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BCSH TRANSFUSION TASK FORCE

ADDENDUM

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Guidelines for the use of fresh-frozen plasma,
cryoprecipitate and cryosupernatant, 2004 (Br. J Haematol
2004,126,11-28)

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British Committee for Standards in Haematology (BCSH): Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant, 2004 (Br. J Haematol 2004,126,11-28)

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The guideline on the use of fresh-frozen plasma (FFP), cryoprecipitate and cryosupernatant is currently under review. While the guideline is being reviewed, the BCSH Transfusion Task Force group would like to issue the following communication and recommendations:

The recently published BCSH guideline "A practical guideline for the haematological management of major haemorrhage" (Hunt *et al*, 2015), recommends that transfusion laboratories seeing major haemorrhage cases due to trauma should consider having prethawed plasma on standby to allow FFP to be immediately available for the management of major bleeding. Some centres are already doing this; however this practice is leading to practical difficulties, including FFP wastage due to the current shelf-life of pre-thawed FFP being only 24 hours.

The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services' Professional Advisory Committee (JPAC) has reviewed the available data on FFP with the view to extending the shelf life of pre-thawed FFP to > 24 hours, and have agreed that:

- the shelf life of thawed methylene blue-treated FFP should remain the same (i.e. 24 hours) and not be extended
- the shelf life of thawed standard FFP can be extended from 24 hours to 120 hours, to enable rapid provision of FFP for the management of unexpected major haemorrhage without excessive wastage (http://www.transfusionguidelines.org.uk/document-library/supporting-papers).

For the purposes of this addendum solvent detergent FFP (Octaplas) is not considered as this is a licensed medicinal product and therefore its shelf-life following thawing is governed by the manufacturer (Octapharma).

Recommendations

Once thawed, standard FFP may be stored at $4 \pm 2^{\circ}$ C in an approved temperature-controlled blood storage refrigerator before administration to the patient as long as the infusion is completed within 24 hours of thawing, or within 120 hours of thawing only for patients who develop unexpected major bleeding (e.g. trauma) and for whom delay in providing FFP is detrimental.

Pre-thawed FFP that is out of a controlled temperature environment (4 ±2°C), can be accepted back into temperature controlled storage if this occurs on one occasion only of less than 30 minutes. Transfusion of FFP should be completed within 4 hours of issue out of a controlled temperature environment.*

Apart from clinical scenarios of <u>unexpected</u> major haemorrhage transfusion laboratories should use FFP that has been thawed for a maximum of 24 hours prior to clinical use due to the fact that clotting factor activity (particularly FV, FVII and FVIII) drops over time during storage at 4 ±2°C.

In order to reduce the risk of bacterial contamination/growth the following mitigating factors must be followed for thawed FFP:

- o Protocols must be in place to ensure that the thawing equipment is cleaned daily and maintained to minimise the risk of bacterial contamination.
- After thawing, and at the time of administration, the content should be inspected to ensure that no precipitate is visible and that the component packaging is intact.
- Thawing methods that do <u>not</u> directly expose units to water <u>must</u> be used to minimise bacterial contamination when thawing FFP that will be stored for up to 120 hours prior to clinical use.

*At present there is a lack of evidence relating to how long thawed plasma can safely remain out of controlled temperature storage. The recommendation in this guideline is based on current practice in other countries and expert opinion, extrapolated from evidence on red cell storage with the aim of minimising FFP wastage while also ensuring safety of the component for recipients. The recommendation may change in the future as a result of research carried out on FFP storage and bacterial growth.

References

Hunt,B.J., Allard,S., Keeling,D., Norfolk,D., Stanworth,S.J., & Pendry,K. (2015) A practical guideline for the haematological management of major haemorrhage. *Br.J.Haematol.* 170(6); 788-803