Position Statement

September 2025

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Estimated residual risk for HBV, HCV and HIV

Background

Residual risk is estimated for current UK whole 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 whole blood 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 WP, 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 estimates for 2022–2024 use data collected under the For the Assessment of Individualised Risk (FAIR) donor selection policy implemented across the UK from June 2021. FAIR allows all potential donors 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.

Estimated risks in the UK between 2022 and 2024

The number of potentially infectious WP donations that testing did not detect during 2022–2024 in the UK was estimated to be around one in one million (Table 1).

Estimated risk remains highest for HBV at 1.09 (95% confidence interval (CI) 0.63–3.35) per million donations tested, with risk for HIV at 0.10 (95% CI 0.04–0.28). This represents a 55% increase in HBV risk from the previous estimate of 0.70 per million (95% CI 0.48–2.50) for 2021–2023, and a 100% increase in HIV from 0.05 per million (95% CI 0.01–0.08). Donations given by first-time donors were estimated to be more likely to have undetected HBV WP infections compared with donations from repeat donors, although for HIV there was negligible difference between the two donor groups.

There were no HCV seroconversions detected during 2022–2024. 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 was also reported as 0.01 per million, and there have been no HCV seroconversions since two in 2020.

In 2024, there were six HIV seroconversions detected among repeat donors. Typically, the number ranges between two and three each year, hence the observed increase in residual risk compared to the previous estimates. Risk behaviours reported by these male and female donors during post-test discussion generally described lower-risk sexual behaviours, rather than those resulting in deferral by FAIR. This aligns with general population data, which show that new HIV diagnoses among heterosexuals, particularly women, remain below pre-COVID levels, i.e. testing rates have not returned to previous levels and suggest a potential for continued HIV transmission within lower-risk individuals.

At the 2024 donation levels of approximately 1.7 million donations each year in the UK, it is estimated that testing did not identify approximately up to two potentially infectious HBV WP donations 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 at least 59 years before a potentially infectious HCV WP donation was not detected and up to 6 years for a potentially infectious HIV WP donation.

The risks between 2018 and 2024 are shown here for rolling 3-year periods, as calculated and published each year by JPAC, and have generally been below one in one million (Figure 1). Donations of convalescent plasma and plasma for medicine are not included. These donations do not enter the routine supply and are required to undergo different testing and processing protocols. While the 2022–2024 estimates are specifically for whole blood donations, calculations for previous 3-year periods include some apheresis plasma donations.

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 and HIV, would be questionable for HEV. However, HEV risks have been calculated elsewhere for apheresis and whole blood donors in England between 2016–2020 (Harvala et al, 2022). 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 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.

References

Harvala H, Reynolds C, Brailsford S, Davison K (2022). Fulminant Transfusion-Associated Hepatitis E Virus Infection Despite Screening, England, 2016–2020. Emerging Infectious Diseases, 28(9):1805–1813. doi.org/10.3201/eid2809.220487

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Table 1

	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)	1.09 (0.63–3.35)	<0.01	0.10 (0.04–0.17)
	First-time (95% CI)	3.04 (2.14–11.93)	<0.10	0.11 (0.04–0.28)
	Repeat (95% CI)	0.91 (0.53–2.66)	<0.01	0.10 (0.04–0.17)
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]	0.92	>100	10.25
	First-time	0.33	>10	9.01
	Repeat	1.10	>100	10.38

Notes on Table 1

1. HBV testing assumed all donations were tested for markers of hepatitis B surface antigen (HBsAg) and HBV DNA using NAT with a WP of 30 days.

2. Anti-HCV testing and HCV RNA testing with a WP of 4 days.

3. Combined HIV antigen/antibody testing and HIV NAT with a WP of 9 days.

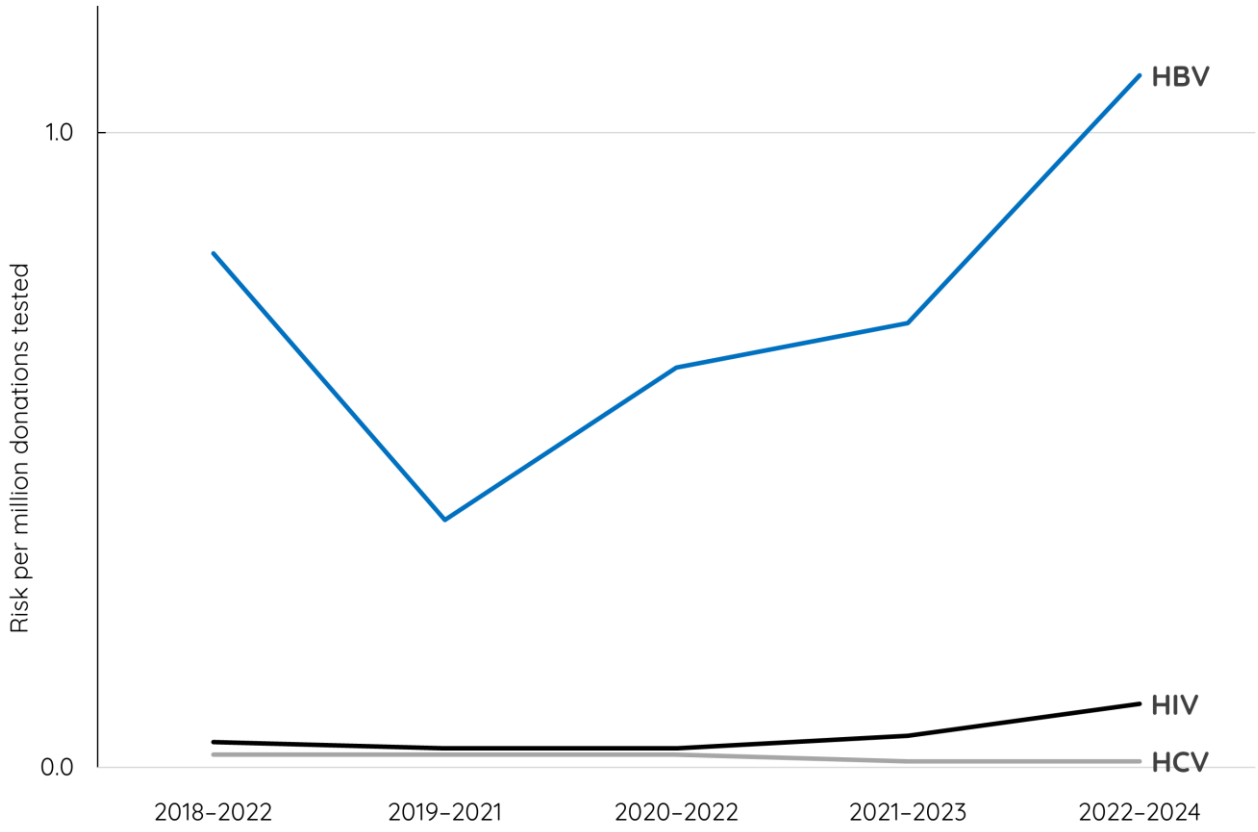
4. The risk due to WP amongst all donations was calculated as the weighted average of the risk amongst first-time and repeat donors, weighted according to the number of donations made from first-time and repeat donors.

   All molecular screening was performed on pooled samples of 24 donations.

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.

Figure 1

The rolling 3-year estimates of risk that a whole blood donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2010–2024 (estimates 2018–2023 are as previously published by JPAC.



Supplementary table

Positive donations made in the UK for current 3-year period (2022–2024), current 6-year period (2019–2024) and the most recently published previous 3-year period (2021–2023). Estimates for 2021–2023 are as previously published by JPAC for whole blood and apheresis donations.

A seroconverter is defined as a repeat donor with markers of HBV, HCV or HIV with a previously negative donation within one year or evidence of recent infection from microbiological results and clinical history and excludes occult HBV. Hence, not all repeat donors with markers of infection are classified as seroconverters.

	Current 3 years **2022–2024**	Current 6 years **2019–2024**	Previous 3 years **2021–2023**
HBV			
Number of positives in first-time donors	185	349	199
Number first-time donors	425,855	870,928	426,370
(Prevalence × 100,000) in first-time donors	43	40	47
Number of positives in repeat donors	10	15	8
Number repeat donors	4,546,248	9,849,222	4,964,716
(Prevalence × 100,000) in repeat donors	0.22	0.15	0.16
Number of seroconverters in repeat donors	9	13	7
Person years (number of repeat donations × IDI)	2,302,686	4,799,895	2,581,245
Incidence per 100,000 person-years in repeat donors	1.10	0.77	0.75
Incidence per 100,000 person-years in new donors	3.70	2.50	2.05
HCV			
Number of positives in first-time donors	78	180	94
Number first-time donors	425,855	870,928	426,370
(Prevalence × 100,000) in first-time donors	18	21	22
Number of positives in repeat donors	5	12	5
Number repeat donors	4,546,248	9,849,222	4,964,716
(Prevalence × 100,000) in repeat donors	0.11	0.12	0.10
Number of seroconverters in repeat donors	0	2	0
Person years (number of repeat donations × IDI)	2,302,686	4,799,895	2,581,245
Incidence per 100,000 person-years in repeat donors	0.00	0.04	0.00
HIV			
Number of positives in first-time donors	13	33	17
Number first-time donors	425,855	870,928	426,370
(Prevalence × 100,000) in first-time donors	3	4	4
Number of positives in repeat donors	13	23	8
Number repeat donors	4,546,248	9,849,222	4,964,716
(Prevalence × 100,000) in repeat donors	0.26	0.23	0.16
Number of seroconverters in repeat donors	9	13	5
Person years (number of repeat donations × IDI)	2,302,686	4,799,895	2,581,245
Incidence per 100,000 person-years in repeat donors	0.39	0.27	0.19
Incidence per 100,000 person-years in first-time donors	0.45	0.30	0.46