

VIEWPOINT

The Need to Expand Access to Hepatitis C Virus Drugs in the Indian Health Service

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The American Indian/Native Alaska population is disproportionately affected by hepatitis C virus (HCV). The most recent national data show American Indian/Alaska Native people with both the highest rate of acute HCV infection and the highest HCV-related mortality rate of any US racial/ethnic group.¹ In 2013, the latest national data available, rates of acute HCV infection were 1.7 per 100 000 American Indian/Alaska Native persons.¹ From 2009 through 2013, their HCV-related mortality rate increased by 23.2%, accounting for 324 deaths in 2013.¹ The American Indian/Alaska Native mortality rate of 12.2 deaths per 100 000 population is more than double the national rate of 5.0 per 100 000.¹ Although prevalence data are limited, one national study estimates 120 000 persons living on Indian reservations are positive for the HCV antibody.² Another study has shown American Indian/Alaska Native veterans born from 1945 to 1965 have an antibody-positive seroprevalence of 10%.³

The Indian Health Service (IHS) is a government agency entrusted to be the primary source for the provision of health care for the American Indian/Alaska Native population. The provision of health services to

Indians/Alaska Natives. Direct-acting antiviral regimens have high rates of achieving sustained virologic response with few contraindications or adverse effects. These advances represent a major shift in treatment options for HCV and may likely reduce HCV-related deaths. Among persons with compensated HCV-related cirrhosis, measured by sustained virologic response, successful treatment can lead to a survival curve similar to that of the general population.⁵

Yet these new HCV drug therapies must be accessible to have meaningful health benefits for patients. Many state Medicaid programs and insurance companies have imposed restrictions to contain costs. Some of these policies mandate significant liver damage as a requirement for eligibility, such as having stage 3 (precirrhosis) or stage 4 (cirrhosis) of the liver on the METAVIR scoring system. These criteria present a quandary: earlier treatment can prevent advanced liver disease, but late-stage liver disease is needed to qualify for treatment. For a clinician, explaining this circular logic to a patient can be frustrating for both parties.

Although direct-acting antiviral drugs have been cited as being cost-effective, cost-effectiveness does not necessarily mean affordable. The public sector in general and IHS specifically have budget constraints that shape treatment decisions; per capita user health expenditures range from \$3099 per year in the IHS compared with \$8097 per year for the US general population.⁴ Only a limited number of American Indian/Alaska Native patients belong to tribes that have

notable incomes stemming from natural resource or gaming royalties. With 1 in 4 American Indian/Alaska Native people living below the poverty line and with an average household income of just higher than \$30 000, paying even a small proportion of the out-of-pocket cost for this potentially life-saving medical treatment is not an option for most patients.

Another federal agency that provides direct patient care, the Department of Veterans Affairs (VA), has added HCV drugs to its formulary and issued guidance that all patients with HCV should be treated, regardless of stage of liver disease. However, the policy change came in the wake of well over a billion dollars from Congress earmarked for HCV, coupled with reduced drug pricing.⁶

The IHS, an agency several times smaller than VA in size and budget (IHS has an annual budget of \$4.6 billion to serve 2.2 million,⁴ whereas the VA has \$59 billion to serve 9 million veterans⁷), has not received supplemental funding for HCV treatment and does not have HCV drugs on its National Core

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members of federally recognized tribes developed from government-to-government relationships between the federal government and Indian tribes. This relationship, established in 1787, is based on Article I, Section 8, of the Constitution and has been given form and substance by numerous treaties, laws, Supreme Court decisions, and executive orders. The IHS is under the US Department of Health and Human Services and comprises a network of health care facilities that collectively serves nearly 2.2 million people across 35 states.⁴ Most facilities are primary health clinics in rural and remote settings, which are often the only source of medical care within a hundred miles. The IHS provides on-site medical care within its clinical and annual budgetary ability free of charge to all federally enrolled tribal members in accordance with the Indian Health Care Improvement Act. However, IHS is not insurance and relies on third-party insurers and other assistance programs to provide health care to its entire population.

Improvements in new treatment options for HCV could have a major effect on the health of American

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Formulary.⁸ Consequently, IHS facilities are highly dependent on Patient Assistance Programs and state Medicaid programs for access to HCV drug therapies. This approach has 2 main drawbacks that can reduce the willingness and ability of IHS facilities to meet clinical need. First, navigating external HCV drug access programs places a heavy time burden on the clinician, which can be daunting when even small IHS clinics can have a backlog of more than 100 patients with HCV. Second, drug access is generally conditional on the patient having advanced disease. These access criteria are not evidence based, nor are they aligned with HCV treatment guidelines from the American Association for the Study of Liver Diseases/Infectious Diseases Society of America, which recommend providing access to HCV drug therapies for all

patients with HCV except for those with other, immediately life-threatening illnesses.

Access to treatment for IHS patients should be a federal priority to fulfill its obligations to tribal nations and American Indian/Alaska Native people. Following the precedent set by the VA, this may require special allocation of funding from Congress to allow access to treatment to meet clinical needs. The consequences of inadequate access to HCV treatment are visible in the continued disparity in morbidity and mortality in American Indian/Alaska Native people. Human rights and health equity are not simply vague ideals—they are guiding operational principles for health care institutions, health care business, and governments—embodied to create a system of equity, especially for marginalized populations.

ARTICLE INFORMATION

Correction: This article was corrected online June 9, 2016, before the print issue for missing a subject in one sentence, a preposition in another, and data in a third.

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