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## BLOOD BULLETIN

Helping Patients Understand Potential
Limitations of Directed Donation
Requests

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## **KEY POINTS**

- Providers play a key role in reducing unnecessary requests for directed donation and communicating the scientific consensus that the community blood supply is safe and rigorously screened.
- Guidelines on selection of a directed donor are discussed to help providers understand medical risks that can arise with selection of family members, parents, or spouses as the blood donor for a specific patient.
- Collecting and processing directed donations involve complex logistics that include additional testing and processing, inventory management controls, and financial implications that may impact both the patient and the hospital.
- State hospital associations and other medical/healthcare organizations should champion a strong community blood supply collected from eligible donors that is available for all patients when needed.

This *Blood Bulletin* discusses issues patients should be aware of when they request that specific individuals donate blood

for their upcoming procedure or transfusions. This type of donor, referred to as a **directed donor**, differs from a **designated donor** which is a person who has been deemed the best candidate to meet a specific medical need, such as compatible red blood cells to match a patient's rare blood type.

Blood products, collected and processed for transfusion, are regulated by the U.S. Food and Drug Administration (FDA) as biologic drugs and must be ordered by an appropriately licensed health care provider. This regulatory framework ensures that transfusion orders are subject to the same standards of safety, traceability, and accountability as other therapeutic agents<sup>1</sup>. Blood transfusion, regardless of the donor, is not without risk. The ordering provider is responsible for initiating informed consent. This must include a discussion of both infectious and noninfectious risks, such as transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and hemolytic reactions, as well as the clinical benefits and available alternatives to transfusion<sup>2-4</sup>. In both planned and emergent clinical settings, the provider must tailor this discussion to the patient's context and document the

consent process. Beyond individual patient counseling, providers must also be prepared to address requests for directed donations, which require familiarity with institutional policies and current transfusion standards.

hospitals restrict directed donations to rare, medically necessary indications due to increased risks and inefficiencies compared to community blood supply. Patient education is essential to reduce unnecessary requests for directed donations, and providers should communicate the scientific consensus that the current blood supply is safe and rigorously screened<sup>5</sup>. In 2023 the FDA specifically cautioned against the selection of directed donors for indications lacking scientific basis; this reinforced that such requests should not be accommodated outside of

medical necessity<sup>6</sup>.

While patients may assume that directed donations are safer, they actually introduce a unique set of medical, logistical, and social challenges that must be carefully explained during the consent process. In addition to compatibility testing, there are broader issues related to infectious disease risk, alloimmunization, product handling, and financial implications that can significantly impact both the patient and the donor.

Directed donors must have an ABO blood type that is compatible with the patient. For instance, type O red blood cell donors can give to all patients, while donors with the same ABO type are always compatible. Patients with AB blood type are unique in that they can safely receive red blood cells from any ABO type. The Rh blood group system should also be matched. Patients requesting directed donations need to understand that compatibility is not guaranteed, and donor testing should always be performed before confirming or committing to the donation.

If possible, the patient should select an individual who has donated blood for the community in the past to decrease the risk of positive infectious disease testing. Several publications confirm that first-time blood donors test positive for infectious disease markers more often than repeat blood donors<sup>7,8,9</sup>. Federal regulations stipulate that any positive infectious screening test results (except syphilis) require that the collected unit be discarded; thus, rendering the unit unavailable for the patient. The blood collection facility will notify both the donor and the patient that the unit is unavailable. Considering the potential social consequences, the patient may want to consider whether knowledge that a donation is unsuccessful will lead to strain on the personal relationship between the patient and the donor<sup>7,8,9</sup>. The reason a donation is unsuccessful will not be disclosed to the patient. Additionally, state public health notification is required for donors confirming positive for certain infectious diseases.

If the patient is a female of child-bearing age, the recommendation is to avoid choosing a spouse or male partner for directed donation. Exposing the female patient to the partner's red blood cell and platelet antigens through transfusion may result in alloantibody formation that can ultimately lead to hemolytic disease of the fetus/newborn or neonatal alloimmune thrombocytopenia<sup>10</sup>. Selection of the partner's parents or siblings should also be avoided.

In the case of a child requiring transfusions for an upcoming surgery or cancer treatment, there are additional details to consider when evaluating the parents as directed blood donors. These include the following:

- » Red blood cell units from a first degree relative require irradiation to prevent a condition known as transfusion-associated graft vs. host disease<sup>11</sup>. Per the FDA, the shelf life of an irradiated red blood cell must be reduced from 42 days to 28 days. Thus, if the patient is expected to need prolonged recovery, the unit will not be available after 28 days. For small children, if the red blood cell unit is irradiated and then the surgery postponed, the unit may require special washing to prevent potassium toxicity or be subject to discard. Not all facilities can wash red blood cells.
- » Exposure of the child to the parent's red and white blood cell antigens may result in HLA antigen alloimmunization. The parent may then be ineligible to donate an organ (such as a kidney) or hematopoietic stem cells should this be required for the child in the future.

» Transfusion reactions are possible with any transfusion, including those donated from the parent. In particular, the chance that the child will experience TRALI is increased compared to the probability of TRALI with transfusion from an unrelated blood donor<sup>12</sup>.

The patient should be informed that they may be charged for directed products due to the extra resources required to process the unit from collection through distribution to the hospital<sup>5</sup>. An insurance company may not reimburse these additional charges. Additionally, if the surgery or treatment is postponed, directed donations may expire and be unavailable before the new surgery date.

If a patient requests donations other than red blood cells, the patient should contact the local blood collection facility for information and feasibility. Apheresis platelet donations are not possible for some donors due to specific eligibility requirements and the length of the procedure. Many facilities will be unable to manufacture directed platelets or cryoprecipitate pools. This is due to the difficulty with tracking five specific donors for the pool and the unique labeling requirements for the product.

State Hospital Associations should be encouraged to advocate for a strong community blood supply that can be collected from all eligible blood donors and used by any recipient in need.

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