

“The Gray Sheet”

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HCV Screening To Skyrocket? CDC Now Recommends It For All Baby Boomers

By David Filmore / [Email the Author](#) / [“The Gray Sheet” Aug. 20, 2012, Vol. 38, No. 34](#)

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Executive Summary

Centers for Disease Control and Prevention says all U.S. baby boomers, no matter their risk status, should be screened for hepatitis C. Doing so could prompt a big increase in testing volume, but it will take some time.

Millions more hepatitis C screening tests would be performed if new recommendations from the Centers for Disease Control and Prevention are successfully implemented, although the process could take some time.

All U.S. baby boomers, no matter their risk status, should be screened for hepatitis C virus, CDC says in an Aug. 16 [report](#) finalizing a proposal released in May. That is a major expansion from prior CDC recommendations, which urged HCV screening only for individuals with specific risk factors, such as prior injection of illegal drugs, HIV infection or having had a blood transfusion prior to universal adoption of donor HCV screening.

The prior recommendations have not been successful, CDC believes, in part because many people are not aware of their risk factors, or do not remember or may not want to discuss risk factors with health care providers.

Most of the 2.7 million to 3.9 million Americans living with HCV do not know that they are infected. The new guidelines emphasize the broader segment of the population where the virus is, by far, most pronounced: those born between 1945 and 1965. The baby boomers account for about three-quarters of all chronic HCV infection among adults in the U.S.

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Up to about 15 million people might reasonably be screened under the prior risk-based recommendations, CDC researchers estimate, although actual screening volumes are less. By comparison, about 60 million HCV antibody tests might be administered if the new guidelines are fully implemented, the scientists estimate. As a result of the additional screening, about 120,000 HCV-related deaths would be averted, they predict.

The potential for a substantial rise in screening volumes could be a boon for test makers, in particular [OraSure Technologies Inc.](#), which makes the only FDA-approved and CLIA-waived rapid, point-of-care HCV antibody test (*OraQuick HCV*).

"We applaud the CDC for issuing this call to action, and we stand ready to work in collaboration with our government, industry, community and health care partners to help ensure that all Americans at risk for HCV have access to testing," said Douglas Michels, CEO of OraSure.

HCV antibodies can also be detected by slower-turnaround, lab-based tests, but a point-of-care option "can play a critical role in expanding testing opportunities and facilitating immediate care for those diagnosed with HCV," said Eugene Schiff, a professor of medicine at the University of Miami and VP of the Chronic Liver Disease Foundation, in a statement circulated by OraSure.

OraSure is already working with public health clinics to incorporate its rapid HCV assay, FDA-approved in 2010, into testing environments. Many of the facilities already employ the firm's rapid HIV screening test, which uses the same platform as the HCV assay. Stephen Lee, the firm's chief science officer, says the CDC recommendations will add momentum to that effort, as well as broaden adoption in the private sector. But, he cautions, the impact will not be immediate.

"In terms of the speed of adoption, it is difficult to say," Lee said in an interview. "In general, adoption of these types of guidelines from CDC takes some time. Frankly [it takes time] for the clinicians in the medical community to respond to them."

Even among people that clearly fit in the high-risk categories previously targeted for HCV screening, antibody testing only takes place in anywhere from 17% to 87% of individuals, depending on the circumstances, according to CDC.

Inadequate insurance coverage and limited access to regular health care are primary barriers to screening, as is a lack of knowledge of hepatitis among many health care providers, the agency says.

CDC says it will conduct "demonstration projects" to help expand access to HCV testing and surveys to evaluate implementation of its recommendations.

Schiff suspects that clinicians will get on board with the new recommendations

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over the next few years, noting in an interview that a significant barrier to screening has now been removed - namely the need for physicians to probe into a patient's HCV-risk history.

"You don't want to have a situation where you have to sit down and explain what these tests are, etc. If you do, it won't be done by primary care doctors," Schiff said. "They don't have the time."

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