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, 2016-2018

October 2019

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 a potentially infectious donation made in the window period (WP) is not detected and may enter the blood supply, 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 2016-2018 was estimated to be 1 in 1 million or less (Table 1). Estimated risk was highest for HBV at 1.04 (95% confidence interval (CI) 0.54- 2.39) per million donations tested. For HCV the risk was estimated at <0.01 (95%CI 0.00 – 0.04) per million donations and for HIV the risk was 0.04 (95%CI 0.01-0.07) per million.
- There was no change from the 2015-2017 estimate for HCV, and the estimate for HIV showed further decline. However, HBV residual risk doubled from 0.46 per million donations to 1.04 per million donations due to an increase in HBV incidence in repeat donors in 2018. This increase is based on the addition of a few incident donors on an already low number (3 in 2017 and 7 in 2018), and as the 95% confidence intervals for the estimates for 2015-2017 and 2016-2018 overlapped, the change is not considered to be statistically significant and could have increased by chance.
- Based on currently available information about the donors included in the calculation, the increase in HBV incidence is not associated with the change in donor selection implemented in November 2017 given that in 2018, the rate of HBV in new donors continued to decline and from conversations with the incident donors only one reported a sexual partner with increased risk behaviour. This donor was MSM and compliant with 3-month deferral.
- At current donation levels of approximately 1.9 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 90 years and one potentially infectious HIV window period donation every 15 years.

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- 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.
- A seroconverter is defined as an HBV, HCV or HIV infected repeat donor with a previously negative donation (PND) within 1 year, or evidence of recent infection from microbiological results and clinical history, which excludes occult HBV. Thus, HBV risk estimated here is based on incidence of acute infections only and does not include occult HBV.

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, 2016-2018

		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 million.	All	1.04 (0.54-2.39)	< 0.01 (0.00-0.04)	0.04 (0.01-0.07)
	New	2.00 (0.67-5.87)	0.02 (0.00-0.32)	0.01 (0.00-0.05)
	Repeat	0.94 (0.43-1.76)	<0.01 (0.00-0.01)	0.04 (0.02-0.10)
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	1.0	171	28
	New	0.5	47	84
	Repeat	1.1	237	26

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.