

CHAPTER 1

Legal and Administrative Issues Related to Transfusion- Free Medicine and Surgery

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Introduction

Few would argue that patient rights should be protected and respected. However, when this right involves a patient's refusal of potentially lifesaving treatment, serious issues come to the fore. In this chapter we will discuss the rights of patients to refuse blood transfusion, and the right and duty of the physician assuming care for such patients. We will also review how the implementation and establishment of bloodless medicine and surgery programs evolved from Jehovah's Witnesses' position on blood, and the lessons that science has learned in the process.

History of Jehovah's Witnesses and blood

The issue involving Jehovah's Witnesses and blood transfusions became most prominent in the 1940s at the height of World War II [1]. Blood was liberally transfused into wounded soldiers, and this led to an increased demand for blood donors. Most individuals in the medical profession, as well as members of the lay community, regarded the practice of blood transfusion as an accepted therapeutic method. But those who were members of the religious organization known as Jehovah's Witnesses did not. And the passage of time has not changed their point of view.

The Witnesses' belief is that God, the Creator of life, views blood as sacred and holy, and therefore it should not be used for the purpose of transfusion, regardless of the consequences [2]. They cite several Bible passages found in both the Old and New Testaments. One such passage is found in Genesis 9:3–4: 'Every moving animal that is alive may serve as food for you. As in the case of green vegetation, I do give it all to you. Only flesh with its soul – its blood – you must not eat.' Leviticus 17:10 says: 'As for any man of the house of Israel or some alien resident who is residing as an alien in their midst *who eats any sort of blood*, I shall certainly set my face against the soul that is eating

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the blood, and *I shall indeed cut him off from among his people.*' Furthermore, Acts 15:28–29 states: 'The holy spirit and we ourselves have favored adding no further burden to you, except these necessary things, to keep *abstaining* . . . from . . . blood.' Although no mention is made of transfusing blood, Jehovah's Witnesses view this directive to 'not eat blood' or 'to abstain from blood' as something that applies to both *oral* and *intravenous* feeding.

While it is true that Jehovah's Witnesses refuse blood, they are not averse to medical and surgical treatment. On the contrary, many of them are physicians, even surgeons. However, as already stated, their position on blood is unequivocal and absolute [3].

Acceptable products, treatments and procedures

Although Jehovah's Witnesses do not accept blood transfusions, accepting products *derived* from red cells, white cells, platelets or plasma is viewed as a decision that individual Witness patients must make for themselves. In a recent issue of *The Watchtower*, the principal journal of Jehovah's Witnesses, a distinction is made between whole blood and its *primary components* (i.e. red cells, white cells, platelets and plasma) and *fractions* [4]. These primary components are unacceptable to devout Jehovah's Witnesses. However, acceptable blood fractions may include plasma proteins such as immune globulins, albumin and cryoprecipitate. Platelet-derived wound-healing factors may also fall into this category of acceptable blood fractions. The rationale of Jehovah's Witnesses in regard to products fractionated from blood is partly based on the complexity of blood itself. Medical practitioners recognize that plasma, for example, consists of many substances such as hormones, inorganic salts, enzymes and nutrients. Plasma also carries proteins such as albumin, clotting factors and antibodies. Jehovah's Witnesses believe that the Bible does not give details about these products that, medically speaking, are not typically defined as blood. Therefore, each individual Witness is instructed to use their conscience in making a decision to accept or refuse these products.

The availability of recombinant growth factors such as erythropoietin (EPO) to stimulate hematopoiesis has been very helpful in minimizing or eliminating a patient's exposure to allogeneic blood. However, while the majority of Jehovah's Witnesses will accept recombinant EPO, since all formulations of the product available in the USA are packaged with a stabilizer that includes trace amounts of human serum albumin, consent must be obtained prior to its use. There are some Witness patients who refuse to accept any blood-derived product, regardless of the amount. Therefore, health care providers should utilize a specific form that allows patients to choose the products, treatments and procedures that are acceptable to them (see Figure 1.1).

Autologous procedures and equipment

Citing other Biblical statements that discuss the use of blood, Jehovah's Witnesses do not allow the preoperative collection and storage of their own

**TRANSFUSION-FREE MEDICINE & SURGERY PROGRAM
(PERSONAL DIRECTIVES)**

Patient: _____ Attending Physician: _____
(Please Print)

I direct that **no blood transfusion** (including whole blood, red cells, white cells, platelets, or blood plasma) are to be given me under any circumstances, even if physicians deem such necessary to preserve my life or health. I will accept non-blood volume expanders (such as dextran, saline or Ringer's solution, or hetastarch) and other non-blood management.

I hereby fully and unconditionally release physicians, anesthesiologists, hospitals and their personnel from liability for any damages, claim or liability related to my refusal of blood or blood products, despite their otherwise competent care.

The following are my wishes and directions regarding procedures, treatments and blood fractions (initial ALL boxes):

PRODUCT/TREATMENT/PROCEDURE	Accept	Refuse
Albumin (minor blood fraction)		
Erythropoietin (contains albumin)		
Immune Globulins (e.g., minor blood fractions, RhoGAM, antivenoms)		
Hemophilic Preparations (clotting factors)		
Tissue Adhesives (e.g., fibrinogen, fibrin glue, thrombin, etc.)		
Cryoprecipitate (intravenous infusion)		
Dialysis & Heart-Lung equipment (non-blood primed)		
Intraoperative Blood Salvage ("Cell Saver") where extracorporeal circulation is a closed circuit without blood storage (non-blood primed)		
Intraoperative Hemodilution (where extracorporeal circulation is a closed circuit)		
Plasmapheresis (similar to dialysis)		

Dated this: _____ day of _____, year _____

Signature: _____
(Patient, Parent or Guardian)

Witness: _____

Figure 1.1 USC Transfusion-Free Medicine and Surgery Program: Personal Decision and Release.

blood for later infusion. For example, Leviticus 17:13 says what a man should do if he killed an animal for food: 'He must in that case pour its blood out and cover it with dust.' According to some Biblical scholars, this act of pouring out blood is best understood as an act of reverence demonstrating respect for the life of the animal and, thus, respect for God who created and continues to care

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for that life [5]. Again, Jehovah's Witnesses' principal journal *The Watchtower* addressed the therapeutic and surgical use of procedures or equipment involving autologous blood. As with fractions of primary components of blood, this too is a matter for personal decision. If the intraoperative cell-saver machine is not primed with blood, and is set up in a closed circuit that is in constant contact with the patient's circulatory system, this is acceptable to many Witness patients. The same principle would apply to the use of dialysis and heart-lung machines, as well as acute normovolemic hemodilution (ANH) (see Figure 1.1).

Organ transplantation

There has been a great deal of confusion over the fact that the doctrine of Jehovah's Witnesses prohibits them from receiving blood transfusions but not organ transplants. Blood itself is often viewed as a 'liquid organ transplant'. Why then do Jehovah's Witnesses view organ transplants differently than they do blood?

About 24 years ago, *The Watchtower* briefly discussed this issue [6]. The principle guiding Jehovah's Witnesses' decision to accept organ transplants or human tissue focuses on their view that while the Bible specifically forbids consuming blood, there is no Biblical command or injunction proscribing the 'taking in' of other human tissue. They mention that meat is not prohibited for human consumption as long as it is properly bled, and therefore this principle can be applied to organ transplantation. However, each member of the Jehovah's Witness faith is instructed to weigh all relevant factors and make a personal, conscientious decision about accepting an organ transplant. In the main, if a human organ transplant does not involve blood or blood products, it is left up to each individual Witness to decide for himself or herself.

Overview of legal principles related to refusal of blood

Refusal of blood as life-sustaining treatment

Does a patient have the right to refuse blood transfusion at the risk of his or her life? Before we address that question, it is important to understand the legal rights of patients to refuse *any* type of medical or surgical treatment.

The basic common law right of bodily self-determination establishes that every person of sound mind is master over his own body. Therefore, such an individual is free to prohibit surgery or medical treatment deemed by others as potentially lifesaving. Over 100 years ago, the US Supreme Court upheld the notion of individual autonomy. It stated that 'no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by unquestionable authority of law' [7].

This fundamental legal principle of bodily self-determination serves as the basis for the doctrine of informed consent. The right to privacy dovetails with informed consent. No doctor or hospital should subject patients to medical and/or surgical treatment without informed consent. The patient must be informed of the name, means and likely consequences of the proposed treatment in order to 'knowingly' determine what should or should not be done to his or her body.

Informed consent

The US President's Commission for the Study of Ethical Problems in Medicine was charged with preparing a report about making health care decisions. The report revealed that informed consent rests on two very important values: (1) the patient's own conception of his personal well being; and (2) the patient's right to self-determination. This commission also concluded that the principle of self-determination 'is best understood as respecting people's right to define and pursue their own view of what is good' [7].

In *Cobbs v. Grant*, a landmark California Supreme Court decision, it was determined that physicians have had a duty to obtain the informed consent of patients before performing certain medical procedures [8]. Over 90 years ago, Justice Benjamin Cardozo stated: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages.' Justice Cardozo's statement was in response to the case of a woman who was admitted to the hospital with abdominal pain and a palpable lump. She gave her doctors consent to physical examination, but she refused surgical examination. However, while under general anesthetic (ether) for further physical examination, surgeons surgically removed a fibroid tumor. Subsequently, gangrene developed in her left arm, and two fingers were amputated. The physicians were held liable for negligence and battery [9,10].

Therefore, doctors who administer treatment or perform surgery without a patient's consent are liable for battery (i.e. for nonconsensual interference with the patient's person). A surgical operation on the body of a person is a technical battery or trespass unless that person or some other authorized person consented to it, regardless of the skill and care employed in the performance of the operation. In addition, a case of battery is established where a physician obtains consent to perform one type of treatment and thereafter performs a substantially different treatment for which consent was not obtained [9,11].

In the precedent setting case of *Cruzan v. Missouri Department of Health*, 497 US 261 (1990), the Supreme Court determined that 'the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is the right to refuse treatment' [7]. Even if a patient refuses treatment that a physician views as life-sustaining, 'the primacy of a patient's interest in self-determination and in honoring the patient's

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own view of well-being warrant leaving with the patient the final authority to decide’.

Specific issues related to refusal of blood in Jehovah’s Witnesses

Competent adults

In view of clearly established laws regarding informed consent, any competent adult has the right to refuse blood. However, Jehovah’s Witnesses’ refusal of blood should be based on a clear understanding of the *consequences* involved in not receiving blood.

At least three high courts have found that the 1st Amendment Free Exercise Clause protects religion-based refusals of medical treatment from state interference [7,12–14]. The fact that Jehovah’s Witnesses’ refusal of blood may be viewed as a nonact or refusal to act rather than a positive, affirmative act is a significant point to consider. Whereas some states have exercised their ‘law enforcement’ authority to limit or prohibit religiously motivated action in order to protect public health, safety or welfare, there is no precedent for prohibiting action motivated by religion when there is no grave or pressingly imminent danger to the public [7,15–18].

Example 1

In re Brown [9,19]

Mrs Brown was a Jehovah’s Witness who was shot by her daughter and consequently required surgery. The doctors recommended a blood transfusion, which she refused to consent to. Thereafter, the state sought and obtained a court order to force a transfusion due to the fact that Mrs Brown was the only eyewitness to the shooting, and if she died from lack of a blood transfusion, she would not be able to testify for the state in the prosecution. The surgery did take place and Mrs Brown did receive blood transfusions.

Mrs Brown required further surgery and again her surgeon recommended blood transfusions. She refused and made an appeal to the court to stop the order. The decision of the court was that the order be vacated and Mrs Brown not be required to submit to, or receive, a blood transfusion against her will. The Supreme Court made the following statement regarding her common law right to privacy:

Each individual has a right to the inviolability and integrity of the person, freedom to choose or bodily self-determination. . . . The right to be left alone. . . which is the most comprehensive of rights and the right most valued by civilized man. Violation of this rule constitutes a battery.

The court also stated that ‘the factual information available to us makes clear that Brown’s position has been consistent throughout: that she wants to live, that she wants the benefits of all that medical science can do for her with the sole and only exception that she rejects any treatment proscribed by the tenets of her religious faith’.

Emergency/incompetent adults (patients known to be Jehovah's Witnesses refusing blood)

Generally speaking, the fundamental right of bodily self-determination does not vanish when a patient loses consciousness or becomes incompetent. That right remains intact even when the patient is no longer able to assert the right [9,20,21]. In addition, when a patient has religious views against certain forms of medical treatment that predate, and are unaltered by, their incapacity, physicians and health care providers are not justified in substituting their own judgment for the patients at the time of treatment.

When refusals of treatment are religiously motivated they are 'usually considered more thoroughly and less likely to change than nonreligious ones because they are not dependent upon predictions of future circumstances, available medical treatment, or preferences' [9,22].

In reality, the main question is whether there is evidence of the patient's previously expressed wishes or refusal, not whether incompetent or unconscious adults in general have the right to refuse treatment.

Example 1

In re Dorone [7,9,23]

Mr Dorone was a 22-year-old Jehovah's Witness man who was seriously injured in an automobile accident and thus rendered unconscious. After being taken to a New Jersey hospital, his medical alert card indicating that he wanted nonblood treatment was found. Thereafter, Mr Dorone was transferred to a Pennsylvania hospital but his personal effects, including his medical alert card, were left behind. He required two more emergent surgeries, one for a subdural hematoma and another to remove a blood clot in his brain.

In each case, the hospital sought and received oral, telephonic court orders to allow blood transfusions against Mr Dorone's previously expressed refusal and over the objections of his family. His family had been excluded from the judicial hearings. The Pennsylvania Supreme Court upheld the prior orders to allow blood transfusions for Mr Dorone. The Supreme Court stated:

When evidence of this nature is measured against third party speculation as to what an unconscious patient would want, there can be no doubt that medical intervention is required. Indeed, in a situation like the present, where there is an emergency calling for an immediate decision, nothing less than a fully conscious contemporaneous decision by the patient will be sufficient to override evidence of medical necessity.

Example 2

Werth v. Taylor [7]

Mrs Werth, a Jehovah's Witness and mother of two children, became pregnant with twins in 1985. In preparation for delivery, she filled out a 'Refusal to Permit Blood Transfusion' form with the hospital. A few months later, she went into labor and upon admission to the hospital her husband filled out another 'Refusal to Permit Blood Transfusion' form in her behalf.

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Subsequent to the birth of her twins, Mrs Werth required an emergency D&C due to bleeding. Prior to performing the procedure, the attending physician again confirmed her refusal of blood with Mr Werth. The D&C was completed but after she continued to bleed and became hemodynamically unstable, Dr Taylor, the anesthesiologist, believed that a transfusion should be given to save her life. Mrs Werth remained unconscious. Despite being informed that Mrs Werth was one of Jehovah's Witnesses, and therefore refused blood, Dr Taylor proceeded with the order for transfusion. In his opinion, this was a life-threatening emergency.

Mrs Werth and her husband did file a medical malpractice and battery suit against Dr Taylor but the trial court accepted his defense that her refusal was not binding. His argument was similar to the Dorone case; he argued that Mrs Werth's refusal was not a conscious, competent, contemporaneous, fully informed refusal made in contemplation of the life-threatening situation that arose. In July 1991, Mrs Werth appealed the trial court's decision to the Michigan Court of Appeals but they upheld the decision in favor of Dr Taylor. The court of appeals did acknowledge that competent adults can refuse medical treatment, but they determined that a life-threatening emergency was different from a routine elective surgery. Applying the Dorone case to Mrs Werth's condition, they believed that the lack of a fully informed, contemporaneous decision was sufficient to override evidence of medical necessity.

These cases raise several legal/ethical questions. Is the requirement of a contemporaneous, fully informed or fully conscious refusal truly practical and realistic? How can an unconscious or noncommunicative patient be able to satisfy this standard?

Example 3

In re Hughes [7]

Mrs Hughes was scheduled for an elective hysterectomy. Before consenting to the surgery, she spoke to her doctor, Dr Ances, about her refusal of blood transfusions due to her religious beliefs. He agreed to perform the surgery without blood. On the morning that Mrs Hughes was admitted to the hospital, she filled out the hospital's standard refusal-of-blood form. The form released the doctor and the hospital from liability for respecting her wishes that no blood products be used. It also stated that she 'fully understood the possible consequences' of her refusal of blood – a key phrase.

Unfortunately the surgery was not uneventful and Mrs Hughes experienced massive bleeding. Despite the conversation she had with Dr Ances before the surgery, and the refusal form she filled out at the hospital, he felt that a blood transfusion was necessary. Mrs Hughes' husband was contacted and after being told that his wife would likely die if she did not receive a blood transfusion, he gave permission. Mr Hughes was not a Jehovah's Witness. Mrs Hughes' sister (who was a Jehovah's Witness) was at the hospital and she eventually discovered that a transfusion had been recommended for her

sister. She objected to the use of blood and decided to contact the Philadelphia Hospital Liaison Committee for Jehovah's Witnesses. This conflict came to the attention of hospital administration and therefore a court hearing was arranged.

Dr Ances testified that Mrs Hughes discussion with him regarding her refusal of blood, though clear and competent, was not in anticipation of such complications that led to massive blood loss. Although Mrs Hughes husband agreed to the use of blood for his wife after being called by the doctor, he stated in court that he knew his wife would not want blood. Mrs Hughes' sister and teenage daughter, testifying on behalf of Mrs Hughes, said that she would not want blood under any circumstances.

The trial court's decision was to grant the hospital authority to transfuse until Mrs Hughes regained consciousness and could again speak for herself. Mrs Hughes was transfused and after regaining consciousness she reiterated her refusal of blood. As stipulated by the terms of the court, the order for transfusion was then terminated.

Mrs Hughes did appeal to the New Jersey Superior Court but the earlier decision of the trial court was upheld. The appellate court did not base their decision on the requirement of a contemporaneous, fully informed or fully conscious refusal. Rather, they ruled that in an emergency involving a refusal of allegedly lifesaving treatment, the refusal will be honored only if there is 'clear, convincing, unequivocal evidence' that the patient's refusal was 'fully informed'. Furthermore, they stated that such a refusal could be established by the patient's 'oral directives, actions or writings'. They also indicated that if there exists even a 'glimmer of uncertainty' about the patient's wishes, the refusal would not be honored.

Indirectly, the court criticized Dr Ances and the hospital. Dr Ances failed to thoroughly discuss with Mrs Hughes all the possible consequences of the surgery. And the hospital's refusal form was lacking in that it did not accomplish its intended purpose.

Example 4

In re Duran [7]

In 1996 Ms Duran was diagnosed with liver failure. As one of Jehovah's Witnesses, Ms Duran sought treatment at the University of Pittsburgh Medical Center since they were known to have successfully performed 'bloodless' liver transplants on Jehovah's Witnesses. Ms Duran and her husband (who was not one of Jehovah's Witnesses) traveled to Pittsburgh in early 1997 to be evaluated for liver transplantation. The transplant team accepted her as a candidate with the stipulation that blood transfusions would not be given under any circumstances.

To ensure that her wishes would be respected, Ms Duran executed a health care durable power of attorney (DPA) form and appointed an elder from a Pittsburgh area congregation of Jehovah's Witnesses to be her health care agent. Ms Duran and her husband moved to Pittsburgh in 1999 after being

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informed that a liver would soon become available. She was transplanted in July 1999. Just a few days later, however, she experienced an episode of organ rejection. Since she was still unconscious, the doctors sought and gained consent for another transplant from her health care agent. 1 week later she was retransplanted. However, her body once again rejected the liver organ.

Ms Duran remained unconscious and despite the poor prognosis for recovery, her doctors recommended blood transfusions as a means to improve her chances of survival. A court hearing was quickly arranged in order to appoint her husband as emergency guardian for the purpose of granting consent for blood to be given. Her health care agent was not informed. The court heard testimony from Ms Duran's attending physician, her husband and her adult sister who was in favor of giving her blood transfusions. Mr Duran was granted authority as her emergency guardian and over a period of 3 weeks multiple blood transfusions were given. Ms Duran died having never regained consciousness.

Ms Duran's health care agent was eventually informed about what transpired and he filed an appeal with the Pennsylvania Superior Court. He challenged the trial court's order on several grounds, namely (1) overriding Ms Duran's oral and written refusals of blood; (2) circumventing her personally appointed health care agent and appointing a guardian with authority to consent to blood; and (3) failing to notify the health care agent of the guardianship petition and trial court hearing. The superior court's decision was to uphold the agent's challenges and it unanimously reversed the trial court's order.

In commenting on its decision, the superior court noted that the right of a patient to 'refuse medical treatment is deeply rooted' in common law. They further explained that Ms Duran's DPA was unequivocal in its pointed refusal of blood transfusions under any circumstance. Furthermore, in regard to the appointment of her husband as emergency guardian, the superior court agreed that since Ms Duran had already appointed a health care representative when she executed her DPA, her husband 'should not have been appointed emergency guardian for the express purpose of consenting to a blood transfusion because his beliefs conflicted with [his wife's] regarding blood transfusion therapy'. They also stated that the trial court should have taken into consideration her unequivocal directions when the very situation contemplated by her DPA arose. Regarding the failure of the trial court to notify her self-appointed health care agent, the superior court ruled that in view of the fact that both Ms Duran's husband and the hospital staff knew where to find her health care agent in an emergency situation, it was 'reasonable under these circumstances' to afford the agent notice of the hearing.

The above case illustrates that despite a patient's right to refuse blood transfusions, certain situations put physicians in hesitation mode, especially

when confronted by other family members. This enforces the necessity of clear policies and procedures within a transfusion-free program to clearly delineate such possibilities in advance. This is mostly true when electively treating adult patients undergoing high-risk procedures. The refusal of blood in such situations should equate with any other consent between physician and patient prior to initiating therapy. Refusal of blood transfusions should not be different from any other directive given by the patient. The consent form developed in a transfusion-free program should clearly stipulate that the patient's wishes should not be questioned, even if the patient becomes incapacitated and even if their life is endangered due to lack of transfusion (see Figures 1.1 and 1.2).

In the case of an emergency, health care providers should do their best to ascertain whether or not the patient has previously expressed his or her position either verbally or in writing. Exercising such due diligence can greatly reduce, if not eliminate, liability and possible legal action.

Emergency/incompetent adults (no information available)

What is the responsibility or duty of the physician/hospital staff when there is no information available?

No physician or hospital is subject to liability based solely on failure to obtain consent in rendering emergency medical, surgical, hospital or health services to any patient regardless of age if (1) the patient is unable to consent; (2) no other person is reasonably available to legally authorize consent; and (3) the hospital and medical staff have acted in good faith and without any knowledge of facts that would negate the consent [7]. However, if it is discovered that a patient's religious status is Jehovah's Witness, reasonable efforts should be made to abort a transfusion and to proceed in a manner that accords with the patient's religious beliefs.

What if questions arise about the patient's Jehovah's Witness status?

Most Jehovah's Witness patients carry a wallet-sized advance medical directive/release card that documents their refusal of blood. However, due to negligence or perhaps unforeseen circumstances, some Jehovah's Witness patients may not always have this document with them. In cases where the patient was previously a patient at the hospital, chart notes can be checked [7,9]. There may also be a family member or friend previously appointed by the patient as health care agent or surrogate decision-maker. In regard to adults who are viewed as incompetent, if they never had decision-making capacity, the law views them as the same as minor children lacking capacity. However, the law is different for those who have had such capacity but are currently incapacitated.

If prior to losing capacity the adult was rational and capable of expressing his or her views and opinions regarding unacceptable treatment, a doctor or hospital is obligated to honor the patient's decision even if the patient is

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**REFUSAL TO PERMIT
BLOOD TRANSFUSION**

REFUSAL TO PERMIT BLOOD TRANSFUSION

I request that no blood or blood derivatives be administered to (name of patient) _____ during this hospitalization. I hereby release the hospital, its personnel, the attending physician, and any other person participating in my care from any responsibility whatsoever for unfavorable reactions or any untoward results due to my refusal to permit the use of blood or its derivatives. The possible risks and consequences of such refusal on my part have been fully explained to me by my attending physician and I fully understand that such risks and consequences may occur as a result of my refusal.

I understand that my attending physician and other doctors who provide services to me are not employees or agents of the hospital. They are independent contractors.

The undersigned certifies that he/she has read the foregoing, received a copy thereof, is the patient, the patient's legal representative, or is duly authorized by the patient as patient's general agent to execute the above and accept its terms.

_____ am / pm Signature _____
Date Time Patient/Parent/Guardian/Conservator/Responsible Party

_____/_____
Witness signature / Witness print name If signed by other than patient, indicate relationship

Translator I have accurately and completely read the foregoing document to _____ (name of patient/person legally authorized to give consent) in _____, the patient's or patient's representative's primary language. He/she understood all the terms conditions and acknowledged his/her agreement thereto by signing this document in my presence

_____ am / pm _____
Date Time Translator signature / Translator print name

TRC1080 (7/04)

**REFUSAL TO PERMIT
BLOOD TRANSFUSION**

P
A
T
I
E
N
T

I
D

FACE

WHITE - MEDICAL RECORD

CANARY - PATIENT

Figure 1.2 Refusal To Permit Blood Transfusion.

incapable of speaking for himself or herself. This applies especially in cases where the incapacitated patient's treatment preferences are based on deeply held religious beliefs. The basic standard for dealing with incompetent or unconscious adults is: What would the patient choose if able to communicate his or her choice? Acceptable evidence of the patient's previously expressed

refusal would be: (1) prior written or oral direction; (2) advance medical directive/release card; (3) living will and medical power of attorney; (4) chart notes; and (5) testimonial evidence from others, that is surrogate decision-makers. While the rest may be questioned, a medical DPA is the best legal document to outline the incapacitated patient's treatment preferences [7,9].

Unlike the situation of an incapacitated patient where the consent clearly expresses the patient's wishes and is obtained prior to the patient's being incapacitated during the same hospital stay, in a situation where the physician is faced for the first time with an incapacitated patient or emergency situation, the standard of care is to administer blood transfusions. This may pose a dilemma for the physician regardless of any available information from a third party or family members. If the patient has a medical alert card, this should be considered as strong evidence of the patient's wishes to refuse transfusion. Having verbal information from family members or friends does not completely satisfy the physician's decision to transfuse or not, since people may change their mind regarding issues related to consent or refusal of blood. Therefore, a hospital policy should be in place to prepare for this dilemma if and when it arises.

More often than not, physicians and hospital staff will favor the voice of a surrogate decision-maker to clarify the issue and mitigate confusion or uncertainty. In regard to surrogate decision-makers, the state statute (RCW 7.70.065 a-f) establishes the following order of priority that should be followed in descending order [9,24]:

- 1 Appointed guardian
- 2 Attorney in fact: DPA
- 3 Spouse
- 4 Children at least 18 years of age
- 5 Parents
- 6 Adult brothers and sisters

The surrogate decision-maker's duty is to use good faith in determining the decision the patient would make if competent and able to speak for himself or herself.

Disagreeing family members

One of the most challenging scenarios arises when a patient's spouse, family member, relative or friend disagrees with the patient's refusal of blood. As previously mentioned, every competent adult has the constitutional right and freedom to determine what shall be done to their bodies. Therefore, courts have uniformly upheld that competent persons have the legal right to accept or refuse medical treatment absent of consent from their spouse or other relatives [7]. It is viewed as a natural corollary to an individual's rights of self-determination and personal autonomy to honor a patient's choice of treatment regardless of the views of the family.

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For example, regarding a non-Witness husband's 'consent' to blood transfusion for his Witness wife, a Florida Supreme Court stated that 'marriage does not destroy one's constitutional right to personal autonomy' [7,25]. The basic rule on spousal consent is that patients who are conscious, mentally capable of consent and who give their consent do not require consent from their spouse, nor is it otherwise material [7,26]. Another reason for the uniformity of case law that supports a patient's choice of treatment despite the disapproval of family or relatives is that family members may have a bias against the patient's interest due to conflicting interests [7,27]. In addition, some family members may base their actions on their own religious beliefs. This may cause them to request treatment that contradicts the patient's wishes or desires [7,28].

In summary, the patient's decision should control their medical treatment. The fundamental rights of personal privacy, bodily self-determination (informed consent) and, for Witness patients, religious freedom would be rendered void if respect for a patient's health care decisions were contingent upon the unanimous agreement of the patient's spouse or relatives. Health care providers should not be unduly concerned about litigation whenever these rights are upheld [7].

Minors

By California statutory definition, a minor is a person under the age of 18 and is not legally able to consent to medical treatment unless the law designates him or her as an emancipated minor [29]. The same law applies in most other states. In most cases, a minor's parents have the legal authority to consent to treatment for their child and consent must be obtained prior to treatment. There is a caveat, however, to such consent. If the minor objects to the treatment, the case should be referred to the hospital attorney if doubt exists about proceeding with treatment. For instance, if the objection is by a minor who is 14 years or older, it may be appropriate to seek legal advice if the parents consent to a procedure that involves significant risk of severe adverse consequences.

Most Witness families recognize the delicate balance between their rights and the legal obligations of the physicians. The US Constitution protects the fundamental right of parents to make decisions concerning the care, custody and control of their children. Therefore, with the exception of an emergency, if a surgeon operates on a child without the parents' consent, the surgeon will be liable for assault [7,9].

Issues arise when the state seeks to interfere with the parents' right to make decisions regarding their child's medical treatment due to the state's interest in protecting those who are disabled or who are unable to protect themselves. If the state perceives that a minor child's life or health is in danger because of a parent's refusal to consent to blood transfusion, they may grant a court order for the transfusion. However, such an order will only be granted if the state's interest in the protection of an innocent third party is 'compelling'. For the state's interest to be compelling it must be proven that there are no alternative nonblood treatments available. When the state's interest is viewed

as compelling and there is risk of imminent harm or death, the court will order that blood be given. The physician or hospital may otherwise be held liable.

Mature and emancipated minors

An exception is sometimes made in the case of a mature minor. A mature minor is one who is able to understand the nature and extent of his or her condition. The patient should also understand the recommended alternatives to blood and should be able to appreciate the consequences of the blood refusal. The decision is not solely dependent on the parents but is based on the patient's clear understanding of the facts.

California Legislature has enacted a series of statutes that authorize particular classes of minors to consent to various medical services [29]. However, a minor who would otherwise have the legal authority to consent to medical treatment may not be permitted to do so if he or she does not fully understand and appreciate the nature and consequences of the proposed health care, including its significant benefits, risks and alternatives. In such a scenario, consultation with legal counsel should be arranged to eliminate any doubt that may exist.

According to the California Health Care Association, when a minor of 15 years or older is living separate and apart from his or her parent(s) or legal guardian, whether with or without the consent or acquiescence of his or her parent(s) or legal guardian, and manages his or her own financial affairs, regardless of the source of income, the minor is capable of giving a valid consent for medical or dental care without parental or guardian consent, knowledge or financial liability. 'Medical care' means 'X-ray examination, anesthetic, medical or surgical diagnosis or treatment, and hospital care' under the supervision and upon the advice of a licensed physician. This is the definition of an emancipated minor.

When dealing with emancipated or mature minors who are Jehovah's Witnesses, physicians do well to have a clear understanding of the laws pertaining to their rights and to proceed in a manner that accords them with the same respect and dignity as they would give to an adult patient. However, decisions made by mature minors should be followed by the hospital only after a court decision is rendered regarding their ability to refuse treatment such as blood transfusion. This will protect health care providers from any potential liability.

Evolution of bloodless programs

Initially Jehovah's Witnesses' adamant refusal of blood and blood products was met with much controversy and frustration by members of both the medical and legal community. Most doctors viewed Jehovah's Witnesses' position as one that 'tied their hands' and prevented them from rendering adequate care under circumstances where profound anemia or significant surgical blood loss might compromise their patient's life. They were proponents of the accepted 'rule' to transfuse a patient if their hemoglobin was below 10 g/dl or their hematocrit was below 30%. Many physicians flatly refused to treat Jehovah's Witnesses due to their refusal of blood. However, due to the continued growth of the Witness

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community, others recognized that this issue was not going away soon, and a few physicians saw a unique opportunity in caring for these patients.

Early pioneers of bloodless medicine and surgery

Everyone wants effective medical care of the highest quality. To that end, a few members of the medical community began to ask the question: 'Are there legitimate and effective ways to manage serious medical problems without using blood?' Fortunately for Jehovah's Witnesses, the answer was yes.

As early as the 1950s, a handful of physicians began to view the Witnesses' refusal of blood not as 'tying their hands', but as just one more complication challenging their skill. Noteworthy among this group of pioneers was Dr Denton Cooley of the Texas Heart Institute. In 1957, Cooley pioneered open-heart surgery without blood support [30,31–34]. Dr Cooley led a team of cardiovascular surgeons who performed thousands of cardiovascular operations on adults and children. In those days, most open-heart surgeries required 20–30 units of blood. In fact, as many as 12 units of blood were used just to prime the heart-lung bypass machine. However, Dr Cooley and his colleagues used innovative methods to prime the bypass machine with nonblood fluids. In time, other techniques were developed to obviate the need for blood. Dr Cooley's experience revealed that 'the risk of surgery in patients of the Jehovah's Witness group was not substantially higher than for others'. This was indeed the genesis of 'bloodless surgery'.

In 1995, Dr Hiram C. Polk Jr, editor-in-chief of the *American Journal of Surgery*, recognized Dr Cooley's outstanding accomplishments [35]. He commented on the trailblazing efforts of Dr Cooley in performing some 1250 'bloodless' open-heart surgeries on patients who requested it due to their religious beliefs. He stated that 'Dr Cooley's blood conservation techniques are applicable to every operation and, therefore, meaningful to all 17 000 readers of *The American Journal of Surgery*'.

Genesis of bloodless medicine and surgery programs

As more and more physicians began to respect Jehovah's Witnesses' position on blood, the atmosphere became less adversarial and much more cooperative. In fact, doctors and hospital administrators learned that the key to managing patients without blood transfusion required proper planning and good coordination between all members of the hospital staff, including nursing, laboratory, pharmacy and social services. Although there are more doctors and hospitals who are willing to cooperate with patients who choose not to accept blood transfusion, a *promise* not to give blood is often not good enough to satisfy some patients. Thus the concept of a structured, formalized 'bloodless' program was born. A bloodless or transfusion-free program offers a group of experienced and skilled physicians, surgeons, anesthesiologists and nurses who are dedicated and committed to 'quality' medical care, without the use of blood. The hospital administration must fully support this program

and make it clear to all staff that once a patient is admitted to the hospital, the patient's refusal of blood should no longer be an issue.

USC University Hospital Program Experience

The administrative team in concert with several key physicians decided to launch the Bloodless Medicine and Surgery Program at USC University Hospital and USC/Norris Cancer Hospital. With a large population of Jehovah's Witnesses residing in California, they came to realize the importance of providing these patients with alternatives to traditional medical and surgical techniques that require transfusions.

In early 1994, the representatives of hospital administration held several meetings with members of the local Hospital Liaison Committee for Jehovah's Witnesses (HLC). Working under the direction of the Hospital Information Services of Jehovah's Witnesses (HIS), headquartered in Brooklyn, New York, the HLC's role is to seek out physicians and hospitals that will offer nonblood management to the Witness community. Presentations about Jehovah's Witnesses' position on health care, specifically blood and blood products, were given to members of the USC faculty.

Subsequently, personal contact was made with individual physicians to determine their willingness to treat Witness patients without blood. The goal of these one-on-one interviews was to ascertain each doctor's comfort level and experience in providing elective and emergent treatment to adults and minors without blood product support.

The program was officially launched in 1997 under the direction of Dr Nicolas Jabbour. The program was promoted using newsletters, seminars, health fairs and medical conferences, and media outlets.

Legal structure of bloodless program

Consent: liability of physician and hospital

The Paul Gann Blood Safety Act, based on California State Law, Health & Safety Code puts the onus on the physician to talk with patients facing the possibility of receiving allogeneic blood, and explain to them the risks, benefits and alternatives. The Paul Gann Act emphasizes alternatives such as preoperative autologous donation, directed donor blood, intraoperative cell-salvage and hemodilution. The physician must note in the patient's medical record that a standardized written summary produced by the State Department of Health Services (DHS) is given to the patient (see Figures 1.3 and 1.4). No other pamphlet, other than the DHS pamphlet, will satisfy the physician's obligation under the law.

Upon admission to the hospital, patients must sign a release-of-liability form that clearly documents their refusal of blood and releases the physician and all hospital personnel from any untoward consequences of such refusal (see Figure 1.2).

■ AUTOLOGOUS BLOOD - Using Your Own Blood

The methods of using your own blood can be used independently or together to eliminate or minimize the need for donor blood, as well as virtually eliminate transfusion risks of infection and allergic reaction.

Option	Explanation	Advantages	Disadvantages
PRE-OPERATIVE DONATION Donating Your Own Blood Before Surgery	The blood bank draws your blood and stores it until you need it, during or after surgery. For elective surgery only.	<ul style="list-style-type: none"> Eliminates or minimizes the need for someone else's blood during and after surgery. Medical conditions may prevent pre-operative donation. 	<ul style="list-style-type: none"> Requires advance planning. May delay surgery. Medical conditions may prevent pre-operative donation.
INTRA-OPERATIVE AUTOLOGOUS TRANSFUSION Recycling Your Blood During Surgery	Instead of being discarded, blood lost during surgery is filtered, and put back into your body during surgery. For elective and emergency surgery.	<ul style="list-style-type: none"> Eliminates or minimizes the need for someone else's blood during surgery. Large amounts of blood can be recycled. 	<ul style="list-style-type: none"> Not for use if cancer or infection is present.
POST-OPERATIVE AUTOLOGOUS TRANSFUSION Recycling Your Blood After Surgery	Blood lost after surgery is collected, filtered and returned. For elective and emergency surgery.	<ul style="list-style-type: none"> Eliminates or minimizes the need for someone else's blood after surgery. 	<ul style="list-style-type: none"> Not for use if cancer or infection is present.
HEMODILUTION Donating Your Own Blood During Surgery	Immediately before surgery, some of your blood is taken and replaced with I.V. fluids. After surgery, your blood is filtered and returned to you. For elective surgery.	<ul style="list-style-type: none"> Eliminates or minimizes the need for someone else's blood during and after surgery. Dilutes your blood so you lose less concentrated blood during surgery. 	<ul style="list-style-type: none"> Limited number or units can be drawn. Medical conditions may prevent hemodilution.
APHERESIS Donating Your Own Platelets and Plasma	Before surgery, your platelets and plasma, which help stop bleeding, are withdrawn, filtered, and returned to you when you need it. For elective surgery.	<ul style="list-style-type: none"> May eliminate the need for donor platelets and plasma, especially in high blood-loss procedures. 	<ul style="list-style-type: none"> Medical conditions may prevent apheresis. Procedure has limited application.
In some cases, you may require more blood than anticipated. If this happens and you receive blood other than your own, there is a possibility of complications, such as hepatitis or AIDS.			
■ DONOR BLOOD - Using Someone Else's Blood			
Donor blood and blood products can never be absolutely 100% safe, even though testing makes the risk very small.			
Option	Explanation	Advantages	Disadvantages
VOLUNTEER BLOOD From the Community Blood Supply	Blood and blood products donated by volunteer donors to a community blood bank.	<ul style="list-style-type: none"> Readily available. Can be life-saving when your own blood is not available. 	<ul style="list-style-type: none"> Risk of disease transmission (such as hepatitis or AIDS), and allergic reactions.
Note	You may wish to check whether donors are paid or volunteer, since blood from commercial (paid) donors may not, in some cases, be as safe as blood from volunteers.		
DESIGNATED DONOR BLOOD From Donors You Select	Blood and blood donors you select who must meet the same requirements as volunteer donors.	<ul style="list-style-type: none"> You can select people with your own blood type who you feel are safe donors. 	<ul style="list-style-type: none"> Risk of disease transmission (such as hepatitis or AIDS), and allergic reactions. May require several days of advanced donation. Not necessarily as safe, nor safer, than volunteer donor blood.
Note	Care should be taken in selecting donors. Donors should never be pressured into donating. Donations from certain family members may require irradiation of blood.		

Figure 1.4 DHS Pamphlet: Transfusion Information and Consent (Paul Gann Blood Safety Act).

Confirming a patient's decision to refuse blood

On occasion, a physician may feel compelled to 'confirm' or 'verify' a patient's decision to refuse blood transfusion. The physician's personal conscience may dictate that he or she *privately* discuss the matter with the patient without any input from family members. Such a discussion is appropriate and usually

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welcome. However, a physician should be careful not to use this session as an opportunity to pressure the patient to revisit his or her refusal of blood. How far should the physician go in 'confirming' the patient's choice of nonblood management without it being viewed as 'badgering' or coercion? Oftentimes this can be a very subtle issue. The goal of this discussion is to give the physician the confidence and peace of mind that withholding blood products is the absolute decision of the patient. On the other hand, if a family member or friend is present to give advice or moral support to the patient (especially in the case of Jehovah's Witnesses), the medical staff should have it clear in mind that the decision being made is the patient's and not the other persons'. If the patient is looking to another person to answer questions being posed to him or her, it can make a physician quite uneasy, and understandably so. This sort of input should be given to the patient during pre-op or some other more appropriate time.

Policies and procedures

An essential step to ensuring the success of a bloodless program is to develop well-defined policies and procedures that are legally, ethically and clinically sound (see Appendix). They should make absolutely clear the role of every member of the medical and hospital staffs who have direct contact with patients refusing blood or blood products. Distinct methods of identifying patients should be implemented, for example colored armbands, computer codes/symbols and chart stickers. A mechanism should be in place to monitor orders to type and crossmatch blood for patients enrolled in the bloodless program. In addition, laboratory draws for blood testing should be ordered judiciously, not routinely.

Highlights of USC Program

The Transfusion-Free Medicine and Surgery Program at USC University Hospital is supported by a comprehensive dedicated team of over 100 medical and administrative professionals. The program has an appointed medical director and program manager. There is also an advisory committee that is designed to steer the development and management of the program. Its core functions are to revise policies and procedures to support the program, and develop mechanisms to measure compliance. In addition, the advisory committee establishes criteria to identify physicians to be included on a transfusion-free medicine panel for the purpose of referring patients, and to ascertain indicators and develop a database for outcome measurement. The committee members may also assist in examining the feasibility of utilizing specific products and services offered by vendors that are designed to minimize blood loss. All in all, the advisory committee serves as a tool to increase quality of care and patient satisfaction within this specialized area of medicine. The collaborative effort of everyone involved has led to steady growth and noteworthy accomplishments (see Figure 1.5). Most notably in

USC transfusion-free program—surgical admissions

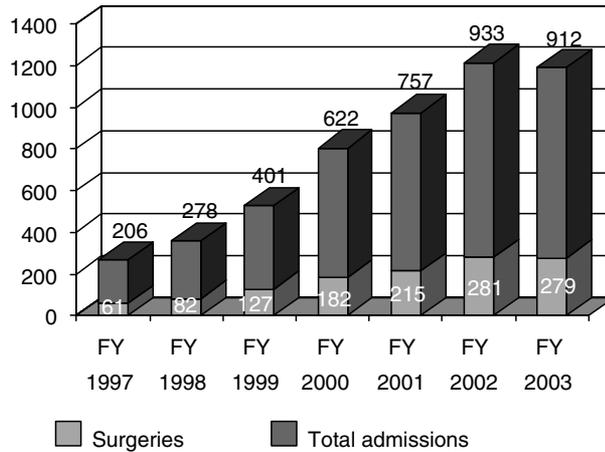


Figure 1.5 USC Transfusion-Free Program growth.

June 1999 the USC liver transplant team led by Dr Nicolas Jabbour, Dr Rick Selby and Dr Yuri Genyk performed the world’s first adult-to-adult living-related live-donor liver transplant in a Jehovah’s Witness patient without blood product. Not long after that, the team performed their first successful pediatric live-donor liver transplant in a child from a Jehovah’s Witness family without blood product transfusion. Other major surgical cases performed at USC University Hospital and the USC Norris Cancer Hospital without blood include prostatectomy, radical nephrectomy, cystectomy, primary and revision hip/knee surgery, neuro-spine and ortho-spine surgery, cardiac bypass and valve replacement surgery, and even heart transplants.

Future extension of transfusion-free programs

When most people hear the words ‘bloodless’ or ‘transfusion-free’, they immediately think of Jehovah’s Witnesses. Historically Jehovah’s Witnesses have been the largest users of bloodless and/or transfusion-free medicine and surgery. However, in recent years the objective of many individuals and organizations, both in the medical community and the lay public, has been to expand this approach to medicine to a much larger population. Religious, ethical and legal issues aside, one must take a hard look at whether or not blood avoidance offers benefits for the community at large.

It is hoped that transfusion-free medicine becomes the standard of care for any medical or surgical patient. One cannot deny that there are many

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modalities that have been heavily relied upon in the past, even as it relates to the use of blood, that are now considered archaic and unscientific.

With ongoing progress in the area of oxygen-carrying products and synthetic clotting factors such as factor VIIA, the future looks brighter in providing a safe and effective alternative to blood transfusions.

References

- 1 Bloodless medicine and surgery – the growing demand. *Awake* 2000; **81**: 3–6.
- 2 *Jehovah's Witnesses and the Question of Blood*. Watchtower Bible and Tract Society of Pennsylvania, 1977.
- 3 *How Can Blood Save Your Life?* Watchtower Bible and Tract Society of Pennsylvania, 1990.
- 4 Questions from readers. *The Watchtower* 2000; **121** (Jun 15): 29–31.
- 5 Questions from readers. *The Watchtower* 2000; **121** (Oct 15): 29–31.
- 6 Questions from readers. *The Watchtower* 1980; **101**: 31.
- 7 *Legally Defending Jehovah's Witnesses' View of Blood*. New York: Patterson, 2001.
- 8 *California Physician's Legal Handbook*. California Medical Association, 1997.
- 9 Legal Considerations for Balancing Patients' Rights and The Bloodless Medicine and Surgery Program. Ralph A. Leaf, Attorney at Law, 1997.
- 10 *Schloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (NY 1914).
- 11 61 Am Jur 2d. Physicians, Surgeons, and Other Healers 197 (1981).
- 12 *In re Milton*, 505 N.E.2d 255 (OH 1987).
- 13 *In re Osborne*, 294 A.2d 372 (DC 1972).
- 14 *In re Estate of Brooks*, 205 N.E.2d 435 (IL 1965).
- 15 *Reynolds v. United States*, 98 U.S. 145, 167 (1878).
- 16 *Harden v. State*, 216 S.W.2d 708 (TN 1948).
- 17 *The Refused Blood Transfusion*, 10 Nat. L.F. 202, 207–09 (1965).
- 18 *The Right to Die*, 9 Utah L. Rev. 161, 163–68 (1964).
- 19 *In re Brown*, 478 So.2d 1033, 1039 (MS 1985).
- 20 *In re Conroy*, 486 A.2d 1209, 1229 (NJ 1985).
- 21 *Winters v. Miller*, 446 F.2d 65,69 (2d. Cir 1971)
- 22 Developments in the Law – Medical Technology and the Law, 103 Harv L Rev 1519, 1670 (1990).
- 23 535 A.2d 452 (Pa 1987). Informed Refusal: Legal Befuddlement.
- 24 President's Commission, Deciding to Forego Life-Sustaining Treatment at 132–33.
- 25 *In re Dubreuil*, 629 So. 2d 819, 827 n.13 (Fla 1993).
- 26 2 Health Law Center, Hospital Law Manual 180 (P. Young 3d 1989).
- 27 President's Commission for the Study of Ethical Problems, *Making Health Care Decisions* 183 (1982).
- 28 Developments in the Law – Medical Technology and the Law, 103 Harv L Rev 1519, 1651 (1990).
- 29 Consent Manual. California Healthcare Association 2001, 28th edn.
- 30 Farmer S, Webb D. *Your Body, Your Choice*. Singapore: Media Masters, 2000: 14–15.
- 31 Cooley DA, Crawford ES, Howell JF, Beall AC Jr. Open heart surgery in Jehovah's witnesses. *Am J Cardiol* 1964; **13**: 779–81.
- 32 Ott DA, Cooley DA. Cardiovascular surgery in Jehovah's Witnesses: report of 542 operations without blood transfusion. *JAMA* 1977; **238**: 1256–8.

Legal and Administrative Issues **23**

- 33 Henling CE, Carmichael MJ, Keats AS, Cooley DA. Cardiac operation for congenital heart disease in children of Jehovah's Witnesses. *J Thorac Cardiovasc Surg* 1985; **89**: 914–20.
- 34 Carmichael MJ, Cooley DA, Kuykendall RC, Walker WE. Cardiac surgery in children of Jehovah's Witnesses. *Tex Heart Inst J* 1985; **12**: 57–63.
- 35 Cooley DA. Conservation of blood during cardiovascular surgery. *Am J Surg* 1995; **170**: 53S–59S.