

## Should Family Physicians Routinely Screen Patients for Hepatitis C?

### No: One-time Screening Still Has Too Many Unanswered Questions

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Of the estimated 2.7 million persons in the United States with chronic hepatitis C virus (HCV) infection in 2010,<sup>1</sup> fewer than 200,000 were successfully diagnosed and treated, with success defined as a sustained viral response (SVR) or clearance of HCV at least three months after discontinuing therapy.<sup>2</sup> Why so few? First, many persons with HCV infection do not develop liver failure for up to 30 years, if ever, and therefore treatment was reserved for patients with evidence of progressive fibrosis or with higher risk of HCV progression (e.g., patients with coexisting human immunodeficiency virus infection). Second, interferon-based HCV therapies had bothersome adverse effects, leading to high discontinuation rates, and often did not clear the virus.<sup>3</sup> Finally, few primary care physicians felt comfortable treating these patients.

In a recent issue of *American Family Physician*, Wilkins and colleagues provided a timely update on screening, diagnosis, and management of chronic HCV infection.<sup>4</sup> Much has changed on this topic over the past few years. The Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force now both recommend one-time screening of all persons born between 1945 and 1965, regardless of risk factors.<sup>5</sup> Several studies have demonstrated SVR rates of more than 90% in patients receiving interferon-free combination regimens.<sup>6</sup> Also, the Project ECHO (Extension for Community Healthcare Outcomes) model tested in New Mexico, Arizona, and Utah demonstrated that with appropriate training, HCV infection treatment managed by a primary



This is one in a series of pro/con editorials discussing controversial issues in family medicine.

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care clinician produced similar outcomes as treatment managed by an infectious disease or gastrointestinal subspecialist.<sup>7,8</sup>

Expanded screening and effective treatments that can be safely prescribed in primary care settings have the potential to substantially reduce the public health burden of HCV infection over the coming years. However, the new treatments are hugely expensive. For example, the approximate price of a single 12-week course of sofosbuvir (Sovaldi), which costs about \$100 to manufacture, is \$84,000. At this price, treating all persons with HCV infections in the United States could end up costing \$250 billion, which amounts to nearly \$1 out of every \$10 dollars spent on health care nationally.<sup>9,10</sup> Treatment could conceivably be cost-effective in the long term if it prevents morbidity and costs associated with cirrhosis and hepatocellular cancer.<sup>11,12</sup> However, even using stricter guidelines for treatment eligibility, the cost of shorter-term HCV treatment threatens to overwhelm the budgets of private and public payers.<sup>12</sup>

Medicare spent an estimated \$9.2 billion on drugs for HCV in 2015, which is nearly twice as much as it spent in 2014 and represents 7% of all Medicare drug spending.<sup>13,14</sup> Because most of the screening cohort born between 1945 and 1965 is younger than 65

years, HCV-related spending is likely to increase over the next few years.

There are also good reasons to wonder if spending additional billions of dollars on HCV screening and treatment will actually improve patient-oriented outcomes that matter. The U.S. Preventive Services Task Force acknowledges the absence of health outcomes data on new treatments and relied on a “chain of evidence” to conclude with moderate certainty that birth cohort screening has a net benefit, reasoning that if selected patients who achieved SVR with older HCV therapies had better long-term outcomes than patients who did not, then newer medications with higher SVR rates should also be effective.<sup>15</sup> However, the absence of randomized trials testing expanded HCV screening strategies is concerning, because any potential benefits need to be weighed against the harms that would occur in approximately four out of five patients with HCV infection who would do well without any treatment.<sup>16</sup> As for the CDC, nine out of the 34 members of the working group that recommended expanded screening in 2012 disclosed financial conflicts of interest, and the CDC Foundation has received more than \$26 million in donations since 2010 from corporations that produce HCV tests or treatments.<sup>17</sup>

In summary, recent innovations in identification and management of patients with HCV infection have left family physicians facing important unanswered questions. Is it worthwhile to modify practice workflows to prioritize screening for HCV in middle-aged and older adults without any known risk factors, who are more likely to be at risk of cardiovascular disease and cancer than HCV infection? In persons who test positive for HCV, who should be treated or referred for treatment, knowing that many will not benefit? Given current scientific uncertainties, limited resources, and evolving guidelines, a reasonable middle ground would be for family physicians to collaborate with subspecialty colleagues and focus HCV testing and therapy on patients who are most likely to have long-term complications from the infection, such as those with human immunodeficiency virus infection or type 2 diabetes mellitus,<sup>18</sup> rather than instituting more broad screening and treating everyone who tests positive.

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