



Advancing Transfusion and
Cellular Therapies Worldwide

Blood Products Advisory Committee

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Statement on Blood Pressure and Pulse as Blood Donor Eligibility Criteria

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AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include approximately 1,800 hospital and community blood centers and transfusion and transplantation services as well as 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For more than 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, and developing and delivering programs and services to optimize patient and donor care and safety.

Thank you for the opportunity to address the committee.

AABB Standards for Blood Banks and Transfusion Services was first published in 1957. Now in its 26th edition, the AABB Standards combine quality management and technical requirements, and provide the basis for accreditation by AABB. The committee responsible for developing the Standards relies on an evidence-based decision making process to modify existing requirements or create new requirements. The requirements in the Standards are based on input from a variety of sources, including AABB members, public members on the program unit, and recognized experts in blood banking and transfusion medicine.

In the 26th edition of Standards, blood donor pulse and blood pressure are no longer required for the qualification of allogeneic donors of whole blood. The committee recognized that taking these measurements is common practice, but elected to remove these items because the available evidence from recent published studies demonstrate no correlation of blood pressure with an

increased risk of reactions, and only a weak correlation of pulse with donor reactions. These data support that blood pressure or pulse measurement has little or no ability to distinguish who among donors will have a reaction from those who will not. There is no evidence that the inclusion of blood pressure and pulse as screening criteria improves donation safety.

Current FDA regulations state that blood pressure should be normal but do not specify acceptable values. In the UK blood pressure is not measured at the time of whole blood donation. The available hemovigilance data from NHS demonstrate low rates of reactions and support the safety of their program (<http://hospital.blood.co.uk/library/pdf/bm27.pdf>)

There are no data to indicate that the measurement of blood pressure, let alone that the use of a specific range of acceptable blood pressure values, improves donation safety. A single measure of blood pressure, especially in the setting of an anticipated blood donation, would never be used clinically to determine a donor's true blood pressure. Inaccurate determinations occur under stress, mismatch of the subject's weight and the cuff size used, ingestion of caffeine or decongestants, recent exercise, smoking, and food intake, among others.

Prior to the 26th edition the BB/TS Standards contained established values of 180/100 for the upper limit of blood pressure. These values, whether commonly used or not, were entirely arbitrary. There is no evidence that otherwise healthy donors with elevated systolic blood pressures would be harmed by blood donation. In fact, the available data from recent studies using multivariate logistic regression analysis demonstrate that higher systolic blood pressures are associated with a decreased risk of reactions (Wiltbank 2008; Trouern Trend 1999). Most notably, at the time of one study, there was no lower limit for blood pressure, and donors with blood pressure below the currently accepted levels did not have an increased risk of reactions (Trouern-Trend 1999). This conclusion is also supported by data from the American Red Cross on a study of more than 70,000 donations in 1997.

The available data demonstrate that blood pressure does not correlate with an increased risk of reactions, and the measurement of blood pressure as a screening measure does not improve donation safety. Informing donors about their blood pressure at each donation may provide a useful public health service by making them aware of the risks of chronic hypertension, however this should be at the option of the blood center as deferral practices based on blood pressure have questionable value in terms of donation safety. We encourage FDA to remove the requirement for blood pressure measurement from the CFR as a means to select donors for allogeneic whole blood donation.

With regard to pulse, there are currently no FDA regulations concerning measurement of pulse in blood donors. AABB Standards previously required that the pulse should be between 50 and 100 beats per minute. The committee recognized that there are no data to indicate that this is appropriate. It is also not universal practice to measure the pulse. As with blood pressure we note that practice in the UK does not include a determination of pulse. HemaQuebec data provided by Dr. Gilles Delage (personal communication Dr. Delage) were included in comments we submitted to the docket for the proposed rule. In this study, 106 autologous donors were accepted for donation in spite of a pulse that did not meet the standard acceptance criteria, no adverse effects were seen. The rate of moderate and severe adverse reactions was no different in a series of over 300,000 donors drawn when pulse measurement was not part of the qualifying criteria (1995-1996) than it was in a series of over 600,000 donors drawn with such criteria in place. Finally, these investigators followed 2005 donors who were deferred for failing pulse criteria for 2-3 years and compared them to 2005 donors who donated on the same day but passed the pulse criteria. There was no significant difference in the incidence of subsequent cardiac events.

The available data from some recent studies suggest that an increased pulse correlates with a slightly increased risk of reactions (Wiltbank). Some have argued that the higher incidence of reactions among donors with a higher pre-donation pulse supports the need to define an acceptable range. It is clear that anxiety prior to a phlebotomy can frequently be the reason for an elevated pulse rate and a mild reaction. However, there are many categories of donors generally accepted to have a much greater risk of reaction than others (e.g. first time donors, females, lower weight donors, younger donors), yet none would support a draconian requirement to prohibit donors in all such high risk groups from donating. An elevated pulse in the setting of a blood donation is not likely a significant health finding for an otherwise asymptomatic individual, and deferred donors need not be sent for further medical evaluation. The committee found no evidence that the measurement of pulse, let alone specific criteria, contributes to donation safety or donor health and the requirement was removed from AABB Standards. To include it in the Code of Federal Regulations (as suggested by the proposed rule) we believe would be a step backward.

We have found no correlation between blood pressure and an increased risk of donor reactions, and only a weak correlation with pulse. In addition, blood pressure or pulse measurement does little or nothing to distinguish those donors who will have a reaction from those who will not, and there is no evidence that the inclusion of blood pressure and pulse as screening criteria improves donation safety. After careful consideration of these findings, the requirements for blood pressure and pulse were removed from the AABB standards. For the same reasons, we encourage FDA to remove the requirements for blood pressure from the CFR and the requirements for pulse from the proposed rule.