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HEV Incidence in the Blood Donor Population in Germany

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Conflicts of interest

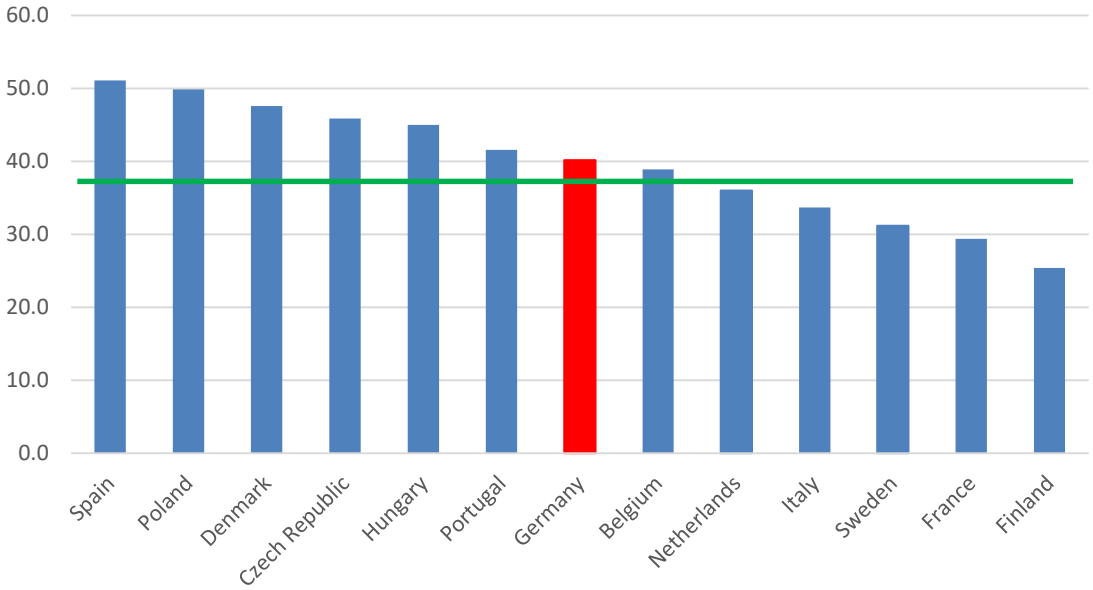
none

HEV

- Non-enveloped virus
- genus *Orthohepevirus*, family *Hepeviridae*
- 4 main genotypes
- Genotypes 3 and 4 are endemic among domestic pigs, wild boar, and rabbits
- Most human infections mild or asymptomatic and self-limiting
- Patients with underlying conditions may progress to liver failure
- Transfusion-transmitted HEV well documented
- Immunocompromised recipients especially vulnerable

Infected meat/environmental exposure account for 99% of infections

Per capita consumption of pork meat in the EU 2021/year (in kg)



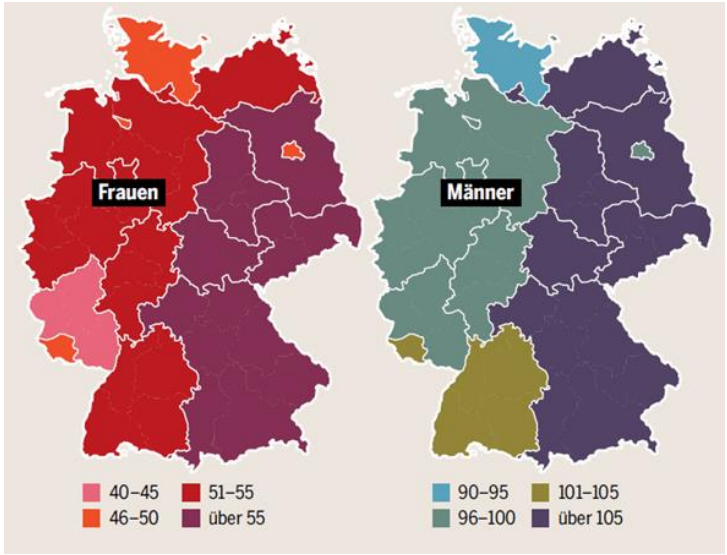
https://de.statista.com, 2023

Germany – homeland of the „Wurst“



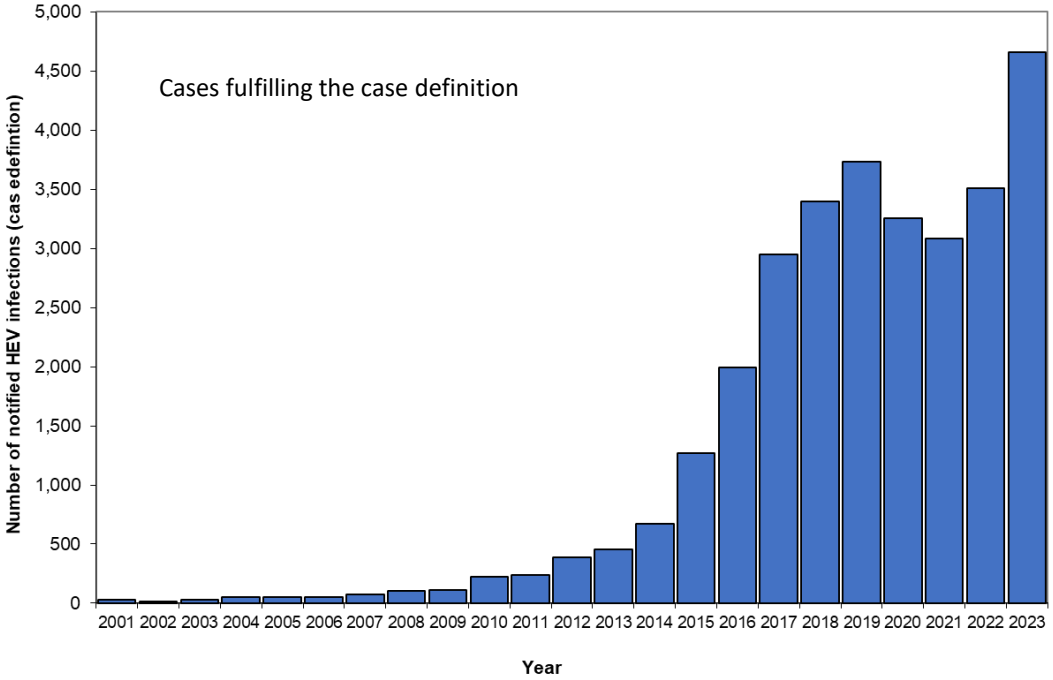
Handelsblatt, 2017

Meat consumption in kg/year



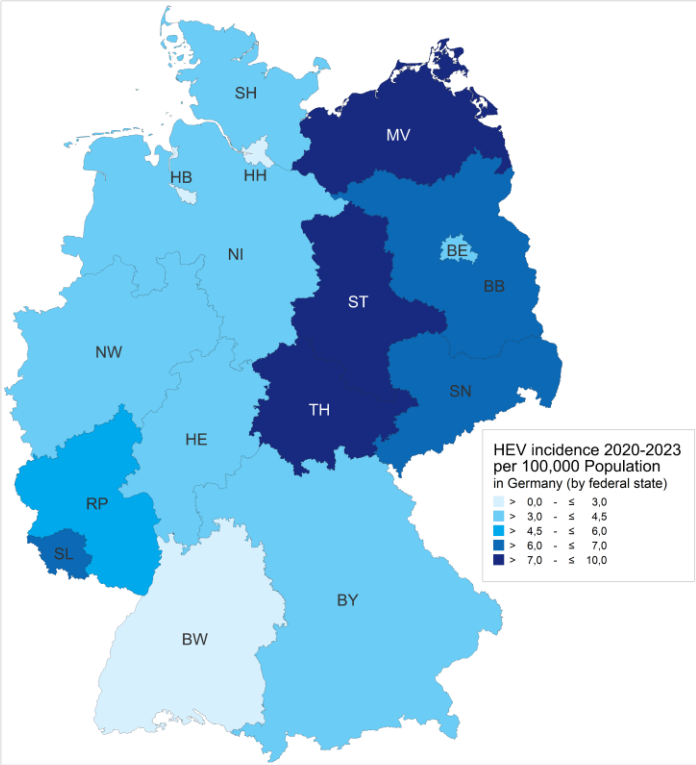
Fleischatlas 2018

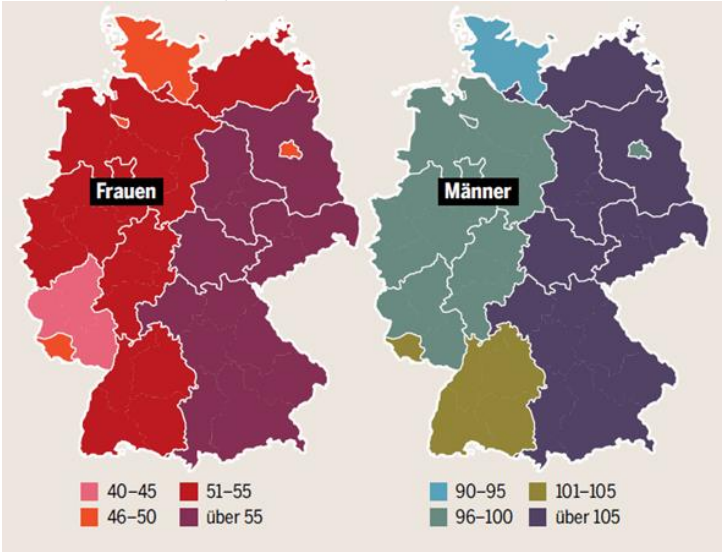
Notified HEV cases – general population



Year	Fatal HEV cases
2014	5
2015	5
2016	7
2017	9
2018	9
2019	8
2020	4
2021	7
2022	13
2023	10

Notified HEV cases/100,000 population – region





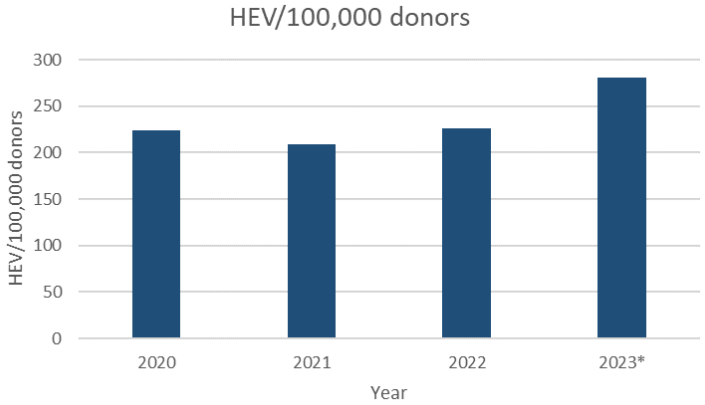
HEV testing of blood donations in Germany

- Became mandatory in January 2020 for blood components and stem cells
- LoD: 2,000 IU/mL at individual donation level
- Pool testing possible
- Test sensitivities ranging from 36 -1785 IU/mL
- Approximately 5 million donations tested annually
- Donor epidemiology includes reporting of tested donations and positive results
- Guidance for lookback procedures in place

HEV infections in the donor population 2020-2023

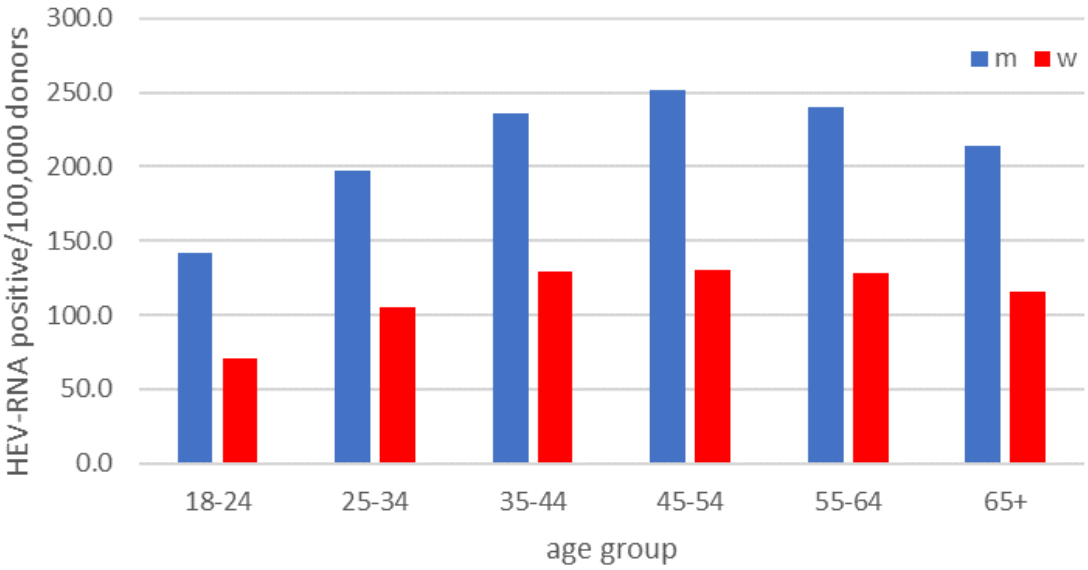
	HEV infections	donors	donations	HEV/100,000 donors	HEV/100,000 donations
2020	3,387	2,024,363	4,969,196	224.4	68.2
2021	2,614	1,711,723	4,424,312	208.6	59.1
2022	3,412	1,994,960	5,009,730	226.5	68.1
2023*	2,101	1,204,782	3,051,867	280.2	68.8

*preliminary data

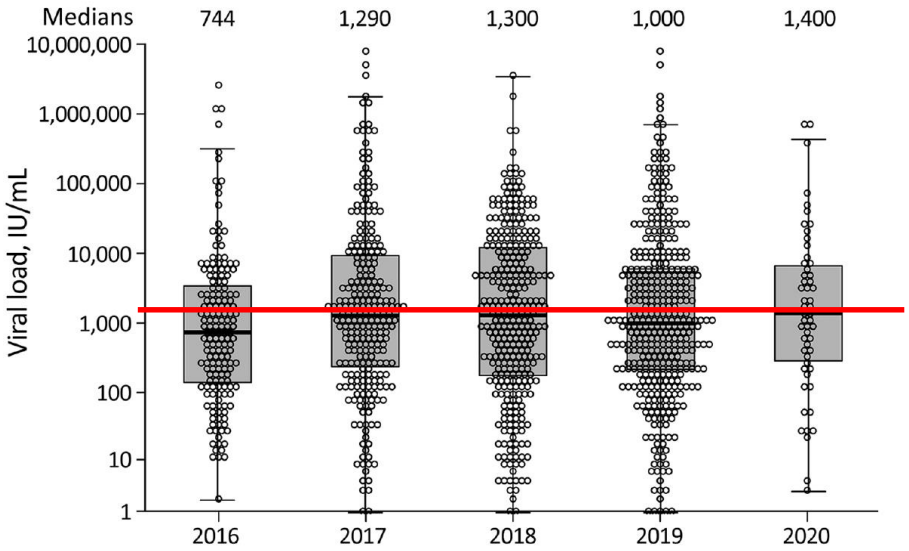


1 in 1,470 donations HEV-RNA-positive

HEV infections in blood donors 2020-2023 – age and sex



HEV infections in blood donors 2020-2023 – corrected prevalence



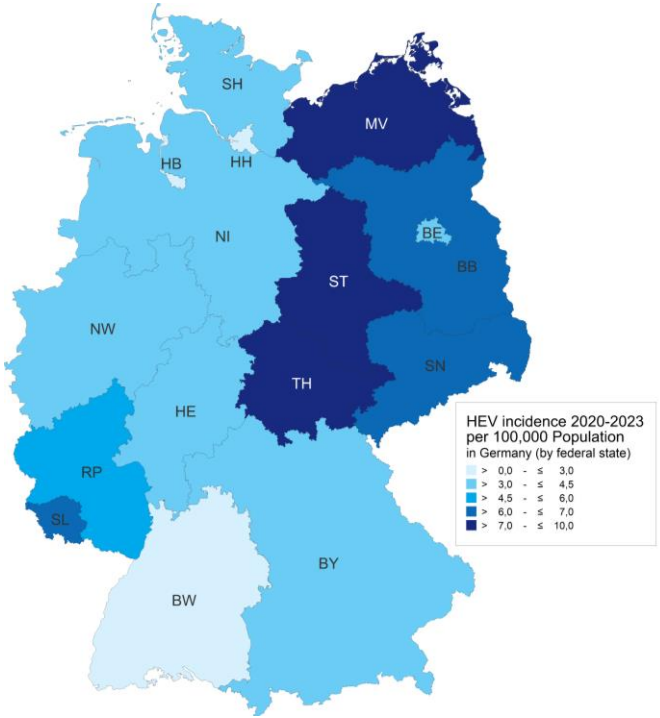
Harvala et al., EID 2022
https://doi.org/10.3201/eid2809.220487

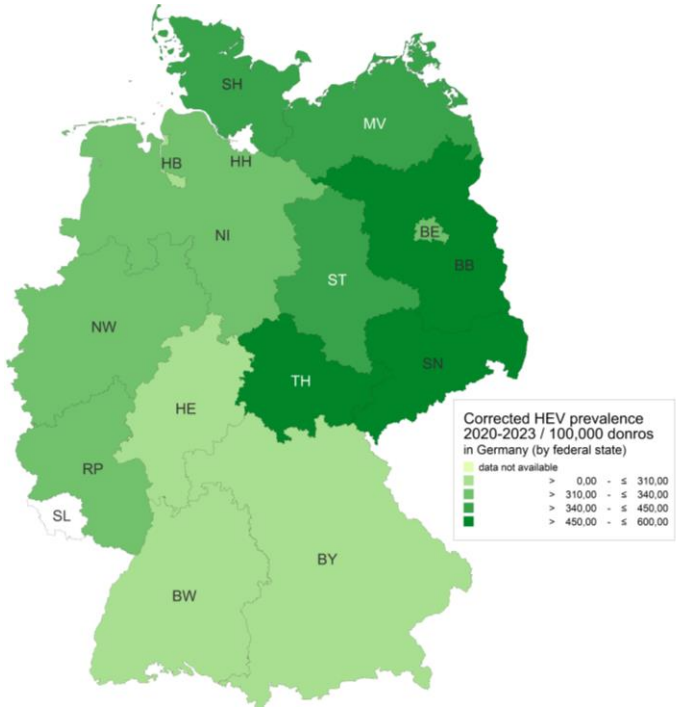
BE with known HEV NAT sensitivity

	Prevalence	Corrected Prevalence **
2020	165.0	321.0
2021	153.8	298.7
2022	172.3	333.9
2023*	173.8	342.4

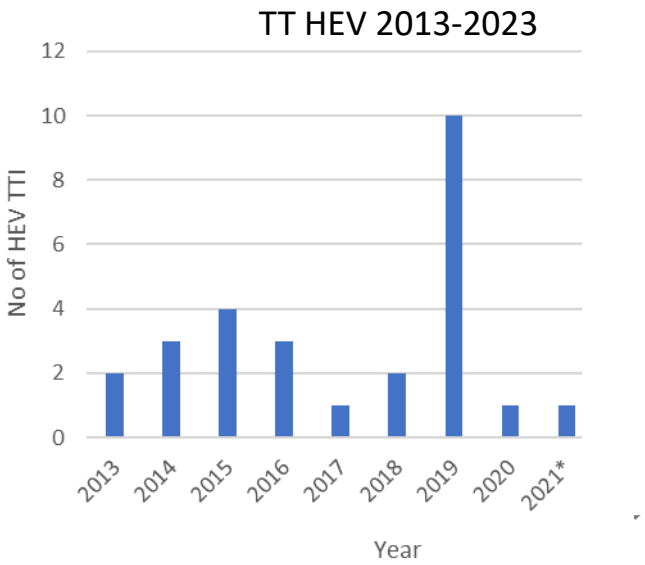
*Data preliminary
** Prevalence corrected for sensitivity of NAT used according to Harvala et al.

Comparison HEV cases general population and blood donors





Haemovigilance data



* Quarantined plasma, collected before implementation of testing

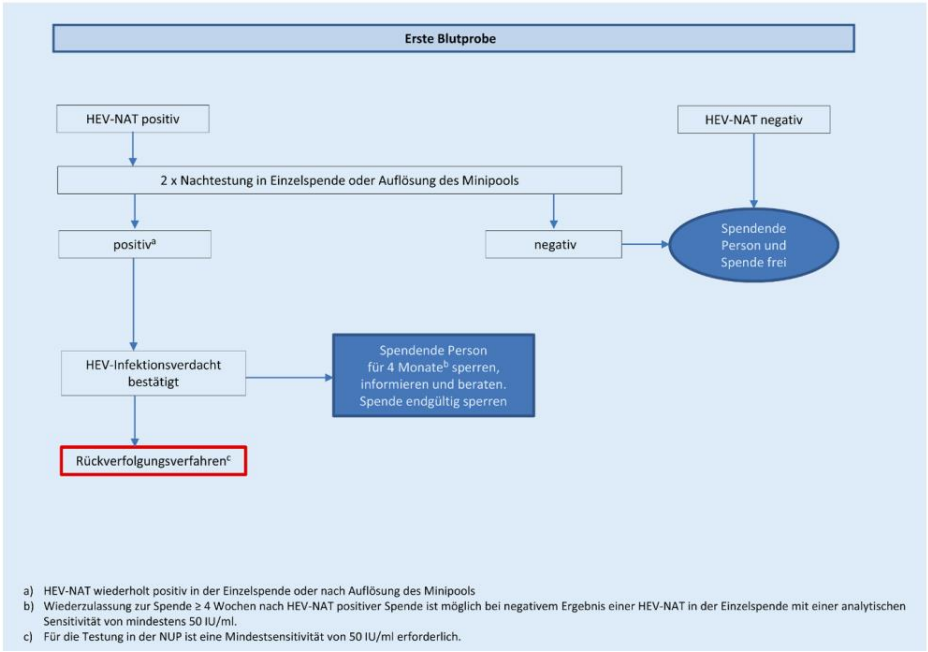
Year	blood component	underlying disease	outcome
2013	EC	n/a	no clinical symptoms
2013	PC	STX	fatal outcome
2014	PC	n/a	no clinical symptoms
2014	PC	n/a	no clinical symptoms
2014	EC	n/a	no clinical symptoms
2015	EC	n/a	no clinical symptoms
2015	EC	n/a	no clinical symptoms
2015	PC	n/a	infection resolved
2015	PC	n/a	infection resolved
2016	EC	STX	chroniv HEV
2016	EC	LTX	n/a
2016	PC	Hematological diseas	no clinical symptoms
2017	EC + PC	STX	chroniv HEV
2018	PC	n/a	n/a
2018	PC	n/a	n/a
2019	PC	STX	NAT+ 1 month after TF
2019	EC+PC	STX	NAT+ 2 months after TF
2019	PC	Hematological diseas	NAT+ 2 months after TF
2019	EC	Trauma	NAT+ 12 days after TF
2019	EC	Cancer	n/a
2019	EC	n/a	n/a
2019	PC	Hematological diseas	infection resolved
2019	EC	n/a	NAT+ 1 month after TF
2019	EC+PC	Cancer	n/a
2019	Plasma	RTX	NAT+ 2 months after TF
2020	PC+Plasma	n/a	n/a
2021	Plasma	n/a	infection resolved

Hemovigilance reports and personal information, PEI

HEV Lookback

Bekanntmachungen – Amtliche Mitteilungen

Anhang D: HEV



a) HEV-NAT wiederholt positiv in der Einzelspende oder nach Auflösung des Minipools
b) Wiederzulassung zur Spende ≥ 4 Wochen nach HEV-NAT positiver Spende ist möglich bei negativem Ergebnis einer HEV-NAT in der Einzelspende mit einer analytischen Sensitivität von mindestens 50 IU/ml.
c) Für die Testung in der NUP ist eine Mindestsensitivität von 50 IU/ml erforderlich.

- HEV-RNA positive donors deferred for 4 months
- Lookback period: 6 months
- In 2022 and 2023 > 300 donor initiated lookbacks

Conclusion

- HEV is endemic in Germany with clear regional differences
- Men are more affected than women in the general population as well as in donors
- 1 in 1,470 donations tested was HEV-RNA-positive in the past 4 years
- Approximately half of all HEV-RNA-positive infections are missed with the NAT sensitivity used
- Screening of blood donations has reduced TT HEV
- No severe outcomes have been reported since testing started
- Current mandatory LoD of 2,000 IU/mL seems justified

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Thank you for your attention!

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