

Strategies for HEV donor screening: no screening/universal/selective

Pierre Tiberghien

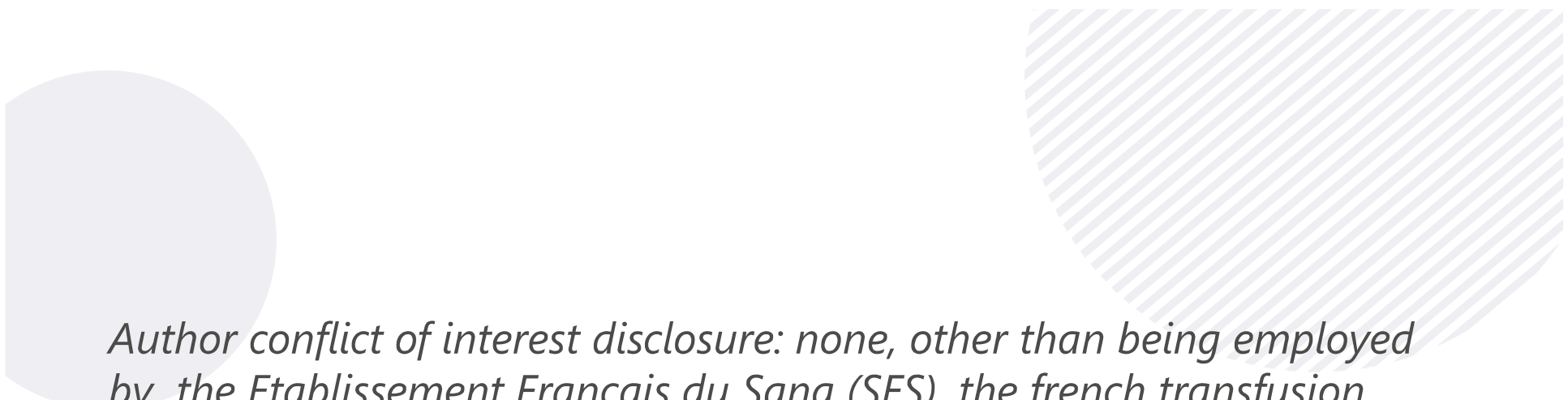
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IPFA/PEI 24rd International Workshop on
"Surveillance and Screening of Blood Borne Pathogens"

Zagreb, Croatia

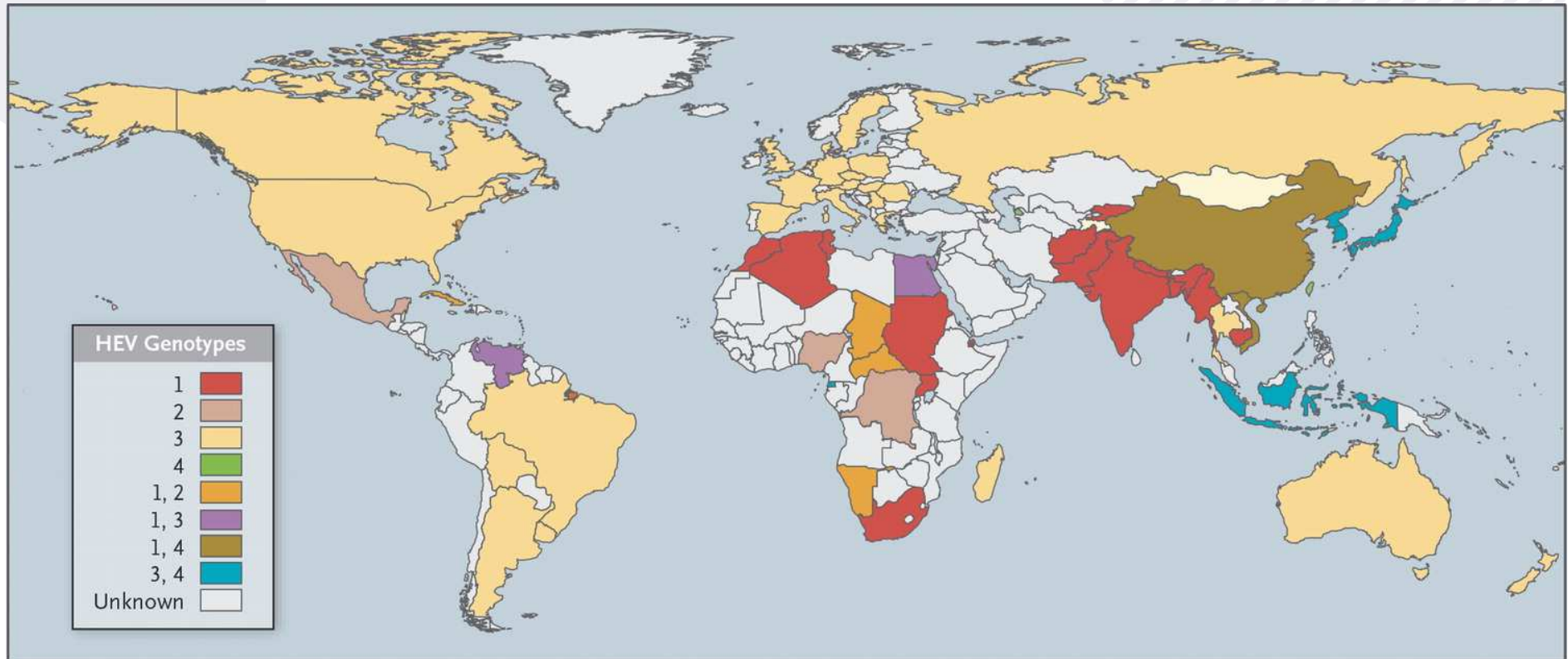
May 16-17th, 2017



Author conflict of interest disclosure: none, other than being employed by the Etablissement Français du Sang (EFS), the french transfusion public service

This presentation reflects the views of the author and should not be construed to necessarily represent EFS's views.

Hepatitis E virus

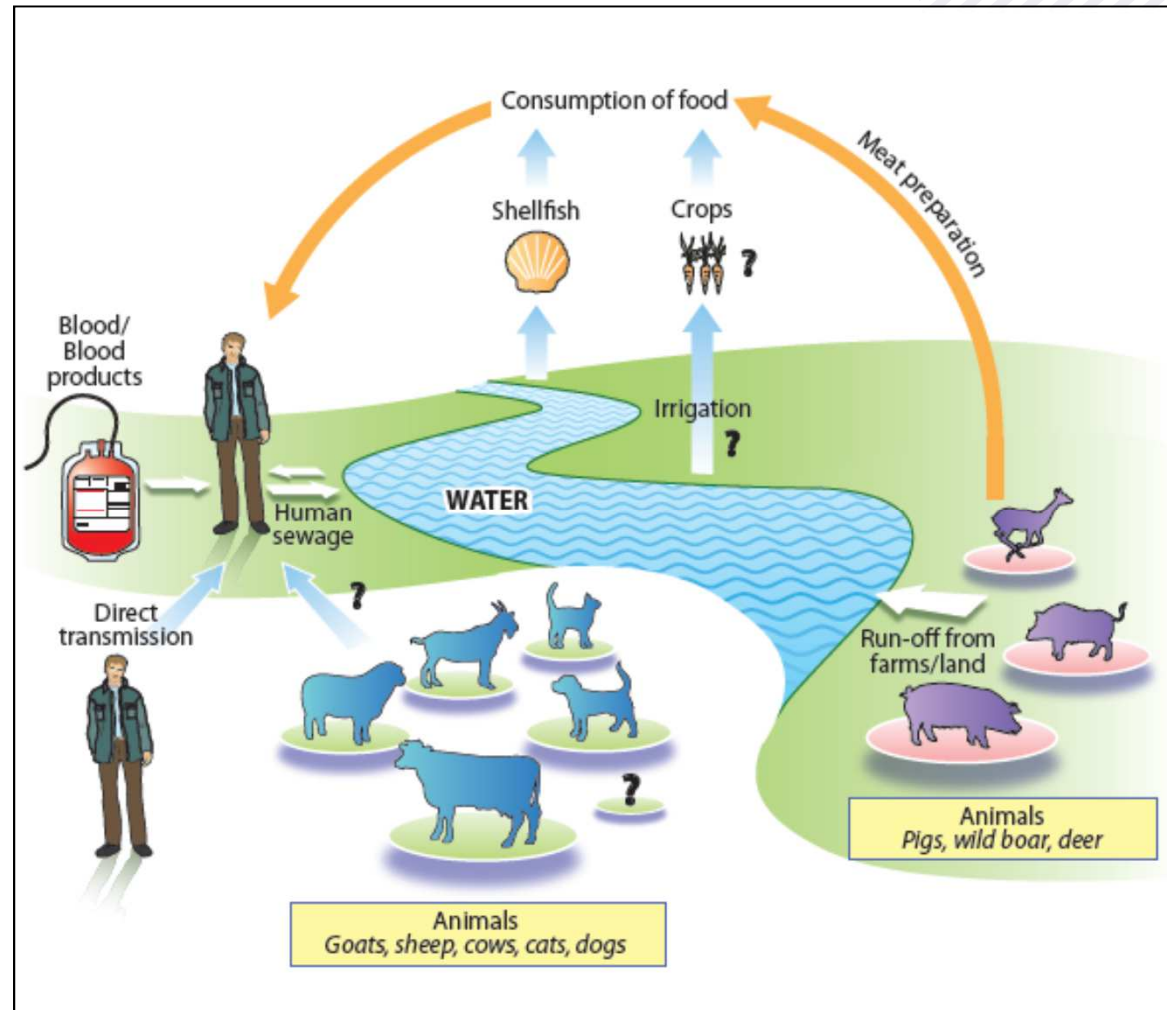


Eyasu Teshale E, Ward JW. *N Engl J Med* 2015; 372:899-901

Occurrence of *transfusion-transmitted hepatitis E*

- Hepatitis E virus (HEV) infection in France (genotype 3 mainly) is a **zoonotic disease** and is **usually an acute self-limiting disease**
- However, HEV may cause **chronic hepatitis** with rapidly progressive cirrhosis in **organ transplant** recipients and patients with hematological malignancy, as well a **fulminant hepatitis** in patients with **chronic liver disease**.
- Hepatitis E virus has been recognized since 2004 as a **transfusion transmissible infectious agent**
- Frequency of RNA HEV positive blood donations in France : **1 out of 2000** in 2013 (*Gallian et al, EID, 2014*). Similar frequencies are observed in several other countries in Europe (Netherlands, Germany, England). More recent data in France suggests a higher frequency (approximately **1/1000 donations**) as in the Netherlands.

Source and route of HEV infection



Source and route of HEV infection (Kamar et al, Lancet 2012)

A Nationwide Survey of Hepatitis E Viral Infection in French Blood Donors

Jean Michel Mansuy,^{1*} Pierre Gallian,^{2,3*} Chloé Dimeglio,^{4,5} Karine Saune,^{1,6} Catherine Arnaud,^{4,5} Bertrand Pelletier,² Pascal Morel,² Dominique Legrand,² Pierre Tiberghien,^{2,7} and Jacques Izopet^{1,6}

Hepatology, 2016

Overall IgG seroprevalence of 22.4% (95 CI: 8%-86.4%)

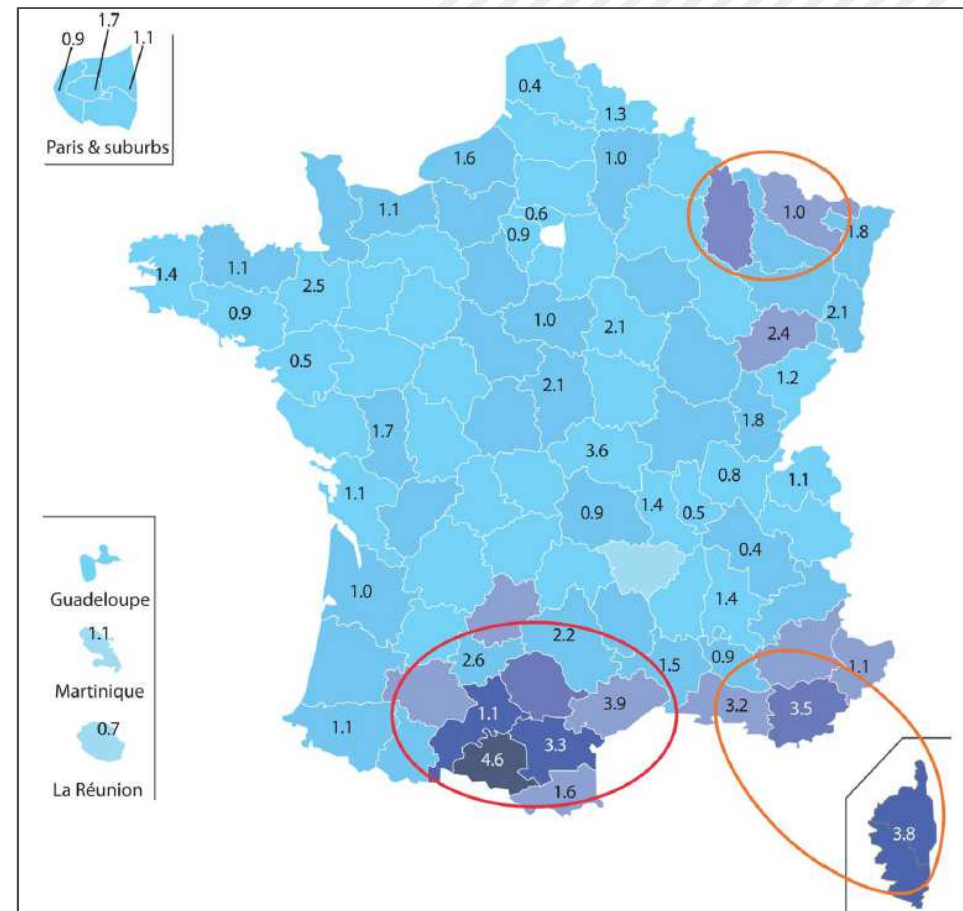
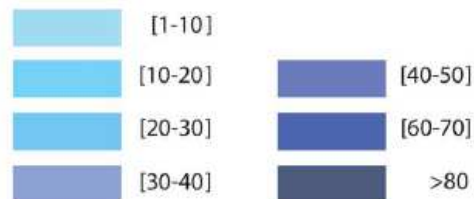


FIG. 1. Prevalence of anti-HEV IgG and IgM: distribution in French administrative areas. A color code describes the anti-HEV IgG seroprevalence classes. Black numbers represent the seroprevalence of anti HEV IgM in each administrative area.

A Nationwide Survey of Hepatitis E Viral Infection in French Blood Donors

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Hepatology, 2016

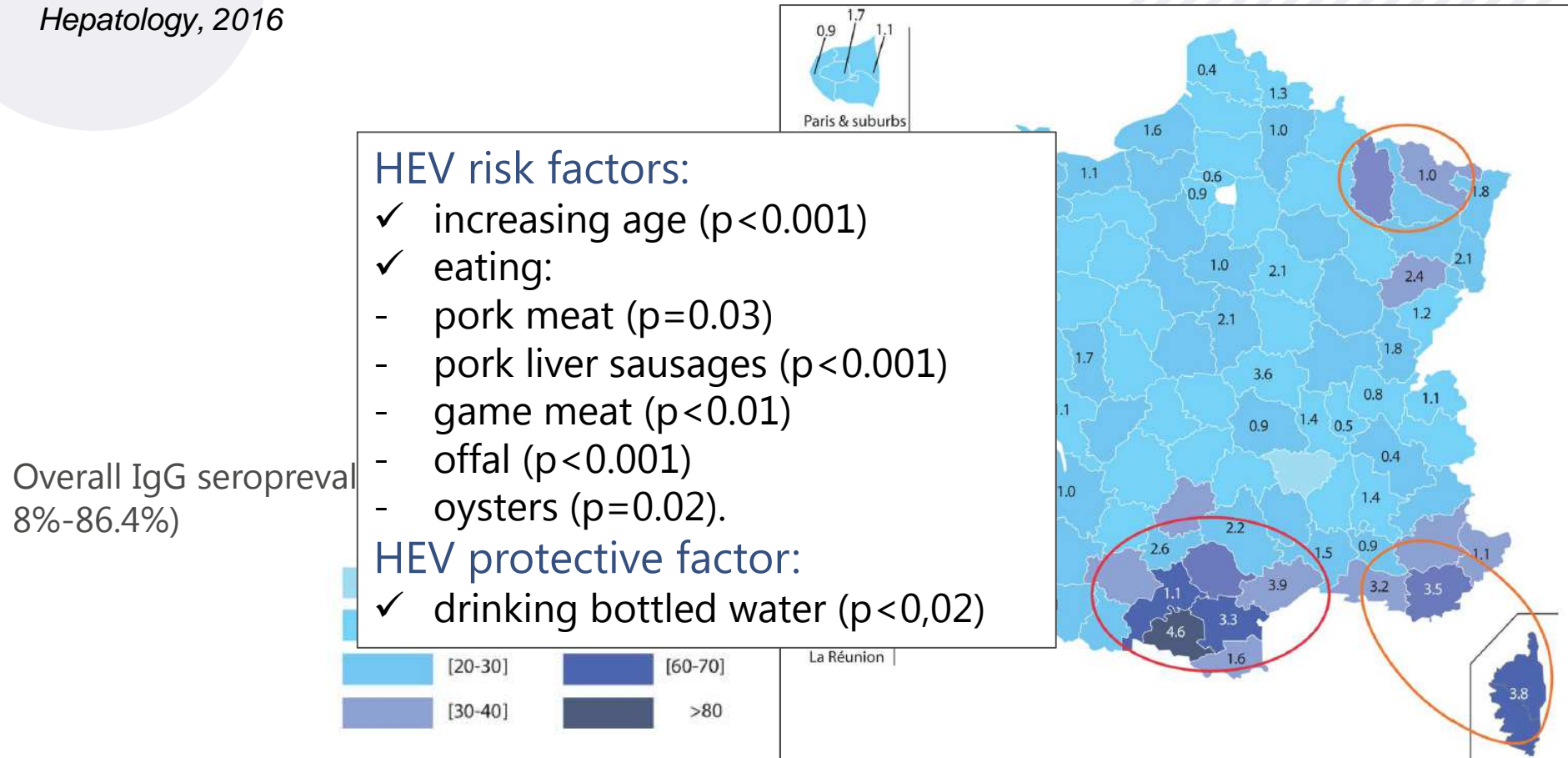
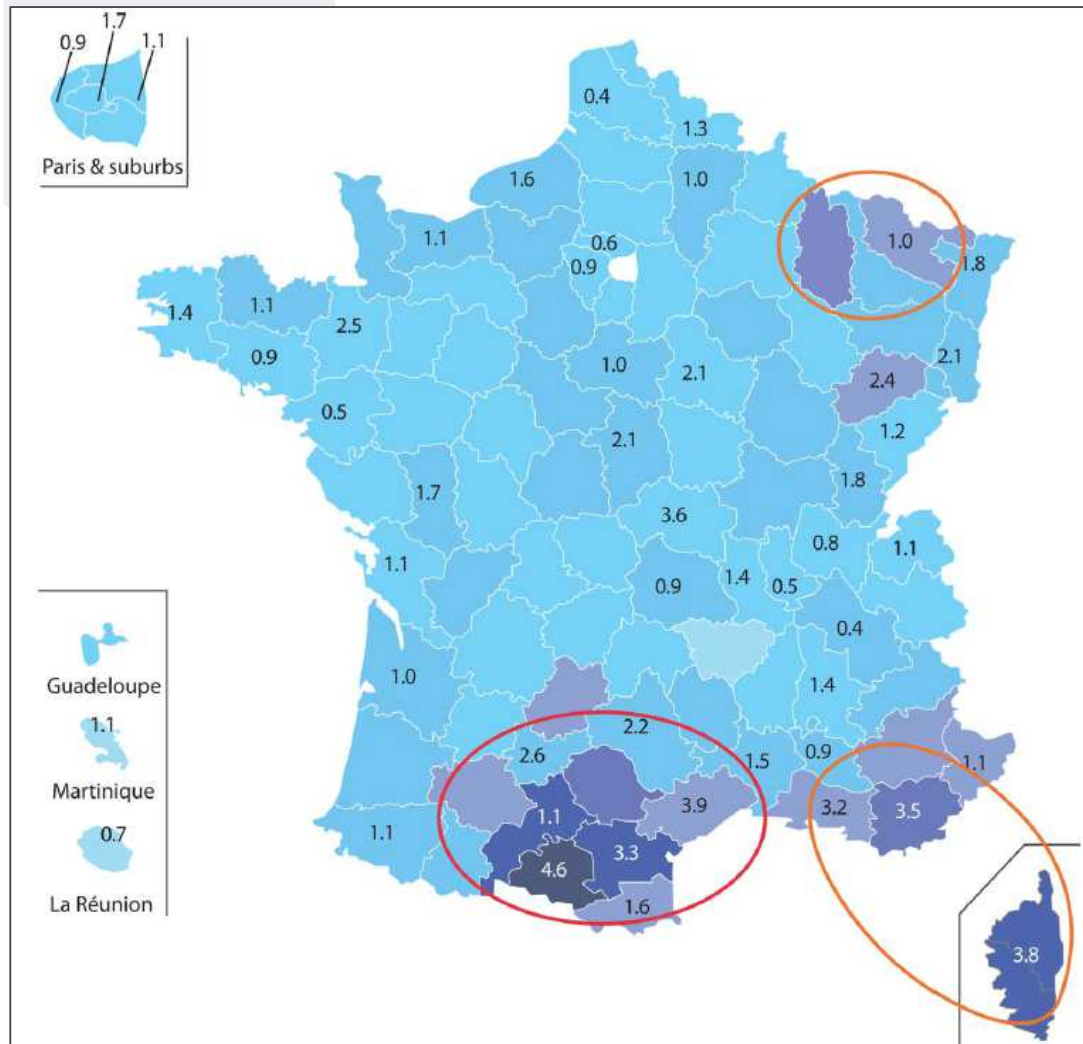


FIG. 1. Prevalence of anti-HEV IgG and IgM: distribution in French administrative areas. A color code describes the anti-HEV IgG seroprevalence classes. Black numbers represent the seroprevalence of anti HEV IgM in each administrative area.

Incidence of HEV infection in blood donors in France



- Overall IgM seroprevalence of 1% (95% CI 0.8%-1.2%).
- Anti-HEV IgM was detected in 1.9% of donors living in a high anti-HEV IgG seroprevalence area and in 0.7% of donors living in a low to medium IgG seroprevalence area ($P < 0.0001$).

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6 Australian Red Cross
Blood Service,
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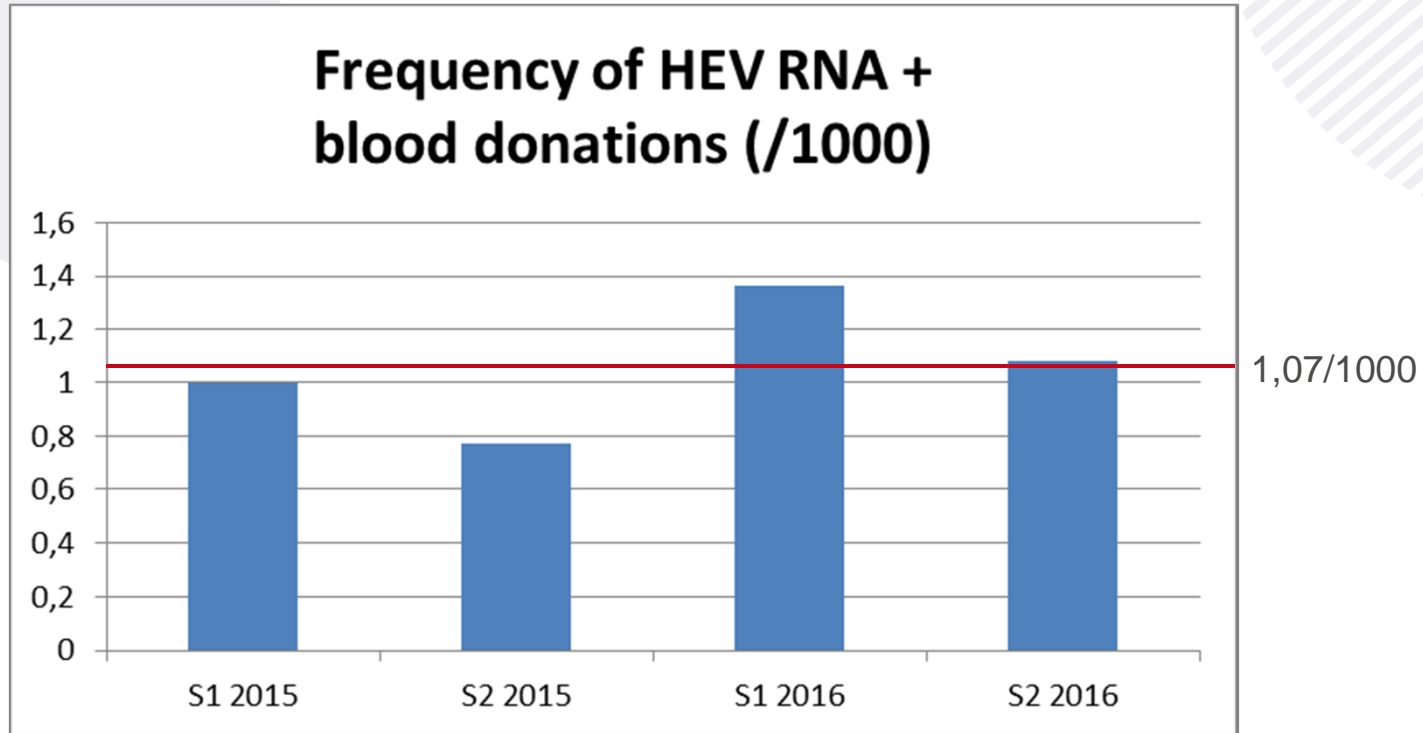
[vhoad@
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First confirmed case of transfusion-transmitted hepatitis E in Australia

MJA 206 (7) • 17 April 2017

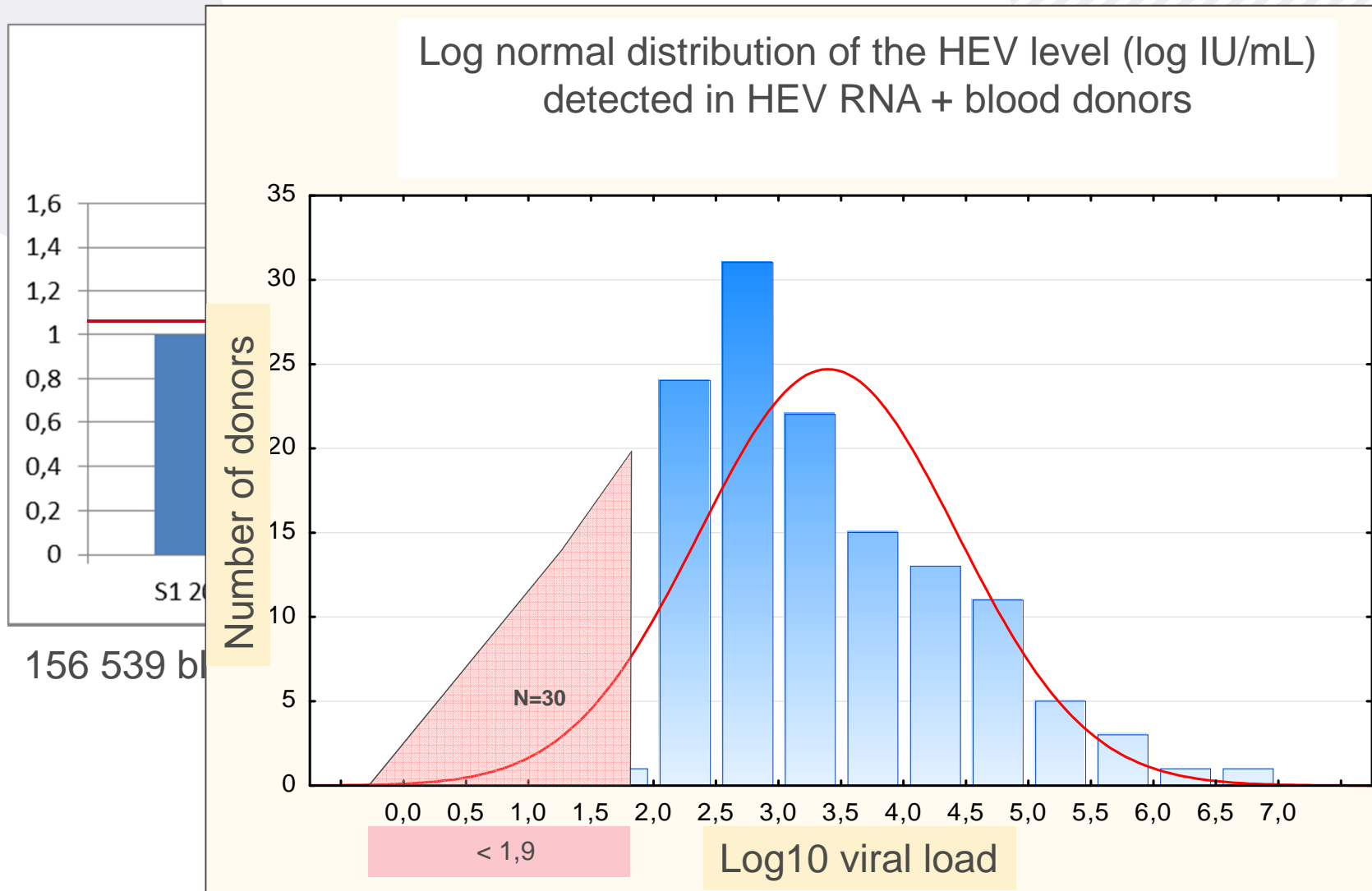
- Chronic hepatitis E successfully treated by ribavirine in a 6 year-old boy having undergone a liver transplantation following liver failure of unknown cause.
- Molecularly identical HEV found in a transfused plasma provided by **a donor having travelled to the south of France in the 2 months before donation** and having eaten local pork products.

Incidence of HEV infection in blood donors



156 539 blood donations

Incidence of HEV infection in blood donors



Transfusion-transmitted hepatitis E in France

- **21 cases of HEV-TT** reported **between 2006 and 2015, most since 2012** with established **transfusion imputability** (viral phylogenetic analysis)
- All cases are **genotype 3** (mainly 3f) except for 1 (genotype 4)
- **All type of blood products are involved:**
 - red blood concentrates (n=5)
 - platelet concentrates (n=9), including pooled whole blood-derived (n=5 + 1 Intercept®) platelets and apheresis (n=3) platelets)
 - plasma (n=7), including solvent-detergent (SD)-plasma (n=4), Intercept® plasma (n=2) and quarantine plasma (n=1)
- Patients, aged **5 to 88 years old**, kidney (n=5) or liver **transplants** (n=3) and **hemopathies** mainly
- All cases suspected by **biological liver abnormalities** (cholestasis or cytolysis), for 2 a result of investigation from another case
- **Spontaneous resolution in 12 patients**
- **Chronic hepatitis requiring ribavirine treatment in 9 patients**, all immunosuppressed, and among which 2 patients developing significant liver fibrosis.

HEV RNA detection for SD-plasma apheresis plasma

From 12/2012 to 12/2014 (interruption of SD-Plasma production by EFS)

- SD-Plasma: 70 liter pool, 100 apheresis plasma donations
- Real Star HEV RT PCR Altona (EUROBIO) : SD 95% = 23 UI/ml (WHO standard)
- 01-12- 2012 -- 01-12-2013 : 558 pools tested = 53234 plasmas
 - Prevalence of ARN-HEV positive pools = 22/558 : 3,94%
 - Prevalence of ARN-HEV positive plasma = 24/53234 : 0,045%
- 1 ARN-VEH+ donation / 2218 plasma donation
- A single HEV RNA-positive sample in each of 20 pools and two HEV RNA-positive samples was found in the remaining two pools.

Transfusion-transmitted hepatitis E in France

Hepatitis E transmission by transfusion of Intercept blood system–treated plasma

Lisette Hauser, Anne-Marie Roque-Afonso, Alexandre Beylouné, Marion Simonet, Bénédicte Deau Fischer, Nicolas Burin des Roziers, Vincent Mallet, Pierre Tiberghien and Philippe Bierling

Blood, 2014

Hepatitis E Virus Infection after Platelet Transfusion in an Immunocompetent Trauma Patient

Emmanuelle Loyrion, Thibaut Trouve-Buisson, Patricia Pouzol, Sylvie Larrat, Thomas Decaens, Jean-Francois Payen

Emerging Infectious Disease, 2017

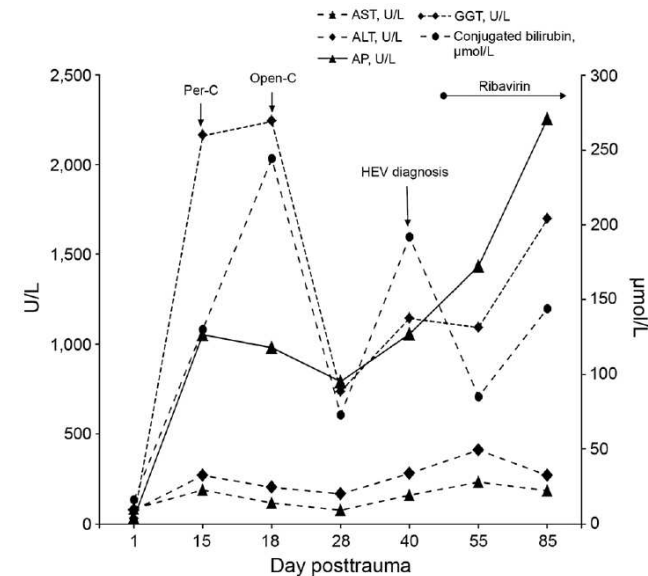


Figure. Time course of liver blood test results from a trauma patient in France who was transfused with an HEV-contaminated blood platelet pool on day 5 posttrauma. ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase; GGT, gamma glutamyl transferase; HEV, hepatitis E virus; open-C, open cholecystectomy; per-C, percutaneous cholecystectomy.

Hepatitis E Virus Infection after Platelet Transfusion in an Immunocompetent Trauma Patient

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Jean-Francois Payen

*Transmission of hepatitis E
by an Intercept® Blood
System - treated pooled
whole blood platelet
concentrate.*

- The HEV infectious dose in the pooled platelet product was ~ 60000 copies.
- Transmission occurred despite a low viral load in this pooled blood product
- The associated red blood cell concentrate did not transmit HEV
- The associated plasma was destroyed for an unrelated cause.

Hepatitis E Virus Infection after Platelet Transfusion in an Immunocompetent Trauma Patient

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Transmission of hepatitis E by an Intercept® Blood System - treated pooled whole blood platelet concentrate.

- The HEV infectious dose in the pooled platelet product was ~ 60000 copies.
- Transmission of HEV by the pooled platelet product
- The association between HEV and platelet concentrate
- The association between HEV and platelet concentrate

**Transfusion Medicine
and Hemotherapy**

Case Report

Transfus Med Hemother 2016;43:198–202
DOI: 10.1159/000445195

Received: December 4, 2015
Accepted: March 2, 2016
Published online: May 3, 2016

Parvovirus B19 Passive Transmission by Transfusion of Intercept® Blood System-Treated Platelet Concentrate

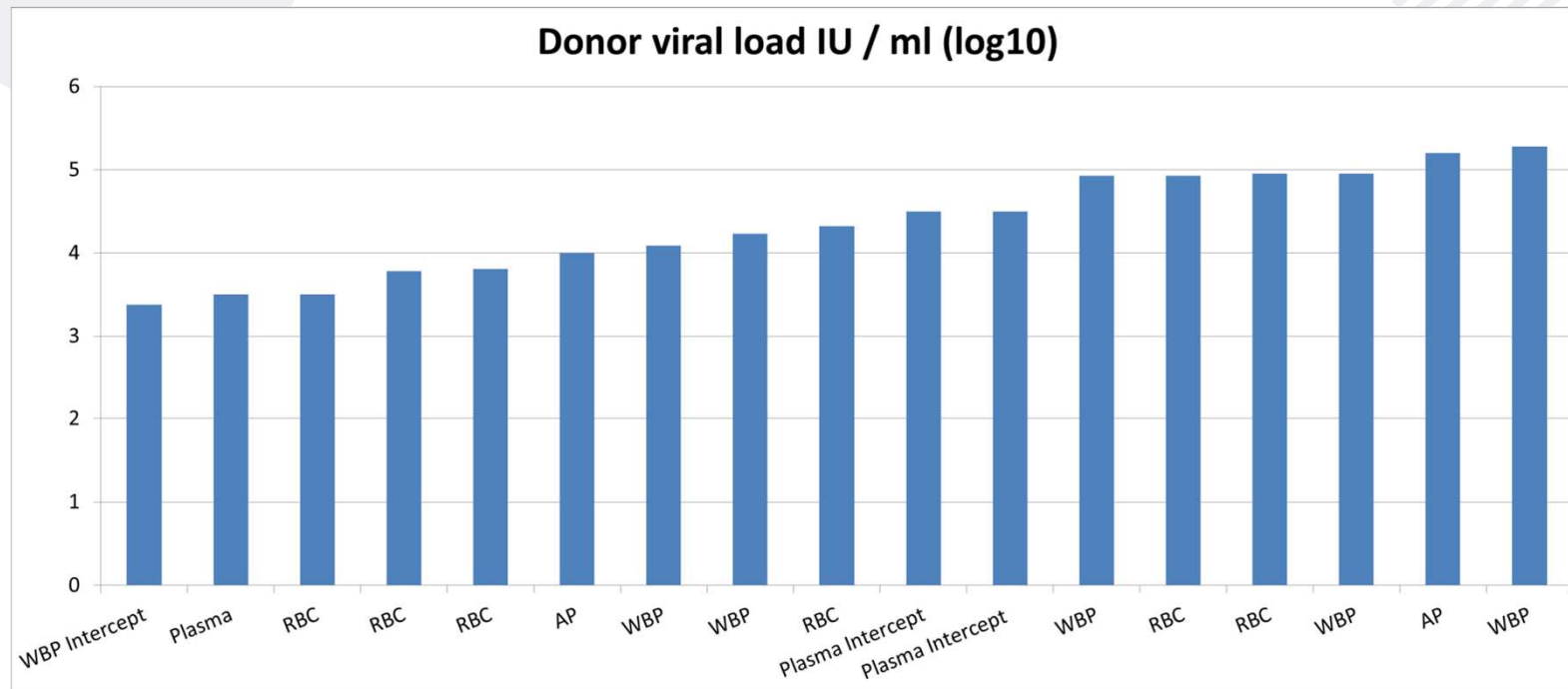
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Transfusion-transmitted hepatitis E in France

Donor viral load



WBP: whole blood
pooled platelet
concentrate
RBC: red blood
concentrate
AP: apheresis platelet
concentrate

HEV RNA testing

Real Star HEV RT PCR Altona (EUROBIO) : SD 95% = 23 UI/ml (WHO standard)

January 2013 to December 2014:

- SD-Plasma produced by the EFS (Bordeaux), 70 liter pool, 100 apheresis plasma donations

Since January 2015:

- A fraction (20 to 30%) of plasma (quarantine or Intercept) intended for high-risk patients:

- ✓ Organ and allogeneic HSC transplantation recipients
- ✓ Other severely immunosuppressed patients
- ✓ Patients with chronic liver disease

Since December 2015:

- All Intercept-treated pooled plasma (5 whole blood-derived plasma resulting in 6 plasma products)

2017: Expanding HEV testing for at least a fraction of all blood products is being considered

Fulminant liver failure from acute autochthonous hepatitis E in France: description of seven patients with acute hepatitis E and encephalopathy

J. M. Péron,¹ C. Bureau,¹ H. Poirson,¹ J. M. Mansuy,² L. Alric,³ J. Selves,⁴ E. Dupuis,¹, J. Izopet² and J. P. Vinel¹ ¹Service d'Hépatogastro-Entérologie, ²Laboratoire de Virologie, ³Service de Médecine Interne, and ⁴Service d'Anatomie et Cytologie Pathologiques, CHU Toulouse Hôpital Purpan, Toulouse, France

Received May 2006; accepted for publication June 2006

- Patients were 65 ± 11 years old. Five were active alcohol drinkers and six had chronic liver disease.
- All hepatitis E virus sequences evaluated (5/7) were of genotype 3.
- All patients but two died (71%).
- When compared with patients with a mild form of acute hepatitis E, active alcohol abuse and chronic liver disease were more frequent in patients with the severe form.

Fatal autochthonous fulminant hepatitis E early after allogeneic stem cell transplantation

Bone Marrow Transplantation advance online publication,
9 January 2017; doi:10.1038/bmt.2016.337

M Carré¹, A Thiebaut-Bertrand¹, S Larrat², V Leroy³, P Pouzol⁴,
N Sturm⁵, S Lhomme⁶, J-Y Cahn^{1,7}, F Garban^{1,7,8} and P Morand²
¹Clinique Universitaire d'Hématologie, CHU de Grenoble Alpes, La
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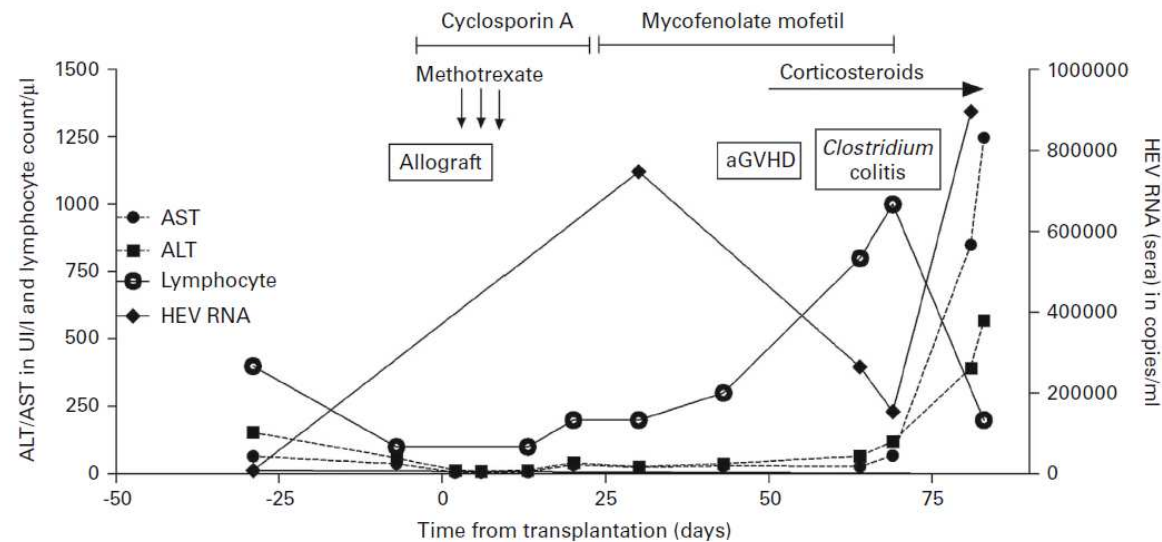


Figure 1. Chronology of liver enzymes level correlated with clinical events, lymphocyte counts and immunosuppressive treatments. The only available value of CD4+ lymphocytes was 0 at day 38. AST (UI/L) (15–37), aspartate aminotransferase; ALT (UI/L) (12–78), alanine aminotransferase.

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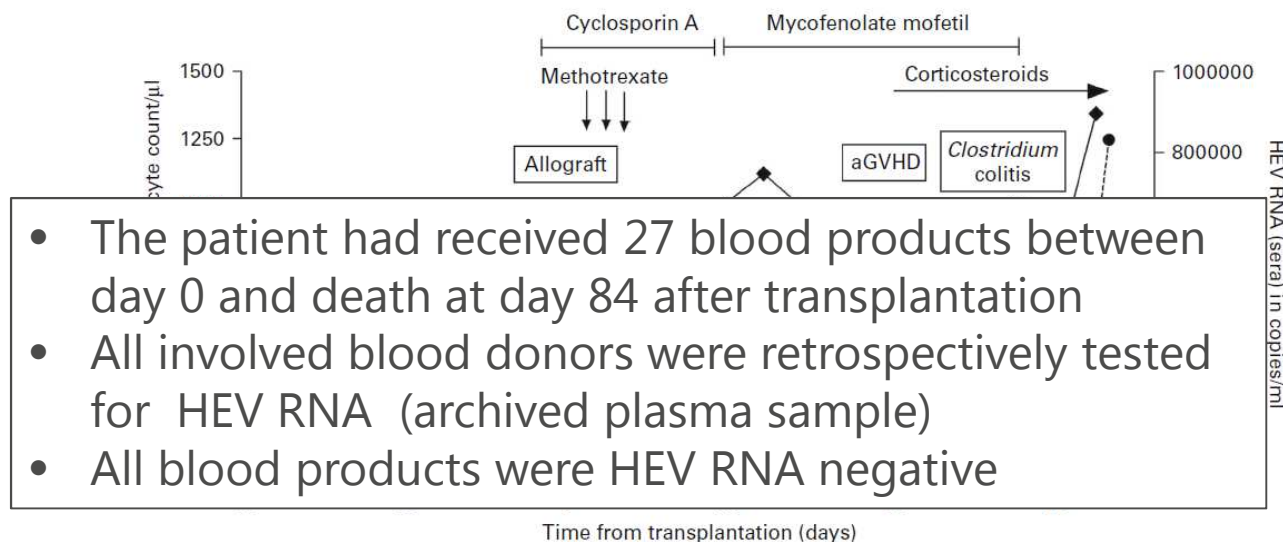


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Strategies for HEV donor screening: no screening? selective? universal?

Hepatitis E risks: pigs or blood—that is the question

Richard S. Tedder,^{1,2,3} Samreen Ijaz,¹ Alan Kitchen,² Ines Ushiro-Lumb,² Kate I. Tettmar,² Patricia Hewitt,² and Nick Andrews⁴

Transfusion, 2017

The transfusion risk of infection only exceeds the annual dietary risk when more than 13 individual donor components are transfused.

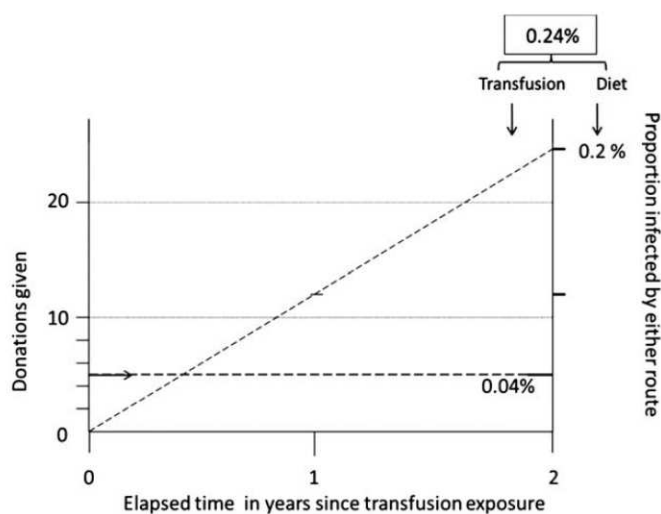


Fig. 4. Outcome at 2 years after receiving five components in a country with an annual seroconversion rate of 0.1%. The combined infection risk is 0.24% comprising both dominant cumulative dietary and smaller transfusion risks.

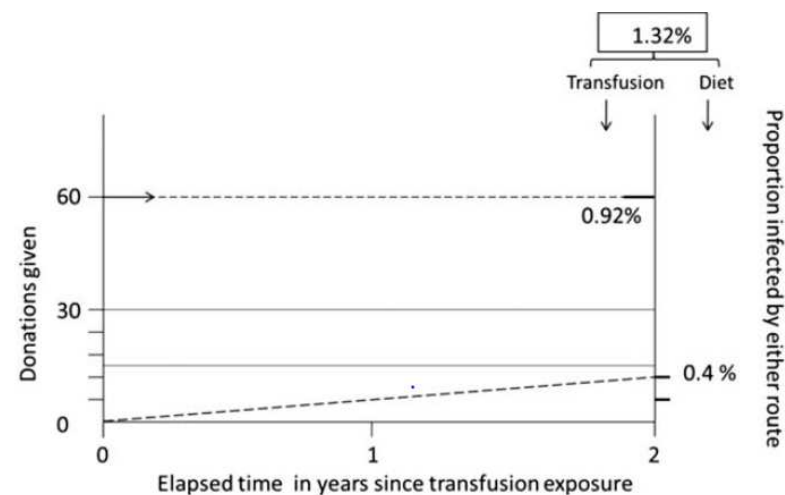
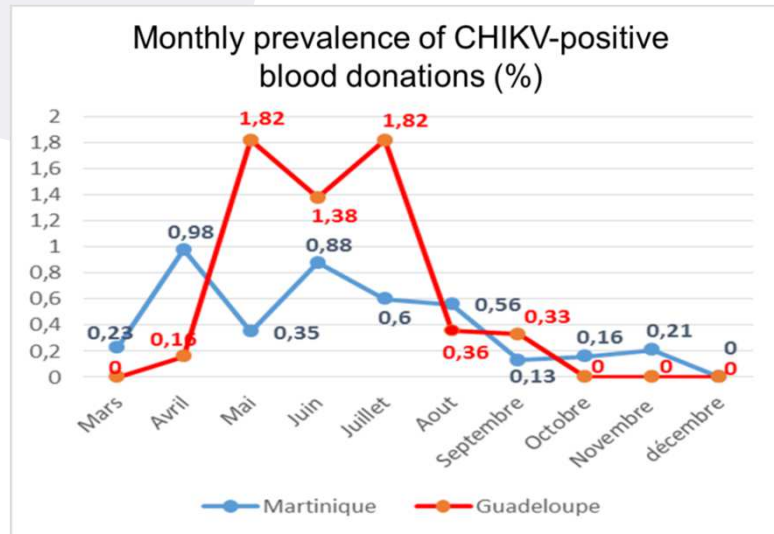


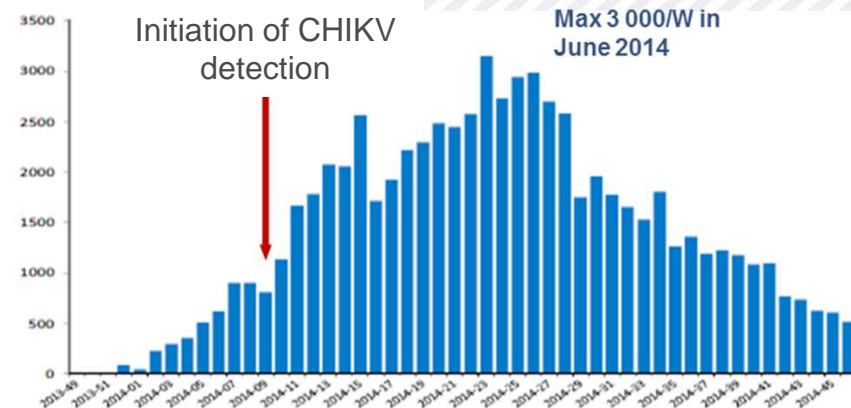
Fig. 5. Outcome at 2 years after receiving 60 components in a country with an annual seroconversion rate of 0.2%. The combined infection risk is 1.32% comprising both dominant transfusion and smaller cumulative dietary risks.

Chikungunya RNA screening in Martinique and Guadeloupe 2014: impact on the burden of the disease ?

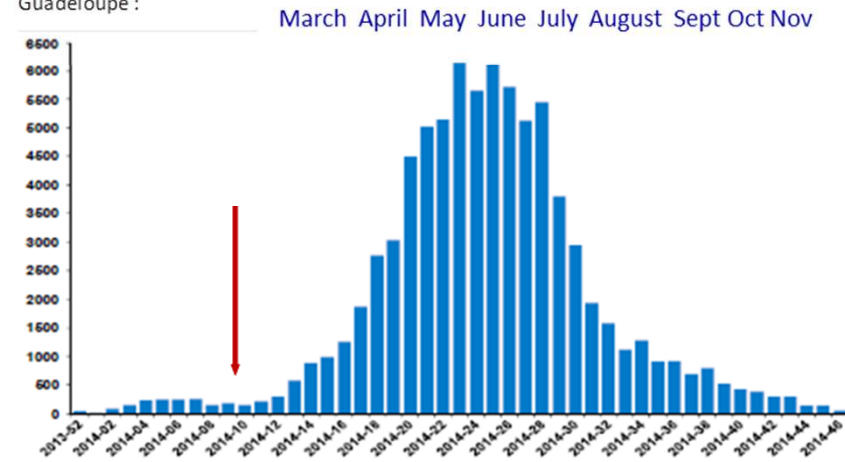


At peak of the epidemic (June 2014), the estimated ratio between CHIKV positive blood donors and reported CHIKV clinical cases was of 1/1000

Martinique :



Guadeloupe :



March April May June July August Sept Oct Nov

Strategies for HEV donor screening:

no screening?

selective?

universal?

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- plasma (n=7), including solvent-detergent (SD)-plasma (n=4), Intercept® plasma (n=2) and quarantine plasma (n=1)
- Patients, aged 5 to 88 years old, kidney (n=5) or liver transplants (n=3)
- No cases of transfusion-transmitted hepatitis E with plasma since 2012
- Less chronic hepatitis E among recent transfusion-transmitted hepatitis E? (cholestasis or other case)
- Chronic hepatitis requiring ribavirine treatment in 9 patients, all immunosuppressed, and among which 2 patients developing significant liver fibrosis.

Transfusion-transmitted hepatitis E in France

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Fraction of products to test in order to insure everywhere permanent availability of HEV-tested blood products ?

- plasma only : 20 to 30 %
- RBC and platelets: over 60 %

liver fibrosis.

Hepatitis E Virus Infection after Platelet Transfusion in an Immunocompetent Trauma Patient

Emmanuelle Loyrion, Thibaut Trouve-Buisson, Patricia Pouzol, Sylvie Larrat, Thomas Decaens, Jean-Francois Payen

Emerging Infectious Disease, 2017

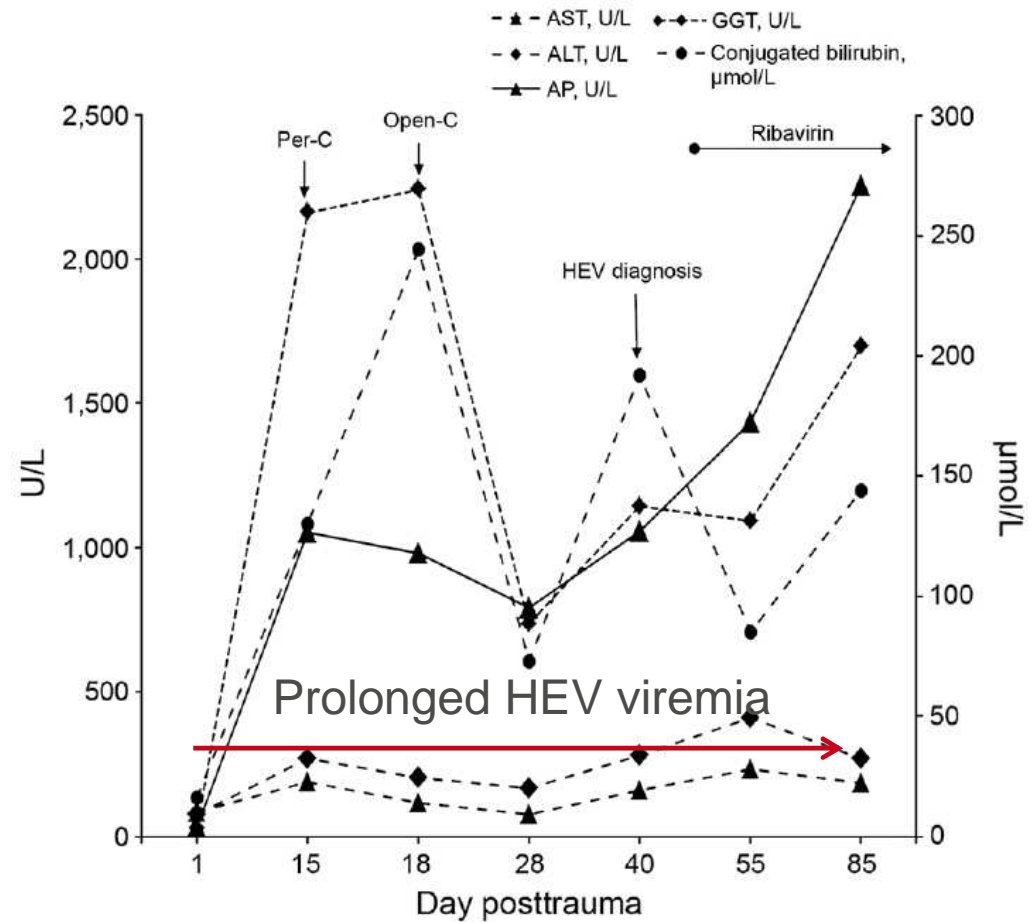


Figure. Time course of liver blood test results from a trauma patient in France who was transfused with an HEV-contaminated blood platelet pool on day 5 posttrauma. ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase; GGT, gamma glutamyl transferase; HEV, hepatitis E virus; open-C, open cholecystectomy; per-C, percutaneous cholecystectomy.

Extra-hepatic manifestations of autochthonous hepatitis E infection

K. L. Woolson[†], A. Forbes[†], L. Vine^{†,‡}, L. Beynon[§], L. McElhinney[§], V. Panayi^{†,§}, J. G. Hunter^{†,§}, R. G. Madden^{†,§}, T. Glasgow[†], A. Kotecha[†], H. C. Dalton[†], L. Mihailescu[†], U. Warshow[‡], H. S. Hussaini[†], J. Palmer[¶], B. N. Mclean^{††}, B. Haywood^{††}, R. P. Bendall^{†,‡‡} & H. R. Dalton^{†,§}

Aim

To report the extra-hepatic manifestations of hepatitis E virus.

Methods

Retrospective review of data of 106 cases of autochthonous hepatitis E (acute $n = 105$, chronic $n = 1$).

Results

Eight (7.5%) cases presented with neurological syndromes, which included brachial neuritis, Guillain-Barré syndrome, peripheral neuropathy, neuromyopathy and vestibular neuritis. Patients with neurological syndromes were younger (median age 40 years, range 34–92 years, $P = 0.048$) and had a more modest transaminitis (median ALT 471 IU/L, $P = 0.015$) compared to cases without neurological symptoms [median age 64 years (range 18–88 years), median ALT 1135 IU/L]. One patient presented with a cardiac arrhythmia, twelve patients (11.3%) presented with thrombocytopenia, fourteen (13.2%) with lymphocytosis and eight (7.5%) with a lymphopenia, none of which had any clinical consequence. Serum electrophoresis was performed in 65 patients at presentation, of whom 17 (26%) had a monoclonal gammopathy of uncertain significance. Two cases developed haematological malignancies, acute myeloid leukaemia and duodenal plasmacytoma, 18 and 36 months after presenting with acute hepatitis E infection.

Conclusions

A range of extra-hepatic manifestations can occur with hepatitis E. Neurological and haematological features of hepatitis E infection are relatively frequent in this UK cohort, and result in significant morbidity which warrants further study.

Aliment Pharmacol Ther, 2014

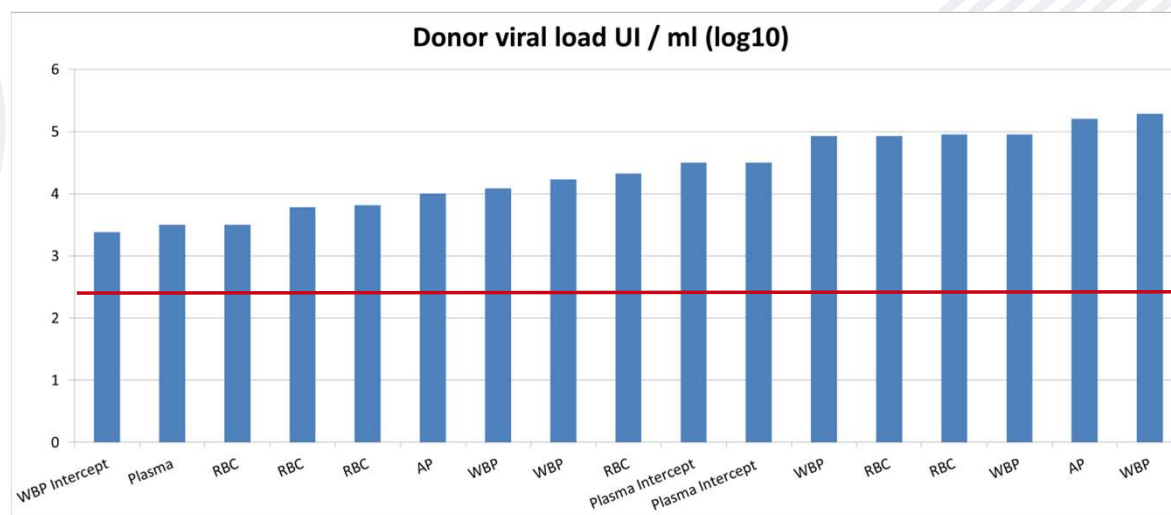
Strategies for HEV donor screening:

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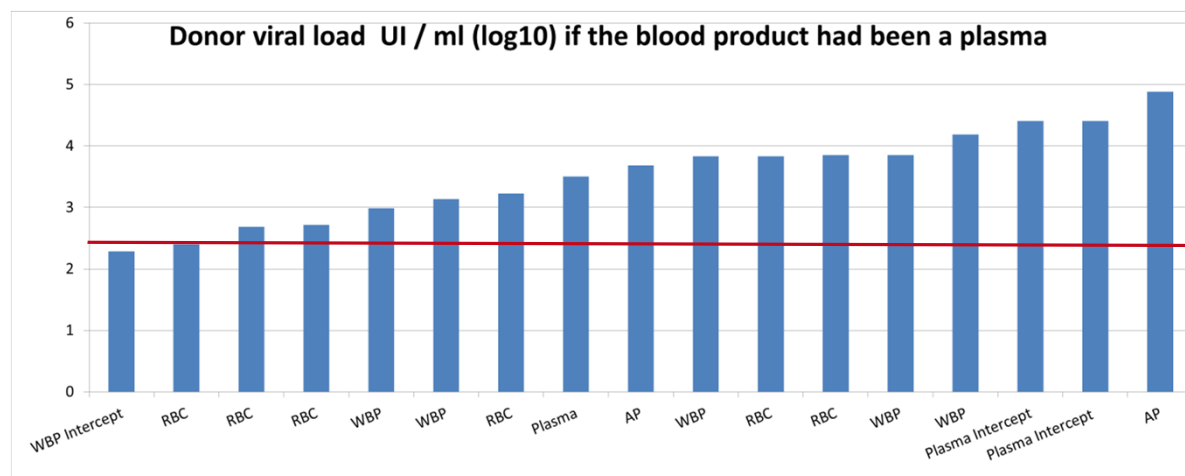
selective?

universal?

Detectability of HEV RNA + donors having resulted in recipient hepatitis E (excluding HEV RNA+ donors having contributed to SD-plasma)



Pool of 24

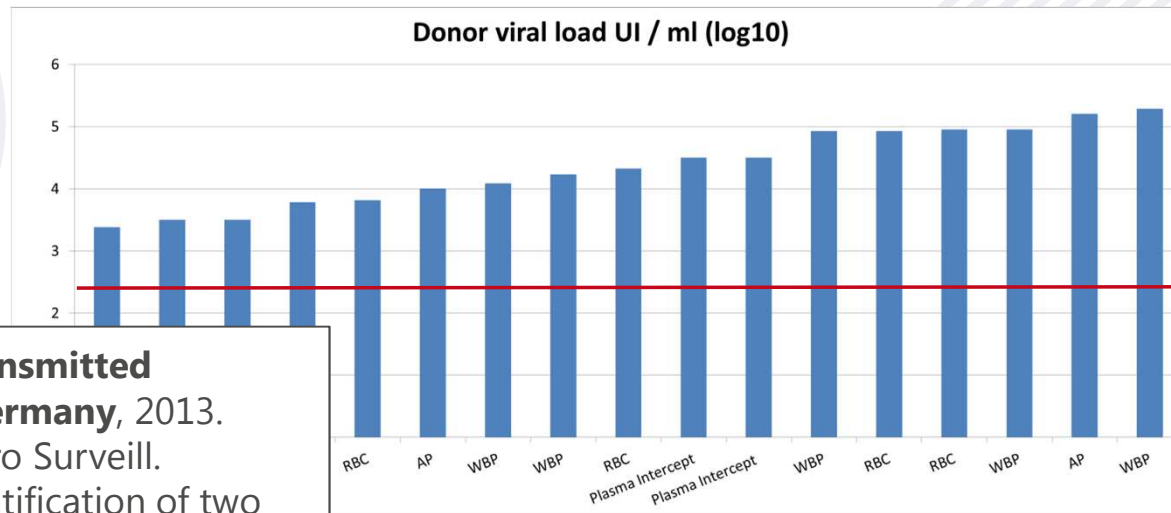


Pool of 24

WBP: whole blood pooled platelet concentrate
 RBC: red blood concentrate
 AP: apheresis platelet concentrate

minimal detectable titer	individual testing	pool of 6	pool of 12	pool of 24
SD 95% UI/ml	12	72	144	288
SD 95% UI/ml log10	1,08	1,86	2,16	2,46

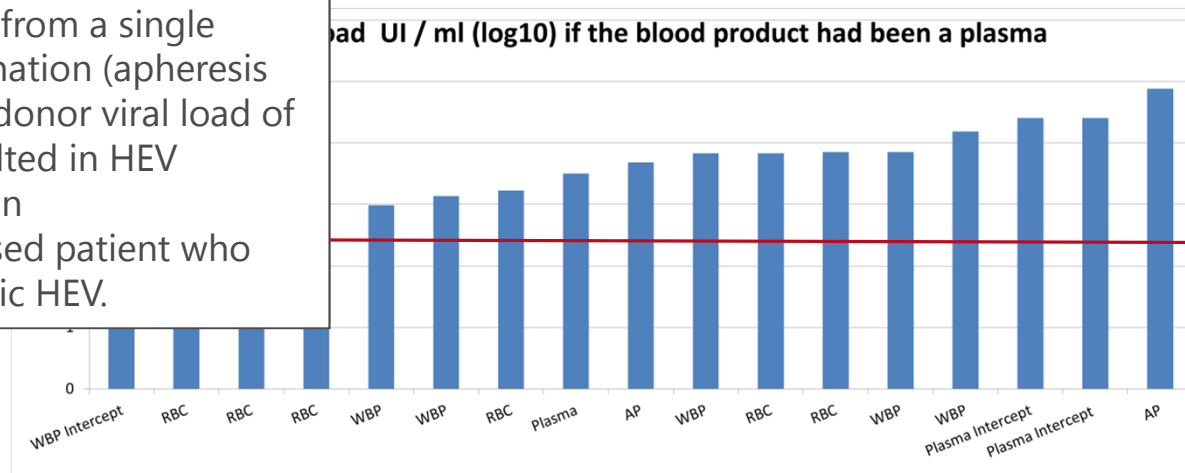
Detectability of HEV RNA + donors having resulted in recipient hepatitis E (excluding HEV RNA+ donors having contributed to SD-plasma)



Pool of 24

Transfusion-transmitted hepatitis E in Germany, 2013.

Huzly D et al. Euro Surveill. 2014;19(21). Identification of two HEV+ donations from a single donor. A first donation (apheresis platelets) with a donor viral load of **120 IU /ml** resulted in HEV transmission to an immunosuppressed patient who developed chronic HEV.



Pool of 24

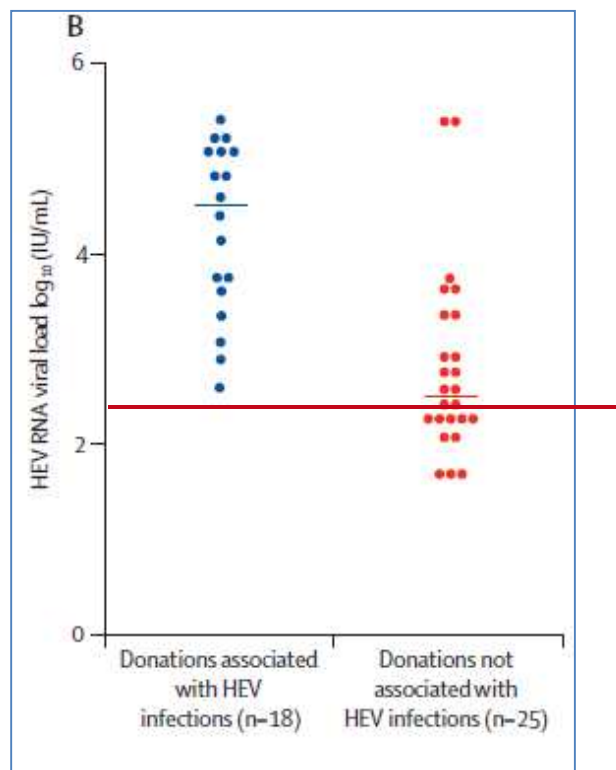
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Hepatitis E virus in blood components: a prevalence and transmission study in southeast England

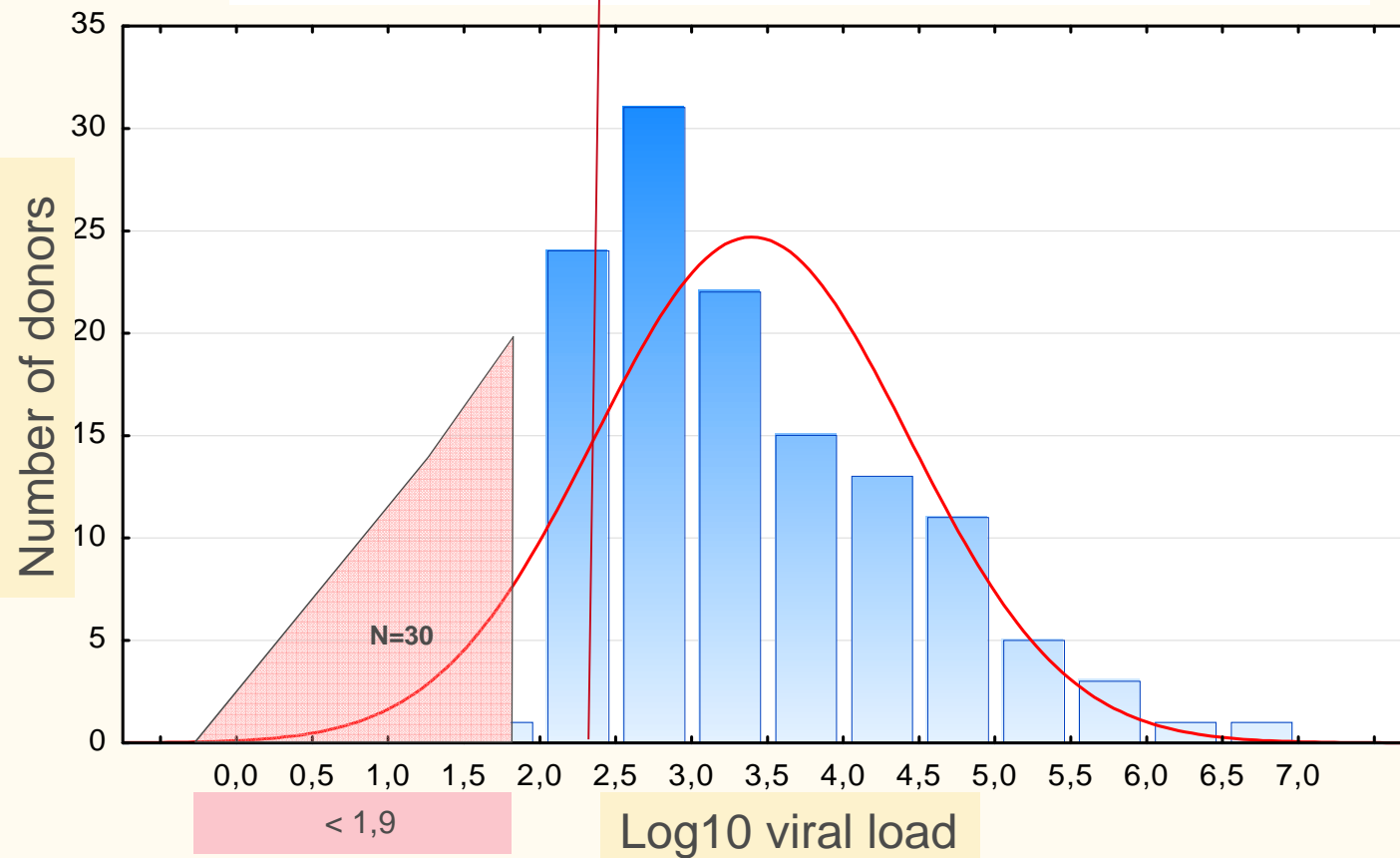
Patricia E Hewitt, Samreen Ijaz, Su R Brailsford, Rachel Brett, Steven Dicks, Becky Haywood, Iain T R Kennedy, Alan Kitchen, Poorvi Patel, John Poh, Katherine Russell, Kate I Tettmar, Joanne Tossell, Ines Ushiro-Lumb, Richard S Tedder

Lancet, 2014



(4.53 IU/mL [range 2.61–5.41] vs 2.57 IU/mL [1.70–5.49], $p < 0.0001$).

Log normal distribution of the HEV level (log IU/mL) detected in HEV RNA + blood donors



Cost-effectiveness of the screening of blood donations for hepatitis E virus in the Netherlands

Anneke S. de Vos,¹ Mart P. Janssen,¹ Hans L. Zaaijer,² and Boris M. Hogema²

- HEV screening of whole blood donations in pools of 24 would prevent 4.52 of the 4.94 transfusion associated chronic HEV infections expected annually, at approximately 310,000 euros per prevented chronic case.
- Per case not curable by ribavirin prevention, costs are approximately 10 times higher.

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- HEV screening of whole blood donations in pools of 24 would prevent 4.52 of the 4.94 transfusion-associated hepatitis E virus infections at an approach of chronic hepatitis E virus infection
- Per case approach

Cost-effectiveness of additional blood screening tests in the Netherlands

Barbara A. Borkent-Raven, Mart P. Janssen, Cees L. van der Poel, Gouke J. Bonsel, and Ben A. van Hout

TABLE 1. Costs, effects and cost-effectiveness of ABSTs in the Netherlands

Test (annual testing costs)	Description	Cases prevented	QALYs gained	Costs prevented (€)	ICER (€ per QALY)
Triplex MP-6-NAT for HBV, HCV and HIV (€8.18 million)	HBV	2.55	0.75	1350	
	HCV	0.51	0.13	185	
	HIV	0.16	0.70	8390	
	All combined	3.22	1.57	9920	5.20 million
	Per case		0.49	2.53 million*	
Triplex ID-NAT for HBV, HCV, and HIV (€8.78 million)	HBV	2.92	0.85	1550	
	HCV	0.53	0.13	193	
	HIV	0.21	0.90	10,812	
	All combined	3.66	1.89	12,556	4.65 million
	Per case		0.52	2.40 million*	
HAV NAT (€578,000)	In total	1.06	0.031	369	18.6 million
	Per case		0.029	545,000*	
HTLV antibody test, new donors (€25,700)	In total	2.22	0.011	214	2.23 million
	Per case		0.005	11,600*	
HTLV antibody test, pediatric recipients (€114,000)	In total	0.24	0.0042	61	27.0 million
	Per case		0.018	481,000*	
HTLV antibody test, all donors (€589,000)	In total	2.53	0.013	245	45.2 million
	Per case		0.005	232,000*	

* Indicates costs of testing per case prevented.

Estimated costs for HEV RNA testing in France:

- Individual testing (100%): 22 to 26 million euros
- Pool of 24 (100%) : 3 to 5 million euros

Relevance of safety measures to avoid HTLV transmission by transfusion in 2014

S. Laperche^{a,*}, J. Pillonel^b

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Disponible sur Internet le 27 septembre 2014

Transfusion Clinique et Biologique, 2014

HTLV transfusion-mediated transmission with clinical impact in France:

- without leucoreduction: 1 to 2 cases annually
- with leucoreduction (and a 10% deleucocytation failure): 1 case every 192 years

HTLV serology for all blood products in France: over 2 millions euros / year

HEV: after having emerged?

No Artifact, Hepatitis E Is Emerging

Zaaijer HL, Hepatology, 2015

HOGEMA ET AL.

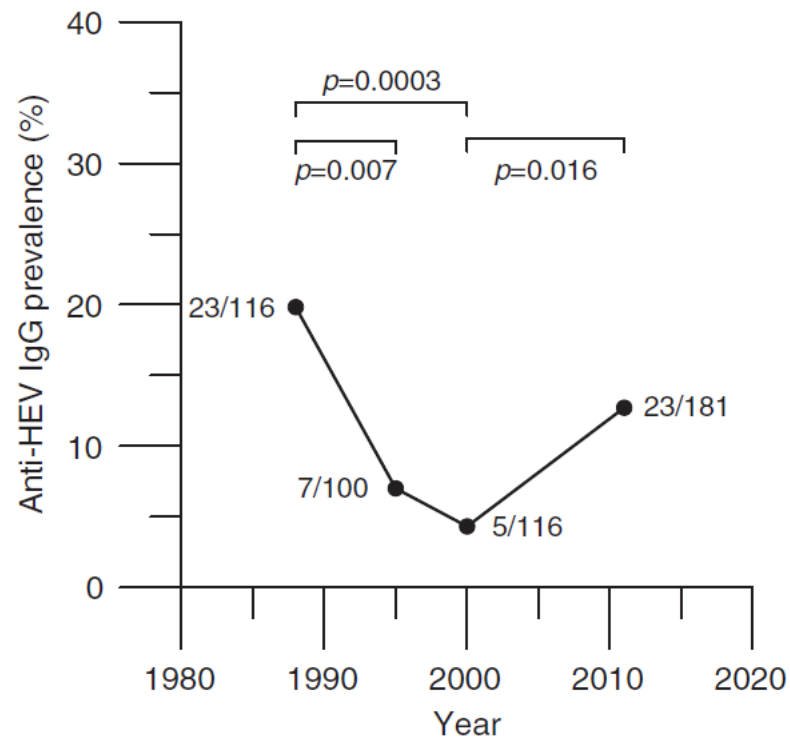


Fig. 2. Anti-HEV IgG seroprevalence among donors aged 18 to 21 in 1988, 1995, 2000, and 2011. The total number of samples and the number of anti-HEV-positive samples are indicated for each time point. The numbers above the bars denote the two-sided p values calculated using the chi-square method.

Hogema et al
Transfusion, 2014
and 2016

01-Jul-2014 01-Jan-2015

Donations in 2013
of positive donations
performed, approxi-
ssion is indicated by

RETURN OF HEV IN THE NETHERLANDS

Strategies for HEV donor screening:

no screening?
selective?

universal

By pool of 24 (to start with, and as of today)