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, 2014-2016

June 2018

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 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 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 2015-2017 was estimated to be less than 1 in 2 million (Table 1). Estimated risk was highest for HBV at 0.47 (95% confidence interval (CI) 0.11-1.14) per million donations tested, and 0.051 (95%CI 0.02-0.1) per million for HIV. As no HCV seroconversions were detected during 2015-2017, HCV risk was estimated to be zero. HCV risk for the 6 years 2012-2017, however, was 0.02 (95%CI 0.0 – 0.08) per million donations.
- At current donation levels of approximately 2-million donations each year in the UK, it is estimated that testing will *NOT* identify approximately one potentially infectious HBV window period donations every year, and one potentially infectious HIV window period donation every 9 years.
- For HBV, 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.
- Since 2016, the definition of seroconverter used in these calculations included infections in repeat donors with a previous negative donation (PND) <1 year. This year, seroconverters with PND>1year AND evidence of recent infection from avidity testing were also included.
- HBV risk estimated here is based on incidence of acute infections and does not include occult HBV.

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(1*) **Joint U**nited **K**ingdom **B**lood **T**ransfusion **S**ervices **Professional Advisory Committee**

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Table: The estimated risk (and 95% confidence interval) that a donation made in the HBV, HCV and HIV infectious window period is not detected on testing: UK, 2015-2017

		HBV[1]	HCV[2]	HIV[3]
The number of potentially infectious window period donations NOT detected in 1 million donations tested (95% CI). This is equal risk x 1 million.	All[4]	0.46 (0.11-1.14)	0	0.051 (0.02-0.10)
	New	1.15 (0.29-4.55)	0	0.013 (0.00-0.05)
	Repeat	0.40(0.08-0.89)	0	0.055 (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	2.1	NA	19.6
	New	0.9	NA	77.9
	Repeat	2.5	NA	18.3

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 these data.