The Clinical Impact of Screening Blood Donations for Hepatitis E Virus in Catalonia

Mafalda Ramos[1]; Mar Riveiro-Barciela[2]; Marta Bes[3]; Brian Custer[4]; Cristina Coll-Ortega[5]; Eli Viayna[5]; Mark Lamotte[1]

[1]Th(is)²Modeling bv, Asse, Belgium; [2]Liver Unit, Hospital Vall d'Hebrón, Barcelona, Spain and CIBERehd; [3]Transfusion Safety Laboratory, Banc de Sang i Teixits, Barcelona, Catalun
Spain and CIBERehd; [4]Vitalant Research Institute, Department of Laboratory Medicine, UCSF, San Francisco, CA, USA; [5]Grifols SA, Sant Cugat del Valles, Spain

ISPOR Europe 2025
9-12 November 2025
Glasgow, Scotland, UK
CO238

BACKGROUND

- Hepatitis E virus (HEV) is the most common cause of acute viral hepatitis worldwide. Genotype (GT) 3 and 4 infections are more prevalent in industrialized and high-income countries
- HEV GT3 and GT4 infections are usually clinically silent but may cause symptomatic infections, particularly in immunocompromised patients or with underlying chronic liver disease due to other etiologies. In the latter risk group, acute-on-chronic liver disease may also develop
- HEV screening in blood donations is not mandatory in many countries. However, certain countries/regions – such as Catalonia (Spain) – has applied universal screening since November 2017
- The incidence of HEV RNA positive blood donations is increasing[1], leading to an increased risk of transfusion-transmitted HEV infection. The Procleix UltrioPlex E assay combines screening for nucleic acid testing (NAT) HIV-1/2, HBV, HCV and HEV, with 100% sensitivity, and could prevent the transmission of HEV infection through blood transfusion

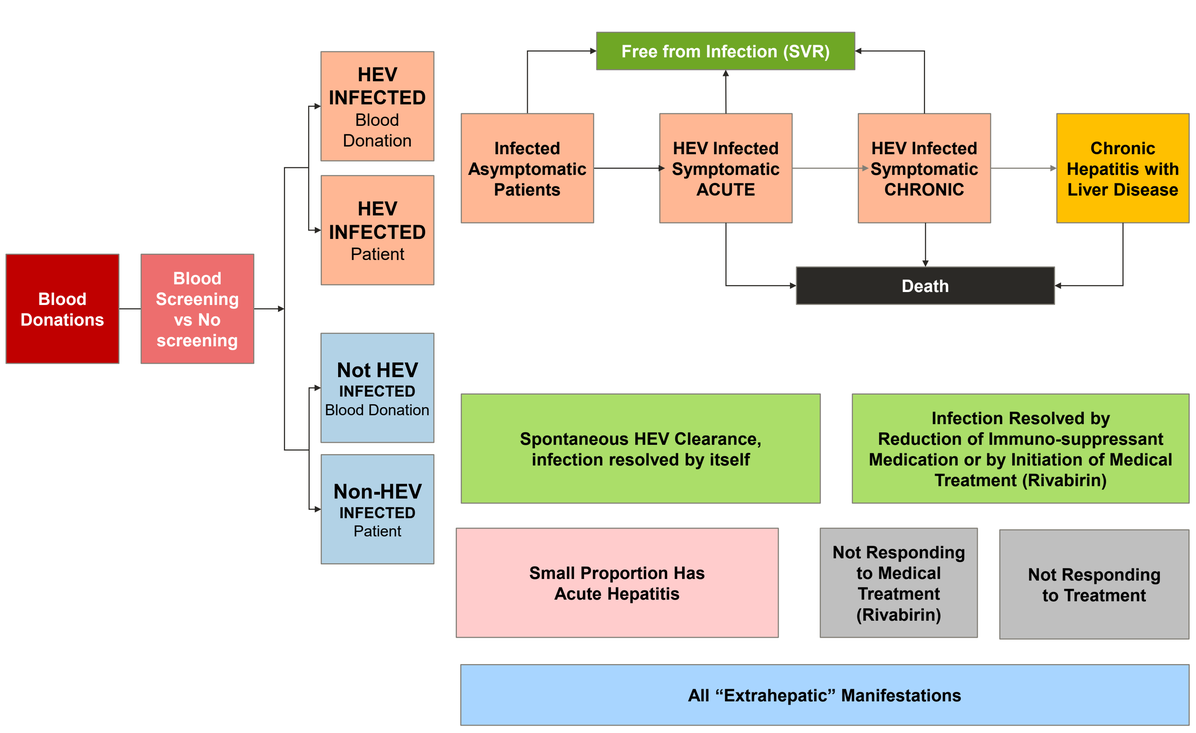
AIM

- This study aims to compare the clinical impact of screening HEV RNA in Catalonia with UltrioPlex E assay against the scenario where screening is not employed

METHODS

- A *de novo* model on transfusion-transmitted-HEV was developed in MS Excel (Figure 1)
- In this model, individual donation NAT screening (ID-NAT) was compared to a scenario without screening blood donations within the context of Catalonia. Local data on the annual number of blood donations and prevalence of HEV has been used as input in the model
- In those patients with symptomatic HEV infection a distinction is made between hepatic and extrahepatic manifestations (figure 1). Hepatic manifestations can be acute hepatitis that can progress to severe acute hepatitis or chronic hepatitis, which could subsequently progress to compensated (CC) or decompensated cirrhosis (DC), hepatocellular carcinoma (HCC) and liver transplant (LT), which can lead to death
- Published literature was used to identify the probability of the different events (Table 1)
- The number of HEV infections, hepatic and extrahepatic manifestations avoided, and the number of deaths avoided by performing ID-NAT screening for 1 calendar year were calculated

Figure 1. Model Conceptualization



METHODS (cont.)

Table 1. Clinical Inputs of HEV Model

Clinical Inputs	Value
Prevalence of HEV RNA in blood donations[2]	0.036%
Asymptomatic[3]	70.00%
Initially asymptomatic that have acute hepatitis[4]	2.00%
Symptomatic[3]	30.00%
Acute hepatitis[5]	27.40%
Acute hepatitis in acute HEV patients (assumption)	100.00%
Probability to clear acute hepatitis spontaneously[6]	34.00%
Risk to progress from acute hepatitis to severe acute hepatitis[7]	0.60%
Risk to progress from acute hepatitis to chronic hepatitis[6]	66.00%
Probability to clear chronic HEV by decreasing immunosuppression[8]	32.00%
Probability to clear chronic HEV by ribavirin monotherapy[8]	85.00%
Risk to progress from CC to DC[9]	10.00%
Risk to progress from CC to HCC[8]	14.00%
Risk to progress from DC to LT[9]	20.00%
Death from severe acute hepatitis[10]	28.60%
Death from CC[9]	5.50%
Death from DC[9]	30.50%
Death from LT[9]	3.96%
Death from HCC[11]	34.00%

CC=Compensated Cirrhosis; DC=Decompensated Cirrhosis; HCC=Hepatocellular Carcinoma; HEV=Hepatitis E Virus; LT=Liver Transplant.

RESULTS

- In the 85,000 Catalonian individuals receiving blood donations in a calendar year with HEV RNA screening, 92 HEV infections could be avoided (table 2)
- Screening with UltrioPlex E avoids 2.65 and 1.69 neurological and hematological manifestations respectively. Moreover, 0.70 HEV related deaths and 1.93 cases of liver disease can be avoided

Table 2. Clinical Outcomes of HEV Model

Clinical Outcomes	WITH UltrioPlex E Screening	WITHOUT UltrioPlex E Screening	Difference
Number of Transfusion Transmitted - HEV infections	0.00	91.80	-91.80
Number cases of liver disease	0.00	1.93	-1.93
Number of liver transplants	0.00	0.07	-0.07
Number of Hepatocellular Carcinoma	0.00	0.21	-0.21
Number of neurological manifestations	0.00	2.65	-2.65
Number of hematological manifestations	0.00	1.69	-1.69
Life expectancy	4.99	4.99	0.0005%*
Number of HEV related deaths	0.0000	0.70	-0.70

HEV=Hepatitis E Virus; * Relative difference

CONCLUSIONS

Screening blood donations for HEV RNA can result in less cases of HEV and related liver disease, hematological and neurological manifestations.

- In the context of increasing incidence of HEV RNA positivity in blood donations, the results of this model indicate that ID-NAT for HEV may prevent further HEV infections in the future
- NEXT STEP: Cost-effectiveness of HEV screening will be assessed

1. Bes et al. Emerg Infect Dis. 2022 Jan;28(1):157-165. doi: 10.3201/eid2801.211466. **2.** Bes, et al. Presented at: 38th ISBT International Congress; 2024 June 23-27; Barcelona, Spain. **3.** Guillois, et al. *Clin Infect Dis*. 2016 Feb 1;62(3):351-7. doi: 10.1093/cid/civ862. **4.** Pischke, et al. *J Hepatol*. 2017 May;66(5):1082-1095. doi: 10.1016/j.jhep.2016.11.016. **5.** Fraga, et al. *Liver Int* . 2018 Apr;38(4):619-626. doi: 10.1111/liv.13557. **6.** Kamar, et al. *Gastroenterology*. 2011;140:1481–1489. **7.** Quickert, et. al. Clin Gastroenterol Hepatol. 2019 Apr;17(5):1004-1006. doi: 10.1016/j.cgh.2018.09.049. PMID: 30902228. **8.** Vos, et al. *Transfusion*. 2017 Feb;57(2):258-266. doi: 10.1111/trf.13978. **9.** Ankcorn, et al. *Value Health*. 2020 Mar;23(3):309-318. doi: 10.1016/j.jval.2019.09.2751. **10.** Jung Woo Choi, et. al. *BMC Infect Dis*. 2022 Jan 18;22(1):62.doi: 10.1186/s12879-022-07050-w. **11.** Rustgi, et al. *J Med Econ*. 2022 Jan-Dec;25(1):347-355. doi: 10.1080/13696998.2022.2026702.

Acknowledgement: This study was funded by Grifols SSNA (Durham, NC, USA).