Informed Consent for Blood Transfusion

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Introduction and History

Although informed consent for medical procedures began evolving in the early decades of the 20th century, the idea of applying it to blood transfusion did not really begin developing until the 1980s when the transmission of infectious agents such as the human immunodeficiency virus and hepatitis C virus alarmed patients and health-care providers alike. In 1986 and 1994, AABB made recommendations to its members for obtaining informed consent from patients for blood transfusion, which eventually became a standard in 2000.

Other accrediting agencies such as The Joint Commission, DNV (Det Norske Veritas), and the College of American Pathologists have also established requirements related to informed consent, and it is required by law in some jurisdictions in the United States (eg, California, New Jersey, and Pennsylvania). During this period of time, obtaining informed consent for transfusion went from being an uncommon practice to one that was followed by a majority of hospitals in the United States. Although informed consent for transfusion is required or recommended in other developed countries, its implementation is heterogeneous in practice.

The Basis of Informed Consent: Ethics

The concept and practice of informed consent lies in five fundamental principles of medical ethics: autonomy, veracity, beneficence, non-maleficence, and justice.[1]

- Autonomy is the principle that individuals have the right to determine the actions they take and the choices they make. In the context of informed consent, it is their right to determine what will be done to their bodies and is rooted in the concept of individual freedom as well as the right to privacy.
- Veracity is the principle that interactions between care providers and patients must be founded on truth telling. The care provider is obligated to convey information as accurately as possible, and also must fulfill any "promises" to the patient in terms of care, follow-through, and not withdrawing care without making alternate provisions.
- Beneficence is the principle that the health-care provider will strive to improve the well-being of the patient, and will act in the best interest of the patient.
- Non-maleficence is the principle that the caregiver strives to avoid doing harm to patients and seeks to protect them from pain and suffering.
- Justice is the principle that is based on the recognition of the equality of all persons who should receive care in proportion to their need. In a financially constrained environment, it means that limited resources should be allocated fairly.

Informed consent is driven largely by the first ethical principle of autonomy, the right of a person to determine what course of medical action to pursue. However, veracity is also at the heart of the information exchange, which makes it possible for a patient to make a truly "informed" decision.

The Basis of Informed Consent: Informed Consent and the Law

The legal definition of informed consent is usually considered to have originated from a decision by Judge Benjamin Cardozo in 1914 who wrote that "every human being of adult years and sound mind has a right to determine what shall be done to his own body."

The modern concept of informed consent was defined in a ruling in *Cobbs vs. Grant* by the California Supreme Court in 1972. In this case the patient, who developed a number of complications of gastric surgery, alleged that the physician had not disclosed to him in advance the possibility of any of those adverse outcomes.

The ruling stated that "as an integral part of a physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each."

The legal understanding of informed consent includes the following key points:

- Consent is a process of communication between a patient and a caregiver, which is proportional to the magnitude of the health-care intervention and its inherent risks.
- The patient must be competent to make an informed decision. This implies that the patient must be able to understand the information being provided and the consequences of action (or inaction).
- Consent must be obtained prior to the intervention, except in certain extenuating circumstances.
- Consent must be made voluntarily, free from pressure or coercion on the part of the health-care provider or any third party.
- Consent is revocable. A patient may withdraw consent at any point.

Generally, informed consent is a matter of state law, so it is important to determine whether the state in which you are practicing has informed statutes or whether specific state law has evolved.

Over time, medical practice and the body of case law has further refined the basic elements of informed consent. These elements include:

- Information provided to the patient.
    - Explanation of intervention.
    - Benefits.
    - Risks.
    - Alternatives.
    - Opportunity for questions/clarification.
- Availability of choices including refusal.
- Autonomous patient decision.
- Documentation of process.

The first of these elements consists of the information, which is provided to the patient by the healthcare provider. This information should include an explanation of the intervention, the anticipated benefits, the material risks, and the alternatives. Part of providing information is ensuring that the patient understands it. To this end, the patient must be given the opportunity to ask questions and seek clarification from a health-care professional capable of providing answers.

The second element of the informed consent process is that the patient must have choices, including that of declining the suggested therapy or choosing an alternative therapy, if available. The third element is that the patient must be able to make an autonomous decision, which is neither coerced nor unduly influenced by the health-care provider or a third party, to accept or refuse the intervention, and is predicated on the competence of the patient.

Finally, the process must be documented.

The Process of Informed Consent: Informing the Patient – The Process of Disclosure

At the core of the consent process is the duty of the health-care provider making the decision to transfuse to inform the patient. The process of providing the patient with information about the intended intervention is called disclosure. Although the health-care provider making the decision to transfuse is usually responsible for carrying out the process of informing the patient and obtaining consent, this task may be delegated to a member of the health-care team who is working on behalf of that health-care provider, such as a nurse practitioner or a medical resident. The principle underlying disclosure is that patients must be provided with adequate information about the transfusion so that they are able to make informed, independent decisions about what they will permit to be done to their own bodies. The principles of veracity and autonomy underlie the words "informed" and "independent decision."

In the decades since the *Cobbs vs. Grant* decision, courts have moved in the direction of applying a patient-oriented standard for what information should be disclosed which is based on supplying information that could reasonably be expected to affect the decision made by a competent patient to accept or reject a proposed medical intervention.

The Process of Informed Consent: Explanation of the Intervention

The first step in the process of disclosure is for the health-care provider to describe the therapeutic or diagnostic intervention. In the case of transfusion, this description is relatively straightforward, but may require some explanation of what the blood components are.

The health-care provider must explain to the patient the rationale behind the transfusion of blood components, and what it may reasonably be expected to achieve. The nature of the anticipated benefit, its magnitude, and the probability that it will be achieved may all affect the willingness of the patient to assume risk.[2]

This discussion is complicated by the fact that the indications for transfusion and its clinical impact are not as well founded in evidence-based medicine as some other medical interventions. Poor clinical outcomes have been shown to correlate with low hemoglobin levels, although

several randomized clinical trials of RBC transfusion have not shown any benefit of transfusing patients to the higher of two target hemoglobin levels.

The data from randomized clinical trials demonstrating the benefits of transfusing other blood components are also limited. With this caveat in mind, the health-care provider must convey to the patient what the benefits may be for that particular patient. Transfusions are often administered to alleviate symptoms, such as transfusing RBCs to an anemic patient with dyspnea, or platelets to a thrombocytopenic patient with gastrointestinal tract bleeding. Transfusions are also frequently used to prevent complications, such as RBCs to a patient with coronary artery disease to prevent cardiac ischemia or platelets to a patient recovering from chemotherapy to prevent spontaneous bleeding. The health-care provider must also communicate to the patient how likely it is that the transfusion will accomplish the therapeutic goal.

The Process of Informed Consent: Material Risks

An important aspect of the informed consent process, and the one that has attracted the most attention, is the disclosure of the risks of transfusion. The legal standard does not require the description of every possible risk; however, the patient should be informed about those risks that would be likely to affect the decision of a prudent person to accept the transfusion. These "material" risks are ones that are likely to influence the decision of the patient to accept or reject the intervention.[3]

The risks of any medical intervention, including transfusion, may be organized in four categories. These categories include:

- High-frequency complications (fever, urticaria).
- Low-frequency complications (HIV infection, mistransfusion).
- Patient-specific complications (volume overload, hypersensitivity).
- Hypothetical/controversial complications (immunomodulation, Creutzfeldt-Jakob prion transmission).

The disclosure of common and patient-specific complications is relatively clear, but the discussion of rare or hypothetical risks is considerably more difficult.

Despite the fact that the frequent complications of transfusion, such as febrile, non-hemolytic transfusion reactions, do not cause significant morbidity, they should be disclosed simply because of the high likelihood that they will occur. Although the possibility of experiencing minor complications such as these are unlikely to dissuade a patient from transfusion, this foreknowledge does help prepare a patient to deal with such a reaction with the understanding that it is not dangerous, albeit uncomfortable.

The health-care provider should also discuss complications of transfusion to which the individual patient may be particularly susceptible, for example, volume overload with associated dyspnea in a patient with impaired cardiac or renal function.

The question of which of the uncommon or rare complications of transfusion should be disclosed to patients is more difficult. In general, risks of a medical intervention that carry the possibility of death, loss of a sensory function, paralysis, or mental impairment would be seen as significant adverse outcomes that most patients would want to know about. The complications of

transfusion most frequently responsible for deaths are transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), acute hemolytic transfusion reactions, and bacterial contamination, so these should be discussed as part of the disclosure process.

It is probably not necessary to list every rare, serious complication of transfusion, if only because an overwhelming amount of frightening information can subvert the disclosure process by impairing the ability of a person to register and understand any of the information being provided to him or her, frightening or otherwise. The disclosure of these very uncommon adverse outcomes is also complicated by the general difficulty of conveying information about the frequency of rare events. Patients may find it difficult to interpret degree of risk when it is expressed numerically, and especially when those numbers are very small.

One approach is to compare the frequency of the transfusion complication to the frequency of a more familiar event such as coin tossing or a motor vehicle accident, or to another medical intervention such as death due to reaction to anesthesia.

Another troublesome area concerns those risks that are hypothetical, or where the association with transfusion is controversial. Recent examples in the transfusion medicine arena include possible transmission of the Creutzfeldt-Jakob prion or infectious agents that are not endemic to the US but may be carried by travelers, and a transient immunosuppression observed in recipients after transfusion of allogeneic blood.

Although it could be argued from an ethical standpoint that such risks should be disclosed, the intent of the informed consent process is to make it possible for the patient to make a rational decision about a medical intervention, and this decision does not require perfect or exhaustive knowledge. In addition, the legal requirement is to provide the patient with information about the "material" risks of the procedure, not "all" or "all possible" risks.

The Process of Informed Consent: Risks -The Patient's Perspective

The patient's understanding of the risks of transfusion may not be entirely congruent with the health-care provider's perception and may also be grounded in a different perspective. Two different cognitive systems may be used in assessing risk: assimilative perspective and precautionary perspective.

The first cognitive system, the assimilative perspective, is based on the principle that a risk does not exist if there is no proof of harm. This perspective bases decision-making on the assessment of scientific and clinical data and relies on the rigor of the scientific method. However, even the scientific approach may have blind spots if the relevant data are not collected or if the research questions are not framed correctly. It also requires conscious, cognitive effort, and is a slow process. The assimilative perspective generally informs the decision-making of health-care providers.

However, risk assessment by patients as well as policy makers has generally relied heavily on the precautionary perspective. This perspective is based on the principle that a risk exists unless there is proof otherwise. It has the benefit of also avoiding risks that are unexpected because scientific and clinical knowledge are inevitably incomplete. However, it often fails to weigh the

risks of not acting, discourages innovation, and has led to increased expenditure of resources for minimal gains in pursuit of a "zero risk" blood supply. The precautionary approach is generally based on an experiential cognitive model where the response to perceived risks is instinctive and rapid.

In addition to the cognitive perspective, a number of other factors may affect a patient's perception of risk. There are four characteristics of a risk that may affect the way a patient perceives and reacts to it: (1) frequency of the adverse outcome, (2) consequences of that outcome, (3) the "dread" quality of those consequences, and (4) their imminence.

A patient's perception of the frequency of an adverse outcome may also be influenced by his or her awareness of its existence. A patient who has a relative or friend with HCV infection is likely to overestimate the likelihood of obtaining such an infection via transfusion. High visibility of a risk in the media can lead to the phenomenon of "social amplification" whereby the perceived frequency of the risk is magnified in the mind of the patient. For example, the public is much more concerned about being attacked by a shark, a very low probability event that is almost always reported in the media, than a dog attack, which is far more common but rarely reported.

The consequences of the complication also affect a patient's reaction to it, with serious outcomes such as death, loss of a sensory function, paralysis, or mental impairment quite naturally influencing the patient's response. In addition, some adverse events are more feared or "dreaded" than others. People may dread being attacked by killer bees or being infected with HIV through transfusion but are not as fearful of motor vehicle accidents or transfusion-associated circulatory overload.

Patients also tend to be more fearful of complications that occur shortly after the medical intervention (ie, are more "imminent") than they are of those that are significantly delayed. The lack of "imminence" may account for the relatively measured reaction to transfusion-transmitted HCV, for example.

The willingness of a patient to take on the risk of a medical intervention may also be affected by other factors, among them the nature and magnitude of the anticipated benefit. Not surprisingly, patients are willing to take on a greater degree of risk for what they consider to be a significant benefit. Risks that are taken on voluntarily are also perceived to be lower, perhaps because the patient feels a sense of control.

Patients are more likely to accept an adverse transfusion outcome that is familiar to them (eg, fever, HCV infection) than one that is not (eg, hypersensitivity rash, Babesiosis). Finally, the assessment of risk may be associated with certain demographic factors. For example, it has been suggested that transfusions may be perceived as riskier by females, minorities, and persons with lower income and education level. Factors affecting the understanding of risk are summarized in Table 1.

Table 1. Factors Affecting the Understanding of Risk

Category	Factor
Demographics	• Gender • Socioeconomic status • Minority status • Educational level
Benefits	• Value of benefit to patient • Magnitude of benefit
Likelihood	• Frequency • Perceived frequency • Familiarity
Nature	• Severity • "Dread" quality
Control	• Voluntariness • Shared

The Process of Informed Consent: Alternatives

Following a review of the proposed hemotherapy and its risks, the health-care provider should discuss possible alternatives. One of the alternatives, of course, is for the patient to decline the transfusion. This situation will be discussed in more detail in the last section.

There are numerous alternatives to transfusion that have been designed to stimulate endogenous production of RBCs, neutrophils, and platelets (eg, cytokines) and to minimize the loss of blood intraoperatively (eg, acute normovolemic hemodilution, blood recovery, and reinfusion) and outside of the operating room (eg, minimizing blood draws for diagnostic and monitoring purposes).

In discussing the various alternatives to component transfusion with the patient, the health-care provider must bear in mind their suitability and availability. Preoperative strategies to avoid transfusions include, but are not limited to, iron supplementation to correct iron deficiency anemia; administration of erythropoietin; and review and modification of anti-platelet, anticoagulation, and non-steroidal anti-inflammatory drug (NSAID) therapy. Perioperative strategies to reduced blood loss include use of cell savers (capture of autologous blood during surgery and reinfusion), laboratory-guided transfusion therapy, use of tranexamic acid, and application of fibrin sealants (plasma-derived surgical hemostatic agents). Pre- and perioperative management of a patient to avoid allogeneic transfusions should occur on an individual basis. It is based on suitability and resource availability at an individual health-care facility.[4]

The Process of Informed Consent: Communication and the Process of Informed Consent

At its core, informed consent is a process of communication between the health-care provider and the patient. Although the preceding sections have dwelt on the obligation of the health-care provider to disclose information, the process must also provide the opportunity for the patient to ask questions and communicate to the health-care provider his or her desires, goals, fears, and

preferences. Communication between patient and health-care provider is vital to this process; however, it is sobering to realize how little patients recall of these interchanges or of the information that was conveyed during the process of obtaining informed consent for transfusion. Results from two surveys found that while 71-80% of consented transfusion recipients remembered the conversation with a health-care provider for a blood transfusion, only 23-56% indicated recollection of specific transfusion risks, and far less, only 12% of patients, had recall of alternatives to blood.[5,6] A lot of factors can affect a patient's cognitive ability to understand informed consent. For example, pain can impact a patient's cognition and it precludes a provider from obtaining a valid informed consent. The elderly patient population is also vulnerable due to age-related decreased physical abilities (hearing and vision loss) and a higher prevalence of impaired cognitive abilities that occur with age. More research should be done in this area to enhance comprehension of informed consent by these vulnerable patient populations.[7-12]

A number of factors may affect our ability to communicate successfully with patients in this setting (Table 2).

Table 2. Communication Obstacles between Patient and a Health-Care Provider during Informed Consent

Communication Obstacles
Linguistic Factors • Medical/technical language • Education/social group • Language
Vulnerable patient population (uncontrolled pain, elderly)
Cultural barriers
Atmosphere
Confidentiality

Translation of Medical and Technical Information: The first communication barrier to overcome is the translation of medical and technical information into language that can be understood by people who do not have much background in medicine or biology. This is further complicated by the low level of health-care provider knowledge of basic aspects of transfusion medicine, or even a clear understanding of the elements of informed consent.

Education and Socioeconomic Status: Differences in education and socioeconomic status between the health-care provider and patient may also be an obstacle to communication. A survey of transfusion informed consent forms found that on average they were written at the junior college level, which is attained by only 26% of people in the US.[3,7-10]

Speaking Different Languages: The third communication barrier is imposed when the health-care provider and patient speak different languages. Even though family members and friends can accompany the patient during a healthcare visit and act as interpreters, most health-care facilities provide language services that include qualified sign and spoken language interpreters, over-the-phone interpretation services, and written information in the patient's preferred language. This

allows for better understanding of disease information, prognosis, risk, and treatment, and leads to improved decision-making ability of patients regarding their health. Overall, a qualified interpreter allows for more accurate and unbiased communication between the healthcare provider and the patient without sacrificing patient confidentiality. Bilingual health-care workers who are proficient in non-English languages also can communicate with the patient without an interpreter.[13]

Cultural factors may also compromise communication between health-care provider and patient, especially if certain topics, such as pregnancy, a diagnosis of cancer, or death, are regarded as awkward, if not taboo.

The Process of Informed Consent: Consent Must Be Voluntary

The principle of autonomy demands that the patient must not be coerced into accepting (or rejecting) therapy by the clinical situation, the health-care provider, or a third party, such as a family member. An effort should be made to give patients the time and unpressured environment to make measured assessments of the benefits, risks, and alternatives of the proposed transfusion, and to make independent decisions.

Although health-care providers should be clear about why they are recommending transfusions, they should avoid over-optimistic assessment of its benefits, or overly dramatic portrayal of the risks of the alternatives, including no transfusion. In fact, overly enthusiastic advocacy has been shown, at least in the research setting, to increase the likelihood of refusal of consent. A patient may also be influenced by the way in which the information presented to him or her is framed.

Information framed as a gain (out of every 100 patients, 99 will do well) as opposed to a loss (out of every 100 patients, 1 will do poorly) is more likely to be perceived positively, even though the described risks are identical.

Finally, the health-care provider should be aware of the possibility that the patient's decision may be influenced by the presence of third parties, such as family members, friends, or spiritual advisors. If third parties have been involved in the discussion, then the health-care provider should attempt to have a private conversation with the patient to confirm that the decision truly represents the wishes of the patient.

Administrative Aspects of Informed Consent: Who May Give Consent

Informed consent is predicated on the competence of the patient. Competence in this context means that the patient can understand what a transfusion is; the information disclosed about benefits, risks, and alternatives; and is capable of making a decision about how to proceed. If an adult patient is incompetent, even temporarily (eg, unconscious, heavily sedated), then consent may be obtained from a guardian, health-care proxy, or next of kin. The surrogate decision maker must conform to the ethical standard of substituted judgment, which requires that decisions must be made with the best interests of the patient in mind, and that would best reflect the patient's own wishes.

It is important to understand that if the healthcare professional identifies that the patient has an impaired capacity in decision making, the patient's decision making could be impaired regarding

a specific type of decision and not to all types of decisions (eg, understanding the disease and the need for surgery but not understanding the need for blood products). It is crucial for a health-care provider to know when to involve a surrogate decision maker in those cases. This process has been described as a sliding-scale share decision making for patient with reduced capacity.[12,14] Although consent must be obtained from a parent or legal guardian to perform any medical procedure on a minor child, there is increasing recognition of the ability of children to participate in a meaningful way in medical decision making, which has led to increasing recognition of the role of obtaining a child's assent to treatment. The assent of a minor who is old enough to understand the procedure is often obtained. The situation for adolescents has become somewhat more complex. Although adolescents are generally considered to be minors for legal purposes, some jurisdictions recognize the concept of the mature minor (Table 3).

The courts have also recognized the status of the "emancipated" minor who may consent to medical procedures on the same basis as competent adults (Table 3).

Table 3. Obtaining a Child's Assent and Consent to Treatment

Term	Explanation of term
The assent of the *minor* who is old enough to understand the procedure is often obtained.	The *minor* can participate in assent to treatment, although consent must be obtained from a parent or legal guardian.
Adolescents are generally considered to be minors for legal purposes; however, some jurisdictions recognize the concept of the *mature minor*.	A mature minor is an adolescent (usually) who is capable of understanding the medical information disclosed, able to make reasonable judgments, and independent enough to make decisions that represent his or her own wishes.
The courts have also recognized the status of the *"emancipated" minor* who may consent to medical procedures on the same basis as competent adults.	Minors are considered to be *"emancipated"* if they are married, in the armed forces, or live independently, managing their own finances.

Administrative Aspects of Informed Consent: Timing

Consent must be obtained prospectively, except in the setting of a true medical emergency. Ideally, the process of disclosure and obtaining consent should be done sufficiently in advance of the transfusion to allow patients the time to reflect on their decisions and request additional information, if needed. Note that some of the alternatives to transfusion may require substantial lead-time to be effective (eg, iron replacement therapy, erythropoietin).

In the setting of a medical emergency, it may be impossible to obtain consent prospectively, or doing so would interfere with good patient care. As is the case with any other emergency medical treatment, transfusion may be carried out without first obtaining consent for patients who may be put at risk of death or serious morbidity by the failure to act. Once the clinical situation has stabilized, it is good practice to explain what emergency steps, including

transfusion, were taken and why, and obtain the patient's agreement that the interventions were warranted.

Administrative Aspects of Informed Consent: Frequency

As a general rule, the informed consent process must be carried out for each medical intervention. In the context of transfusion, the definition of medical intervention is not so clear. For example, medical intervention could be considered to be a plan to which a patient with a myelodysplastic syndrome has consented for a series of RBC transfusions aimed at maintaining the hemoglobin level at a specific target.

A medical intervention may be considered to be all of the transfusions given to a patient during an admission for a surgical procedure. It could also be argued that each transfusion represents an independent medical decision in which the patient should be a partner, and therefore the informed consent process should be repeated.

Since there are no universally accepted standards, each institution must develop a policy for handling consent for repeated procedures in conjunction with counsel and considering local precedent. If consents covering multiple transfusions are permitted, then some limits should be imposed as to the number of events, or the period of time over which the consent is operative. Note that the consent process must be repeated if there are any material changes to the information that was initially disclosed to the patient, including changes to any patient-specific risks, even if institutional policy allows for a documented informed consent process on one occasion to cover multiple events.

It is also good medical practice to obtain the patient's approval prior to administering each transfusion, even if the patient has consented to undergoing multiple procedures. Patients have the right to revoke their consent at any time, in which case any transfusions in progress must be terminated immediately.

Administrative Aspects of Informed Consent: Products and Requiring Consent

When patients are admitted to a hospital, they usually sign a general "consent to treat," which covers many diagnostic and therapeutic interventions. Interventions with the potential for significant morbidity or mortality require the specific informed consent of the patient, however. Most hospitals develop policies, specifying which interventions require documented informed consent (eg, central line placement, most surgical procedures, most endoscopy procedures). This list includes transfusion of blood components and transplantation of tissues and organs. Blood components, tissue and organs are biologically complex and vulnerable to contamination with infectious agents, and thus may carry significant risk.

The risk of infectious disease transmission is much lower for recombinant clotting factors concentrates as well as highly processed plasma derivatives and tissues, so practices regarding consent for their use are not uniform (Table 4).

Table 4. Hemotherapies and Tissues Requiring Informed Consent

Hemotherapy	Consent Required	Consent Variable
Products	Blood components • Whole blood derived: RBC, plasma, platelets, cryoprecipitate • Apheresis derived: RBC, platelets, plasma	Plasma-derived proteins: albumin, IVIG, RhIG, hyperimmune globulins, PCC, FVII, FIX, ATIII Recombinant proteins: FVIII, FIX, FVII, erythropoietin, GCSF, GMCSF Highly processed tissue-bone plugs
Procedures	Patient-donor: cellular therapy product collection PABD Therapeutic phlebotomy Therapeutic apheresis	Acute normovolemic hemodilution Intraoperative blood recovery and reinfusion Postoperative blood recovery and reinfusion

RBC, red blood cells; PABD, preoperative autologous blood donation; IVIG, intravenous immunoglobulin; RhIG, Rh immunoglobulin; PCC, prothrombin complex concentrate; FVII, factor VII; FVIII, factor VIII; FVIX, factor IX; ATIII, antithrombin III; GCSF, granulocyte cell stimulation factor; GMCSF, granulocyte/macrophage cell stimulating factor.

Administrative Aspects of Informed Consent: Documentation

The process of obtaining informed consent for transfusion must be documented in the patient's medical record. Informed consent is not this document, however; rather, it is the entire process of engaging in a meaningful dialogue with the patient. The document merely attests to the fact that the process was carried out.

At a minimum, this document should note that:

- The procedure was explained.
- The benefits, risks, and alternatives, including refusing therapy, were discussed.
- An opportunity for questions was provided, and the patient's questions, if any, were answered.
- The patient consented (or not) to the procedure.
- The patient and the healthcare provider making the disclosure signed the document.

Some institutions also require notation of the specific risks, benefits, and/or alternatives discussed, in addition to the minimum information listed above.

There are different ways in which this documentation can be accomplished. A *hand-written note* in the patient's chart is adequate, assuming it covers the elements listed above, although many institutions use some sort of form, which can be designed to prompt the health-care provider who is obtaining consent for the essential elements. *Forms specifically designed for transfusion* may be used. Alternatively, the consent for transfusion may be incorporated into the *consent form*

used for surgery or other invasive procedures. Some institutions use forms with detailed information about the risks, benefits, alternatives, etc., but others use forms that are quite generic.

The decision as to what type of form to use generally reflects the preference of counsel at each institution. Risks of transfusion that are specific to the patient (eg, risk of transfusion-associated circulatory overload in a patient with existing congestive heart failure) should be captured in the notes in the chart or on the form.

Increasingly, documentation of informed consent for transfusion will exist in the patient's electronic medical record, which has the advantage of making it readily available to anyone involved in the care of the patient.

Informed Consent for Patients: The Duty of the Institution

Each institution has a duty to its patients to have systems in place for obtaining and documenting informed consent for transfusion. The medical director of the hospital transfusion service is required by both AABB and the College of American Pathologists to play a role in developing and implementing these procedures.

At a minimum, elements of consent shall include all of the following:

- A description of the risks, benefits, and treatment alternatives (including non-treatment).
- The opportunity to ask questions.
- The right to accept or refuse transfusion

The policies and procedures developed to ensure that a process of informed consent is carried out prior to transfusion should specify at a minimum:

- Which products or procedures require informed consent.
- Who may carry out and document the informed consent process (eg, physicians, nurse practitioners).
- Who may give informed consent (eg, the issue of minors, incompetent adults).
- When informed consent must be obtained (ie, frequency, duration, procedure-related).
- What information should be conveyed to the patient.
- How informed consent will be documented.
- How staff will be trained and continued competence assured.
- How compliance with the policy will be assessed.
- How emergency situations will be handled (waiver of consent).
- How refusal of care will be handled and documented.

Refusal of Consent: Jehovah's Witnesses and Other Patients

As described earlier, informed consent is based on the ethical and legal principles of autonomy and the right of a competent patient to determine what medical interventions he or she will accept.

These rights include that of refusing a recommended medical intervention, even one that is potentially life-saving. The right to refuse treatment has been consistently upheld by a body of case law and judicial decisions in the United States as well as abroad.

It is the obligation of the health-care provider to respect the patient's autonomy and honor the decision however difficult it may be for a health-care provider who does not share the patient's belief system, and particularly when the consequences of refusal could be death or permanent injury.

The Approach to the Patient Who Refuses Therapy: Disclosure and Choice

As a very first step, it should be determined whether or not the individual health-care provider or the institution is equipped to care for patients who refuse transfusion and other hemotherapies.

If not, and if the situation does not call for emergent care, then arrangements should be made to transfer care to health-care providers who are prepared to handle these patients. Meanwhile, the health-care provider is obligated to care for the patient according to his or her wishes and may not "abandon" the patient, which would be unethical and illegal.

In an elective situation, the approach to the patient who may refuse transfusion is similar to the approach for any patient and includes a description of the planned transfusion and its rationale, and the disclosure of the risks, benefits, and alternatives.

The blood components proscribed for Jehovah's Witnesses include: red cells, leukocytes, platelets, and plasma. Note that a few other religious groups proscribe blood transfusion, and patients refuse transfusions for other reasons as well. Assumptions should not be made about which hemotherapies a patient will or will not accept, but rather the options should be reviewed for each patient. The consequences of refusing transfusion should also be explained carefully, especially if there is a chance of a very serious adverse outcome, such as death, loss of a limb or sensory function, or mental impairment. The patient should also understand the possible benefits of the hemotherapy that would be given up. It is important that the patient states explicitly a willingness to incur these serious consequences, including death, loss of limb, etc., rather than to receive a transfusion. For patients refusing transfusion, the discussion of possible alternatives assumes special importance. It should be explicitly explained to the patient which of the alternatives are both available and suitable for the circumstances that the patient would accept.

Documentation of Refusal

Once a plan specifying which therapies the patient will accept and which will be refused has been agreed to by the patient and care providers, it should be made a part of the medical record and available to those health-care providers who will be participating in the care of the patient. Paradoxically, it is useful to inform the blood bank about patients who are refusing transfusion since it is well positioned to prevent inadvertent transfusion.

At a minimum, a "refusal of care" document must state that the consequences of declining care were explained to the patient, alternatives were discussed, and that the patient is willing to accept these consequences, including death, rather than accept transfusion. Both the responsible health-care provider and the patient should sign the document. The refusal of care may be documented by a note written into the medical record or a form.

Many Jehovah's Witnesses have either executed advance medical directives specifying their wish to refuse transfusions or carry with them a form provided by the Jehovah's Witness church. It is also a good practice to make a copy of this document as a part of the patient's medical record.

Table 5 lists some accepted and not accepted hemotherapies for Jehovah's Witnesses.

Table 5. Hemotherapies Acceptable and Not Acceptable to Jehovah's Witnesses.

Unacceptable Treatments	Personal Decision	Acceptable Treatments
• Whole blood • Red blood cells • White blood cells • Platelets • Plasma • Preoperative autologous blood donation	• Intraoperative or postoperative blood recovery and reinfusion • Acute normovolemic hemodilution • Intraoperative autologous blood component preparation ✓ Plateletpheresis ✓ Fibrin gel ✓ Platelet gel • Cardiopulmonary bypass • Apheresis • Dialysis • Plasma derivatives ✓ Cryoprecipitate ✓ Albumin ✓ Clotting factor concentrates ✓ Immune globulins ✓ Vaccines ✓ Fibrin glue • Epidural blood patch • Cellular therapy products • Solid organ transplantation	• Intraoperative conservation techniques ✓ Controlled hypotension ✓ Anatomic dissection ✓ Hemostatic surgical tools ✓ Meticulous surgical hemostasis ✓ Regional anesthesia ✓ Minimally invasive surgery ✓ Topical hemostatic agents • Phlebotomy • Angiography • Pharmacologic hemostatic agents ✓ Desmopressin ✓ Tranexamic acid ✓ c-Aminocaproic acid ✓ Aprotinin ✓ Recombinant clotting factor concentrates (VII, VIII, IX) • Recombinant hematopoietic growth factors (albumin free) ✓ Erythropoietin ✓ GCSF ✓ GMCSF • Perfluorocarbon based oxygen carriers • Non-blood volume expanders

- ✓ Crystalloid solutions
- ✓ Hydroxyethyl starch

GCSF, granulocyte cell stimulation factor; GMCSF, granulocyte/macrophage cell-stimulating factor.

Refusal of Care in Emergencies

Emergency situations, especially those involving significant blood loss, raise special concerns in Refusal of Care situations where the opportunity to explore the patient's wishes is minimal.

There are several situations in which the patient's wish to refuse transfusion must be honored, namely:

- The patient is competent, conscious, and refuses transfusion (with or without a signed refusal document).
- The patient is incompetent temporarily (eg, unconscious, sedated, in extreme pain) or is incompetent chronically but:
    - There is some sort of documentation of refusal in the medical record (eg, refusal of care document, advance directive).
    - The patient is carrying an advance directive or a form provided by the Jehovah's Witnesses (with valid signatures), or such a form is provided by a third party (eg, family member, church member).
    - There is documentation (eg, notation in the medical record) that the patient is a Jehovah's Witness, or member of another religions group that forbids transfusion.
    - The patient previously expressed orally the wish to refuse transfusion to someone involved in the emergency care of the patient.
    - The patient's refusal is communicated by next-of-kin, health-care proxy, or guardian (if chronically incompetent).

If the medical team providing emergency care is unaware that the patient is a Jehovah's Witness or if none of the above conditions are met, then transfusions given for standard indications do not constitute battery.

Who May Refuse Care

Patients who are considered to be competent to consent for medical care including transfusion may also refuse therapy, even if death or injury are likely to ensue. However, in situations where the patient is not competent to consent to or refuse care, and third parties make these determinations, conflicts may arise.

The Incompetent Adult

A guardian or health-care proxy for a permanently or temporarily incompetent adult may refuse transfusions, including those that might be life-saving, if there is reasonable evidence that, when competent, the patient expressed a desire to refuse transfusions, even at the cost of life. These circumstances are clear if the patient executed an advance medical directive or was an active member of the Jehovah's Witness church, as described above. The situation is more difficult if

the beliefs of the patient while competent are not clear or were not expressed directly to the substitute decision maker. Under these circumstances, the courts have usually ruled that the interest of the State in sustaining life and protecting the well-being of the patient outweighs the authority of the substitute decision maker to refuse care, which might result in permanent harm to the incompetent patient.

Competent Adults with Dependents
Conflicts have also arisen in situations where the death of a competent adult due to refusal of transfusion would leave minor children without parents and means of support. In some cases, competent adults with minor dependents have been required by the courts to undergo life-sustaining treatments including transfusion. These cases pit the adult's rights of free speech and practice of religion against the interests of the State in providing for the well-being of the children by preventing the loss of a parent as well as preventing them from becoming wards of the state. In other cases, parents have been permitted to refuse therapy if they could demonstrate that their dependent children would be adequately provided for in the event of their demise. More recently, however, courts have been ruling that the right of the parent to make an autonomous determination about refusing therapy overrides the interest of the State in preserving the well-being of the dependents.

Pregnant Women
Conflicts may also arise where refusal of care by a pregnant woman may endanger the life of her fetus, especially if the pregnancy has progressed to the point when the fetus would likely be viable if born at that point, usually by the third trimester. Courts have frequently ordered transfusion and other therapies to preserve the life of the mother and thus that of the fetus, based on the interest of the State in protecting the lives of the unborn until such time as they can make medical decisions for themselves.

Minors
The situation in which parents have wished to refuse life-saving therapy for children on religious grounds has also created difficulties for health-care providers. In general, however, case law has established that parents do not have life or death authority over their children and do not have absolute rights to refuse treatment for religious (or other) reasons for their minor children. The parental right to accept or refuse medical care on behalf of the child is outweighed by the interests of the State in preserving life, and in particular ensuring the survival of the child to the point when he or she is competent to make health-care decisions independently.

Minors in general may neither consent to, nor refuse, medical therapy, especially if it is intended to prevent serious injury or death. The situation with respect to mature minors is particularly fraught with difficulty, and legal decisions involving adolescents refusing transfusion for religious reasons have been inconsistent. Hence, it is important to consult hospital counsel. Emancipated minors are considered to be equivalent to competent adults for the purposes of consenting to or refusing therapy.

Hospitals that do not have the expertise or infrastructure to care for patients who refuse transfusion should at least develop a process for referring the patients to appropriately equipped facilities. Institutions that do plan to manage patients who refuse transfusion should develop and

implement suitable policies and procedures that assure high quality care that is consistent with the beliefs and wishes of these patients.

Conclusion

The processes of medical decision-making and informed consent have become irrevocably intertwined as patients increasingly expect that they will be well informed and participate actively in the decision to undergo any medical intervention. These expectations also exist for blood transfusions and other hemotherapies that carry risks of adverse outcomes and are still shadowed by memories of the discovery of HIV and HCV transmission by transfusion. The existence of both these tangible risks and a patient's perception of risk make it even more appropriate to carry out the process of informing the patient and obtaining consent. This process may be therapeutic as well by contributing to the patient's understanding of these risks as well as through the sense of control that making an informed and deliberate choice can foster.

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