NATIONAL BLOOD AUTHORITY
AUSTRALIA

Better Practice Case Study:
The Royal Children's Hospital Melbourne Extended Life Plasma Protocol

Implementing the Extended Life Plasma protocol – how to reduce wastage and keep your clinicians happy, it's easier than you think!

BACKGROUND

The Royal Children's Hospital, Melbourne (RCH) introduced the use of Extended Life Plasma (ELP) in December 2012 following extensive in-house safety and efficacy testing. The Royal Children's Hospital maintains an inventory of 2 units of group AB ELP for use when the Massive Transfusion Procedure is activated or for situations where thawed plasma is required without delay. Unused, thawed plasma of any blood group is also converted to ELP if the criteria is met.

As a result of implementing an ELP protocol, the laboratory at the Royal Children's Hospital can not only provide thawed plasma in a timely manner but has also significantly reduced the wastage of unused thawed fresh frozen plasma across all clinical areas.

WHAT IS EXTENDED LIFE PLASMA?

Extended Life Plasma (ELP) is thawed Fresh Frozen Plasma (FFP) which can be stored between 2° to 6° Celsius for up to 5 days from the time of thawing. FFP contains varying amounts of coagulation factors and is stored frozen until required for transfusion when rapid provision is limited by the time taken for thawing. Thawed plasma is used to treat patients who are haemostatic abnormalities, usually in the context of bleeding. The availability of ELP in inventory allows the provision of thawed plasma with minimal delay.

WHO ARE THE ROYAL CHILDREN'S HOSPITAL?

The Royal Children's Hospital Melbourne

The Royal Children's Hospital, Melbourne (RCH) is a major specialist paediatric hospital in Victoria, providing a full range of clinical services, tertiary care and health promotion and prevention programs for children and young people.

The hospital is the designated state-wide major trauma centre for paediatrics in Victoria and a nationally funded centre for cardiac and liver transplantation. Its campus partners are the Murdoch Children's Research Institute and The University of Melbourne Department of Paediatrics, which are based onsite with the hospital.

Laboratory Transfusion Services at the RCH are provided by Laboratory Services with a 24 hour blood bank operating within the Core Laboratory. Clinical transfusion advice can be obtained from the Haematologists within Laboratory Services.

Ms Mary Comande is the senior scientist in the transfusion laboratory at the RCH.

IMPLEMENTING THE ELP PROTOCOL

Australian and New Zealand Society for Blood Transfusion (ANZSBT) Framework

The ANZSBT 2013 publication *Extended Life Plasma: A Framework for Preparation, Storage and Use*[1] outlines the validation requirements for laboratories wanting to implement the use of ELP. The first edition of the publication formed the basis for implementing the protocol at the RCH.

"*Validation testing wasn't as onerous as we thought it would be. Once we engaged our Coagulation team and Bacteriology department in the project, all we needed to do was decide on a number of units that we wanted to test so that we could compare our data (factor levels and sterility testing) to that published by the Blood Service. We decided on testing at least 30 units as we didn't want to waste too many bags of plasma but we wanted to sample a number plasma donations that was comparable to the number the Blood service tested.*

Note, the second edition of the framework, which was published after we completed our validation study, states that transfusion laboratories may elect to validate their processes by performing sterility testing and/or measuring coagulation factor levels on expired units of ELP, but that the testing was not specifically required.– **Mary, Blood Bank Senior Scientist**

Validation Studies

When the Massive Transfusion Procedure (MTP) was first implemented at the RCH, the laboratory commenced a protocol whereby two units of group AB FFP were thawed and stored in the Blood Bank laboratory the fridge for 5 days in case required for rapid release in a trauma situation. If not used within the 5 days, the plasma was sent to the Bacteriology laboratory for sterility testing and an aliquot was frozen for coagulation factor testing.

Sterility Testing

The ELP project received great support from the Bacteriology staff at the RCH, who happily performed 7 day aerobic and anaerobic cultures on the unused 5 day ELP during the validation period. The sterility data revealed no bacterial growth in all samples after 7 days.

The process of sterility testing is ongoing; all unused ELP units continue to be cultured for bacterial growth to allow the laboratory to remain comfortable with their process. There have been no positive test results to date and in excess of 200 ELP bags have been tested.

"What we are doing is just a continuation of what we are normally do for a blood product reaction so if any other lab has a protocol for how they follow up blood product reactions then it is just a modification of that, it is not as extensive as what we would normally do for a blood product reaction but it is a similar sort of thing and they should be used to doing similar stuff. There was no additional training for micro staff. It's a simplified version of our already set protocol". – **Gena, Microbiology Senior Scientist**

Coagulation Factor Testing

In addition to sterility testing, the project was supported by the Coagulation staff at the RCH who tested the coagulation factor levels in the ELP bags. After setting up the blood cultures, the bacteriology laboratory returned an aliquot from each of the 30 bags to the coagulation department for freezing. The coagulation laboratory performed batch testing on the frozen aliquots for factors V, VII and VIII. A publication produced by Mary and her colleagues, and showcased at HAA 2013, supports the findings of the Blood Service where most factor levels are maintained at haemostatic levels for up to five days post thawing.

Factor	Reference Range (IU/mL)	Average Result in ELP (IU/mL)
Factor V	0.60 – 1.40	0.75 $\pm$ 0.20
Factor VII	0.60 – 1.50	0.87 $\pm$ 0.18
Factor VIII	0.50 – 2.00	0.64 $\pm$ 0.17

From "Implementation of Extended Life Plasma" Poster Presentation, Mary Comande, Sharon Yong, Helen Savoia, HAA 2013[2]

"*You need to be comfortable with the coagulation factor levels in ELP, so we thought we would confirm the factor levels ourselves*". – **Mary, Blood Bank Senior Scientist**

Transfusion committee endorsement:

At the conclusion of the ELP project, project details including the aims, methodology, risk assessment of using ELP, together with validation data, were presented to the RCH Hospital Transfusion Committee for consideration. The RCH Hospital Transfusion Committee endorsed the use of ELP as an interchangeable product with FFP at the RCH in December 2012. An inventory of 2 AB ELP has been maintained in the laboratory since that time.

Staff Training

"*Once we got approval to go ahead, the staff were very supportive as they don't want to waste any precious products*". – **Mary, Blood Bank Senior Scientist**

Following implementation, the laboratory set up a procedure for ELP. All laboratory staff undergo training that covers what ELP is, and how to prepare, issue or discard the product. Training records are completed and signed off by the staff member and trainer. Additionally, the transfusion nurse consultants assist in disseminating information throughout the rest of the hospital about all changes in the blood bank – including the introduction of ELP. Information about ELP is also readily available on the intranet site.

THE LABORATORY PROCESS

When a request for FFP is received at the laboratory, staff first review existing thawed FFP and ELP stock. FFP is only thawed if there is no suitable thawed plasma available. The date and time of thawing is documented on the swing tag attached to the bag. If the thawed product is not used and remains under controlled storage conditions at 2 - 6°C, the product is "converted" to ELP. At this point, an additional luggage label is attached to the plasma that identifies it as ELP.

Two units of group AB FFP are kept thawed as ELP at all times for emergency use. A sign on the front of the fridge is updated daily and allows staff to quickly see available ELP and date of expiry. The AB ELP is reserved for trauma patients for 3 days, after which time it can be re-directed for any patient requiring FFP for a further 2 days. This practice ensures group AB plasma is readily available for trauma patients whilst reducing unnecessary wastage.

The laboratory maintains a log of all ELP and its fate, either used or discarded. The ELP and its expiry date and time are easily identified by pink swing tags, which were selected as they stand out well against the laboratories normal swing tags. As FFP is thawed, the time is recorded so that if, or when, the FFP is converted to ELP, the time of expiry can be correctly noted on the new tag.

POST IMPLEMENTATION

Communication

After the initial implementation of the ELP process, clinical staff were relatively quick to come on board. 75-80% of the plasma goes to operating theatres, mostly for cardiac cases, and it was the staff involved in these cases that were largely responsible for disseminating the information. The Hospital Transfusion Committee also assisted with communicating the new protocol hospital-wide.

"I don't think the message got out to all the theatre staff initially, so we had a lot of phone calls asking about the additional swing tags attached to the thawed plasma and was does ELP mean? While the phone queries did take time to manage, I did also welcome the calls as it indicated to me that clinical staff are checking the blood products carefully and taking notice of changes! We also made copies of the endorsement that the transfusion committee provided just in case they had any queries. We have a team of registrars and haematologists where we can refer any clinical issues or questions." – **Mary, Blood Bank, Senior Scientist**

Impacts - Supply

Mary believes the most significant impact the implementation of the ELP protocol has had, is the ability to provide plasma immediately to those cases that may require plasma quickly such as bleeding cardiac and trauma cases.

"Access to ELP assists in diffusing some of the stress associated with meeting the blood product requirements of bleeding patients; if you need to issue a lot of blood products and you're worried about putting things in the water bath and you're the only person on and it's the evening, access to ELP allows you that little bit of breathing space to complete all the things you need to do and provide the products

to the patients in a controlled manner. There is nothing worse than going to the thawer and finding that the FFP bag has split and you have to delay the issue of the FFP for another 20 mins!" **Mary, Blood Bank Senior Scientist**

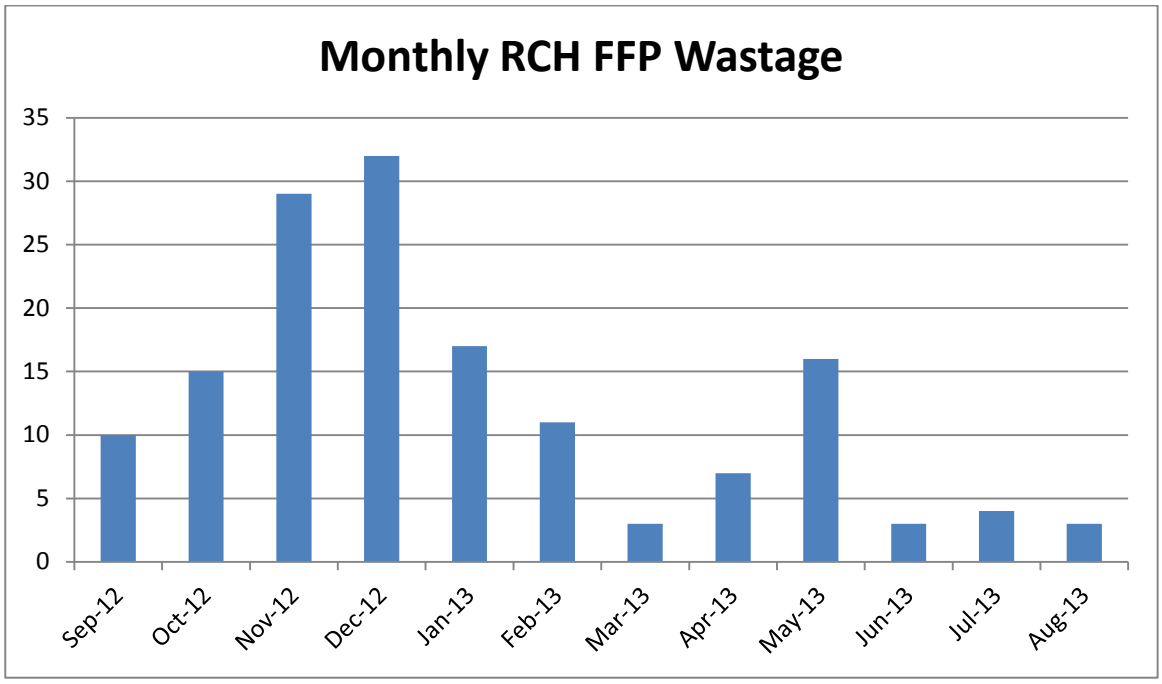
The laboratory has a policy that ensures that group AB FFP is not given to all patients. The AB ELP inventory is 'reserved' for trauma use for 3 days from thawing, however the products are made available to any patients that require FFP after day 3 to ensure the AB ELP does not expire. In the situation where a patient requires FFP and the group AB ELP inventory is only a day or two old, group specific FFP is thawed for the patient.

"I think we use more AB plasma than we did previously, but we are trying to mitigate this by only using the AB ELP for our general pool of patients when the product is at least 3 days old." – **Mary, Blood Bank Senior Scientist**

Impacts - Wastage

The use of ELP in the RCH has had a significant impact on wastage rates. Mary believes this is due to the ability to use the already thawed ELP for patients they would have otherwise had to thaw additional FFP for.

"In the months immediately after the decision to have 2 units of ELP readily available to support the introduction of the new MTP at the RCH (Jan-Feb 2013), we were hitting very high figures of FFP wastage – sometimes in excess of 20-30% ,which was really difficult to deal with. However after we introduced our diversion strategy, where unused Day 3 group AB ELP could be used for any other patient requiring FFP, our wastage dropped to <5% and has remained at that level."



From "Implementation of Extended Life Plasma" Poster, Mary Comande, Sharon Yong, Helen Savoia, HAA 2013

How will ELP work for other health providers

While the process of implementation of ELP at the RCH has been a relatively simple one, Mary believes that an ELP protocol may not be suitable for all laboratories and each laboratory should consider the pros and cons of their situation. An ELP protocol may work for a laboratory provider that supports a

health service where there are regular and frequent opportunities to use thawed plasma (e.g. daily cardiac surgery) other than trauma cases.

"Your lab needs to have a regular avenue to utilise your ELP product to make the process worthwhile. I don't believe you should implement ELP for 'just in case' trauma situations and not have anyone else you can direct the product to. I would imagine that a small path laboratory that only has infrequent requests for FFP would not be a candidate to implement an ELP protocol as the product would be wasted. Conversely, if your lab supports a busy trauma service or a cardiac surgery unit where FFP is often requested urgently, then the ELP protocol would be useful." – **Mary, Blood Bank Senior Scientist**

For more information

To see other case studies in the series visit http://www.blood.gov.au/case-studies

---

Contact Officers

For further information please contact:

Mary Comande, Senior Scientist Blood Bank, The Royal Children's Hospital and The Royal Women's Hospital Melbourne mary.comande@rch.org.au

---

Acknowledgements

Thank you to the following people without whom this case study would not have been possible:

- Mary Comande, Senior Scientist Blood Bank, The Royal Children's Hospital Melbourne
- Gena Gonis, Senior Scientist Bacteriology, The Royal Children's Hospital Melbourne
- Vanessa Whatmough, Manager, Media Strategy and Engagement, Corporate Communications, The Royal Children's Hospital Melbourne
- Dr Helen Savoia, Acting Director, Laboratory Services The Royal Children's Hospital Melbourne
- Brenda White, Director, Laboratory Services The Royal Children's Hospital Melbourne

---

References

1. Australian and New Zealand Society for Blood Transfusion (ANZSBT). 2013. *Extended Life Plasma: A Framework for Preparation, Storage And Use.* Second Edition. Australian & New Zealand Society of Blood Transfusion Ltd., Sydney.

2. Comande, M., Yong, S., Savoia, H. 2013. *Implementation of Extended Life Plasma*. Poster Presentation HAA 2013