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

1.	Paper for the JPAC meeting on:	11 November 2011	
2.	Date submitted:	17 October 2011	
3.	Title (including version no.):	Thawing temperature of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP	
4.	Author(s):	Rebecca Cardigan	
5.	Brief summary:	Equipment used in hospitals to thaw plasma components cannot meet the current UK recommendation of thawing at 37°C. This has been raised as a non-compliance when hospitals have been inspected by the MHRA since the capability of current equipment is to thaw between 33 and 37°C. SACBC were therefore asked to review whether there should be any tolerance around the 37°C value.	
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 from SACBC	
7.	Any other relevant information:		

Thawing temperature of FFP, cryoprecipitate, cryodepleted plasma and MB-treated FFP

Current recommended thawing temperatures for frozen plasma components are summarised in the table below.

	Temperature	Component
Red Book 7 th Ed	37 ⁰ C	All frozen plasma components
CoE 16 th Ed	37 ⁰ C	Only stated for cryoprecipitate
BSQR	Not stated	
AABB 27 th Ed	30-37 ⁰ C	All frozen plasma components

Many of the plasma thawers in use within hospitals and Blood Services operate between 33-37°C. This has been raised as a non-compliance when hospitals have been inspected by the MHRA since the UK Guidelines state that plasma components should be thawed at 37°C, with no degree of tolerance. SACBC were therefore asked to review this subject.

Von Heymann et al 2006 (1) compared units of FFP thawed either 1) at 37 °C for a 30 min cycle, 2) at 42 °C until thawed (about 5 mins) or 3) in a microwave to achieve a surface temperature of 35 °C (about 6 mins). No significant differences were observed in levels of fibrinogen, fibrin monomers, FV, FVII, FVIII, D-dimers, α_2 antiplasmin or protein S. Isaacs et al 2004 (2) compared FFP thawed at 22, 37, 45 or 60°C. They found that fibrinogen levels, INR and PTT in plasma thawed at 22°C or at 45°C were not significantly different to units thawed at 37°C.

These data suggest that although thawing at 37°C is optimal, there is a wide tolerance in temperature around 37°C which would be acceptable for thawing plasma components. Further, equipment currently in use within the UK thaws plasma at 33-37°C without apparent issue.

Recommendation

SACBC recommend that the thawing temperature of all frozen plasma components be changed from 37° C to $33-37^{\circ}$ C.

The text in plasma specifications should be changed from:

'The component should be thawed at 37 °C in a waterbath or other equipment designed for the purpose, within a vacuum sealed overwrap bag. Protocols must be in place to ensure that the equipment is cleaned daily and maintained to minimize the risk of bacterial contamination.'

To:

'The component should be thawed at 33 - 37 °C in a waterbath or other equipment designed for the purpose, within a vacuum sealed overwrap bag according to a validated procedure. Protocols must be in place to ensure that the equipment is cleaned daily and maintained to minimize the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no cryoprecipitate is visible and that the container is intact.

References

(1) von Heymann C, Pruss A, Sander M, Finkeldey A, Ziemer S, Kalus U, Kiesewetter H, Salama A, Spies C: Thawing procedures and the time course of clotting factor activity in fresh-frozen plasma: a controlled laboratory investigation. Anesth Analg 2006; 103(4):969-974.

(2) Isaacs MS, Scheuermaier KD, Levy BL, Scott LE, Penny CB, Jacobson BF: In vitro effects of thawing fresh-frozen plasma at various temperatures. Clin Appl Thromb Hemost 2004; 10(2):143-148.

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