INTRODUCTION OF EXTENDED LIFE PLASMA (FFP-EL) INTO NEW ZEALAND

On 11th December 2017, NZBS will be introducing Extended Life Plasma. This will provide an opportunity to improve the timeliness of delivery of thawed plasma in trauma and massive haemorrhage settings and will help larger hospitals to reduce discard rates of the thawed component.

Clinical Fresh Frozen Plasma (FFP) in New Zealand is currently produced from apheresis plasma given by male donors. Once thawed the component has a shelf life of 24-hours. There is increasing evidence to support the proactive early use of FFP in massive haemorrhage and trauma situations. Thawed FFP is provided as part of the Massive Transfusion Protocol (MTP) with the goal of achieving a 1:1 ratio of red cells to plasma during the immediate management of these clinical scenarios.

Two problems emerge in doing this. Firstly, the time taken to thaw FFP can delay the early availability of plasma and secondly, changing clinical circumstances can result in the thawed plasma not being transfused, resulting in expiry of the component.

NZBS has now received approval from Medsafe to extend the shelf life of thawed frozen plasma from 24-hours to 5 days (120hrs). The longer storage period for the thawed component is associated with a gradual reduction in non-labile coagulation factors, but this is considered unlikely to impact on the clinical effectiveness of the component.

However, extended life plasma (FFP-EL) will not be useful as a source of Factor VIII or Factor V since the level of these factors fall more rapidly. Clinical FFP is however, rarely, if ever, used for these indications in New Zealand.

Two approaches for the introduction of ELP exist. The first is that this replaces the current standard FFP component. This is the approach used in most large hospitals in Australia. In England, the use of ELP is restricted to patients with major haemorrhage or trauma with standard FFP being supplied for all other indications. In both countries, the use of ELP is not recommended for hospitals with limited trauma work.

New Zealand will follow the approach in place in Australia. Individual hospitals will supply thawed plasma either with a 24-hour shelf life (thawed FFP) or with a 5-day (120hrs) shelf life (FFP-EL) but not both. NZBS is currently working with individual hospital Blood Banks to determine which approach will be most appropriate. We anticipate that most major DHBs will elect to use FFP-EL. Smaller hospitals with low usage of thawed plasma may however decide to stay with the current 24-hour shelf life.

There are two potential risks associated with the extension of the shelf life of thawed plasma.

The first is that it might increase the risk of bacterial contamination. This is reduced by keeping the stored plasma at between 2 and 6 degrees Celsius in a dedicated blood refrigerator. There is however, no evidence from Australia or the UK that this is a major concern.

The second potential risk relates to leakage of plasticisers such as DEHP (Di (2-ethylhexyl) phthalate) into the plasma. This is a particular concern when plasma is transfused to neonates. Neonatal FFP is not normally used in massive transfusion settings and so no clinical benefit will arise from extending the shelf life. For this reason, NZBS will be maintaining a 24-hour shelf life for neonatal thawed plasma at all sites.

What about Cryoprecipitate?

The shelf life of thawed cryoprecipitate is currently 4-hours with no plans to change this. There are two reasons for this. The component specification for Cryoprecipitate requires FVIII levels to be maintained at a specified level. This relates to its historic use in haemophilia treatment. Factor VIII is a labile coagulation factor and levels fall quickly once the component is thawed. Secondly, thawed Cryoprecipitate is stored at room temperature since refrigeration leads to protein precipitation. Storage at room temperature also increases the risk of bacterial contamination.