

Hepatitis E virus *genotype 3*, the Dutch experience

TTID - WP June 26th 2015

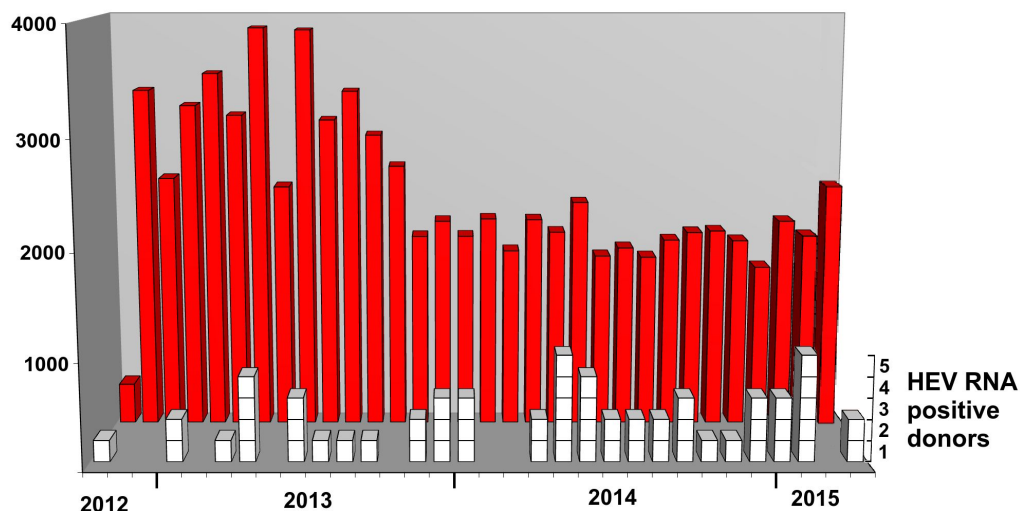
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Monthly donorscreening for HEV RNA in NL

~2000 donations/month; in pools of 96; for SD-plasma production

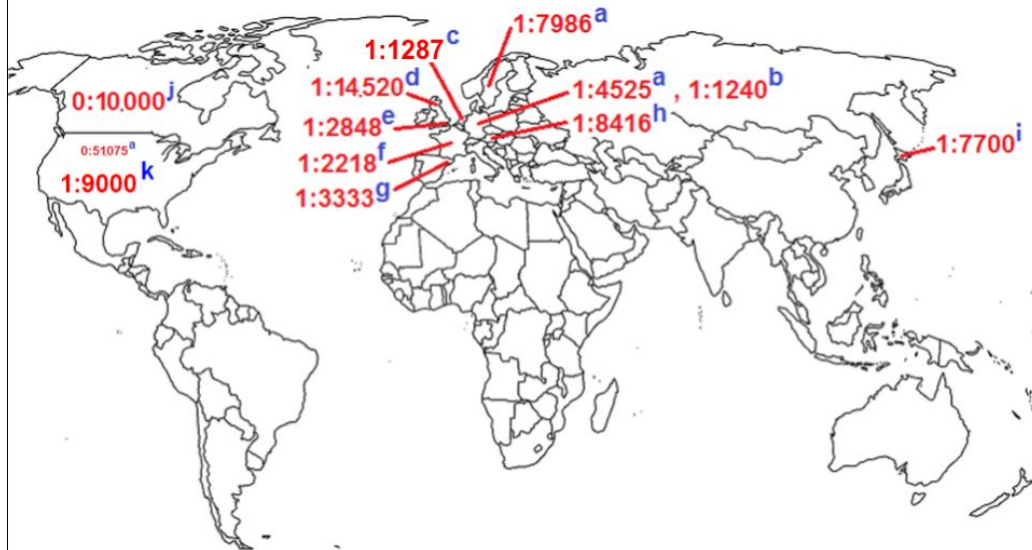
Dutch donations screened for HEV RNA



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overall: 57 / 73341 (1:1287) donations HEV RNA+
last 12 months: 1:852 HEV RNA+

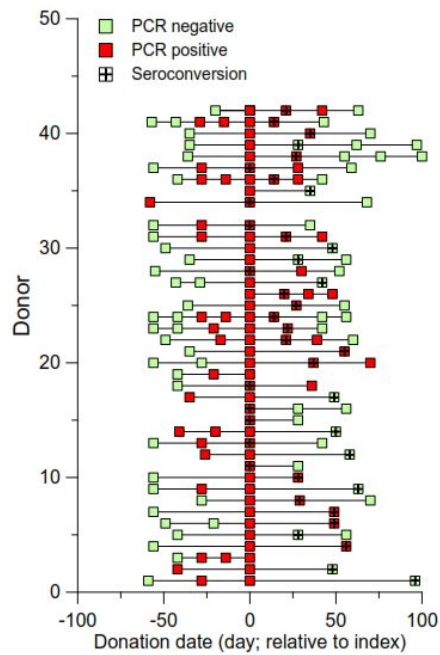
HEV RNA positive blood donors



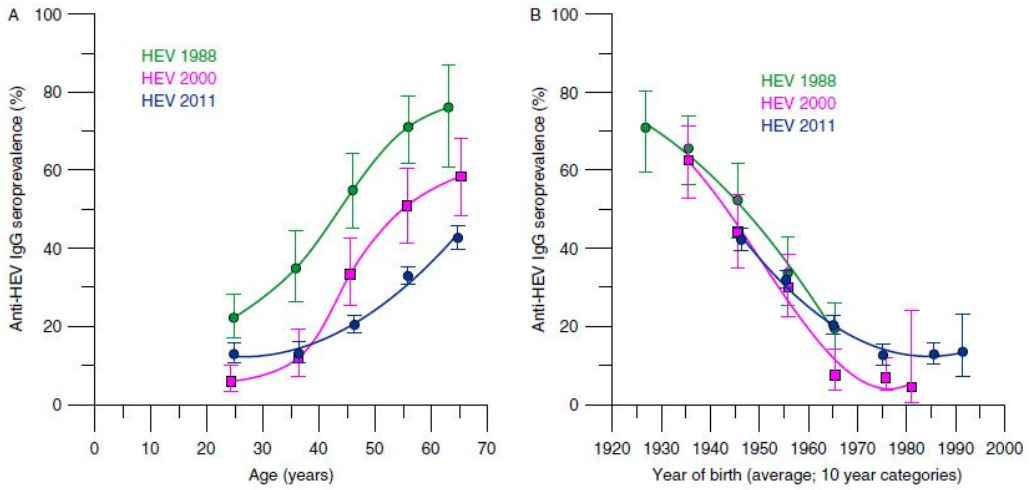
a) Baylis, Vox 2012; b) Vollmer, JCM 2012; c) Sanquin, submitted 2015; d) Cleland, Vox 2013;
 e) Hewitt, Lancet 2014; f) Gallian, EID 2014; g) Saulea, Transfusion 2014; h) Fischer, PlosOne 2015;
 i) Ikeda, ISS 2009; j) CBS Surveillance Report 2014; k) pers. communication J.S. Epstein.

Course of infection in 41 NL blood donors

- all donors seroconvert
 - index donations:
 2/3 seronegative
 HEV RNA range:
 pos < 20 - 2,3E6 IU/mL
 - avg. duration of viremia:
 68 days
 - normal or slightly elevated ALT
- (submitted)

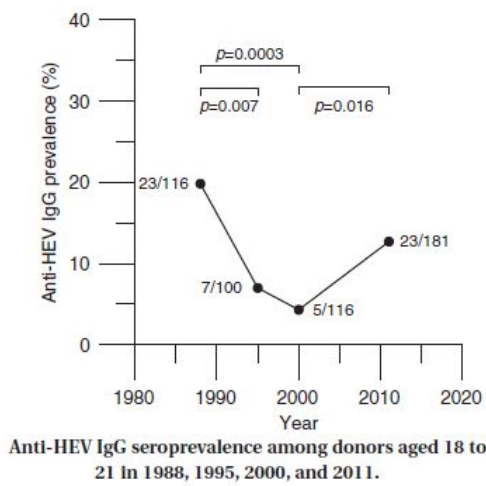


anti-HEV seroprevalence: age cohort effect



Hogema ea , Transfusion 2014

anti-HEV seroprevalence: recent increase among young donors

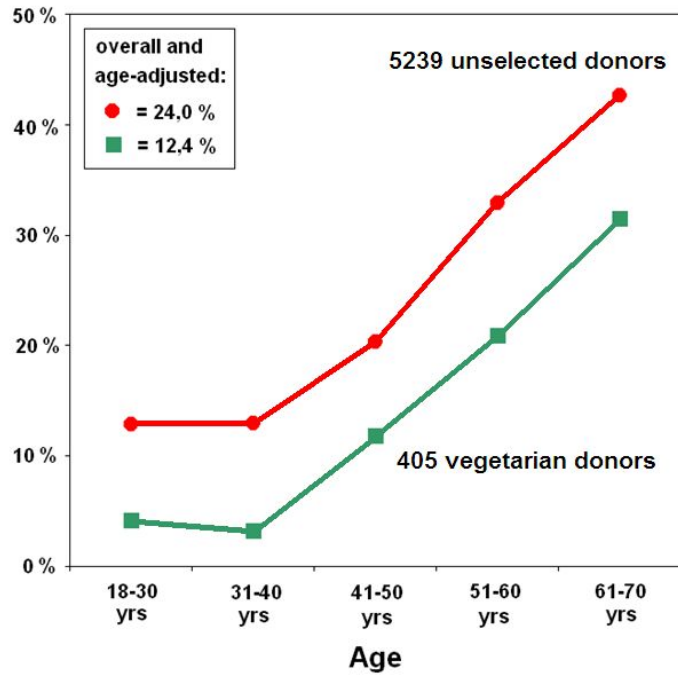


Hogema ea , Transfusion 2014

HEV antibodies in Dutch donors (2011)

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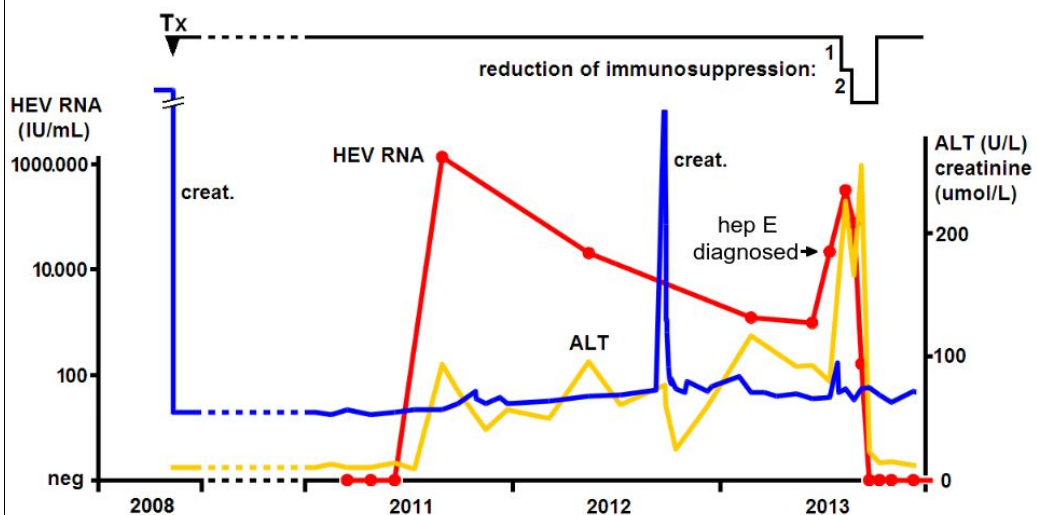
less
HEV
among
vegetarian
donors



(AMC) boy A, 10 yrs

2006: severe pneumococcal infection → HUS → kidney Tx in 2008

2011-2013: chronic hepatitis eci, 'drug induced liver injury' (dili) ?



step 1 = mycophenolate mofetil: 800 to 600 mg/m²/day
 step 2 = tacrolimus: 0.1 to 0.05 mg/kg/day
 (prednisolone remained unmodified at 2 mg/m²/day)

HEV: inactivation and removal

Sanquin's ad interim assessment of HEV and blood safety:

Effective removal or inactivation:

- Planova15N or Planova20N filtration
- Pasteurisation at 60 °C
- Immunoaffinity chromatography purification

Limited or no inactivation:

- SD treatment
- Low-pH treatment
- Alcohol fractionation
- Neutralisation by anti-HEV antibodies
(due to a protective lipid layer covering HEV virions in blood:
only neutralisation in serum or cell cultures after SD- or protease treatment)

See:

Summary of workshop presentations in Appendix to reflection paper, of the "EMA Workshop on viral safety of plasma-derived medicinal products with respect to hepatitis E virus" (London, Oct. 28th/29th, 2014); aimed to be released for public consultation in July 2015.

"Post-transfusion hep E" in NL ; policy

Cave pseudo transmission:

11 cases of "post-transfusion hep E" notified to Sanquin:

10 : all implicated donations HEV PCR negative.

1 : 1 implicated donor HEV RNA pos. (low viremia, aHEV-IgG +++).

> donorscreening only would have prevented 1/11 notified Dutch cases.

(NB several HEV transmissions via transfusion have been reported elsewhere)

Sanquin's point of view:

- Instead of (selective) donorscreening, transmission routes to donors and patients must be clarified and removed.

- June 12th 2015: For the time being this approach is supported by expert meeting at National Institute for Public Health.

- [impact of policy elsewhere, eg. in UK?](#)

HEV team at Sanquin:

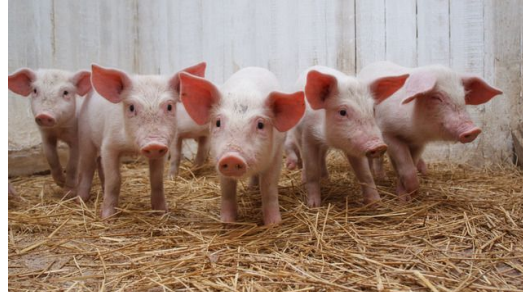
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