Position Statement

September 2024

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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, 2021–2023

Background

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 one million, which is the number of potentially infectious donations not detected in one million donations tested, with 95% confidence intervals (by simulation), and the number of millions of donations tested before one 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 the Advisory Committee on the Safety of Blood, Tissues and Organs (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 2021-2023 in the UK was estimated to be less than one in one million (Table 1). Estimated risk remains highest for HBV at 0.70 (95% confidence interval (CI) 0.48–2.50) per million donations tested, similar to the previous estimate of 0.63 million (95% CI 0.46–1.61) for 2020–2022. There were no HCV seroconversions detected during 2021–2023, however HCV risk is unlikely to be zero so is reported here as less than 0.01 per million donations, based on an estimated value of 0.01 had one seroconverter been observed over three years. HCV risk for the previous estimates in 2020–2022, however, was 0.02 (95% CI 0.00–0.09) per million donations based on two seroconversions. While HIV risk increased to 0.05 (95% CI 0.01–0.08) per million this is within the 95% confidence intervals of the previous estimate of 0.03 (95% CI 0.00–0.08) per million for 2020–2022.

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.

Table 1. The estimated risk (and 95% confidence interval; CI) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period (WP) donation: 2021–2023

	Donor type	HBV[1]	HCV[2]	HIV[3]
The number of potentially infectious WP donations NOT detected in one million donations tested. **This is equal to risk × 1 million.**	**All[4] (95% CI)**	0.70 (0.48–2.50)	<0.01	0.05 (0.01–0.08)
	New (95% CI)	1.73 (1.34–6.21)	<0.10	0.11 (0.01–1.04)
	Repeat (95% CI)	0.61 (0.43–1.69)	<0.01	0.05 (0.01–0.09)
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]**	1.42	>100	18.93
	New	0.58	>10	8.90
	Repeat	1.63	>100	20.95

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

[2] Anti-HCV testing and HCV RNA testing with a WP of four days.

[3] Combined HIV antigen/antibody testing and HIV NAT with a WP of nine 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.

The estimates for 2021–2023 include the first 2.5 years of data collected under the FAIR (For the Assessment of Individualised Risk) donor selection policy implemented across the UK from June 2021. FAIR allows all gay, bisexual and other men who have sex with men (GBMSM) to donate if they have not had anal sex with a new sexual partner or multiple sexual partners within three months and no other exclusions apply.

At the 2023 donation levels of approximately 1.8 million donations each year in the UK, it is estimated that testing did not identify approximately one potentially infectious HBV window period donation per year. The risks are expected to be considerably smaller for HCV and HIV, and at current donation levels it is estimated that it could be over 50 years before a potentially infectious HCV window period donation was not detected and up to 10 years for a potentially infectious HIV window period donation.

The estimates have remained below one in one million for over 10 years (Figure 1).

Donations of convalescent plasma and plasma for medicine are not included here. These donations do not enter the routine supply and are required to undergo different testing and processing protocols.

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 three 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 seven-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 two-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.

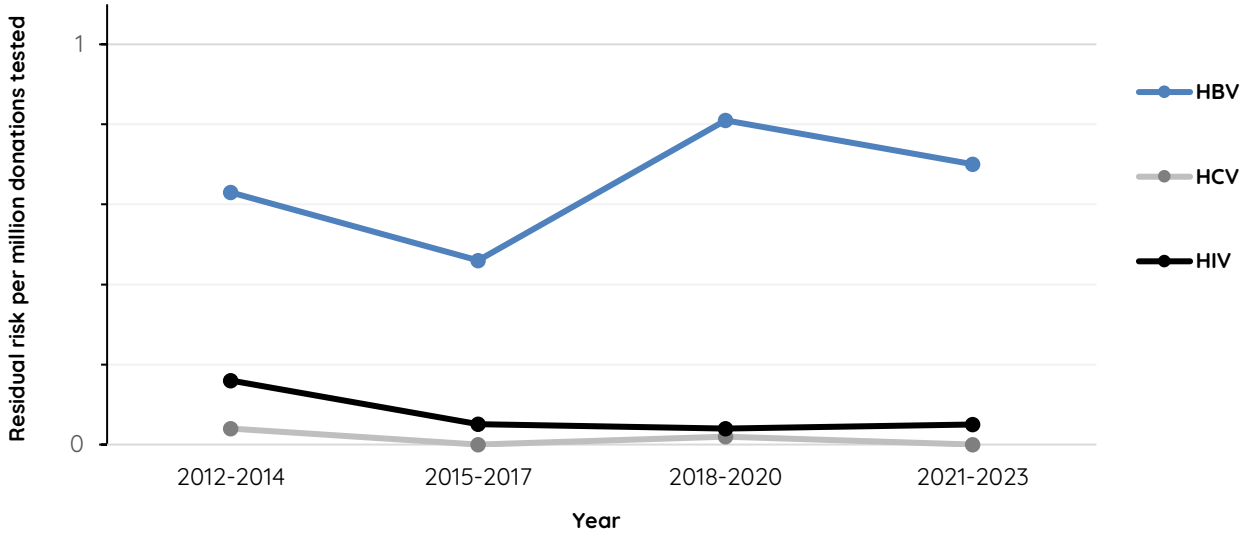

Figure 1. The estimated risk that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation for three-year periods from 2012-2014 to 2012-2023

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

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