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Committee for Medicinal Products for Human Use (CHMP)

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).

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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										
Organisation A responsible for collecting										
Centre 1										
Centre 2										
Summary of Organisation A										
Organisation B responsible for collecting										
Centre 1										
Centre 2										
Summary of Organisation B										
Summary per country										

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												
Organisation A responsible for collecting												
Centre 1												
Centre 2												
Summary of Organisation A												
Organisation B responsible for collecting												
Centre 1												
Centre 2												
Summary of Organisation 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.

3. Assumptions and parameter values and sources used in risk estimation in study period

Parameters to be reported by a) value and b) source, for annual risk estimates. One table is needed for each infection, and per worst case scenario (if applicable) according to Table 4.

Parameter	***Description, use***	***a) Value[a]***	***b)Source[b] (notes)***
1. No. of newly acquired infections (seroconversions) in "repeat tested donors"	Numerator for incidence.		(Ideally an exact and total count. If an estimate from a sample, this should be explained and justified. Definitions must be given for seroconversions.)
2. Person years observed in "repeat tested donors"	Denominator for incidence.		(Ideally an exact total count of days between donations. Estimates also acceptable, e.g. from a count of a representative sample of donors, or from: No. of donations from repeat donors x mean interdonation(*) interval expressed in years (*) Interdonation interval derived from counts of donations and donors in a year.
3. Ratio of the i) mean interdonation interval for all donors to ii) median[c] 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.		(must be based on data from this donor population)
4. HBsAg adjustment *For HBV estimates only:* *(see Section 10.3)*	Adjustment for the effect of the transient nature of HBsAg on detection of new HBV infections in repeat donors.		(must use interdonation interval values that are true/justified for this donor population)
5. New donors *If donations from "first time tested donors" are used:* *Options* a. New donor incidence estimate b. New donor incidence adjustment. *(see Section 10.2)*	a) Incidence: To use in formula 6 to estimate new donor window period risk b) New donor incidence adjustment: To multiply "repeat tested donor" incidence to estimate "first time tested donor" incidence (to then use in formula 6 to estimate new donor window period risk)		
6. Infectious window period	Period of time soon after infection for which testing does not detect infectivity.		(can be from: publications; own data from seroconversion panels; expert opinion and or expert-adjusted values from publications. Source must be explained and/or cited.)

[a] Value for the same calendar year as per table 4
[b] Own/local data must be used, unless "publications" is specified as a suitable source. If published data from other countries/regions are used for any parameters, this should be explained/justified.
[c] The median should be used because the distribution of interdonation intervals for seroconverting donors can not be expected to approximate to a normal distribution (as those for all donors can).

4. "Worst case" risk estimates – by donations

Results of "worst case" estimation(s) of "window period" risk per million donations i.e. infectious donations undetected by all routine testing performed prior to donation storage and/or pooling.

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 one collection organisation picked based on relatively high incidence in repeat donors and a "worst case" risk estimate for whole blood donors from one collection organisation picked based on relatively high incidence and/or the use of first time donors with relatively high prevalence.