Position Statement

September 2023

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The estimated residual risk that a donation made in the infectious window period is not detected on testing:

Risks specific for HBV, HCV and HIV in the UK, 2020-2022

Summary

- Residual risk is estimated for current UK blood donation testing strategies as the risk that a potentially infectious donation made in the window period (WP) is not detected and may enter the blood supply. This is calculated as risk multiplied by 1 million, which is the number of potentially infectious donations NOT detected in 1 million donations tested, with 95% confidence intervals (by simulation), and the number of millions of donations tested before 1 of those infectious donations can be expected to be missed. The values calculated here do not represent the risk of transmission. Furthermore, because the risk estimates depend upon the concept of an infectious window period, and calculations for the traditional blood-borne viruses use incidence rates based on observed seroconversions in repeat donors, this method of calculating risk cannot necessarily be applied to all infections for which donation testing is carried out.
- The estimates for HBV are for acute infections only and do not consider risk due to occult HBV. Hepatitis B core antibody screening for blood donations was rolled out across the UK in 2022 in response to a review carried out by SaBTO. This has already had an impact in increased detection of potentially transmissible hepatitis B virus from donors with occult hepatitis B, which have been removed from the blood supply.
- The number of potentially infectious window period donations that testing did not detect during 2020-2022 in the UK was estimated to be less than 1 million (Table 1). Estimated risk remains highest for HBV at 0.63 (95% confidence interval (CI) 0.46-1.61) per million donations tested. This is greater than, but within the 95% confidence interval of, the previous estimate of 0.39 per million (95% CI 0.07-0.98) for 2019-2021. For HCV the risk was estimated at 0.02 (95% CI 0.00-0.09) per million donations and for HIV the risk was 0.03 (95% CI 0.00-0.08) per million. The point estimates of these values were unchanged from 2019-2021 calculations.
- Donations given by new donors were estimated to be more likely to have undetected WP infections compared with donations from repeat donors, although for HBV and HIV there was less difference between the two donor groups.
- The estimates for 2020-2022 include the first 18-months of data collected under the For the Assessment of Individualised Risk (FAIR) donor selection policy implemented across the UK from June 2021. FAIR allows all MSM to donate if they have not had anal sex with a new sexual partner or multiple sexual partners within 3-months and no other exclusions apply.
- At the 2022 donation levels of approximately 1.8 million donations each year in the UK, it is estimated that testing did NOT identify approximately 1 potentially infectious HBV window period donation per year. The risks are considerably smaller for HCV and HIV, and at current donation levels it is estimated

that it could be up to 34 years to miss one potentially infectious HCV window period donation, and up 17 years to miss one potentially infectious HIV window period donation.

- The estimates have remained below 1 in 1 million for over 10 years (Figure 1).
- Donations tested and found positive from convalescent plasma and plasma for medicine donors are not included here.
- HEV residual risk estimates are not routinely calculated, hence not included here. This is primarily because of uncertainty of the duration of the WP and the fluctuating incidence of HEV in the donor population. This means that the relevance of the traditional incidence WP method across 3-years, as used here for HBV, HCV or HIV, would be questionable for HEV. However, HEV risks have been calculated elsewhere for apheresis and whole blood donors in England between 2016-2020.[1] Estimates were shown to fluctuate year on year and based on a 7-day WP ranged from 23.79 to 39.34 per million for apheresis donors, and 22.70 to 46.03 per million for whole blood. Risks for both groups increased 2-fold if a 14-day WP was used instead. These estimates are considerably higher than for HBV, HCV or HIV, and it should be noted that while HEV is a blood borne virus, its main route of transmission is zoonotic with humans generally exposed through diet.

Table 1: The estimated risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2020-2022

	Donor type	HBV[1]	HCV[2]	HIV[3]
The number of potentially infectious window period donations NOT detected in 1 million donations tested. **This is equal to risk × 1 million.**	**All[4] (95% CI)**	0.63 (0.46 – 1.61)	0.02 (0.00 – 0.09)	0.03 (0.00 – 0.08)
	New (95% CI)	1.42 (1.15 – 6.45)	0.10 (0.00 – 0.93)	0.04 (0.00 – 0.39)
	Repeat (95% CI)	0.57 (0.50 – 1.39)	0.01 (0.00 – 0.02)	0.03 (0.00 – 0.06)
The number of millions of donations tested before a potentially infectious WP donation would NOT be detected. **This is equal to 1/(risk × 1 million).**	**All[4]**	1.7	64	33
	New	0.8	10	21
	Repeat	1.8	116	34

[1] HBV testing assumed all donations were tested for markers of HBsAg and HBV DNA using NAT with a window period of 30 days.

[2] Anti-HCV testing and HCV RNA testing with a window period 4 days.

[3] Combined HIV antigen/antibody testing and HIV NAT with a window period 9 days.

[4] The risk due to WP amongst all donations was calculated as the weighted average of the risk amongst new and repeat donors, weighted according to the number of donations made from new and repeat donors.

All molecular screening was performed in pooled samples of 24 donations

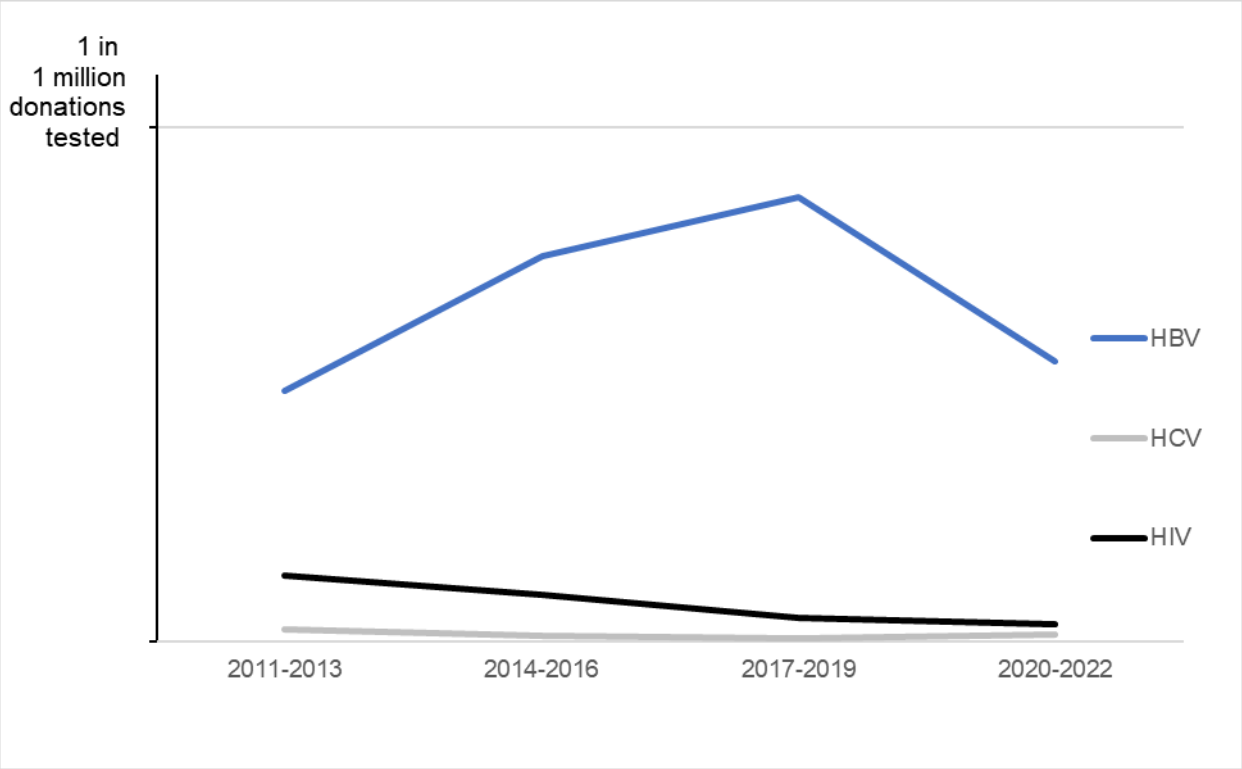

Figure 1: The estimated risk that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation for 3-year periods from 2011-2013 to 2020-2022

These estimates were produced using data, published results from papers and opinion collected by the NHSBT/UKHSA Epidemiology Unit. Data are checked regularly to ensure accuracy; however, the estimates may be revised if new or additional information is received.

Please acknowledge NHSBT/UKHSA Epidemiology Unit when quoting.

The model used to estimate the residual risks is peer reviewed, was developed, and is employed by, members of the ISBT TTI Working Party SRAP (Surveillance, Risk Assessment & Policy) subgroup.

References

1. Harvala et al., Fulminant Transfusion-Associated Hepatitis E Virus Infection Despite Screening, England, 2016-2020. *Emerging Infectious Diseases* (2022). doi.org/10.3201/eid2809.220487 (accessed 11/10/23)

Dr Stephen Thomas
Professional Director – JPAC