# A WINDOW OF OPPORTUNITY

## Changing the Hepatitis C Virus Screening and Treatment Paradigm While There Is Still Time

### Executive Summary

James C. Capretta*
Principal and Director of Health Policy Consulting
Civic Enterprises, LLC

and

Michael J. O'Grady, Ph.D.*
Principal, O'Grady Health Policy, LLC

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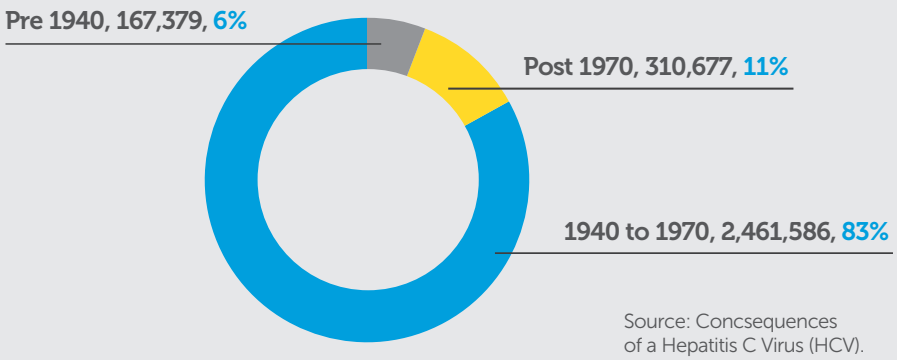
## Changing the Hepatitis C Virus Screening and Treatment Paradigm While There Is Still Time

**There are nearly 4 million Americans who are infected with HCV, making it the most common blood-borne viral infection in the United States.[1] And yet, despite its prevalence, the disease has not been the focus of a great deal of public health attention due to the unusual nature of the disease's epidemiology and progression.**

More than 80% of the population infected with HCV is concentrated in the baby boomer generation as shown in Figure 1. The virus is primarily transmitted by contact with infected blood, something that occurred with much more frequency several decades ago due to that generations' higher participation in certain high risk activities and a blood supply that was not screened for HCV.

FIGURE 1:
**HCV-Infected U.S. Population by Birth Year**




Source: Concsequences of a Hepatitis C Virus (HCV). Millman, May 2009.

Those infected with HCV will typically experience a long period, as long as 20 or more years, with no noticeable symptoms. However, over time, the virus causes increasing damage to the liver. Eventually, for a sizeable subpopulation, the virus will cause liver failure or liver cancer, both of which are costly to the healthcare system and usually fatal. For many patients with advanced liver disease, the only viable option may be expensive and dangerous liver transplantation.

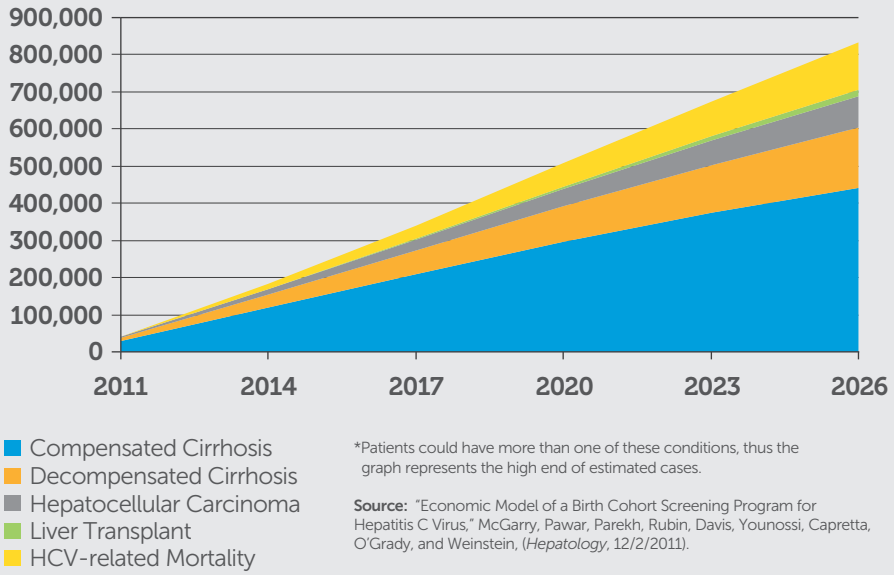
And yet, a large number of Americans with HCV are still unaware they have the disease. Up to four of five cases remain undiagnosed. Consequently, these patients are at a high risk of developing serious liver disease before anything is done to treat and potentially eliminate the virus. Given the

[1] Pyenson, B., Fitch,K., Iwasaki, K. *Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease*, Milliman, Inc., May 2009. Commissioned by Vertex Pharmaceuticals.

natural progression of the disease and the age cohort most at risk, the cost of treating advanced liver disease is expected to fall heavily on the Medicare program, with costs rising from about $5 billion today to $30 billion annually as the baby boomer generation ages.[2]

FIGURE 2:

## Onset of Serious Liver Disease Will Rise Rapidly In Coming Years with Risk-Based Screening*




*Patients could have more than one of these conditions, thus the graph represents the high end of estimated cases.

**Source:** "Economic Model of a Birth Cohort Screening Program for Hepatitis C Virus," McGarry, Pawar, Parekh, Rubin, Davis, Younossi, Capretta, O'Grady, and Weinstein, (*Hepatology*, 12/2/2011).

Figure 2[3] shows the coming surge of HCV-induced liver disease and makes it clear that there is now a very limited window of opportunity to address this public health crisis. The number of Americans experiencing serious liver disease can be reduced significantly with effective treatment. But that can only happen if more of those infected with HCV are aware of their condition and seek treatment. There is still time for that to occur, but not much time. By the end of this decade, it may be too late for several hundred thousand Americans to avoid the damage that untreated HCV may cause to their health.

Until recently, the standard of care for HCV was a drug regimen that produced a cure in 40 to 80 percent of cases.[4] New therapies, recently approved by the FDA, have shown higher cure rates and the potential to cut treatment time in half for many patients.

But first, there has to be a diagnosis.

Currently, the U.S. policy for screening for HCV is based on physicians making a risk assessment on a patient-by-patient basis. Because of the stigma and awkwardness of asking about sexual and drug-related behavior that may have occurred decades earlier, physicians are hard pressed to effectively and efficiently administer a risk-based screening protocol for the disease. Consequently, the current approach to screening, in place since 1998, leaves a large percentage of the infected population undiagnosed. Given the concentration of the disease in the baby boomer generation, and that most of this population has not yet developed the more serious complications of HCV, there is a narrow window of opportunity to address an epidemic of liver diseases by systematically screening aging baby boomers for the virus.

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[2] Pyenson, B., Fitch,K., Iwasaki, K. *Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease*, Milliman, Inc., May 2009, p. 14. Commissioned by Vertex Pharmaceuticals.

[3] **Compensated cirrhosis** of the liver refers to early liver damage in which the body functions well despite the damaged liver tissue. Often times, patients with compensated cirrhosis show no symptoms of disease. **Decompensated cirrhosis** means that the liver is extensively scarred and unable to function properly. **Hepatocellular Carcinoma** is liver cancer.

[4] Fried MW, Shiffman ML, Reddy KR, Smith C, Marinos G, Goncales FL Jr. *Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection*. N Engl J Med 2002; 347:975-982.

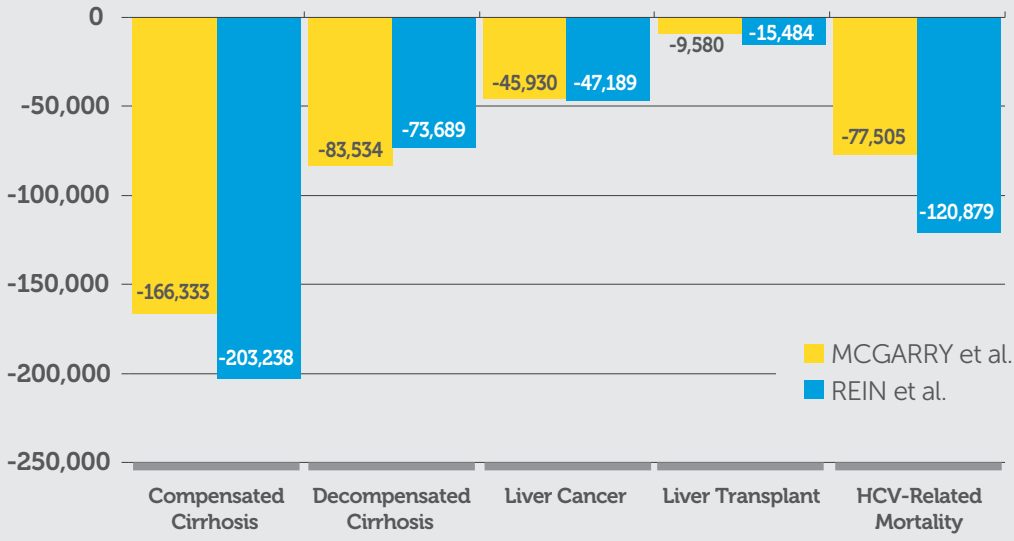
# The Latest Research

Two new studies, independently conducted, modeled the clinical benefits that would ensue if the United States were to replace the current risk-based screening protocol with an age-based screening approach.[5] Both studies, which were published in the Fall-Winter of 2011, come to the same basic conclusion: screening for Hepatitis C based on age, as well as risk factors, will yield better clinical outcomes and be cost effective at the same time. A one time age-based screening could specifically target persons born between 1945-1965, which is the segment of the population most likely to be carrying the virus.

Figure 3 compares the results of the two new studies. Both studies estimated significant clinical improvements using this newer, more effective screening protocol, compared to risk-based screening used today, including:

- **166,000 to 203,000 fewer cases of compensated cirrhosis of the liver,**
- **73,700 to 83,500 fewer cases of decompensated cirrhosis of the liver,**
- **46,000 to 47,000 fewer cases of liver cancer,**
- **9,600 to 15,000 fewer liver transplants, and**
- **77,500 to 120,900 fewer deaths from Hepatitis C.**

FIGURE 3:
## Reductions in HCV-Related Disease Burden from Implementing Birth-Cohort Based Screening




*Cumulative clinical impact over the duration of the model.

**Source:** "Economic Model of a Birth Cohort Screening Program for Hepatitis C Virus," McGarry, Pawar, Parekh, Rubin, Davis, Younossi, Capretta, O'Grady, and Weinstein, (*Hepatology*, 12/2/2011).
"The Cost-Effectiveness of Birth-Cohort Screening for Hepatitis C Antibody in U.S. Primary Care Settings," Rein, Smith, Wittenborn, Lesesne, Wagner, Roblin, Patel, Ward, and Weinbaum, *Annals of Internal Medicine*, published online 11/4/11.

[5] "Economic Model for a Birth Cohort Screening Program for Hepatitis C Virus," McGarry, Pawar, Parekh, Rubin, Davis, Younossi, Capretta, O'Grady, and Weinstein, (forthcoming, *Hepatology*, winter 2011), supported by Vertex Pharmaceuticals.
"The Cost-Effectiveness of Birth-Cohort Screening for Hepatitis C Antibody in U.S. Primary Care Settings
Rein, Smith, Wittenborn, Lesesne, Wagner, Roblin, Patel, Ward, and Weinbaum, *Annals of Internal Medicine*, published online 11/4/11. http://www.annals.org/content/early/2011/11/03/0003-4819-156-4-201202210-00378.full

Additional screening will mean additional spending, but the return on investment is substantial with the potential for dramatically improved clinical outcomes. Total spending would rise moderately, but the result could be tens of thousands of fewer premature deaths and substantially higher cure rates among a vulnerable population.

To assess whether or not such a cost is justified, economic analyses of medical interventions have typically used a measure of "cost-effectiveness" known as "dollars per quality-adjusted life years (QALYs) gained." QALYs are a measure of benefit that take into account clinical improvements for patients by combining both improvements in the patient's quality of life and improvements in survival. The costs include any additional medical expense (in this case, of diagnosing and treating additional HCV patients) less reductions in future spending associated with the patient's clinical improvement. Thus a $/QALY measure provides an indication of the relative clinical benefits on a dollar basis, that potentially can be compared across populations, diseases and medical interventions.

Both studies used dollars per quality adjusted life year as their measure of cost effectiveness. Both teams found that moving toward one time birth-cohort screening would be a very cost-effective intervention. As shown in Figure 4, the present-value of future additional health spending from birth-cohort screening for HCV would be between $19.0 and $26.7 billion over the next several decades. These patients would gain between 532,300 and 707,896 additional quality-adjusted years of life. Thus, spending for every additional life year gained is estimated to be between $35,700 and $37,720 (quality adjusted), which is well below the thresholds used in most of Europe and the United States to determine whether an intervention is cost-effective, and similar to cervical cancer or hypertension screening.

FIGURE 4:
## Cost-Effectiveness of Birth-Cohort Screening

| | MCGARRY et al. (1946 - 1970) | REIN et al. (1945 - 1965) |
|---|---|---|
| Present Value of Additional Costs Over the Life of the Baby Boom + Generation | $26.7 billion | $19.0 billion |
| Incremental Quality - Adjusted Life-Years (QALYs) | 707,896 | 532,200 |
| $/QALY | $37,770 | $35,700 |

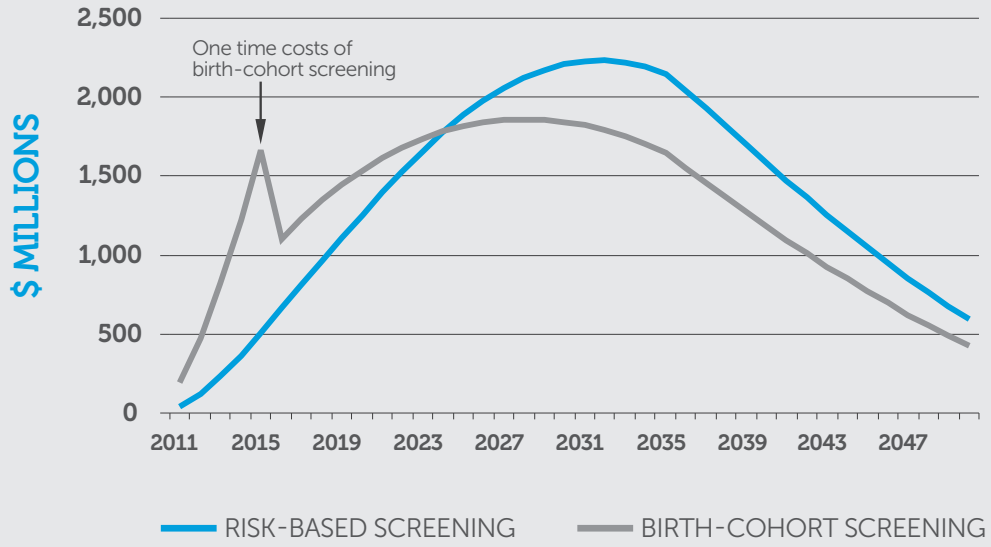
**Source:** "Economic Model of a Birth Cohort Screening Program for Hepatitis C Virus," McGarry, Pawar, Parekh, Rubin, Davis, Younossi, Capretta, O'Grady, and Weinstein, (*Hepatology*, 12/2/2011).
"The Cost-Effectiveness of Birth-Cohort Screening for Hepatitis C Antibody in U.S. Primary Care Settings," Rein, Smith, Wittenborn, Lesesne, Wagner, Roblin, Patel, Ward, and Weinbaum, *Annals of Internal Medicine*, published online 11/4/11.

Furthermore, because of the disease's unique manifestation in the baby boomer population, there is a rare opportunity to improve clinical outcomes while modestly reducing Medicare overall costs. The improved effectiveness of this new screening results in fewer serious and expensive treatments being necessary later in life. These reductions serve to reduce Medicare spending. On a present value basis, the analysis shows net spending on the population age 65 and older dropping by $200 million. Given that the vast majority of those aged 65 and older are enrolled in Medicare, the move toward birth-cohort screening results in a modest improvement in Medicare's long-term financial outlook.

Indeed, as shown in Figure 5, by 2025, the costs of screening and treatment for those ages 65 and older under the birth cohort screening protocol will start to be outweighed by reduced complications from, and thus reduced medical expenditure for, liver disease.

FIGURE 5:

**Future Annual Spending on HCV for Age 65+: Risk-Based vs. Birth-Cohort Screening**




**Source:** Unpublished tables produced in conjunction with "Economic Model for a Birth Cohort Screening Program for Hepatitis C Virus," McGarry et. al., (*Hepatology*, 12/2/2011).

Seldom in the world of health policy are both the problems and the solutions as clearly defined as they are in the fight against Hepatitis C.

- Current risk-based screening has proven ineffective at properly identifying Americans at risk for this deadly disease. The latest research shows that one time HCV screening of everyone born between 1945-1965 can significantly increase the number of cases identified early enough to prevent the worst effects of the deadly and expensive complications that come with untreated HCV.
- Spending will increase as more people are diagnosed and treated, but a significant percentage of the increase will be offset by reduced spending on cirrhosis of the liver, liver cancer, liver failure, and liver transplants.

The policy choices are clear, as the two recent studies both demonstrate. Making progress in the fight against HCV will require an investment in terms of better screening to find the patients with the disease. But if that is done, the potential clinical and quality of life benefits for the patients are significant, and well worth the cost by reasonable standards.

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