



Advancing Transfusion and  
Cellular Therapies Worldwide

AABB Statement to the Food and Drug Administration's Blood Products Advisory Committee

17 November 2016

Management of Iron Deficiency Associated with Blood Donation

Presented by Steven Kleinman, MD  
Senior Medical Advisor

AABB is pleased to have this opportunity to provide comment to the FDA on the management of iron deficiency associated with blood donation. AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 2,000 institutions and 8,000 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries.

Four years ago, in December 2012, AABB issued an Association Bulletin with recommendations for “Strategies to Monitor, Limit, or Prevent Iron Deficiency in Blood Donors.” Given the subsequent completion and publication of important research studies, AABB’s Donor Health and Safety Committee is actively preparing updated recommendations to be issued in an Association Bulletin with the goal of protecting the health and safety of our donors and the patients we serve.

Because a unit of donated whole blood contains a mean of 250 mg of iron, iron deficiency commonly results from regular blood donation. This is of particular concern for pre-menopausal women, who typically have lower iron reserves and experience greater physiological iron loss, as compared to men. Indeed, almost two-thirds of female, and half of male, frequent blood donors are iron deficient. Iron deficiency, in addition to predisposing individuals to fatigue and impaired cognitive performance, can, with continued blood donation, lead to iron deficiency anemia.

Therefore, strategies to mitigate iron loss are required to protect the health of our altruistic volunteer donors, while ensuring we maintain continuous blood supply availability for the patients we serve. Interventions such as changing the donation interval or limiting donations in high school-age donors must be evaluated with respect to group and type specific inventories (e.g, O neg) as well as overall inventories. Blood collection facilities can provide valuable data

8101 Glenbrook Road  
Bethesda, MD 20814-2749  
301.907.6977 MAIN  
301.907.6895 FAX  
[www.aabb.org](http://www.aabb.org)

on donation frequency by blood group, Rh type, and age so that the impact of changes in allowable donation frequency can be evaluated.

Iron supplementation programs have proven effective in two US member collection facilities and several international member centers. How these programs are implemented and maintained needs to be examined along with the utility of performing ferritin testing to identify and treat iron-deficiency in donors.

AABB has been actively examining these issues through its Donor Health and Safety Committee and stands ready to facilitate evidence-based discussions to formulate recommendation strategies. Furthermore, AABB's structure and organization positions the association to develop impactful standards, promote donor awareness, and provide supportive educational materials.

Thank you for the opportunity to provide these comments today.