A similar process can be used to ensure that a database of HLA- or HPA-typed apheresis platelet donors is available to identify compatible donors for HLA/HPA-alloimmune, transfusion-refractory recipients or patients with HPA-alloimmune thrombocytopenia. Because there is additional cost involved, selectivity in donor testing is recommended. Donors who may be targeted for HLA and/or HPA testing should be established platelet donors with a high level of commitment as well as a consistent record of presenting for scheduled appointments. The staff conveying the importance of the commitment to the donor must be clearly educated about the purpose and be able to explain expectations to the potential donor. The donor must consent to testing and the added obligations before the sample is collected. If female donors are approached to participate in this program, testing to exclude HLA antibodies in previously pregnant women must be employed to mitigate recipient transfusion-related acute lung injury (TRALI) risk. It is advisable to maintain a database of typed donors so that they can be easily contacted and scheduled when acutely needed.

In many collection sites, the team struggles with booking adequate numbers of appointments, high deferral rates, and high procedural interruption rates. The cost to recruit fixed-site donors can be a deterrent for many small blood centers. A plan to rebook dedicated donors while they are at the site to donate is a great way to ensure donations are planned on a day and at a time when the donated component can be best utilized and is convenient for the donor. The donor can be approached by the staff during their donation time, or on their way out by the front desk staff. A reminder call or text message can prevent day of donation no-shows and the consequent lack of available inventory for recipients in need.

Staff Training

To protect the safety of the donor as well as the blood supply, it is imperative that staff are thoroughly trained and competency is assessed on a regular basis. In most US states, donor center staff need only have a high school diploma to meet the requirements for a phlebotomy position in a donor center. Training, ongoing education, and competency assessments should cover donor eligibility as well as specific eligibility requirements for apheresis procedures and all applicable standard operating procedures (SOPs). Training should include basic principles of apheresis technology and operation of the instrument, as well as quality control of the product and the instrument, along with its maintenance. Special consideration should be given to venous access proficiency and management of potential adverse events. In addition to technical knowledge, excellent customer service is imperative for the success of any apheresis donor program. Therefore, staff must be able to pay particular attention to the donors' needs and well-being throughout the procedure.

Donation Eligibility

For any donation process, the determination of eligibility considers donor—as well as recipient—safety, ensuring that neither is injured in the process of collection or subsequent transfusion of donated components. In the United States, donor eligibility is regulated by the FDA's Center for Biologics Evaluation and Research (CBER) and other regulatory bodies that are covered in greater detail in Chapter 12. US apheresis procedures should follow FDA guidance documents and federal regulations, AABB standards, equipment manufacturers' operating instructions, and local policies and procedures. To implement a new apheresis program, staff must be trained on applicable SOPs and operation of the collection equipment, and all equipment must be qualified for the intended processes and procedures.

All blood donors are asked numerous questions to determine their suitability for the intended donation. These questions consider risk factors for the donor as well as the recipient and consider medications, travel history, sexual history, immunizations, pregnancy status, cardiac and pulmonary health, infectious disease, cancer, and receipt of blood or other tissues, to name a few. Donor health history questionnaires are available in full-length and abbreviated versions. Donors qualify for an abbreviated version after frequent donation, the most recent donation having occurred within 6 months. More recently, self-administered questionnaires have become available, which afford increased convenience to donors. An approved uniform questionnaire is available on both the FDA and AABB websites. In addition, donors must be assessed for their overall health status and receive a miniphysical, including an arm inspection for skin lesions at the site of venipuncture to rule out evidence of intravenous drug use (needle marks), temperature, blood pressure, pulse, and weight determination. In addition, hemoglobin or hematocrit are also measured.

Apheresis platelet donors specifically must be evaluated for medications that may impair platelet function and, consequently, the effectiveness of the platelet component. Platelet donors are thus asked about the use of antiplatelet medications, including products containing aspirin, for which donors are deferred from platelet donation for a period of 48 hours. Other antiplatelet medications and their deferral periods in the United States include the following: piroxicam (Feldene): 2 days; prasugrel (Effient): 3 days; ticagrelor (Brilinta): 7 days; clopidogrel (Plavix): 14 days; ticlopidine (Ticlid): 14 days; and vorapaxar (Zontivity): 1 month.

After the donor has agreed to an apheresis procedure and the health history is completed, the nurse or donor center employee must explain the potential risks and provide a description of the procedure and its potential duration to the donor to fulfill informed consent requirements. This explanation must include time and opportunity for the donor to ask clarifying questions and must be renewed on specific timelines for plasma, platelet, and RBC donors. The donor should be given ample opportunity to withdraw consent at any time during the procedure.

Additional requirements include a predonation platelet count of at least 150,000/μL. It is recommended that this count be taken before the first donation; however, it is acceptable to collect a sample during the procedure, which can be evaluated at a later point, as long as the collection does not target a triple platelet donation. If a platelet count is performed on samples collected before the procedure begins, this count may be used to qualify the donor for the next platelet procedure. In addition, it is permissible to use an average count from previous donations or the manufacturer's recommended default. Potential donors who have undergone a splenectomy are excluded from platelet donation on some versions of instrument software (eg, Trima v7) due to increased risk of postprocedure platelet counts significantly lower than expected.

Plateletpheresis collection procedures may be performed on a donor up to 24 times in a 12-month period with no more than two procedures in a 7-day period, and the pause between donations should be at least 2 days after a single collection or 7 days after double- and triple-unit collections. Plasmapheresis collection procedures may be performed every 4 weeks (28 days) or less frequently without the need for additional donor criteria and testing that is required for more frequent plasma donation. Although a white blood cell count before the procedure is no longer required, any abnormalities reported by the cell counter outside an established acceptable range should be evaluated. The donor's red cell and plasma losses must be reviewed, and eligibility is determined on a rolling 12-month basis in addition to the projected loss from the current donation. The maximum allowable 12-month plasma loss

(excluding anticoagulant) for all collections is 12,000 mL for donors weighing 175 lb or less, and 14,400 mL for donors weighing more than 175 lb. US regulations do not define a maximum red cell loss for all collections in a rolling 12-month period. Each establishment should have written SOPs consistent with the regulations for the appropriate donation frequency/intervals and maximum allowable red cell loss per donation.

Donor eligibility for 2 units of RBCs or 1 unit of RBCs with a concurrent plasma donation by apheresis is defined by the operator's manual for each instrument, along with the aforementioned guidelines. RBC and plasma collection procedures may be performed every 56 days, and double RBC collection procedures may be performed every 112 days. For all apheresis RBC procedures, the donor generally receives 0.9% sodium chloride (normal saline) to maintain donor blood volume.

TRALI Mitigation

Pulmonary transfusion reactions continue to represent potentially avoidable medical complications. Donor factors in TRALI are considered in the eligibility determination for donors. Previously pregnant female blood donors are at highest risk for HLA [and sometimes concurrent human neutrophil antigen (HNA)] antibodies. To limit transfusion of donor leukocyte antibodies, all donors are asked about pregnancy status. If they have been pregnant, they cannot donate high-plasma-volume blood components (ie, plasma, apheresis platelets, or whole blood for transfusion) or they must be tested for HLA antibodies after their most recent pregnancy. Should these donors test positive, they are deferred from further plasma or apheresis platelet procedures. Males and never-pregnant females known to have HLA or HNA antibodies are similarly deferred from these procedures, although such antibodies are not prospectively sought by most collection centers.

Emerging Infectious Diseases

New infectious diseases emerge from time to time, some of which are potentially transmissible via transfusion and consequently pose a potential hazard to the blood supply. Environmental changes and increasing global travel are responsible for the emergence of new pathogens or known pathogens spreading to new areas. Recent years have seen the spread of West Nile virus, transmitted by mosquitoes. Nucleic acid testing, in addition to a 120-day deferral from onset of illness or diagnosis, was implemented in response to the spread of this illness. Screening for Zika virus, also transmitted by mosquitoes, was initiated for all donations in 2016, along with a 120-day deferral after diagnosis or symptom resolution. In 2017, the FDA published recommendations to assess potential donors for Ebola infection, and questions were added to the donor questionnaire to evaluate travel to areas of Ebola risk, as well as the possibility of sexual contact with someone who has an Ebola infection or direct contact with someone who has an Ebola infection within the preceding 8 weeks. Seventeen years after an outbreak of severe acute respiratory syndrome (SARS), another novel coronavirus (SARS-CoV-2) is being evaluated for its implications on blood donation. For most of these diseases, deferral for travel history is often considered an easy way to mitigate risk in nonendemic areas. However, keeping donors informed and updated can be difficult, and often donors do not return after a lengthy deferral period. Donors who travel frequently may only rarely be eligible for donation, and during peak travel seasons, the number of deferrals rises. Screening for the pathogens or pathogen inactivation are other possible options to mitigate risk of disease transmission, by identifying unsuitable units. Vigilance in safety measures therefore continues to be an ever-present part of determining donor eligibility.