The International Journal of Transfusion Medicine
Vox Sanguinis

Vox Sanguinis (2010) **98**, 479

LETTER

DOI: 10.1111/j.1423-0410.2009.01258.x

Vox Sanguinis

Hepatitis E virus and blood donors in Germany

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Dear Editor,

Adlhoch *et al*. recently reported a case of indigenous hepatitis E virus (HEV) infection in a German plasmapheresis donor [1]. Shortly after donation (24 h) the donor developed acute hepatitis which was reported to the health authorities. It was subsequently confirmed that the donor was infected with HEV. Analysis of archived plasma samples revealed that on the day of donation, the donor had elevated levels of alanine transaminase (ALT) of > 1000 IU/l and was HEV RNA, anti-HEV IgM and anti-HEV IgG positive. In the proceeding 2 weeks, all markers were negative except for HEV RNA. In Germany, nucleic acid testing (NAT) is performed for HCV (and HIV-1) RNA, not for HEV RNA. Mandatory ALT testing was suspended in 2003, being considered to be of limited benefit for transfusion-relevant viruses [2]. However, under the previous requirements, the elevated levels of ALT observed in this donor would have resulted in deferral, at least for one of the donations. In nationwide studies in Japan, approximately 1.1% of donors with elevated ALT (> 200 IU/l) were HEV RNA positive, usually correlating with anti-HEV IgM, with significantly higher prevalence/incidence observed around Hokkaido [3].

In our study, we investigated 109 ALT positive plasma donations collected at the German Red Cross blood bank in Frankfurt (Main) before 2003 when ALT testing ceased. The ALT levels in the donations exceeded 68 IU/ml, all mandatory screening markers were negative. Using sensitive ID NAT, we found all panel members negative for HCV RNA, HBV DNA and HAV RNA. Subsequently, testing was performed for anti-HEV IgM and IgG using commercial ELISA assays (MP Diagnostics, Illkirch, France and Mikrogen GmbH, Neuried, Germany). Confirmatory testing was performed by immunoblot (*recom*Blot HEV IgG/IgM; Mikrogen). Samples were considered positive when both ELISAs and the confirmatory test were positive. From our data, six (5.5%) of the samples were positive for IgG. No confirmed IgM positive samples were identified.

The samples were analysed for HEV RNA using a modified RT-PCR method targeting ORF3 and capable of detecting 10 DNA copies per reaction [4]. Plasma samples were extracted using the COBAS AmpliPrep (Roche Diagnostics GmbH, Penzberg, Germany) and the total nucleic acid isolation kit according to the manufacturer's instructions. Positive controls included HEV positive human plasma and swine samples. All 109 ALT positive samples were negative for the presence of HEV RNA.

Taken together these results suggest that HEV is not a major cause of elevated levels of ALT (> 68 IU/l), at least in German blood donors, and whilst the case reported by Adloch *et al*., clearly demonstrates a diagnostic window period for HEV, further studies are required to determine the prevalence/incidence and clinical significance of HEV RNA in the Germany blood donor population and elsewhere.

References

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Received: 24 August 2009,
accepted 29 August 2009

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