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Implementing a hemodilution program

A blood banker indicates that her medical center is considering implementing a hemodilution program. She has questions regarding the hemodilution program's oversight and regulatory compliance. As part of her medical center's due diligence they have spoken to a representative at CBER, whom they quote as saying that **FDA** inspectors would NOT have purview over perioperative blood recovery programs. However, they discovered that the **AABB** has issued new Standards for perioperative autologous collection programs and that the AABB will offer a SEPARATE accreditation for such programs. The inquiring blood banker also reports that a perioperative program can be assessed (and hence accredited) as part of a facility's JCAHO survey, thus not requiring separate AABB accreditation. According to **JCAHO** Laboratory Standards, Standard QC.5.1.5 requires that cell salvage processes must be addressed in written policies and procedures, and the director's responsibilities for these activities must be defined. Finally, the College of American Pathologists (**CAP**) Transfusion Medicine Inspection Checklist (*MS Word*) (*PDF*) also addresses perioperative autologous blood collection and administration as part of the hospital laboratory accreditation process.

Editor's NOTE: The First Edition of the **AABB** Standards for Perioperative Autologous Blood Collection and Administration is **now in print** and available from AABB; the stock number is 013100OL01. The cost is \$85.00 for non-members and \$65.00 for members. The effective date for compliance will be the first quarter of 2002. The AABB standards offer a systematic way of ensuring all regulatory requirements are met, and the transfusion service would play a critical role in this process. The AABB Standards for Perioperative Autologous Blood Collection and Administration also require that the perioperative program has defined executive management, and the program has a medical director who is a licensed physician that is qualified by training and/or experience. Since the AABB committee creating these standards included liaisons from the FDA, one could assume that compliance with this new AABB document would allow for compliance with FDA expectations. In addition, the College of American Pathologists' newest Transfusion Medicine **Checklist** (as above) has **three questions that are germane to perioperative autologous blood recovery and reinfusion programs**. They are:

- QUESTION: TRM.41525 Is the authority, responsibility, and accountability of the perioperative blood recovery and reinfusion program defined?
- QUESTION: TRM.41550 Is an acceptable procedure for intraoperative or perioperative blood recovery defined?
- QUESTION: TRM.41600 Is the transfusion service Medical Director involved in establishing policies and procedures related to intra- and peri-operative collection and reinfusion procedures?

The inquiring institution asks other Transfusion Services for **feedback or suggestions regarding their role in a perioperative program and the steps taken to insure that all quality requirements are met**. Finally, in the process of instituting the cell salvaging procedures, the inquiring laboratory has questions regarding **how other laboratories monitor the patient's coagulation status**. Has any transfusion service determined if after a certain volume of washed cells has been given back to the patient there is a need for assessment of replacing coagulation factors and the assessment of platelets and fibrinogen?

The following response has been submitted:

1. **A blood banker whose hospital implemented a perioperative blood collection program** reports the following experience. "The first hurdle is to establish which physician will be responsible for this program. Most of the time the lab or blood bank director is assigned this responsibility. I recommend following the AABB Standards for Perioperative Autologous Blood Collection in setting up this program. If the lab or another department assumes responsibility, follow the Quality program approach. You will probably need both a hospital administrative policy and a department policy defining the program, who is responsible, how are all parties accredited, what is to be done, etc. You will need technical procedures to include quality control, equipment maintenance, infusion of the salvaged products, storage of salvaged products, etc. Note: if your hospital decides to employ an outside vendor, the vendor still needs to supply SOPs. The responsible department must review

SOPs annually and review QC at defined intervals."

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