Legal and Ethical Considerations in the Transfusion of Infected or Untested Autologous Blood

Jay P. Brooks, MD, MBA, and Joan E. Ferrell, MT(ASCP), JD

Key Words: Ethics; Legal; Autologous transfusion; Infected

Abstract

Autologous blood transfusion grew in popularity in response to the recognition of transfusion-transmitted HIV and a lack of effective screening. Laboratory screening and donor deferrals have decreased the need for autologous transfusion. The issue of banking blood that has not been tested or has been tested and found positive for serious infectious diseases raises ethical and legal issues that must be addressed by transfusion services, transfusion committees, physicians, and administrators. This article provides a summary of pertinent federal and state laws regarding autologous blood transfusion and a framework to assess the ethical implications of various strategies.

In terms of avoiding transfusion-transmitted infections, preoperative autologous blood donation yields the safest blood possible. Autologous blood transfusion has been performed for more than 150 years. During the early to mid-1980s when the risk of transfusion-transmitted HIV was as high as 1:100 in some areas and no test existed to detect its presence, interest in and demand for this lifesaving alternative increased. Studies have demonstrated that fear of contracting an infectious disease, particularly HIV, from transfusion has been a primary motivating factor in the decision to donate autologous blood.

The number of autologous collections peaked at 1,117,000 in 1992, representing 8.5% of the blood supply. By 1997, autologous units collected had declined to 611,000 representing 4.9% of the blood supply. The reasons for the decline in autologous donations have not been studied, but the fact that the allogeneic blood supply is now virtually free of HIV and hepatitis is a likely cause. Other factors that have been cited for the decrease include increased costs, patient inconvenience, and possible clerical errors.

Although current demand for autologous transfusion is considerably less than it was in the 1980s and 1990s, it remains a staple of clinical transfusion medicine practice. If a transfusion-transmitted infection emerges in the future that is capable of evading screening procedures and capturing the public’s attention, there would likely be a resurgence in autologous transfusion.

The justification for the use of autologous blood has traditionally been that it is the safest product available, providing patients with a source of blood free of infections that may still be escaping the screening processes of the allogeneic blood supply. However, in attempts to satisfy patient requests, transfusion medicine centers may be putting other patients at risk.
of acquiring a blood-borne infection by banking and then mistransfusing autologous blood that may harbor serious infectious diseases. We examined the ethical and legal issues surrounding the banking of infected and potentially infected autologous blood, and we describe various strategies that transfusion services can use to deal with them.

**Autologous Transfusion**

**Risks Averted**

Although the extensive testing for serious transfusion-transmitted diseases has dropped the risk of allogeneic transfusion to an extremely low level, a unit of autologous blood from a noninfected donor should be zero. Autologous donations also provide blood free of prions capable of producing variant Creutzfeldt-Jakob disease, assuming the donor is negative. Although donor deferrals aimed at decreasing the risk of this agent have been in place for several years, no laboratory test is in place, and, presumably, the allogeneic blood supply may be capable of transmitting variant Creutzfeldt-Jakob disease, albeit at a very low level.

Autologous blood should reduce the likelihood of transfusion-related acute lung injury (TRALI), at least the immune-mediated variety. However, most severe cases of TRALI are related to components containing relatively large amounts of plasma such as platelets and plasma. Patients who require plasma and platelet transfusions would almost certainly require transfusion beyond autologous deposits, and it is reasonable to assume that the decline in TRALI risk attributable to preoperative autologous donation would be insignificant.

**Risks Not Averted**

Many of the risks associated with allogeneic transfusion also accompany autologous blood transfusion. Bacteremia of the donor or subsequent contamination of the blood unit obviously can be seen with autologous and with allogeneic transfusion.

One of the major risks and the number one preventable risk of blood transfusion is mistransfusion. The risk of giving the wrong patient the wrong blood is estimated to be many magnitudes of risk higher than the risk of acquiring viral illnesses from a blood transfusion. The review by Linden et al of the New York State experience that examined all transfusion-associated incidents showed that approximately 1:19,000 units were mistransfused.

Few studies have addressed the issue of mistransfusion of autologous units. A 1992 College of American Pathologists survey reported that almost 1% of surveyed institutions had issued autologous blood to the wrong patient on at least 1 occasion in the preceding year. This study revealed that 20 autologous units were transfused to the wrong patient. By using this figure along with the total number of autologous units transfused in 1992, Shulman (written communication, December 7, 2006) estimated the risk of mistransfusion to be 1:25,000 autologous units transfused. A Canadian study spanning 1988 to 1995 showed 1 mistransfusion in approximately 9,500 autologous transfusions. A 1997 study in Japan revealed 1 mistransfusion in approximately 25,000 autologous units transfused. A report from New York State for a 4-year period showed 2 mistransfusions in 124,601 autologous units transfused, for a rate of approximately 1:62,000.

That the published data on autologous mistransfusion fail to show a strikingly decreased mistransfusion rate is not surprising. Although efforts may be made to specially handle and segregate autologous units in the transfusion medicine service, most transfusions are performed by non–transfusion service personnel who are beyond the control or oversight of the transfusion medicine service. Multiple studies have shown that most transfusion errors occur outside the transfusion medicine service.

**Storing Infected and Untested Blood**

According to a 2003 College of American Pathologists survey, most US transfusion services transfuse autologous blood that is untested or that tests positive for an infectious disease. In the survey of 3,561 facilities, 84% stored autologous blood; 82% did not test autologous units drawn at their own institutions; 15% allowed routine storage of HIV+ units; 49% allowed storage of HIV+ units with special authorization; and 36% did not permit storage of HIV+ units. For hepatitis B virus (HBV), the figures were 21%, 53%, and 27%, respectively, and for hepatitis C virus (HCV), 25%, 51%, and 24%, respectively. With the percentages of facilities willing to always store HIV+ autologous blood at 15% and HCV+ blood as high as 25%, the question is: Why? Perhaps hospital staff believe that offering autologous blood transfusion to all patients is the fairest course. Another explanation is that they believe that they have excellent policies and procedures in place to minimize the risks of mistransfusion and that storing blood positive for serious infections does not present an unacceptable risk for their other patients.

Another possibility is that facility staff believe that the federal Americans With Disabilities Act (ADA) requires them to offer autologous blood to patients regardless of the infectivity of their blood. In a 1998 Association Bulletin, the American Association of Blood Banks (AABB) advised its member institutions that a recent case brought under the ADA, Bragdon v Abbott, “...may render unlawful those policies that deny HIV-infected patients the opportunity to use their own blood. Blood centers and hospitals that have such policies or procedures should, with the assistance of counsel,
consider carefully whether they can defend their actions successfully given the sweep of the Bragdon decision and the ADA's prohibition.\textsuperscript{24} The bulletin puts forth 3 possible defenses to liability under the ADA but concludes “[c]ourts can be expected to reject these defenses…”\textsuperscript{24} The upshot of the AABB bulletin is to put its members on notice that denying transfusion of HIV+ autologous blood would be at their own peril and likely run afoul of federal law. In a 2006 Standards Source, the AABB reiterates its stance: “A review of recent case history suggests that it would be discriminatory to offer autologous blood donation to most individuals, but not to those infected with HIV.”\textsuperscript{25}

What Are the Laws Regarding the Provision of Autologous Blood?

Federal Law

The case cited by the AABB as probably requiring facilities to store and transfuse infected autologous blood is Bragdon v Abbott.\textsuperscript{25} In Bragdon, a patient disclosed to her dentist that she was HIV+. The dentist declined to fill her cavities in his office, offering instead to perform the procedure in a hospital. The dentist would not have charged an additional fee, but the patient would have had to pay additional costs associated with the use of hospital facilities. The US Supreme Court ruled that HIV infection is a disability under the ADA, even if the infection has not progressed to the symptomatic phase. The Court acknowledged that the ADA did not require the practitioner to treat her if her infectious condition posed a direct threat to the health or safety of others. The Supreme Court remanded the case to the Court of Appeals to decide whether the patient’s HIV infection posed a direct threat to the dentist. The Court of Appeals decided that the dentist had not established proof that the patient’s HIV+ status posed a direct threat to his health.\textsuperscript{27} However that same court stated:

“…we again find that Dr. Bragdon did not submit evidence to the district court demonstrating a genuine issue of material fact on the direct threat issue. Absent such a showing, the district court appropriately entered summary judgment in favor of Ms. Abbott. In espousing that view, we emphasize the case-specific nature of our determination. Our disposition is confined to the facts of record here (as they were presented in the nisi prius court). The state of scientific knowledge concerning this disease is evolving, and we caution future courts to consider carefully whether future litigants have been able, through scientific advances, more complete research, or special circumstances, to present facts and arguments warranting a different decision.”\textsuperscript{27}

A recent law review article specifically addresses the issues of the transfusion of HIV+ autologous blood, the Bragdon decision, and the position of the AABB.\textsuperscript{28} Shulman-Cutler\textsuperscript{28} cites 2 defenses that could be raised by facilities that might be sued under the ADA for refusal to store and transfuse infected autologous blood: (1) the direct threat defense and (2) that HIV-infected patients may not necessarily have a major life activity that is substantially limited by the infection. Shulman-Cutler\textsuperscript{28} points out that in finding that patients with HIV in an asymptomatic phase were protected by the ADA, the Court relied on then current information that women with HIV had about a 25% risk of transmitting the virus to their children, 8% even with retroviral therapy, and that this met the standard of substantially limiting a major life activity.\textsuperscript{26} She argues that the current estimate of less than 2%, or even less if cesarean section occurs, might not reach the level required for the Court to consider HIV as substantially limiting a major life activity. She further states that a patient who is past the age of reproduction could not rely on reproduction as a major life activity that has been substantially limited. Regarding her views on the “direct threat” issue:

“The AABB’s position regarding the storage and transfusion of infected autologous blood may need further development in the area of ‘direct threat.’ However, in light of increased knowledge of transfusion-transmission errors, the AABB in publishing suggested guidance that minimized the effectiveness of a ‘direct threat’ defense might not have fully considered all of the currently available evidence regarding the degree to which mistransfusion can occur.”\textsuperscript{28}

The Bragdon decision neither directly nor indirectly addressed the issue of blood transfusion. If such a case does reach the Court, it is reasonable to assume that it would examine whether having HIV+ blood on the shelf available for autologous transfusion would pose a direct threat to the health or safety of others. Despite efforts to ensure that the right patient gets the right blood, mistransfusions occur.\textsuperscript{14,15,17-19} When a unit of RBCs is mistransfused to a recipient, simple calculations will show that there will be a 35% chance that the transfusion will be ABO incompatible. If the unit is HIV+, however, there will be a 100% chance that it will be capable of transmitting HIV. In our opinion, it is likely that the Court would conclude that the presence of HIV+ autologous blood would pose a direct threat to the safety of other patients. However, until the US Supreme Court rules directly on this issue, any ideas as to what the Court might rule are mere conjecture. In blood banking, erring on the side of patient safety has become our mantra. If the Supreme Court rules that HIV+ blood must be offered in an autologous setting, this will become the law of the land.

State Laws

We searched the laws of all 50 states and the District of Columbia in 2 electronic databases, Findlaw (http://www.findlaw.com/11stategov/) and Lexis-Nexis (http://web.lexisnexis.com/universe/), for the terms “autologous” and “transfusion.” Where the link did not allow for a search, applicable statutes and codes were browsed. Thirty-six states and the
District of Columbia had no laws regarding autologous transfusion or the testing of donated blood [Table 1]. Fourteen states were found to have laws dealing with autologous transfusion or infectious disease testing of donated blood for transfusion, and the laws are summarized in Table 2.29-46 People involved in crafting autologous policies would be well advised to consult their facility’s legal counsel and local blood banking societies to determine which laws affect them.

Florida and West Virginia have laws that explicitly provide for patients to receive autologous blood. Florida’s law states: “Any person residing in this state shall be entitled and allowed to participate in a program to donate his or her own blood, in order to have such blood available for autologous, or self-derived, transfusion at the time of a planned medical need.”34

Likewise West Virginia mandates autologous transfusion to be offered.

“All any person may, in contemplation of elective surgery or other elective medical procedures for which a blood transfusion may be required, request the health care provider conducting such surgery or medical procedure, or any private, public or nonprofit blood bank, to make or cause to be made appropriate provisions to store and bank that individual’s blood for use during such surgery or medical procedure. The health care provider or the private, public or nonprofit blood bank shall, upon such request, store and bank a person’s blood and the health care provider shall use such blood in the elective surgery or medical procedure to the extent such blood is available.”45

New Jersey law is ambiguous.41 It requires that health care facilities accept autologous blood from a licensed blood bank that has been tested and prepared in accordance with the NJ Department of Health Standards. Depending on what the Department of Health Standards are, autologous blood positive for certain or all infectious diseases may be required to be accepted. Or such blood may be exempted from the requirement. A letter to the NJ Department of Health failed to elicit a response.

Ohio, Oklahoma, and Tennessee have statutes that require blood for transfusion be tested and found negative for HIV.42-44 These states do not exempt autologous donations and seem to forbid the practice of transfusing even autologous blood that is HIV+. Other infectious agents are not addressed, so blood positive or not tested for other serious infections such as HBV and HCV would presumably be allowed to be transfused.

Most states do not address the issue of autologous transfusion or the testing of donated blood for transfusion. Several states address the issue of HIV testing of donated blood: some require HIV testing of all donated blood with prohibitions of transfusing any blood found positive, some states have similar laws but exempt autologous donations from this requirement, and others exempt autologous donations from HIV testing requirements altogether. The states that require blood for transfusion be tested and found negative for HIV+ blood would seem to prohibit the practice of autologous transfusion of HIV+ blood. Other infectious agents such as HBV and HCV would seem not covered by the prohibition. Florida and West Virginia have laws that require health care providers to store and transfuse autologous blood. At least in these 2 states, it seems that even infectious autologous blood must be provided.

### Municipal Laws

Given the many municipalities within the United States, we did not look at local laws. It is possible that municipalities may have laws that require autologous transfusion. People involved in crafting autologous policies would be well advised to consult their facility’s legal counsel and local blood banking societies to determine which laws affect them.

### Balancing Risks and Benefits of Banking and Transfusing Infected Autologous Blood

It could be argued that allowing infected autologous blood into the transfusion medicine service would increase the risks to technologists and other personnel involved in handling and crossmatching the units. Although some small increased risk might be attributable to the handling of an infected unit, technologists already handle infectious material in compatibility samples and minimize their risks by the use of universal precautions. The overall increase in risk to technologists and other transfusion medicine personnel would be minimal.
The main area of increased risk would be to other patients. The risk of mistransfusion of blood is many times greater than the associated infectious risks of allogeneic transfusion and has been found to be as high as 1:19,000. The largest study of mistransfusion of autologous blood estimated a rate of 1:25,000 autologous units transfused.15

What about the benefit of autologous blood transfusion for people with a serious infectious disease? The benefit would be the aggregate risks averted. (The following numbers are approximations of published figures rounded for ease of calculation.) Consider quantifiable risks as follows: HBV, 1:2,000,000; HCV, 1:1,900,000; mistransfusion (allogeneic), 1:19,000; and mistransfusion (autologous), 1:25,000. By receiving predeposited blood, an HIV+ recipient would avoid the risk of HBV and HCV infection, so the likelihood of receiving blood negative for these infections would be 1. If an HIV+ person receives an allogeneic transfusion, the chance of not receiving HBV or HCV would be as follows: 199,999/200,000 × 1,899,999/1,900,000 = 0.9999945. The difference in chance of not receiving HBV or HCV from an autologous transfusion vs an allogeneic transfusion is 1 – 0.9999945 = 0.0000055. This model captures only the benefits regarding HBV and HCV but could be expanded to include all quantifiable, avoidable risks.

What is the risk to other patients in terms of storing autologous infected blood in the transfusion medicine service? The relevant risk is the additional risk added by the mistransfusion of an infected unit of blood. To ascertain this, if we are dealing with units known to be infectious, the risk is 1:25,000 times the number of units of infected blood stored in the blood bank during a given period. If there is 1 unit of infected autologous blood transfused in a given period, the risk is 1:25,000, or 0.00004. In the unlikely event there are 5 units transfused, the additional risk is 5:25,000, or 0.00002.

The benefit of an autologous transfusion to an uninfected patient would be similar to that of an infected patient, but the avoidance of the chance of infection would increase the benefit to the uninfected patient by a small amount. From a pure risk-benefit perspective, the relevant risks of avoiding another infection for an infected donor are less than the risks to a patient receiving a mistransfusion of infected autologous blood.

**Strategies for Autologous Transfusion**

The real benefit for autologous transfusion peaked during the early 1980s when the risk of HIV transfusion in blood was as high as 1:100 in some populations. With the advent of screening, the benefit of infection avoidance by predonation has significantly declined. This is not to say that there are no benefits to patients. Autologous transfusion certainly provides psychological comfort to some patients, and this should not be disregarded. There are also issues of autonomy: the right of patients to choose their own treatment. Although this right is far from absolute, it is one that has gained respect in recent years. The following options represent some of the strategies for handling untested or infected autologous blood.

**Offer Autologous Blood to All**

Providing autologous blood to all, including infected blood or untested blood, maximizes respect for individual
autonomy and also eliminates possible conflicts with federal and state laws. This seems to be the only position compatible with Florida law. Although there would be an increase in overall transfusion risk, this could be mitigated by implementing state-of-the-art bar coding and radiofrequency identification device technologies.\textsuperscript{50,51} To the extent this position would drive efforts to develop better identification technology, overall transfusion safety could ultimately be improved. From a legal standpoint, if a patient were to receive a mistransfusion, the facility would likely be found liable for negligence in a malpractice action. Also it seems that this strategy would run afoul of state laws in Ohio,\textsuperscript{42} Oklahoma,\textsuperscript{43} and Tennessee,\textsuperscript{44} at least in regard to the provision of HIV+ autologous blood.

**Transfuse Only Tested Blood Negative for Markers of Major Infectious Diseases**

This strategy would prohibit transfusion of untested blood and blood positive for HIV, HBV, HCV, and other major infections and allow the transfusion of blood positive for an infectious marker but unlikely to transmit infectious diseases. Autologous blood positive for markers such as antibodies to hepatitis B core antigen or serologic test for syphilis, which rarely cause infections, would be allowed. This policy would keep units capable of transmitting HBV, HCV, and HIV off the blood bank shelves and increase overall patient safety. The right of patients not to be mistransfused with infected blood would be viewed as paramount. However, individual autonomy would be restricted because patients with major infectious diseases are not allowed the choice to participate in an autologous transfusion program. This strategy seems to run afoul of state laws requiring transfusion in Florida,\textsuperscript{34} and West Virginia.\textsuperscript{45}

**Allow Units Positive for Major Infections Only in Exceptional Circumstances**

Certain patients, such as patients with multiple alloantibodies or antibodies to high frequency antigens may, by nature of their clinical situation, derive special benefit by receiving their own blood. In such cases, the increased benefit to the patient could shift the risk-benefit analysis. This position would recognize individual autonomy and individual need. The increased risk to other patients would be at least partially offset by the benefits accruing to the patient. The decision to accept such units could be made by the medical director, who should document the reason such units were accepted to help ensure the decisions were evidence-based and not arbitrary. It seems this strategy would violate state laws requiring autologous transfusion in Florida,\textsuperscript{34} and West Virginia.\textsuperscript{45} Such a policy would violate Ohio,\textsuperscript{42} Oklahoma,\textsuperscript{43} and Tennessee\textsuperscript{44} laws if HIV+ units were transfused.

**Use Untested Autologous Blood but Not Blood Testing Positive for Infectious Agents**

This strategy would attempt to respect individual autonomy by allowing all to donate autologous blood at the facility and ostensibly maximize overall blood safety because no known units of infected blood were being transfused. However, untested units have a higher than usual risk of infection,\textsuperscript{52} and this policy would decrease overall transfusion safety. If a unit of infected blood were to be transfused, the fact that no known infected units were present in the blood bank would not likely be a viable defense to a malpractice action. In the case of autologous blood positive for HIV, this practice would seem to violate the laws of states requiring testing of autologous blood such as Indiana,\textsuperscript{36} Michigan,\textsuperscript{39} Ohio,\textsuperscript{42} Oklahoma,\textsuperscript{43} and Tennessee,\textsuperscript{44}

**Transfuse No Autologous Blood**

Ethically, this policy does not discriminate against any particular group of patients. A service offered to none cannot be a service denied only to a specific group or groups. Autonomy of patients is restricted in favor of overall patient safety. This strategy would violate the laws of states requiring autologous transfusion such as Florida,\textsuperscript{34} New Jersey,\textsuperscript{31} and West Virginia.\textsuperscript{45}

**Bar Transfusion of Only One Type of Infected Unit**

A facility could single out HBV, HCV, HIV, or some other infection and specifically bar only blood containing that infectious agent. The scientific reason for disallowing participation in autologous blood donation programs by certain patients with infectious diseases would be to protect recipients from receiving a mistransfused infected unit. HBV, HCV, and HIV are all serious, life-threatening illnesses. It would be illogical to single out only one, although facilities in Ohio, Oklahoma, and Tennessee that wanted to have a policy favoring maximum patient autonomy would be in the curious position of allowing patients with HBV and HCV to participate in an autologous blood program but, to comply with state law, excluding patients with HIV from participating in their program. Absent such legal restriction, singling out persons with a specific infectious disease and allowing others with equally serious transmissible diseases to participate in an autologous program would be arbitrary and unethical. Such a policy would violate the laws of Florida,\textsuperscript{34} and West Virginia.\textsuperscript{45}

**Policies in Europe**

In Great Britain, patients positive for HBV, HCV, or HIV are not considered for autologous donation.\textsuperscript{53} In its 2004 directive,\textsuperscript{54} the European Commission enumerated deferral criteria for autologous donors that included history of HBV, HCV, HIV, and human T-lymphotropic virus 2. However, member states are allowed to “establish specific provisions for autologous donations by such persons.”\textsuperscript{54}
Discussion

The various strategies reflect differing values and concerns. In deciding which strategy to implement, one key factor is an estimate of a facility's likely mistransfusion rate. A hospital with state-of-the-art electronic patient and blood identification systems such as bar coding or a radiofrequency identification device would be expected to have a lower rate of mistransfusion than published estimates and might more confidently offer autologous transfusion to all. A facility with no more than the usual safeguards in place might be more hesitant to take the risks of offering autologous transfusion to patients with transmissible diseases. If an emphasis is on patient autonomy, more risk may be tolerated. If the emphasis is on overall patient safety, less risk will be tolerated.

These issues go beyond the purview of the transfusion medicine service to include other medical staff and hospital administrators. In deciding which policy to implement, it would be advisable to address the issue through a hospital’s medical staff committee structure. The transfusion committee would be a natural place to develop a policy and, if the facility has one, an ethics committee’s input might be helpful. The medical director of the transfusion medicine service should take a leadership role in articulating what the institution’s policy should be. Whatever strategy is considered, the need for support by the medical staff, administration, and legal counsel is essential for ensuring that a policy is legally and ethically sound and supported by the key players.

From the 1Department of Pathology, University of Oklahoma Health Sciences Center and Veterans Affairs Medical Center; and 2OU Medical Center, Oklahoma City.

Address reprint requests to Dr Brooks: Dept of Pathology, University of Oklahoma College of Medicine, 940 Stanton L. Young Blvd, Room 451, Oklahoma City, OK 73104.

Disclaimer: This article summarizes various federal and state laws. It does not give legal advice.

References

Brooks and Ferrell / ETHICAL LEGAL INFECTED AUTOLOGOUS BLOOD

34. Fla Stat §381.0604.
35. Ill §693.140.
36. Ind Code 16-41-12.
38. La Rev Stat 40:1299.147.
43. Okla Stat §2167.1.
45. Va Code §16-3C-9.
46. Wis Stat §252.13.