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Wiener, Janet and Linas, Benjamin P. Cost-effective Screening and Treatment of Hepatitis C. LDI Issue Briefs. 2018; 22 (4).

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Cost-effective Screening and Treatment of Hepatitis C

Abstract

In just five years, hepatitis C has changed from a difficult-to-treat chronic condition to one that is readily cured by a short course of medication. Medical breakthroughs have now created the possibility of eliminating the transmission of HCV, but also bring a new challenge for the health system—how to identify individuals carrying the hepatitis C virus (HCV), and how to pay for life-saving treatments. This Issue Brief reviews recent evidence on the cost-effectiveness of screening and treatment strategies, and makes the case for universal, one-time HCV screening for all US adults.

Keywords

Hepatitis C, HCV, HCV screening, cost-effectiveness

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Cost-effective screening and treatment of Hepatitis C

In just five years, hepatitis C has changed from a difficult-to-treat chronic condition to one that is readily cured by a short course of medication. Medical breakthroughs have now created the possibility of eliminating the transmission of HCV, but also bring a new challenge for the health system—how to identify individuals carrying the hepatitis C virus (HCV), and how to pay for life-saving treatments. This Issue Brief reviews recent evidence on the cost-effectiveness of screening and treatment strategies, and makes the case for universal, one-time HCV screening for all US adults.

Background

More than 3.5 million people in the US are chronically infected with HCV, and about 19,000 die each year from HCV-related diseases. Hepatitis C is a leading cause of liver cancer and the leading cause of liver transplants; baby boomers (people born during 1945-1965) account for three-quarters of all cases and hepatitis C-related deaths. The incidence of HCV infection is rising in younger people, primarily because of injection drug use.

A high proportion (from 45% to 85%, according the CDC) are unaware that they have the disease, and may infect others. In 1998, the CDC recommended HCV testing only for people at high risk—such as a history of injection drug use or exposure to blood products before effective screening—a strategy that left most people unaware of their status. Because of a disproportionately high prevalence of hepatitis C among baby boomers, the CDC augmented their recommendations in 2012 to include one-time testing of all people in that birth cohort. In 2013 the US Preventive Services Task Force (USPSTF) gave this recommendation a “B” grade, which meant that the screening would be covered by insurance with no cost-sharing under the Affordable Care Act. A few months later, the first efficacious direct-acting anti-virals hit the market, offering a nearly 90% cure rate and the potential to eliminate transmission of HCV. That potential, however, was limited by the initial price tag (\$84,000 per course of treatment) and the budget impact on public payers, such as Medicaid and Departments of Corrections, who cover a disproportionate number of people with HCV. In response, these payers have limited treatments to patients with advanced disease or used other restrictions.

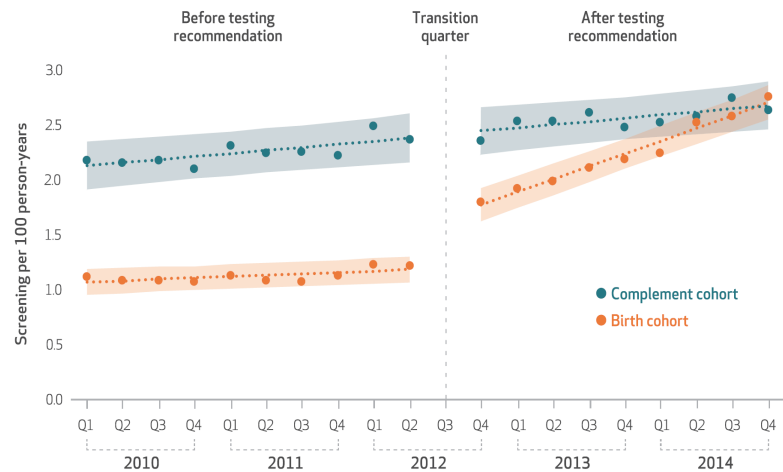
In an era of effective treatments, identifying people with hepatitis C takes on even greater urgency as the beginning step in a “cascade of care” leading to cure, and potential elimination of HCV transmission. But the combination of a prevalent disease with an expensive cure, and the burden of treatment on public budgets, creates a significant economic barrier to HCV care.

THIS ISSUE BRIEF REVIEWS RECENT EVIDENCE ON THE COST-EFFECTIVENESS OF HCV SCREENING AND TREATMENT STRATEGIES, AND MAKES THE CASE FOR UNIVERSAL, ONE-TIME SCREENING FOR ALL US ADULTS.

New screening guidelines have an impact

In a study of the effects of the new CDC testing guidelines, [Barocas, Wang, White, et al. \(2017\)](#) found an “immediate and sustained impact of hepatitis C testing guidelines on clinical practice.” They analyzed hepatitis C screening rates in 2.8 million commercially insured adults before and after the recommendations, using a cohort born after 1965 (but at least 18 years old) as a comparison group. As shown below, they found a 49% increase in screening rates among the birth cohort after the release of the recommendations, but no increase among the comparison cohort.

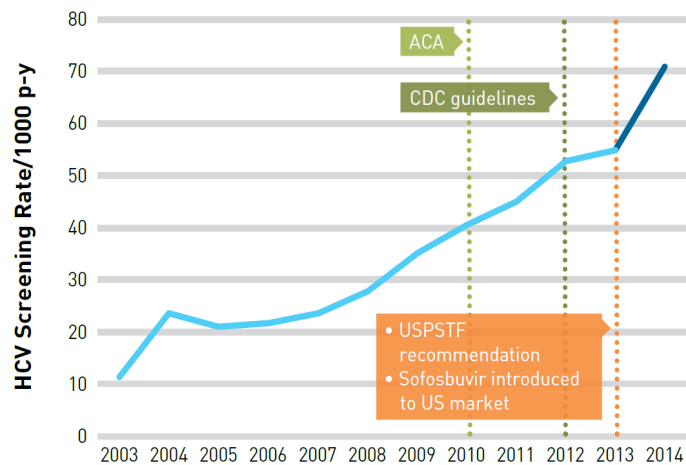
Figure 1
 Trends in quarterly hepatitis C screening rates in the United States per 100 person-years in 2010-14, by age cohort



Source: Joshua A. Barocas, Jianing Wang, Laura F. White, Abriana Tasillo, Joshua A. Salomon, Kenneth A. Freedberg, and Benjamin P. Linas. Hepatitis C Testing Increased Among Baby Boomers Following The 2012 Change To CDC Testing Recommendations. *Health Affairs*, 2017 36:12, 2142-2150

[Rodriguez, Rubenstein, Linas, et al. \(2018\)](#) confirmed the effects of the CDC and USPSTF screening recommendations in an observational study of 665,000 adults visiting Kaiser Permanente clinics between 2003 and 2014. They documented a steady increase in screening over time, with a noticeable jump in screening after the USPSTF recommendations. As shown below, HCV screening jumped 29% from 2013-2014, compared to 4% from 2012-2013.

Figure 2
 HCV screening rate over time, Kaiser Permanente, 2003-2014



Source: Rodriguez CV, Rubenstein KB, Linas B, Hu H, Horberg M. Increasing hepatitis C screening in a large integrated health system: science and policy in concert. *American Journal of Managed Care*, 2018 May 1;24(5):e134-e140.

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Adjusting for other factors, the authors found that screening in the birth cohort more than doubled, which represented a 20% greater increase than screening in other age groups. The authors point out that insurance coverage for screening and the availability of effective treatment after the USPSTF recommendation may have led to a greater increase in screening than screening guidelines alone.

HCV treatment provides good value

Despite its cost, HCV treatment provides good value for the money, as expressed in terms of cost-effectiveness. In a recent review, [Linas and Nolen](#) (2018) note that most studies in the past five years find that HCV treatment falls within the generally accepted value of \$100,000 per quality-adjusted life year (QALY). They note that these studies do not reflect price decreases that have occurred in the past 1-2 years—but the substantial cost burden remains. A critical question is not whether to treat patients with HCV, but when, because of the significant lag time between infection and disease. Facing costs that could overwhelm fixed budgets, many payers have restricted treatments to those with advanced disease (for example, liver cirrhosis) or those who are alcohol- or drug-free.

In one study, [Linas, Morgan, Pho, et al.](#) (2017) modeled the cost-effectiveness and budgetary impact of different treatment strategies, from a payer's point of view. They found that the five-year budgetary impact of treating HCV was high (\$1-\$2.3 billion per 10,000 HCV-infected patients, depending on the treatment regimen). They confirmed that the treatment strategies are cost-effective; compared to treating more advanced disease only, treating early disease is likely cost-effective, and may even be cost-saving, because it prevents many years of decreased quality of life and increased health care costs associated with HCV infection. They conclude that payers seeking to control costs would do better by price negotiations in a newly competitive drug market rather than by treatment restrictions. Treating all HCV-infected people with the least costly direct-acting antiviral would be the cost-control strategy that produces the best outcomes.

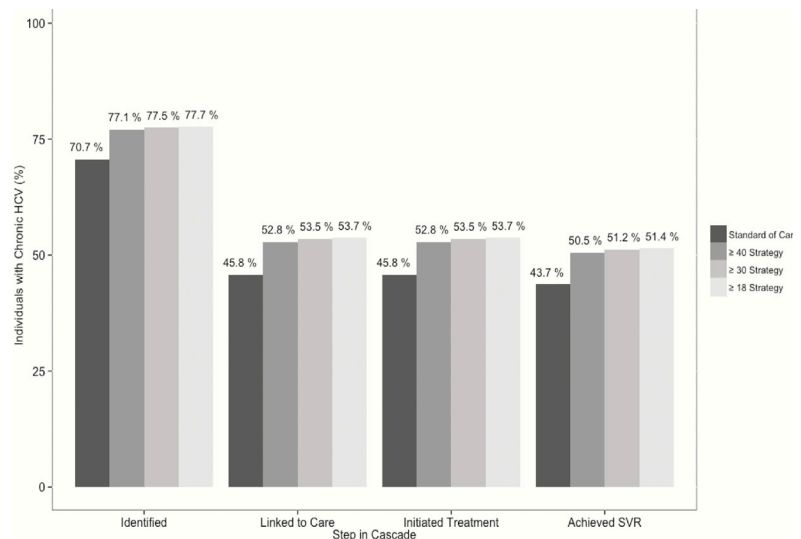
There is some evidence that public payers are relaxing their eligibility restrictions (such as disease severity and substance use abstinence) for hepatitis C treatment. [Kapadia, Jeng, Schackman, and Bao](#) (2017) looked at Medicaid drug utilization data from 2014 to 2016, and found that states that loosened their restrictions had a more rapid increase in prescriptions of direct-acting antivirals than states maintaining their restrictions. The 31 states that implemented Medicaid expansion under the Affordable Care Act saw much more of an increase in utilization than states that did not.

What's the optimal HCV screening strategy?

Using a simulation model, [Barocas, Tasillo, Eftekhari Yazdi, et al.](#) (2018) compared the clinical costs, outcomes, and cost-effectiveness of four HCV testing strategies: the existing one (one-time testing for all persons born between 1945 and 1965); one-time testing for adults aged 40 or higher, 30 or higher, or 18 or higher. All strategies included targeted testing of people at higher risk, such as those who inject drugs. As shown below, expanded age-based strategies increased identification and lifetime cure rates.

ONE-TIME SCREENING OF ALL US ADULTS WOULD BE COST-EFFECTIVE, PROVIDING THE GREATEST QUALITY-ADJUSTED LIFE EXPECTANCY AND LOWEST COST PER QALY GAINED.

Figure 3
HCV continuum of care over a lifetime, by strategy



Source: Joshua A. Barocas, Abriana Tasillo, Golnaz Eftekhari Yazdi, Jianing Wang, Claudia Vellozzi, Susan Hariri, Cheryl Isenhour, Liisa Randall, John W. Ward, Jonathan Mermin, Joshua A. Salomon, Benjamin P. Linas. Population-level Outcomes and Cost-Effectiveness of Expanding the Recommendation for Age-based Hepatitis C Testing in the United States. *Clinical Infectious Diseases*, Volume 67, Issue 4, 1 August 2018, Pages 549–556, <https://doi.org/10.1093/cid/ciy098>

The authors estimate that the existing strategy would identify 71% of all HCV-infected people, and 44% of them would be cured over a lifetime. Compared to existing screening, a strategy of age 18 or older would result in 256,000 additional people identified, 28,000 additional cures, and 4,400 fewer cases of hepatocellular liver cancer over the lifetime of this age group. For people born outside the baby boomer cohort, case detection rates would increase from 74% to 85%, and cure rates would increase from 49% to 61%. Overall, this would represent a 21% reduction in liver-attributable mortality, and an increase in life expectancy from 67.2 to 68.2 years among the affected population.

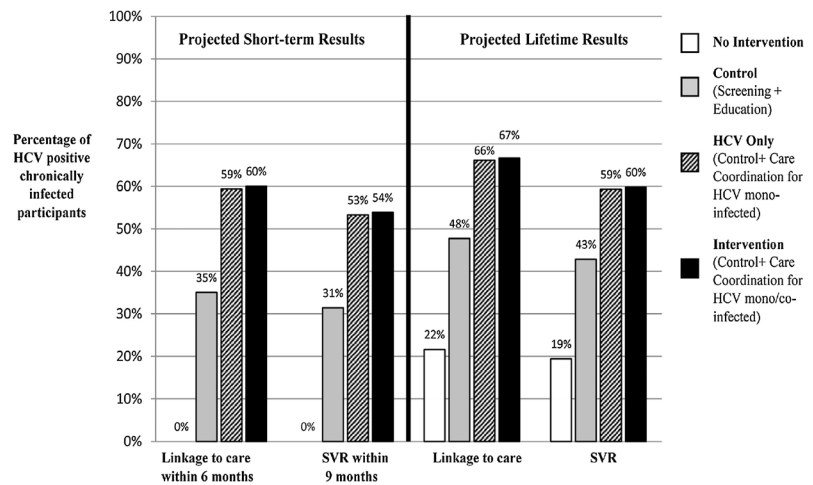
All strategies decreased the costs related to managing chronic HCV and advanced liver disease. The cost of HCV testing in the existing strategy amounted to \$2,500 per case diagnosed; in the 18 and over strategy, the cost of testing increased to \$4,400 per case diagnosed. The 18 and over strategy was cost-effective, providing the greatest quality-adjusted life expectancy and the lowest cost/QALY gained (\$28,000 per QALY).

Figure 3 above also illustrates the importance of linking identified patients to care in an overall strategy that produces high cure rates. [Schackman, Gutkind, Morgan, et al. \(2018\)](#) modeled the cost-effectiveness of screening and treatment linkages in a high-risk population of patients in a methadone maintenance treatment (MMT) program, using data from a randomized trial. The study estimated costs and outcomes of on-site HCV screening and education or HCV screening, education, and active care coordination, compared to no intervention. The model took into account the probability of reinfection if patients engaged in injection drug use risk behavior.

As shown in Figure 4, on-site screening and education resulted in a projected 35% linking to care within six months and 31% achieving cure (sustained virologic response). Adding an active coordination component resulted in 60% linking and 54% achieving cure. The active care coordination intervention had a cost-effectiveness ratio of \$24,600/QALY gained, compared to no intervention, and \$76,500/QALY gained, compared to screening and education alone. Thus, the authors conclude that HCV care coordination interventions that include screening, education and active linkage to care in MMT settings are likely cost-effective at a conventional \$100,000/QALY threshold.

IN ECONOMIC MODELS AND REAL-WORLD PRACTICE, IDENTIFYING PATIENTS WITH HEPATITIS C AND LINKING THEM TO EARLY TREATMENT PROVIDES GOOD VALUE FOR OUR HEALTH CARE DOLLAR.

Figure 4
Projected short-term and lifetime continuum of care results, by intervention group



Source: Schackman BR, Gutkind S, Morgan JR, Leff JA, Behrends CN, Delucchi KL, McKnight C, Perlman DC, Masson CL, Linas BP. Cost-effectiveness of hepatitis C screening and treatment linkage intervention in US methadone maintenance treatment programs. *Drug and Alcohol Dependence*, 2018 Apr 1;185:411-420. doi: 10.1016/j.drugalcdep.2017.11.031.

In an economic analysis of a real-world HCV care coordination program in two New York City clinics, [Behrends, Eggman, Gutkind, et al.](#) (2018) found that the cost of a 5.6-month care coordination intervention was less than \$800 including overhead. The authors proposed a three-part payment model tied to each phase of the program: enrollment to treatment initiation, treatment initiation to treatment completion, and a bonus payment for laboratory evidence of sustained viral response.

Policy Implications

Hepatitis C treatment lies at the crossroads of science, economics, and policy. As [Linás and Nolen](#) (2018) note, with effective treatments in hand, the challenge has shifted from the biology of curing a virus to the public health problem of identifying and treating millions of HCV-infected people.

The economics of the problem highlight the difference between cost-effectiveness, from the health system or societal perspective, and the budget impact for payers, especially public ones. There is considerable evidence that a variety of strategies for screening and treating HCV provide good value for their cost, at conventionally accepted standards for value. This is especially impressive given that the costs used in these analyses were higher than HCV treatments today; as competing medications enter the market, the cost of a cure has dropped from \$84,000 to \$26,400 (before discounts) for some regimens.

Screening recommendations from the CDC and USPSTF have increased HCV testing in clinical practice, especially among the baby boomer cohort that they target. However, evidence suggests that one-time testing of all people 18 and over would be more cost-effective, identify more cases, and yield greater cures. Given the impact of the previous change in CDC and USPSTF recommendations, changing them again would likely result in more screening and more treatment.

But what is cost-effective may not be affordable within specific budgets. Further, future savings may not accrue to the same payers that would have to absorb the considerable present costs of screening and treatment. This is particularly true for payers with disproportionately high prevalence of HCV infection in their populations, such as Medicaid and correctional institutions.

AT THIS TIME, THE QUESTION
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Given this context, some policymakers are exploring new ways to pay for HCV treatment. For example, the Secretary of Health in Louisiana is exploring a [subscription-based payment model](#) in which the state would pay a drug manufacturer a fixed purchase price for the length of a multi-year contract. The price would provide unlimited treatment access for people covered by Medicaid or in Louisiana’s correctional system. If structured properly, the model would allow the state to spread the costs of treatment across budget years, while expanding the manufacturer’s reach into populations that are not now being treated.

The National Academies of Sciences, Engineering, and Medicine proposed a [novel strategy](#) that involves drug manufacturers competing to license their patent to the federal government for use in low-income and vulnerable populations. In that case, generic manufacturers could supply Medicaid and correctional institutions with HCV treatments at much lower cost, while protecting the market share of drug manufacturers in the private market.

Conclusion

In economic models and in real-world practice, identifying patients with hepatitis C infection and linking them to early treatment provides good value for our health care dollar. We conclude that:

1. Routine screening for HCV, without effort to identify risk factors, is cost-effective and even cost-saving in some venues.
2. HCV treatment is cost-effective, even with high-cost medications and even with high reinfection rates.

At this time, the question is not “should” we test and treat, but “how will we pay for it?” This is not a trivial question, but it is one that is best answered through financial instruments, not treatment restrictions. Rather than seek strategies that minimize cost by limiting treatment courses, health care systems and policymakers should negotiate aggressively holding the “chip” of large volume to drive down cost and should design financing schemes that help them to disperse cost over time.

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This Issue Brief is supported by the Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV (CHERISH), a National Institute on Drug Abuse-funded Center of Excellence (P30DA040500).

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