

Joint UKBTS Professional Advisory Committee (¹)

Position Statement

Shelf life of fresh-frozen plasma following thawing

January 2015

Prepared by: The Standing Advisory Committee on Blood Components

***This document will be reviewed whenever further information becomes available.
Please continue to refer to the website for in-date versions.***

Background

In 2011 the UK Standing Advisory Committee on Blood Components (SACBC) was asked by JPAC to review the current evidence on whether the shelf life of standard fresh-frozen plasma (FFP) following thawing can be extended from 24 hours to 5 days, in order to:

- 1) reduce the wastage of plasma
- 2) improve availability of FFP for urgent use, e.g. trauma
- 3) pilot the remote supply of plasma to hospitals by NHSBT

To this end the literature was reviewed with 2 main issues in mind: (1) the efficacy of the components; and (2) the risk of bacterial contamination and other side effects.

This work has been accepted for publication and will be published online shortly as follows: Cardigan R, Green L. Thawed and liquid plasma: what do we know? Vox Sanguinis 2015. For further details please contact the Chair of the JPAC Standing Advisory Committee on Blood Components. Email: rebecca.cardigan@nhsbt.nhs.uk

Recommendations of the 2011 paper for standard FFP

After careful consideration JPAC recommended that the shelf life of FFP following thawing, which is currently 24 hours, should **not be changed** because:

- the laboratory data showed that coagulation factors declined during storage and therefore there is a possibility that their efficacy would also decline
- there are no clinical studies evaluating the use of FFP which have been thawed and stored for 5 days
- That it would not be possible for hospitals to label plasma beyond 24 hours of thawing as a separate component, since this would require them to hold a manufacturing license from the Medicines and Healthcare Regulatory Authority (MHRA) under the Blood and Safety Quality Regulations.
- there may be a new recommendation from the Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) in 2012 for the type of FFP to be used in the UK
- it was felt that there wasn't a strong clinical drive for extending the shelf life of FFP

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Further considerations for extending the shelf life of FFP to 48 or 72 hours

In March 2012, the National Blood Transfusion Committee requested that JPAC examine the evidence on efficacy and safety of extending the shelf life of thawed FFP to 48-72 hours. The following was reviewed: 1) coagulation factor content of FFP at 48-72 hrs; and 2) clinical demand and potential reduction in FFP wastage (through a national questionnaire) should thawed FFP be extended to 48-72hrs. A summary of key points is given below.

- There have been no clinical studies to evaluate the efficacy of thawed FFP stored beyond 24 hours (extended-thaw FFP).
- Several laboratory studies have described the haemostatic parameters of standard FFP at Day-2 (24 – 48 hours) or Day-3 (48–72 hours) after thawing. In similar fashion to thawed FFP stored beyond Day-5, FVIII appears to be the main factor that reduces significantly at Day-2 or Day-3; this reduction does not meet the European/UK requirements for FFP. Further, these studies differ significantly with regard to methods of FFP collection, preparation and storage, as well as the availability of coagulation factor results (e.g. some studies lack data for Day-2 and others do not include all clotting factor levels).
- The questionnaire results showed that the majority of participants were satisfied with FFP delivery times but there is still room for improvement. Half of the respondents had concerns about the possible loss of efficacy with extended-thaw FFP, and just over a third would definitely use it for treating major haemorrhage. Only a minority predicted significant wastage reduction.

After discussion, JPAC considered that at the current time there should be no change in the specification for Fresh-Frozen plasma in relation to its shelf-life following thawing, which shall therefore remain at 24 hours if stored at 4°C. The rationale for this conclusion was 1) there was an unknown effect of extended storage of thawed plasma on the clinical efficacy of the component since clinical studies on thawed plasma are lacking 2) the use of extended thawed plasma could not easily be restricted to selected patient groups as the component is not labelled as a separate product.

This recommendation will be reviewed should more data become available.

(¹) **Joint United Kingdom Blood Transfusion Services Professional Advisory Committee**