

PCORI ANNOUNCES \$50 MILLION IN HEPATITIS C RESEARCH FUNDING

February 13, 2015 , By Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor, Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services

Hepatitis C virus (HCV) research recently received a significant boost with a commitment of up to \$50 million in funding from the Patient-Centered Outcomes Research Institute Exit Disclaimer (PCORI) for comparative clinical effectiveness research (CER) studies on the best ways to diagnose and treat HCV infection. PCORI posted application materials Exit Disclaimer earlier this month and announced a May 5, 2015 application deadline.

“HCV is a major health threat that can have devastating consequences for infected people and their families,” said PCORI Executive Director Joe Selby, MD, MPH, in a press release Exit Disclaimer announcing the funding commitment. “Recently approved medications are immensely promising and offer vast improvements over previous therapies, but as yet there’s no ‘real-world’ evidence of their long-term effectiveness nor comparative evidence to help inform decisions about screening, diagnosis, and treatment of HCV.”

A non-profit, non-governmental organization, PCORI was established through the Affordable Care Act (ACA) of 2010 with a mandate to improve the body of evidence used to make informed health decisions, in large part by funding comparative CER. The goal of PCORI’s work is to determine which of the many healthcare options available to patients and those who care for them work best in particular circumstances. In its short history, PCORI has awarded over \$670 million in funds to 360 research projects covering a variety of topics and approaches.

To focus proposed HCV studies PCORI has identified four priority research questions:

How do new regimens of oral antiviral medications for the treatment of hepatitis C infection compare in long-term virologic response and adverse effects?

What are the comparative benefits and harms of treating patients with hepatitis C infection at the time of diagnosis versus waiting to treat only those patients who show early signs of progression of liver disease or other manifestations of hepatitis C infection?

What are the predictive factors of liver disease progression? How can they be combined to predict patients at low risk of progression?

Which HCV screening methods, confirmatory testing strategies, and clinical settings lead to the best rates of detection and linkage to treatment?

What is the comparative effectiveness of interventions to support the care of hard-to-treat patients with chronic hepatitis C infection (e.g., substance abusers, persons with complex medical regimens, the mentally ill), as measured by receipt of treatment, medication adherence, patient quality of life, and sustained viral response?

“PCORI’s research investment is a welcome addition to the federal and nonfederal efforts underway to enhance our nation’s response to viral hepatitis,” observed Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases. “The findings from this research will make important contributions to expanding our understanding of how to make best use of the new all-oral curative treatments as we work across sectors to pursue the goals of the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis.”

PCORI's funding announcement invites applications from private or public sector research organizations, including college/university hospitals or healthcare systems, laboratories, manufacturers, or units of local, state or federal government. PCORI has developed multiple applicant training materials Exit Disclaimer to inform and assist applicants on the review process, and to underscore PCORI's commitment to "research done differently."

Letters of intent are due March 6, 2015, applications are due on May 5, 2015, and PCORI anticipates announcing awards in September 2015.

- See more at: <http://blog.aids.gov/2015/02/pcori-announces-50-million-in-hepatitis-c-research-funding.html#sthash.aovQ4jxM.dpuf>