INTRODUCTION

Assessment and maintenance of donor health are of paramount importance to a blood center, as is the need to ensure the collection of a safe and effective component for recipient use. Individuals may present for donation with asymptomatic anemia. The anemia itself may indicate an underlying condition that would result in donor deferral. In addition, regular donation may result in significant ferritin loss and subclinical anemia. Therefore, the measurement of donor hemoglobin as a means of determining donor eligibility is required by the AABB *Standards for Blood Banks and Transfusion Services (BBTS Standards)*[1] as well as Food and Drug Administration (FDA) regulations[2] and guidelines.[3]

Acceptable hemoglobin levels differ depending upon type of donation (allogeneic or autologous whole blood, plateletpheresis, or 2-unit red cell donations). In lieu of direct measurement of hemoglobin level, the donor's hematocrit may be assessed. Several methods are available for determining hematocrit, as well as qualitative and quantitative hemoglobin levels. The advantages, disadvantages, and technical and quality assurance considerations of each method must be weighed before determining the appropriate method to be employed to ensure protection of the donor and reliability of the component.

RATIONALE FOR DONOR HEMOGLOBIN SCREENING

Hemoglobin or hematocrit testing (hereafter called hemoglobin testing) is the only laboratory test routinely performed before donation. Measuring donor hemoglobin is intended to protect the

health of the donor and to ensure the transfusion of an effective product to the recipient.

One specific concern regarding donor health is the prevention of the collection of blood from a donor with iron deficiency. Iron stores may be depleted in repeat blood donors, particularly females of childbearing potential with physiologic iron loss resulting from menstruation and pregnancy. Each unit of whole blood contains approximately 250 mg of iron.[3] In the healthy individual, storage iron is released and absorption in the gastrointestinal tract is increased to compensate for loss caused by donation. A majority of the body's iron is in the form of hemoglobin in the circulating red cells. Storage iron is present in the marrow macrophages, spleen, and liver. Concerns have been raised that non-anemic iron deficiency has a significant potential impact on quality of life, symptoms and risk to the pregnant woman and developing fetus. This does not mean that female donors of childbearing potential cannot be accepted for donation if iron replacement programs are in place, but it does mean that one needs to recognize and acknowledge the risks in a population at high risk for iron deficiency in the first place.[4-7]

Perhaps more important to donor safety than the specific predonation minimum hemoglobin level is the ability of the screening method to detect donors who are *significantly* anemic or who would be left significantly anemic by blood donation. Whole blood donation typically lowers the venous hemoglobin level by 1 to 2 g/dL. The actual decrease depends on the predonation hemoglobin level, the donor's blood volume, and the volume drawn. Thus, it is necessary to ensure with a *high* degree of certainty that no donor with a predonation venous hemoglobin level below approximately 11 g/dL is accepted. Allowing for measurement error, the minimum hemoglobin level accepted for donation must exceed this value for autologous donations.

The AABB *BBTS Standards* and corresponding FDA guidance for the establishment of a specific minimum hemoglobin level for whole blood donors are identical.[1, 3] The minimum criteria differ only among different types of donation.

The majority of donation types in the United States (US) require a minimum hemoglobin level of 12.5 g/dL (females) and 13.0 g/dL

(males). This exceeds the lower limit of normal. Minimum hemoglobin levels may differ in other countries. [1,4] Donor collection centers should have a policy to address safety considerations for donors who identify as transgender or non-binary.

Total hemoglobin in a unit of whole-blood-derived red blood cells is not directly regulated but has a lower limit of 45 g per unit the United States and 40 g per unit in Europe.[9,10] Characteristics of a unit have been delineated by AABB *BBTS Standards* for apheresis red cells, which states that the hemoglobin content of such a unit must have a mean of ≥60 g of hemoglobin with 95% of units sampled containing >50 g of hemoglobin.[1]

The selection and implementation of a testing method for allogeneic donor hemoglobin must comply with regulatory standards; however, neither the FDA nor AABB specify the test method. The methods for screening allogeneic whole blood donors need not meet the same accuracy and precision requirements expected in a laboratory setting. Rather, the purpose of the hemoglobin screening procedure is to maintain compliance with the relevant regulations and standards and to provide reasonable accuracy so that donation does not cause symptomatic anemia. Most US blood centers use fingerstick (capillary blood) samples for hemoglobin/hematocrit determinations. These samples tend to give slightly higher values than venous samples, particularly near the cutoff values.[11] A noninvasive measurement, not involving a blood sample but using measurements through the skin has been approved in the US. Hemoglobin is measured by following optical changes after a brief occlusion of blood flow in a finger (occlusion spectroscopy).[12]

AVAILABLE METHODS FOR HEMATOCRIT AND HEMOGLOBIN TESTING

The selection of methods depends, in part, on the accuracy requirements discussed above, as well as on the blood collection site (mobile or fixed, availability of electrical power) and the technical sophistication of the staff. Because most blood is collected apart