

Blood Donor Informed Consent

At the time the American Red Cross Blood Donor Service was inaugurated (1941), every blood donor was required to sign a “release” before donating blood.²⁶ This blood donor release was not put in place to signify that donors were making informed decisions to proceed voluntarily with donation. The release was more of a record that donors were embarking upon blood donation “at his or her own risk,” and basically provided “an absolution” and a protection for everyone associated with the donation process in the event that donors experienced harm.²⁶

The informed consent process for blood donation has undergone changes since the early 1940s but there are virtually no data examining whether donors today comprehend the risks of donation any better than they did 60 years ago.^{22,23,27} The usual and current donation process involves giving donors several written information sheets that may or may not contain comprehensible information on potential or real risks associated with donation. It is common that donors are given a few minutes to read the information presented to them. In addition, the collection facility staff does not generally review with donors the written information to ensure comprehension. It is projected that even previous donors who have donated many times without adverse incidents may be surprised to learn that they are at risk for fainting; that they could have false-positive infectious disease tests; or that they are personally responsible for any follow-up medical examinations or procedures that might be incurred or recommended, including associated costs. Compared to whole-blood donors, however, apheresis or hematopoietic stem cell (HSC) donors are more likely to undergo a truly informed consent process because of the complexity involved in the collection process, and/or because medications may be administered to donors as part of the donation process.²⁷

Although there are studies examining the adequacy of informed consent in various areas of medicine, there are virtually no studies of the informed consent process for blood donation. One study on informed consent for umbilical cord blood donation found a concerning lack of comprehension by women consenting to the donation.²⁸ Another study on donor comprehension suggested that comprehension may be related to how information is presented.²⁹ A third study directly assessed the adequacy of the informed consent process as generally performed in most blood centers.³⁰ That study found that a significant percentage of whole-blood donors were unaware of, or did not comprehend, the risks associated with blood donation.³⁰ Additional studies are needed on the informed consent process in blood and blood-component donation,

particularly as blood-component collection procedures become more complex and may involve administration of drugs to donors, and as new infectious disease screening tests are added (often under research protocols).

The donation of blood and blood components has a long history of being viewed as a safe procedure, and this perception may have contributed to a certain “sense of security” and complacency for transfusion medicine personnel. In fact, whole blood donation has often been promoted as a possible health benefit for donors. However, only in recent years have scientifically based studies been performed to examine the risks associated with donating blood. Several recent studies demonstrate that between 7% and 21% of blood donors suffer some negative reaction or injury.³¹ Common reactions include vasovagal symptoms, bruising, fatigue, and arm soreness.^{31,32} Less common reactions are nausea and vomiting, hematoma, or sensory changes.^{31,32} Rarely, arterial puncture, nerve damage, thrombophlebitis, and infection may occur.^{33,34} However, these are real and significant risks that are often undisclosed and unexplained to donors before donation. Donors undergoing apheresis or HSC procedures have other risks in addition to those common to whole-blood donation, including exposure to certain medications or “donor enhancement drugs” (eg, corticosteroids, granulocyte colony-stimulating factor, and/or hydroxyethyl starch).^{21,22,27}

Transfusion medicine professionals have an obligation to protect donors from harm. This is an ethical duty central to the profession and upheld by the codes of ethics of the AABB and the ISBT. A donor “bill of rights” has been advocated by some transfusion medicine professionals to ensure that the protection of donors remains in the forefront of practice.^{22,27} Promoting the well-being of donors includes respecting them as persons and upholding their autonomous and voluntary participation in a robust informed consent process related to donation.

Informed Consent for Blood Transfusion

Blood transfusion is a medical intervention potentially associated with adverse outcomes. Thus, obtaining and documenting a patient’s informed consent before transfusion therapy is legally and ethically necessary except in emergency and life-threatening situations.^{19,23} Transfusion therapy is a component of many medical and surgical interventions—sometimes as a lifesaving intervention—and it has the potential to be taken for granted by treating physicians or viewed as simply another part of a normal, routine therapeutic plan for which a patient’s informed

consent is not needed. But what might be considered “routine” or “automatic” therapy by physicians may not be viewed as such by patients. For example, adult Jehovah’s Witnesses with decision-making capacity immediately come to mind as patients for whom the principle of individual autonomy is critical when considering alternatives to transfusion before any medical or surgical intervention.^{35,36} All competent informed adults have the right to refuse therapy—including potentially lifesaving blood transfusion—and physicians have an ethical duty to respect this right.

Documentation of informed consent for transfusion can take different forms.¹⁹ A progress note that includes the core elements of the informed consent process as it relates to transfusion written by the physician is sufficient documentation. A separate form for documenting informed consent for transfusion is also acceptable, as is incorporating the consent for transfusion into a preoperative informed consent document. However, simply having a signed note or form in the medical record does not document that the consent was “informed,” nor is handing patients a consent form and asking them to read and sign it.²⁰ Informed consent is a process, and a process of education, that occurs over time between physicians and patients (or patients’ surrogate decision makers), and can include other clinicians who provide or reinforce different aspects of the disclosed information and use different information-education formats (eg, written, oral, video). Thus, for blood transfusions, persons obtaining patients’ informed consent must have sufficient knowledge in transfusion medicine to provide accurate and timely information, as well as the ability to answer potential questions. An important role for the transfusion medicine professional is to provide transfusion medicine education for those health-care professionals who participate in the informed consent process.²³

There have been few studies examining the informed consent process for blood transfusions. In 1993, Eisenstaedt et al found that although 62% of the US hospitals surveyed required written informed consent for transfusion, there was little indication that true informed choice had been achieved.³⁷ A 2007 study from Canada showed that in 75% of cases, there was no documentation in patients’ medical records that discussion about risks, benefits, and alternatives to blood transfusion had occurred.³⁸ Although written informed consent for transfusion is not required in Canada, this study points to a significant breakdown in the physician-patient relationship. Unpublished data from Penn State Hershey Medical Center show that documentation in patients’ medical records of informed consent for transfusion occurs approximately 67%

to 71% of the time. However, as noted in other studies, the quality of the informed consent process is unknown. The lack of documentation of informed consent before transfusion is troubling. Equally concerning is the lack of studies examining the adequacy of the informed consent process when it has been documented to have occurred. The difficulties associated with obtaining true informed consent are not limited to transfusion medicine, but are evident in all of medicine. This is an important area for further study and research.

Conclusions

Ethical concepts and practices derived from respect for patient autonomy (eg, that individuals with decision-making capacity have the right to make informed choices regarding health care) are relatively recent concepts in medicine and research. This is also true as it relates to informed consent in transfusion medicine. Central to the ethics of informed consent is that it is a process of education over time and in the context of respect for persons, participation, collaboration, and negotiation.

Transfusion medicine professionals are frequently in the challenging position of trying to balance the needs and expectations of patients, donors, hospital administrators, physicians, regulators, payers, and society in general. However, transfusion medicine professionals must continue to work and advocate for the ethical treatment of both donors and recipients. This is even more critical as “donor-enhancing drugs” are developed to promote cellular collections from otherwise healthy donors; as new technologies are developed to harvest blood cells and components; as donors increasingly serve as research subjects for infectious disease testing undergoing development; and as adverse risks to transfusion continue to be associated with significant morbidity and mortality. Central to future debates on informed consent in transfusion medicine will be objective studies of its adequacy and efficacy, and how best to realize the ethical principles by which it is supported. This is an important and desirable ideal for the profession to strive to achieve.

References

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2. Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press, 1986:53-113.