

Health Affairs

At the Intersection of Health, Health Care and Policy

Cite this article as:

Adam L. Beckman, Alyssa Bilinski, Ryan Boyko, George M. Camp, A. T. Wall,
Joseph K. Lim, Emily A. Wang, R. Douglas Bruce and Gregg S. Gonsalves
New Hepatitis C Drugs Are Very Costly And Unavailable To Many State
Prisoners

Health Affairs 35, no.10 (2016):1893-1901
doi: 10.1377/hlthaff.2016.0296

The online version of this article, along with updated information and services, is
available at:

<http://content.healthaffairs.org/content/35/10/1893>

**For Reprints, Links &
Permissions :**

http://content.healthaffairs.org/1340_reprints.php

Email Alertings : <http://content.healthaffairs.org/subscriptions/etoc.dtl>

To Subscribe : <https://fulfillment.healthaffairs.org>

Health Affairs is published monthly by Project HOPE at 7500 Old Georgetown Road, Suite 600, Bethesda, MD 20814-6133. Copyright © by Project HOPE - The People-to-People Health Foundation. As provided by United States copyright law (Title 17, U.S. Code), no part of may be reproduced, displayed, or transmitted in any form or by any means, electronic or mechanical, including photocopying or by information storage or retrieval systems, without prior written permission from the Publisher. All rights reserved.

Not for commercial use or unauthorized distribution

By Adam L. Beckman, Alyssa Bilinski, Ryan Boyko, George M. Camp, A. T. Wall, Joseph K. Lim, Emily A. Wang, R. Douglas Bruce, and Gregg S. Gonsalves

DOI: 10.1377/hlthaff.2016.0296
HEALTH AFFAIRS 35,
NO. 10 (2016): 1893–1901
©2016 Project HOPE—
The People-to-People Health
Foundation, Inc.

New Hepatitis C Drugs Are Very Costly And Unavailable To Many State Prisoners

ABSTRACT Prisoners bear much of the burden of the hepatitis C epidemic in the United States. Yet little is known about the scope and cost of treating hepatitis C in state prisons—particularly since the release of direct-acting antiviral medications. In the forty-one states whose departments of corrections reported data, 106,266 inmates (10 percent of their prisoners) were known to have hepatitis C on or about January 1, 2015. Only 949 (0.89 percent) of those inmates were being treated. Prices for a twelve-week course of direct-acting antivirals such as sofosbuvir and the combination drug ledipasvir/sofosbuvir varied widely as of September 30, 2015 (\$43,418–\$84,000 and \$44,421–\$94,500, respectively). Numerous corrections departments received smaller discounts than other government agencies did. To reduce the hepatitis C epidemic, state governments should increase funding for treating infected inmates. State departments of corrections should consider collaborating with other government agencies to negotiate discounts with pharmaceutical companies and with qualified health care facilities to provide medications through the federal 340B Drug Discount Program. Helping inmates transition to providers in the community upon release can enhance the gains achieved by treating hepatitis C in prison.

Hepatitis C is the most common bloodborne viral infection in the United States.^{1–3} It was a cause of more deaths in 2013 than sixty other infectious diseases combined, including HIV, pneumococcal disease, and tuberculosis.⁴ While the prevalence of hepatitis C in the noninstitutionalized US population is approximately 1 percent, the prevalence among prison inmates is about 17 percent.^{1,5,6} Nearly one-third of all Americans with hepatitis C spend at least part of the year in a correctional facility.⁵

Since hepatitis C is primarily spread through drug injection and infrequently through sexual intercourse, and since 20–55 percent of inmates have injected drugs, treating prisoners infected with hepatitis C can prevent transmission of

the virus.^{6–9} Consequently, providing hepatitis C treatment for inmates presents a unique public health opportunity to reduce the nationwide epidemic.^{6,10,11} Moreover, the US Supreme Court ruled in *Estelle v. Gamble*¹² that prison officials cannot be deliberately indifferent to the known medical needs of inmates and must provide adequate medical care.¹³ Historically, many prisoners with hepatitis C have not received treatment, despite a high rate of infection in the inmate population.^{14–16} However, no studies in the past fifteen years have shown the number and distribution of inmates in each state prison system who receive treatment.

New direct-acting antiviral oral treatments for hepatitis C, including sofosbuvir (Sovaldi) and the combination drugs ledipasvir/sofosbuvir (Harvoni) and sofosbuvir/velbatasvir (Epclusa),

Adam L. Beckman was an undergraduate at Yale College and research assistant at the Yale Global Health Justice Partnership, both in New Haven, Connecticut, when completing this work.

Alyssa Bilinski is a PhD candidate in health policy in the Harvard Graduate School of Arts and Sciences, in Cambridge, Massachusetts.

Ryan Boyko is a PhD candidate in the Department of Epidemiology of Microbial Diseases at the Yale School of Public Health, in New Haven, and a fellow at the Yale Global Health Justice Partnership.

George M. Camp is co-executive director of the Association of State Correctional Administrators, in Hagerstown, Maryland.

A. T. Wall is director of the Rhode Island Department of Corrections, in Cranston.

Joseph K. Lim is an associate professor of digestive diseases and director of the Yale Viral Hepatitis Program, Yale University School of Medicine, in New Haven.

Emily A. Wang is an associate professor of general medicine at Yale University School of Medicine.

R. Douglas Bruce is an associate clinical professor of medicine at Yale University School of Medicine and chief of medicine of the Cornell Scott-Hill Health Center, in New Haven.

Gregg S. Gonsalves (gregg.gonsalves@yale.edu) is codirector of the Yale Global Health Justice Partnership, a research scholar in law and lecturer in law at Yale Law School, and a PhD candidate in the Department of Epidemiology of Microbial Diseases at Yale School of Public Health.

recently entered the market.^{17–20} Compared with the former standard of care—pegylated interferon alpha and ribavirin administered for six to twelve months—direct-acting antivirals are much more effective. They have a cure rate of more than 90 percent, have almost no side effects, are oral regimens instead of injections, and shorten treatment duration to two to six months.²¹ The increased simplicity, efficacy, and tolerability of direct-acting antivirals improves the feasibility of implementing hepatitis C treatment in the prison setting.

Prison officials understand the desirability of using these treatments. The Federal Bureau of Prisons' Clinical Practice Guidelines, which were adopted in April 2016 by the federal prison system, recommend the use of direct-acting antivirals for treating hepatitis C in many instances.²² However, the high price of direct-acting antivirals such as sofosbuvir and ledipasvir/sofosbuvir (US retail prices in 2015 for a twelve-week course were \$84,000 and \$94,500, respectively) is a major barrier to implementation of hepatitis C treatment within state prison systems.^{23,24}

Recent studies have demonstrated that treating hepatitis C in state prisons is both feasible and cost-effective.^{6,21,25} However, data on contemporary hepatitis C treatment rates and the purchasing of direct-acting antiviral regimens in state prison systems are lacking.

We administered a survey to the directors of the departments of corrections in all fifty states, inquiring about current hepatitis C care practices in state correctional facilities. Findings from this study can inform efforts to increase treatment opportunities for incarcerated patients with hepatitis C and prevent further transmission of the infection within prisons and upon individuals' release.

Study Data And Methods

DESIGN AND SAMPLE In February 2015 we sent an introductory e-mail message to the commissioners of the fifty state departments of corrections describing the study and including a link to module 1 of the online survey questionnaire. In October 2015 participants were given an opportunity to review their responses to ensure accuracy and were invited to participate in module 2. At this stage, nonrespondents to the introductory message were invited again to participate in module 1 and asked to participate in module 2 as well.

Both modules of the questionnaire can be found in the online Appendix.²⁶ No incentives were offered for participation in the survey.

DATA COLLECTION AND MEASUREMENTS Mod-

ule 1 was the primary survey module. It included questions about the number of inmates in a state's prisons known to be infected with hepatitis C (including both acute and chronic hepatitis C) on or about January 1, 2015,²⁷ the number of prisoners receiving any form of hepatitis C treatment (including both new direct-acting antiviral regimens and older interferon-based regimens) at that time, the availability of relevant resources for inmates with known hepatitis C, the annual amount of prison spending on hepatitis C treatment, and efforts being undertaken by the prisons to acquire sofosbuvir and ledipasvir/sofosbuvir regimens.

Module 2 focused on the price of direct-acting antivirals. It asked how much money the state's prisons were paying as of September 30, 2015, for a twelve-week course of sofosbuvir and for a twelve-week course of ledipasvir/sofosbuvir. Respondents were also asked what arrangement was being used to acquire the medicines at the price they paid.

In addition, we used publicly available data from the Bureau of Justice Statistics on inmates in state prisons on December 31, 2014, to describe the approximate population of inmates in each state facility.²⁸

DATA ANALYSIS We summarized responses to the survey items using frequencies, means, and medians. All analyses were conducted using the statistical software R, version 3.1.2, or Microsoft Excel, version 14.4.9.

ETHICS APPROVAL The Human Investigation Committee at Yale University determined that the study did not meet criteria for approval as human subjects research and was therefore exempted from review.

LIMITATIONS This study had several limitations. First, the design was cross-sectional and did not capture how treatment access, drug prices, and available medical resources might have changed over time. Nonetheless, we provide important information about hepatitis C-related medical care for a vulnerable population that is challenging to study.

Second, estimates of inmates known to be infected with hepatitis C were provided by state departments of corrections and were therefore limited by the departments' access to information about hepatitis C in the states' prison systems, different hepatitis C screening practices across states, and the frequency with which hepatitis C registries were updated. For example, we report that overall 10 percent of prisoners were known to be infected with hepatitis C on or about January 1, 2015. However, a recent study estimated the 2006 prevalence of hepatitis C in US prisons at 17.4 percent, by extrapolating from seroprevalence data provided by state correctional

systems with routine hepatitis C testing.⁵

Our data do not represent an estimate of hepatitis C prevalence in state prisons, since states that do not routinely test inmates for hepatitis C may be unaware of hepatitis C infections. Instead, we captured the number of inmates known by state departments of corrections to be infected, and we thereby provide a perspective on the surveillance data used by those departments to guide hepatitis C practices.

Third, our estimate of the proportion of inmates with known hepatitis C who were receiving treatment had limitations. Since the prevalence of hepatitis C is likely greater than the prevalence of prisoners known to be infected, the proportion of inmates with hepatitis C (diagnosed and undiagnosed) receiving treatment is probably even lower than what we report. Also, the proportion of inmates with hepatitis C being treated did not include inmates who might have received treatment previously, were clinically ineligible for treatment, or might have spontaneously cleared the infection (which occurs in 15–25 percent of hepatitis C cases).²⁹

Future research is needed to characterize the proportion of inmates with hepatitis C involved in the entire treatment cascade. Nonetheless, our study provides previously unavailable information at the state level about access to hepatitis C therapies among patients in the prison setting.

Study Results

RESPONDENTS AND RESOURCES RELATED TO HEPATITIS C Representatives from forty-nine of the fifty state departments of corrections completed module 1 of our Hepatitis C and State Prisons Survey. Collectively, these departments reported having 1,348,716 inmates incarcerated as of December 31, 2014 (99.8 percent of the total US state prison population) (data not shown).

Departments of corrections in forty-one states (84 percent) reported data on hepatitis C infections and treatment (Exhibit 1). Seventeen states reported offering routine opt-out hepatitis C testing (in this testing, inmates receive the test as a matter of routine unless they opt to be excluded). Medication-assisted treatment programs for substance use disorders were available through fourteen state departments of corrections.

Ten states used only internal medicine or family practice physicians to provide treatment to prisoners with hepatitis C (Exhibit 1), but the other thirty-nine states reported that physicians with specialty training (for example, in gastroenterology, liver disease, infectious disease, or addiction medicine) were treating patients known to have hepatitis C.

Eighteen of the states participating in the Medicaid eligibility expansion under the Affordable Care Act (ACA) were enrolling prisoners in Medicaid before their release, the point at which their eligibility would begin (data not shown). That practice could help inmates transition to using health care resources in the community.

PRISONERS INFECTED WITH HEPATITIS C

► **REPORTED CASES OF HEPATITIS C:** In the forty-one states with corrections departments that reported data on hepatitis C infection and treatment, the proportion of inmates who were reported to be infected with the virus on or about January 1, 2015, ranged from 1 percent in North Carolina to 41 percent in New Mexico, with a

EXHIBIT 1

Characteristics of state prison systems and hepatitis C-related medical care for inmates

	State prison systems	
	Number	Percent
REGION		
Northeast	10	20
Midwest	12	24
South	14	29
West	13	27
INMATE POPULATION		
0–4,999	7	14
5,000–19,999	18	37
20,000–49,999	17	35
50,000 or more	7	14
COLLECTED AND REPORTED DATA ON HEPATITIS C INFECTIONS AND TREATMENT		
Yes	41	84
No	8	16
HAD ROUTINE OPT-OUT HEPATITIS C TESTING		
Yes	17	35
No	32	65
HAD SPECIALISTS FOR HEPATITIS C CARE		
Yes	39	80
No	10	20
HAD MEDICATION-ASSISTED TREATMENT PROGRAMS FOR SUBSTANCE USE DISORDERS		
Yes	14	29
No	35	71
YEARLY SPENDING ON HEPATITIS C TREATMENT		
Less than \$1 million	15	31
\$1–\$4.9 million	26	53
More than \$5 million	5	10
Not reported	3	6
PERCENT OF OVERALL DRUG SPENDING USED FOR HEPATITIS C DRUGS EACH YEAR		
Less than 10	27	55
10–19.9	7	14
20 or more	8	16
Not reported	7	14

SOURCE Authors' analysis of data for 2015 from the Hepatitis C and State Prisons Survey, module 1, and the Bureau of Justice Statistics. **NOTES** One of the fifty state departments of corrections did not respond to module 1 of the survey. Numbers of inmates incarcerated are as of December 31, 2014. Percentages may not sum to 100 because of rounding. "Specialists" are physicians in fields other than internal medicine or family practice.

median of 10 percent (interquartile range [IQR]: 8–13) (for a map of the United States that shows the reported proportion of hepatitis C–positive prisoners in state prisons, see the Appendix).²⁶ This overall proportion corresponded to a total of 106,266 prisoners (10 percent) in the forty-one states that reported data on hepatitis C infection and treatment.

► **PRISONERS RECEIVING TREATMENT:** Among the forty-one states that reported data on inmates known to have hepatitis C and their treatment, 949 inmates (0.89 percent of the 106,266 inmates with known hepatitis C) were receiving any form of treatment for the virus on or about January 1, 2015 (data not shown). Demographic data were reported for 800 of these 949 inmates. Of the 800 inmates, 658 (82 percent) were male, 455 (57 percent) were ages 41–60, 297 (37 percent) were white, and 192 (24 percent) were African American.

At the state level, the median proportion of prisoners with known hepatitis C being treated at this time was 0.45 percent (IQR: 0.12–1.48). This proportion varied across the forty-one states, ranging from 0.0 percent in Oklahoma,

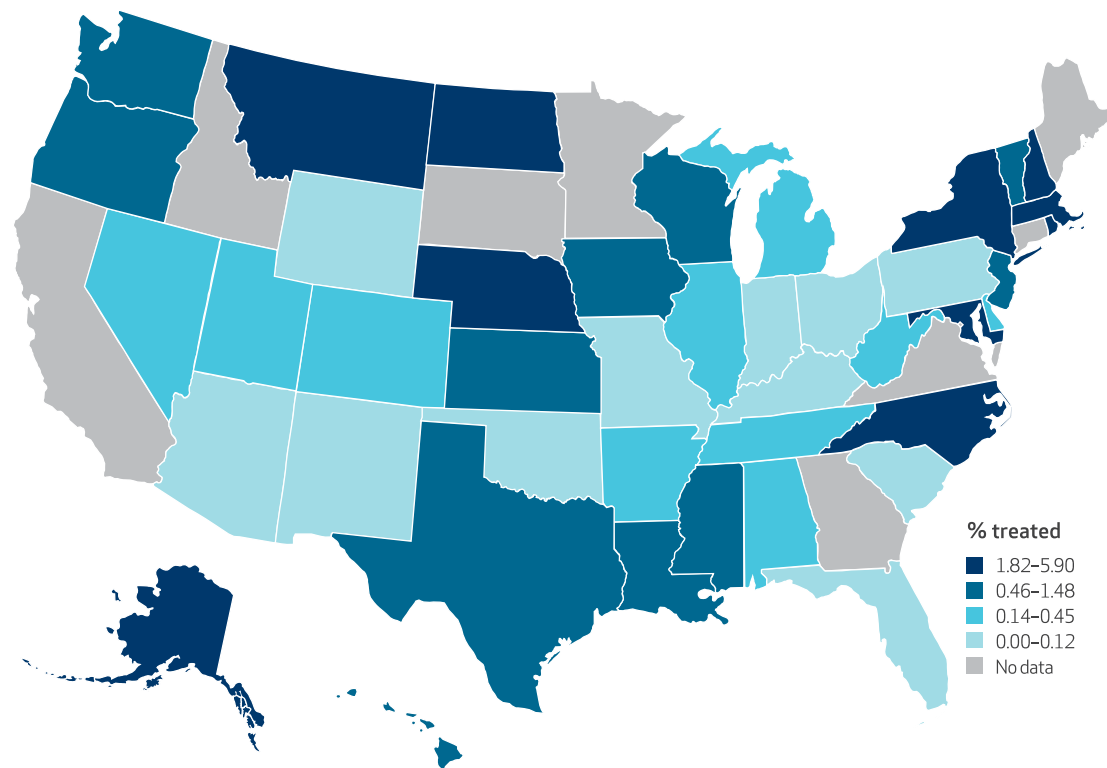
Pennsylvania, South Carolina, and Wyoming to 5.9 percent in New York (Exhibit 2) (for a list of proportions by states, see the Appendix).²⁶ Twenty-seven of the states (66 percent) were treating fewer than 1 percent of prisoners known to have hepatitis C.

States with a relatively high proportion of inmates reported to have hepatitis C did not necessarily treat a greater number of patients than states with a relatively low proportion of inmates with known infections (for a side-by-side comparison of the proportions of inmates with hepatitis C and inmates with hepatitis C who were receiving treatment, see the Appendix).²⁶ None of these figures accounted for inmates with known hepatitis C who might have completed treatment before January 1, 2015, or been otherwise ineligible for treatment.

► **REPORTED SPENDING ON TREATMENT:** At least \$39.8 million was spent yearly on hepatitis C treatment by the forty-one departments of corrections that reported data on spending (for an explanation of how this amount was calculated, see the Appendix).²⁶ Departments reported spending a median of 6 percent (IQR: 3.0–16.5)

EXHIBIT 2

US state prisoners receiving any treatment for hepatitis C as a proportion of inmates with known hepatitis C infections, January 1, 2015



SOURCE Authors' analysis of data for 2015 from the Hepatitis C and State Prisons Survey, module 1. **NOTES** "Treated" means receiving any hepatitis C treatment on or about January 1, 2015. "No data" means that the state did not participate in the survey or had missing data.

Further expansion of hepatitis C testing, particularly for inmates with HIV or substance use disorders, is necessary.

of their annual drug spending on hepatitis C drugs. Sixteen states devoted 10 percent or more of their drug spending to hepatitis C drugs, and eight states devoted 20 percent or more (Exhibit 1).

► **PROTOCOLS FOR TRIAGING TESTING AND TREATMENT:** States varied in their reported hepatitis C testing protocols. For the thirty-two states without routine opt-out hepatitis C testing (Exhibit 1), the main indications for being tested included having abnormal results from other tests (twenty-nine states; data not shown), HIV (twenty-seven states), or a substance use disorder (sixteen states).

States used a variety of factors to prioritize hepatitis C treatment for inmates who tested positive for the virus. In terms of clinical criteria, forty-one states reported that patients with cirrhosis were prioritized for receiving hepatitis C treatment (for a bar graph of criteria used to triage which inmates received hepatitis C treatment, see the Appendix).²⁶ Twenty-three states reported prioritizing treatment for patients with chronic hepatitis C. In terms of nonclinical criteria, forty-four states considered the length of a patient's remaining prison sentence in triaging patients for hepatitis C treatment. Five states reported taking into account a patient's likelihood of recidivism, and twelve states said they considered a patient's chance of reinfection (for example, by engaging in risky behaviors). (The survey did not ask whether longer sentences, a higher likelihood of recidivism, or a greater chance of reinfection led to a higher or lower priority for treatment.)

States could also indicate that they used "other" criteria to prioritize treatment for prisoners; those states were asked to explain what the criteria were. Five states noted weighing a prisoner's compliance with treatment for drug use, alcohol abuse, or both. Three states considered

prisoners' mental health conditions. In addition, ten states noted triaging based on the aspartate aminotransferase to platelet ratio index (APRI), a tool for assessing the severity of liver scarring, and four states reported that they followed all of the Federal Bureau of Prisons guidelines.²²

REDUCED PRICES FOR MEDICATIONS At the time that the departments of corrections were completing module 1 of the survey, forty-four (90 percent) states were taking steps to acquire the direct-acting antivirals sofosbuvir and ledipasvir/sofosbuvir at a price lower than the US list price (data not shown). The strategy most frequently used (by twenty-nine states; 66 percent) in an attempt to acquire sofosbuvir at a lower price was direct negotiations with pharmaceutical companies. California, Maryland, Texas, and Wisconsin were the only four states to report having already signed a contract with Gilead Sciences Inc. to obtain sofosbuvir, but eight states (18 percent) were seeking such a contract.

Sixteen states pursuing a reduced price for sofosbuvir (36 percent) were pursuing discounts through the federal 340B Drug Discount Program, a program created under the Veterans Health Care Act of 1992 that offers discounted drug prices to eligible health care organizations with sizable low-income, vulnerable patient populations. Thirteen states (30 percent) indicated that they were addressing the prices of sofosbuvir through pooled procurement (for example, collaborating with other state correctional systems or organizations to purchase the medication in a greater quantity than a single organization would purchase alone and thus to get a reduced price).

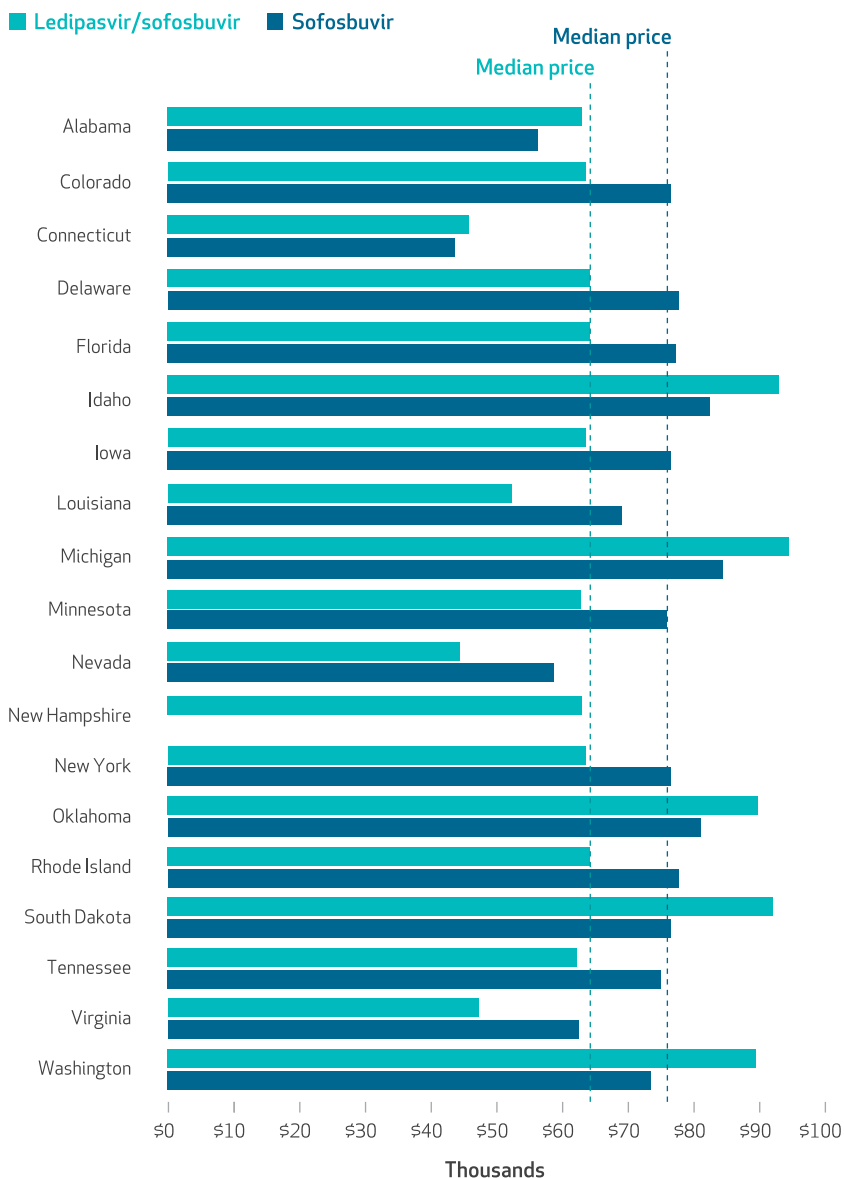
States could also indicate that they were trying "other" approaches; those states were asked to explain what approach they were using. Five states (9 percent) reported that they were addressing the price of sofosbuvir through discounts from the Minnesota Multistate Contracting Alliance for Pharmacy, a purchasing organization for government agencies that provide health care services.

PRICE OF PURCHASING MEDICATIONS Thirty-one (63 percent) of the forty-nine states that responded to module 1 of the survey also responded to module 2. As of September 30, 2015, all thirty-one states were either seeking to acquire or had purchased sofosbuvir, ledipasvir/sofosbuvir, or both. The states that provided financial data were paying a median of \$76,084.50 for a twelve-week course of sofosbuvir and \$63,509.00 for a twelve-week course of ledipasvir/sofosbuvir (Exhibit 3).

For sofosbuvir, the lowest price was \$43,418, in Connecticut, and the highest was \$84,000, in Michigan. As of September 30, 2015, two of the

EXHIBIT 3

State prison systems' cost of purchasing a twelve-week course of sofosbuvir and a twelve-week course of the combination drug ledipasvir/sofosbuvir, September 30, 2015



SOURCE Authors' analysis of data for 2015 from the Hepatitis C and State Prisons Survey, module 2.
NOTES The median prices were those paid by the state prison systems that provided data (eighteen for sofosbuvir and nineteen for ledipasvir/sofosbuvir). In the United States in 2015, the retail cost of a twelve-week course of sofosbuvir (Sovaldi) was \$84,000 (median price: \$76,085) while the cost of a twelve-week course of ledipasvir/sofosbuvir (Harvoni) was \$94,500 (median price: \$63,509).

three states paying the lowest price (Connecticut and Nevada) were pursuing discounts through the 340B Drug Discount Program, and the third (Alabama) was using direct negotiations with Gilead. The three states paying the highest price were using direct negotiations (Oklahoma) or no strategy (Idaho and Michigan).

For ledipasvir/sofosbuvir, the lowest price was \$44,421, in Nevada, and the highest was \$94,500, in Michigan (Exhibit 3). The three

states paying the lowest price (Nevada, Connecticut, and Virginia) were pursuing discounts through the 340B Drug Discount Program. The three states paying the highest price (South Dakota, Idaho, and Michigan) were not using any strategy.

Discussion

We found that only 0.89 percent of the 106,266 inmates known to have hepatitis C in states with departments of corrections that provided the relevant data in our survey were receiving any form of treatment on or about January 1, 2015. This finding comes despite evidence that treating hepatitis C in the prison setting is cost-effective and may be critical for ameliorating the national hepatitis C epidemic.^{10,21,25} Increasing the financial resources for prison health care and reducing the prices for direct-acting antivirals may be necessary to make it feasible to expand hepatitis C treatment in state correctional systems.

To our knowledge, this study is the first in fifteen years in the peer-reviewed literature to document the number of prison inmates receiving hepatitis C treatment, and the only one to do so since the release of direct-acting antivirals. Though limited, previous reports about hepatitis C treatment in state prisons suggest that treatment has not been provided to many inmates with the virus.¹⁴⁻¹⁶ Most recently, a monograph from the Coalition of Correctional Health Authorities and the American Correctional Association reported that 56 percent of surveyed correctional systems treat fewer than twenty inmates with known hepatitis C on average per year,¹⁶ which is consistent with our observation that few inmates with known hepatitis C receive treatment. Our study expands on previous work by making recent treatment data available at the state level. That information is critical for meeting best-practice standards and guiding policies set by state departments of corrections.¹⁴

THE PRICE OF DIRECT-ACTING ANTIVIRALS We also found that numerous state departments of corrections were receiving smaller discounts on the prices for sofosbuvir and ledipasvir/sofosbuvir than other state and national agencies. Though information about pricing discounts is often confidential, the US Senate Committee on Finance's 2015 report on the pricing of sofosbuvir and ledipasvir/sofosbuvir noted that the Federal Bureau of Prisons, Department of Defense, and Department of Veterans Affairs receive at least a 24 percent discount on these drugs and that Medicaid receives at least a 23 percent discount.³⁰ Moreover, recent reports indicate that the Department of Veterans Affairs and

Downloaded from <http://content.healthaffairs.org/> by Health Affairs on October 5, 2016 by HW Team

Many departments are forced to make difficult decisions about triaging patients, leaving many inmates without any treatment.

Medicaid programs that accepted the conditions of offered rebates may receive more than a 50 percent discount.³¹ In contrast, ten of eighteen state departments of corrections received less than a 10 percent discount on sofosbuvir as of September 30, 2015, with Michigan paying the full \$84,000 list price, and five of nineteen states received less than a 10 percent discount on ledipasvir/sofosbuvir.

While other researchers have pointed to a lack of transparency related to the pricing of direct-acting antivirals as a major problem,³² we are the first to report the prices paid by some state departments of corrections and to highlight the gaps in knowledge or capacity among states on how to obtain lower prices. Moreover, we found that eight of the departments of corrections in this study were spending 20 percent or more of their pharmacy budget on hepatitis C treatments. Therefore, without increased discounts or funding, price may remain a barrier to expanding the use of direct-acting antivirals in state correctional facilities.

Our findings also reveal that at the time of our study, only a few states were using some price reduction strategies. Other state departments of corrections might secure lower prices by adopting some of these strategies. For instance, pooled procurement by state correctional systems could lead to greater purchasing power, which could drive down the price of direct-acting antiviral medications. State departments of corrections might benefit from working with county or other state agencies, such as the Medicaid program, to receive lower prices. Thirteen of the forty-nine states that responded to our survey reported being involved in pooled procurement.

The federal 340B Drug Discount Program may offer another vehicle for securing discounts (usually 20–50 percent) on drugs.³³ Although state prisons do not qualify for the program,

institutions that are eligible for it, such as federally qualified health centers, can partner with prisons and provide health care services to incarcerated people—and in such cases, the incarcerated people can be considered patients of the entity eligible for the program. Sixteen of the departments of corrections in our sample reported pursuing discounts through the 340B program, and this mechanism was used by three of the four departments paying the lowest prices for sofosbuvir and all four of the departments paying the lowest prices for ledipasvir/sofosbuvir.

Finally, since many inmates will eventually be released into society, after which the federal government may bear a substantial proportion of the costs of untreated hepatitis C, a coordinated federal initiative to treat people with hepatitis C—including in the correctional setting—might be appropriate. Future research should investigate which strategies are most effective for achieving the largest discounts for and the greatest access to expensive hepatitis C medications.

TRENDS IN HEPATITIS C CARE IN STATE PRISONS

Our results also document several important trends in hepatitis C care that are occurring in some state prison systems. First, forty-one state departments of corrections (84 percent) reported data on hepatitis C cases and the number of inmates receiving treatment for hepatitis C. Collecting and reporting such up-to-date data are critical to monitoring the epidemic and designing appropriate responses.

Second, seventeen departments (35 percent) reported offering routine opt-out hepatitis C testing, which is more than the eleven state prison systems that reported using any form of routine testing in a 2012 survey.³⁴ The difference may mean that this practice has become increasingly widespread in recent years. However, further expansion of hepatitis C testing, particularly for inmates with HIV or substance use disorders, is necessary.

Third, fourteen state departments of corrections have medication-assisted treatment programs for substance use disorders. These programs may help reduce the chance that inmates who receive treatment for hepatitis C will become reinfected through future drug injection while incarcerated or after release.

Fourth, the vast majority of states reported that physicians with specialty training (for example, in gastroenterology, liver disease, infectious disease, or addiction medicine) were treating patients known to have hepatitis C; only 20 percent of the states did not report that hepatitis C treatment was provided by specialist physicians. Training both specialist and nonspecialist physicians in hepatitis C treatment within prison

systems is essential to ensuring that appropriate care is provided to inmates.

Fifth, among states participating in the ACA's expansion of eligibility for Medicaid, eighteen were enrolling prisoners in Medicaid before their release—when their eligibility would begin. Correctional systems that clinically evaluate inmates for hepatitis C treatment before discharge and help them enroll in Medicaid may effectively connect them to treatment after their release. State Medicaid programs have been restricting access to direct-acting antivirals, but some programs have recently announced that beneficiaries with hepatitis C will be eligible for the medications.^{35,36}

For inmates receiving hepatitis C treatment in prison, transitioning care from prison to the community upon release is critical to ensuring that health gains achieved in treatment are not lost. To accomplish this goal, the statute forbidding Medicaid involvement in the care of inmates may need to be reconsidered. A reasonable alternative would be to allow Medicaid to pay for high-priority public health treatments such as hepatitis C medications.

Finally, most state corrections departments in our survey reported prioritizing hepatitis C

treatment for patients with cirrhosis and certain comorbid conditions, as recommended by the Federal Bureau of Prisons' Clinical Practice Guidelines.²² Future research into the concordance between state prison practices and such guidelines is essential, as guidelines are regularly updated with changes in treatments for hepatitis C.

Conclusion

Given the high burden of hepatitis C within correctional environments, greater access to hepatitis C treatments would cure many of the individuals at the highest risk of spreading hepatitis C infection.⁹ However, the substantial price of treatment prevents many state corrections departments from purchasing the quantities of medications necessary to treat all of those in need. As a result, many departments are forced to make difficult decisions about triaging patients, leaving many inmates without any treatment. Efforts at the state and federal levels, such as increasing targeted funding and pursuing greater drug discounts, could make hepatitis C treatment more readily available for those who require it in state correctional facilities. ■

The authors appreciate feedback from Elizabeth Bradley, Yale School of Public Health; Alice Miller, Yale Law School and Yale School of Public Health; Judith Resnik, Yale Law School; and Christine

Ricardo, Yale Law School. The authors thank the commissioners of state departments of corrections for their time and efforts; Brittany Brothers, of the Association of State Correctional

Administrators, for her assistance in administering the survey; and the Arthur Liman Public Interest Program at Yale Law School and the Association of State Correctional Administrators.

NOTES

- Denniston MM, Jiles RB, Drobeniuc J, Klevens RM, Ward JW, McQuillan GM, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med.* 2014;160(5):293-300.
- Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med.* 2006;144(10):705-14.
- Centers for Disease Control and Prevention. Surveillance for viral hepatitis—United States, 2011 [Internet]. Atlanta (GA): CDC; [last updated 2015 May 20; cited 2016 Aug 9]. Available from: <http://www.cdc.gov/hepatitis/statistics/2011surveillance/commentary.htm>
- Ly KN, Hughes EM, Jiles RB, Holmberg SD. Rising mortality associated with hepatitis C virus in the United States, 2003-2013. *Clin Infect Dis.* 2016;62(10):1287-8.
- Varan AK, Mercer DW, Stein MS, Spaulding AC. Hepatitis C seroprevalence among prison inmates since 2001: still high but declining. *Public Health Rep.* 2014;129(2):187-95.
- He T, Li K, Roberts MS, Spaulding AC, Ayer T, Grefenstette JJ, et al. Prevention of hepatitis C by screening and treatment in U.S. prisons. *Ann Intern Med.* 2016;164(2):84-92
- Harrison PM, Beck AJ. Prisoners in 2002 [Internet]. Washington (DC): Bureau of Justice Statistics; [revised 2003 Aug 27; cited 2016 Aug 9]. (Bulletin No. NCJ 200248). Available from: <http://www.bjs.gov/content/pub/pdf/p02.pdf>
- Spaulding AC, Weinbaum CM, Lau DT-Y, Sterling R, Seeff LB, Margolis HS, et al. A framework for management of hepatitis C in prisons. *Ann Intern Med.* 2006;144(10):762-9.
- Martin NK, Vickerman P, Grebely J, Hellard M, Hutchinson SJ, Lima VD, et al. Hepatitis C virus treatment for prevention among people who inject drugs: modeling treatment scale-up in the age of direct-acting antivirals. *Hepatology.* 2013;58(5):1598-609.
- Rich JD, Allen SA, Williams BA. Responding to hepatitis C through the criminal justice system. *N Engl J Med.* 2014;370(20):1871-4.
- Rich JD, Allen SA, Williams BA. The need for higher standards in correctional healthcare to improve public health. *J Gen Intern Med.* 2015;30(4):503-7.
- Estelle v. Gamble*, 429 U.S. 97 (1976).
- Spaulding AS, Kim AY, Harzke AJ, Sullivan JC, Linas BP, Brewer A, et al. Impact of new therapeutics for hepatitis C virus infection in incarcerated populations. *Top Antivir Med.* 2013;21(1):27-35.
- Beck AJ, Maruschak LM. Hepatitis testing and treatment in state prisons [Internet]. Washington (DC): Bureau of Justice Statistics; 2004 Apr [cited 2016 Aug 9]. (Special Report No. NCJ 199173C). Available from: <http://www.bjs.gov/content/pub/pdf/htsp.pdf>
- Spaulding A, Greene C, Davidson K, Schneidermann M, Rich J. Hepatitis C in state correctional facilities. *Prev Med.* 1999;28(1):92-100.
- Coalition of Correctional Health Authorities, American Correctional Association. Hepatitis C in correctional settings: challenges and op-

- portunities [Internet]. Alexandria (VA): ACA; 2015 Apr [cited 2016 Aug 9]. Available from: http://www.aca.org/ACA_PROD_IMIS/Docs/OCHC/HCVinCorrectionalSetting_Final.pdf
- 17 Liang TJ, Ghany MG. Current and future therapies for hepatitis C virus infection. *N Engl J Med*. 2013; 368(20):1907-17.
 - 18 Lawitz E, Mangia A, Wyles D, Rodriguez-Torres M, Hassanein T, Gordon SC, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med*. 2013;368(20):1878-87.
 - 19 Lawitz E, Poordad FF, Pang PS, Hyland RH, Ding X, Mo H, et al. Sofosbuvir and ledipasvir fixed-dose combination with and without ribavirin in treatment-naïve and previously treated patients with genotype 1 hepatitis C virus infection (LONESTAR): an open-label, randomised, phase 2 trial. *Lancet*. 2014; 383(9916):515-23.
 - 20 Feld JJ, Jacobson IM, Hézode C, Asselah T, Ruane PJ, Gruener N, et al. Sofosbuvir and velpatasvir for HCV genotype 1, 2, 4, 5, and 6 infection. *N Engl J Med*. 2015; 373(27):2599-607.
 - 21 Liu S, Watcha D, Holodniy M, Goldhaber-Fiebert JD. Sofosbuvir-based treatment regimens for chronic, genotype 1 hepatitis C virus infection in U.S. incarcerated populations: a cost-effectiveness analysis. *Ann Intern Med*. 2014;161(8): 546-53.
 - 22 Federal Bureau of Prisons. Evaluation and management of chronic hepatitis C virus (HCV) infection [Internet]. Washington (DC): BOP; 2016 Apr [cited 2016 Aug 9]. (Clinical Practice Guidelines). Available from: https://www.bop.gov/resources/pdfs/hepatitis_c.pdf
 - 23 Hoofnagle JH, Sherker AH. Therapy for hepatitis C—the costs of success. *N Engl J Med*. 2014;370(16):1552-3.
 - 24 Editorial Board. Costly hepatitis C drugs for everyone? *New York Times*. 2015 Sep 2.
 - 25 Moorjani H, Koeningmann C, Kim MJ, Spaulding AC. Prisoners treated for hepatitis C with protease inhibitor, New York, USA, 2012. *Emerg Infect Dis*. 2015;21(1):186-8.
 - 26 To access the Appendix, click on the Appendix link in the box to the right of the article online.
 - 27 *Acute hepatitis C* refers to an illness that takes places within the first six months after exposure to the hepatitis C virus. *Chronic hepatitis C* refers to illness that occurs when the virus remains in the body, which can last a lifetime.
 - 28 Carson EA. Prisoners in 2014 [Internet]. Washington (DC): Bureau of Justice Statistics; 2015 Sep 17 [cited 2016 Aug 16]. Available from: <http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5387>
 - 29 Centers for Disease Control and Prevention. Hepatitis C FAQs for health professionals [Internet]. Atlanta (GA): CDC; [last updated 2016 Jul 21; cited 2016 Aug 9]. Available from: <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>
 - 30 US Senate Committee on Finance. The price of Sovaldi and its impact on the U.S. health care system [Internet]. Washington (DC): The Senate; 2015 Dec [cited 2016 Aug 9]. Available from: [http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)
 - 31 Seeking Alpha. Gilead Sciences' (GILD) CEO John Martin on Q4 2014 results—earnings call transcript. Seeking Alpha [serial on the Internet]. 2015 Feb 3 [cited 2016 Aug 16]. Available from: <http://seekingalpha.com/article/2880996-gilead-sciences-gild-ceo-john-martin-on-q4-2014-results-earnings-call-transcript?part=single>
 - 32 Trooskin SB, Reynolds H, Kostman JR. Access to costly new hepatitis C drugs: medicine, money, and advocacy. *Clin Infect Dis*. 2015;61: 1825-30.
 - 33 Government Accountability Office. Drug pricing: manufacturer discounts in the 340B Program offer benefits, but federal oversight needs improvement [Internet]. Washington (DC): GAO; 2011 Sep [cited 2016 Aug 9]. (Report No. GAO-11-836). Available from: <http://www.hrsa.gov/opa/programrequirements/reports/gaooversightneeded09232011.pdf>
 - 34 Beckwith CG, Kurth AE, Bazerman L, Solomon L, Patry E, Rich JD, et al. Survey of US correctional institutions for routine HCV testing. *Am J Public Health*. 2015;105(1):68-71.
 - 35 Graham J. Medicaid, private insurers begin to lift curbs on pricey hepatitis C drugs. *Kaiser Health News* [serial on the Internet]. 2016 Jul 5 [cited 2016 Aug 9]. Available from: <http://khn.org/news/medicaid-private-insurers-begin-to-lift-curbs-on-pricey-hepatitis-c-drugs/>
 - 36 Barua S, Greenwald R, Grebely J, Dore GJ, Swan T, Taylor LE. Restrictions for Medicaid reimbursement of sofosbuvir for the treatment of hepatitis C virus infection in the United States. *Ann Intern Med*. 2015;163(3):215-23.