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, 2018-2020

October 2021

Prepared by: The Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI)

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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, 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 2018-2020 in the UK was estimated to be less than 1 in 1 million (Table 1). Estimated risk remains highest for HBV at 0.81 (95% confidence interval (CI) 0.28-1.75) per million donations tested. For HCV the risk was estimated at 0.02 (95%CI 0.00-0.14) per million donations and for HIV the risk was 0.04 (95%CI 0.01-0.10) per million.
- HBV risk was almost unchanged than estimated for 2017-2019 at 0.87 (95% CI 0.35 – 1.70) per million donations tested and HCV was higher than <0.01 (95% CI 0.00 – 0.05). HIV risk was unchanged.
- At the 2020 donation levels of approximately 1.7 million donations each year in the UK, it is estimated that testing did *NOT* identify approximately 1.2 potentially infectious HBV window period donations. The risks are considerably smaller for HCV and HIV, and at current donation levels it is estimated that it could be up to 22 years to miss one potentially infectious HCV window period donation, and up 14 years to miss one potentially infectious HIV window period donation. 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 new and repeat donors were equally likely to have undetected WP infections.
- The estimates for 2018-2020 presented here are based on data collected under the donor selection policy that allowed men who have sex with men (MSM), and others with sexual partners who are at increased risk of infections to donate 3-months after last sexual contact. In general, the estimates have remained below 1 in 1 million for the last 10 years and show safety has been maintained after donor selection guidelines changed for sex between men from a lifetime deferral to 12 months in 2011 and to a 3-month deferral in 2017.
- Donations testing results for convalescent plasma in England are not included here, although were not excluded from the denominator for Scotland and Wales.

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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, 2018-2020

	Donor type	HBV	HCV	HIV
The number of potentially infectious window period donations NOT detected in 1 million donations tested. This is equal to risk x 1 million.	All	0.81	0.02	0.04
	95% confidence interval	(0.28 - 1.75)	(0.00-0.14)	(0.01 - 0.10)
	New	1.63	0.15	0.04
	95% confidence interval	(0.34 - 5.48)	(0.00-1.40)	(0.00-0.43)
	Repeat	0.73	0.012	0.04
	95% confidence interval	(0.24 - 1.53)	(0.00-0.028)	(0.01 - 0.08)
The number of millions of donations tested before a potentially infectious WP donation would NOT be detected. This is equal to 1/(risk x 1 million).	All	1.2	41	26
	New	0.6	7	23
	Repeat	1.4	81	27

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.