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EDITORIAL

New, Expensive Treatments for Chronic Hepatitis C: Insuring Good Outcomes?

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The advent of new treatments for chronic hepatitis C virus (HCV) in the USA presents a rare opportunity but also poses substantial challenges. These highly effective treatment regimens improve sustained virologic response rates to well over 90 % among chronically HCV-infected patients, though their price can exceed $50,000 per patient. Despite findings that such treatments offer good value [1–3], their high price challenges the affordability of their delivery to all eligible patients. It is estimated that there are more than 3 million free-living people in the USA with chronic HCV infections as well as nearly 1 million incarcerated or institutionalized people with such infections [1, 4].

In this issue of *Digestive Diseases and Sciences*, Stepanova and Younossi describe important characteristic of large segments of the HCV-infected population in the USA, using data from the 2005–2012 National Health and Nutrition Examination Survey (NHANES) [5]. Though NHANES does not cover incarcerated or institutionalized individuals, the study findings are directly relevant to the vast majority (>80 %) of those with chronic HCV infections in the USA.

The authors reported two principal findings: The first is that the number of individuals eligible for treatment has increased substantially, which they note is due primarily to the safety of the newer, interferon-free regimens that have far fewer contraindications, enabling treatment for those who were ineligible for the prior regimens. The second is that, as of 2012, HCV-infected individuals had relatively low levels of insurance coverage compared to otherwise similar uninfected individuals. Combining these findings, the authors conclude that although the potential for broad population health benefits from treatment has expanded, the lack of insurance poses a serious barrier to achieving these benefits.

The first point—that the massive pool of individuals who can benefit from treatment has expanded with the commensurate challenge of paying for care—is well taken and of prime importance. Combined with the higher per-patient costs, the total potential expenditures to treat all eligible individuals are now estimated in the hundreds of billions of dollars [1, 2]. Who is likely to pay?

The traditional mechanism for paying for medical care, especially expensive care, in the USA is via health insurance; yet, in the USA, insurance is split across many payers. A substantial fraction of the potential burden falls on public payers such as Medicaid, prison healthcare systems, the VA Healthcare System, and increasingly on Medicare as the birth cohorts with the highest HCV prevalence reach the age of Medicare eligibility. Likewise, private commercial insurers shoulder a substantial share [2].

The total burden of paying for HCV treatment depends on treatment price, and in the world of prescription drugs, there is not one price for all. Both public payers such as VA and private pharmacy benefit managers such as Express Scripts and CVS/Caremark are able to garner substantial drug price discounts, given their formularies, market power, and the arrival of multiple competitor treatments [6, 7]. Yet, other payers, particularly Medicare, remain statutorily hobbled in their inability to negotiate drug prices. It seems strikingly irrational that Congress would demand testimony from drug manufacturers about high prices, as it did with Gilead Sciences, Inc., makers of one of the new

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treatments [8], while at the same time failing to address the inability of Medicare to consider costs in its coverage decisions and the explicit prohibition of considering cost-effectiveness enshrined in the Patient Protection and Affordable Care Act, more commonly referred to as the ACA or "ObamaCare." The total burden of paying for new HCV treatments could potentially be lowered by addressing such limitations to the market.

This brings us to Stepanova and Younossi's second point—that the uninsured will not be able to access treatment. They may face the highest and most unaffordable treatment prices since as members of the class of uninsured, they have the least market power. Yet, given developments in the US insurance market since 2012 (the latest year analyzed by the authors) due to the ACA and the consequent national increase in insurance coverage to tens millions of Americans through insurance exchanges and Medicaid expansions [9], it is likely that the fraction of uninsured HCV-infected individuals has declined as well.

But even in this new insurance landscape, the question remains as to whether insured individuals, particularly those newly insured, are underinsured when it comes to HCV treatment. Whether and how generously insurers cover chronic HCV treatment remains an open question, though the lack of coverage reported by NHANES likely correlates with poverty which would imply that unless coverage is generous and co-insurance and co-payments low, the treatment rate among newly covered individuals with chronic HCV may be low.

In addition to negotiating lower HCV drug prices, sophisticated payers and health systems may adopt potentially more palatable alternatives to not covering HCV treatments or requiring large out-of-pocket outlays from patients. Such alternatives include patient prioritization schemes to spread the budgetary burden over multiple years. How best to efficiently prioritize treatment to patients most in need within limited budgets while actively monitoring the untreated to ensure that they do not progress to advanced liver disease is an important open question that deserves additional research. Further, even if treatment is offered at a lower price, not all patients take it up immediately or, in some cases, ever. While we have seen treatment rates increase with newer, more effective, less toxic regimens [10], the national patient demand for the newest regimens almost certainly differs from the historical demand for prior less effective, more toxic regimens.

In summary, Stepanova and Younossi should be commended for not only characterizing a large sector of the HCV-infected population in the USA, but also calling out important challenges to achieving the potential benefits of the new treatments, which economic forces and policies may already have begun to address. As noted, the expanded patient pool eligible for the new therapies multiplied by their high per-patient cost raises affordability concerns, although the magnitude of these concerns depends upon price competition between the multiple new treatment regimens now available, payers' abilities to use their market power to negotiate lower prices, and the magnitude and timing of patient demand and uptake of treatment which is related not only to regimen quality but also to insurance status and insurance generosity. Future research should seek to understand whether the complex, evolving patchwork of markets, systems, and policies that comprise US healthcare will help or hinder the attainment of value within the new era of HCV treatment.

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Compliance with ethical standards

Conflict of interest None.

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