

## Significant Changes and Response to Comments Received to the 4<sup>th</sup> edition of Standards for a Patient Blood Management Program

Please note that public comments that were submitted address the proposed 4th edition of Patient Blood Management Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 4th edition of Patient Blood Management Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	SC/RC	Comment	Change Made?	Outcome
1.0	SC	NA	NA	The committee elected to add the term “evidence based” to the standard for completeness. The addition ensures that all decisions are based in quantifiable fact that can be proved.
1.1.1	SC	NA	NA	The committee added the term “provider” as a person able to serve in the role of medical director. This addition ensures that the standards mirror the reality of the field.
1.1.1	RtC	I object to the use of the word "provider". The medical director should be a physician.	NO	The committee noted this comment but did not feel that a change would be appropriate. Currently there are a number of staff shortages that this expansion will address. It should be noted that the qualifications would ensure that the program would have to have an individual that fits the role based on their education, training and experience.
1.1.1.2	SC	NA	NA	The committee added a record retention requirement to standard 1.1.1.2 to ensure that the individual who is designated as a medical director designee has their personnel record to indicate as much.
Activity Level, Item 2	SC	NA	NA	The committee replaced the term “in accordance with” with “consistent with” for clarity.
Activity Level, Item 8	SC	NA	NA	The committee added the clause “assessment and management” for clarity replacing the term “optimization.” The term “status” replaced “function” for accuracy as it relates to patient coagulation.
Activity Level, Item 10	SC	NA	NA	The committee added the clause “iatrogenic blood loss” for completeness and clarity.
Activity Level, Item 12	SC	NA	NA	The committee removed the clause “under any circumstances” as it was more guidance than standard. The addition of the parenthetical “(including providers) and

				“and noted in the patient’s medical record” was included for completeness.
Activity Level, Item 13	SC	NA	NA	The committee elected to add the clause “massive hemorrhage” to entry 13, and throughout the Standards (5.11.1, 5.17, and 8.3) where massive transfusion is included. The committee noted that massive hemorrhage does imply other strategies than just transfusion of blood. Noting that massive transfusion is a part of any massive hemorrhage protocol. Including both terms can serve as a bridge to potentially moving towards one universal term. The committee also added the clause “...for all patient populations” for clarity to ensure that all patients that could be considered for all mtp/mhps.
Activity Level, Item 13	RtC	I would like to see the language throughout this document changed from massive transfusion protocol to massive hemorrhage protocol. Use of MHP implies the inclusion of other strategies outside of transfusion of blood components such as factor concentrates, pharmaceuticals, cell salvage, topical hemostats etc.	YES	The committee noted this comment and agreed with the request. The committee added the term “massive hemorrhage protocol” anywhere “massive transfusion protocol” is included as a bridge to a universal term in the future.
Activity Level, Item 15	SC	NA	NA	The committee replaced the clause “where blood is not an option” with “for whom blood is not an option” for clarity. The change has been made throughout the document wherever this terminology is used.
Activity Level, Item 15	RtC	I recommend maintaining the verbiage "blood is not an option" throughout the document as there are patients that do not necessarily decline blood component therapy, but blood is not an option due to lack of readily available units e.g. patients with rare blood types, access to blood components etc.	YES	The committee agreed with this comment and made the change as requested.

Activity Level, Item 16	SC	NA	NA	The committee replaced the term “patient population(s)” with “clinical settings” for clarity. It should be noted that in the situation described, this is defined by the clinical situation versus the patient.
Activity Level, Item 20	SC	NA	NA	The committee removed the term “defined” as the committee deemed it unnecessary with the inclusion of the clause “...inpatient and...” to ensure that the full patient population (both inpatient and outpatient) served by the Standards covered in the chart.
Activity Level, Item 20	RtC	I suggest changing “Red Blood Cells ordered” to “red blood cells components or units ordered for transfusion.”	NO	The committee did not feel that the change was necessary at this time and did not feel that this inclusion would strengthen the standard.
Activity Level, Item 21	SC	NA	NA	The committee edited entry 21 by removing the clause, “nonoperative” to reflect that this requirement applies to more than just that patient population.
Activity Level, Item 21	RtC	Recommend adding the word "all" before patients as indeed, all patients, whether medical or surgical, should be evaluated and treated based on the etiology of the anemia.	YES	The committee agreed with this comment for clarity and removed the term “all.” This inline with the change to remove “nonoperative” from the entry provides full clarity.
Activity Level, Item 23	SC	NA	NA	The committee expanded element 23 for clarity. The inclusion of “patients at risk for Red Blood Cell transfusion and/or adverse consequences of postsurgical anemia.” will better reflect what occurs in a PBM program.
Activity Level, Item 23	RtC	Urgent patients may also be treated with short or ultra-short therapies using hematinic agents to stimulate erythropoiesis in the perioperative period. See 5.6.2.	NO	The committee noted this comment but did not feel that a change was needed at this time and felt that this addition would be beyond the scope of the current set of Standards.
Activity Level, Item 24 (New)	SC	NA	NA	The committee added new entry #24 to the edition and was added in recognition that these Standards reflect cardiac surgical settings. This will act as an activity level 1 requirement.
1.5.1 (New)	SC	NA	NA	The committee added new standard 1.5.1 to the edition and was based on language in

				the <i>Standards for Blood Banks and Transfusion Services</i> . This standard ensures that as a part of the PBM program’s operational continuity plan, all certified programs will have plans in place to address potential inventory shortages.
1.5.1 (New)	RtC	Suggest removing "a" after "shall have"	YES	The committee agreed with this comment and removed the term accordingly.
2.1.3.1 (New)	SC	NA	NA	The committee added new standard 2.1.3.1 to the edition for completeness. This standard appears in other sets of AABB Standards requiring that action be taken when competence has not been demonstrated.
2.1.4	SC	NA	NA	The committee edited standard 2.1.4 to ensure that the facility defined education given to individuals in the patient blood management program was focused on actual patient blood management. The wording that appeared previously was deemed to lack specificity.
3.0	SC	NA	NA	The committee expanded the content of standard 3.0 for clarity. The understanding would be that PBM programs are typically only a part of the decision-making process as it relates to equipment and agreements.
3.1.3 (New)	SC	NA	NA	The committee added new standard 3.1.3 to the 4th edition for completeness. This standard which requires that PBM programs have processes in place to minimize the risk and impact of internal and external data breach has been added to all other AABB Standards.
3.2.1	SC	NA	NA	The committee included the new clause, “or the requirements of an equivalent accrediting body” to standard 3.2.1 requiring for parallel construction with other standards (6.0 and 7.0) where the same language exists.
Chapter 4, 4.0	SC	NA	NA	The committee has replaced the title of chapter 4 and standard 4.0 from “Supplier and Customer Issues” to “Suppliers and Customers” to reflect similar changes made in every other set of Standards.
4.2.2	SC	NA	NA	The committee edited standard 4.2.2 for clarity by moving the clause, “are performed by a third party provider” to appear earlier in the same sentence.

				However, the intent of the content or standard has not changed.
4.2.2	RtC	Suggest removing "the" after "provider performs."	YES	The committee agreed with this comment and removed the term as requested.
5.0	SC	NA	NA	The committee replaced the clause “patients who decline blood” with “patients for whom blood is not an option” for parallel construction throughout this edition.
5.1.1, #4 (New)	SC	NA	NA	The committee created new subnumber 4 to standard 5.1.1 for completeness. This addition ensures that individuals with heavy bleeding potential are addressed in this edition of Standards. The entry reads, “Patients with or at risk for coagulopathy are evaluated and managed.”
5.1.3	RtC	The first line is not very clear and I think will not be obvious to 2nd or 3rd language English speakers.	YES	The committee agreed with the comment submitted and clarified the language in the first line to focus on not using blood while ensuring that individuals were able to meet activity level requirements.
5.1.3	SC	NA	NA	The committee edited standard 5.1.3 to include “coagulopathy” to mirror the inclusion of it to standard 5.1.4 as well. The committee also re-arranged the standard in a manner to appear as a list for legibility. In the narrative portion of the standard, the committee replaced the term “establish” with “utilize” and removed two clauses “when available” and “when possible” that are difficult to assess.
5.1.3, #1	SC	NA	NA	The committee added the clause “and coagulopathy” for completeness.
5.1.3, #2	SC	NA	NA	The committee added the clause, “...and promoting blood recovery” as this should be a part of all guidelines associated with patient blood management.
5.1.3, #3	SC	NA	NA	The committee added the clause, “...without the use of blood components” for clarity. The focus of this subnumber is on not using blood components while remaining in concert with the activity level requirements for the program.
5.1.4.1	SC	NA	NA	The committee edited standard 5.1.4.1 by replacing the clause “transfusion guidelines” with “PBM guidelines”, ensuring the standard reflects a focus on PBM guidelines (which includes transfusion) rather than being more restrictive.

5.1.5	SC	NA	NA	The committee edited the lead sentence of standard 5.1.5 for clarity by including the term “review” to the standard, while also including “defined intervals” concerning educational materials for the PBM program. This ensures that educational materials are reviewed and shared at times set forth and validated by the program.
5.1.5, #1	SC	NA	NA	The committee elected to replace the term “elements” with “strategies” for clarity while also including, “surgical” to the areas where PBM strategies need to be created and available.
5.1.5, #4 (New)	SC	NA	NA	The committee created new subnumber 4 requiring that PBM programs have strategies focused on coagulopathy evaluation and management in surgical patients. This addition is in line with edits made to standard 5.1.4.
5.4.1	SC	NA	NA	The committee revised standard 5.4.1 for clarity. The committee added the term “component” to ensure specifics are in line for single unit transfusion strategies. The committee also replaced the term “patient populations” with “clinical settings” to allow for parallel structure with other standards throughout the edition.
5.5.3	SC	NA	NA	For completeness, the committee expanded the standard include “under transfusion” to align with “over transfusion” which was included previously. The committee also included a crossreference to standard 9.0 referencing corrective and preventive action.
5.6.1	SC	NA	NA	The committee edited the lead sentence in standard 5.6.1 to include the clause “procedural/surgical” patients for completeness.
5.6.1, #5	SC	NA	NA	The committee elected to remove the following from subnumber 5 “including clinically indicated preoperative autologous blood donation, intraoperative blood recovery, hemostatic agents, acute normovolemic hemodilution, treating postoperative anemia with medications, and/or anemia tolerance.” as it was deemed to be guidance and not a requirement. These elements have been reincluded into the guidance for this standard.

5.6.2	SC	NA	NA	The committee edited the lead sentence of standard 5.6.2 for legibility and clarity. The committee added the clause, "...patients undergoing urgent or...". This addition does not change the intent of the standard merely clarifies it.
5.6.2, #3	SC	NA	NA	The committee edited subnumber 3 to include a requirement that there be an assessment of a patient for pre-existing anemia. This addition was included to mirror language included in chapter 1.
5.6.2, #5d (New)	RtC	Add new subletter "d": d) management of coagulation status with rapid testing	YES	The committee agreed with this comment and added a new subletter d to subnumber 5 which reads as follows, "utilization of program-defined rapid testing for coagulation management." The purpose of the addition was done for completeness recognizing that rapid testing is a means to stop bleeding.
5.8	SC	NA	NA	The committee edited standard 5.8 for clarity, however the intent of the standard has not changed. The committee also included the new elements of "iron and micronutrient replenishment" for completeness. This was included understanding that this is a means of treating patient with anemia.
5.8	RtC	Did you really want to use the word "repletion" here as opposed to "replacement"? the use of "repletion", when associated with food means engorgement or oversaturation. Is that the intent of using this word? I would think that using "replacement" would mean to restore the iron level to the pre-anemic state and would cover both inadequate iron restoration and excessive iron administration.	YES	The committee noted this comment, and as a result replaced "repletion" which was included in the proposed edition with "replenishment" for clarity. Replenishment ensures that the intent is to get the patient back to baseline.
5.8	RtC	In addition to "iron repletion" would add "iron as well as other	YES	The committee agreed with the intent of this comment, and added the clause "other micronutrient" with regard to replenishment.

		hematinic (e.g. vit B12, folate, zinc) repletion.		
5.11, #3	SC	NA	NA	The committee edited subnumber 3 for clarity by replacing “prenatal” with “antepartum and postpartum” to expand where anemia management takes place, expanding the focus of the standard.
5.11.1, #1 (New)	SC	NA	NA	The committee added new subnumber 1, “Patients for whom blood is not an option” to the edition for completeness, matching similar requirements throughout the edition.
5.11.1, #3 (5.11.1, #2)	SC	NA	NA	The committee added the term “implantation” to subnumber 3 clarifying the requirement to read, “placental implantation abnormalities.” The change was made for accuracy.
5.11.1, #4 (5.11.1, #3)	SC	NA	NA	The committee added the term “massive hemorrhage” to the standard to read, “massive transfusion/massive/hemorrhage” for parallel construction throughout the edition.
5.13	SC	NA	NA	The committee added the term “plan” to the second sentence of the standard. This change does not affect the intent of the standard, but merely clarifies the requirement.
5.15	RtC	I suggest replacing “RED Blood Cell orders in outpatient setting” to “red blood cell transfusion orders in the outpatient setting.”	YES	The committee agreed with this comment and edited the standard to read, “Red Blood Cell.” The change does not alter the effect of the standard.
5.17, #7	SC	NA	NA	The committee elected to replace the term “type” with “category” in subnumber 7 for accuracy.
5.17, #16 (New)	SC	NA	NA	The committee added new subnumber 16 for completeness. The addition of “bloodless program enrollment/evaluation of effectiveness.” brings the standards into conformance with current practice.
6.2.1.1, #2	SC	NA	NA	The committee added the term “indelible” into subnumber 2 for completeness. This ensures that the standard remains consistent with requirements set forth in all other sets of AABB Standards.
6.2.1.1, #3 (New)	SC	NA	NA	The committee added new subnumber 3 for completeness, requiring that all records be “identified as a copy.” This ensures that the



				standard remains consistent with requirements set forth in all other sets of AABB Standards.
6.3	SC	NA	NA	The committee edited the standard replacing the clause “participate in the development” with “develop”, putting the onus on the PBM program to develop all new policies, and changes to all existing policies, processes and procedures that affect the quality of PBM program activities.
8.3, #6 (New)	SC	NA	NA	The committee added new subnumber 6 to standard 8.3 requiring that PBM programs “Use of perioperative blood management techniques.” This ensures that the standard remains in conformance with the requirements contained in the activity level chart in chapter 1.
8.3, #8 (8.3, #7)	SC	NA	NA	The committee added the term “massive hemorrhage” to the standard to read, “massive transfusion/massive/hemorrhage” for parallel construction throughout the edition.
8.3, #10 (8.3, #9)	SC	NA	NA	Subnumber 10 has been edited to focus the requirements of the subnumber on PBM activities and a move away from transfusion activities. This edit has been made to parallel other changes throughout the edition.