SPECIAL ARTICLE

Regulating Transfusion Therapy

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Several recent events are worthy of notice by the practicing physician since they affect blood bank services to his patient. The Food and Drug Administration has announced that it has extended Federal regulation from interstate to intrastate blood banking. As a first step, all blood banks, including hospital blood banks, must register.* The action can mean a new set of standards and rules over and above any local standards already existing. New rules may be promulgated for the protection of the patient, but they should be expected to bear only indirectly on the good of the patient. The first effects of such rules will be to protect the donors, the blood banks and the rule-makers. Existing Federal regulations for interstate blood banks specify that only the blood donor area needs to be under the supervision of a physician. The other steps in what is called the manufacture, preparation and processing of human blood can be supervised by anyone with an understanding of the involved scientific principles and techniques. The new Federal controls extend to hospital blood banks that receive their entire supply from other blood banks and then only crossmatch and transfuse with no further processing. The actual prescribing of blood is considered the practice of medicine and not under Federal regulation.

At the same time as the Federal rule was in print, the American Board of Pathology was administering, on January 27, the first examination for certification in the new subspecialty of blood banking. The examination was given not only to clinical pathologists but also to diplomates of other Boards. For continued progress and safety in blood transfusion, some trained physicians are needed whose interest is in this specialty. They can be clinically-oriented physicians who know the limitations and resources of the laboratory or laboratory-oriented physicians who have not lost their contact with the bedside.

A certified subspecialist in blood banking is not needed in each hospital. On the other hand, no physician would want to rely only on the existing local and state standards or any new Federal standards to protect his patient. Of necessity, legal standards are minimal standards that apply to the average case. At each hospital there must continue to be an interest not only in legal standards but also in patient-oriented standards for transfusion services. Those standards remain within the practice of medicine and cannot be all set down in a rule book.

Patient-oriented standards for a hospital blood bank should be defined in relation to the capacity of that blood bank in that hospital. Transfusion therapy requires much more than direction by a serologist. Blood grouping and crossmatching only protect against most immediate ill effects of transfusion. Serology is an excellent guarantee of the safety of transfusion, it does not guarantee effective transfusion therapy. The defining authority should be a physician, but not a committee of physicians. It should be one person who has a direct responsibility to the patient who receives blood from that transfusion service and who knows the capacity of that transfusion service. The medical director should know not only what the transfusion service does, can do and cannot do, but also he must know what patients can do and cannot do in response to transfusion. The physician who is in charge of each hospital blood bank must set the standards as his own defining authority, but he must consider first his fitness to do so.

Even more than many other things in medicine, blood transfusion is a calculated risk. The patient-care physician should be aware of the size of the risk. Much of the risk is clerical error, and the physician contributes to that. Failure of communication plays a large part, as does the propensity for human hands to write down a mirror image of data assembled in the human brain. It is, unfortunately, too common for the group AB blood to be called its inverse, Group O; for A to be called B; and for Billy Green to get No. 10883 which was really No. 10833 for Bobby Brown. As automated data processing comes into more general use, it will eliminate some of the human errors and will introduce errors of its own.

Actually, the entire blood bank operation is fantastically safe if we consider what it is, an enormous physiologic experience in which tens of thousands of times a day large transfers of complex biologic materials, including viable cells, are made between unrelated humans. Obviously the good news that this is safe has gotten around in our lifetime. The surgical resident who orders blood transfusion may complete his training without seeing a serious transfusion reaction. He should be told that there is a one percent chance the patient will make anti-red cell antibodies which may interfere with future pregnancy or transfusion, and perhaps a greater chance for the evocation of anti-leukocyte antibodies which can interfere with future platelet transfusion and perhaps with transplantation. Also, even with universal application of tests for the hepatitis associated antigen, no test is now available or on the horizon which will eliminate the hepatitis risk.

Despite the events of January 1973, it behooves each physician to continue to keep abreast of what is the available and the proper transfusion therapy for the individual patient.