

Research shows age-based screening for the hepatitis C virus could lead to fewer cases of advanced liver disease and related deaths



### Highlights

- Researchers from OptumInsight's life sciences group conducted a study in conjunction with scientists from a number of leading academic and medical centers to evaluate the medical benefits and cost-effectiveness of screening the "baby boomer plus" generation born from 1946 to 1970 for the hepatitis C virus (HCV).
- The study comes at a time when U.S. health authorities are considering age-based or birth-cohort screening—especially for the baby boomer plus generation, the single largest demographic group perceived most at risk—and in the wake of the FDA's approval of the first two new treatments for HCV in 20 years.
- The researchers demonstrated that the additional costs of birth-cohort screening would be offset by tens of thousands of fewer cases of HCV-related liver cancer, liver transplants, and deaths—and that if the United States continues its current HCV screening practice, about one million HCV-infected residents between 40–64 years of age will remain undiagnosed.

## Background

Hepatitis Awareness Month, May 2011, produced a number of breakthroughs in the long and usually forgotten fight against hepatitis C, including:

- Approval of the first new treatments in 20 years
- An unprecedented action plan from U.S. health authorities to improve prevention and treatment
- Research results from a study by OptumInsight's life sciences group demonstrating the life-saving health benefits and cost-effectiveness of a proposed major change in screening for the disease

The U.S. Food & Drug Administration's (FDA) approval of the two new drugs, Merck & Co.'s Victrelis and Vertex Pharmaceuticals' Incivek, provides patients and providers with significant improvements to the HCV treatment regimen over the current standard of care, which has serious side effects and is limited in its effectiveness. The new drugs are "game changers" according to John Ward, MD, director for viral hepatitis at the U.S. Centers for Disease Control and Prevention (CDC). "We're going from about 40 percent clearance with current therapies or previously standard therapy to over 75 percent with the addition of one of these new drugs," Dr. Ward asserted.<sup>1</sup>

The U.S. Department of Health and Human Services' (HHS) new "Combating the Silent Epidemic" action plan seeks to improve prevention and treatment of HCV, a disease sometimes referred to as the "silent" or "hidden" epidemic because so few know they have it and so little is done to diagnose and treat it. Experts believe that up to 90 percent of people carrying HCV in the United States do not know they have the disease, which often shows no symptoms until serious, life-threatening damage has already been done.

As part of HHS' first-ever comprehensive HCV action plan, U.S. health authorities are considering age-based or birth-cohort screening, a new approach to testing for the virus that involves screening all those in a single demographic group perceived most at risk. Under current HHS guidelines, doctors only test individuals for HCV infection if they appear to be at high risk because of drug use, sexual practices, or intimacy with an infected person.

At the same time, a research team led by OptumInsight's life sciences group released a scientific study showing that screening individuals for HCV based on age rather than risk can reduce lifetime cases of, and deaths due to, advanced liver disease. The data demonstrated the medical benefits and cost-effectiveness of screening all members of the single largest demographic group in the United States with the highest HCV infection rate: members of the "baby boomer plus" generation born between 1946 and 1970.

## Challenge

The researchers from OptumInsight's life sciences group, Baylor University Medical Center, the Harvard School of Public Health, and the National Opinion Research Center at the University of Chicago faced a number of challenges. They wanted to confirm medical benefits from birth-cohort screening while also demonstrating its cost effectiveness. Those objectives, which could help support policy change and funding for a major shift in HCV testing, were also shared by Vertex Pharmaceuticals, which sponsored the independent study.

Another challenge for the researchers was estimating the size and composition of the HCV-infected population in the United States. While surveillance is conducted by the CDC and other health agencies, because HCV is asymptomatic for so long, the data is incomplete on who carries the virus, when they were infected, or how far the disease has progressed.

"We had to model our way into those estimates," said Lisa J. McGarry, director of health economics and outcomes research within OptumInsight's life sciences group and lead author of the study. "It ended up being more complicated than we expected," she added.

Many "boomers" were infected through blood transfusions that took place years before health authorities identified the hepatitis virus and started screening the blood supply. Others may have caught the virus while "experimenting" with intravenous drugs. With those days far behind them,

---

Recent breakthroughs in the fight against HCV include the approval of two new treatments, a bold action plan from U.S. health authorities to improve prevention and treatment, and research by OptumInsight™ showing tremendous benefits from a major change in screening.

---

---

The researchers needed to confirm the medical benefits and cost-effectiveness of birth-cohort screening while estimating the size and composition of the United States' HCV-infected population.

---

most boomers don't imagine they're at risk, and the stigma of having contracted HCV as a "drug user" discourages them from discussing past behavior with their doctors. Because HCV causes few or no symptoms for years or decades, they don't think to see a specialist until they begin to suffer from liver damage caused by long-term exposure to the virus. Experts recognize that stigma severely limits testing and treatment while also fostering the spread of the virus. HHS' new action plan is committed to raising public awareness and reducing stigma.

"Every person living with hepatitis C would benefit from knowing it, so that they don't unknowingly transmit it to others," said Dr. Ward, the CDC viral hepatitis expert who helped develop the HHS HCV plan. In addition to curbing transmission, better screening would improve care because patients are easier to treat—especially with the new, better drug regimens—before the liver is damaged by chronic inflammation and scarring, known as cirrhosis. As many as 30 percent of infected individuals develop cirrhosis, and anywhere from 1 to 4 percent of those patients go on to develop liver cancer. Seeking to halt this perilous cascade are health officials like Dr. Ward, who warned that patients "should be in care so that they understand what they can do to protect their livers."<sup>2</sup>

## Solution

In order to predict the impact of changing to birth-cohort screening and overcome the challenges of doing so, the researchers turned to scientific modeling. They simulated the "natural history" of HCV with the aid of a mathematical technique called a Markov model. The inputs were synthesized from surveillance data, published literature, expert opinion, and other secondary sources. The researchers estimated that there are 102 million people in the "boomer plus" target cohort, of whom 1.6 million are infected with HCV and undiagnosed. They modeled both the costs and health outcomes of the new age-based screening strategy over the life of the birth cohort, and compared the results to the current risk-based approach.

The researchers ran their model to evaluate how the birth-cohort screening and subsequent treatment with the then-current standard of care (pegylated interferon and ribavirin) would affect progression to advanced liver disease and mortality. Then, as those initial results were being analyzed, the researchers proceeded to re-run the study using the new, more-effective treatment regimens based on the Merck and Vertex drugs, which dramatically improve treatment and patient outcomes.

## Results

The final results of OptumInsight's study showed that while birth-cohort screening would cost an additional \$37,700 per quality-adjusted life year gained<sup>3</sup> compared to risk-based screening, improved birth-cohort screening would result in 46,000 fewer cases of HCV-related liver cancer, 10,000 fewer liver transplants, and 78,000 fewer deaths.

The study results demonstrate that if the United States continues its current HCV screening practice, about one million HCV-infected U.S. residents between the ages of 40 and 64 will remain undiagnosed. Most of them will progress to advanced liver disease, and many will die. Simply changing to testing "boomers" in a birth-cohort screening program could change that. Moreover, the shift to birth-cohort screening would be cost-effective at a level considered acceptable in the United States: less than \$50,000 per quality-adjusted life year gained.

Scientists from OptumInsight's life sciences group and other researchers presented initial study results at the Digestive Disease Week 2011 conference in Chicago on May 8, 2011, and the final results are to be published in an upcoming issue of *Hepatology*. Medical reporters and others have recognized that the study has significant cost and public-health implications. To date, the study has been covered by Bloomberg, *The Hartford Business Journal*, *Internal Medicine News*, Medscape, WebMD, and MedPage, and the news release has been picked up by many other outlets. The coverage has helped raise awareness of the potential for birth-cohort screening among key stakeholders, including the CDC.

---

Using a Markov model to simulate the "natural history" of HCV, the researchers evaluated how birth-cohort screening and subsequent treatment would affect progression to advanced liver disease and mortality.

---

---

The study showed that the additional costs of birth-cohort screening are offset by tens of thousands of fewer cases of HCV-related liver cancer, liver transplants, and deaths, as numerous media outlets have reported since the researchers' initial presentation of their findings.

---

## Implications

The research led by OptumInsight's life sciences group provides the first quantitative validation for HCV screening of the baby boomer plus generation, which carries the heaviest burden of this disease. If broadly implemented, birth-cohort screening could save lives and improve patient quality of life.

In 2010, a report from the National Academies' Institute of Medicine (IOM) found that HCV is not widely recognized as a serious public health problem, and that the current approach to the prevention and control of chronic hepatitis C (as well as hepatitis B) is not working. While the IOM report did not support birth-cohort screening, it did state that "it will be necessary to expand screening programs to identify those who are infected and help them find medical services."

According to the leading liver-disease medical group, the American Association for the Study of Liver Diseases (AASLD), the new Patient Protection and Affordable Care Act (ACA) will "provide the opportunity to expand preventive health services, which could include screenings for HBV and HCV if [HHS] takes action to define these screenings as a benefit under Medicare." The AASLD also sees benefits from increased access to screening resulting from the ACA for 32 million Americans who were previously uninsured.

A number of stakeholders are exploring the potential benefits of birth-cohort screening. The CDC has two separate studies of its own underway exploring the merits of such testing. One study is analyzing existing data to determine the cost-effectiveness of current risk-based screening. The other CDC study will conduct prospective HCV testing of individuals born from 1945 to 1965 and compare the findings with the risk-based data. The CDC Foundation is supporting an initiative with a leading patient advocacy and support group, the Viral Hepatitis Action Coalition, to gauge the merits of birth-cohort screening.

The CDC has indicated it plans to update its recommendations for the prevention and control of HCV based on all of the latest research. The U.S. Preventive Services Task Force advises the CDC on such matters, and its chair, Virginia Moyer, MD, told WebMD the study by OptumInsight's life sciences group offers "the kind of evidence that might help us move forward with an update" of recommendations on HCV testing that she acknowledges have not been revised in five years.<sup>4</sup>

The OptumInsight study, according to researchers, reinforces the benefits of broad-based earlier detection. Lead researcher McGarry concluded, "Once you have advanced liver disease, treatment is much less likely to benefit you."

## About OptumInsight

OptumInsight is part of Optum™, a leading health services business dedicated to making the health system work better for everyone. OptumInsight specializes in improving the performance of the health system by providing analytics, technology, and consulting services that enable better decisions and results.

<sup>1</sup> <http://www.wbur.org/npr/137347068/new-drugs-offer-hope-for-hepatitis-c-sufferers>

<sup>2</sup> *Ibid.*

<sup>3</sup> *Quality-adjusted life year* refers to units of measure of utility which combine life years gained as a result of health interventions/health care programs with a judgment about the quality of these life years. Source: National Information Center on Health Services Research and Health Care Technology (NICHSR), "Glossary of Frequently Encountered Terms in Health Economics," <http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html>

<sup>4</sup> <http://www.webmd.com/hepatitis/news/20110509/experts-propose-age-based-hepatitis-c-testing>

---

The OptumInsight study provides the first quantitative validation for HCV screening of the baby boomer plus generation—a measure that, if implemented, could save lives and improve quality of life for thousands of individuals. The CDC, which has two separate studies of its own underway exploring the merits of such testing, is expected to update its recommendations for the prevention and control of HCV based on all the latest research.

---

---

Learn more about how OptumInsight can help your organization address the changing global economic and regulatory competitive landscape by identifying, analyzing, and measuring the value of your life sciences products.

Contact us at **866.306.1321** or **connected@optum.com**.



13625 Technology Drive, Eden Prairie, MN 55344

Optum and its respective marks are trademarks of Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners. Because we are continuously improving our products and services, Optum reserves the right to change specifications without prior notice. Optum is an equal opportunity employer.

11-26990 09/11 © 2011 Optum. All Rights Reserved.