

Date of publication: 29 March 2016

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 16 - 2016

Fresh Frozen Plasma, Leucocyte Depleted

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

Background

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 due to trauma should consider having pre-thawed 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 thawed FFP being only 24 hours.

JPAC have therefore reviewed the available data on FFP with a view to possible extension of post-thaw shelf-life to enable rapid clinical provision without excessive wastage. JPAC agreed that the shelf-life of Fresh Frozen Plasma, Leucocyte Depleted following thawing should be changed from 24 hours to a maximum of 120 hours to permit the use of extended-thawed plasma according to revised BCSH guidelines. An addendum to BCSH Guidelines for the use of fresh frozen plasma, cryoprecipitate and cryosupernatant is expected to be published soon. Further details on the rationale for this change can be found in the JPAC supporting paper posted on <http://www.transfusionguidelines.org.uk/document-library/supporting-papers>.

These changes **DO NOT** apply to specifications for plasma components other than 7.15 Fresh Frozen Plasma, Leucocyte Depleted i.e. they **DO NOT** apply to 7.16, 7.17, 7.18, 7.19, 7.20, 7.27 and 7.28.

The following changes are necessary to specification 7.15: Fresh Frozen Plasma, Leucocyte Depleted.

7.15.2: Labelling

Change the penultimate bullet point as follows:

- a warning that the component must be used within 4 hours of thawing if maintained at $22 \pm 2^{\circ}\text{C}$, or up to a maximum of 120 hours of thawing if stored at $4 \pm 2^{\circ}\text{C}$, depending on indication.

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7.15.3: Storage

Change the fourth and fifth bullet points, and two additional points added as follows:

- Protocols must be in place to ensure that the 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 insoluble cryoprecipitate is visible and that the container is intact. If to be stored thawed for an extended period (>24 hours from thawing), thawing methods that do not directly expose units to water must be used to minimise bacterial contamination.
- Once thawed, the component must not be refrozen and should be transfused as soon as possible. If delay is unavoidable, the component may be stored and should be used within 4 hours if maintained at $22 \pm 2^{\circ}\text{C}$ or up to a maximum of 120 hours if stored at $4 \pm 2^{\circ}\text{C}$, but it should be borne in mind that extended post-thaw storage will result in a decline in the content of labile coagulation factors.
- Pre-thawed FFP that is out of a controlled temperature environment ($4 \pm 2^{\circ}\text{C}$), 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.
- For indications other than unexpected major haemorrhage, the component should be used within 24 hours of thawing.

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