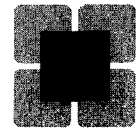

Quality assurance and safety of the blood supply

THE DECISION to transfuse blood components is the responsibility of the physician ordering the blood. Physicians and transfusion service directors alike have viewed the blood bank as a support service that exists to assure sufficient supplies of blood and blood products are available, properly tested, accurately cross matched, promptly delivered, and properly investigated in the event of a transfusion reaction. These important services continue under the oversight of the hospital's transfusion committee.[1]

■ *See Hoeltge et al (pp 267–272)*

What has been added in recent years is that the hospital transfusion committee has become responsible for establishing criteria for quality assurance. The hospital transfusion committee must establish guidelines for transfusion of blood components and must approve a procedure for monitoring clinicians' adherence to these guidelines. This change has taken place largely due to requirements of the Joint Commission on Accreditation of Health Care Organizations (JCAHO).

JCAHO REQUIREMENTS

To meet JCAHO accreditation requirements, documentation must establish that a therapeutic program, procedure, or drug is appropriate for the care of the patient. Appropriateness of care is monitored and measured against standards established by the medical staff. These guidelines for standards of care should be taken into account by each physician in each decision-making process. Procedures should afford a physician not in compliance with guidelines an opportunity to medically justify his or her rationale for therapy. Procedures are also needed to monitor compliance when a physician's rationale for therapy cannot be medically justified. In addition, there must be a process whereby criteria for appropriateness of care are re-evaluated as new scientific information becomes available.

In this issue of the *Cleveland Clinic Journal of Medicine*, Hoeltge et al describe documentation of the appropriateness of blood component therapy using a computer-assisted algorithm. This important paper describes a workable method for addressing the problem of quality assurance in transfusion practices.

CONSENSUS CONFERENCES

That there is such a problem can be readily discerned by noting the topics of recent Consensus Conferences sponsored by the National Institutes of Health. In September 1984, a conference on the indications and risks of fresh frozen plasma was held; the use of this component had inexplicably increased tenfold over the previous 10 years.[2] In October 1986, a similar conference was held on the use of platelets,[3] and in June 1988,[4] a conference was sponsored by the National Heart, Lung and Blood Institute to review perioperative use of red cells. One of the conclusions of the conference on red cells was that there is no scientific evidence to support the assumption that mild-to-moderate anemia contributes to perioperative morbidity or to support the "10/30" rule (10 g of hemoglobin per dL/30% hematocrit), which had been the traditional trigger for perioperative transfusion. While the practice of medicine by consensus has shortcomings, the information made available by these meetings should be considered by hospital transfusion committees when updating transfusion criteria.

ROLES OF PHYSICIAN AND DIRECTOR

A vital part of the quality assurance program described by Hoeltge et al is the mechanism for and encouragement of physician input in cases where transfusion could not be justified by established criteria. One value of a good quality assurance program is the opportunity for education.

The director of the transfusion service should be an expert in transfusion medicine—a discipline that covers all aspects of transfusion from the recruitment of the blood donor to the administration of appropriate blood components to the patient—and is thereby a valued consultant in a field whose body of knowledge has grown enormously. Conversely, the physician has the opportunity to educate the director of the transfusion service about the clinical aspects of patient care. This interaction permits grassroots continuing medical education from which both physicians and patients profit.

This interaction is also necessary to avoid the practice of medicine by rote. While criteria provide essential guidelines, they are no substitute for sound clinical judgment based on documented medical information and experience.

THE SAFETY ISSUE

The hospital transfusion committee and quality assurance programs must also be viewed in the broader context of their roles in improving safety of transfusion—an issue of major concern for both physicians and patients. A safe blood supply has always been a primary goal of transfusion medicine.

This discipline has just celebrated its 50th anniversary. For its first 46 years, the blood supply was perceived as being safer than it actually was by both physicians and the public. Blood has always enjoyed a "magical" quality. Its value was rightly held in high esteem, although its risks were underestimated.

During the past four years, however, since the AIDS epidemic has been recognized as a serious threat to the nation's health, the blood supply has been perceived as far less safe than it actually is. Blood is and will continue to be an invaluable therapeutic modality, without which physicians could not perform many therapeutic procedures such as heart and vascular surgery, cancer chemotherapy, joint replacement, trauma, and transplantation.

Nonetheless, transfusion therapy carries with it some risks. Those risks are predominantly of an allergic, immunological, and infectious nature. The most common infectious risk continues to be transfusion-associated non-A, non-B hepatitis.[5] This risk has probably decreased over the past two years since the inception of nonspecific testing for alanine aminotransferase (ALT) and antibody to hepatitis B core antigen (anti-HBc). There is now the hope that, with the isolation of the virus believed responsible for most non-A, non-B hepatitis, a specific test will become available, further improving the safety of the blood supply.[6]

While hepatitis is the most common infectious disease caused by transfusion, the one most feared is AIDS. This infection is a very low-risk but very high-consequence transfusion-associated complication. The resulting concern is understandable. The most effective way to prevent transfusion-associated AIDS is by educating potential donors whose behavior places them at risk for AIDS infection not to donate blood.

This process has worked well, but it is not perfect. When testing commenced in March 1985, the Northern Ohio Red Cross Blood Services found 24 of 150,000 (0.016%) donors whose blood tested positive for the antibody to the human immunodeficiency virus (anti-HIV). Of the first 200,000 donors in 1988, blood samples of two (0.0013%) tested positive for anti-HIV.

Serologic testing for anti-HIV is effective, although not unequivocal, in screening for infected blood donated by a few who do not respond to education. Since 1985, when testing started, seven blood donors have been reported to have transmitted infection during the "window" period (prior to development of detectable antibody).[7] More sensitive tests are being developed.

As another adjunct to safe transfusion practices, the use of pre-deposit autologous donation has increased enormously.[8] Selected patients planning elective surgery may donate blood for their own use. There has also been an enormous increase in another form of autologous donation—intraoperative salvage—a procedure previously used by only a few surgeons,[9] but now more widely accepted as a method to reduce or eliminate the need for homologous blood when major blood loss is anticipated. The availability to patients of the opportunity for autologous donation should be included in quality assurance criteria.

Safety measures, such as effective donor education and screening, testing of donor blood, and use of alternatives to homologous blood (such as autologous transfusion), contribute to transfusion safety. Despite these measures, there will probably never be a zero-risk blood supply. Additional precautions are needed.

Careful evaluation by the physician of the risks and benefits of transfusion for each patient is critical. The safest unit of blood is the one that is never given! The availability of colleagues in the transfusion service to consult prospectively about indications, dosage, and appropriate blood products is another vital support. Finally, a strong quality assurance program, as described by Hoeltge et al, is essential to ensure that no blood is transfused if the patient can recover without it, that the quantity of blood products used is no greater than absolutely necessary, and that only the specific components that are medically indicated are transfused. Collectively, these measures will make transfusion therapy as safe as is humanly possible.

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