Current Practices of Hepatitis C Antibody Testing and Follow-up Evaluation in Primary Care Settings: A Retrospective Study of Four Large, Primary Care Service Centers

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ABSTRACT

Purpose: According to previous studies, The Centers for Disease Control and Prevention's 1998 risk- and medical indication-based recommendations for HCV screening have had limited effectiveness. CDC is now proposing a new recommendation for one-time HCV testing of persons born from 1945-1965. In the current study, we collected data on the effectiveness of CDC's 1998 recommendations to establish a baseline of service utilization information for comparison.

Methods: We retrospectively collected electronic medical record data from all newly enrolled patients who utilized at least 1 primary care outpatient service over a five-year period in 4 large primary care service institutions; The Henry Ford Hospital System, The Mount Sinai Medical Center, The University of Alabama, Birmingham and the University of Texas, Houston. We collected data on hepatitis C antibody (anti-HCV) testing and subsequent within–system HCV RNA testing, genotyping, and biopsies.

Results: We collected data from 208,752 individuals representing 1,279,207 outpatient visits. A total of 17,409 of these individuals (8.3%) received an HCV antibody test of whom 1,102 (6.3%) were anti-HCV positive. Of those who tested anti-HCV positive, 750 (68.1%) received a HCV RNA test, of whom 548 (73.1%) were RNA positive. Of the 548 confirmed with HCV infection, 403 (73.5%) received a genotype test of whom 74.1% were genotype 1, 20.1% were other genotypes, and 5.2% had missing or inconclusive results. We observed 56 biopsy stage results among the 548 patients who were RNA positive for HCV. Of these, 6 were in stage zero, 20 in stage 1, 13 in stage 2, 8 in stage 3, and 7 in cirrhosis. A total of 26,939 individuals had indications for screening based upon the 1998 guidelines. Of these 7,141 (26.5%) received anti-HCV testing. By risk factor, 26.2% of those with elevated liver enzymes, 61.8% of people with HIV, 24.1% of people with hemophilia, 76.0% of those who had undergone hemodialysis, 33.7% of those with evidence of injecting drug use, and 33.3% of those who had received a transfusion prior to 1992 had been tested for HCV. This compares to 5.7% of those without risk factors and 4.7% of those (without risk factors) who were born during 1945-1965.

Conclusions: Across all patients, only 8.3% of individuals with a primary care visit were screened for HCV, and screening rates were also low for individuals with possible clinical indicators or prior risks of exposure to HCV. Less than ideal numbers of patients who were positive for anti-HCV received HCV RNA testing and genotyping. However, many patients were transitorily affiliated with the testing institution and some may have received specialist care elsewhere.

Primary Findings

With the exception of elevated liver enzyme tests, the vast majority of patient records contained no risk factor information.

- **Only 2.6% of patient records contained information about risk factors other than elevated liver enzymes**
  - **37.7% of these were tested for HCV antibody**
  - **22.6% of those with risk information who were tested were positive**
    - **This represents 0.2% of the patient population**
- **10.6% of patients had an elevated ALT or AST test and no other risk indication**
  - **23.7% of these were tested for HCV antibody**
  - **8.7% of those with elevated ALT who were tested were positive**
    - **This represents 0.2% of the patient population**
- **5.6% of patients with no documented risk for HCV were tested**
  - **1.9% of these were positive for HCV**
    - **This represents 0.1% of the patient population**
- **73.4% of those with documented indications for testing were not tested.**

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BACKGROUND

The hepatitis C virus (HCV) is a percutaneously transmitted virus that causes progressive liver damage in a portion of those infected with it. Although the existence of non-A, non-B hepatitis had been postulated since the 1970's the virus itself was first isolated in 1989 and a commercial blood test to identify the virus was not in widespread use until 1991. In the years prior to 1991, large numbers (approximately 2 to 3 million) Americans were infected with the disease either through drug use, contaminated blood products or other means of transmission.

In 1998, CDC published hepatitis C testing guidelines with the intent of identifying chronically infected but still asymptomatic Americans with the disease. These guidelines prioritized antibody testing of those with an identified possible exposure to HCV (intravenous drug use, recipients of transfusions prior to 1992, those who received clotting factors, those on hemodialysis, children born to HCV infected mothers) those with possible clinical indicators of disease (elevated liver enzyme tests) and those with HIV.

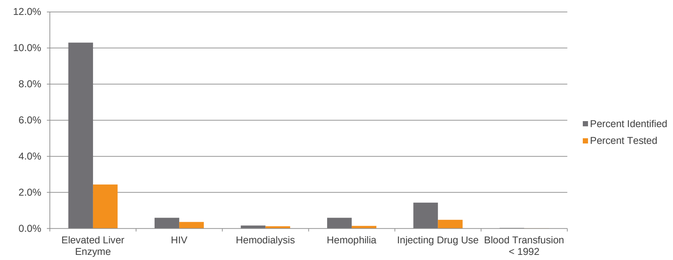
If fully implemented, CDC's 1998 recommendations would likely be highly effective at identifying individuals who are asymptomatically and chronically infected with HCV. Unfortunately, the demands of modern health care mean that patient exposure risks may never be elicited and primary care providers probably do not prioritize the identification of HCV in clinical settings.
In this study, CDC sought to test the effectiveness of the 1998 clinical guidelines as implemented in primary care settings. Specifically, we sought to test the following questions;

- Do physicians elicit the risk information necessary to enable HCV antibody testing under the 1998 guidelines?
- When risk information is available in the patient record, are patients tested for HCV?
- When patients are tested for HCV under the 1998 guidelines, does the testing yield substantial new cases of HCV?

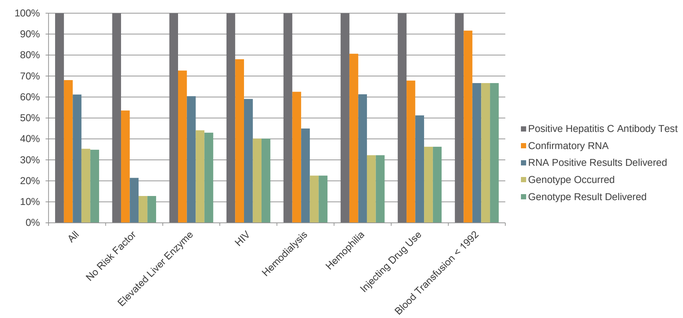
Secondary points of interest that were also evaluated in this study include the percentage of antibody positive patients that receive follow-up care, and the liver health status of those who are initially diagnosed.

Results

Percentage of Population with Each 1998 Indication for Testing and the Percent of the Population with Each Indication that were Tested



Percentage of Those who Test Antibody Positive Who Receive Follow-up Services



DESIGN

We partnered with four regional primary care centers (Birmingham, AL; Detroit, MI; Houston, TX; and New York, NY) to collect five years of electronic medical record (EMR) data for all patients that newly joined each primary care system. New patients were defined as those not previously entered into the EMR prior to Jan. 1, 2005, and who had at least one primary care visit to the system. We followed each patient from the date of their first visit through Dec. 31, 2010. Patients with HCV at system entry were excluded from the study. For each patient we collected information on;

- Indications for HCV testing (according to CDC's 1998 guidelines)
  At least one elevated ALT or AST test, HIV, Hemophilia, Hemodialysis, Illicit percutaneous drug use, a blood transfusion prior to 1992.
- Indicators of HCV antibody testing and results
- Indicators of HCV clinical follow-up care
  Confirmatory testing, genotyping, biopsy
- Patient factors
  Age, ethnicity, insurance, inferred income, marital status

We used diagnostic ICD-9 codes and natural language processing of text notes recording in the EMR to identify indications for HCV testing under the 1998 CDC Guidelines.

Conclusions

Patient records lacked the information needed to indicate Testing. Patients indicated for screening were not routinely tested. Patients who tested antibody positive were inconsistently linked to follow-up care.

We found little evidence that physicians routinely elicit the type of risk factor information that would enable them to systematically identify a substantial portion of those asymptomatically infected with HCV in primary care. Only 2.6% of the records examined contained information on patient risks other than elevated liver tests. An additional 10.6% of patient records contained information indicating on elevated liver enzyme tests.

Further, our records indicate that even when risk factor information indicating the need for testing was available in the patient record, patients inconsistently received the HCV antibody test. Less than 40% of those with reported possible exposures to HCV were antibody tested for the disease. Of those with elevated liver enzymes (a possible clinical indicator of disease) less than 23% were tested.

This low rate of testing is unfortunate because our research indicates that testing by risk factor was highly effective at identifying patients with disease. Fully 22.6% of patients with reported risk exposures to HCV who were tested were found to be antibody positive. Likewise, 8.7% of those with elevated liver enzymes who were tested were found to be positive. This information suggests that the 1998 CDC Guidelines, if used, would be highly effective at prioritizing primary care patients for HCV testing. Patients with HIV and those that received hemodialysis were tested at much higher rates (62% and 76% respectively) than patients with other testing indications.

Our study also found suboptimal rates of follow-up evaluation following a diagnosis. Of all those who tested antibody positive for HCV, only 68% received a confirmatory RNA test, and only 57% of those who received an positive confirmatory test were tested for and received the results of their genotype test. On a positive note, our evidence indicates that the vast majority (98.7%) of patients that were genotype tested received their results. This evidence may suggest that linking patients to specialist evaluation services following a positive antibody test is an area for additional policy concentration.

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