodologies. First, a semi-structured interview and focus group of providers and care teams were conducted at the two treatment facilities that treated the largest number of enrollees. Participants were asked specifically about perceived barriers that patients faced to participating in the program, as well as challenges experienced by providers and care teams in treating patients enrolled in the program. To determine treatment outcomes of enrollees, reported laboratory data was used to determine rates of follow-up for all enrollees and rates of sustained virologic response (SVR) for all patients who had adequate follow-up. These rates were then analyzed for differences in treatment facility volume, transmission risk factor, age cohort, and race/ethnicity using chi-square tests.

Results: The interview and focus group provided insights into the experiences of program participants. Specifically, enrollees often faced barriers including providing documentation to

enroll in ADAP and handing competing priorities such as housing and transportation. Care teams found that some aspects of enrolling and treating patients through the program were time- and personnel-intensive and required a high degree of care management, and they suggested specific changes that might make working with the program easier. The outcomes data showed that the two highest-volume treatment facilities had better rates of follow-up than low-volume facilities, $X^2(1, N = 111) = 5.56$, $p = 0.018$. However, there was no difference in rates of SVR between the two facility types among those patients who did receive adequate follow-up, $X^2 (1, N = 78) = 0.18$, $p = 0.67$. There was no difference in rates of follow-up or SVR when analyzed by transmission risk factor, age, or race/ethnicity.

Conclusions: Major barriers to patient enrollment and retention can be addressed by intensive care management through treatment facilities. However, this requires numerous, dedicates care management personnel and is time-intensive. High-volume treatment facilities have higher rates of patient follow-up, possibly because they have more auxiliary support staff dedicated to care management. Across both high- and low-volume facilities, and all patient demographics, there is no difference in treatment outcomes among patients who receive adequate follow-up. Therefore, treatment programs and facilities should continue to support and expand care management services in addition to medical therapies to achieve the best treatment outcomes.

Introduction

Hepatitis C virus (HCV) is a blood-borne virus that leads to hepatitis in both the acute and chronic stages. While the acute phase is self-limited, infected persons will usually develop chronic HCV infection. Chronic HCV infection is progressive in nature and, over the course of

years, can cause cirrhosis and hepatocellular carcinoma in 70-85% of infected people, making it the leading cause of liver transplantation in the United States.

HCV is primarily transmitted through injection drug use, blood transfusions prior to 1992, clotting factor concentrate transfusion prior to 1987, and male to male sex (MSM There were estimated to be 41,200 new cases of HCV in the United States in 2016, a fourfold increase in the number of new infections since 2005, the majority of which were undiagnosed and under-reported (1). Given modern standards of screening blood and clotting prior to transfusion and the increasing HCV incidence among young people in urban, suburban, and rural areas, it is commonly accepted that the recent increase in transmission of HCV reflects the opioid and injection drug use epidemic in the United States (2). It is estimated that 2.4 to 3.5 million adults in the United States are infected with HCV. Deaths from HCV have been steadily increasing as well, with HCV accounting for more deaths annually than 60 other infectious diseases combined, including HIV (3). In Chicago, 26,535 people were living with HCV in 2016 with 3,026 newly reported cases of HCV that year (4).

Because HIV and HCV share overlapping risk factors (IV drug use, exposure to infected blood products, and MSM), it is unsurprising that there are high rates of HIV-HCV co-infection. 25% of people living with HIV in the United States are coinfected with HCV, and nearly 75% of people with HIV who use injection drugs are coinfected with HCV (5). Additionally, coinfection with HIV more than triples the risk of liver disease caused by HCV and accelerates the rate of liver disease onset.

HCV has historically been treated with pegylated-interferon (PEG-IFN) alpha plus ribavirin (RBV), which produced relatively poor rates of sustained virologic response (SVR) of 40-50% and were associated with intolerable side effects. In 2011, the first direct-acting

antivirals (DAAs) were released for HCV treatment to be used in combination with PEG-IFN plus RBV with rates of SVR near 70%, though still accompanied by extensive side effects. In 2013, the first all oral HCV treatment regimens characterized by the use of DAAs without interferon were developed, with the achievement of SVR in more than 90% of patients and with much more favorable side effect profiles. There are now multiple well-tolerated, all-oral regimens with highly successful SVR rates available for the treatment of HCV (6). However, these drugs carry a high burden of cost to patients, with an initial treatment regimen ranging in cost from $26,500 to $94,500, depending on the choice of drug and duration of treatment (7), severely limiting patient access to treatment.

The AIDS Drug Assistance Program (ADAP) is a program funded by the Illinois Department of Public Health that provides medications to low-income, defined as below 500% federal poverty line, Illinois residents infected with HIV. In 2016, ADAP added five HCV medications to their formulary (8), allowing ADAP-eligible people co-infected with both HIV and HCV to access HCV treatment, and therefore lower their risk of complications from chronic HCV infection and limit transmission to other people. Notably, this provided an accessible treatment option for patients without severe liver disease. Liver disease is defined based on the degree of fibrosis scaled from F0 to F4, where F0 corresponds to the absence of liver fibrosis and F4 corresponding to complete fibrosis, or cirrhosis. When the ADAP HCV treatment pilot program was launched in 2016, co-infected patients were eligible to have their HCV treated through ADAP while having a minimum liver fibrosis score of F1. By contrast, in 2016, Illinois Medicaid required people with HCV to have a liver fibrosis score of F3 to be eligible for treatment coverage.

Following the launch of the new ADAP HCV Treatment Program in 2016, 111 patients were enrolled in the initial pilot program. The focus of this project was to determine the outcomes of the ADAP HCV Treatment Program in treating HCV in enrolled patients co-infected with HIV and HCV. Primarily, what are the rates of SVR among patients enrolled in the program, and what patient and treatment facility characteristics predict rates of SVR? Additionally, what are the barriers or challenges to patient and provider use of the program?

Implications for public health practice: This study evaluates both the participant experience and effectiveness of a government-funded treatment program for HCV. Feedback from care teams treating patients enrolled in the program can provide suggestions of ways to improve the program for patients and providers, leading to more utilization and success of the program. Additionally, analyzing rates of treatment effectiveness based on patient retention and rates of cure will inform stakeholders on the value of such a program for the community. If the program is deemed to be successful, it might be expanded to allow even more patients to access treatment. The results of this study were communicated to stakeholders at IDPH through a written report of the data, as well as to the community at the 2018 Infection Control Conference.

Methods

This project was composed of two main methodologies. The first arm of the project was a qualitative analysis of a semi-structured focus group and interview with personnel (providers, pharmacists, and care managers) from a representative sample of facilities caring for patients enrolled in the program. A focus group and an interview were conducted at the two treatment facilities with the largest volume of patients enrolled in the study. Researchers contacted these personnel through email to arrange a mutual time for these sessions. The interview was conducted with the head pharmacist at one facility and the focus group consisted of providers, a

pharmacist, and care managers at the other facility. The goal of this focus group and interview was to elicit provider-level feedback regarding the ADAP HCV Treatment Program. Topics included the prior approval process, ordering medications through the Pharmacy Benefit Manager, and barriers faced by providers and patients to participating in the program. See Appendix 1 for the complete questionnaire used to direct these sessions. The interview and focus group were audio recorded and the sessions were later transcribed. The transcriptions were then analyzed by extracting the main themes expressed by the treatment teams related to key topics of interest.

The second arm of this project was a quantitative analysis of the virologic response to treatment outcomes of enrolled patients. The data for this analysis was extracted from several existing datasets. Demographic data including age, gender, race, zip code, transmission risk factor, and treatment start date were collected from three separate databases: 1. Provide Enterprise, the IDPH Ryan White case management system, 2. eHARS (Enhanced HIV/AIDS Reporting System), which houses surveillance information for people treated for HIV in Illinois, and 3. I-NEDSS (Illinois' National Electronic Disease Surveillance System), the Illinois infectious disease reporting site. Laboratory data including HCV RNA levels and testing dates were collected from I-NEDSS when available and from HepCCATT (Hepatitis C Community Alliance to Test and Treat), a separate HCV registry compiled through public/private partnerships.

Patients were enrolled in the program from March 2016 through July 2017. Laboratory data were collected from program inception through April 2018. Treatment outcomes were analyzed based on two factors: 1. the rate of adequate follow-up for each patient's HCV treatment, which was operationalized as having had at least one HCV RNA test at least 6 months

after treatment start date to capture patients who were continuing to be followed for their HCV care, and 2. SVR, which was defined as having at least one negative HCV RNA test at least six months after treatment start date without any subsequent positive HCV RNA tests to capture patients with laboratory values consistent with sustained cure of their HCV. Of note, SVR can only be assessed in patients who have had adequate follow-up. We examined these outcomes by treatment facility volume, transmission risk factor, age, and race and evaluated for significant differences using chi-square analyses.

Results

The qualitative data obtained from the interview and focus group were classified into three domains: 1. barriers to patient enrollment in ADAP for HCV treatment, 2. challenges providers and treatment facility staff face in participating in the ADAP HCV Treatment Program, and 3. how IDPH can further support sites that care for patient participating in the ADAP HCV Treatment Program. Table 1 displays the emergent themes from this interview and focus group.

A total of 111 patients were enrolled in the program. Seventy-eight (70%) patients received adequate follow-up, and of those 78 patients, 75 (95%) achieved SVR. data were further analyzed by treatment facility volume, transmission risk factor, age, and race/ethnicity for follow-up rates and rates of SVR among those who achieved follow-up.

The first sub-analysis was by treatment facility volume. The 111 enrolled patients received their care at 16 different facilities. However, 78 of those 111 patients received their care at one of two facilities (deemed “high-volume facilities”), while the remaining 33 patients received their care at the 14 other facilities (deemed “low-volume facilities”), each caring for 5 or fewer patients enrolled in the program. Rates of follow-up were compared between high- and

low-volume facilities, and rates of SVR were subsequently compared between these groups among patients who received follow-up. These results are summarized in table 3. Sixty (77%) of patients treated at a large-volume facility had adequate follow-up, while only 18 (55%) of those treated at small-volume facilities did, $X^2(1, N = 111) = 5.56$, $p = 0.018$. Among the patients who received adequate follow-up, there was no difference in rates of SVR between high-volume (97%) and low-volume (94%) facilities, X^2 $(1, N = 78) = 0.18$, $p = 0.67$ (table 2).

We next evaluated for differences in rates of follow-up and SVR by transmission risk factor category. Eighty-four percent of patients reported their transmission risk factor to be MSM (men who have sex with men), IDU (intravenous drug use), or a combination of the two. The remaining patients identified their risk factor as heterosexual contact or NIR (no identifiable risk factor). There was no difference in rates of follow-up between these transmission risk factor groups (X^2 $(4, N = 111) = 5.45$, $p = 0.24$) or in rates of SVR among those patients who received adequate follow-up (X^2 $(4, N = 78) = 2.74$, $p = 0.60$) (table 3).

Next, we performed a similar analysis for age and race/ethnicity. For the analysis of age, enrollees were divided into two age cohorts: baby boomers (born 1945-1964) and non-baby boomers (born 1965-1994). These results are summarized in table 5. There was no difference in rates of follow-up between the two age cohorts (X^2 $(1, N = 111) = 0.019$, $p = 0.89$) or in rates of SVR among those who received adequate follow-up (X^2 $(1, N = 78) = 5.45$, $p = 0.24$) (table 4). For the analysis of race/ethnicity, there was no difference in rates of follow-up between black, white, Hispanic, and other/unknown race patients (X^2 $(3, N = 111) = 2.09$, $p = 0.55$) or rates of SVR among those who received adequate follow-up (X^2 $(3, N = 78) = 1.42$, $p = 0.70$) (table 5).

Discussion

This study aimed to evaluate the ADAP HCV Treatment Program after its inception in 2016. The evaluation had two main methodologic branches. First, a qualitative study was performed to gain insight to the barriers faced by both patients and their care teams in working with this program for HCV treatment. This was done by conducting and interview and a focus group with providers and other care team members at the two treatment facilities that treated the majority of patients enrolled in the program. The second branch of the study was a quantitative analysis of the outcomes of treatment for patients enrolled in the program. This study evaluated for rates of follow-up for all patients enrolled in the study and rates of SVR for patients who achieved adequate follow-up. These data were sub-analyzed by treatment facility volume (low vs high), transmission risk factor, age, and race.

The interview and focus group conducted at the two treatment facilities with treating the majority of patients enrolled in the ADAP HCV Treatment Program revealed several challenges faced by both patients and their care teams when participating in the program. Regarding barriers faced by patients, enrollment requires patients provide information about their income and insurance status to qualify for the program, which might delay or discourage enrollment. Additionally, a lack of stable housing and access to transportation to attend medical and care management appointments introduce additional barriers and competing priorities for patients that make it difficult to stay engaged in treatment for the necessary 2-3 months to achieve cure. Therefore, in addition to medication assistance programs, care management services focused on supporting housing and transportation services are also crucially important to treatment success. However, this intensive level or care management requires adequate staffing power, and treatment facilities that do not have those resources may struggle to enroll patients in the

212 treatment program or provide the services necessary for patients to follow-up throughout their
213 treatment.

214 The qualitative data also shone light on other aspects of the program that can be
215 improved. One factor that was discussed in the interview and focus group was working with the
216 pharmacy benefit manager. Ordering medication through the pharmacy benefit manager requires
217 additional steps by the provider or treatment staff, requires a prior approval, and has led to delays
218 in patients obtaining their medications. Additionally, inadequate communication between IDPH,
219 treatment facilities, and the pharmacy benefit manager can lead to further delays. Improved
220 communication on the part of IDPH and a streamlined process for ordering and obtaining
221 medications would further support treatment facilities in allowing patients to access their
222 medications. Additionally, while the care teams at both treatment facilities found the program to
223 be highly beneficial to their patients co-infected with HIV and HCV, there are many more
224 patients that are infected with HCV alone and are unable to access treatment who would benefit
225 from a similar medication assistance program.

226 Our quantitative analysis focused on rates of follow-up and rates of SVR among patients
227 who received adequate follow-up. Our first sub-analysis evaluated for whether or not there were
228 differences in outcomes based on where patients were being treated for the HCV. In the initial
229 cohort of patients enrolled in this program, the vast majority were treated at one of two facilities,
230 while the rest were treated among 14 other sites. Our analysis shows that patients treated at the
231 high-volume facilities had better rates of follow-up than those treated at the low-volume
232 facilities. However, among those patients who had follow-up, there was no difference in rates of
233 SVR between high- and low-volume facilities. Therefore, overall differences in rates of SVR
234 between the two facility types is arguably driven by differing rates of follow-up. We postulate

that this may be due to differences in care management resources and staffing power. Data from the interview and focus group showed that one of the challenges faced by care teams is providing the intensive care management required for patient follow-up, as well as navigating the enrollment process and ordering medications from the pharmacy benefit manager, all of which require trained personnel that all facilities may not have.

This analysis was also conducted for transmission risk factor, age, and race/ethnicity. There were no differences in rates of follow-up or SVR between variables in these analyses. For the evaluation of transmission risk factor, the results may have been affected because one category or transmission was both MSM and IDU, both of which are risk factors of interest alone. It is unlikely that enrollees in this transmission risk factor category are inherently unique from those in the MSM only or IDU only groups, so by including this category, a true difference between the MSM ad IDU risk factor groups may have been missed.

For the evaluation of difference in outcomes by age, two age cohorts were included: baby boomers (born 1945-1964) and non-baby boomers (born 1965-1994).The decision to use two cohorts rather than age as a continuous variable was made to capture the two distinct age groups seen in HCV infection. Baby boomers are at risk for HCV infection primarily due to the transmission of HCV through blood transfusions prior to 1992 and clotting factor concentrate transfusion prior to 1987. By contrast, the HCV epidemic among younger generations is driven primarily by the IDU epidemic. However, because the population enrolled in this program is also infected with HIV and therefore likely has risk factors of contracting blood-born infections, it may not be reflective of the baby boomer population at large and may not be that unique from the non-baby boomer population.

Public health implications: The results of this study have the potential to directly impact public health practice. Within the program itself, the information learned from the care teams can direct efforts to improve the program. Namely, improving communication with the pharmacy benefit manager to streamline the ordering of medications, supporting social services such as housing and transportation to help facilitate patient retention in treatment programs, and potentially expanding funding sources to cover treatment for patients who are infected with HCV alone, since ADAP funds can only be used to pay for medications for people with HIV.

The outcomes data in this analysis suggests that government-funded treatment programs for HCV can be highly effective in achieving cure in people who otherwise might not have access to these medications, regardless of their history of IDU, age, or race. When patients stay in treatment programs and are not lost to follow-up, they have extremely high rates of cure. Per this analysis, one predictor of patient retention is the treatment facility from which they receive their care. Facilities that are more accustomed to utilizing the program to treat patients with HCV (i.e. the high-volume facilities) are more likely to achieve higher rates of patient follow-up during treatment, potentially due to strong HCV care management services. This is unsurprising, given that HCV treatment requires a prolonged 8-12 week course. By providing support in during enrollment and connecting patients to services such as housing and transportation during treatment, care management is likely an essential part of patient retention and, therefore, achieving cure.

Limitations: While the qualitative aspect of this study provided a unique perspective from the providers and care teams, we were only able to arrange an interview and focus group with the two facilities that treated the majority of enrollees and were not able to gain such insights from the 14 other facilities. Therefore, when hypothesizing about the difference in follow-up rates

between the high- and low-volume treatment facilities, we had to extrapolate what we learned from the qualitative data we had from the high-volume facilities to explain challenges potentially faced by other facilities.

A major limitation in the quantitative analysis is the limited number of patients who received adequate follow-up but did not achieve SVR (i.e. had a positive HCV RNA test more than six months after starting treatment). Only three patients continued to have a positive HCV RNA level six months after starting treatment. While this speaks to the effectiveness of treatment when paired with adequate follow-up, it makes this study underpowered to detect differences in treatment outcomes between the groups studied here. So while this analysis did not detect difference in treatment outcomes by facility size, risk factors, age, or race, true differences may still exist. Additionally, given the small sample size of 111 included in this study, some analyses including transmission risk factor and race/ethnicity that have several subgroups are ultimately underpowered to detect true difference among these subgroups.

Another limitation to this analysis is the reporting of negative laboratory data. Depending on facility site and the outside laboratory each site uses to process specimens for RNA analysis, negative RNA tests may or may not be electronically reported to I-NEDSS or collected by HepCCATT. The reporting of negative HCV RNA tests has previously been inconsistent, and it is therefore possible that there is additional patient laboratory data (i.e. negative results) that was not included in this analysis, so rates of follow-up and SVR may actually be higher than reported here.

Future directions: The results of this analysis warrant further study. Future investigations might assess for the experience of patients themselves who are enrolled in this program to learn more about the challenges they face directly from the patients themselves. Additionally, surveys,

interviews, or focus groups directed towards providers and care teams at low-volume treatment facilities can be conducted to learn about the challenges they face, which may be unique from those faced by the high-volume facilities. Regarding the treatment outcomes data, chart reviews of enrollees for any missing or unreported laboratory data may allow for a more robust analysis of the rates of SVR.

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Appendix 1. Focus group/interview guiding questionnaire

1. When did you first become aware of the ADAP pilot program for HCV treatment?
2. How were your first informed about the ADAP pilot program for HCV treatment?
3. Did you notice barriers that prevented patients from enrolling in ADAP? What were they?
4. Did you experience any other issues regarding patient enrollment in ADAP? What were they?
5. Describe your experience with the Prior Approval form and process.
6. Did you encounter issues when ordering medications from the Pharmacy Benefit Manager? What were they?
7. What types of screening tests/labs are performed at your clinical site? Examples: Antibody testing, gentyping, RNA testing, Fibrosis score
8. What barriers do you or your facility face to participating in the ADAP pilot program for HCV treatment?
9. What additional support could have been provided by IDPH?

Table 1. Emergent themes from semi-structured interview and focus group conducted at two large-volume treatment facilities

Patient barriers to participating in the ADAP HCV Treatment Program	- Trouble gathering required documentation for enrollment (e.g. pay stubs, insurance cards) - Unstable housing - Lack of access to transportation to medical and care management appointments
Provider/staff barriers in caring for patients enrolled in the ADAP HCV Treatment Program	- Adequate patient care requires intensive case management for all enrolled patients - Medications must be ordered from the pharmacy benefit manager, which causes delays in placing medication orders, approval, and patient attainment of medications - The above are both time intensive and require adequate staffing power
How IDPH can further support treatment facilities caring for patients enrolled in the ADAP HCV Treatment Program	- Improving communication with pharmacy benefit manager so that patients can access their medications as soon as they are approved. Alternatively, consider broadening relationships with other pharmacies - Notifying sites when a patient's Prior Approval request is approved - Direct notifications of the program to people at a site who are best able to implement the program - Look into expanding the program to treat patients with HCV alone

Table 2. Rates of follow-up and SVR by treatment facility volume

	All patients				Patients who received adequate follow-up			
Facility volume	Follow-up	Lost to Follow-up	Total	X^2	SVR	No SVR	Total	X^2
Low	18 (55%)	15 (45%)	33	5.56*	17 (94%)	1 (6%)	18	0.18
High	60 (77%)	18 (23%)	78		58 (97%)	2 (3%)	60	
Total	78	33	111		75	3	78	

*$P < 0.05$

Table 3. Rates of follow-up and SVR by transmission risk factor category

	All patients				Patients who received adequate follow-up			
Transmission category	Follow-up	Lost to Follow-up	Total	X^2	SVR	No SVR	Total	X^2
Adult MSM	23 (74%)	8 (25%)	31		23 (100%)	0	23	
Adult IDU	30 (70%)	13 (30%)	43		28 (93%)	2 (7%)	30	
Adult MSM & IDU	12 (63%)	7 (37%)	19		11 (92%)	1 (8%)	12	
Adult heterosexual contact	3 (43%)	4 (57%)	7		3 (100%)	0	3	
NIR	10 (91%)	1 (9%)	11	5.45	10 (100%)	0	10	2.74
Total	78	33	111		75	3	78	

MSM = men who have sex with men, IDU = intravenous drug use, NIR = no identifiable risk factor

Table 4. Rates of follow-up and SVR by age cohort

	All patients				Patients who received adequate follow-up			
Birth year	Follow-up	Lost to Follow-up	Total	X^2	SVR	No SVR	Total	X^2
1945-1964	46 (71%)	19 (29%)	65		44 (96%)	2 (4%)	46	
1965-1994	32 (70%)	14 (30%)	46		31 (97%)	1 (3%)	32	
Total	78	33	111	0.019	75	3	78	0.076

377 **Table 5. Rates of follow-up and SVR by race/ethnicity**

	All patients				Patients who received adequate follow-up			
Race/ethnicity	Follow-up	Lost to Follow-up	Total	X^2	SVR	No SVR	Total	X^2
Black	39 (75%)	13 (25%)	52		38 (97%)	1 (3%)	39	
White	17 (65%)	9 (35%)	26		16 (94%)	1 (6%)	17	
Hispanic, any race	12 (75%)	4 (25%)	16		11 (92%)	1 (8%)	12	
Other/unknown	10 (59%)	7 (41%)	17	2.09	10 (100%)	0	10	1.42
Total	78	33	111		75	3	78	

378