
1. ORGANIZATION

1.0 Organization

The patient blood management program (herein after referred to as the program) shall have a structure that clearly defines and documents the parties responsible for the oversight and review of patient blood management (PBM) activities and the relationship of individuals responsible for key quality functions. This interdisciplinary program shall be patient-centered, evidence-based, data-driven, and outcomes-focused.

Guidance

The primary purpose of this chapter is to ensure that a PBM program (hereinafter “the program”) has statements of quality goals or objectives. All individuals involved in activities that are related to the provision of PBM should understand the quality goals and objectives of the program and their responsibility for fulfilling those goals and objectives. Another purpose is to ensure that management at the highest level of the program is ultimately responsible and accountable for quality in the activities covered by *PBM Standards*. *PBM Standards* also requires that the relationship of individuals or departments that are responsible for key quality functions for the PBM program are defined. An organizational chart is one means of meeting this standard.

1.1 Executive Management

The program shall have a defined executive management structure. Executive management shall have:

- 1) The responsibility and authority for oversight and review of the program.
- 2) The authority to establish or change the program’s quality system.
- 3) The responsibility for compliance with these *PBM Standards* and applicable laws and regulations.
- 4) The responsibility for collecting and reviewing of data on PBM including patient outcomes and program performance metrics.
- 5) The responsibility to identify stakeholders and to communicate results to these stakeholders.

Guidance

Although others in the facility may be more involved in carrying out the quality system, executive management is ultimately responsible and accountable for the quality of the activities covered by *PBM Standards*. Executive management of the program should play a visible role in supporting and implementing the quality system throughout the program.

Executive management is defined as the highest-level personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the program and who have the authority to establish or to make changes in the program’s quality policies. Based on this definition and the structure of this chapter, the medical director is required to be a member of executive management (see Standard 1.1.1). Executive management may be an individual or a group of individuals. The program must define the structure of executive management in its policies. An organizational chart may be considered.

1.1.1 Medical Director Qualifications and Responsibilities

The program shall have a medical director who is a licensed provider/physician and qualified by education, training, and/or experience.

- 1.1.1.1 The medical director's responsibilities shall include, but not be limited to:
- 1) Leadership and oversight on clinical issues.
 - 2) Consultative and support services on PBM matters that relate to the care and safety of patients.
 - 3) Identification of program resources needed to conform to these *PBM Standards*.
 - 4) Communication of program results and opportunities for improvement to executive management and hospital staff at least annually.

Guidance

Standard 1.1.1.1 requires that the medical director approve and ensure that the program adheres to a written quality manual and operational policies, processes, and procedures.



- 1.1.1.2 The medical director may delegate these responsibilities to another qualified individual(s); however, the medical director shall retain ultimate responsibility.

- 1.1.2 Executive management shall define the activities of the PBM program tied to patient outcomes.

- 1.1.2.1 A PBM program can be designated as a program activity level 1, 2, or 3 program. To be designated a specific activity level, the program shall be responsible for or have direct involvement with oversight and monitoring of the following activities:

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
1	Evidence of institutional support for the PBM program at the hospital administration level	X	X	X
2	Metrics regarding transfusion appropriateness consistent with transfusion guidelines	X	X	X
3	Documentation of transfusion including patient consent, observation, adverse events, and outcomes	X	X	X
4	Budgeting to the level of care required by implementing these <i>PBM Standards</i>	X	X	X
5	Pretransfusion patient testing and evaluation	X	X	X
6	Patient- or case-specific assessment of potential blood usage	X	X	X
7	Preprocedural blood ordering, including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients	X	X	X
8	Preprocedure assessment and management of patient coagulation status	X	X	X

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
9	Monitoring of blood components wastage and cause	X	X	X
10	Minimize blood loss due to laboratory testing (iatrogenic blood loss)	X	X	X
11	Process for managing the blood needs of unidentified patients and resolving their identification	X	X	X
12	Processes to identify, before or upon admission, patients who may decline transfusion with notification to the appropriate individuals (including providers) and noted in the patient's medical record	X	X	X
13	Massive transfusion/massive hemorrhage protocol for all patient populations with documented evaluation of activation and protocol workflow effectiveness with evidence of its use	X	X	X
14	Transfusion care and anemia management of preterm, neonate, infant, and pediatric critical care patients, if applicable	X	X	X
15	PBM care for obstetric patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (eg, placental abnormalities), and plans for patients for whom blood is not an option	X	X	X
16	Single-unit transfusion strategies for defined clinical settings	X	X	X
17	Management of acquired coagulopathy	X	X	X
18	Blood conservation strategies for service lines associated with high blood usage	X	X	N/A
19	Processes and/or equipment to facilitate rapid decision-making concerning anemia and coagulation management	X	X	N/A
20	Evaluating and managing iron and micronutrient deficiencies in patients with Red Blood Cells ordered in the inpatient and out-patient populations	X	X	N/A
21	Evaluation and management of identified anemia in patients	X	N/A	N/A
22	Program to care for patients who decline use of blood or blood-derived components	X	N/A	N/A
23	Identification and management of pre-surgical anemia before elective procedures for patients at risk for Red Blood Cell transfusion and/or adverse consequences of postsurgical anemia	X	N/A	N/A
24	PBM care for patients undergoing cardiac surgical or structural heart procedures	X	N/A	N/A
25	Use of perioperative techniques consistent with current AABB <i>Standards for Perioperative Autologous Blood Collection and Administration</i>	X	N/A	N/A