

Executive Summary — USMI Roundtable Discussion

Comprehensive Screening for HCV: The Federal Role as Catalyst

Washington, D.C.

November 6, 2003

The **U.S. Medicine Institute for Health Studies** convened a roundtable discussion on November 6, 2003, to examine how federal agencies can increase collaboration on hepatitis C virus (HCV) infection and how their approaches best can be coordinated with other government and private efforts. Medical management of persons with HCV infection is on the verge of an exciting new era, with genetic advances promising more specific, noninvasive diagnostics and more effective pharmaceutical treatments. The time is ripe, participants agreed, to strengthen collaborations across the spectrum of public and medical education, clinical research, case management, treatment, and prevention, in order to take maximum advantage of these advances as they reach fruition.

Background

Hepatitis C virus infection is the most common chronic bloodborne infection in the United States and a major cause of cirrhosis, liver cancer and liver transplantation. According to CDC, a conservative estimate of 1.8% of the U.S. population — about 4 million individuals — have become infected with HCV; about 3 million are chronically infected. HCV is transmitted primarily through contact with blood or blood products; a majority of infections (about 70%) produces few or no symptoms to prompt early diagnosis.□

Despite a dramatic drop in new infections since 1989 primarily because of a decrease in cases among injection drug users, the frequency of chronic disease caused by HCV infection is rising because of the long lag between infection and chronic disease manifestations.□

Roundtable Discussion/Recommendations

The roundtable discussion assessed how public and medical education, screening and testing, clinical research, case management, treatment, and prevention should interact and emphasized the influence of the federal government in shaping screening and testing programs, with “screening” defined as asking about personal behavior patterns associated with increased risk of HCV, such as drug abuse, and “testing” defined as actual testing for evidence of infection with HCV. Because the Department of Veterans Affairs deals with a significant HCV caseload and has developed an extensive patient registry (now containing 215,000 individuals), its public health approach — systematic screening for risk behaviors associated with HCV infection, offering testing for those identified with such behaviors, and providing a full spectrum of treatment and support to those whose tests are positive for HCV — was held up by the group as an important model for other clinical and public health programs.

Discussants agreed that a dormant ad hoc federal interagency working group on HCV should be reinvigorated. The working group will include all federal agencies dealing with HCV — Veterans Affairs Department, Defense Department, National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, Bureau of Prisons, Substance Abuse and Mental Health Services Administration, and Centers for Medicare and Medicaid Services — and be expanded to include state representatives as well. The Department of Veterans Affairs offered to provide administrative support for reinitiating this federal interagency working group on HCV, in collaboration with the National Institutes of Health.

Roundtable participants agreed there is need for increased provider education in assessing personal behaviors. Too often, clinicians do not ask questions that might point to heightened risk of infection. A tool kit available from CDC is an important resource for providers that now is being distributed on a limited basis, and VA provides an algorithm for its providers, but more needs to be done. Participants expressed concern about insufficient numbers of clinicians with pertinent expertise — hepatologists and other gastroenterologists, and infectious-diseases specialists — to manage HCV patients, a situation unlikely to improve in the near future. Thus, efficient use of HCV experts needs to be combined with increased education, training and deployment of, nurses, nurse practitioners, physicians assistants and internists, including infectious disease specialists, to increase capacity for HCV diagnostics, care, drug treatment, monitoring and followup.

Because HCV infection tends to strike those at the lower end of the socioeconomic scale, it has no potent constituent advocacy group to lobby for increased funding for research, screening, testing and treatment. Concern over insufficient or nonexistent funding permeated the group's discussions throughout the roundtable session. Participants agreed that a business case analysis would help demonstrate to policymakers that behavior assessment and subsequent testing for HCV, with appropriate case management of those who test positive, can prevent long-term complications (e.g., end-stage liver disease or hepatocellular carcinoma) and expensive treatment (e.g., liver transplantation) in the future. It was suggested that VA's extensive case registry contains data that could be used to help prepare a public-health "business case model."

Both basic and clinical research issues were addressed by the group: the need for long-term natural history and pathogenesis studies, non-invasive ways of identifying the stage of liver disease; how to determine which patients will have progressive liver damage due to HCV; how to identify which patients will respond to therapy. The federal role was seen as identifying research opportunities, supporting the requisite research infrastructure, catalyzing collaborations to address these research issues between large health care systems (with large HCV caseloads, such as the Federal Bureau of Prisons, Indian Health Service, and VA) and encouraging multidisciplinary work.

Workshop participants emphasized throughout their discussions that HCV is an infectious agent requiring a public health approach, the goal being to halt the transmission cycle as well as to offer optimum case management to those infected. Lack of sufficient resources for public health in general, and HCV in particular, was seen as the main obstacle to achieving this goal.

Roundtable participants: Miriam Alter of CDC; Cynthia Bascetta of GAO; Victoria Cargill of NIH; Robert DeFraités of the Army; Lawrence Deyton of VA; Helen Fox Fields of ASTHO; Laura Hanen of the National Alliance of State and Territorial AIDS Directors (NASTAD); Jay Hoofnagle of NIH; Leslye Johnson of NIH; Thomas Kresina of NIH; Sandra Lehrman of NIH; Harold Margolis of CDC; Susan Mather of VA; Laurie Schowalter of NASTAD; Leonard Seeff of NIH; and John Ticehurst of Johns Hopkins University.

This roundtable discussion was sponsored by Roche, with additional funding provided by other USMI core sponsors. A listing can be found at www.usminstitute.org



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