CDC's Recommendations for One-time Hepatitis C Virus Testing for Persons Born During 1945–1965: Public Health’s Role and Key Elements for Effective Implementation
Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965

The recently issued CDC recommendations for HCV testing\(^1\) are intended to augment the “Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease” issued by CDC in 1998. In addition to testing adults of all ages at risk for HCV infection (e.g., injection-drug use, needlestick injuries), CDC recommends that:

- Adults born during 1945-1965 should receive one-time testing for HCV without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence).
- All persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions (Strong Recommendation, Moderate Quality of Evidence).

Why a New Recommendation?

HCV can result in chronic infection that often remains clinically silent for decades while increasing risk for liver disease and liver cancer, which can be severe or even fatal. It is important for those infected to be aware of their status so they can be linked to care and take appropriate actions to limit further spread of the virus. However, most of the 3.2 million Americans chronically infected with HCV do not know it, in spite of risk-based screening strategies\(^i\).

For a number of reasons, risk-based screening can miss those unaware of their transmission risks and those with risks in the distant past. Because persons born during 1945-1965 account for three-fourths of all U.S. HCV infections and 73 percent of HCV-associated mortality, CDC recommends that all persons in this birth cohort get tested for HCV infection one time without prior ascertainment of HCV risk. This testing strategy, if fully implemented, would identify 800,000 previously undiagnosed cases and avert 120,000 deaths.

Improved Treatment Options

As HCV-associated morbidity rises, we are also seeing an increasing capacity to address the burden of HCV disease. Understanding of HCV’s natural history and monitoring and treatment options have improved over time. Development of antiviral drugs for HCV is accelerating; recently-approved protease inhibitors have significantly increased rates of viral clearance (when either drug is used in combination with standard pegylated interferon and ribavirin regimens). All-oral regimens are now on the horizon, and, coupled with Affordable Care Act implementation, should increase access to antiviral treatment and mitigate some of the barriers associated with interferon use (e.g., treatment toxicity, complexity of management). Even with currently available triple drug therapy, the average duration of treatment required to achieve sustained virologic response (SVR) is decreasing. SVR—viral clearance—is associated with significantly improved patient outcomes, including decreased incidence of hepatocellular carcinoma and all-cause mortality. Not all patients require antiviral treatment, and many for whom treatment is not currently the best option can be monitored as they receive other clinical prevention services (e.g., counseling to abstain from or decrease alcohol consumption, getting vaccinated for hepatitis A and B as needed). However, early diagnosis and evaluation are critical, as those with treatment indications will respond less favorably if therapy is delayed. Many patients currently have advanced disease, and as the baby boomer cohort ages, more adverse health outcomes are expected. We cannot delay our public health response.

For these reasons, CDC and the Association of State and Territorial Health Officials (ASTHO) are developing a public health approach to implement the birth-cohort-based HCV testing recommendations.

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\(^{i}\) Public health can learn from experiences in implementing routine HIV screening. The U.S. Preventive Services Task Force evidence review on routine HIV screening can be accessed here: http://www.uspreventiveservicestaskforce.org/uspstf13/hiv/hivadultart.htm.
This includes: increasing awareness of the recommendations within the public health, provider, and payer communities; identifying the public health role in expanding screening and linkage to care; and developing tools. To inform development of the key elements and actions necessary for effective implementation, CDC and ASTHO convened a public health panel on Feb. 11, 2013, that included local, state, and federal public health experts and partners (see Acknowledgements). The meeting:

1. Provided an overview of HCV epidemiology and screening recommendations.
2. Shared best practices from health department viral hepatitis programs.
3. Identified potential barriers and facilitators to implementation.
4. Identified tools needed to support implementation.

This meeting report summarizes the ideas, recommendations, and needs identified by panel participants.

**Elements of Implementation: HCV Testing, Surveillance, Education, and Collaborations in Care**

Most of the 10 Essential Public Health Services correspond to the key elements of implementation of CDC’s HCV recommendations (including testing, surveillance, education, and collaborations in care). Implementation of these elements happens in the states, and we use them as examples and can learn from their experiences. The table below includes some of the barriers, facilitators, and tools identified by participants in the public health panel:

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<tr>
<th>BARRIERS</th>
<th>FACILITATORS</th>
<th>TOOLS</th>
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<tr>
<td><strong>Testing</strong></td>
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<td>• A recent article estimated that if a primary care provider did all recommended screenings it would take 7.4 hours each day.²</td>
<td>• There is some existing integration with HIV testing programs.</td>
<td>• Routine testing laws—NY has a bill pending, modeled on the HIV routine testing law, which would require the offer of HCV testing to baby boomers.</td>
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<td>• Most state labs do HCV testing in-house and report some excess capacity.</td>
<td>• Lab Efficiencies Initiative, which includes component to help labs bill.</td>
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<td>• The 2013 U.S. Preventive Services Task Force (USPSTF) recommenda-</td>
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<td>tion could lead to development of quality measures and clinical decision support.³ The similar CDC and USPSTF recommendations strengthen the SHO &quot;bully pulpit&quot; and a call for local action.</td>
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<td><strong>Surveillance</strong></td>
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<td>• Limited resources at the state or federal level for hepatitis surveillance.</td>
<td>• Other data sources such as cancer registries, National Health and Nutrition Examination Survey (NHANES), vital records, and BioSense.</td>
<td>• Agreements with labs and payers for automated electronic reporting.</td>
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<td>• Lab reporting generates high volume of cases, but states have limited capacity for data entry or followup.</td>
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¹ On June 25, 2013, USPSTF issued its final recommendations on Screening for Hepatitis C Virus Infection in Adults, which include screening for HCV infection in persons at high risk for infection and offering one-time screening for HCV infection to adults born between 1945 and 1965 (http://www.uspreventiveservicestaskforce.org/uspstf/usphepc.htm).
BARRIERS | FACILITATORS | TOOLS
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**Education**
- The field is rapidly changing and it is difficult to stay up to date.
- Providers are overwhelmed with information.
- Integration with other educational efforts and comprehensive harm reduction.
- AIDS Education and Training Centers are an established resource.
- CDC developed sample press releases and other communications tools.
- University of Alabama at Birmingham and University of Washington curriculum/continuing medical education (CME) for providers.

**Collaborations in Care**
- The current turnaround for Infectious Diseases Society of America/American Association for the Study of Liver Diseases guidelines is 18 months.
- Public health and primary care have health information technology needs.
- Fits with requirements for patient-centered medical home certification.
- Baby boomers often have access to primary care.
- Treatment options for HCV continue to improve.
- Project ECHO can be used to link specialists and primary care.

**Testing**

When expanding HCV testing to baby boomer populations, it is critical to ensure that HCV ribonucleic acid (RNA) testing is conducted for all persons who test HCV antibody-positive. A positive antibody test alone is insufficient to differentiate current (active) infection (i.e., viremia) from past resolved infection. Rapid point of care testing for HCV antibody is now available, and some sites choose to utilize these tests, which allow onsite detection of antibodies within minutes. If the antibody test is positive, the site should immediately collect a specimen of venous blood for HCV RNA testing, with follow up at a subsequent visit.

**FIGURE.** Recommended testing sequence for identifying current hepatitis C virus (HCV) infection

*For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

†To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.


* In May 2013, CDC published updated guidance on HCV testing for clinicians and laboratorians, including a simplified algorithm to help ensure that any reactive HCV antibody test result is followed by a test to detect HCV RNA, which indicates current HCV infection (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm).
Capacity is also an essential consideration. Surveys by the Association of Public Health Laboratories (APHL) and the National Alliance of State and Territorial AIDS Directors (NASTAD) provide an understanding of state laboratory and health department capacity, respectively, to implement expanded HCV testing.

The 2012 APHL survey found that more than half of state labs (24 out of 32 respondents) do HCV testing in-house, with only a small number doing nucleic acid testing (7). The volume ranges widely, from eight to 60,000 tests per year. There is some excess capacity, with underutilized equipment. The equipment is designed for high throughput, and the labs estimate they could test 50-100 more samples each day with adequate reimbursement and supplies. State labs can perform a reference lab role (e.g., confirmatory testing, genotyping). Some labs already have strong links to health information exchanges, and others are working on it. Labs are billing Medicare and Medicaid, but only a few are billing private insurance. The Laboratory Efficiencies Initiative includes a component to help state labs develop billing.

The 2011 NASTAD survey found that about 20 state health departments support HCV testing, mostly in community-based organizations, sexually transmitted disease (STD) clinics, corrections, and substance abuse treatment settings. The health departments provided 85,000-90,000 screening tests and 3,000 confirmatory tests that year. Testing is often conducted in coordination with HIV testing, and funding comes from multiple sources, including federal, state, and local funds.

In some states, carry-forward funds were also used; for example, when a viral hepatitis prevention coordinator position was temporarily vacant in one state, the remaining funds were repurposed for testing. In addition, some state funds were available for testing. Fifteen percent of respondents are currently doing birth cohort testing, and an additional 20 percent plan to in the next year.

**Surveillance**

CDC builds a composite of different data sources for a picture of HCV in the United States. The National Notifiable Diseases Surveillance System does not meet CDC’s needs for chronic hepatitis surveillance because chronic HCV is not reportable in most states, but enhanced state surveillance sites collect additional information. NHANES can collect data on hospitalizations, transplants, and mortality. CDC collaborates with the state public health labs and the BioSense program to obtain testing data and plans to partner with pharmacies to track usage of new drugs.

In most states, limited or nonexistent resources are available for surveillance. For example, Arkansas lacks dedicated funding for hepatitis surveillance. The state has an estimated 34,000 people living with HCV, but only 290 cases in its surveillance system. To examine HCV burden, the health department harnessed other surveillance capacity. A CDC/Council of State and Territorial Epidemiologists fellow is reviewing lab reports, and an MPH student is doing data entry. In 2006-2008, Arkansas did a “mini-NHANES” study; Blue Cross covered the cost to test 14,000 samples for HCV and add three HCV questions to the survey. The study found a 2 percent prevalence rate, with more than one third of those affected lacking health insurance (with Affordable Care Act Implementation, this number should improve). In this rural state, the majority of people live nowhere near HCV treatment sites.

Without increased funding, states need ways to integrate. According to a NASTAD survey, on a given day there were approximately 150,000 HCV lab slips in health departments, without staff capacity to enter them or conduct followup. There is opportunity for collaboration within health departments (e.g., 10 percent of HIV prevention funds can be used for integrated screening). States can also partner with industry; for example, companies have donated rapid test kits for use in high-volume areas.
As testing expands, surveillance is an important health department role that cannot be compromised.

**Florida: Support for HCV Testing in Local Health Departments**

In the past five years, state hepatitis program funding has declined 55 percent, but the health department has used a number of approaches to support HCV testing. Lessons learned include:

- HCV testing is often integrated with other services at the local level, which is especially successful in rural areas where one nurse provides all services.
- Linkage to care is the most difficult thing. Health centers refer patients to the health department, which provides hepatitis A and B vaccine, counseling, and support groups.
- Engaging providers and the community is critical. The health department developed a trifold brochure to educate providers and convenes a Viral Hepatitis Council, modeled after HIV community planning.

Surveillance generates the necessary data to compel primary care engagement. Such surveillance should include quality of care and performance measures. We need a national health information technology infrastructure, with lab-to-lab exchange (e.g., influenza surveillance) and use of information from electronic medical records. There is an opportunity to cross-fertilize with informatics, by working with trained staff in hospitals or insurance companies to learn what data they have and how it might contribute to surveillance. A better way must be found to capture relevant data and to use it most effectively (e.g., create hierarchy for disease investigation). North Carolina’s collaboration with LabCorp for automated reporting shows the value of partnerships with the private sector. The numbers are overwhelming for case-based reporting, but if messaging can be optimized to surveillance systems, electronic lab reporting shows promise for identifying who is in care and their clinical outcomes.

**Massachusetts: Using State and Local HCV Surveillance Data for Policy Development**

The MAVEN (Massachusetts Virtual Epidemiologic Network) disease reporting system is integrated with electronic lab reporting and with some medical record systems. With automated reporting, the volume of HCV cases is high. There is a need to triage the cases so that local health departments can conduct further investigation. Through a vital records match, Massachusetts found about 10 percent all-cause mortality for persons diagnosed with HCV. There is a disparity between HCV and HIV all-cause mortality within three years of diagnosis (616 and 75 deaths, respectively), which indicates that persons with HCV are getting into care late in their disease. Surveillance also identified an alarming increase in cases among youth, which are recent exposures. The health department uses such data to inform policy (e.g., integration with HIV services); it is also used for planning by the Massachusetts Viral Hepatitis Coalition.

**Education**

CDC has developed an array of communications materials to educate providers and consumers. Materials include TV/digital public service announcements (PSAs), radio PSAs, airport dioramas, website buttons, an infographic, “snackable” Twitter content, posters, and manuals for providers where high risk patients are served. CDC also partnered with academic institutions to develop curriculum and CME opportunities. The University of Alabama at Birmingham will provide distance education for frontline providers, with a curriculum that encompasses common competency domains. The University of Washington will offer an online case-based curriculum covering prevention, management, and treatment. A CDC focus group of providers found that written summaries of recommendations are helpful and persuasive, especially when they contain data on the number of undetected cases and cost savings. However, some providers
expressed resistance to implementing the expanded testing recommendations due to lack of insurance coverage.

Health departments can engage on this issue by hosting events such as testing days. Being nimble at including new information is a challenge, as the field is changing so rapidly. Providers receive a great many emails, and public health leadership should be sensitive to that reality. Health center providers, for example, would prefer a pull system where they can go somewhere to access information and would benefit from access to a single summary of all cutting-edge clinical guidelines instead of many separate guidelines. They rely on CDC as a primary source of information. We should consider public/private partnerships and using technology platforms to disseminate information (e.g., apps). Clinical decision prompts can also be developed to educate providers (e.g., a prompt in the electronic medical record to test for HCV based on date of birth; prompts to avoid unnecessarily ordering the “hepatitis panel”).

**Minnesota: Initiatives for HCV Education Among Health Professionals**

Minnesota has limited hepatitis funding and hepatitis activities are fully integrated with its HIV program. The annual Viral Hepatitis Symposium is linked with the AIDS Education Training Center and provides continuing nursing education. It highlights the latest developments in hepatitis and also includes messages about HIV and STDs. Minnesota is moving toward a comprehensive harm reduction approach. There are also regional and tribal events, such as the HCV and Harm Reduction Tribal Summit—the first in the nation. The White Earth Nation has an HCV coalition that was ratified by the tribal government. The White Earth Nation doubled baby boomer screening since the recommendation was released even though they are addressing other health issues. The White Earth Nation identified 51 HCV cases in 2012 (67 percent were boomers) vs. six in 2008. Minnesota plans to integrate baby boomer testing with the successful approaches the state has built for risk-based testing.

**Collaborations in Care**

When implementing expanded testing, public health can ensure HCV care through collaboration with partners such as community health centers. Community health centers are architects of a system of care that integrates primary care and public health. Such integration requires a common aim and common outcomes; to support thoughtful integration, public health leaders can join the boards of community health centers.

There are needs (e.g., IT infrastructure) and opportunities (e.g., patient-centered medical home certification) that should be recognized when building partnerships with community health centers. For example, during the past 30 to 40 years, Massachusetts has mainly relied on community health centers, not public clinics. When Massachusetts closed their STD clinics, the state found that patients started going to primary care and safety net providers. Other states can learn from this experience as they implement health reform.

Washington state is trying to find ways to align infectious disease work, move out of disease-specific silos, and move toward a functional model. This effort is part of the state’s “agenda for change” action plan. With alignment, the health department can consider issues such as: should county health departments be chasing down every case of chlamydia or should they make room for HCV work? The state’s health department is working on partnership, workforce, skills development (e.g., understanding healthcare delivery and billing), and policy development.
Washington: Partnerships with the Healthcare Delivery System to Influence Screening and Linkage to Care

Washington state saw the HHS Viral Hepatitis Action Plan as an opportunity to reframe its state program. Health department leadership supports realignment and integration. Because the health department has limited resources for HCV, the program developed guiding principles for integration with HIV services and engages systems with the greatest expertise (e.g., community health centers [CHCs]). The program integration with HIV generated savings, which allowed the state to fund a demonstration project with Harborview Medical Center that includes baby boomer testing. Washington was also able to fund an expansion of the telemedicine Project ECHO to an urban, underserved setting. This expansion has served 429 new patients and is cost-effective.

With Program Collaboration and Service Integration, CDC funds also allow for flexibility. But hepatitis is organizationally located in many places in state health departments, not just in programs funded by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

We can learn from the HIV program goals to simplify and support. The HCV baby boomer recommendations simplify who to test, and the new therapies will simplify treatment. Baby boomers often have access to primary care and may be in specialty care. But often those with elevated alanine aminotransferase are not tested (40-50 percent of abnormal liver function tests are not followed up with hepatitis screening). We can coordinate with chronic disease programs and information in existing medical databases (30 percent of male baby boomers are on statins and have liver tests every year). In primary care, a person with HCV can be monitored for hepatocellular carcinoma and counseled to reduce their alcohol intake and lose weight, even before treatment. Now, patients often do not find out about their hepatitis infection until they present with liver cancer. It is important to empower primary care providers in what they can do. Clinics that do a good job with screening have performance measures, links to specialty care, and professional education. The Veterans Affairs and Ryan White clinics have strong wraparound services.

We also need to consider how to link specialists and primary care (e.g., the telemedicine Project ECHO) and how to build care models to support primary care. Lack of infrastructure is the biggest barrier, in spite of the available science. We need more treating specialists and primary care providers who are able to effectively diagnose, refer, and collaborate in providing care. We should ensure that there are referral resources and involve greater numbers of gastroenterologists and infectious disease physicians in HCV care. Currently, there are approximately 2,000 hepatologists, 6,000 infectious disease physicians, and 12,000 gastroenterologists in the country.

The Public Health Approach to Implementation

Public health leadership can support the key elements of implementation (testing, surveillance, education, and collaborations in care) for the CDC recommendations by:

- Increasing awareness of the recommendations within the public health, provider, and payer communities.
- Identifying the public health role in expanding screening and linkage to care.
- Developing tools to support implementation.

In the following sections, ASTHO provides tips and next steps identified by panel participants to operationalize these three recommendations to achieve greatest impact.
The Role of Public Health Leadership

Public health leaders can elevate the importance of the testing recommendations through a number of channels, such as interaction with the media, testifying at the legislature, and communication with health professionals. There are many lessons from the 2009-2010 H1N1 influenza pandemic response on how to use the health official’s “bully pulpit” for effective communication. There is a lag time between recommendations and standard setting, and communications from health officials can begin to reduce this. Radio stations and local television channels are often willing to provide air time for health officials. Health officials should use the media proactively, not just in response to an emergency.

It is important to make the connection between what the health department is doing and best practices for providers. There is a level of training required for providers (e.g., selecting the right type of test), and the role of training centers will be important. If the numbers of recognized HCV cases increase greatly in the two to three years, do we have the capacity for those in whom treatment is indicated? Where do we want this capacity built? How will it be funded? Health officials can promote infrastructure strengthening and education of the public health and healthcare workforce.

Health officials are positioned to broker relationships and drive collaboration. CDC and the states have reorganized to integrate viral hepatitis with HIV and STDs, but health officials also need to reach out to other public health programs (e.g., chronic disease) and across sectors. Many public health initiatives, such as workplace wellness programs, reach the baby boomer population.

Tips

✓ When bad situations are identified in the media (e.g., outbreaks), turn them into positive action.
✓ Package your message about HCV with other complementary priorities.
✓ Use the new recommendations as a springboard for other recommendations.
✓ Consider creative messaging to target baby boomers, like linking HCV screening with other issues of aging.
✓ Use your voice as a credible source of information for providers. Consider opportunities like grand rounds presentations, publications, and provider letters to raise awareness of the recommendations.
✓ Recognize that when you send letters, you need to follow up. When you think you have communicated, do it 10 times more.
✓ All politics is local. Work with city/county health officers, medical associations, and leadership of healthcare facilities and health plans to encourage implementation of the CDC recommendations.
✓ Provide the local context. Create a compelling story about the importance of HCV testing by matching surveillance data with mortality records, the cancer registry, all payers database, and other sources.
✓ Think about other opportunities, such as governors or health officials who are baby boomers publicly getting an HCV test.
Next Steps for Public Health Leadership

Public health leaders can ensure the baby boomer testing recommendation is widely communicated among providers and patients in their jurisdictions. To facilitate communications strategies, CDC and ASTHO developed a toolkit with resources such as talking points for a radio program, prepared slides for talks, op-eds, press releases, and a dear provider letter.

Leadership can also support a comprehensive approach to prevention, by ensuring good surveillance to identify groups at high risk for new transmissions (e.g., young injection drug users) while also highlighting the baby boomer population at most immediate risk for disease progression. In addition, many of the barriers and opportunities for viral hepatitis programs reflect the broader transformation in public health and healthcare. Public health leadership on these issues can support viral hepatitis programs, while also advancing core public health goals:

- Align with ASTHO’s ongoing work on integration of public health and primary care. More information is available at http://www.astho.org/Programs/Infectious-Disease/Integration/Public-Health-and-Primary-Care-Integration/.
- Align with chronic disease initiatives (e.g., link the test to colorectal cancer screening, coordinate with workplace wellness programs) and partners (e.g., local American Cancer Society chapters).
- Consider how to link specialists and primary care (e.g., Project ECHO) and build care models to support primary care.
- Empower primary care providers in what they can do to improve HCV outcomes (e.g., alcohol and weight reduction counseling).
- Identify “carrots” to offer private providers.
- Engage systems with the greatest capacity and expertise (e.g., CHCs).
- Leverage HIV funding and support realignment.
- Collect input from the field on workforce needs and core public health priorities.
- Strengthen surveillance and public health informatics (e.g., convene subject matter experts to design the right-sized HCV surveillance system).
- Develop analytic resources and population health statistics (data to drive policy).
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References


ASTHO Hepatitis C Communications Toolkit

This new web-based communications toolkit provides information and tools to help state and territorial health officials communicate about CDC’s HCV testing recommendations with both healthcare providers and the public. Access sample op-eds, talking points, and training materials, as well as clinical guidelines, testing recommendations, and presentation videos from the meeting summarized in this report. The toolkit is available at http://www.astho.org/Hepatitis/.