



Advancing Transfusion and  
Cellular Therapies Worldwide

**Statement of AABB  
Before the Blood Products Advisory Committee  
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AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include 1800 hospital and community blood centers, transfusion and transplantation services and 8000 individuals involved in activities related to transfusion and transplantation medicine. For over 50 years, AABB has established voluntary standards and inspected and accredited institutions. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. AABB's highest priority is to maintain and enhance the safety and availability of the nation's blood supply.

At this meeting of the Blood Products Advisory Committee (BPAC), the committee has been asked to consider the extent to which available scientific data may support potential changes to further standardize processing of plasma products for transfusion and to identify additional scientific studies that would be helpful to resolve current areas of uncertainty. In preparation for this meeting, AABB consulted its Clinical Transfusion Medicine Committee (CTMC) to determine how various plasma components are being used in clinical practice and if changes in preparation of these components would improve clinical outcomes. Plasma is most commonly transfused into patients with multiple coagulation defects. The most common uses are for patients undergoing surgery and experiencing surgical blood loss, trauma patients, patients with impaired clotting resulting from liver disease, patients on excessive coumadin therapy, and treatment of patients with Thrombotic thrombocytopenic purpura (TTP).

For treatment of the conditions listed above, Factor VIII levels in the transfused plasma are not critical to the therapeutic effect of the component. Specifically, Factor VIII levels in patients experiencing general surgical bleeding are usually above normal, since Factor VIII is an acute stress response protein. In patients with liver disease, Factor VIII levels are generally normal. Factor VIII plays no role in coumadin reversal. The CTMC noted that Factor VIII is critical only in the case of treatment of Factor VIII deficiency. In that case, plasma components would be used to treat Factor VIII deficiency only in the rare instance that factor concentrate is not available.

Fresh Frozen Plasma (FFP), Plasma Frozen Within 24 Hours of Collection (FP24), and Thawed Plasma are used interchangeably in many facilities, especially at large tertiary care hospitals with busy Level I trauma centers. One of the physician members of the CTMC also reported using these components interchangeably in a busy therapeutic apheresis center. There are, however, specific treatment indications for FFP and FP24; an example is the treatment of neonates with coagulopathies. In summary, when used appropriately, FFP, FP24 and Thawed Plasma are all widely used and can produce good clinical outcomes.

AABB believes there is no current problem with the efficacy of plasma for transfusion. In the absence of new data, therefore, there is no clinically compelling reason to require changes in the preparation and storage of plasma components. In fact, much of the literature reviewed at this meeting attempts to judge the quality of plasma for transfusion through the measurement of Factor VIII levels in the components. As noted above, Factor VIII is generally not clinically relevant to the therapeutic benefit of plasma components. In addition, AABB cautions that Factor VIII is not an appropriate surrogate for the measurement of levels of other more stable coagulation factors in stored plasma components. There is no evidence that adding a requirement aimed at preserving Factor VIII content would result in an increase in the therapeutic value of plasma components. Furthermore, such a requirement could send clinicians the erroneous message that FFP can be used for Factor VIII replacement, when that component is clearly not the treatment of choice in case of Factor VIII deficiency.

AABB believes that, given all of the competing priorities in transfusion medicine, there is no need to require changes in present methods of preparation of plasma for transfusion. Any changes to regulation should be based on evidence of beneficial clinical outcomes. AABB believes that the time and effort spent in reducing inappropriate ordering of plasma transfusions by clinicians would produce greater benefits to patients than would result from focusing on changes in plasma preparation. A commitment of resources and research dollars to the plasma production area will detract from other issues that can better benefit clinical outcomes.