Southwest Texas Regional Advisory Council

STRAC REGIONAL WHOLE BLOOD* PROGRAM
MEMORANDUM OF UNDERSTANDING

**Whole Blood refers to Low Titer O-Positive Whole Blood*

PURPOSE

The purpose of this Memorandum of Understanding (MOU) is to establish a framework for collaboration among program stakeholders in the development, operation, and maintenance of the Regional Whole Blood Program. This agreement defines the roles, responsibilities, and expectations of each participating organization to ensure the appropriate collection, distribution, and utilization of Low Titer O+ Whole Blood in compliance with regulatory guidelines. While not legally binding, this MOU serves to guide cooperative efforts enhancing patient care outcomes across the region.

BACKGROUND

The STRAC Whole Blood Program was established in 2018 as a multi-disciplinary, multi-institutional initiative involving regional helicopter and ground EMS agencies, regional trauma centers, South Texas Blood & Tissue (STBT), and STRAC. It was created by likeminded professionals dedicated to developing a program that ensures appropriate, timely, and early resuscitation using Low Titer O+ Whole Blood in pre-hospital and rural hospital settings. The program's objectives include managing the regional supply of donors to meet demand without excess waste, maintaining strict compliance with regulatory guidelines, and sustaining an evidence-based system of care to optimize patient outcomes.

DEFINITIONS

Circular of information for the Use of Human Blood and Blood Components: In accordance with FDA requirements under 21 CFR 606.122, this circular must be available for review by transfusion Services, prescribing physicians, and staff anywhere blood is issued or transfused. https://www.aabb.org/news-resources/resources/circular-of-information

Rotation site: EMS agency or hospital with return privileges to STBT (ensuring the LTOWB is rotated through to a higher usage rotational center).

Rotation center: Trauma Center receiving LTOWB already cycled through the prehospital or rural hospital setting. This process is intended to be free of bias, agnostic to any entity and in the best interest of those involved.

Transfusion Administration Service (TAS): A service provider responsible for receiving and transmitting orders of blood for transfusion, transporting blood to the transfusion site, performing the transfusion, monitoring the patient during transfusion, reporting outcomes, and ensuring the traceability of the unit is maintained.

Transfusion Site: The patient care area where a transfusion is performed.

ROLES AND RESPONSIBILITES

A. All Participating Agencies and Facilities Agree to the Following:
   1. Program Resources & Training
      - Program updates and training information are available at: www.strac.org/blood.
   2. Regional Process Improvement
      - This is a regional process improvement program. All data and shared information will be used solely to enhance the delivery of care in the Southwest Texas region.

3. Governance and Participation
    - The STRAC Regional Whole Blood Committee will serve as the guiding body for the regional Low Titer O+ Whole Blood (LTOWB) program.
    - Membership includes all EMS agencies (air and ground), healthcare facilities (or systems), and organizations contributing to the supply, administration, accounting, and patient care aspects of LTOWB.
    - The committee meets monthly, and each member agency/organization is required to attend at least nine (9) meetings annually. All agencies will be given attendance credit for cancelled meetings. Compliance will be evaluated annually in accordance with the STRAC Fiscal Year, Sep-Aug.
    - Key program execution and operational decisions will be made by consensus among all participating members.
    - Any agencies not meeting a program requirement, to include Committee Meeting attendance, will meet with the WB Program Manager to discuss a 6-month performance improvement plan. If no improvements are made, a re-evaluation of deficiencies will be conducted and dismissal from Regional Whole Blood Program may be recommended. Dismissal recommendations will be referred to and decided by the WB Committee Chair, STRAC Executive Director, and the WB Program Manager. Dismissal from the program will be for 12 months and consideration for re-entry into the program will require a performance improvement process verification.
4. Clinical and Administrative Support
    - South Texas Blood & Tissue (STBT) will provide administrative training on ordering, managing, and storing LTOWB at participating sites.
    - Each agency and facility will designate a primary point of contact to address concerns and actively participate in discussions and decision-making.
5. Blood Supply Standardization
    - To maintain regional consistency, STBT will serve as the single supplier of rotational LTOWB.
6. Performance Improvement and Data Sharing
    - Agencies and facilities will provide clinical and administrative performance improvement data as requested by STRAC.
7. Documentation Requirements
    - Prehospital LTOWB transfusions must be documented using the STRAC Regional Prehospital Blood Product Transfusion Record (Appendix B).
    - This record is not a replacement for an agency's electronic patient care record (EPCR) but serves as a real-time communication tool between EMS providers, receiving emergency departments, and hospital blood banks/transfusion services.
    - Hospital blood banks/transfusion services must receive immediate notification when untyped and uncross-matched blood has been administered.
    - The Transfusion Administration Service (TAS) shall be responsible for recording the final disposition of blood or blood components, ensuring proper tracking and compliance with AABB standards.

PROCEDURES

A. Receiving Blood
1. Agencies and facilities will follow STRAC and STBT protocols for blood product ordering and delivery.
2. Blood and blood components shall be inspected each time they are received to verify the following:

- The unit has remained in a validated transport container or storage device within the specified period.
- The unit appearance meets visual inspection criteria.
- The unit has an attached label or tag indicating the donation identification number, and compatibility testing has not been performed.

3. Receipt of a unit of blood shall be annotated using the STRAC Whole Blood app. Agency representative will log into the app, select "Initial Receipt" and scan all appropriate bar codes assigning the unit to their agency. (https://youtu.be/J97vpADyn0E?si=7oZuEQfL9ODvMu4x)

B. Storing and Transporting Blood

1. Temperature Monitoring & Recording
   - Low Titer O+ Whole Blood will be stored in an approved program cooler between the temperatures of 1-6*C. The program blood supplier, South Texas Blood and Tissue acceptance criteria regarding product suitability for return to available inventory for re-issue is based on the visual temperature indicator (Safe-T-Vue 10). A white indicator means the blood has been kept below 10*C for the duration of issuance. If the indicator turns red, the blood temperature reached or exceeded 10*C. (Appendix A)
   - In those instances where the cooler temperature has deviated from the 1-6*C range, corrective action and blood temperature verification using an infrared thermometer must be performed. Documentation of corrective action and temperature findings shall be maintained by the TAS should a deviation occur.
   - The TAS shall ensure all containers are validated for the handling, storage, and transport of blood and blood components.
   - Blood containment temperatures shall be continuously monitored in accordance with procedures established by the program administrators and the Whole Blood Committee.
   - Temperature recordings must be documented at least every four (4) hours.
   - If a temperature deviation occurs rendering the product unusable (Safe-T-Vue 10 color conversion from white to red), it must be reported immediately to agency leadership, South Texas Blood and Tissue, and STRAC WB Program Manager.
2. An inventory check, utilizing the STRAC Whole Blood app will be conducted daily. Ideally, this should be performed during the daily Thermal Insulated Chamber (TIC) exchange. During the handling of the unit for scanning in the app, the unit should be inspected for any clots, bag leaks, frothing, or any other suspicious defects.

C. Equipment

1. General Equipment Use
   - All equipment used in the handling, storage, transport, and administration of blood shall be operated in strict accordance with the manufacturer's written instructions and shall be limited to devices explicitly specified on the approved products list referenced in Appendix C "Approved Products List".
   - Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.
   - Except for 0.9% sodium chloride, drugs or medications shall not be added to blood or blood components unless: they have been approved for the use by the FDA or Competent Authority or there is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.
2. Coolers
   - Storage and transport devices must be designed to maintain proper temperatures.

- Blood and blood components shall remain within the acceptable temperature range during storage and transport.

3. Warming Devices
    - Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood components.

D. Administration

1. Verification Prior to Administration
    - Immediately before transfusion, the following information shall be verified:
        - The intended unit for transfusion meets TAS protocol and has not expired.
        - Unit ABO group.
        - Unit appearance meets visual inspection criteria.
        - The unit has remained in compliance with temperature requirements during storage/transport.
2. The patient shall be monitored for potential transfusion-related adverse events by the TAS until the time of transfer of care.
3. Documentation & Compliance
    - All EMS agencies will use the STRAC Whole Blood form to notify the receiving hospital and/or other prehospital care providers of the patient's transfusion status, the unique patient identifier (Texas EMS Wristband), and any transfusion-related adverse reactions through the continuum of care.
    - The statement on the STRAC Whole Blood form indicating stating the "clinical situation was sufficiently urgent to require emergency release of un-crossmatched blood before completion of compatibility testing" shall be signed, either physically, or electronically, by the ordering physician.
    - The STRAC Whole Blood Application ("Whole Blood App") shall be utilized for inventory management, and transfusion documentation.

E. Reporting and Process Improvement

1. All organizations shall capture, assess, investigate, and monitor failures to meet specified requirements both local and programmatic, and any adverse events or non-compliance issues related to blood administration.
2. All organizations shall collect data, perform analysis, and follow up on issues requiring corrective/preventive action, including near-miss events.
3. The TAS shall have a process for providing relevant unit and/or patient information as requested when notified by the blood collection facility and/or transfusion service.
4. The TAS shall have a process for the monitoring of blood utilization and wastage.
5. STRAC will maintain program records using data from prehospital providers, STBT, and receiving facilities.
6. If a fatality is suspected or confirmed to have occurred as a result of a transfusion, this is to be considered a Sentinel Event and shall notify organizational leaders and STRAC Whole Blood Program Manager immediately. The Program Manager will notify STBT, UH, STRAC Leaders, and any appropriate stakeholder to initiate investigation and FDA notification if required.

TERM

This MOU is a living document and will be evaluated every 3 years. The signatories are attesting to the commitment of their organization to follow and enforce the practices, roles, and responsibilities for their organizations as delineated in this MOU.

This memorandum of understanding is in effect on the date on which it is signed and remains in effect until written notification is received revoking the Memorandum of Understanding with the STRAC. All parties reserve the right to terminate this MOU at any time, with or without cause. Thirty (30) day written notification is required for termination of the MOU.

ORGANIZATION: _____

(Indicate Hospital or Agency Name here)

PRIMARY POC: _____

(This is a role, not a person. Example ED shift supervisor)

PRIMARY POC CONTACT INFORMATION (EMAIL/PHONE):

_____

(Business URL only, NO gmail/yahoo, etc., personal accounts)

POC FOR PROVIDING FEEDBACK (OUTCOMES DATA FOR TRAUMA AND MEDICAL):

_____

(This is a role, not a person. Example ED shift supervisor)

POC FOR PROVIDING FEEDBACK CONTACT INFORMATION (EMAIL/PHONE):

_____

(Business URL only, NO gmail/yahoo, etc., personal accounts)

<table>
<tr><th colspan="2">Southwest Texas Regional Advisory Council</th></tr>
<tr><td>By: _____
Donald Jenkins, MD, Regional Whole Blood Committee Chair

_____
Date</td><td>By: _____
Eric Epley, Executive Director

_____
Date</td></tr>
<tr><th>South Texas Blood & Tissue</th><th>Hospital: _____</th></tr>
<tr><td>By: _____
Mark Fite, EVP/COO
South Texas Blood & Tissue Center

_____
Date
Address: 6211 IH-10 West
San Antonio, TX 78201</td><td>By: _____
Hospital or System CEO

_____
Date
Address:</td></tr>
<tr><th colspan="2">EMS Agency: _____</th></tr>
<tr><td>By: _____
EMS Agency Leadership

_____
Date

Address:</td><td>By: _____
EMS Medical Director

_____
Date

Address:</td></tr>
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APPENDIX A
PREHOSPITAL BLOOD PRODUCT TRANSFUSION RECORD

STRAC
Southwest Texas Regional Advisory Council

Prehospital Blood Product Transfusion Record

Patient Name:	Transporting Agency Run / Case #:	Receiving Facility Medical Record #:

Product Unit Number (Affix sticker below, or write unit number)	Product Type (Check One)	Transfusion Date & Start Time	Transfusion Complete (Check One)	Transfusion Reaction (Check One)	Transporting Medic/RN Initials
1. Affix Sticker Here or Write Unit #	☐ PRBC ☐ Plasma ☐ LTOWB		☐ Yes ☐ Ongoing	☐ Yes ☐ No	
2. Affix Sticker Here or Write Unit #	☐ PRBC ☐ Plasma ☐ LTOWB		☐ Yes ☐ Ongoing	☐ Yes ☐ No	
3. Affix Sticker Here or Write Unit #	☐ PRBC ☐ Plasma ☐ LTOWB		☐ Yes ☐ Ongoing	☐ Yes ☐ No	

Name of Air Medical/Ground Agency and Aircraft ID/Medic Unit #	Receiving Facility (Check One):	Type of Call (Check One):
	☐ University Hospital ☐ Brooke Army Med Center ☐ Other: _____	☐ Scene Call ☐ Interfacility Transfer

Reason for Transfusion:	Comments:
☐ Trauma ☐ OB/GYN ☐ GI Bleed ☐ Other	

Mandatory Blood Product & Blood Form Tracking:

☐ **Transporting crew:** keep **White Copy**; give the yellow and pink copies ***AND*** the blood bag to the Emergency/Trauma Team.

☐ **Emergency Department:** keep **Yellow Copy**; give the **Pink Copy** *AND* the blood bag to the Blood Bank/Transfusion Services. **Notify blood bank if this Rh+ blood product was transfused to a female of unknown blood type.**

☐ **Transporting Crew:** Using the Whole Blood App, select "Administer to Patient"→Scan the bag→Take a picture of Blood Form→click submit.
OR
Send a copy of Blood Form to **MEDCOM** via text image to **(210) 417-7016**, or email MEDCOM@strac.org, or FAX: (210) 233-5825

Actions to take for suspected transfusion reaction:
- ✓ **STOP TRANSFUSION**
- ✓ Disconnect tubing from infusion site; flush site with normal saline
- ✓ Keep line open with normal saline
- ✓ Re-initiate new transfusion if deemed clinically essential
- ✓ Document actions taken in 'Comments' section of ePCR
- ✓ Give unused blood, tubing and form to receiving hospital

Blood Bag & Form given to: _____ _____
PRINTED NAME *SIGNATURE*

The clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing.

_____ _____
EMS Physician PRINTED NAME *SIGNATURE*

Version 4, Aug 2025

APPENDIX B
LTOWB BLOOD PRODUCT TAG

APPENDIX C
APPROVED PRODUCTS LIST

All items used in this program are to be FDA approved to ensure program integrity. This approved products list allows the Regional Whole Blood Program to maintain the highest of standards and promote interoperability within our region. When considering a new product for inclusion to this list, approval will be sought by authorized representatives of the three major stakeholders of this program—South Texas Blood & Tissue, University Health and Executive Leaders/Chair of the Whole Blood Committee.

Contact the manufacturer or distributor directly for most recent pricing. Costs listed below are to provide an estimate of costs to start a program.

LOW TITER O+ WHOLE BLOOD:
South Texas Blood & Tissue is the only authorized vendor of blood in this program.

BLOOD COOLERS:
Blood cooler products are to be validated and approved for use by all stakeholders of this program. Validation of the cooler will be conducted by a laboratory designated by STBT at the expense of the recommending organization.

Pelican Credo Cube w/ Thermal Isolation Chamber System (TIC)
NAME: Credo PROMED Series 4, 2L STANDARD TAN BAG w/ inserts
COST: $790 + $316 (additional TIC**)
Contact BoundTree for purchasing

Total (approx.) cost: $1106

Delta Development Delta ICE 2L SMART Blood Cooler
Cost: $4480 + $880 (additional TIC **)
Email: sales@deltadevteam.com or contact BoundTree

Total (approx.) Cost: $5360

**Need to purchase 2 Thermal Isolation Chambers. This will allow one to always be in the freezer and ready for easy swap out at change of shift.

Delta Dev Autonomous Portable Refrigeration Unit (APRU) 6L
Cost: $10,000
Email: sales@deltadevteam.com

BLOOD WARMERS:

The prehospital industry is exploding with new devices. The program recommends identifying which one is best for your agency or mission. Of note: when price comparing, a device may be cheaper on the outset, but the expendable items (proprietary blood tubing) may be very pricey.

To facilitate the program's emphasis on standardization for the continuity of care, STRAC recommends the use of the QinFlow warmer for all rotation sites and rotation centers participating in the regional whole blood program. QinFlow has adopted a "Unplug-Replug" strategy to create a seamless patient handoff for the entire continuum of emergency care. The disposable tubing in their warmer can be used with their prehospital focused equipment and hospital-based equipment in addition to facilitating patient handoff, this inter-operability strategy supports a regional mass casualty incident response in which blood and blood warmers will be sent to the point of need.

QinFlow
https://www.qinflow.com/products-and-solutions/
Warrior Lite Portable Warmer System
Item: Q11100000U
Unit Price: $3,782
QinFlow Disposable Tubing Unit: $40 each

Belmont Buddy Lite
https://www.belmontmedtech.com/products/the-belmont-buddy-lite
Prices not publicly available.

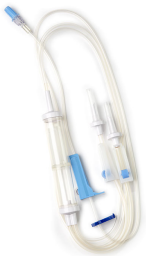
CONTINOUS TEMPERATURE MONITORING:

A device to continuously monitor the temperature in the blood cooler is required. This product is to be centrally monitored by MEDCOM using the MEDCOM Tempstick account.

Temp Stick:
This is a Wi-Fi based option.
Pricing: Approx. $140 plus access to wifi
www.tempstick.com

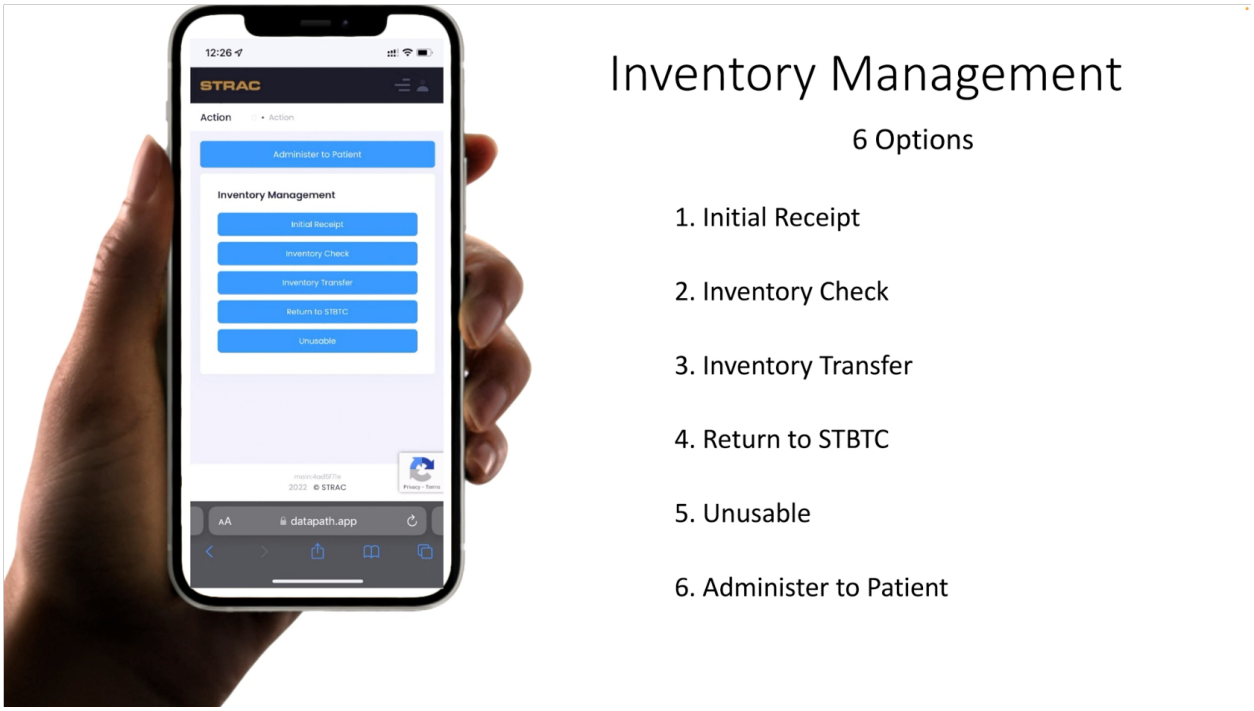
MISCELLANEOUS

Filtered Blood Tubing:
Y-type Blood/Solution Set with Standard Blood Filter (these spike into blood bag and connects into proprietary warmer tubing)
Roughly $300 for a case of 50 (depends on vendor)
Sold by almost all vendors that have IV tubing (Boundtree, etc).



Pressure Bags: Any standard pressure bag will work. You may already have these on your vehicles. Useful if LTOWB will be given through an IO.

APPENDIX D
STRAC Whole Blood Application



strac.wholeblood.app

Option	How to Use
Administer to Patient	Scan Unit Number Bar Code; Take photo of completed Blood Form; click submit
Initial Receipt	Select only when picking up unit from STBT; scan all 4 unit barcodes; click submit
Inventory Check	Done DAILY; Scan Unit Number Bar Code; click submit
Inventory Transfer	Select only if handing off YOUR unit to another agency but is not currently being transfused.
Return to STBT	Select when returning unused unit to STBT. Scan Unit Number Bar Code; click submit.
Unusable	Select only if unit is rendered unusable due to temperature variance, damage to bag prior to use, or unsafe to use due to clot, froth, or debris in bag.

APPENDIX E
South Texas Blood and Tissue Center MCI Letter

South Texas Blood & Tissue | HEROES IN ARMS

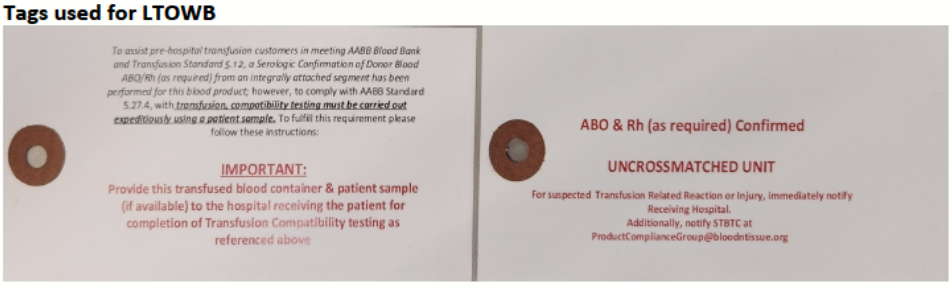
Low Titer O Whole Blood

What is low titer O positive whole blood (LTOWB)?
LTOWB is type O-positive whole blood that has low levels of anti-A and anti-B antibodies (titer < 1:256). LTOWB can be transfused to patients of any blood type. LTOWB is collected in a CPDA-1 bag allowing for a 35-day shelf life. LTOWB is unmodified and contains rbcs, platelets and plasma. LTOWB is non-leukoreduced and averages around 500 mLS. (Source AABB)

Low Titer O Whole Blood facts:

- 35-day (CPDA-1) Shelf Life
- Non-leukoreduced
- Volume 500 mLs (approx)
- Titer of <1:256
- ISBT Product Code E0068V00

Tags used for LTOWB



In order to facilitate compliance with 5.27.4, the tie tag instructs transfusing agency to provide blood container (with integrally attached segments to receiving facility/transfusion service.)

How to store and return LTOWB?
If you did not order this product, you are able to return the unused bag if stored correctly. Once removed from the shipping container, whole blood must always be kept in a temperature-controlled refrigerator between 1°C and 6°C.

For additional information please call 210-731-5550

SAN ANTONIO 6211 IH 10 West • San Antonio, TX 78201 • 210-757-5550 • 855-326-5765

Appendix F
Regional Transfusion Recommendation