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Appendices to Guideline on epidemiological data on blood transmissible infections

Note: This document contains appendices to Guideline on epidemiological data on blood transmissible infections (EMA/CHMP/BWP/548524/2008. Rev 1).

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7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Table 1. "First time tested donor" population

Results of NAT testing without confirmation and results of additional screening tests should be reported separately using an adapted copy of the tabular format below.

Calendar year:	No of donors tested in the given period (A)	HIV			HCV			HBV		
		No of positive donors		HIV Rate per 100 000 donors (B+C)/A x 100 000	No of positive donors		HCV Rate per 100 000 donors (D+E)/A x 100 000	No of positive donors		HBV Rate per 100 000 donors (F+G)/A x 100 000
		HIV 1/2 Antibody (B)	HIV 1 NAT only (C)		HCV Antibody (D)	HCV NAT only (E)		HBsAg (F)	HBV NAT only (G)	
Country 1										
Blood establishment A responsible for collecting										
Centre 1										
Centre 2										
Summary of* Blood establishment *A*										
Blood establishment B responsible for collecting										
Centre 1										
Centre 2										
Summary of Blood establishment B*										
Summary per country*										

Table 2. "Repeat tested donor" population

Results of NAT testing without confirmation and results of additional screening tests should be reported separately using an adapted copy of the tabular format below.

Calendar year :	No of donors tested in the given calendar year (A)	No of donations in the given calendar year (B)	Donation frequency[a] (B/A)	HIV			HCV			HBV		
				No of positive donors		HIV Rate per 100 000 donors (C+D)/A x 100 000	No of positive donors		HCV Rate per 100 000 donors (E+F)/A x 100 000	No of positive donors		HBV Rate per 100 000 donors (G+H)/A x 100 000
				HIV 1/2 Antibody (C)	HIV 1 NAT only (D)		HCV Antibody (E)	HCV NAT only (F)		HBsAg (G)	HBV NAT only (H)	
Country 1												
Blood establishment A responsible for collecting												
Centre 1												
Centre 2												
Summary of* Blood establishment *A*												
Blood establishment B responsible for collecting												
Centre 1												
Centre 2												
Summary of* Blood establishment *B*												
Summary* per country												

[a] In cases where there are two sub-sets of donors (plasmapheresis and whole blood), give the frequency of donation separately for the two sub-sets.
* If both whole blood recovered plasma and plasmapheresis plasma are collected, data should also be summarised separately for each of these two categories.

Table 3. Parameter, values and sources used in "Window period risk" estimation

Parameters to be reported by a) value and b) source, for annual "window period risk" estimates. For each selected "worst case" scenario (see section 11), three separate tables should be provided, i.e. one table for each viral marker (HIV, HBV, HCV).

Parameter	***Description, use***	***a) Value[a]***	***b)Source (notes)***
1. Incidence in "repeat tested donor" for one calendar year (expressed per 100,000 donors)	If "incidence" in "repeat tested donors" is made over 1 calendar year, the calculation would equal the rate of positive "repeat tested donors" in a calendar year (section 8.2.) Incidence in "repeat tested donors" in the year under reporting is estimated using formula 5.		Rate of positive "repeat tested donors" per 100 000 donors for each viral marker in a calendar year. From table 2. (Guideline section 11. The rate values selected from table 2 should represent reasonable "worst case(s)".)
2. Ratio of the i) mean interdonation interval for all donors to ii) median[b] interdonation interval for seroconverting donors	Check for validity of method. If this ratio is far from 1, risk estimates may be over- or under- estimates and this should be discussed.		(Guideline section 10.1; It should be based on data from this donor population)
3. HBV incidence adjustment factor *For HBV estimates only:*	Adjustment for the effect of the transient nature of HBsAg and HBV DNA on detection of new HBV infections in repeat donors.	if IDI >77 days: 2.9 if IDI ≤77 days: 1.3	(Guideline section 10.3; An interdonation interval should be used that is true/justified for this donor population)
4. "First time tested donor" incidence adjustment factor *(Only required if plasma is used from "first time tested donors")*	Factor to be used to estimate "first time tested donor" incidence (to then use in formula 6 to calculate estimation of "window period risk" per million donations for "first time tested donors")	3	(Guideline section 10.2; Any alternative "first time tested" donor incidence adjustment factor" chosen should be explained and justified; where appropriate the source should be cited)
5. Viraemic window period	Period of time soon after infection for which testing does not detect infectivity. (According to formula 6, the value should be expressed in years)	HCV: 8 days HIV: 15 days HBV: 35 days	(Guideline section 10.1; Any alternative "viraemic window period" chosen should be explained and justified; where appropriate the source should be cited)

[a] Value for the same calendar year as per table 4
[b] The median should be used because the distribution of interdonation intervals for seroconverting donors cannot be expected to approximate to a normal distribution (as those for all donors can).

Table 4. "Worst case" estimates of "window period risk"

Results of "worst case" estimation(s) of "window period risk" per million donations, i.e. viraemic donations undetected by all routine testing performed prior to donation storage and/or pooling. The risk estimation for "first time tested donors" is only required if plasma from "first time tested donors" is used.

Calendar year:	**a)** Results of estimation of "window period risk" per million donations for **"repeat tested donors"**			**b)** Results of estimation of "window period risk" per million donations for **"first time tested donors"**			**c)** Results of estimation of "window period risk" per million donations for **all donors (i.e. weighted average of a) and b) according to the potential representation in a manufacturing pool**		
	HBV	**HCV**	**HIV**	**HBV**	**HCV**	**HIV**	**HBV**	**HCV**	**HIV**
Case 1[a]									

[a] In applications covering very diverging plasma sources and/or testing strategies it might be appropriate to perform and present different potential "worst case" calculations, for example
- a "worst case" risk estimate for plasmapheresis donors from a blood establishment selected on the basis of relatively high viral markers' rates in "repeat tested donors"
- a "worst case" risk estimate for whole blood donors from a blood establishment selected on the basis of relatively high viral markers' rates in "repeat tested donors" and/or the use of "first time tested donors" with relatively high viral markers' rates in "first time tested donors".