

but it has proven politically fraught. On the patient side, cost sharing is often misperceived as merely a mechanism for shifting costs to enrollees, but it can help limit the use of low-value services. Crude cost-sharing implementations, such as across-the-board high deductibles or copayments, however, can discourage high-value as much as low-value spending.<sup>4</sup>

Thus, the options available to policymakers must be assessed on the basis of their effects on both spending and health outcomes. Higher payments for high-value services may spur innovations that improve the length and quality of life. But these advances bring tough choices, and a one-size-fits-all solution probably can't both achieve public policy goals and meet individual priorities. There is a strong rationale for public

plans to ensure that all people have access to highly beneficial care, regardless of their ability to pay. Public programs could cover many more people if their resources were focused on high-value care, rather than on covering all services for fewer people. But many people may be willing to pay more for innovations even of limited or uncertain health benefit, and insurers can tailor plans to generate value to attract enrollees. If we're willing to pay \$150,000 for each quality-adjusted extra year of life (a commonly used estimate), then we ought to view a 10% increase in spending per capita as a good investment if it extended average life expectancy by 2.5 days. That number may give readers pause — hence the importance of clarifying our spending priorities and focusing on care that produces real value for patients. With such a focus, we could feel more confident

that higher health care spending was worth it.

Disclosure forms provided by the authors are available at NEJM.org.

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 An audio interview with Dr. Baicker is available at NEJM.org

## People with Hepatitis C Who Inject Drugs — Underserved, Not Undeserving

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The development of highly curative direct-acting antiviral (DAA) therapy for hepatitis C virus (HCV) infection has transformed clinical management of HCV and provided the impetus for the World Health Organization's ambitious HCV-related targets for 2030. These targets include marked improvements in prevention (including expanded harm reduction for people who inject drugs), upscaling of HCV screening and linkages between screening and other health ser-

vices to enable treatment for 80% of people with chronic hepatitis C, and a 65% reduction in HCV-related deaths and a 90% reduction in new infections from 2015 levels.<sup>1</sup>

Of 71 million people with chronic hepatitis C globally, an estimated 6.1 million are people who inject drugs, and injection drug use is responsible for most new infections in many countries.<sup>2</sup> To reduce the burden of HCV, public health and clinical responses should focus on key

populations: people with advanced liver disease (to reduce HCV-related mortality) and those at high risk for transmitting HCV (to reduce the incidence of HCV infection). Although these populations overlap, the latter is younger, is more highly marginalized, and tends to lack access to care.

A comparison of HCV responses in Australia, Canada, and the United States is informative (see table). Starting in 2013, the licensing of expensive DAA regi-

Demographics and Statistics Related to Injection Drug Use and Hepatitis C Virus Infection in Australia, Canada, and the United States.*			
Factor	Australia	Canada	United States
<b>Overall</b>			
Total population 15–64 yr of age (millions)	16.6	25.3	216.9
Estimated no. of people with HCV infection	129,000	205,000	2,936,000
No. of new HCV diagnoses	11,890	8,378	146,502
Year of DAA availability, by type			
Early access or licensed	2014	2014	2013
Government-subsidized	2016	2014	Limited
National unrestricted access	2016	2019	None
DAA treatment uptake among people with HCV (%)	39	19	37
HCV-related deaths per 1000 population			
2015	3.6	6.1	7.6
2018	2.5	5.3	6.2
<b>People who have recently injected drugs</b>			
No. of people who inject drugs per 1000 people 15–64 yr of age	6	7	10
No. of people who inject drugs (total)	93,000	171,900	2,248,500
No. of people with HCV infection who inject drugs	16,700	65,000	895,000
Proportion of overall HCV infections (%)	14	31	31
HIV prevalence (%)	1.3	11.3	8.7
Needles and syringes distributed per person who injects drugs (per year)	461	148	30
Opioid agonist therapy coverage (%)	52	24	19
DAA treatment uptake (%)	47	NA	NA
HCV RNA prevalence			
2015 (%)	51	53	40
2019 (%)	18	NA	NA

\* The number of new HCV diagnoses is based on 2018 data for Australia and Canada and 2017 data for the United States. Direct-acting antiviral (DAA) treatment uptake is as of the end of 2018 and reflects the percentage of persons who had ever received treatment. Data are from the National Drug and Alcohol Research Centre and the Kirby Institute at UNSW Sydney, the British Columbia Centre for Disease Control, the Canadian Network on Hepatitis C, and the Center for Disease Analysis. HCV denotes hepatitis C virus, and NA not available.

ments resulted in clinical prioritization of people with more advanced liver disease. In Australia and Canada, DAAs were initially available under pharmaceutical companies' compassionate-use programs for people with cirrhosis. Government subsidization of DAAs in Canada in 2014 (through provincial programs) focused on people with advanced fibrosis,

although the population eligible for subsidized therapy has since been broadened. Access to government-subsidized DAAs in Australia starting in 2016 (through a single-payer federal program) was unrestricted, although early data showed higher uptake among older patients and those with cirrhosis. In the United States, a more complex set of payers and restric-

tions was involved, but the initial goal was similar: to reduce deaths from complications of liver disease. The reversal in previously increasing trends in HCV-related liver transplantation, hepatocellular carcinoma, and liver-related mortality in all three countries demonstrates the population-level effects of DAAs.

The countries diverge, however, when it comes to political leadership, development of national HCV strategies, and public health responses to HCV. The Australian government developed a model under which it received unrestricted access to DAAs over a 5-year contract period with an annual expenditure cap — the so-called Netflix model.<sup>3</sup> The price of DAAs was estimated at U.S.\$7,352 to U.S.\$10,736 per course,<sup>3</sup> considerably lower than in the United States. There were no access restrictions based on stage of liver disease or ongoing drug or alcohol use, and all physicians could prescribe DAAs. Roughly 85,000 people with HCV (of an estimated 188,000) were treated by the end of 2019, with more than 6000 physicians prescribing DAAs. Uptake of these medications has been higher among marginalized populations, including people who inject drugs, people with recent incarceration, and HIV-infected men who have sex with men, than among other people with HCV.<sup>4</sup>

High uptake of DAAs among people who inject drugs has more than halved the prevalence of active HCV infection (from 51% in 2015 to 18% in 2019) in this population and has resulted in reductions in new infections among younger at-risk populations. Several initiatives included in Australia's national HCV-strat-

egy framework — its fifth since 2000 — have enabled this success, including government funding for community-based organizations; education and no-cost HCV screening for affected communities; integrated HCV-treatment programs in drug-dependency clinics, community clinics for people who inject drugs, and prisons; and enhanced HCV-prevention approaches, particularly needle- and syringe-delivery programs and opioid agonist treatment. Broad use of harm reduction has been pivotal for primary prevention and for helping connect people with screening and treatment services — and therefore for reaping the population-level benefits of using HCV treatment as prevention.

The opioid epidemic is a public health emergency. We believe that efforts to prevent overdose deaths should include large-scale investment in drug-dependency treatment, naloxone distribution, expansion (in Canada) and implementation (in the United States) of overdose-prevention sites, and safe drug supply initiatives, which involve prescribing or distributing drugs for injection under a public health framework. We hope Philadelphia's proposed overdose-prevention site portends a more pragmatic, health-oriented approach to harm reduction. But it will be important to address all social and health needs of people who use drugs. HCV prevention and treatment should therefore be part of a comprehensive package of interventions.

The response to HIV in the United States, which has included establishing broad access to government-funded antiretroviral therapy, demonstrates that major public health initiatives can have

population-level effects. Although the population of people at risk for HIV has expanded, the number of new infections among people who inject drugs has been stable, which is indicative of the success of a treatment-as-prevention approach. HCV is more easily transmitted by means of injection-drug use than is HIV, but Australia's example demonstrates that this and other barriers are not insurmountable.

We believe that several initiatives are essential for eliminating HCV among people who inject drugs. First, primary prevention should be strengthened by expanding harm-reduction approaches, since “treating your way out of” a worsening HCV epidemic isn't feasible. The more than 10-fold difference in the number of needles and syringes distributed per person who injects drugs in Australia as compared with the United States highlights this prevention gap. The endemic nature of HCV among people who inject drugs means that local and sporadic action will have limited effects. A comprehensive national approach to harm reduction, including federal funding for needle-exchange programs, is needed to reduce the risk of both primary infection and post-treatment reinfection. HCV reinfection rates in this population are about 5% per year, and they are higher in areas with low harm-reduction coverage.

Second, HCV (and HIV) screening and treatment services and drug-dependency services should be integrated, as recommended by the National Academies of Sciences, Engineering, and Medicine.<sup>5</sup> Cross-discipline education and training for infectious disease and addiction medicine physicians are under way and will enhance

integration, as will training of primary care physicians in both areas. Community-based services that “de-silo” mental health, physical health, and social services, such as the C-Change project in Philadelphia, are ideal.

Third, access to DAAs should be broadened, and unnecessary administrative barriers, such as prior-authorization requirements, should be reduced. Restrictions based on substance use should be removed. Innovative Netflix-style DAA pricing models, such as those recently adopted in Louisiana and Washington State, could be expanded. Access to treatment for HCV reinfection is also essential. The high uptake of DAAs within the Veterans Affairs system, which places no restrictions on DAA access, is a testament to the importance of optimization of health care systems. The relatively low uptake of DAAs in Canada as compared with Australia — both countries with universal health care — is a reflection of the earlier adoption of unrestricted access in Australia and its coordinated, strategic approach.

Fourth, screening innovations, such as rapid point-of-care HCV assays, should be further evaluated to increase linkage to care. Fifth, enhanced national surveillance, including monitoring of the prevalence of HCV RNA in representative populations of people who inject drugs, is needed to evaluate HCV-elimination strategies.

Finally, key to improving HCV prevention and treatment among people who inject drugs is alleviating the burden of stigma and discrimination — undoubtedly a factor influencing advocacy and overall response. The stigma and

discrimination experienced by most people with HCV who inject drugs — including discrimination by clinicians — prevents access to high-quality health care. We should address both the “undeserving” label that is applied to people who inject drugs by much of the public and the fact that these populations continue to be underserved by the health sector. The Australian response to HCV demonstrates that national leadership and an approach involving community organizations, academia, health care professionals, and government can

provide equitable access to highly effective and cost-efficient preventive and therapeutic interventions.

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## Hepatitis C Treatment in Prisons — Incarcerated People’s Uncertain Right to Direct-Acting Antiviral Therapy

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Direct-acting antiviral (DAA) drugs have transformed the treatment of hepatitis C virus (HCV) infection. With cure rates above 95% and minimal side effects, DAAs are far more efficacious and safer than previously used therapies and have quickly become the standard of care for HCV. Public and private health insurance policies now routinely cover DAAs; some plans impose access restrictions on the basis of drug and alcohol use and disease stage,<sup>1</sup> but insured patients with chronic HCV regularly obtain treatment with DAAs. Access remains much more elusive, however, for one group that is disproportionately affected by HCV: incarcerated people.

People incarcerated in prisons account for approximately one third of HCV cases in the United

States.<sup>2</sup> An estimated 17% of them are infected, as compared with 1% of the general population, but only a small minority have received DAA treatment.<sup>3</sup> Untreated HCV may lead to cirrhosis, hepatocellular carcinoma, liver failure, and death. Because people flow in and out of jails and prisons, HCV prevalence in these institutions also affects prevalence in the community.

For most prison systems, offering DAAs to all HCV-infected people would be enormously — perhaps prohibitively — expensive, and few have done so. Instead, some prisons rely on ad hoc decisions about who may receive this treatment. But the dominant approach, which aligns with recommendations from the Federal Bureau of Prisons,<sup>4</sup> is to implement prioritization protocols de-

signed to limit DAA access to people with the most advanced conditions. These protocols are controversial, both because they explicitly ration a highly efficacious treatment and because they rely on imperfect measures, such as the aspartate aminotransferase-to-platelet ratio index (APRI), to assess disease progression.

Unlike most other wealthy countries, the United States recognizes no general legally enforceable right to health care. Certain groups do have a circumscribed right to health care, however, and incarcerated people are one such group. Courts have interpreted the Eighth Amendment of the Constitution, which prohibits cruel and unusual punishment, as requiring the government to provide medical care to people who have been convicted and incar-