News from the CDC: Translating science into HCV infection screening recommendations

Rebecca L Morgan, MPH, Bryce D Smith, PhD, Geoff A Beckett, PA-C, MPH

Centers for Disease Control and Prevention, Atlanta, GA, USA
Correspondence to: R L Morgan
evf5@cdc.gov

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Hepatitis C virus (HCV) infects an estimated 3.2 million persons in the U.S. [1]. Recent estimates indicate that in 2007, the mortality rate of HCV was 4.6 deaths per 100,000 population (n=15,106) [2]. Chronic HCV is a leading cause of hepatocellular carcinoma and its complications are a leading indication for liver transplantation [3, 4]. In addition, an estimated 39% to 85% of infected persons are unaware of their status [5, 6].

The National Health and Nutrition Examination Survey (NHANES), a national, multistage probability cluster sample of the U.S. civilian, noninstitutionalized population, collects information on HCV infection. Based on analyses of NHANES data published over the last decade [1], a birth cohort of persons with comparatively higher prevalence of HCV infection was identified. Persons born from 1945 through 1964 account for an estimated 65.6% of all persons infected with HCV [1]. The estimated prevalence of HCV infection in this birth cohort is 2.2 million.

In 2010, the Institute of Medicine published a national strategy for the prevention and control of HCV and hepatitis B virus (HBV) [7]. In response, the Department of Health and Human Services (HHS) issued an action plan for the prevention, care and treatment of viral hepatitis [8]. The HHS Action Plan contains specific strategies and screening recommendations including: implementing routine HCV testing of all persons for whom it is recommended as part of standard of care in a reformed health care system and improving linkage to care and treatment for HCV-infected persons. In 1998, the Centers for Disease Control and Prevention (CDC) published recommendations for HCV screening among persons with behaviors, exposures, or clinically-defined risk indicators [9], which included: (1) persons who have ever injected drugs; (2) persons who received clotting factor concentrates produced before 1987, were ever on long-term hemodialysis, or had persistently abnormal alanine aminotransferase levels; (3) recipients of transfusions or organ transplants prior to July 1992; (4) healthcare workers after occupational exposures; and (5) children born to HCV-infected women.

Following more than a decade of scientific advances, the Division of Viral Hepatitis (DVH) is updating the 1998 recommendations through a two-stage process. The first stage will focus on developing target screening recommendations that can effectively target persons born from 1945 through 1965, a demographic that, as noted below, includes almost two-thirds of prevalent HCV infections. The second stage will entail a comprehensive update of the 1998 recommendations for HCV screening and prevention. Guidance will be targeted to clinicians and to professionals and agencies implementing HCV screening programs in community health centers, through health departments, and in other venues.

To examine the evidence for a birth cohort screening strategy, DVH conducted a systematic review of HCV prevalence among persons born from 1945 through 1965. Seven databases were searched to capture peer-reviewed and grey literature from 1995 through 2011 including EMBASE, PubMed, and Cochrane. In addition to conducting a systematic review, DVH adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology for the development of these recommendations. GRADE provides standards for a rigorous, systematic and transparent approach to the development of recommendations in two parts: evaluating the quality of the evidence and assessing the strength of the recommendations.

To lead and to provide input throughout the process, three advisory groups were developed: a DVH steering committee, a CDC Internal Work Group, and an External Work Group. The DVH Steering Committee, working with a GRADE methodology consultant, led the process, conducted the systematic reviews, and assessed the quality of the evidence. The Internal Work Group consisted of staff from all divisional units (e.g., i.e., Laboratory Branch, Epidemiology and Surveillance Branch, and Prevention Branch) of DVH. The External Work Group included representatives from federal agencies (e.g., Department of Veterans Affairs, Substance Abuse and Mental Health Services Administration), primary care provider organizations (e.g., American Medical Association,

American Academy of Family Physicians), state and city health departments and advocacy groups (e.g., Adult Viral Hepatitis Prevention Coordinators, National Viral Hepatitis Roundtable), and medical specialty organizations (e.g., American Association for the Study of Liver Diseases, American Gastroenterological Association). Other experts including hepatologists, economists and guideline methodologists also participated.

The Internal and External Work Groups were involved from the inception of the birth cohort guidelines development process through regular teleconferences, in-person meetings and a half-day GRADE workshop. All members disclosed academic and financial conflicts of interest using an established form from the International Committee of Medical Journal Editors (http://www.icmje.org/coi_disclosure.pdf). Both work groups provided input and reviewed the scope, key questions, analytic framework, outcomes, systematic review methods and findings.

Summaries of the findings from the systematic review and the results of earlier work group determinations of evidence on patient-important outcomes were presented at a two-day consultation with members of both work groups in August 2011. Internal and External Work Group members reached a consensus on the strength of the recommendations by discussing the quality of available evidence, benefits versus harms, values and preferences, and cost implications.

The drafted recommendations document is currently undergoing the Office of Management and Budget's Peer Review, CDC clearance, and public comment, which will allow input from the public at large. Publication of the birth cohort recommendation is expected in the Morbidity and Mortality Weekly Report (Recommendations and Reports) in 2012. In an effort to translate the recommendations into practice, dissemination, implementation, and evaluation activities will follow the release of the

recommendations. Ongoing activities include the Know More Hepatitis campaign and the development of testing and counseling modules. These recommendations will be updated based on evaluation findings and new scientific research.

The birth cohort recommendations were developed using a methodology focused on the quality of the evidence regarding the prevalence of HCV infection among persons born from 1945 through 1965 and an assessment of the potential harms and benefits of routine, one-time screening. A transparent, rigorous, and standardized methodology improves the likelihood of a well-supported recommendation that will have the intended public health impact: to reduce the burden of hepatitis C and HCV-associated disease.

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