Health Alerts

Health Update #168 - Hepatitis C Virus Screening and Diagnostic Testing - 04/13/06

Epidemiology

Hepatitis C virus (HCV) infection is a major public health problem, a leading cause of chronic liver disease throughout the world, and the leading cause of death from liver disease in the United States (U.S.). In New York State, there are an estimated 237,000 people with chronic hepatitis C (CHC) based on surveys from the Centers for Disease Control and Prevention (CDC).

Between 1-8 weeks after transmission of hepatitis C, HCV RNA becomes detectable by PCR testing. Although most patients will have some liver function test (LFT) abnormalities from 6-12 weeks after transmission, only about a quarter will have the syndrome of malaise, abdominal pain, and jaundice that characterizes acute hepatitis C disease. Although patients may spontaneously clear the virus, 80-100% of patients remain HCV RNA positive. Acute HCV infection is often asymptomatic or presents with non-specific symptoms. Jaundice occurs in less than 25% of cases. As a result, acute infection is not easily recognized and few patients come to medical attention.

HCV infection is a reportable disease in New York State (10NYCRR2.1). The Erie County Department of Health (ECDOH) automatically receives all positive hepatitis test results directly from most clinical laboratories. Currently, ECDOH is following individuals with multiple, unconfirmed, positive HCV enzyme immunoassay (EIA) antibody screening tests; reflecting inefficient use of medical resources and poor patient care.

In October 2005, the New York State Department of Health (NYSDOH) published Clinical Guidelines for the Medical Management of Hepatitis C (available at NYSDOH Web site at www.health.state.ny.us/diseases/communicable/hepatitis).

Below are recommendations for HCV screening and diagnostic testing based on the NYSDOH HCV Guidelines and recommendations from several Erie County gastroenterologists.

Risk Assessment and Screening

Persons at increased risk for HCV infection should be screened for serum HCV antibody (EIA). Approximately 90% of patients with HCV have identifiable risk factors for infection. The relative risk for HCV infection for patient selection for screening is presented in Table 1. There is no recommendation for serial or periodic screening unless there has been repeat or ongoing high-risk behavior.

In addition, HCV testing should be available to any patient who requests it. However, there is insufficient evidence to support routine screening in asymptomatic persons not at increased risk for HCV infection, because the risks of screening and the subsequent diagnostic testing in a low risk population, if positive, may have risks outweighing the benefits.

Table 1
Relative Risk Factors for Hepatitis C Transmission

High Risk	Injection drug use	Blood or blood product transfusion or transplantation prior to 1992
Moderate Risk	High-risk sexual activity*	Vertical transmission from mother to baby
Low risk	Occupational exposure	Sexual activity between long-term spouses/sexual partners
Very low/No risk	Casual contact	Household contact

*Sexual transmission of HCV is not clearly understood. However, certain high risk sexual behaviors have been associated with HCV transmission such as anal sex, sex with trauma, sex in the presence of a sexually transmitted disease (STD), and sex without a condom.

Diagnostic Testing for HCV[1]

Active Infection

All patients suspected of having HCV infection should be tested for HCV antibody using an EIA screening test. Confirmatory tests must be performed to resolve false positive test results and to determine patient management. Detection of HCV RNA in blood is the currently accepted "gold standard" for diagnosis of active HCV infection and is recommended by most gastroenterologists and hepatologists. Therefore, a positive EIA should be followed by either a qualitative or quantitative test for HCV RNA in the blood. A qualitative HCV RNA test will confirm active HCV infection. A quantitative HCV RNA test will determine the HCV viral load and assist for treatment eligibility. The cost of a quantitative HCV RNA test may run $100-200 over the qualitative HCV RNA test.

The currently available qualitative HCV RNA tests are polymerase chain reaction (PCR) or transcription-mediated amplification (TMA), e.g., Amplicor HCV test 2.0 (PCR; Roche), COBAS Amplicor HCV test 2.0 (PCR; Roche), or VERSANT HCV RNA Assay (TMA; Bayer).

For immunocompromised patients at high risk with unexplained elevated ALT value and a negative screening EIA, a qualitative test for detection of HCV RNA should be performed to diagnose HCV infection.

Quantitative PCR HCV RNA tests should be obtained for patients with diagnosed active HCV infection (i.e., HCV RNA detected) or for patients with suspected active HCV infection (i.e., HCV EIA positive) who may be candidates for antiviral therapy to measure the HCV viral load with either Versant^{tm} HCV RNA 3.0 (branched chain DNA [bDNA]; Bayer), COBAS TaqMan^{tm} HCV (quantitative polymerase chain reaction [qPCR]; Roche), or Celera HCV QT ASR (qPCR; Abbott).

Since Erie County has limited available gastroenterologists and hepatologists, primary care providers are encouraged to complete the laboratory evaluation for active HCV infection by obtaining a qualitative test for HCV RNA for their patients who test positive for HCV antibody. For those patients who confirm HCV RNA positive, a quantitative RNA test, i.e., a viral load

test, provides vital information for determining if a patient is a pharmaceutical treatment candidate.

For additional information please contact the Erie County Health Department at (716) 858-7697 during regular business hours.

[1]The use of proprietary names does not constitute endorsement by ECDOH