AABB | JOINT COMMISSION™

Patient Blood Management Certification

Patient Blood Management Certification Program

Review Process Guide

2026

What's New in 2026

Updates effective in 2026 are identified by <u>underlined text</u> in the activities noted below.

<u>Changes effective January 1, 2026</u>

No changes for January 2026.

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Patient Blood Management Certification
Program Overview

Patient Blood Management (PBM) is an evidence-based, multidisciplinary approach to optimizing care of patients who might need transfusion. It encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications, as well as minimization of blood loss and optimization of patient red cell mass.

The Patient Blood Management certification program is a collaborative effort between AABB and Joint Commission. The AABB-Joint Commission Patient Blood Management Certification promotes patient safety and quality and will help hospitals realize the maximum benefits of establishing a comprehensive patient blood management program. This voluntary hospital certification is based on the AABB Standards for a Patient Blood Management Program.

The goals for certified organizations include the following:

- Risk reduction in fewer adverse events and incidents

- Improved patient outcomes

- Reduced hospital stays, readmissions, and lengths of stay

- Ensuring blood availability for those most in need

- Optimized care for those who may need transfusion

- Fostering collaboration throughout the hospital

- Providing a competitive edge in the marketplace

- Enhanced staff recruitment and development

- Cost savings

The on-site certification review will be conducted by one or two reviewers, based on whether the organization is accredited by AABB for Blood Banks and Transfusion Services. For organizations that are AABB-accredited for Blood Banks and Transfusion Services, a Joint Commission surveyor will perform a one-day review. Organizations that are not AABB-accredited for Blood Banks and Transfusion Services will be evaluated by two reviewers (one Joint Commission surveyor and one AABB assessor) for a one-day review.

Patient Blood Management Certification
Organization Review Preparation

The Patient Blood Management Certification Review Process Guide describes each activity of the Joint Commission on-site certification review. Organizations should read each of the following activity descriptions, which include:

- The purpose of the activity

- Descriptions of what will happen during the activity

- Discussion topics, if applicable

- Recommended participants

- Any materials required for the session

Share these descriptions organization-wide, as appropriate.

Pre-Review Phone Call
A Joint Commission account executive will contact your organization by phone shortly after receiving your application for certification. The purpose of this call is to:

- Confirm information reported in the application for certification,

- Verify travel planning information and directions to main location for review,

- Confirm your access to the Joint Commission Connect extranet site and the certification-related information available there (on-site visit agenda, Certification Review Process Guide, etc.), and

- Answer any organization questions and address any concerns.

Logistics
- While on-site, the reviewer will need workspace for the duration of the visit. A desk or table, telephone, access to an electrical outlet and the internet are desirable.

- Some review activities will require a room or area that will accommodate a group of participants. Group activity participants should be limited, if possible, to key individuals that can provide insight on the topic of discussion. Participant selection is left to the organization's discretion; however, this guide does offer suggestions.

- The reviewer will want to move throughout the hospital and blood bank during Individual Tracer Activity, talking with staff and observing the day-to-day operations of the organization along the way. The reviewer will rely on organization staff to find locations where discussions can take place that allow for confidentiality and privacy, and that will minimize disruption to areas being visited.

- While the reviewer will focus on current patients that are included in the patient blood management program, they may request to see some closed records as well in order to verify compliance with the Patient Blood Management Certification requirements.

The sample agenda for the on-site review appears later in this guide and will be posted to your *Joint Commission Connect* extranet site. The review agenda presents a suggested order and duration of activities. Prior to the review date, please discuss the agenda and activities with the

Account Executive. When the reviewer arrives, discuss any agenda changes during the on-site visit.

Documentation Requested from the Program
Although the majority of documentation review will occur as part of individual tracer activity, it is helpful to have the references and resources staff use in their day-to-day activities available.

The reviewer may request the following items to assist in patient tracer selection during the Reviewer Planning session:

- Current list of patients receiving blood transfusions or who may likely receive a blood transfusion (see suggested tracer patient list)
- If there are a limited number of admissions, a list of discharged patients who received blood transfusions
  - This request can go back as far as the past four months for initial reviews
- Performance improvement action plans that demonstrate how data have been used to improve program care and services, when available
- The reviewer may also request the following documents:
  - Organizational chart with hierarchy of responsibilities to the program
  - Executive management roles and responsibilities
  - Interdisciplinary team qualifications, job descriptions, training, and competency
  - Patient-centered quality plan
  - Emergency management plan and communication system
  - Equipment maintenance and information management records
  - Supplier evaluations and contract agreements
  - Policies and procedures for patient blood management
  - Patient information regarding blood transfusion, blood management
  - Educational materials given to patient/family
  - Record retention policies
  - Information management procedures and records
  - Procedures for deviations, nonconformances, and adverse events
  - Program assessments and performance improvement

Preparing for Patient Tracer Selection
Organizations are encouraged to begin identifying patients for individual tracer activity in advance of the review date. The reviewer will still be involved in the selection of the specific patients, but it will ease the pressure and burden on staff in trying to find the types of patients that the reviewers want to trace. Availability of this information will greatly facilitate the Reviewer Planning session and allow the individual tracer activity to proceed in a timely manner.

If there are a limited number of active patients at the time of the on-site review, or the active patients do not meet all of the selection criteria, closed records may be reviewed to observe the program's interaction with as much of the target population as possible.

Depending on the services provided by the organization, suggested tracer patients may include:

- Patients receiving a massive transfusion

- Patients receiving regular transfusions

- Patients that decline blood products or transfusions

- Patients with chronic anemia

- Patients receiving stem cell transplants

- Patients with elective surgery (preoperative, postoperative)

- Patients from the intensive care, pediatrics, obstetrics, or oncology departments

Preparing for Competence Assessment and Credentialing
As the process to obtain personnel and credentials files may be time-consuming, particularly if files are stored off-site, organizations may consider identifying files to request in advance of the on-site review to facilitate the organization's retrieval efforts. The reviewer will still be involved in the selection of personnel files to review, but the availability of this information will allow the Competence Assessment and Credentialing session to proceed in a timely manner.

Suggested personnel files to request may include:

- PBM medical director

- PBM coordinator

- Midlevel practitioner that orders blood

- Medical technologist in the blood bank

- Perfusionist

- RN from the ICU, ER, or OR

- Anesthesiologist

Questions
Questions about the Patient Blood Management certification standards and elements of performance:

- Contact AABB at standards@aabb.org.

Questions about on-site review process, agenda, scheduling, or other questions:

- Call your Joint Commission Account Executive.

Patient Blood Management Certification
Certification Review Notification and Postponement Policies

Notice of Initial Certification On-site Review
If this is your program's first time through the certification process you will receive a thirty (30) day advance notice of your on-site review date(s). Notice will be provided via e-mail to the individuals identified on your account as the Primary Certification Contact and CEO. Also, thirty (30) days prior to your review, the Notification of Scheduled Events section on your organization's extranet site, *Joint Commission Connect*, is populated with the event along with a link to the reviewer(s) name, biographical sketch and photograph.

Notice of Re-Certification On-site Review
Your organization will receive notice from Joint Commission seven (7) business days prior to the first day of the scheduled review date(s) for Patient Blood Management re-certification. The notice will be emailed to the individuals identified on your account as the Primary Certification Contact and CEO and will include the specific review date(s) and the program(s) being reviewed. Additionally, once the reviewer arrives onsite, the Notification of Scheduled Events section on your organization's extranet site, *Joint Commission Connect*, is populated with the review event including a link to the reviewer(s) name, biographical sketch and photograph.

Review Postponement Policy
Joint Commission may not certify a program if the Organization does not allow Joint Commission to conduct a review. In rare circumstances, it may be appropriate to request a review postponement. An organization should direct a request for postponement to its Account Executive. A request to postpone a review may be granted if a major, unforeseen event has occurred that has totally or substantially disrupted operations, such as the following:

- A natural disaster or major disruption of service due to a facility failure
- The organization's involvement in an employment strike
- The organization's cessation of admitting or treating patients
- The organization's inability to treat and care for patients and its transference of patients to other facilities

Joint Commission may, at its discretion, approve a request to postpone a review for an organization not meeting any of the criteria listed above.

Your organization's Certification Account Executive can answer questions about these policies or put you in contact with other Joint Commission staff that can assist you.

Patient Blood Management Certification
Reviewer Arrival

Duration

10 minutes

Participants

- Reception, Security, or Information Desk Staff
- Organization/Program Contact
- Individual or individuals that will provide the Safety Briefing to the reviewer(s), if different than the organization or program contact

Procedures

1. The reviewer will arrive at the location identified as the main or primary site between 7:45 and 7:50 a.m.

2. The reviewer will report to the reception area, security officer, information desk, or administrative office upon arrival and provide the reviewer's name, identification and purpose for the visit.

3. If a program contact is not waiting for the reviewer, the reviewer will ask security or reception to phone the program contact. The reviewer will wait for an escort unless instructed to proceed to another location by the organization/program contact.

4. The reviewer will follow organization visitor procedures as instructed by security or the program contact (e.g. sign in, wear organization visitor identification).

5. While this is an announced visit, the reviewer will still confirm that the organization/program contact has been able to access their extranet site and locate information about the review, including

   - Notification of scheduled Joint Commission event authorizing your presence
   - Reviewer name, picture, and biographical sketch
   - Scheduled review date

6. Please inform the reviewer about

   - Working space for the day
   - A secure location to place belongings and access them as needed throughout the day

7. The organization is requested to provide the reviewer(s) with a Safety Briefing (informal, no more than five minutes) sometime during this activity. The purpose of this briefing is to inform the reviewer(s) of any current organization safety or security concerns and how Joint Commission staff should respond if your safety plans are implemented while they are on site. Situations to cover include:

   - Fire, smoke, or other emergencies

- Workplace violence events (including active shooter scenarios)
- Any contemporary issues the reviewer may experience during the time they are with you (for example, seasonal weather-related events, anticipated or current civil unrest, or labor action)

8. Inform the reviewer if there will be a roster of patient blood management program leaders and staff attending the Opening and Orientation activities or if attendees will sign in. A roster or sign in sheet with the names of staff encountered and their roles in the program can be helpful with the review process.

9. Plan to leave at least 15 minutes of the opening conference to review the visit agenda and for questions and answers.

Patient Blood Management Certification
Opening Conference

Objectives

1. Introductions of program representatives and reviewer(s)

2. Describe the structure of the review

3. Discuss the review agenda, highlighting any changes necessary to facilitate the site visits or increase participation in group activities

4. Answer any open questions about the visit or review process

Duration

10 minutes

Participants

Program administrative and clinical leadership and others at the discretion of the organization

Other Information

If available, the following items are helpful to the reviewer:

- Roster or sign-in sheet of participants

- Organization chart or names of program leadership, titles and roles

Procedures

During

The reviewer will:

- Provide a brief self-introduction including background and relevant experience.

- Explain the purpose of the certification review.

- Ask organization attendees to introduce themselves.

- Describe each component of the review agenda, discuss the plans for tracer activity, potential tracer patients, and areas to visit. Make changes to the schedule if necessary.

- Explain that most of the review activity occurs at the point where care, treatment and services are provided. The term "Individual Tracer" denotes the review method used to evaluate organization/program compliance with standards.

- Remind the program that they want to be as least disruptive to patient care as possible. They will suggest that the program limit the number of staff accompanying them on tracer activity to three or less.

- Introduce the new SAFER™ matrix feature of the Summary of Certification Review Findings Report.

- Mention the post-review Clarification process.

- Dialogue about what the reviewer can do to make this a meaningful review for the program.

- Ask if there are any questions about the review.

- Answer questions and encourage representatives to ask questions throughout the review.

After

The reviewer will transition into the Orientation to the Patient Blood Management Program session.

Patient Blood Management Certification
Orientation to the Patient Blood Management Program

Objectives
Become familiar with the patient blood management program, including:

1. An understanding of the patient blood management program philosophy and approach

2. A better understanding of the patient blood management program structure and scope

3. How well integrated the program is throughout the organization

Duration
50 minutes

Participants
Program administrative and clinical leadership and others at the discretion of the organization

Notes
Materials that may prove useful for this session:

- Organization chart for the program, if available

- Copies of slides, if the program is making a formal presentation

Procedures

During
If a presentation is planned, the reviewer will ask the presenter to indicate if they would like to take questions during or at the conclusion.

The organization is asked to provide a high-level overview of their patient blood management program through either a formal presentation or in discussion with reviewer. The focus should be on the following:

- Program scope

- Program mission, goals, and objectives

- Program structure and relationship to the organization structure

- Program leadership and executive management responsibilities

- Interdisciplinary team members, including roles and responsibilities

- Organizational supports for the patient blood management program

- Development and implementation of the program (e.g., timeline, successes and opportunities, challenges, and barriers)

- Patient blood management program activities

- Identify the program level designation

- Any unique program communication regarding patient rights and responsibilities and their right of refusal of care, treatment, and services offered

- Assessing practitioner and staff competence in patient blood management

- Organizational support for patient blood management program practitioners and staff education and specialized training

- Processes supporting credentialing, privileging, and licensure/ registration/certification, education and experience verifications

- Evaluating and improving the program's performance

After

Determine if there are additional documents the reviewer would like to see as a result of the orientation discussions.

The reviewer will transition to the System Tracer – Data Use session for a more in-depth discussion regarding how the program is using data to evaluate and improve the program's performance.

Patient Blood Management Certification
System Tracer – Data Use Session

Objectives

1. To learn how the patient blood management program is using data to evaluate the safety and quality of care provided to patients

2. To understand and assess the program's performance improvement process

Duration

30 minutes

Participants

Program leaders, clinical leaders, and others at the discretion of the program

Data Requirements

- For initial certification, the organization should provide four months of data

- For recertification, the organization should provide twelve months of data

Procedures

During

During this activity, the reviewer and organization will discuss:

- Program performance measurement and improvement activities
  - Performance improvement plan review including priority setting
  - Data collection and data quality monitoring
  - Data analysis and dissemination
- Program data available for, and used in decision-making
- Program evaluation by leaders and staff
- Recently implemented program improvement
- Ongoing performance monitoring
- Taking actions to improve

Patient Blood Management Certification
Reviewer Planning Session

Duration
30 minutes

Participants
Program contact or staff, if requested by the reviewers

Procedures

Before
- Explain to the organization the purpose of this session
- Make sure all necessary documents are available, especially patient lists.

During
The reviewer will:

- Describe to program representatives the types of patients they want to trace and request assistance in identifying individuals that fit the description. Tracer selection should include representation of the target population(s).

  Note: This may or may not be possible to accomplish using a list of active patients. The reviewer and program representative may need to proceed directly to a patient care unit and ask the staff to help identify patients.

- Select a minimum of five (5) tracer patients
  - Patients selected should present the opportunity to trace care, treatment and services through as many of the potential departments, areas, sites or services that support or participate directly in the patient blood management program or support the work of the program in any unique way.
  - Patients should have different characteristics, such as demographics, age, sex, or situations or other factors that would influence patient care.
  - As blood bank/transfusion services and perioperative services are integral to the patient blood management program, a tracer patient that will incorporate a visit to the blood bank and interaction with staff from perioperative services will be selected.
- Suggested tracer patients may include:

- Patients receiving a massive transfusion

- Patients receiving regular transfusions

- Patients that decline blood products or transfusions

- Patients with chronic anemia

- Patients receiving stem cell transplants

- Patients with elective surgery (preoperative, postoperative)

- Patients from the intensive care, pediatrics, obstetrics, or oncology departments

- If there are a limited number of active patients at the time of the on-site review, or the active patients do not meet all of the selection criteria, closed records will be reviewed to observe the program's interaction with as much of the target population as possible.

- As the process to obtain personnel and credentials files may be time-consuming, particularly if files are stored off-site, the reviewer may begin requesting files earlier in the day to facilitate the organization's retrieval efforts. Program staff should inform the reviewer of how much time is needed to retrieve personnel and credentials files.

- Select a minimum of five (5) personnel files to review, which may include:
  - PBM medical director
  - PBM coordinator
  - Midlevel practitioner that orders blood
  - Medical technologist in the blood bank
  - Perfusionist
  - RN from the ICU, ER, or OR
  - Anesthesiologist
  - Additional files may be requested during tracer activity

Documentation Requested from the Program
The program is requested to provide the following items to the reviewer to assist in patient tracer selection.

- Current list of patients receiving blood transfusions or who may likely receive a blood transfusion (see suggested tracer patient list)

- If there are a limited number of admissions, a list of discharged patients who received blood transfusions
  - This request can go back as far as the past four months for initial reviews

- Performance improvement action plans that demonstrate how data have been used to improve program care and services, when available

- The reviewer may also request the following documents:

- Organizational chart with hierarchy of responsibilities to the program
- Executive management roles and responsibilities
- Interdisciplinary team qualifications, job descriptions, training, and competency
- Patient-centered quality plan
- Emergency management plan and communication system
- Equipment maintenance and information management records
- Supplier evaluations and contract agreements
- Policies and procedures for patient blood management
- Patient information regarding blood transfusion, blood management
- Educational materials given to patient/family
- Record retention policies
- Information management procedures and records
- Procedures for deviations, nonconformances, and adverse events
- Program assessments and performance improvement

Patient Blood Management Certification
Individual Tracer Activity

Objectives

1. Follow a patient's care, treatment, and services to confirm the program's compliance with the patient blood management certification requirements.

2. Evaluate the program's design and implementation of processes that facilitate the integration of patient blood management across the organization.

Duration

Variable per patient tracer conducted; tracing of multiple patients in multiple locations occurs during the blocks of time noted on the agenda

Participants

Staff, program representatives and management who have been involved in an individual's care, treatment, or services.

The reviewer will require an escort during each of the blocks of tracer time.

Procedures

A significant portion of the agenda is designated to patient tracer activity. The number of patients traced during this time will vary. Tracer activity begins on the inpatient unit where the patient is receiving care, treatment and services, or in the case of a discharged patient, the location from which they were discharged.

During

- The reviewer will use the patient's record to discuss and map out the patient's course of care, treatment and services. The number of staff participating in this stage of the tracer should be limited.

- The reviewer will follow the map, moving through the organization, as appropriate, visiting and speaking with staff in all the areas, programs, and services involved in the patient's encounter. There is no mandated order for visits to these other areas. Reviewers will speak with any staff available in the area.

- Throughout tracer activity, the reviewer will:
  - Observe program staff and patient interaction
  - Interview staff about the care, treatment and services they provide and their knowledge of the patient blood management program
  - Interview patients or families, if appropriate and permission is granted by the patient or family
  - Review policies, processes, and procedures for patient blood management
  - Discuss equipment maintenance and quality control issues
  - Inquire about the processes for document control and record retention
  - Observe environmental conditions

Blood Bank/Transfusion Services:

- For organizations that ARE accredited by AABB for Blood Banks and Transfusion Services, the reviewer will:

    - Confirm that equipment controlled by the blood bank or transfusion service is controlled in accordance with the manufacturer's instructions and/or the current edition of AABB Standards for Blood Banks and Transfusion Services.

    - Verify that pretransfusion testing policies are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.

    - Confirm that documents and records related to transfusion medicine are created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

    - Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

- For organizations that ARE NOT accredited by AABB for Blood Banks and Transfusion Services **(see Appendix B for additional guidance)**, the reviewer will:

    - Identify the process to make sure equipment controlled by the blood bank or transfusion service is controlled in accordance with the manufacturer's instructions and/or the current edition of AABB Standards for Blood Banks and Transfusion Services.

    - Review pretransfusion testing policies to make sure they are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.

    - Ask staff how documents and records related to transfusion medicine are created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

    - Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

Perioperative Services (see Appendix C for additional guidance):

- The reviewer will:

    - Confirm that equipment controlled by the perioperative program is controlled in accordance with the manufacturer's instructions and/or the current edition of AABB Standards for Perioperative Autologous Blood Collection and Administration.

    - Verify that document and records related to the perioperative program are created and controlled in accordance with the current edition of the AABB Standards for Perioperative Autologous Blood Collection and Administration or the requirements of an equivalent accrediting body.

    - Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current edition of AABB

Standards for Perioperative Autologous Blood Collection and Administration or the requirements of an equivalent accrediting body.

- For Program Activity Level 1 organizations:

  - If the perioperative program is already accredited by AABB, this requirement has been satisfied.

  - If the perioperative program is not accredited by AABB, the reviewer will confirm that the AABB requirements for cell salvage or processing of perioperative blood products (e.g., platelet gel, platelet-rich plasma) are met in accordance with the AABB Standards for Perioperative Autologous Blood Collection and Administration.

After

- As necessary, pull additional records to verify standards compliance issues identified during the Individual Tracer.

- As necessary, request other documentation to confirm procedures and validate practice.

Competence Assessment and Credentialing Session

Objectives

1. Learn more about the organization's competence assessment process for program staff, licensed independent practitioners, and other credentialed practitioners.

2. Learn more about the organization's orientation, education, and training processes as they relate to program staff, licensed independent practitioners, and other credentialed practitioners encountered during Individual Tracers.

3. Identify competence assessment process-related strengths and potential risk points.

Duration

30 minutes

Participants

Individuals responsible for:

- Aspects of the organization's human resources processes that support the patient blood management program

- Orientation and education of program staff

- Assessing program staff competency

- Assessing program's licensed independent practitioners and other credentialed practitioners' competency, when applicable.

Procedures

During

- The reviewer will participate in a facilitated review of selected files, based on the patient blood management program team and individuals encountered during tracer activity

- Files stored off-site may not need to be reviewed as long as the local files include the following information:

  - Job descriptions for all program staff, licensed independent practitioners, and other credentialed practitioners

  - Experience, education, and abilities assessments for program staff and licensed independent practitioners

- Information on orientation for staff, licensed independent practitioners, and other credentialed practitioners to the organization, to the program, to job responsibilities, and/or clinical responsibilities

- Ongoing education and training for program staff and licensed independent practitioners

- Competency assessment for program staff

- Facility-defined education for individuals that order and transfuse blood

Patient Blood Management Certification
Summary Discussion

Objectives

1. This time will be utilized for a final discussion prior to the reviewer's report preparation and the exit conference.

2. Obtain any additional information or documentation required to resolve issues identified during the review.

3. Follow-up on potential findings that could not be resolved in other on-site activities.

Duration
30 minutes

Participants
As requested by the reviewer, depending on the issue(s) to be discussed

Preparation for Summary Discussion

May require documentation or staff interview based on open issues.

Summary Discussion Description

Topics that may be addressed include:

- Any issues not yet resolved

- The identified Requirements for Improvement (RFIs)

- Sharing best practices to inspire quality improvement and/or outcomes

- Determination if RFIs will be discussed in detail at closing

The reviewer will work with the organization's certification contact to organize and conduct the summary discussion.

Patient Blood Management Certification
Reviewer Report Preparation

Objectives
1. Complete the entry of observations made throughout the survey
2. Prepare an event summary to share with the program

Duration
45-60 minutes

Participants
Program participation is not required

Procedures
The reviewer will:

- Analyze observations and determine if there are any findings that reflect standards compliance issues.

- Make arrangements with the program representatives to print and copy the report for:

  - The organization, if it is being distributed to Program Exit Conference participants

  - Each reviewer

- Inform the program contact that they are ready to proceed with the Program Exit Conference

Patient Blood Management Certification
Program Exit Conference

Objectives

1. Present the Summary of Certification Review Findings Report (only if desired by the CEO)

2. Review identified standards compliance issues and note that all findings of less than full compliance require resolution through an Evidence of Standards Compliance submission

3. Review required follow-up actions

Duration

30 minutes

Participants

- Program and clinical leaders

- Other staff at the discretion of the organization

Procedures

During

- The reviewer will share a report of their on-site experience and observations.

- The reviewer will highlight strengths and progress and will note any potential areas of vulnerability and how these relate to the standards and what the program will see reflected in the Summary of Certification Review Findings. The reviewer will also present the newest feature of the Summary report, the SAFER™ matrix, and will discuss the display of Requirements for Improvement, if any, and the significance of their placement.

- The reviewer will not go through the report item by item with the group assembled for the Program Exit Conference. If the organization desires this level of report discussion, it is recommended that it occur with just a small number of program representatives.

- The reviewer will mention the post-review clarification process and any potential follow-up actions that may be required.

Sample Agenda (1 Reviewer, 1 Day)
Patient Blood Management Certification

For use in organizations accredited by AABB for Blood Banks and Transfusion Services

Time	Activity & Topics	Suggested Organization Participants
8:00 – 8:10	**Opening Conference** - Introductions - Brief review of agenda - Dialogue about what reviewer can do to make this a meaningful review for the program.	- Program administrative and clinical leadership - Others at program's discretion
8:10 – 9:00	**Orientation to the Program** - Program scope - Program mission, goals and objectives - Program structure, and program relationship to the organization structure - Program leadership and executive management responsibilities - Interdisciplinary team members, including roles and responsibilities - Organizational supports for the patient blood management program - Development and implementation of the program (e.g., timeline, successes and opportunities, challenges, and barriers) - Patient blood management program activities - Identify the program level designation - Any unique program communication regarding patient rights and responsibilities and their right of refusal of care, treatment, and services offered - Assessing practitioner and staff competence in patient blood management - Organizational support for patient blood management program practitioners and staff education and specialized training - Processes supporting credentialing, privileging, and licensure/ registration/certification, education and experience verifications - Evaluating and improving the program's performance	- Program administrative and clinical leadership - Others at program's discretion

Time	Activity & Topics	Suggested Organization Participants

9:00 – 9:30	**System Tracer – Data Use**
	- Program performance measurement and improvement activities
	  ▪ Performance improvement plan review including priority setting
	  ▪ Data collection and data quality monitoring
	  ▪ Data analysis and dissemination
	- Program data available for, and used in decision-making
	- Program evaluation by leaders and staff
	- Recently implemented program improvement
		- Program leaders, clinical leaders
		- Others at program's discretion

9:30 – 10:00	**Reviewer Planning Session** - Individual patient tracer selection - Personnel and credentials files Note: Tracer selection requires a list, census report or other summary of patients currently receiving blood transfusions or who may likely receive a blood transfusion.	- Organization's review coordinator
10:00 – 12:00	**Individual Tracer Activity** - Tracer activity begins where the patient is currently receiving care, treatment and services - Interactive review of patient record(s) with team member or organization staff actively working with the patient—map patient's course of care, treatment and services up to the present and anticipated for the future - May include a patient and family interview, if they are willing to participate	- Staff, program representatives, and management involved in the patient's care, treatment, or services
12:00 – 12:30	**Lunch**	
12:30 – 2:30	**Individual Tracer Activity – continued** - Additional tracer activity - Blood bank and perioperative services review - Note: Personnel and competency files for blood bank and perioperative staff will be reviewed at this time.	- Staff, program representatives, and management involved in the patient's care, treatment, or services

Time	Activity & Topics	Suggested Organization Participants

2:30 – 3:00	**Competence Assessment and Credentialing Process**
	- Discussion during this session will focus on:
	  - Processes for obtaining team member credentials information
	  - Orientation and training process for program team
	  - Methods for assessing competence of practitioners and team members
	  - In-service and other ongoing education activities available to program team members
	
	Note: The reviewer will request personnel records and credentials files to review based on team members and staff encountered or referred to throughout the day. Program staff should inform the reviewer of how much time is needed to retrieve personnel and credentials files.
		- Individual with authorized access to personnel and credentials files
		- Individual familiar with program-specific requirements for team members

3:00 – 3:30	**Summary Discussion** This time will be utilized for a final discussion prior to the reviewer's report preparation and the exit conference. Topics that may be discussed include: • Any issues not yet resolved (IOUs). • The identified Requirements for Improvement (RFIs). • Sharing best practices to inspire quality improvement and/or outcomes. • Educative activities of value to the program (i.e., knowledge sharing related to the latest scientific breakthroughs). • Were the goals of your team met during this review? • What made the review meaningful to the team?	- Program Leaders - Program's Joint Commission contact - Others at Program's discretion -
3:30 – 4:00	**Reviewer Report Preparation**	
4:00 – 4:30	**Program Exit Conference**	- Program administrative and clinical leadership - Others at program's discretion

Sample Agenda (2 Reviewers, 1 Day)
Patient Blood Management Certification

For use in organizations <u>not</u> accredited by AABB for Blood Banks and Transfusion Services

Time	Activity & Topics	Suggested Organization Participants
8:00 – 8:10	**Opening Conference** - Introductions - Brief review of agenda - Dialogue about what reviewer can do to make this a meaningful review for the program. -	- Program administrative and clinical leadership - Others at program's discretion
8:10 – 9:00	**Orientation to the Program** - Program scope - Program mission, goals and objectives - Program structure, and program relationship to the organization structure - Program leadership and executive management responsibilities - Interdisciplinary team members, including roles and responsibilities - Organizational supports for the patient blood management program - Development and implementation of the program (e.g., timeline, successes and opportunities, challenges, and barriers) - Patient blood management program activities - Identify the program level designation - Any unique program communication regarding patient rights and responsibilities and their right of refusal of care, treatment, and services offered - Assessing practitioner and staff competence in patient blood management - Organizational support for patient blood management program practitioners and staff education and specialized training - Processes supporting credentialing, privileging, and licensure/ registration/certification, education and experience verifications - Evaluating and improving the program's performance	- Program administrative and clinical leadership - Others at program's discretion

Time	Activity & Topics		Suggested Organization Participants
9:00 – 9:30	**System Tracer – Data Use** - Program performance measurement and improvement activities ▪ Performance improvement plan review including priority setting ▪ Data collection and data quality monitoring ▪ Data analysis and dissemination - Program data available for, and used in decision-making - Program evaluation by leaders and staff - Recently implemented program improvement		- Program leaders, clinical leaders - Others at program's discretion
9:30 – 10:00	**Reviewer Planning Session** - Individual patient tracer selection - Personnel and credentials files Note: Tracer selection requires a list, census report or other summary of patients currently receiving blood transfusions or who may likely receive a blood transfusion.		- Organization's review coordinator
10:00 – 12:00	**Reviewer 1:** **Individual Tracer Activity** - Tracer activity begins where the patient is currently receiving care, treatment and services - Interactive review of patient record(s) with team member or organization staff actively working with the patient—map patient's course of care, treatment and services up to the present and anticipated for the future - May include a patient and family interview, if they are willing to participate	**Reviewer 2:** **Blood Bank Review** - Equipment - Pretransfusion testing - Records - Nonconformance	- Staff, program representatives, and management involved in the patient's care, treatment, or services
12:00 – 12:30	**Lunch**		
12:30 – 2:30	**Reviewer 1:** **Individual Tracer Activity – continued** - Additional tracer activity	**Reviewer 2:** **Perioperative Services Review** - Equipment - Records - Nonconformance	- Staff, program representatives, and management involved in the patient's care, treatment, or services
2:30 – 3:00	**Competence Assessment and Credentialing Process** Discussion during this session will focus on: - Processes for obtaining team member credentials information - Orientation and training process for program team		- Individual with authorized access to personnel and credentials files - Individual familiar with program-

Time	Activity & Topics	Suggested Organization Participants
	- Methods for assessing competence of practitioners and team members - In-service and other ongoing education activities available to program team members Note: The reviewer will request personnel records and credentials files to review based on team members and staff encountered or referred to throughout the day. Program staff should inform the reviewer of how much time is needed to retrieve personnel and credentials files.	specific requirements for team members
3:00 – 3:30	**Summary Discussion** This time will be utilized for a final discussion prior to the reviewer's report preparation and the exit conference. Topics that may be discussed include: • Any issues not yet resolved (IOUs). • The identified Requirements for Improvement (RFIs). • Sharing best practices to inspire quality improvement and/or outcomes. • Educative activities of value to the program (i.e., knowledge sharing related to the latest scientific breakthroughs). • Were the goals of your team met during this review? • What made the review meaningful to the team?	- Program Leaders - Program's Joint Commission contact - Others at Program's discretion -
3:30 – 4:00	**Reviewer Report Preparation**	
4:00 – 4:30	**Program Exit Conference**	- Program administrative and clinical leadership - Others at program's discretion

Appendix A – Guidance to Program Activity Levels

Overview

The Patient Blood Management (PBM) Certification program is designed to evaluate organizations with varying levels of complexity. The three program activity levels (Level 1, 2, and 3) are based on the services and capabilities at each organization.

- A small hospital may have a clinical program and services that meet the program level activities described as Level 3.

- A large hospital might have a clinical program and services that incorporates all the activities described for Level 1.

- It should be recognized that one level is not superior to another and merely reflects differences in the activities performed by the hospital in which the PBM program resides.

Each organization that applies for Patient Blood Management Certification is required to designate an activity level prior to the on-site review. The electronic application (E-App) includes an Eligibility Requirements section that prompts the organization to select the appropriate activity level for their PBM program.

Applicability of Standard PBMOR.4

During the on-site review, the PBM program will be evaluated for compliance with the expectations that reflect their designated program activity level. The expectations for each activity level are presented in Standard PBMOR.4, Elements of Performance (EPs) 2-24. Standard PBMOR.4, EP 1 applies to all activity levels.

As each activity level addresses organizations with different capabilities, the PBM program's activity level will determine which EPs are applicable during the certification review:

- Activity Level 1: EPs 2-24 are applicable

- Activity Level 2: EPs 2-20 are applicable

- Activity Level 3: EPs 2-17 are applicable

Additional Guidance

The following table provides examples of questions that can help determine whether a PBM program has addressed all the applicable EPs. Although there may be some overlap between the items on this list, taken as a whole, the activities described reflect the total scope of activities performed by a PBM program.

Standard PBMOR.4 – The executive management defines, oversees, and monitors the activities of the program.

The program is responsible for, or has direct involvement with, oversight and monitoring of the following activities:

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
2. Evidence of institutional support for the patient blood management program at the executive level. • Does the program have the full support of the medical director of the parent facility, including financial support and information technology (IT) support with specific IT staff to assist with implementing clinical workflows and data reporting? • Does the program have dedicated Transfusion Safety Officers or other individuals who are tasked with overseeing the PBM program? • Is there a direct liaison relationship between the PBM program and the executive management of the parent facility?	X	X	X
3. Metrics regarding transfusion appropriateness in accordance with transfusion guidelines. The PBM program must establish evidence-based metrics or key performance indicators to evaluate adherence to transfusion guidelines for every transfusion. The medical and nursing staff must have guidance on transfusion appropriateness criteria. This can be provided within order sets or built into the computer blood order entry system as clinical decision support or choices for mandatory entry fields. Outside of the order sets, this might also take the form of routine educational programs, in-service sessions, or posted information on the program-specific website. Reporting of the overall facility transfusion appropriateness rate and the rates for specific care areas would satisfy this item. Examples include: • Inpatient vs outpatient. • Extra- vs intraoperative care. • Medical vs surgical critical care. • Cardiology. • Hematology/oncology. • Obstetrics. • Orthopedics. It may useful to perform reporting at hierarchical levels (hospital-wide, by department, by surgical procedure, by physician, etc.) and risk-adjustment methods can be used to facilitate comparisons between groups or physicians. Powerful tools for changing behavior and sustaining change include:	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
• Reporting metrics such as "percentage >1-unit Red Blood Cell (RBC) transfusion orders." • Reporting metrics such as "percentage RBC transfusion orders above hemoglobin threshold established by facility guidelines." • Benchmarking the blood-ordering physicians with peer comparisons. • Providing surgeons and anesthesiologists with blood utilization peer comparisons (common surgical procedures or pretransfusion hemoglobin threshold vs posttransfusion hemoglobin target would also meet the intent of this requirement).			
4. **Documentation of transfusion including patient consent, observation, adverse events, and outcomes.** Documentation of the practices and processes associated with transfusion is imperative in a PBM program. This includes the entirety of the informed consent process, including consent for (or refusal of) transfusion, patient identification, patient and component correlation, the infusion procedure with vital signs monitoring, reporting of adverse reactions, and posttransfusion documentation of whether the transfusion had the intended effect. Laboratory-related documentation includes patient identification, proper sample labeling, reporting of sample labeling errors and process improvements, and any errors related to blood typing of patients and components that could result in mistransfusion.	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
Budgeting to the level of care required by the implementation of these PBM Standards. The PBM program should take into account the total cost of its program including personnel, equipment, reagents, supplies, other facility-specific program costs, as well as accreditation costs. To garner support and funding for maintaining operations, the PBM program should also take into account impact of the following: • The financial savings in terms of the acquisition cost of blood components not used. • Activity-based savings for transfusion procedures not performed. • Other potential cost savings related to better patient outcomes [eg, shorter length of stay, decreased intensive care unit (ICU) time, fewer infections, fewer re-operations, decreased kidney injuries, etc]. The financial impact and cost savings of a PBM program can affect departments differently. For example, while the laboratory may see a cost reduction due to fewer RBC units transfused, the pharmacy may see an increase in costs for agents used for preoperative and/or outpatient anemia management [eg, intravenous (IV) iron] or intraoperative hemostatic agents [eg, tranexamic acid (TXA)]. When determining the budget for the program it is important to involve all affected areas, including laboratory services (blood bank, coagulation, and hematology), pharmacy, perioperative services, infusion center, and other relevant facility departments or services. Any new revenue that is generated also needs to be considered. For example, outpatient anemia management efforts may add new revenue (from new infusion and injection procedures) in addition to new costs associated with the procedure and medications. New tests may add new revenue. The objective is to determine the total financial impact of the PBM program as follows: – $$$$ cost of program (this is the budget) + $$$$ savings from blood not given + $$$$ savings from transfusion procedures not done – $$$$ cost of other quality benefits (see above) + $$$$ new revenue (e.g., outpatient anemia management) = Total financial impact	X	X	X
5. Pre-transfusion patient testing and evaluation.	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
This item applies to all patients in the facility who may need a transfusion, and it also covers all blood components that could be transfused. Patients with massive blood loss, patients who are unidentified, and those who decline transfusion as a treatment are covered in other items. The intent of this item is for the PBM program to collaborate with the transfusion service for ensuring proper ordering, timeliness of pre-transfusion testing, and appropriate blood and blood component availability for safe transfusion practice. Examples of clinical situations and activities covered under this item may include: • Processes established to ensure that testing is completed well in advanced of the date of an intervention to avoid unnecessary delays in procedure start time and patient inconvenience. Patients affected include those having an elective invasive intervention (ie, surgery, interventional radiological procedures, interventional cardiology procedures) or a prenatal patient at time of delivery where a type and screen and/or RBC units on hold are ordered. • Processes established to ensure sufficient number of compatible, antigen-negative RBC units are available for patients with positive antibody detection test results and red cell alloantibodies. Such patients include those who are scheduled for an elective surgical procedure or who are pregnant and at the time of delivery where a type and screen and/or blood components on hold may be ordered. • Processes established for timely communication and ordering of other blood components, such as plasma and platelets, to be on hold for a surgical or invasive procedure to ensure these components are available at the time of the procedure. • Processes in place for timely blood availability for nonprocedure/medical/postprocedure patients with symptomatic anemia or hemoglobin levels below a defined threshold when a blood transfusion request is ordered. Collaborating with the hematology/oncology service for patients receiving chemotherapy who will be seen in the clinic and/or who anticipate RBC transfusion can provide a more efficient and timely process for blood availability for these outpatients. In addition, for transfusion services with limited capacity, having a stock of irradiated RBC units or common antigen-negative RBC units can avoid delays for			

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
those patients receiving outpatient transfusions on a regular basis. • Processes in place for all patients whose blood type has been confirmed before the selection of type-specific RBCs for transfusion (e.g., a second blood type based on either historical or current testing is in the blood bank information system). • Other categorization may be considered, as determined by the facility and patients served. This item also involves the different transfusion situations for patients who need blood urgently or those whose transfusion needs are otherwise time dependent. For patients with emergency blood needs, low titer group O whole blood, group O red cells, and group A or AB plasma or platelets may be given on an emergency release basis. In these cases, proper documentation of the urgency is required as an interim measure while blood typing, antibody detection, and crossmatching are being completed. For patients with more routine transfusion needs, blood typing, antibody detection, and crossmatching should be completed before blood is released. Additional transfusion-related testing [e.g., complete blood count, platelet count, medication history, platelet function testing, international normalized ratio (INR), partial thromboplastin time (PTT), fibrinogen tests] should be ordered and completed to best direct the most appropriate selection of blood component(s) therapy and in the right amount(s).			
6. **Patient- or case-specific assessment of potential blood usage.** This item applies to all patients in the facility who may need a transfusion and all blood components that could be transfused. Patients with massive blood loss, patients who are unidentified, and those who decline transfusion as a treatment are covered in other items. The intent of this item is for the PBM program to have a means for assessing whether the patient may need blood transfusion(s) and if so, the quantity needed for a particular surgery or invasive procedure.. The program	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
may have patient-centered processes in place for the assessment such as the following (not all inconclusive): • Is the patient anemic at the time of the assessment? If "yes," is there time to correct • before the intervention? If "no," weigh the harm/benefit of delaying the intervention while anemia is treated. • Is there history of transfusion or formation of red cell alloantibodies? If "yes" is a type and screen done earlier than if the answer was "no" so that there is sufficient time to ensure blood is available for the procedure? • Is there history of excessive surgical bleeding, a diagnosed coagulation abnormality, or other bleeding tendency? If "yes," is there time for evaluation including additional coagulation testing and/or specialty consultation? • Are blood components with special attributes required? For example, is the patient refractory to platelet transfusions, are irradiated cellular blood components required, or is there a transplant procedure with an ABO-mismatched organ planned? The program needs to have a facility-defined maximum surgical blood order schedule (MSBOS) for certain operations. It is important that this schedule be reviewed and updated on a regular basis, as needed. A common approach to developing the MSBOS is to retrospectively evaluate intraoperative RBC utilization by major surgical procedure (i.e., RBC units transfused per case). The quantity of RBCs transfused at the 90th percentile would become the maximal surgical blood order for that specific procedure. An alternative approach might involve the use of predictive analytics at an institution. For example, using preoperative variables (hemoglobin, coagulation testing, etc.) to predict blood use during liver transplantation. This strategy could be applied to surgical procedures with high but variable intraoperative blood requirements. Nonsurgical patients should also be evaluated for risk of requiring any blood transfusion as well as quantity of units that may be needed. This may involve institutional guidelines such as laboratory value thresholds, patient signs and symptoms, and patient-centered decision making.			

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
7. Preprocedure blood ordering, including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients. This item applies to all patients in the facility who may need a transfusion before, during, or after an invasive procedure while also covering all blood components that could be transfused. This item also overlaps with considerations posted in Item 5 and the reader is encouraged to review that section. Patients with massive blood loss, patients who are unidentified, and those who decline transfusion as a treatment are covered in other items. The following might be considered: 1. For all patients, is there an evidence-based, regularly reviewed, and updated-as-needed blood transfusion ordering process that takes into account the following: • Is the patient actively bleeding? • Is the patient symptomatic? If "yes," is the patient at high risk for an ischemic event? • Is there a documented coagulation abnormality? • Is there a focus on giving cellular blood components (red cells, platelets) one unit at a time and then reassessing for symptoms or laboratory evidence of response before giving further transfusion? 2. For patients with coagulation abnormalities: • Is the abnormality documented with appropriate laboratory data or viscoelastographic testing? • Are options other than, or in addition to, transfusion (e.g., antifibrinolytic agents, DDAVP, vitamin K, other reversal agents, idarucizumab, andexanet alpha, protamine sulfate, prothrombin com-plex concentrates, other agents) considered in a standardized or patient-specific manner? • Does the order include the indication, the (least) number of units needed, the rate of administration, and consideration for patients with increased likelihood of circulatory overload, which could include the use of diuretics, avoiding back-to-back transfusions, or volume reduction (if platelet transfusion)? 3. For type and screen testing and blood component ordering: • Is there a policy (e.g., Surgical Blood Order Schedule) that guides what testing needs to be per-formed (e.g., type and screen only or type and screen	X	X	X

including "x" number of crossmatched RBC units) for certain surgical procedures? • Is this testing performed before the day of surgery? • For elective surgical patients who have not been transfused or pregnant in the preceding 3 months, is there a policy or procedure to obtain samples for blood bank testing more than 72 hours from the date of scheduled surgery? • Is there a facility policy (or pre-anesthesia, nursing, or other provider-assigned checklist) to note that the type and screen has been completed and blood is available for the patient before surgery start time? If no, who is responsible for reviewing the status of transfusion-related testing? • If testing is incomplete, who is responsible for approving whether the procedure can start and is this documented in the medical record? • Does documentation state why the surgical case must proceed and include a plan for blood loss reduction and transfusion if needed (emergency release units or transfusion alternatives)? • Does the facility track completion of type and screen testing before surgical start time as a patient safety metric? • It is imperative that the patient's transfusion history be reviewed long before the day of surgery. If the patient has a history of red cell antibodies, platelet refractoriness, severe transfusion reactions, or special needs (irradiation, etc), are processes established for alerting the transfusion service to the patient's upcoming procedure? • Identifying those patients with red cell antibodies and/or requiring specialty blood components as early as possible provides ample time for planning and procuring the appropriate blood components. Does the program have processes to identify who is responsible and how the review is conducted? • All patients must have a "current" (as defined by the facility; see above) type and screen and, as applicable, crossmatches ordered and performed before the start of the surgical procedure. The number of crossmatches ordered should be based on the anticipated RBC utilization typical for the scheduled procedure. Additional crossmatches should be ordered if the patient has a higher risk of bleeding based on preprocedure assessment (see Items 5 and 8). Before the selection of type-specific RBC units, the patient's blood type must be confirmed with a second sample (AABB BBTS Standards 32nd Edition, Standard 5.14.5). If the patient has no historical typing, what processes are in place for identifying			

such patients and performance of the repeat blood type?

• For postprocedure blood component orders, does the order include the indication, the (least) number of units needed, the rate of administration, and consideration for patients with increased likelihood of circulatory overload, which could include the use of diuretics, avoiding back-to-back transfusions, or volume reduction (if platelet transfusion)?

• For patients with a history of platelet refractoriness likely to need platelet support during a surgical procedure or following the procedure, it is imperative that the transfusion service works with the blood supplier to ensure an adequate number of irradiated, crossmatched, or HLA-matched platelets, as applicable. For such patients receiving HLA and/or crossmatched platelets does the ordering process, if applicable, include follow-up laboratory tests to measure effectiveness?

4. For all patients with positive antibody detection results or historical red cell antibodies:

• Processes will depend on the transfusion service capabilities and what resources it has for antibody identification, antigen typing, and/or other advanced immunohematology testing. Distance from the blood supplier and immunohematology reference laboratory hours may also be import-ant. Policies should indicate timely notification if there is delay in blood availability for a planned surgical procedure or when blood is urgently requested. Additionally, policies should address when compatible blood is not available due to complexity of patient's alloantibodies or during blood component shortages. Are non-emergent procedures delayed or rescheduled? Are alternative options considered for patients whose surgery cannot be delayed?

• For patients with a history of red cell antibodies (allo- or autoantibodies) preprocedure antibody detection testing should be completed before the surgery date to ensure that an adequate number of antigen-negative RBC units are available the day of the procedure. The facility should define the time limit that a blood bank sample is acceptable for pretransfusion testing before an elective surgical procedure (e.g., 14 days, 30 days). Preprocedure crossmatching is recommended for patients with complex antibodies and/or histories of autoantibodies if there is a reasonable likelihood of needing RBC transfusions during or following the procedure.

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
8. Pre-procedure optimization of patient coagulation function. The PBM program should have processes in place for preprocedural assessment of the patient's bleeding risk and optimization of the patient's hemostatic before the procedure. This item pertains to invasive procedures that may or may not be surgeries (as in obstetric delivery; interventional procedures in radiology, cardiology, and other services; placement of spinal anesthesia; collecting cerebrospinal fluid; obtaining bone marrow samples; and other invasive procedures). For elective procedures: • Is there a mechanism for assessment of bleeding history and medication review, including prescribed and over-the-counter medications and supplements, to determine if certain medications should be discontinued and, if so, the related safety and timing of them? • Just prior to the procedure, is the same history reviewed and cessation (when and which) of medications confirmed? • Are specific guidelines in use that dictate which medications should be held and for how long, prior to the planned procedure? • If medications were supposed to be stopped but were not, is there a process for what to do to ensure patient safety and limit blood loss? Options may include: delaying the procedure, giving pharmaceutical reversal agents or blood components, giving medications during the procedure to minimize bleeding (for example, an antifibrinolytic agent), selecting other modalities to reduce bleeding (eg, acute normovolemic hemodilution, blood recovery/reinfusion, using minimally invasive procedures), using a different anesthesia type, or changing the patient's position. For urgent procedures: • Is there a mechanism for assessment of bleeding history and medication review, including prescribed and over-the-counter medications and supplements, to determine the medications taken and when the last dose was given? • Are lab tests done to correlate with the history? Examples include INR if the patient is taking vitamin K agonists, platelet function tests if the patient is taking P2Y12 inhibitors or aspirin, and anti-Factor Xa studies if the patient is taking anti-Factor Xa medications, etc. • For patients with increased bleeding risk is there a plan to minimize blood loss? Options may include delaying the procedure, administering medications such as DDAVP or antifibrinolytics, considering other blood conservation therapies (e.g., acute	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
normovolemic hemodilution, blood recovery/reinfusion), using minimally invasive procedures, administering a different anesthesia type, or changing the patient's position. • Are there guidelines and available modalities for maintaining normothermia? • Is there a process to ensure avoidance of acidosis? • Are there specific/separate guidelines for withholding anticoagulation before and after neuraxial anes-thesia? For patients receiving chronic anticoagulation: • Are there preprocedure guidelines that assess the bleeding and thromboembolic risk and that stratify patients into high-, moderate-, and low-risk categories? • Do the guidelines contain recommendations for therapy interruption and resumption of anticoagulation? • Is there a mechanism for ensuring the guidelines are recognized and utilized? For patients with known bleeding history and/or coagulation defects [hemophilia, deficiency of von Willebrand factor (vWF)] is there a mechanism for their identification and development of a plan for infusing factor concentrates and management of bleeding?			
9. **Monitoring of blood components wastage and cause.** As part of the appropriateness of blood utilization, the PBM program should have processes in place to monitor and report on percent of wastage for the individual blood components and the cause for the wastage. The program should define "wastage" (i.e., whether "in date" components, expired components, or both), investigate the potential reasons, and identify a threshold for meaningful tracking and reporting on wastage to the executive management. Monitoring by site of wastage occurrence (e.g., blood bank, operating room, emergency department, patient care unit, outpatient infusion, other) and the reason (e.g., expired on shelf, broke in processing, ordered not used, returned out of temperature) is key to aid in corrective action and process improvement when wastage exceeds established thresholds. Additional guidance on wastage can be found under Standard PBMPC.22.	X	X	X
10. **Minimize blood loss due to laboratory testing.** The PBM program is required to ensure that policies and processes are in place for minimizing blood loss due to phlebotomy and laboratory testing for all patients.	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
11. Process for managing the blood needs of unidentified patients and resolving their identification. The PBM program needs to assess the content, effectiveness, and safety of hospital policies and processes for unidentified patients who potentially require blood components as well as the process for reconciliation once the patient's identity is known. If deficits are identified, the PBM program will be part of the redevelopment process.	X	X	X
12. Processes to identify, prior to or upon admission, patients who may decline transfusion under any circumstances with notification to the appropriate individuals. The PBM program should have policies and processes for identifying patients who decline blood transfusions. The process should be standardized and apply to all patients. When a patient is identified as declining transfusion as a part of their care, there should be a process whereby this status or directive is reliably recognized by all caregivers.	X	X	X
13. Massive transfusion protocol with documented evidence of its use. The PBM program needs to have an established protocol for managing massively hemorrhaging patients, including those in the emergency department and existing inpatients. Although some small and/or acute critical access hospitals (e.g., less than 25-50 beds) may not have all blood components in stock or accessible in a short time, protocols for such hospitals may be to transfuse components and/or medications they do have and transfer the patient to a higher level acuity hospital for further management. The MTP may include use of items other than blood components, including medications. There should be a way to identify when the MTP was last updated, the individuals involved in its development, and that the protocol is evidence based. A plan for, or evidence of, ongoing review of the protocol to keep current with medical evidence should also be in place. The MTP should be developed collaboratively by relevant stakeholders, such as the trauma service, transfusion service, emergency department, and anesthesia. Criteria for MTP activation need to be established and operational aspects outlined, such as blood availability and timely delivery. Blood transfusion administration, ongoing patient monitoring, and transfusion goals should be addressed. If pharmaceutical agents (e.g., antifibrinolytics) are part of the MTP, criteria for their use, dosing, and administration should be defined. A process for MTP termination is required to be in place. The PBM program needs to have	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
ways to review or evaluate MTP use, effectiveness, and overall quality to identify performance improvement opportunities.			
14. Transfusion care and anemia management of pre-term, neonate, infant, and pediatric critical care patients, if applicable. The PBM program needs to be involved in the development, documentation, and oversight of transfusion and anemia management of preterm, neonate, infant, and pediatric patients. There must be clearly defined consensus in each institution on the age and weight-based definitions of anemia and transfusion indication, especially within each specific clinical environment (neonatal ICU vs pediatric ICU vs hematology/oncology, and general pediatrics). The PBM program must monitor adherence to these transfusion guidelines and treatment of anemia.	X	X	X
15. Patient blood management care for obstetric patients including postpartum hemorrhage known high bleeding risk (e.g., placental abnormalities), and plans for patients for whom blood is not an option. Blood loss is a part of every obstetric delivery process. Blood loss can be substantial, rapid, life-threatening, and result in death. Postdelivery anemia is common, can be severe, and has several management options. PBM not only addresses the health and safety of the pregnant patient but also includes consideration for the newborn. The PBM program needs to be involved in the development, documentation, and oversight of transfusion, bleeding, and anemia management care(s) for the pregnant patient and newborn. PBM for newborns outside of the settings of high risk for hemolytic disease of the fetus and newborn (HDFN) and neonatal alloimmune thrombocytopenia (NAIT) are described elsewhere. The PBM program needs to assess the use, effectiveness, and safety of related hospital policies and processes, including protocols for recognition and management of postpartum hemorrhage (PPH), patients for whom transfusion is not an option, and newborns with known or high risk of HDFN or NAIT. Management of postpartum hemorrhage may include an obstetric-specific or general patient MTP.	X	X	X
16. Single-unit transfusion strategies for defined patient population(s). Dosage is an important aspect of transfusion practice. In	X	X	X

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
order to avoid overtransfusion, the implementation of single-unit RBC ordering has been shown to reduce transfusion requirements. It is recommended that in nonbleeding, stable patients RBCs are ordered 1 unit at a time and the patient is assessed after the transfusion is completed to determine if additional units are needed. The PBM program monitors and evaluates the practice of single-unit RBC transfusion for nonbleeding, stable patients. The program may implement decision support to encourage the prescribing of RBC units one at time in defined patient populations.			
17. Manage acquired coagulopathy. When acquired coagulopathy is suspected, due to ongoing or massive blood loss, trauma, cardiopulmonary bypass, supratherapeutic anticoagulation, or other cause: • Is there an algorithm for diagnosis and treatment? • Are there protocols for rapid reversal of anticoagulants? There should be access to rapid laboratory evaluation, which includes standard coagulation evaluation (PT/INR, PTT, fibrinogen, thrombin time) and platelet count. Viscoelastic assays (ROTEM, TEG) should be utilized when available. • Component-directed transfusions should be performed with transfusions targeted to specific deficiencies with a goal of hemostasis that avoids overtransfusion. Topical hemostatic agents (fibrin sealant, thrombin gel) should be used when appropriate. • Pharmacologic interventions for platelet dysfunction (desmopressin and prothrombin complex con-centrates) should be available and utilized as needed. Antifibrinolytics should be available for use when appropriate.	X	X	X
18. Blood conservation strategies for service lines associated with high blood usage. PBM programs at these levels should be aware of the services using the most blood. These may include cardiovascular surgery, trauma surgery, oncology, or other areas. One area to consider is the outpatient transfusion service, including patients who may be receiving RBCs for iron deficiency anemia (see also Item 20). The high blood use service lines should define their strategies to minimize blood loss and transfusion and be able to demonstrate that the strategies are used.	X	X	N/A
19. Processes and/or equipment to facilitate rapid decision making with regard to anemia and coagulation management.	X	X	N/A

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
• MTP is one such process and is discussed elsewhere. • Other processes and equipment may include established point-of-care testing methods (hemoglobin determination, viscoelastographic coagulation testing, and other point-of-care tests). • Another option is the use of algorithms for blood component or medication therapy based on abnormal coagulation results. • The program may have a plan for rapid turnaround for testing performed in the laboratory or other care areas to aid in the management of critically bleeding patients. • Patients may be those in the emergency department, operating room, delivery suite, ICUs, or other areas. • This testing can be used proactively to assess potential for blood use, or it can be used during a bleeding event to identify the specific components or other hemostatic therapy (medications, surgical intervention, or interventional radiologic procedure) needed for the patient's care. This item addresses more than the equipment that may be used, the actual use of the equipment, and the safety of the patient. The program should focus beyond just having equipment available to that of the specific and timely use of the results in the clinical decision-making process. This involves awareness of care team members on the testing available, that the testing is used appropriately, that results are communicated rapidly and effectively, and that the team knows how to act on the results.			
20. Evaluating and managing iron and micronutrient deficiencies defined patients with red blood cells ordered in the outpatient setting. Outpatient transfusion services frequently transfuse RBCs for iron deficiency anemia. For PBM programs at Activity Levels 1 and 2, anemic patients should be evaluated to ensure they are receiving the appropriate therapy(s). Therapies may include transfusion, intravenous iron therapy, use of erythropoiesis-stimulating agents (ESAs), administration of other micronutrients (vitamin B12, folic acid, vitamin C, others), or combination therapy. Although transfusion can correct anemia, it does not replete iron stores.	X	X	N/A
21. Evaluation and management of anemia in non-operative patients. Patients with certain medical conditions (e.g., those with	X	N/A	N/A

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
kidney disease, heart failure, and gastrointestinal bleeding) and not having invasive procedures (eg, vaginal delivery) are at risk for anemia that may or may not be severe enough to merit transfusion. These patients need to be assessed for possible transfusion with a single-unit strategy if they are asymptomatic. They also need to be assessed, by protocol or process determined by the facility, if anemia tolerance or treatment by another method (e.g., iron therapy if the patient is found to be iron deficient) is the best practice for the individual patient's care.			
22. Program to care for patients who decline use of blood or blood-derived components. The PBM program considering certification for Level 1 needs to have policies and processes in place for caring for and managing those individuals who decline blood or blood- derived components. This goes beyond identifying patients who decline transfusions as noted in Item 12. To meet this requirement the facility needs to show evidence of a formal program for (or standardized approach to) managing all patients identified as declining blood transfusion, all or some components, and for any reason. This item requires policies, processes, and procedures to be in place to manage these patients. This includes documentation of standardized care offerings and considerations agreed upon or consented to by the patient or parents and guardians of minor children. The documentation should be identifiable within the medical record for all caregivers. Care offerings may include: • Noting if the patient has a bloodless care advanced directive ("No Blood" card) and that it was reviewed. • Using a checklist documenting acceptance or refusal for some or all of the following: –Medications or coagulation "fractions" to prevent or stop bleeding. –Medications to manage anemia. –Reinfusion of shed autologous blood. –Any circumstances under which transfusion may be considered and requires the patient's transfer to a facility with additional care options. • Using processes that may include autologous blood recovery and reinfusion, minimal lab testing and test sample volume, alerts to the blood bank if the patient refuses blood transfusion, and consultation with medical specialists in the areas of hematology,	X	N/A	N/A

Element of Performance	Activity Level 1	Activity Level 2	Activity Level 3
pharmacy, transfusion or other areas.			
23. Identification and management of pre-surgical anemia before elective procedures for which type and screen or type and crossmatch is recommended. The PBM program considering certification for Level 1 must have policies, processes, and procedures in place for management of presurgical anemia. To meet this requirement the PBM program should have a defined program for identifying, evaluating, diagnosing, and managing anemia in patients who are being scheduled for certain elective surgical procedures. Patients considered for this program may be those needing type and crossmatch before surgery, those with risk of substantial blood loss during surgery or cumulatively during the hospital stay, those with risk of moderate or greater anemia (hemoglobin <10 g/dL) on admission and having surgery with anticipated low blood loss, and those who decline transfusion. The program may be within a presurgical clinic, a referral process to an anemia clinic or medical subspecialist used by surgeons and/or primary care clinicians, a component of the preoperative physical examination, or other standardized care process.	X	N/A	N/A
24. Use of perioperative techniques consistent with current AABB Standards for Perioperative Autologous Blood Collection and Administration. The PBM program considering certification for Level 1 must ensure the facility is in full compliance with the current edition of Standards for Perioperative Autologous Blood Collection and Administration as it relates to intraoperative and postoperative autologous blood recovery and reinfusion as well as perioperative autologous component production such as platelet rich plasma. For those organizations that are already AABB-accredited for perioperative autologous blood collection and administration, the requirement for this section is met.	X	N/A	N/A

N/A: EP is not applicable to the activity level

Program Activity Levels Diagram
According to Standard PBMOR.4, a PBM program can be designated as a program activity level 1, 2, or 3. To be designated as such, the program shall be responsible for or have direct involvement with oversight and monitoring of specific activities. A Level 2 program is responsible for activities in Levels 2 and 3. A Level 1 program is responsible for activities in Levels 1, 2, and 3.

PBM ACTIVITY LEVEL

LEVEL 1
Evaluation and Management of Anemia in Non Operative Patients
Program to Care for Patients who Decline Blood or Blood Derived Components
ID and Management of Pre Surgical Anemia
Use of Techniques in the AABB Periop Standards

LEVEL 2
High Service Line Blood Conservation Strategies
Processes and Equipment for Decision Making for Anemia and Coag Management
Evaluation and Management of Iron and Micronutrient Deficiencies

LEVEL 3
Institutional Support | TX Appropriateness Metrics
Patient Consent, Observation and Adverse Events | Budgeting to the Level of Care
Pre TX Patient Testing and Evaluation | Patient/Case Specific Assessment of Blood Use
Pre Procedural Blood Ordering | Massive TX Protocol | Blood Loss Minimization
Pre Procedure Optimization of Coag Function | Blood Wastage and Cause
Managing Blood Needs for Unidentified Patients
Patients who may Decline TX and Notification
TX Care and Anemia Management of Pre Term, Neonates, Infants and Pediatric Critical Care Patients
PBM for OB Patients | Single Unit TX Strategies
Management of Acquired Coagulopathy

Appendix B – Frequently Asked Questions (FAQs)

FAQ: Expectations for PBM Standards Referencing AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration

> **Standard PBMEQ.5**
> The program defines quality control activities for equipment controlled by other departments.
>
> **Element of Performance 2 [AABB Standard 3.2.1]**
> Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program shall be controlled in accordance with the manufacturer's written instructions and/or the current editions of AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration.

Q. What is the responsibility of the Patient Blood Management Program for compliance with this requirement?

A. Examples of equipment that would be covered by this standard include:
- Blood warmers
- Storage devices for blood and blood components (including alarm systems)
- Cell savers
- Computer systems or information systems

Examples of activities that surveyors may ask about:
- How is equipment qualified and installed?
- Is equipment used in conformance with manufacturer's written instructions?
- Is equipment uniquely identified and its use recorded in a manner that permits traceability?
- What is the calibration program in place for equipment?
- How are equipment malfunctions or failures investigated?

Q. What are required elements of equipment control?

A. If the blood bank or perioperative program are not accredited by AABB, a surveyor would likely seek to learn about the policies, processes, and procedures that are in place for the following activities:
- A process for selection of equipment, including information systems
- A process qualification of equipment (installation, operational, and performance qualification)
- Policies, processes, and/or procedures for unique identification of each piece of equipment and for equipment use
- A program of monitoring/maintenance to ensure that equipment remains fit for use
- Record-keeping associated with the activities described above.

In many cases, the PBM program may not have direct control over this equipment; in fact, the PBM program may not be considered the true "owner" of any single piece of equipment.

However, equipment requirements contained in the BB/TS and Periop Standards can have a significant impact on transfusion safety and patient care. If the hospital blood bank/transfusion service or perioperative program are AABB-accredited, then these requirements will have been met and additional redundant inspection will not be necessary. However, for facilities where these departments are not accredited by AABB or another equivalent accrediting body, the PBM program should seek to have documented evidence showing that:

1) The appropriate requirements, contained in chapter 3 of these two publications and summarized above, have been shared with the affected departments.
2) That these departments have developed policies, processes, and procedures, based on the quality system of the PBM Standards, to satisfy these requirements.
3) That the continued conformance to these standards by those departments is verified and ensured through occasional assessments or audits.

Standard PBMPC.10
The program has guidelines for phlebotomy, transfusion orders, and for pre- and posttransfusion patient care.

Element of Performance 2 [AABB Standard 5.5.1]
The program reviews, revises, or creates the policies, processes, and procedures regarding pretransfusion testing. These policies are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.

Q. What activities are part of "pretransfusion testing?"

A. Pretransfusion testing is an essential aspect of transfusion safety and encompasses a significant portion of transfusion service-related activities. Examples of these activities include:

- Patient samples (collection, identification, and retention)
- Requests for Blood/Blood Components
    - Information
    - Conformance with sample label
- Serologic confirmation of donor blood group/type
- Pretransfusion testing of patient blood
- Comparison of current results with previous records
- Selection of Compatible Blood
    - Routine
    - Special Circumstances
- Crossmatch
- Labeling
- Use of Computer to detect ABO incompatibility
- Resolution of discrepancies between order, records, unit
- Urgent requirements for blood/blood components

Examples of questions a surveyor may ask:

- How are patients uniquely identified?
- What does your institution accept for unique identifiers on the sample?
- Does the written procedure define when and where blood sample tubes should be labeled?

- Show me/describe your procedures for performing an ABO/Rh type.
- What testing do you do to detect unexpected red cell antibodies?
- What patient testing is required before you issue a unit of RBCs? Granulocytes? Plasma or Platelets?
- What is your policy for preparing Whole Blood or Red Blood Cells for transfusion to recipients with a history of clinically significant antibodies?
- Under what circumstances, if any, do you transfuse Rh-positive red cells or platelets to Rh-negative recipients and how is this documented?
- Under what circumstances do you perform computer crossmatches?

Q. Why is pretransfusion testing part of my PBM certification?

A. Pretransfusion testing is an essential aspect of the safe practice of transfusion medicine. The blood bank or transfusion service must ensure that samples for testing are labeled and controlled, and that test results are recorded and communicated. A mistake in the sample collection or identification process, or a failure to ensure that samples for pretransfusion testing are collected from the correct individual, can increase the likelihood of an incompatible blood transfusion. Because non-infectious serious hazards of transfusion, or NISHOTs, are more common than infectious hazards, the control of activities related to pretransfusion testing is of paramount importance.

In addition to preventing NISHOTs, pretransfusion testing is also important to ensure that special transfusion requirements are met – particularly for chronically transfused patients or those with clinically significant antibodies. As such, pretransfusion testing is an important part of clinical decision-making surrounding transfusion.

Sample Handling and Labeling
The use of two independent identifiers for the patient helps ensure accurate and positive identification of patients, samples, and blood components. The label on a patient sample must be affixed to the sample containers before the individual obtaining the sample leaves the side of the patient, and there must be a mechanism to identify the date of sample collection and the individual(s) who collected the sample. Labels must be complete, accurate, and legible. The transfusion service must confirm that all identifying information on the request is an agreement with the sample label, and in the case of a discrepancy, a new sample must be obtained. (See standard 5.11.2 in the *Standards for Blood Banks and Transfusion Services*)

Testing
Patient blood must be tested for ABO group, Rh type. If the unit to be transfused is either Red Blood Cells, Granulocytes, or Whole Blood, pretransfusion testing for unexpected antibodies to red cell antigens must also be performed as well. If discrepant results are obtained for ABO group, only group O Red Blood Cells may be issued.

Methods of testing for unexpected antibodies to red cell antigens shall be validated and must demonstrate clinically significant antibodies. Additional testing must be performed when clinically significant antibodies are detected. Control systems must be in pace to ensure the validity and accuracy of antibody testing results. And in patients who have been transfused in the preceding 3 months, or patients who have been pregnant during that timeframe, or if the patient's transfusion or pregnancy history are uncertain or unavailable, the sample for testing must be drawn within 3 days of the scheduled transfusion.

> **Standard PBMDR.1**
> The program develops, validates, and implements policies and procedures or documents and records.
>
> **Element of Performance 3 [AABB Standard 6.0]**
> Documents and records related to transfusion medicine or perioperative programs are created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services, AABB Standards for Perioperative Autologous Blood Collection and Administration, or the requirements of an equivalent accrediting body.

> **Standard PBMDN.1**
> The program captures, investigates, and reports deviations, nonconformances, and adverse events.
>
> **Element of Performance 5 [AABB Standard 7.0]**
> The program ensures that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services, AABB Standards for Perioperative Autologous Blood Collection and Administration, or the requirements of an equivalent accrediting body.

Q. Which records are included here?

A. Just as with equipment, a PBM program may not possess extensive records of its own. PBM programs must have the ability to pull meaningful information from existing systems – patient medical records and the laboratory information system, for example – in order to report on their overall performance. In order for this information to be recorded and available, a system for record-keeping must be established to ensure that records are complete, accurate, and retrievable.

Examples of questions a surveyor might ask include:
- How are records ensured to be complete?
- How does the records system provide for retrieval in a time period appropriate to the circumstances?
- What is the process for protection of manual and electronic records from unauthorized or accidental destruction or modification?
- Were any records found that were not recorded in permanent media?
- How does the record system make it possible to
    - Trace any blood or blood component, product, or tissue from source to final disposition?
    - Review the records applying to the specific component?
    - Investigate adverse reactions manifested by the recipient?
- How are archived records accessed after the method/hardware used to archive them has been changed or updated?

Q. What are my responsibilities in capturing and investigating adverse events and deviations?

A. An important aspect of monitoring the efficacy of a PBM program and of transfusion safety is to ensure that adverse reactions to transfusion are captured, investigated, and reported. These requirements therefore are designed to provide an infrastructure of record-keeping and adverse

event reporting that will allow the PBM program to accurately assess its own performance with respect to patient outcomes.

Many of these requirements are mirrored in the requirements of other accrediting bodies. In hospitals where the blood bank and/or perioperative program are not accredited, a careful review of these two standards should be performed to ensure that current practices are consistent with AABB Standards.

Examples of questions a surveyor might ask include:
- What is the process for capturing information about deviations from policies, processes, and procedures and failures to meet specified requirements?
- What is the process to ensure that deviations from or failures to meet specified requirements are:
  o Assessed?
  o Investigated?
  o Monitored?
- What is the process for investigating these events and determining their cause(s)?
- How is the medical director involved in development of adverse transfusion event protocols?
- Where are the signs and symptoms of a transfusion reaction recorded?
- Who is notified? At what stage of the evaluation do you notify them?
- When do you decide to interrupt or discontinue the transfusion?
- When there is a suspected adverse event related to perioperative product collection and/or administration, how does the policy address ensuring that this evaluation does not delay proper clinical management of the patient?
- How does the procedure address possible hemolytic reactions?
- What is the process for comparing patient identification with product labels & records?

FAQ: Expectations for PBMRS.2, EP 6 (Facility-Defined Credentials)

Standard PBMRS.2
Staff are qualified, trained, and competent to perform their responsibilities.

Element of Performance (EP) 6 [AABB Standard 2.1.4]
Individuals who order and/or transfuse blood meet facility-defined requirements for education related to patient blood management

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Q: What is the expectation for compliance with PBMRS.2, EP 6?

A: This standard requires credentialing of all individuals who order and/or transfuse blood. The glossary defines credentials as follows:

"Defined requirements for training, education, and experience within each facility that qualify individuals to perform specific procedures."

The goal of this standard is to ensure that blood transfusions, which are one of the most frequently performed procedures during hospitalizations in the United States, are only ordered by individuals with knowledge of the indications for that particular therapy. Similarly, individuals responsible for the transfusion of blood should be qualified to recognize problems and adverse reactions, and to understand the appropriate course of action in the event an adverse reaction is suspected.

In order to satisfy the requirement, patient blood management (PBM) programs should:
1. Develop requirements for the qualification of individuals who can order and/or transfuse blood.
2. Ensure that these requirements are met for any individual allowed to order and/or transfuse blood.
3. Be able to demonstrate to surveyors, through documents and records, that individuals who order and/or transfuse blood are qualified to do so. (This is required by Standard PBMRS.2, EP 3, Qualification, which states that "[p]ersonnel performing critical tasks shall be qualified to perform assigned activities…")

Credentialing or qualification of these individuals should include educational content that is relevant to the activity in question. For example, education required for individuals who order blood should include indications for transfusion of blood components and also information about situations under which transfusions may not be appropriate or indicated. The educational requirements for individuals who transfuse blood should include information about risks of transfusion and recognition of transfusion reactions. Both sets of individuals should also be familiar with hospital policies and protocols around informed consent for transfusion.
The educational programs may be developed internally or may be offered by external organizations such as AABB. In some cases, a PBM program may want to test the knowledge of individuals who order blood.

The educational content or certification materials used to meet this requirement can be developed by the PBM program or can be purchased from an external source (e.g., AABB's Patient Blood Management modules.) Regardless of the educational content used to credential these individuals, the program should be able to demonstrate that requirements for credentialing have been defined and met for all individuals who order and/or transfuse blood in the hospital.

Note: It is recognized that in the initial phase of this certification, some hospitals may not have completed credentialing of all individuals. However, the expectation is that all hospitals applying for certification should have defined the educational or training criteria for internal credentialing. The actual delivery of the education or training may be folded into the next annual cycle of training and competency assessments for these individuals. Hospitals in the process of implementing this credentialing program should be able to demonstrate to surveyors that the credentialing requirements are in place, that educational or training materials have been prepared, and that there is a timeline for the credentialing of all individuals who order or transfuse blood.

Appendix C – Additional Guidance for Perioperative Services

The following is a list of potential questions to ask during the perioperative services review. DO NOT use this as a checklist of topics to cover, but rather as suggested areas to explore.

- What is your perioperative autologous blood management program's organizational structure?
    - Show me your current organizational chart or written top down description of organizational structure.

- Show me evidence of your program's quality system.
    - How do you ensure that your quality system is understood and implemented by all personnel?

- What is the process to ensure that the requirements of AABB Standards and of regulatory agencies are incorporated into your documents and practices?
    - Who is the approving authority for medical and technical policies, processes, and procedures?
    - How are clinical situations that warrant exceptions to policies, processes, and procedures handled?

- What evidence exists that all devices have been validated for their intended use from collection through administration?

- What is the process to ensure that equipment monitoring, and maintenance conforms to manufacturer's written instructions, applicable regulations, and requirements?

- What is the process for investigating equipment malfunctions, failures, or adverse events associated with equipment, removal from service and reporting to the manufacturer when indicated?
    - What is the process to assess the effect on patient safety when equipment is found to be out of calibration?
    - What is the process used to alert personnel to malfunctioning/out-of-service equipment?
    - What is the process to ensure that necessary requalification is performed after equipment repair?

- Where do you store perioperative autologous blood components?
    - What temperatures are defined as acceptable for storage of collected perioperative products?

- Is the storage device used exclusively for perioperative salvaged products? If not, how are these products distinguished and/or kept separate from any other blood products?

- Is there validation to show that the storage device maintains proper temperature?

- Who is responsible for maintenance of the storage devices?

How are storage temperatures monitored? If not continuously monitored, is monitoring done at least every 4 hours? How are storage temperatures recorded every 4 hours?

If there is an automatic temperature monitoring process: what is your downtime procedure?

- If a third-party provider is used for perioperative autologous blood collection and administration, where can I find documentation that defines the qualifications of your third party provider?
  If the perioperative services are provided by a contract group, what involvement does the local medical director have in the oversight of the program?

- What is the process for developing, validating, and implementing new or changed processes and procedures (to include SOP, equipment, labels)?

- Show me/describe how you would prepare (assessor selected perioperative products).
  How do you ensure that aseptic methods are used throughout your processes?

- Review records for compliance with AABB Reference Standards 5.1.8A-C (pages 66-68)

- How is the medical director involved in the development of perioperative processes and procedures?

- What is the process to ensure that perioperative products are collected with a physician's order? (Acceptable documentation can include: standing orders based on certain procedures, verbal orders if documented, surgical listings/schedules, procedure record, documentation on the anesthesia record.)

- How do you document the inspection of perioperative products prior to transfusion?

- How are products labeled to identify the patient, the product content, and the expiration of the product?

- Are inspection criteria clearly defined and do they comply with manufacturer's written instructions?

- What do you do to ensure the risk of air embolism is minimized?
  Can you show me a written policy that pertains to prevention of air emboli?

- Review a sample of patient medical records for required product administration documentation.
  Review records of disposition for products that were not transfused.

- Are criteria for reporting adverse events documented?
  Were there any adverse events reported?

  Review documentation of any adverse events.

- How does the record system make it possible to trace any perioperative product from source to final disposition?

  How is does the record system make it possible to review the records applying to the specific product and to investigate adverse reactions manifested by the patient?

- What is the process for investigating possible adverse events related to administration of perioperative products?

  Does the procedure state that administration of the product will be interrupted if the recipient experiences complications?

  When there is a suspected adverse event related to perioperative product collection and/or administration, how does the policy address ensuring that this evaluation does not delay proper clinical management of the patient?

- What quality indicator data are collected and evaluated?

Reference Standard 5.1.8A—Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components					
Item No.	Collection Type	Storage Temperature	Time from the Start of Collection to Expiration[#]	Time from Completion of Processing to Expiration[#]	Special Conditions
1.	Acute normovolemic hemodilution (whole blood)	Room temperature	8 hours	N/A	None
2.	Acute normovolemic hemodilution (whole blood)	1-6 C	24 hours	N/A	Storage at 1-6 C shall begin within 8 hours of start of collection
3.	Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)^	Room temperature	N/A	8 hours	None
4.	Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)	1-6 C	N/A	24 hours	Storage at 1-6 C shall begin within 4 hours of completion of processing
5.	Intraoperative blood recovery without processing	Room temperature	N/A	8 hours	None

Item No.	Component Type	Storage Temperature	Expiration time		Special Conditions
6.	Shed blood under postoperative or posttraumatic conditions with or without processing	N/A	8 hours	N/A	None
7.	Combined intraoperative and postoperative blood recovery with processing	Room temperature	Postoperatively processed units: 8 hours from the start of postoperative collection	Intraoperatively processed units: 8 hours	None
8.	Red Blood Cells prepared by apheresis and intended for reinfusion	Room temperature	8 hours	N/A	None
9.	Red Blood Cells prepared by apheresis and intended for reinfusion	1-6 C	24 hours	N/A	Storage at 1-6 C shall begin within 8 hours of collection

^ Can include blood recovered from surgical sponges
# If manufacturer's written instructions are more stringent than this requirement, they shall be followed.

Reference Standard 5.1.8B—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion

Item No.	Component Type	Storage Temperature	Expiration time from start of collection	Special Conditions
1.	Platelet-rich plasma intended for reinfusion	Room temperature	8 hours	None
2.	Platelet-rich plasma intended for reinfusion *	1-6 C	24 hours	Storage at 1-6 C shall begin within 8 hours of collection
3.	Plasma intended for reinfusion	Room temperature	8 hours	None

4.	Plasma intended for reinfusion	1-6 C	24 hours	Storage at 1-6 C shall begin within 8 hours of collection

* The storage requirements herein apply only to components not intended for platelet activity.

Reference Standard 5.1.8C—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application

Item No.	Component Type	Storage Temperature	Expiration#	Special Conditions
1.	Platelet-rich plasma intended for topical use or injectable use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
2.	Platelet-poor plasma intended for topical use or injectable use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
3.	Thrombin intended for topical use	Room temperature	Within 8 hours after component preparation (or not to exceed device manufacturer's recommendations)	Shall be used before the patient leaves the operating room or clinical procedure area
4.	Bone Marrow Aspirate Concentrate intended for topical use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area

If manufacturer's written instructions are more stringent than this requirement, they shall be followed.

Appendix D – Additional Resources

AABB Educational Resources

AABB has several resources available to help organizations develop a comprehensive PBM program. Please visit the following websites for more information:

http://www.aabb.org/pbm/Pages/default.aspx
AABB offers resources that address the various aspects of PBM, helping organizations achieve their goals of optimizing patient outcomes, preventing unnecessary blood usage and auditing physician compliance with established criteria for transfusion.

http://www.aabb.org/pbm/Pages/pbm-resources.aspx
Access the AABB PBM resources available to address the various challenges within your facility and improve patient care.