**Purpose:**

To provide instructions for ordering, receiving, storing, and selecting INTERCEPT pathogen-reduced plasma for transfusion to burn patients who are enrolled in the PROPOLIS (Plasma Resuscitation Without Lung Injury).

**Policy:**

* Study patients are consented by the Burn Research team.
* Frozen plasma components are stored at ≤ -18°C segregated from standard plasma units to prevent inadvertent use by non-study patients.
* Thawed plasma components are stored at 1-6°C and segregated from standard plasma units to prevent inadvertent use by non-study patients.
* Plasma will be from group A or O donors and tittered to be low titer Anti-A and/or Anti-B. Usage for patients will be by expiration date and volume and not determined by patient blood type.
* Plasma components are automatically ordered and shipped from Vitalant or their contracted vendor as plasma is used.
* Plasma exchange orders are placed by the Burn research nurse in Epic with a comment regarding PROPOLIS study.
* Each enrolled patient will be issued multiple units of pathogen-reduced plasma. If pathogen-reduced plasma is not available, contact Burn research nurse and notify of possible delay.
* Transfusion reactions related to the transfusion of pathogen-reduced plasma will be reported to HMC TSL and worked up per standard policy. TSL Medical Director/designee will consult with research and bedside nurses.

**Procedure notes and limitations:**

* Components from blood supplier are to be allocated and issued only to patients approved and enrolled in clinical study.
* Units thawed and not transfused to the intended participant will be refrigerated and used on the next enrolled participant. Place unit on appropriate shelf and notify the research coordinator. These units have a 24-hour expiration and will be discarded if not used.
* Patients must be admitted to Harborview and enrolled to study within 8 hours of sustaining the burn injury and all resuscitation fluids will be delivered between hours 0-24 postburn.

**Principle**

PROPOLIS is an open-label, prospective, randomized, controlled multi-center clinical trial. This trial is aiming to 1) reduce the amount of fluid given during the first 24 hours after a burn and 2) reduce the incidence of lung injury and other complications related to the administration of fluids. The overall decrease in the amount of fluids received should decrease the potential for lung injury, decrease days in the hospital, and improve survival.

Pathogen-reduced components are collected from donors eligible for blood donation. These units are FDA approved. This is not a clinical trial to receive approval for use through the FDA.

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| 1 | Receive plasma into inventory* Inspect unit and receive into Sunquest inventory
* Store plasma in the ≤ -18C freezer, utilizing F3 first and then creating space in F2 if necessary.
* Place original ODR in managers door.
 | Order Distribution Report (ODR)Receiving Blood Products into InventoryBlood Product Inspection PolicyVisual Inspection of Plasma ProductsSQ Blood Product EntryBlood Product Storage Policy |
| 2 | Patient is enrolled.* The Burn research nurse will make initial contact with TSL and verify volume needed and if correct volume of plasma is available.
* Burn research nurse will place Epic order for Non-nephrology Plasma Exchange with PROPOLIS comment.
* Place a photocopy of the plasma exchange order in the manager’s mailbox.
* Document patient’s name and MRN on whiteboard
 | SQ Order Entry Process |
| 3 | Bedside Staff:* When ready to transfuse, the bedside staff will release the initial transfuse order in Epic and the release will print in TSL.
* When transfusions are complete, bedside staff will discontinue any remaining transfuse tasks.

TSL:* Begin thawing units as soon as the Non-nephrology Plasma Exchange order is received. Do not wait for the release to print, there is very limited time to begin transfusion.
* Select units by expiration date and volume that will get closest to plasma exchange. Do not give less, go over if needed (i.e. 1200ml requested but thawing units can give you either 1195ml or 1205ml, select the units giving 1205ml).
* Thaw plasma, preferentially using Helmer Quickthaw waterbath.
* Perform Blood Component Prep using BCP.
* Label check unit and apply new label.
* Allocate thawed plasma to patient and place in portable refrigerator.
* Issue and deliver fridge to patient floor having them sign the Portable Refrigerator Log (PRRL) upon delivery.
* Floor will call when the fridge is ready to be returned.
* If any unit is return unused, do not return to regular inventory. These units are only to be used by PROPOLIS patients.
* Place a photocopy of the final PRRL in the managers door.
 | Portable Refrigerator LogThawing Products Using the Helmer Quickthaw SystemVisual inspection of Plasma ProductsSQ Preparation of Thawed PlasmaSQ Blood Label Check (BLC) and VerificationManual Label Verification FormSQ Blood Order ProcessingBlood Product Issue ProcessSQ Blood Product Issue |
| **Step** | **Action** | **Related Documents** |
| 4 | If transfusion reaction is suspected:* Verify bedside nurse has stopped the transfusion
* Contact LMR/Medical Director
* LMR/Medical Director will work with Burn research and bedside nurses to send a transfusion reaction investigation (sample if necessary and form)
* Floor will place transfusion reaction workup request in Epic.
 | Transfusion Reaction InvestigationSQ Order Entry Process |
| 5 | Manager will complete REDCap Plasma Tracking Database once units have been issued to the patient. This will trigger the blood supplier to send more components. |  |

**Contact Information for Burn Research team:**

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**References:**

Technical Manual. Bethesda, MD: AABB Press, current edition

Standards for Blood Banks and Transfusion Services. Bethesda, MD: AABB Press, current edition

Plasma Resuscitation without Lung Injury (PROPOLIS), Protocol V2.0, 20 July 2021