University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA 98195 Transfusion Services Laboratory Policies and Procedures Manual Original Effective Date: 10-28-2020
Revision Effective Date:

Number: PC-0079.01

TITLE: Blood Storage and Inventory Management at Northwest Campus

PURPOSE

To describe the policies and process for storing and managing blood inventory at UWMC Northwest campus.

LOCATION

Northwest Lab Transfusion Support Service (TSS) Montlake Transfusion Service Laboratory (TSL)

PRINCIPLE & CLINICAL SIGNIFICANCE Principle

Blood and blood components are stored in a manner to maintain the safety, efficacy and potency of the component for transfusion from collection to transfusion. Storage conditions and expiration dates vary depending on the component type and are mandated and strictly enforced by the Federal Food and Drug Administration (FDA). Accrediting agency standards align and support the regulations set forth by the FDA.

Inventory quantities of blood components must be sufficient to meet the routine patient needs, allow for unanticipated increases in utilization due to emergencies and minimize component outdating.

Clinical Significance

Strict storage requirements are in place to assure the safety, purity, and potency of all blood components are maintained.

POLICIES

Storage of Blood Components

- TSL and TSS will store and transport blood components in a manner to meet or exceed the standards mandated by the FDA and supporting accrediting organizations.
- Only trained TSL and TSS laboratory staff are allowed access to blood components prior to components being issued for transfusion. Access is controlled through badge access or 24/7 staff monitoring.
- Blood components are stored as specified in <u>Table 1:</u> Blood Component Storage Conditions below. Components not maintained in these storage conditions will be evaluated by the transfusion staff and disposed of as necessary.

Table 1: Blood Component Storage Conditions

| Type of Component | Storage Equipment | Storage Temperature |
|--|---|-----------------------------------|
| Red blood cellsThawed plasma | Refrigerator/Haemobank | 1° to 6°C |
| Frozen plasmaFrozen cryoprecipitate | Freezer | ≤ -18°C |
| Platelets | Platelet Incubator with continued agitation | 20° to 24°C with gentle agitation |
| Thawed cryoprecipitate | Store at room temperature | 20° to 24°C no agitation |
| Granulocytes | Store in the shipping container until issue— do not place in platelet incubator | 20° to 24°C no agitation |

- Storage equipment temperatures are monitored 24/7 by integral equipment alarms. Alarms
 are validated and maintained per regulation. Alarm checks are performed quarterly and
 temperature measuring devices are calibrated annually or per manufacturer requirements.
 Additionally, a wireless electronic monitoring system alerts Montlake TSL staff if
 temperatures exceed the acceptable range
- Components not stored according to these conditions will be evaluated by the TSL management and disposed of as required.
 - UWMC TSL medical director approval is required prior to placing blood components back into available inventory when it is determined that required storage conditions were not maintained. If approved, the deviation from SOP should be documented on a Quality Improvement form (QI) including the reason for the deviation and name of the UWMC TSL medical director approving return to inventory so their signature can be obtained.
- In the event of storage equipment failure, blood components should be removed to an alternate acceptable storage within 30 minutes of storage device failure and Montlake TSL notified immediately

| Primary Storage | Move to |
|--------------------|--|
| Haemobank | Blood Refrigerator |
| Blood Refrigerator | Haemobank |
| Plasma Freezer | Chemistry -30°C Freezer. Use Plasma Freezer Downtime temperature log to record Chemistry freezer temp every 4 hours. |
| Platelet Chamber | Platelet room temperature shipping container |

- Inventory is stored in a manner to ensure units are segregated appropriately in storage in the following manner:
 - Quarantined, autologous and directed units are physically segregated from other stock
 - Blood components stored in the Haemobank are assigned individual compartments designated by BloodTrack courier software. BloodTrack will automatically quarantined blood components when visual inspection and temperature documentation does not meet requirements
 - Validated blood component shipping containers supplied by blood suppliers will be used for transport between UWMC Montlake and Northwest campuses

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Inventory Management

- Inventory levels are maintained between the minimum/critical and par levels in order to
 provide prompt patient care and reduce wastage. Inventory par and minimal/critical levels
 are listed in Appendix 1 Blood Component Inventory Levels. These levels should be
 considered guidelines that can be adjusted as necessary in response to patient needs
- Generally, one component shipment will be sent during the day from Montlake TSL to Northwest TSS to maintain daily par levels
- Additional shipments are sent as needed to ensure the ability to respond to patient needs in a timely manner

 Components should be returned to Montlake TSL based on expiration to prevent wastage unless there is a shortage of available components.

| Component | Return when |
|---|-------------------------------|
| Red Blood Cell Frozen Plasma Frozen Cryoprecipitate | Less than 5-day shelf life |
| Thawed plasma | Less than 48 hours shelf life |
| Platelet | Less than 24 hours shelf life |

• TSL Montlake Campus Responsibilities:

- o Inventory levels should be monitored and reconciled by each shift daily
- Prepare and set up daily par level shipments to NW campus in the morning.
 Shipment may split into multiple deliveries to accommodate frozen blood components
- Prepare and send additional blood components to NW when inventory is at critical level
- Monitor and respond to all alerts in BloodTrack manager including when units are removed from the Haemobank during emergencies
- Release allocated blood components in Sunquest when crossmatch has expired or beyond the dereservation date in BloodTrack manager
- Request short dated blood components be returned to TSL unless there is an anticipated transfusion for the short dated blood components

• TSS Northwest Campus Responsibilities:

- o Inventory levels should be monitored and reconciled by each shift daily
- Notify TSL if there are discrepancies with inventory count at NW
- Identify short-dated allocated blood components and notify TSL if short-dated components need to be released from allocation
- Call and notify TSL when inventory is emergently issued and additional inventory is required
- Return any short-dated, expired and quarantined blood components to TSL as directed by TSL.

SPECIMEN REQUIREMENTS:

NA

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REAGENTS/SUPPLIES/EQUIPMENT:

| Reagents: | Supplies: | Equipment: |
|-----------|-----------|------------|
| NA | NA | NA |

QUALITY CONTROL:

NA

INSTRUCTIONS:

<u>Daily Inventory Reconciliation –to be performed by TSL and TSS Appendix 1: Blood Component Inventory Levels</u>

Daily Inventory Reconciliation -to be performed by TSL and TSS

| Daily if | Inventory Reconciliation –to be performed by TSL and TSS | | |
|----------|---|--|--|
| STEP | ACTION | | |
| 1 | Log into SmarTerm to print the Blood bank inventory report | | |
| | Enter the following who | en prompted | |
| | Prompt | Enter | |
| | FUNCTION: | XXX, press [Enter] | |
| | HOSPITAL ID: | U | |
| 2 | Arrow down to: | "Lab Inquiry Functions", press [Enter] | |
| | Arrow down to: | "Blood Bank Inventory", press [Enter] | |
| | Hospital ID [1] or 2: | 1, press [Enter] | |
| | Area: | NWBB | |
| | PRINTER | LIS Device # of the SQ printer, press [Enter] | |
| 3 | Retrieve the SQ blood bank inventory report from printer | | |
| 4 | Log in to the Haemobank by scanning your UWMC ID Badge or entering in your EID# | | |
| 5 | Double click on the qu | antity in the "Red Cells" column. | |
| | If | Then | |
| 6 | Montlake TSL | Compare and reconcile the inventory report with the inventory stored in the Haemobank Review blood bank summary report and determine par level of blood components to send to NW as specified in Appendix 1: Blood Component Inventory Levels Release components that have expired crossmatch or dereservation date in Sunquest and BloodTrack Manager respectively Release and request for return any short-dated blood components that may not be able to be transfused prior to expiration | |

| STEP | ACTION | | |
|------|--|---|--|
| | Northwest TSS | Compare and reconcile the inventory report with the inventory stored in the Haemobank Physically verify components stored in non Haemobank storage match ABO/Rh type listed on the blood bank inventory report. Notify ML if there are any discrepancies Short-dated components (allocated to patients): verify if components are required for transfusion. Notify ML TSL for components that will not be issued and can be released from allocation Return any expired and quarantined blood components to ML- refer to SOP: Quarantine and Disposition of blood components at Northwest Campus Communicate to ML TSL for any blood components that are required immediately | |
| 7 | Initial and date Blood Bank Inventory Summary reports | | |
| 8 | File reports and discrepancy paperwork in the appropriate location | | |

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES

CALIBRATION:

NA

PROCEDURE NOTES AND LIMITATIONS:

- Due to inventory shortages, it may not be possible to completely fill orders and adjustments may be necessary to optimize product distribution at remote storage locations
- Dry ice: Special precautions may be required to prevent burns when handling dry ice.
 Insulated gloves should be worn when there is a risk of contact with skin. Dry ice should always be handled in a well-ventilated area and must be packaged in a manner that would allow the gas to escape as the dry ice dissipates. See the Clinical Laboratory Safety Policy for additional information and precautions regarding handling dry ice.
- For autologous, rare or difficult to replace units, it may be necessary to preserve units that have been exposed to temperatures outside of the acceptable range. In these circumstances, the TSL medical director approval is required. Approval and reason for deviation to the SOP must be documented. Contact Montlake TSL for follow up with TSL Medical Director.

REFERENCES:

NA

RELATED DOCUMENTS:

SOP Quarantine and Disposition of Blood Components at Northwest Campus

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| UWMC SOP Appr | oval: | |
|--|-------------------------------|-----------------|
| UWMC CLIA Medical Director | manlen | 10/20/20 |
| | Mark H. Wener, MD | Date |
| Transfusion Service Manager | Nina Sen | Date 10 16 20 |
| Compliance Analyst | Mrufini Olark Christine Clark | Date 10-16-2020 |
| Transfusion Service Medical Director | Monica B. Pagano, MD | Date 10-19-2020 |
| UWMC Biennial R | eview: | |
| | | Date |
| | | Date |

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APPENDIX:

Appendix 1: Blood Component Inventory Levels

| Red Blood Cell Components | PAR level | Minimum/Critical Level ¹ | | | |
|---|-----------|-------------------------------------|--|--|--|
| O Positive | 16 | 6 | | | |
| O Negative | 8 | 4 | | | |
| A Positive | 14 | 6 | | | |
| A Negative | 4 | 1 | | | |
| B Positive/Negative | 2 | 1 | | | |
| Note: All red blood cells are irradiated and leukoreduced | | | | | |
| Plasma | PAR level | Minimum/Critical Level ¹ | | | |
| 0 | 4 | 2 | | | |
| А | 4 | 2 | | | |
| AB | 4 | 2 | | | |
| Pooled Cryoprecipitate | PAR level | Minimum/Critical Level ¹ | | | |
| Any type | 2 | 1 | | | |
| Platelet | PAR level | Minimum/Critical Level ¹ | | | |
| Any type | 1 | 0 | | | |
| ,, .,p.c | | | | | |

¹ Order if critical level if reached prior to standard daily delivery