Association for the Advancement of Blood & Biotherapies

Emergency Prehospital and Scheduled Out-of-Hospital Transfusion Services 1st Edition

Audra L. Taylor – AABB Committee Chair

Whole Blood Summit

15 July 2025

Who is AABB?

- Association for the Advancement of Blood and Biotherapies.
- Inception in 1947.
- Core objectives to provide high standards of safety for patients, donors and facilities.
- Governed by its Board of Directors.
- Membership includes physicians, nurses, scientists, researchers, administrators, clinical laboratory scientists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in more than 50 countries.

In The Beginning…….

AABB Standard 5.15.1 (added in 31st ed): permissible to use low titer group O whole blood for recipients of known or unknown ABO group as follows: recipients shall receive ABO group-compatible red blood cell components, ABO group-specific whole blood or low titer group O whole blood (for non-group O or for recipients who ABO group is unknown.

THOR-AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program

Mark H. Yazer, Philip C. Spinella, Eric A. Bank, Jeremy W. Cannon, Nancy M. Dunbar, John B. Holcomb, Bryon P. Jackson, Donald Jenkins, Michael Levy, Paul E. Pepe, Jason L. Sperry, James R. Stubbs & Christopher J. Winckler

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In The Beginning

Charge By Board of Directors

AABB released the first edition of *Standards for Out-of-Hospital Transfusion Administration Services in 2018*, while in 2022, in conjunction with members of THOR, staff worked on the *Pillars of Prehospital Recommendations*.

Throughout 2022 and early 2023 AABB has received queries from the membership surrounding prehospital and out of hospital concerning the need for standardization and the desire for accreditation.

AABB staff requests from the AABB Board of Directors approval to stand up a new standards committee focused on merging the Out-of-Hospital Transfusion Administration Standards with elements of the Pillars of Prehospital Recommendations into a cohesive document based on AABB's updated quality system essentials for out of hospital and pre hospital accreditation.

Committee Members

PREHOSPITAL AND OUT-OF-HOSPITAL STANDARDS COMMITTEE

Committee Members
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Consultant
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Armed Services Blood Program–Barbara J. Bachman, MS, MT(ASCP)SBB
Food and Drug Administration–Victor Baum, MD
ICCBBA–Karen Moniz, MHA, MT(ASCP)SBB
International Association of Emergency Medical Services Chiefs–Eric Bank, LR, NRP
National Association of Emergency Medical Technicians–
Gary Peterson, PhD, MSc, FP-C, CCP-C, NRP
Trauma Center Association of America–Martin A. Schreiber, MD

What are Standards

- Since 1957, AABB standards have been the backbone of AABB's mission.

- Combine the field's leading quality management system essentials with technical requirements designed to ensure optimal quality and safety for donors, patients and staff.

- AABB standards:
  - are currently applied to AABB-Accredited facilities in more than 50 countries and other facilities to advance their quality and safety measures.
  - combine internationally accepted quality management system requirements with relevant technical requirements for each discipline.
  - are based on AABB's quality system framework which leads the field in quality standards worldwide.
  - incorporate both technical and quality systems standards

- Each edition of AABB's Standards are based on best medical practice, scientific data, principles associated with good manufacturing practices and quality assurance, and applicable regulations.

What are Standards

- All sets of AABB Standards are *effective for two years* and represent requirements that must be implemented by AABB-accredited facilities.

- *A requirement contains the word "shall," which indicates that the statement is mandatory.* Failure to meet the requirement would constitute a nonconformance under the AABB Accreditation Program.

- There are rare instances in which a standard uses the term "may." A statement that uses "may" is not a requirement.

- *When the pencil symbol precedes a standard, users are required to maintain a record of that activity in order to meet the standard.*

- A requirement in the AABB Standards may be associated with a requirement in the U.S. Code of Federal Regulations (CFR). Unless the standard specifically requires users to follow the requirements in the CFR, the reference is for information only.

Emergency Prehospital Standards

For transfusion delivered outside of a hospital setting.

Includes fire departments, police departments, ground and air ambulances.

Standards form the basis for AABB's Accreditation program.

To become accredited, a program must be in compliance with the current edition of the standards.

Quality System Essentials (QSEs)

QSE 1 – Organization
QSE 2 – Resources
QSE 3 – Equipment
QSE 4 – Suppliers and Customers
QSE 5 – Process Control:
    Prehospital Activities
    Out of Hospital Activities
QSE 6 – Documents and Records
QSE 7 – Deviations, Nonconformances, and Adverse Events
QSE 8 – Internal and External Assessments
QSE 9 – Process Improvement
QSE 10 – Facilities and Safety

Glossary

*Guidance

> *"AABB quality systems build strong operational processes. By focusing on quality systems as the basis for building operational processes, a facility can execute operations with accuracy and precision while preventing failure."*
>
> — Lorna Riach, MA, BS, MT(ASCP), Boston Children's Hospital

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.

1.0 Organization
The organization shall define the parties responsible for the provision of products or services.

1.1 Executive Management
The organization shall have a defined executive management.
Executive management shall have:
1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these Prehospital and Out-of-Hospital Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

1.1.1 Medical Director Qualifications and Responsibilities
The Transfusion Administration Service (TAS) shall have a medical director who is a licensed physician and qualified by education, training, and/or experience in activities required by these Prehospital and Out-of-Hospital Standards. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures and for the consultative and support services that relate to the care and safety of the transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

1.1.2 The TAS shall have a structure that clearly defines and documents the parties responsible for the activities described in these Prehospital and Out-of-Hospital Standards, and the relationship of individuals responsible for key quality functions.

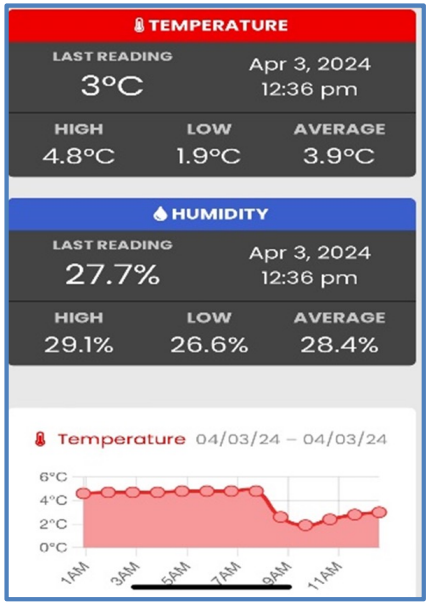
Storage and Transport Devices for Blood and Blood Components

Storage and transport devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.9 applies.

3.8.1 Alarm Systems
Storage devices shall have alarms and shall conform to the following standards:

3.8.1.1 The alarm shall be set to activate under conditions that will allow enough time for proper action to be taken before products reach unacceptable conditions.
3.8.1.2 Activation of an alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.

Blood Unit Transport Cooler temperatures are monitored continuously providing fidelity for all consortium members



Incoming Receipt, Inspection, and Testing

Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.

✎**4.3.1** The TAS shall verify that two ABO blood group tests have been performed on Whole Blood or Red Blood Cells by the blood supplier as defined by agreement.*
*21 CFR 640.5(b).

4.3.2 The TAS shall return blood and blood components as defined in agreements.

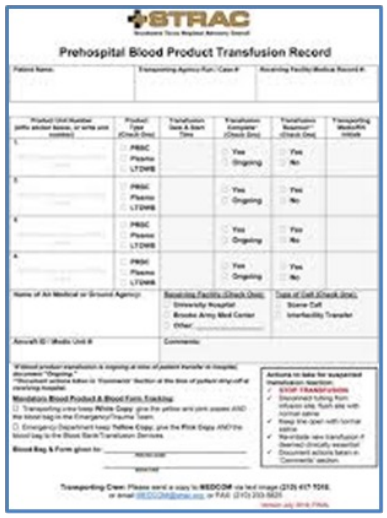
Administration of Blood

There shall be a protocol for the administration of blood and blood components, including the use of infusion devices and ancillary equipment, and the identification, evaluation, and reporting of adverse events related to transfusion. The TAS medical director shall participate in the development of the protocols. The protocol shall be consistent with the Circular of Information for the Use of Human Blood and Blood Components. Standard 7.3.3 applies.

5.3.1 Immediately before transfusion, the following information shall be verified:
1) The intended unit for transfusion meets the TAS protocol and has not expired.
2) Unit ABO group.
3) Unit appearance meets visual inspection criteria.
4) The unit has remained in compliance with temperature requirements during storage/ transport.
5) The informed and/or implied consent has been obtained.

5.3.2 All information attached to the container shall remain attached.

✎**5.3.3** The patient shall be monitored for potential transfusion-related adverse events by the TAS until the time of transfer of care. Standard 7.3.3 applies.



5.3.4 The TAS shall have a process to notify the receiving hospital and/or other prehospital care providers of a patient's transfusion status, with a unique patient identifier, including any transfusion-related adverse reactions through the continuum of care.

5.3.4.1 The TAS shall provide materials related to prehospital transfusion (eg, patient samples, empty bags, and segments) for follow-up testing and for identification of blood and blood components transfused (eg, the name of the component, the donor ABO/Rh type, the donation identification number.) Standard 4.1.3.1 applies.

Requirements for Uncrossmatched Blood and Blood Components

The TAS medical director shall determine the appropriate ABO - RhD component selection for uncrossmatched units of blood and blood components issued as well as the maximum quantity of blood products that can be transfused to each patient in an emergency setting.

5.4.1 The TAS shall have a policy concerning the selection of the Rh type of blood products for transfusion of blood to patients of childbearing potential.

5.4.2 The TAS shall have a policy for the transfusion of pediatric patients in emergent situations.

✎**5.4.3** Records shall contain a signed statement from the ordering physician indicating that the clinical situation was sufficiently urgent to require emergency release of uncrossmatched blood before completion of compatibility testing. The TAS medical director signature could occur before or after the release/transfusion of the blood, as defined by local, state, federal, or Competent Authority regulations.*

*21 CFR 606.160(b)(3)(v) and 21 CFR 606.151(e).

Transfusion Reactions

The TAS shall provide clear instructions to the patient's responsible caregivers and/or health care personnel regarding post-transfusion instructions, including recognition and steps for managing a suspected transfusion reaction. Standard 5.8.4 applies.

7.3.4.1 If a transfusion reaction is suspected or detected, the patient's treating physician and TAS medical director shall be notified.

7.3.4.2 The TAS shall have a process to notify the transfusion service or receiving hospital.

Timeline

September 2023 — Committee Formation

- Committee Chair
- Invite Committee Members
- Equal representation – Out of hospital and Prehospital

Q4 2023 – Q2 2024 — Develop the Standards

- Series of zoom calls
- One “in person” meeting – STB&T
- Series of zoom calls

Q3 2024 - Present — Refine and Publish

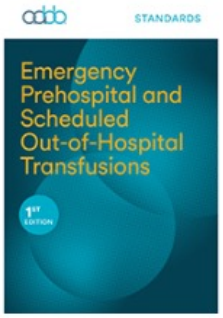
- Public Comment
- AABB Staff Comments
- AABB Board of Directors

Now Available

STANDARDS FOR EMERGENCY PREHOSPITAL AND SCHEDULED OUT-OF-HOSPITAL TRANSFUSIONS

Standards & Accreditation

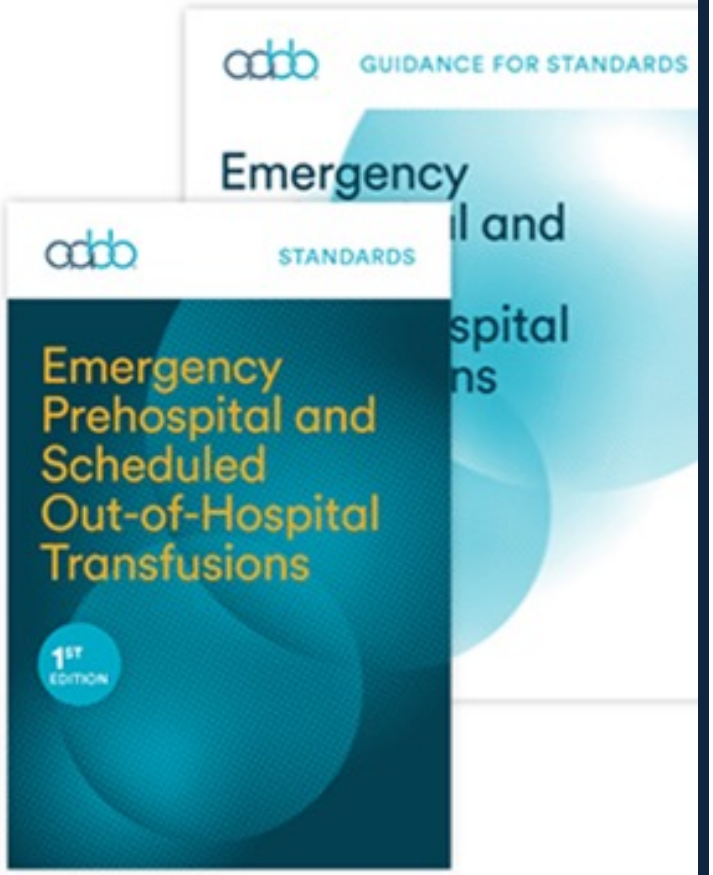
Standards –
About AABB Standards +
Purchase Standards
Standards Portal +
Accreditation +
Quality +



The *Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions* will maintain and enhance the quality and safety of services provided by prehospital transfusion services (EMS services) and out-of-hospital transfusion services (including infusion centers, nursing homes, long-term care facilities, hospice or home care settings), and provide the basis for accreditation by AABB.

Current edition: first edition in development, **notify me when available**
Effective date: Jul 1, 2025
Revision cycle: 24 months

So……What's Next?



1. To develop and update standards for out of hospital and prehospital services.
2. *Obtain input and review existing requirements of the Standards for Out of Hospital Transfusion Administration and expand the Standards to include prehospital requirements.*
3. *In coordination with staff, develop guidance for the Standards and create records of rationales for changes existing requirements.*
4. *Update the Standards to reflect recommendations of the Donor History Questionnaire Task Force, Transfusion Transmitted Diseases Committee and the associated Accreditation Committee.*
5. *Review and respond to requests for clarification and variances to the Standards as needed.*
6. *Develop interim/emergent standards as needed for submission to the Board of Directors*
7. *Monitor the development of new technologies with potential application to cellular therapies and develop or modify standards when appropriate.*

Accreditation (since 1958)

aabb | Accreditation

Why accreditation?

- **Mark of distinction** - inspires trust in the community
- **Evidence of operational excellence** across the organization - through on-site assessment

➢ **Strengthens community partnerships, ultimately:**

  - Improving blood supply management through confidence in safe handling and storage
  - **Reducing unnecessary waste and negative impact on blood availability**

- **Foundation for risk mitigation strategies:**

  AABB's Quality Systems approach, helps facilities:

  - Identify & resolve quality and safety concerns
  - Proactively monitor and address recurring challenges in operations

- **NO COST TO SUBMIT APPLICATION**

Prehospital Accreditation

AABB Accreditation for Emergency Prehospital Transfusion Services is a highly collaborative, educational process to advance patient safety

- **First steps in the accreditation process:**
  - **AABB designates technical specialist to assist** with questions and challenges throughout the accreditation process.
  - **Facility performs a self – assessment** to align their processes with AABB standards.
  - **Technical specialist reviews self- assessment**, working closely with the facility to achieve alignment with standards.
  - **When ready, facility proceeds** to an on-site assessment.

- **Once accredited:**
  - **AABB's ongoing support** for safe and effective operations
  - **AABB's member experts** in the vein-to-vein community
  - **Regulatory Support**
  - **Continuing Education** and additional resources
  - **Advances in the field** improving patient care and safety
  - **AABB Assessor Training opportunities** – supporting individual and facility success
  - **Professional development** and leadership – Committees and working

The Accreditation Process

- AABB's Accreditation Assessment is:
  - NOT A PASS/FAIL TEST
  - NOT A TIMED TEST
- Highly collaborative, instructive process
- Designed to drive successful completion
- Intended to allow you to move at your own pace
- Intended to respect your daily responsibility to provide emergency services as your #1 priority
- Reference Cost:
  - Depends on many factors
  - Contact

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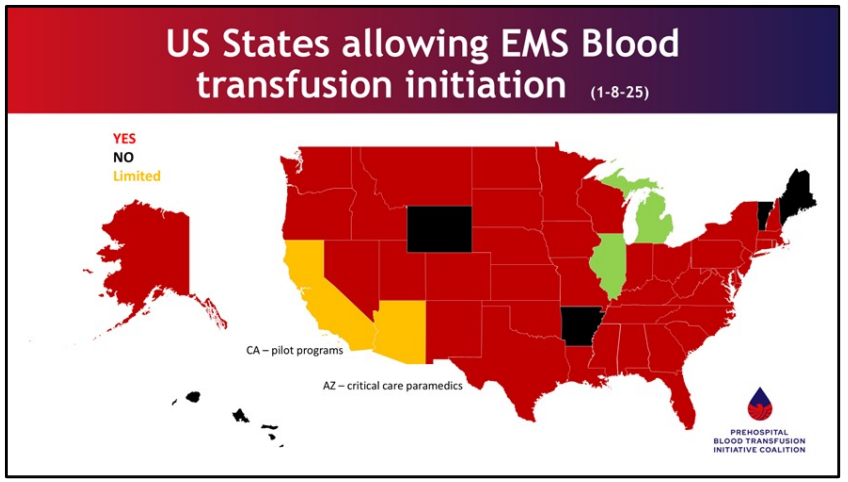
BECOME A VOLUNTEER AABB ASSESSOR

In Summary

- We can do this!!
- Blood products move with patients all of the time
- Blood Administration in the Hospital happens away from the Transfusion Service
- Don’t forget the requirement for a Physician’s Signature
- If a unit is started in the field…..you will not get a Pre-Transfusion Sample
- There is a difference:
  - TAS (Transfusion Administration Service) = A Service Provider
    - Responsible for the Prehospital and Out of Hospital Standards
    - Orders for blood products, transport, blood administration, monitor patient, report outcomes, ensure traceability
  - TS (Transfusion Service) = A Facility
    - Responsible for BBTS Standards in their facility
    - Performs ABO/Rh/compatibility testing
    - Stores, selects, issues blood products
- The Circular of Information *shall be* available at all times



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Thank You!