

should look carefully at its own situation and anticipated needs when planning.

Legal Considerations

It is extremely important to seek the advice of counsel in the early stages of planning for a blood recovery service. State laws relating to autologous transfusion should be reviewed as early as possible in the planning process. Some states have enacted laws dealing with the availability of autologous transfusion and with informed consent regarding these options.⁶⁵ Each institution should follow its policy on informed consent before performing these procedures. Some states have regulations limiting the roles for different health-care professionals that may affect which personnel can assume responsibility for various aspects of the program. In addition to state laws, regional practices may vary throughout the country. Therefore, the institution should also investigate the local standard of care as policies and procedures are developed. In the situation of patients with religious objections to transfusion, specific informed consent should be documented after the options have been thoroughly discussed with the patient and a plan has been agreed upon.

REGULATORY REQUIREMENTS

Two agencies promulgate regulations concerning the provision of blood recovery services: the FDA and, in some states, the State Department of Health. The FDA addressed blood recovery in the 1989 and 1990 memoranda concerning autologous blood and the classification of medical devices.^{66,67} The FDA stipulates that recovered units of autologous blood that are removed from the patient and stored in the blood bank must meet all of the requirements in Title 21 CFR part 606, Current Good Manufacturing Practices for Blood and Blood Components.⁶⁸

VOLUNTARY STANDARDS

Voluntary standards with respect to blood recovery have been established by several professional organizations including the AABB, the College of American Pathologists (CAP), the Society for the Advancement of Blood Management (SABM), and The Joint Commission. In the current edition of the AABB *Perioperative Standards*²¹ the AABB has established minimum requirements for the assessment of blood recovery services. The CAP assessment includes questions to determine adequate physician oversight and the presence of safe procedures and monitoring of the program. The SABM standards are not tied to an accreditation program.

The Joint Commission defines multiple areas of responsibility and authority for hospital activities, including blood recovery. Performance Improvement requires a hospital to collect and assess data and to utilize that data for improving institutional performance.⁶⁹ Leadership requires service directors to assess qualifications and competency of all individuals who provide patient care services and are not licensed, independent practitioners. Information Management outlines necessary requirements for the medical record. Human Resources deals with staffing, job expectations, competency, and training. Environment of Care deals with maintenance of equipment.⁶⁸ Quality System Assessment requires that the hospital conform to the AABB *Standards for Blood Banks and Transfusion Services*, that the staff be knowledgeable concerning blood transfusion, and that the transfusion service medical director participate in the evaluation of adverse reactions.⁷⁰

QUALITY ASSURANCE

Quality Assurance (QA) should be an integral part of the provision of a program for perioperative autologous blood recovery and reinfusion. QA ensures that the important steps in the process of rendering a service or providing a product are followed and the

service or product satisfies all applicable quality standards and expectations for meeting patient needs.

The FDA has recommended that hospital transfusion services conform to the quality assurance guidelines proposed in the 1995 Quality Assurance Memorandum.⁷¹ The AABB has also developed the outline for a quality plan to help transfusion services and blood banks develop their QA programs.^{71,72} Whatever approach is used to organize the quality plan for the autologous blood recovery and reinfusion service, it should certainly be an element of the hospital or transfusion service QA program.

Program Implementation

Once the decision has been made to initiate a program, sufficient time should be allowed before initiation of the service for the development of protocols and quality assurance procedures. Successful programs usually result when all of the departments directly involved in or affected by the blood recovery service (eg, blood bank, nursing, surgery, anesthesia, transfusion committee) participate in this phase of planning and development. At a minimum, the procedures should be reviewed by personnel representing these departments. In addition, the hospital legal and quality assurance departments should be involved in the early stages of planning as well as in the final review of policies and procedures. Sufficient lead time should also be designed into the implementation phase to allow for training of involved personnel.

Physician interest is also important. Establishing a program is much easier and more effective if the surgeons and anesthesiologists are well informed about the techniques and benefits of blood recovery and are committed to the success of the program.

Lastly, the patient should be involved through a process of informed consent. At a minimum, elements should include all of the following: 1) a description of the risks, benefits, and treatment alternatives (including no treatment); 2) an opportunity to ask and receive answers to questions; and 3) the right to accept or refuse treatment.⁷⁴