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

1. Paper for the JPAC meeting on:	4th July 2013
2. Date submitted:	13th June 2013
3. Title (including version no.):	Shelf-life (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:	In 2011 JPAC approved a change in the minimum storage temperature of frozen plasma components from ≤ -30°C to ≤ -25°C (JPAC 11-57) 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.) The evidence that was reviewed also supported an extension of shelf-life for from 24 to 36 months. At that time there was no need to extend the shelf-life of frozen components, and this was therefore kept at 24 months. SACBC have been asked to consider extending the shelf-life of FFP in order to maximise the plasma donations from Club 96 donors. The attached paper summarises the data available.
6. Action required by JPAC: (What do you want JPAC to do in response to this paper?) e.g. • 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	To endorse the recommendation that the shelf-life of frozen components be extended from 24 to 36 months at the current storage temperature of ≤ -25°C.
7. Any other relevant information:	JPAC 11-57

([1]) **J**oint **U**nited **K**ingdom **B**lood **T**ransfusion **S**ervices and **H**ealth **P**rotection **A**gency **Professional Advisory Committee**

Shelf-life (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 7th Ed	≤ -30^{0}C	24 months
CoE 16th Ed	≤ -25^{0}C	36 months
	-18^0 to -25^{0}C	3 months
BSQR		3 – 36 months according to process
AABB 27th Ed	≤ -18^{0}C	12 months
	≤ -65^{0}C	7 years (for FFP only)

SACBC considered whether it would be appropriate to extend the shelf-life of frozen plasma components in order to 1) bring the Red Book in line with CoE Guidelines and 2) make the most efficient use of Club 96 donations.

Kotitschke and colleagues (1) performed a multicentre trial measuring the stability of FFP during storage at 4 temperatures: -20^{0}C, -25^{0}C, -30^{0}C and -40^{0}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^{0}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^{o}C	After 36 months at -25^{o}C	After 24 months at -30^{o}C	After 24 months at -40^{o}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^{0}C or below for 24 months, or -25^{0}C or below for 36 months.

Two studies have shown that coagulation factors in MBFFP are stable for 27 months and 39 months at <-30^{o}C (Lambrecht et al 1997; Gravemann et al 2009). 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 shelf-life of all frozen plasma components be changed from 24 to 36 months in line with CoE Guidelines.

References

1. Kotitschke R, Morfeld F, Kirchmaier C-M et al. Stability of fresh frozen plasma: results of 36-month storage at –20^{0}C, -25^{0}C, -30^{0}C and –40^{0}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.

3. Gravemann U, Recihenberg S, Mohr H, Walker H, Muller T. Storage stability of methylene blue treated plasma. ISBT 2009 poster.