Joint UKBTS Professional Advisory Committee(*)

Position Statement

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, 2017-2019

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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 for acute infections only, this method of calculating risk cannot necessarily be applied to all infections for which donation testing is carried out.
- The number of potentially infectious window period donations that testing did not detect during 2017-2019 was estimated to be less than 1 in 1 million (Table 1). Estimated risk was highest for HBV at 0.87 (95% confidence interval (CI) 0.35-1.70) per million donations tested. For HCV the risk was estimated at <0.01 (95%CI 0.00 – 0.05) per million donations and for HIV the risk was 0.04 (95%CI 0.01-0.09) per million.
- HBV risk here was lower than estimated for 2016-2018 at 1.04 (95% CI 0.54- 2.39) per million donations tested and represents a return to a similar level seen in previous years. The decrease in risk is due to an estimated HBV incidence of zero in repeat donors in 2019. HBV and HCV risks were unchanged.
- It is important to note that the higher HBV residual risk estimated for 2016-2018 was due to an increase in incidence in 2018 when there were a few more recent infections detected on an already low number (3 in 2017 and 7 in 2018). The 7 infections were not associated with the change in the donor selection guidelines implemented in November 2017 that defers donors with sexual partners with increased risk behaviours for 3-months. Only one reported a sexual partner with increased risk behaviour and compliant with the 3-month deferral.
- At current donation levels of approximately 2 million donations each year in the UK, it is estimated that testing will *NOT* identify approximately two potentially infectious HBV window

period donations every year, one potentially infectious HCV window period donation every 76 years and one potentially infectious HIV window period donation every 12 years.

- For HBV and HCV, donations given by new donors were estimated to be more likely to have undetected WP infections compared with donations from repeat donors. For HIV, donations given by repeat donors were more likely to have undetected WP infections than donations from new donors.

Table: The estimated residual risk (and 95% confidence interval) that a donation made in the HBV, HCV and HIV infectious window period is not detected on testing: UK, 2017-2019

		HBV	HCV	HIV
The number of potentially infectious window period donations NOT detected in 1 million donations tested (95% CI). This is equal to risk x 1	All	0.87 (0.35-1.70)	<0.01 (0.00-0.05)	0.04 (0.01-0.09)
	New	1.90 (0.69-4.93)	0.04 (0.00-0.45)	0.02 (0.00-0.11)
	Repeat	0.77 (0.32-1.47)	<0.01 (0.00-0.01)	0.05 (0.01-0.09)
The number of donations (millions) tested before a potentially infectious WP donation would NOT be detected. This is equal to 1/(risk x 1 million).	All	1.1	145	23
	New	0.5	29	62
	Repeat	1.3	247	22

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 on pooled samples of 24 donations.

These estimates were produced using data, published results from papers and opinion collected by the NHSBT/PHE 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/PHE 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) sub group.