

## The Role of HEV Infection in U.S. Patients with Suspected Drug Induced Liver Injury

*Dr. Robert J. Fontana, Division of Gastroenterology and Hepatology, University of Michigan, Dr. Paul H. Hayashi, Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Dr. Jay H. Hoofnagle, NIH/NIDDK, Dr. Huiman Barnhart, Duke University, Mr. Ronald E Engle, Hepatic Pathogenesis Section, LID, NIAID, National Institutes of Health and Dr. Patrizia Farci, Nih/Niaid*

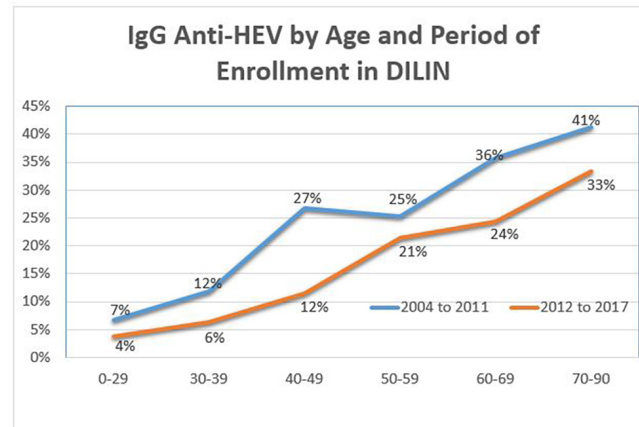
### Abstract Text

**Background:** A decreasing prevalence of anti-HEV IgG serostatus in the general United States population has been noted. Nonetheless, sporadic acute HEV infection continues to be reported and may account for some cases of suspected drug induced liver injury (Gastro 2011: 141: 1665). Our study aim was to determine the incidence of presumed acute HEV infection in consecutive DILIN patients and identify risk factors for anti-HEV serostatus.

**Methods:** Baseline serum samples in patients enrolled in the ongoing DILIN prospective study between 2004 to 2017 were tested for anti-HEV IgG and positive samples were also tested for anti-HEV IgM, using ELISA techniques. HEV RNA testing was done on anti-HEV IgM (+) cases using PCR. Presenting features and 6-month outcomes were analyzed by anti-HEV serostatus.

**Results:** Among 1730 patients enrolled, 346 were reactive for anti-HEV IgG (20%) of which 21 were also positive for anti-HEV IgM (1.2%). HEV RNA was detected in 6 of 20 anti-HEV IgM (+) samples tested to date. Participants with anti-HEV IgM were significantly older than those with and without anti-HEV IgG (median age= 64 vs 59 vs 48 years,  $p=0.001$ ), and were more likely to be male (81% vs 47% vs 42%,  $p=0.001$ ), while racial and ethnic distributions were similar in the 3 groups. Subjects with anti-HEV IgM were less likely to die during follow up than those without (0% vs 7.2%) but other clinical features including severity scores and peak values of serum enzymes and bilirubin were similar in the 3 groups. Seroprevalence rates of anti-HEV IgG rose significantly with age, increasing from 5.6% below the age of 30 to 37.6% above the age of 70 years. Furthermore, age-specific rates were consistently lower in those more recently enrolled (i.e 2012 to 2017 vs 2004-2011) and there was a similar trend for anti-HEV IgM decreasing from 2.7% in the first 5 years to less than 1% during the last 5 years.

**Conclusion:** 1.2% of patients enrolled into the DILIN prospective study were anti-HEV IgM (+); these subjects with suspected acute infection were most commonly elderly men. The incidence of acute HEV infection appeared to decrease and age-specific rates of anti-HEV declined during the 14 years of the DILIN prospective study. These results suggest a cohort effect in anti-HEV prevalence and a declining rate of acute HEV infection in the United States.



### Disclosures

Robert J. Fontana – abbvie: Grant/Research Support; Gilead: Grant/Research Support; BMS: Grant/Research Support; Alynam: Consulting

The following people have nothing to disclose: Paul H. Hayashi, Jay H. Hoofnagle, Ronald E Engle, Patrizia Farci

Disclosure information not available at the time of publication: Huiman Barnhart