

Joint UKBTS / HPA Professional Advisory Committee (1) Summary Sheet

1. Paper for the JPAC meeting on:	10 November 2011
2. Date submitted:	22 September 2011
3. Title (including version no.):	Storage temperature (when frozen) of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP
4. Author(s):	Rebecca Cardigan, Chair of the SAC on Blood Components
5. Brief summary:	<p>SACBC considered the evidence to support changing the temperature of storage of frozen plasma components from $\leq -30^{\circ}\text{C}$ to $\leq -25^{\circ}\text{C}$ in order to 1) bring the Red Book in line with CoE Guidelines and 2) make plasma storage more efficient (reduced running costs and purchase costs of lower specification freezers etc.)</p> <p>SACBC recommend that a C/N is not issued, but that this change is incorporated into changes to chapter 8 of the Red Book.</p>
6. Action required by JPAC: (What do you want JPAC to do in response to this paper?) e.g.	To endorse the recommendation
<ul style="list-style-type: none"> • endorse a specific recommendation • advise where there is a choice of possible actions • advise on priorities within the work plan • provide a steer on policy 	
7. Any other relevant information:	

(1) **Joint United Kingdom Blood Transfusion Services and Health Protection Agency Professional Advisory Committee**

Storage temperature (when frozen) of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP

The quality of plasma after frozen storage is determined by how plasma is processed prior to storage, followed by the temperature and length of time it is stored frozen prior to use. Current recommended storage times/temperatures for frozen plasma components are summarised in the table below.

	Temperature	Storage time
Red Book 7 th Ed	$\leq -30^{\circ}\text{C}$	24 months
CoE 16 th Ed	$\leq -25^{\circ}\text{C}$	36 months
	-18° to -25°C	3 months
BSQR		3 – 36 months according to process
AABB 27 th Ed	$\leq -18^{\circ}\text{C}$	12 months
	$\leq -65^{\circ}\text{C}$	7 years (for FFP only)

SACBC considered whether it would be appropriate to change the temperature of storage of frozen plasma components from $\leq -30^{\circ}\text{C}$ to $\leq -25^{\circ}\text{C}$ in order to 1) bring the Red Book in line with CoE Guidelines and 2) make plasma storage more efficient (reduced running costs and purchase costs of lower specification freezers etc.)

Kotitschke and colleagues (1) performed a multicentre trial measuring the stability of FFP during storage at 4 temperatures: -20°C , -25°C , -30°C and -40°C over a period of 24-36 months. The source plasma was derived from both apheresis (which was frozen within 4 hours of collection) and whole blood (frozen within 6 and 24 hours of collection). Three pools of plasma were stored and tested at 13 different centres.

All plasmas showed normal values for total protein, factors VIII, IX, V, fibrinogen and anti-thrombin at time zero, and after storage time of 24 months at -20°C and 36 months at all other temperatures investigated. Data extracted from this paper on levels of FVIII and FV, which are the most labile coagulation factors in plasma, are shown below.

	Starting value	After 24 months at -20°C	After 36 months at -25°C	After 24 months at -30°C	After 24 months at -40°C
FVIII (IU/ml)					
Pool 1	1.00	0.95	0.95	0.93	1.03
Pool 2	0.83	0.81	0.84	0.84	0.90
Pool 3	0.90	0.80	0.75	0.84	0.88
FV (U/ml)					
Pool 1	0.98	0.96	1.00	1.02	0.99
Pool 2	0.97	0.82	0.99	0.93	0.85
Pool 3	0.84	0.79	0.75	0.86	0.70

These data show that the changes in these factors during frozen storage are minimal. The largest determinant of plasma quality is what happens to plasma prior to freezing rather than during storage in its frozen state.

These data support storing frozen plasma at -20°C or below for 24 months, or -25°C or below for 36 months.

There are no data on storing Methylene Blue (MB) treated plasma above -30°C . However, as for standard FFP, Lambrecht et al have shown that storage of frozen MB-treated FFP for 27 months has minimal affect on plasma coagulation factors. There is therefore no reason to believe that the stability of MB-FFP at -25°C would be any different to that of untreated FFP. Current CoE Guidelines permit pathogen inactivated plasma to be stored at the same temperature and for the same length of time as standard FFP.

Recommendation

SACBC recommend that the temperature of storage of all frozen plasma components be changed from $\leq -30^{\circ}\text{C}$ to $\leq -25^{\circ}\text{C}$ in line with CoE Guidelines. The shelf-life should remain 24 months.

References

1. Kotitschke R, Morfeld F, Kirchmaier C-M et al. Stability of fresh frozen plasma: results of 36-month storage at -20°C , -25°C , -30°C and -40°C . *Infus Ther Transfus Med* 2000; 27: 174-180.
2. Lambrecht B, Selz A, Herms O, Marks F, Mohr H. Stability testing of fresh plasma after photodynamic virus inactivation (MB/light treatment) during a 27 month storage period. *Infusionther Transfusionsmed* 1997; 24: 290.