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Strategies for improving hepatitis C treatment access in the U.S.: State officials address high drug prices, stigma, and building treatment capacity

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Abstract

Context—Curative treatments for hepatitis C virus (HCV) can alter the course of a devastating epidemic, but high drug prices have contributed to restrictions on HCV treatment access.

Objective—We aimed to learn how state health agencies have responded to the challenges of treatment access for HCV.

Design—Qualitative study using semi-structured key informant interviews, focused on aspects of HCV treatment access, between June 2016 and March 2017. Content analysis was used to identify dominant themes.

Setting—United States

Participants—Eighteen health officials and treatment advocates across six states, selected using purposive sampling.

Results—Drug pricing is the most important barrier to access, encouraging restrictive authorization criteria from payers that in turn discourage providers from offering treatment. However, payers have not experienced the budget impact that was initially feared. Although authorization criteria are being lifted for fee-for-service Medicaid programs, ensuring that

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managed care organizations follow suit remains a challenge. The effect of stigma, a shortage of treating providers, and lack of political motivation are additional challenges to expanding treatment. The response to the HIV epidemic can augment or inform strategies for HCV treatment delivery, but this is limited by the absence of dedicated funding.

Conclusions—While treatment eligibility criteria for HCV treatment are improving, many other barriers remain to achieving the scale-up needed to end the epidemic. Political disinterest, stigma, and a lack of specialty providers are continued barriers in some jurisdictions. States may need to invest in strategies to overcome these barriers, such as engaging in public and provider education and ensuring treatment by primary care providers is reimbursed. Despite uncertainty about how federal policy changes to Medicaid may affect states' ability to respond, states can identify opportunities to improve access.

Keywords

Hepatitis C; Medicaid; Antiviral Agents; Health Services Accessibility; Qualitative Research

Introduction

Hepatitis C virus (HCV) infection affects an estimated 5 million Americans,[1] and is a leading infectious cause of death and liver transplantation.[2,3] Since 2014, new, highly effective HCV medications called direct acting antivirals (DAAs) have largely replaced prior treatments. DAA regimens contain oral medications taken daily for 8 to 12 weeks with minimal toxicity and can cure HCV, with efficacy of over 90% for most populations.[4] There is emerging evidence that treatment can limit continued HCV transmission.[5–7] The scale-up of DAA treatment, combined with strategies to prevent transmission and address substance use disorders, can alter the epidemic curve and is an important cornerstone of national hepatitis elimination agendas.[8–10] Improving access to treatment is also central to multiple state and local plans to address viral hepatitis.[11–15]

The cost of DAAs has received negative attention from activists, media, and the healthcare sector. With early prices approaching $84,000 per treatment course,[16] DAAs have been at the forefront of national dialogue on rising prescription drug costs. Anticipating these costs, Medicaid programs instituted criteria limiting treatment to those with severe disease, substance use abstinence, a subspecialist provider, and suppressed HIV viral loads.[17,18] In 2015, the Centers for Medicare and Medicaid Services (CMS) instructed Medicaid programs to improve treatment access by lifting restrictions.[19] Judicial decisions in response to lawsuits have also largely supported expanded treatment access.[20] State strategies for providing coverage for expensive DAAs have varied, and the factors influencing policy change remain unknown.

To determine state-level factors affecting DAA treatment expansion and its influences on public health programming, we interviewed health officials and treatment advocates with expertise in HCV treatment. We focused on Medicaid access for several reasons, but incorporated insights into other payers when offered. HCV prevalence is higher in Medicaid enrollees than the privately insured.[21] Incident HCV occurs primarily in non-elderly people who inject drugs, a population likely to receive insurance through Medicaid even though substance use disorder alone does not qualify uninsured individuals for Medicaid.[22–24] State decisions on the federal Medicaid expansion differ, and we were able to elicit contrasts between states based on these policy differences. Finally, policymakers can directly influence Medicaid restrictions, although they operate within budgetary constraints. Hypothesizing that the HIV/HCV coinfected individuals may have additional coverage options, we also interviewed experts in HCV treatment coverage for this subpopulation. We deliberately selected respondents from six states with diverse policy environments to identify common challenges, variations across settings, and recommend strategies for other jurisdictions.

Methods

We conducted key informant interviews with experts in HCV treatment access in the United States from June 2016 to March 2017. The research team consisted of physicians with experience in HCV treatment (S.K., C.J., K.M.), and two health policy researchers with qualitative research experience and expertise in federal and state policies for HIV and HCV treatment (E.M. and B.S.).

We used purposeful sampling to select six states,[25] aiming for diverse geography, total population sizes, Medicaid expansion status, and published treatment eligibility criteria for HCV treatment coverage.[26] For each state, we identified up to three health officials with complementary expertise in how HCV treatment is publicly financed. We also identified experts from treatment advocacy organizations and federal programs to gain a national perspective. Additional participants were recruited through snowball sampling until no new themes emerged from further data collection.[25] We approached 24 candidates: 18 agreed to interview, four declined due to lack of expertise and recommended alternative candidates, and two declined and did not provide additional referrals. Table 1 shows characteristics of states and participants. To respect participants' expressed desire for anonymity, states and job titles are not reported. The human subjects protocol was approved by the Weill Cornell Medicine IRB.

We used a semi-structured interview guide (supplementary exhibit A1) which focused on facilitators and barriers to HCV treatment, the contrast between treatment access for persons co-infected with HIV versus with persons mono-infected with HCV, specific treatment eligibility criteria in state Medicaid programs, and expectations regarding future HCV treatment access. While we focused on some respondents offered insight into other payers, which we incorporated into the findings.

Interviews were conducted over the telephone by one investigator (S.K.), lasted approximately 1 hour, and were digitally recorded and transcribed.

De-identified transcripts were coded using content analysis.[27] A codebook (supplementary exhibit A2) was developed based on the first four transcripts and updated iteratively with each new transcript.[28] Two investigators (S.K. and C.J.) coded all transcripts independently, resolved discrepancies by consensus, and synthesized themes in the coded text. The coding guide and themes were reviewed by the full team during multiple meetings. We conducted member checking, in which participants were offered the opportunity to provide feedback on an early draft, with the final draft incorporating their comments.[25] All data were coded in NVivo Software (QST International Pty Ltd., Version 11).

Results

Five distinct themes emerged from the data. These themes and representative quotes are summarized in Table 2.

Treatment cost triggers multiple barriers to expanding HCV treatment coverage

Every respondent identified high treatment costs as the most significant barrier to treatment. High initial costs when DAAs came onto market in 2014 spurred payers to limit access to treatment: "Cost concerns were just so overwhelming…and state Medicaid programs… had not budgeted for these drugs and were just grappling with how they could make access a reality." One health official was "surprised that our Medicaid initially resisted [providing] comprehensive coverage for the HCV medications…of course, it was primarily cost driven." In some states, cost reduced enthusiasm within health agencies for prioritizing HCV treatment. A state Medicaid official, referring to competing funding needs of other, more prevalent, diseases, stated that "there's so many other populations of people that are bigger than that who also need [treatment]…Can't help everybody."

The publicity around treatment cost prompted clinical societies, policymakers, and providers to prioritize HCV treatment among those with severe disease. This later worsened access: "The national guidelines didn't really do us any favors…when they came out with that list of priorities, it was pretty much the nail on the coffin." In 2014, most state Medicaid programs had imposed eligibility criteria to restrict treatment access based on these priorities, such as requiring high disease severity, proof of abstinence from substance use, and using a specialist treating provider. One respondent attributed these criteria to "rationing, because [payers] feel like they need to contain cost." Respondents from every state indicated that criteria based on disease severity, which began by requiring advanced fibrosis in many states, are generally becoming less restrictive. Restrictions based on substance use and prescriber specialty were not consistently being relaxed in the states we sampled. The feeling that access needs to be limited to contain costs may also affect providers' willingness to treat HCV: one health official who surveyed local providers reported that many providers stated, "We're so afraid to begin to start somebody on treatment because it's so expensive." Even as payers are relaxing treatment eligibility criteria, providers may be informally adapting similar criteria in the office setting to determine a patient's readiness for treatment, limiting the impact of more lenient policies.

All respondents expressed frustration about the lack of transparency in drug pricing and treatment utilization, which hampered efforts to improve access. Health officials in five states described difficulties accessing information on treatment coverage and drug prices from private payers and other governmental agencies. This lack of transparency "made it hard to hold any party accountable, and that makes it difficult for the work of advocates or providers or patients." A treatment advocate was "frustrated by the lack of information…the media is very quick to jump on a $1,000 a pill headline…but there's also been a lack of nuance about the fact that the wholesale acquisition cost for drugs is not actually what anybody pays." On the other hand, another respondent noted the potential benefit of some degree of secrecy: "many of the states where you have seen changes in the last year, part of the motivation for those changes has been behind the scenes negotiations with the drug companies to get more favorable rebate agreements."

Despite the strong consensus about the negative impact of cost on treatment access, the effect on payers was less severe than initially feared. A health official stated that "if everyone had presented for care simultaneously and we had paid full price for those drugs, it would have broken the bank for Medicaid and even strained the ability of our HIV drug assistance program to keep up…neither one of those was a reality." Respondents described several factors that mitigated the impact of high drug costs on payers: the medical eligibility restrictions that payers used to limit treatment access were effective in doing so; newer medications brought competition to the marketplace, thus lowering prices; and some states have offered additional payments to insurance plans to motivate HCV treatment.

Treatment eligibility criteria changes by fee-for-service Medicaid are not always adopted by managed care plans

Even as fee-for-service Medicaid criteria have improved, respondents in four states discussed the continued variability in the practices of Medicaid managed care plans. "The policy gets operationalized by…managed care plans…and they each operationalize the policy in their own way. Some…err on the side of approval and some err on the side of being very conservative and denying many requests." One treatment advocate explained that managed care cannot have more restrictive authorization criteria than the state fee-for-service program, but this requirement is not universally enforced: "Even where the state has been pretty clear with the managed care plans that they must follow the standard in fee-for-service or something more generous, the managed care plans to some extent do what they want to do and it's tough for the state to go around and enforce its standards against every managed care plan."

An official in another state was frustrated by the effect of this variability on providers: "one provider developed a spreadsheet looking at all the various plans…It was all over the place in terms of what the requirements were. That takes away from direct patient care." The complexity of the prior authorization process discourages providers from offering HCV treatment and allows payers a way to "insert cogs into the machine." For example, an advocate described one plan "has things that seem like almost blatant obfuscation, like fax numbers where you send your prior [authorization] and then they say they never received it." These processes, while not as explicit as eligibility restrictions described above, can "take hours on the phone…on hold…and filling out endless paperwork just to get the drug approved…It's a hidden cost of this work. I think those are being used even with open access, to restrict the flood, to dam up the demand a little bit and make it trickle a little bit more."

Stigma, patient engagement, and provider availability are additional barriers to treatment access

Respondents in all states identified stigma around HCV and injection drug use as a second major barrier to HCV treatment access that affected policymaking, providers, and patients. One treatment advocate felt that stigma was “underlying everything we see, because while treatment is certainly very expensive, when you look at it compared to treatments for other big infectious diseases or big diseases in general, it’s not that much different. But I think because it’s a disease that predominantly impacts low-income people, people of color, people who are drug users, the perception is very, very different.” Stigma may also affect provider willingness to screen and treat HCV: “There are a lot of providers out there that don’t want to screen for hep-C because they think they’re going to bring in this flood of people who are drug users, and they don’t want to take care of those individuals.”

Patients and providers may also be reluctant to initiate treatment due to a perceived lack of urgency and negative experiences with older treatments. Because HCV has a long asymptomatic latency period before affecting health outcomes, linking HCV patients to treatment is not perceived to be “as urgent as it feels with some other diseases, notably HIV.” One health official described “a little bit of a hangover from when the treatment regimens were more complicated, more toxic and less effective, so providers are a little bit slow to change their practice.” Another described a similar effect for patients: “people with hepatitis C infections got such a negative image of hepatitis C treatment based on the pretty horrific experiences of the interferon treatments and their low efficacy that we didn’t see people banging down the doors at the very beginning.”

Respondents in every state perceived a shortage of providers who were qualified to treat HCV, although this concern was highest in states with large rural HCV populations. In two southern states, teaching hospitals were the most common places to receive HCV treatment, but these hospitals did not cover a wide geographic area. One health official noticed, “If you’re not…where there’re a lot of providers—and there’s an awful lot of rural [areas]--you’re not going to be travelling…to the doctor unless you’re almost dead.” In one Midwestern state, a large area “has really poor access to specialty care and very poor access to…medication therapy, substance use disorder, and even primary care is tough.” States have responded to this in two ways: some states have attempted to lift requirements that the prescribing provider be a subspecialist, and some have invested in programs to encourage primary care providers to treat HCV. Respondents in three states mentioned programs that offered telephone or electronic consultation for HCV treatment, and officials in one other state were hoping to implement such a program.

An evolving political and fiscal environment can influence treatment access

Federal and state political and fiscal environments can either facilitate or hinder treatment access. In one southern state, a health official observed that federal support for HCV is insufficient to finance treatment through public programs, and supplemental state support is limited due to competing priorities. In another state, fiscal difficulties diminished public health funds, impairing both direct treatment coverage and the ability to fund innovative programs and provider outreach initiatives. Officials in two states credited their state’s political commitment to public health programs in facilitating HCV treatment access: “everyone in the administration recognized the importance of these drugs…[and that] the whole issue should be addressed equitably across all state payer sources.”

Several factors affect the politics surrounding HCV treatment, in turn influencing state Medicaid programs and insurance plans. Media and advocacy groups have criticized restrictive policies. The Centers for Medicare and Medicaid Services also issued guidance that criticized restrictions. Judicial decisions in several states ruled against treatment restrictions: “States are getting to the point where they are worried that if somebody brings a lawsuit in the state, that they will have no choice but to make the change.”

Finally, the 2016 presidential election and potential changes to or repeal of the Affordable Care Act are relevant. In contrast to primarily optimistic outlooks in interviews conducted before the election, respondents who were interviewed after the election expressed concern. For example, respondents in the summer of 2016 felt that “there is a lot of hope for access to be broadened,” and hoped that “the straggling health plans [would] get on board and increase access.” In contrast, a respondent in November 2016 foresaw “a worsening medical situation for people who can’t meet a covered group in Medicaid. A larger monetary burden on the Department of Health to help to cover people that either were terminated from Medicaid, couldn’t get coverage through their employer plan, had no insurance…” A health official in March 2017, referring to the federal proposals at the time, felt that the recent improvements made by their state in terms of treatment access might be at risk: “We are an expansion state. If that were to change, that would limit access to a lot of people where we just finally made a couple baby steps in getting people able to be treated.”

Individuals coinfected with HIV have additional mechanisms to facilitate HCV treatment

Although individuals coinfected with HIV are often more marginalized than HCV monoinfected individuals, they have better access to HCV treatment as a result of government programs for HIV care. Respondents also contrasted the strong political and advocacy movement surrounding HIV to the current HCV environment, where affected populations have limited political voice. Respondents noted that AIDS Drug Assistance Programs (ADAPs) can facilitate treatment access by providing direct medication coverage for HIV and related conditions, purchasing insurance for enrollees, and paying copays and coinsurance. Some ADAPs cover HCV treatment for coinfected individuals who are not eligible for Medicaid, as income requirements for enrolling in ADAP are generally more lenient than they are for Medicaid. In every state we studied, ADAP’s requirements for approval of HCV medications were minimal compared to requirements of Medicaid programs, though this may not be representative of all state ADAPs. As programs that primarily provide treatment coverage, ADAPs are generally “not able to cover…cost of lab testing and medical visits,” though some programs have launched initiatives to do so. While most states called ADAP a “payer of last resort,” allowing individuals to receive HCV therapy from ADAP if that therapy was denied through their primary insurance plan, one state program did provide “gap coverage on a drug by drug basis.” This variation can confuse providers and slow uptake: even in states where ADAPs covered HCV treatment, respondents indicated that providers were not always aware that ADAP programs could be used in this way. In addition to ADAP, existing HIV program infrastructure can provide additional services such as housing support, care coordination, and specially funded centers and health homes. These mechanisms can either promote HCV treatment access directly or fund innovative programs.

Discussion

We interviewed state and national experts to understand barriers to DAA uptake and promising policy strategies to improve access in public programs. Our findings show that state Medicaid programs imposed eligibility criteria for a DAA prescription, and our respondents felt that imposing these criteria was motivated by the cost of therapy. However, actual costs have been lower than anticipated due to access limitations, negotiated discount prices, and market competition. This, in addition to legal and political pressure to provide treatment, has motivated some payers to lighten eligibility criteria, although this trend is inconsistent among states and insurance plans. Despite a diverse selection of states, themes were largely similar between respondents. Where respondents noted distinct challenges were in states with a large rural population, and those in which political and financial commitment was felt to be lacking.

Studies of prior authorizations and denials for HCV DAA have found rates of denials up to 30% and long wait times before authorization decisions.[29,30] Treatment eligibility criteria, which have drawn criticism for being overly restrictive, are improving among fee-for-service Medicaid programs.[26] Findings from our study indicate that these changes are primarily related to lower-than-expected demand, increased market competition, and political and legal pressures. Our respondents also stressed the variability among managed care plans and the lack of transparency in their practices as significant barriers to understanding the coverage landscape.

Even in states where access is not strongly limited by insurance requirements, rural areas are impacted by provider supply. For instance, a 2012 study in Wisconsin showed that of 72 counties, 51 had no infectious diseases or gastroenterology providers.[31] This finding is especially relevant for HCV given the ongoing rural opioid epidemic. Efforts to address this include using telemedicine to augment patient access to specialty consultation, or tele-mentoring to provide specialist support to primary care providers.[32–34] Implementation of these efforts, however, requires a commitment to public health infrastructure, funding, and billing mechanisms to compensate telemedicine or tele-mentoring activities.

In our states, individuals co-infected with HIV/HCV have better access to DAA treatments than mono-infected individuals. While some have called for a response to HCV that mimics the Ryan White HIV/AIDS Program for HIV, this is unlikely to develop in the current political climate. Despite this, states can leverage a robust HIV treatment infrastructure to promote policies that focus on HCV treatment by utilizing existing links between public health officials and providers. For example, policy solutions designed to target HIV, such as mandatory testing laws, have inspired similar strategies for HCV.[35] Coordinated care delivery models that are effective in HIV can also be applied to patients with HCV, such as patient navigation to improve linkage to care, and integration of primary care providers to improve treatment capacity.[36]

Recent federal healthcare reform proposals, which would phase out the Medicaid expansion and restructure Medicaid funding by creating a block grant or setting per capita limits, threaten a significant decrease in Medicaid funding. Respondents in non-expansion states already noted the difficulty in providing treatment to populations ineligible for Medicaid coverage – it is likely that these populations would increase and lose access to healthcare, including HCV treatment. The impact of policy changes is likely to vary among states: those that are economically unable, or politically unwilling, to support improved access to high-cost drugs in the face of increased budgetary pressures may not continue to relax authorization criteria.

Our study has limitations. We selected geographically and politically diverse states to solicit a range of perspectives, but with a qualitative sampling design the findings should not be interpreted as the average response. We recruited individuals whose jobs were focused on treatment access. Further research with individuals responsible for allocating state resources may reveal different results. This work is subject to researcher bias, which we attempted to minimize by having two investigators independently code transcripts, a diverse research team, ongoing meetings to discuss the codebook and results, and participant validation of themes.

Eliminating the HCV epidemic and meeting goals in federal and state action plans will take a concerted effort from public health and healthcare infrastructure. While overcoming the price barrier is necessary, our findings show that it is not sufficient. Growing the provider workforce in high-need areas, addressing urban-rural disparities in access to care, and mitigating the effects of stigma will be important steps for DAA treatment scale-up. The committed, multi-level response to the HIV epidemic that has evolved over the past thirty years can serve as an example, but reforms that threaten Medicaid budgets and public health funding will pose significant challenges. While our study detailed many barriers, it was clear that the therapeutic innovations of the past few years have provided important opportunities to lessen the burden of HCV.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Implications for Policy and Practice

- To improve HCV care cascades and reduce the burden of disease, it is important for state Medicaid programs to continue to prioritize expanding access to guideline-concordant HCV treatment despite uncertainties in funding and the policy environment.
- To improve patients’ linkage to and engagement in HCV treatment, state and local health departments can educate and engage providers, patients, advocates, and other stakeholders to reduce HCV-related stigma and misconceptions about medication side effects and current coverage rules.
- To address persistent gaps in treatment capacity, especially in rural areas with limited access to specialist care, state and local health departments could systematically assess variation in treatment capacity in areas of high HCV prevalence and adopt strategies such as telementoring to improve the supply of HCV treating providers where needed.

Table 1

Characteristics of selected states and study participants' professional roles

States Included in Study	Number of interviews
State 1: Northeast region, Medicaid expansion, no severity criteria, no substance use criteria	2
State 2: West region, Medicaid expansion, lenient severity criteria, no substance use criteria	2
State 3: South region, no Medicaid expansion, lenient severity criteria, no substance use criteria	3
State 4: South region, no Medicaid expansion, no severity criteria, need for documented substance use abstinence.	1
State 5: Northeast region, Medicaid expansion, no severity criteria, no substance use criteria	3
State 6: Midwest region, Medicaid expansion, strict severity criteria, need for documented substance use abstinence	3
Professional Role of Key informants	
State health official – Division of Viral Hepatitis	5
State health official – Division of AIDS	5
State health official – Division of Infectious/Communicable Disease	2
State health official – Medicaid office	1
Advocacy or professional organization member	3

Sources: Severity criteria from National Viral Hepatitis Roundtable 2016,[19] Medicaid expansion status from Kaiser Family Foundation website[29]

Notes: Severity criteria are categorized as follows: strict criteria require a diagnosis of cirrhosis (a score of F3 or F4 on the Metavir fibrosis scoring system), representing a diagnosis of cirrhosis, whereas lenient criteria offer treatment at lower METAVIR scores.

Table 2

Summary of themes and representative quotes

Theme	Key Points	Representative Quote
Treatment cost	• Anticipation of high costs inspired access restrictions from Medicaid • Lack of transparency about drug pricing • Impact of cost has been less severe than feared	"If everyone had presented for care simultaneously and we had paid full price for those drugs, it would have broken the bank for Medicaid and even strained the ability of our HIV drug assistance program to keep up… neither one of those was a reality."
Medicaid managed care plans	• Medicaid managed care plans have variable access restrictions even within a state • Complex prior authorization requirements discourage providers from offering treatment	"The policy gets operationalized by…managed care plans…and they each operationalize the policy in their own way. Some…err on the side of approval and some err on the side of being very conservative and denying many requests."
Stigma, patient engagement and provider availability	• Stigma around hepatitis C and substance use prevents providers from offering treatment • Lack of urgency because of long asymptomatic period • Shortage of treating providers, especially in rural areas	"There are a lot of providers out there that don't want to screen for hep-C because they think they're going to bring in this flood of people who are drug users, and they don't want to take care of those individuals."
Political and fiscal environment	• Political motivation to support access varies across states • Media, advocacy, and judicial rulings promote political support for access • Potential repeal of the Affordable Care Act will significantly hinder treatment access	"We are an expansion state. If that were to change, that would limit access to a lot of people where we just finally made a couple baby steps in getting people able to be treated."
HIV/HCV coinfection	• Improved access to treatment because of AIDS Drug Assistance Programs • Program infrastructure to support vulnerable populations	"The HIV epidemic was changing and needs were changing, but there was an incredible infrastructure here. Why don't we start using that for hepatitis?"

Sources: Authors' analysis of interview data