Joint UKBTS Professional Advisory Committee (*)

Position Statement

The estimated risk that a donation entering the blood supply is a potentially infectious window period donation: risks specific for HBV, HCV and HIV in the UK, 2013 - 2015.

March 2017

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

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Summary

- Although current blood donation screening strategies used by the UK Blood Services minimise the risk of transfusion transmitted infections in the UK, on very rare occasions potentially infectious donations are not detected and may enter the blood supply. This is mostly because a blood donation is made during the potentially infectious 'window period' (WP) early in the course of infection when the test in use may not detect the marker of infection. Here, we calculate window period risk as the risk multiplied by 1 million, which is the number of potentially infectious donations in 1 million donations entering the blood supply with 95% confidence intervals (by simulation), and the number of millions of donations entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation.

- The number of potentially infectious window period donations that entered the UK blood supply between 2013 and 2015 was estimated as less than one per million donations tested for HBV, HCV and HIV (Table). The estimated values for each virus was almost unchanged from the estimates from 2012-2014

- At current donation levels of approximately 2.1 million donations each year in the UK, it is estimated that testing will *NOT* identify approximately one potentially infectious HBV window period donations every 0.6 year, one potentially infectious HCV window period donation every 19.3 years and one potentially infectious HIV window period donation every 2.7 years.

- Donations given by new donors and entering the blood supply were estimated to be more likely to be infectious compared with donations from repeat donors, with the exception of HIV.

- Of the three viruses, HBV was estimated to be the virus most likely to be missed during 2013-2015 due to a window period donation.

- Despite anti-HTLV testing of blood donations in the UK, the risk is currently not estimated. This is because of uncertainty about the presence and/or duration of an infectious window period for HTLV and about the relevance of the calculation, given that widespread leucodepletion of all components significantly reduces the risk of onwards transmission to patients.

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Table: The estimated risk (and 95% confidence interval) that a donation entering the UK blood supply is a potentially infectious HBV, HCV or HIV window period donation: 2013 - 2015.

Risk due to window period		**HBV[1]**	**HCV[2]**	**HIV[3]**
Number of potentially infectious window period donations in 1 million donations entering the blood supply (95% CI). This is equal to risk x 1,000,000	All donations	0.79 (0.22 – 1.30)	0.025 (0.01 - 0.04)	0.18 (0.12 - 0.27)
	Donations from new donors	2.07 (0.48 – 4.73)	0.07 (0.01 - 0.42)	0.03 (0.01 - 0.11)
	Donations from repeat donors	0.68 (0.20 – 1.12)	0.02 (0.01 - 0.04)	0.19 (0.10 - 0.25)
Number of donations (millions) entering the blood supply before 1 of those donations can be expected to be a potentially infectious donation. This is equal to 1/(risk x 1,000,000)	All donations	1.3	40.5	5.7
	Donations from new donors	0.48	15.1	31.0
	Donations from repeat donors	1.5	47.6	5.3

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.