

Recommended Interventions to Reduce the Risk of Iron Deficiency in Blood Donors

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ABSTRACT

Numerous studies indicate that US blood donors, especially women, have a high prevalence of iron deficiency. Iron is lost with each blood donation, and since donors are eligible to donate blood every eight weeks, it is a challenge to maintain iron balance in frequent blood donors. Prior to blood donations, donors are screened for anemia but not for iron deficiency. Several interventions have been considered to address this public health issue including deferral from donation due to decreased iron stores measured by ferritin levels, iron replacement therapy, education for donors regarding their iron status, extension of inter-donation interval, and restriction of number of donations within a year. A combined approach of education, to encourage donors to take iron supplements and to seek the care of their physicians when necessary, and iron replacement therapy, to replace the iron lost in blood donation, is recommended to address this public health issue.

INTRODUCTION

Iron is an essential nutrient necessary for cognitive development and function, immune status, physical capacity, and work performance of adults and children.^{1,2} Iron is a component of heme in hemoglobin, which binds and transports oxygen throughout the body and is also necessary for certain enzymatic reactions.² Iron deficiency is the most common nutritional deficiency worldwide. It is the most prevalent nutrient deficiency in developed countries. Iron deficiency can result in decreased immune and mental function as well as reduced physical performance.²

Anemia is a condition in which the body does not have enough healthy red blood cells to carry adequate oxygen to its tissues. Iron deficiency anemia, caused by a shortage of iron in the body, is the most common type of anemia worldwide. The World Health Organization (WHO) estimates that two billion people worldwide are anemic, most due to iron deficiency.³ The association of iron deficiency with diminished cognitive function is well established.⁴ In young children, iron deficiency has shown to be associated with poor psychomotor performance and short term memory, changes in behavior, irritability, and reduced responsiveness to stimuli.⁵ Iron deficiency anemia is also responsible for poor pregnancy and perinatal outcomes in women.³

Iron deficiency is a disorder that, without treatment, progresses through three stages: Stage one involves decreased iron stores, which is clinically diagnosed by a decrease in serum ferritin. There is no decrease in hemoglobin levels at

this stage and therefore no anemia. Stage two of iron deficiency involves iron deficient erythropoiesis, which is defined by an inadequate quantity of iron to form heme, an essential component of hemoglobin. There is no anemia present at this stage, but decreased ferritin and microcytosis (decreased red cell volume) are clinical indicators of iron deficiency. Stage three is defined by decreased iron stores and iron deficiency anemia.⁴

BACKGROUND

Epidemiology of iron deficiency in the US

The Centers for Disease Control and Prevention (CDC) collects data on the prevalence of iron deficiency in the US using the National Health Nutrition and Examination Survey (NHANES). The CDC reported that the prevalence of iron deficiency in men 16 to 69 years of age was 1% in 1988-1994. The prevalence of iron deficiency was highest in women ages 12-49 years old at 11% (95% confidence interval (CI): 10.0,11.0).⁶ In 1999-2000, the prevalence of iron deficiency increased to 12% in women and 2% in men but iron deficiency anemia was reported in only 4% and 1% of women and men, respectively.⁶ This trend of high prevalence of iron deficiency continued in the NHANES survey 2003-2006 in women ages 12 to 49 years old. After 2002, women 12-49 years of age were selected as a high risk group, and data collection for all other groups was discontinued by NHANES.⁷ Iron deficiency is more common in women due to menstruation, pregnancy, childbirth, and breastfeeding.⁸

The estimated prevalence of iron deficiency prior to 2003 was based on the three indicator model including ferritin, transferrin saturation, and erythrocyte protoporphyrin. However, prevalence estimates starting in 2003 were computed using a new model called the body iron model, which includes the measurement of serum Transferrin Receptor (sTfR) along with ferritin.⁷ Serum ferritin was utilized in both models and is the most sensitive indicator of iron deficiency.⁹ The prevalence of iron deficiency was calculated, based on serum ferritin level, from 2003 to 2010 using available NHANES data and was found to have increased from 11% to 14.8% (95% CI: 13.76,15.84) in women ages 12-49 years.¹⁰ The analysis was conducted using SAS 9.4.

Iron deficiency impacts all racial/ethnic groups, but some are more likely to be affected than others. Prevalence of iron deficiency in Mexican American (22%) and African American (19%) women was twice that of Non-Hispanic White (10%) women in 1999-2000.⁶ The same trend of iron deficiency

was observed across racial/ethnic groups in NHANES 2003-2006.⁷ Moreover, people who have had blood loss, such as those who have experienced gastrointestinal bleeding or undergone major surgery or trauma, are also at risk for developing iron deficiency.¹¹

Public Health Problem

Iron deficiency can develop in frequent blood donors.¹² Blood donors are routinely screened for anemia by fingerstick hemoglobin testing prior to every donation. However, this test does not test for iron deficiency, which is diagnosed based on decreased ferritin levels. Hemoglobin screening for anemia is only effective in diagnosing late stages of iron deficiency.¹³ Serum ferritin is the most readily available biomarker for the assessment of iron stores and is a sensitive marker for iron deficiency.^{8,14,15} Based on WHO criteria, ferritin levels of <15 ug/L in adults indicate depleted iron stores.¹ Sensitivity of ferritin testing is 89% for diagnosis of iron depletion compared to hemoglobin testing, which is only 26%.⁹ Due to the current hemoglobin screening process, iron deficient donors with acceptable hemoglobin levels continue to donate blood, further depleting their iron stores by 200 to 250 mg with each whole blood donation.¹⁶ Although there is acknowledgement by the blood bank community that regular blood donations may result in iron deficiency, routine testing for iron status has not yet been implemented. This may be due to increased costs for laboratory testing, fear of losing donors due to logistic inconveniences or operational complexities, or challenges and risks of recommending or providing iron replacement therapy to donors.¹⁷

Donors provide a valuable service by donating their blood, which is utilized to save the lives of those that need blood transfusions. It is important to monitor donor well-being in order to protect their health and to maintain a healthy donor pool.

Blood Donor eligibility criteria in the US

Whole blood and blood component donation eligibility criteria are established and enforced in the US by the Food and Drug Administration (FDA) and AABB (formerly known as the American Association of Blood Banks). Blood donors may donate whole blood every eight weeks or six to seven times a year and double red blood cells every 16 weeks or up to three times per year.¹⁸ All donors undergo screening for vital signs along with anemia, which is based on fingerstick hemoglobin or hematocrit testing, prior to donation. Decreased hemoglobin indicates anemia, which can be caused by a number of conditions, such as chronic kidney disease, cancer, hematological disorders such as thalassemia and hemolytic diseases, and does not always reflect decreased iron stores. In 2016, the FDA revised donor requirements and mandated a minimum hemoglobin of 13.0 g/dL instead of the previously acceptable level of 12.5 g/dL for males. The minimal acceptable hemoglobin for females remained 12.5 g/dL but could be lowered to 12.0 g/dL if the blood establishment took additional steps deemed acceptable by the FDA to assure that donor safety was maintained.¹⁹ The impact of these changes on the prevalence of iron deficiency in blood donors remains to be seen.

Epidemiology of iron deficiency in blood donors

Iron deficiency is not a new problem in blood donors and is one that has been studied for several decades.⁶ One of the earlier studies was conducted by Simon and colleagues where they reported that iron deficiency in first time male blood donors (n=505) was non-existent and was 12% in first time female donors (n=516).⁸ However, repeat donors contributed to an overall iron deficiency prevalence of 8% in male and 23% in female donors. Reduced iron stores were defined as ferritin of <12 ng/mL in this study. The higher prevalence of iron deficiency in female donors was attributed to menstruation.⁸ These findings were later confirmed by other studies.²⁰⁻²³

The Retrovirus Epidemiology Donor Study-II (REDS-II) Donor Iron Status Evaluation (RISE) study assessed iron deficiency, defined by absent iron stores (AIS) as measured by ferritin level of <12 ng/mL, and iron deficient erythropoiesis (IDE) which was defined by log (soluble transferrin receptor/ferritin) of ≥ 2.07 .²⁴ From the 2,425 donors enrolled in the study, 15% of donors reported AIS and 42% reported IDE prior to donation. All donors, excluding the 10% that were deferred due to low hemoglobin, were required to donate a unit of whole blood. This study reported that 66% of female and 49% of male frequent blood donors, defined as women who had donated two or more times a year and men who had donated three or more times a year or equivalent double red blood cell donation in the US, had IDE.^{16,24} Of these, 27% of females and 16% of males had AIS. Gender, donation frequency, and country of birth as well as female age were significantly associated with iron deficiency. Female donors were 1.8 times more likely to have AIS and 2.8 times more likely to have IDE than males, when standardized for age, menstrual status, and pregnancy.¹² Female donors that were younger than 29 years old were 3.1 to 3.9 times more likely to have AIS and 3.1 to 4.9 times more likely to have IDE compared to those that were 40-49 years old. Frequent donors with seven to nine donations in the past two years were 13.5 times more likely to be iron deficient while those with less than or equal to four donations were 5.3 times more likely to be iron deficient compared to first time donors.¹² Previous studies had reported similar findings as well.²⁵ Asians had a lower prevalence of iron deficiency (p=0.03) than White, African American, and Hispanic donors, but the difference was not statistically significant.²⁴

An earlier phase of REDS-II conducted a demographic analysis on 715,000 blood donors from its six blood centers from 2006 to 2007.^{26,27} This study reported 13% donor deferral due to low hemoglobin. Women were 11 times (17.7% vs. 1.6%) more likely to be deferred due to low hemoglobin than men. Women in all age groups had a higher rate of deferral compared to men. Women of childbearing age and those over the age of 60 years had a higher rate of deferral than post-menopausal women between the ages of 51 to 60 years. In men, the odds of deferral increased 1.5 times with each increase in age of ten years in all age groups. Moreover, the odds of African Americans being deferred due to low hemoglobin were reported to be more than twice as much as Whites.²⁶

A study conducted in Denmark reported that 13% of male

blood donors had ferritin levels of <30 ug/L and 1.5% had levels of <15 ug/L.²⁸ Of the female donors, 43% had ferritin levels of <30 ug/L and 11% had levels of <15ug/L.²⁸ Iron supplements were offered to 82% of the donors, those who were iron deficient and those deferred due to anemia. There was no requirement for donor follow-up, which makes it difficult to assess the effectiveness of iron supplementation, but the study reported that a very small number of the donors voluntarily reported that they had low hemoglobin due to medical conditions such as leukemia, cancer, thalassemia, and anemia of chronic disease.²⁸

A higher prevalence of iron deficiency in blood donors is common worldwide and is of particular concern in premenopausal women due to ongoing monthly blood loss and pregnancies. Frequent blood donors are constantly at risk of iron deficient erythropoiesis, which can result in iron deficiency anemia.²⁹ Donor screening for iron deficiency and deferral due to decreased hemoglobin can prevent the onset of and complications of anemia. A primary prevention approach to prevent iron deficiency would result in maintenance of a healthy donor pool. Several interventions have been suggested to address iron deficiency in blood donors.

INTERVENTIONS FOR REDUCING IRON DEFICIENCY IN BLOOD DONORS

AABB has provided recommendations to blood collection organizations regarding management of iron deficiency in blood donors, which include screening for serum or plasma ferritin levels, extension of the inter-donation interval and restriction of the number of donations within a year, education for donors regarding their iron status, and iron replacement therapy.^{30,31} These recommended interventions are merely suggestions and are not actually common practice during blood donations. Some of these interventions have been introduced at the population level to reduce iron deficiency in blood donors and their effectiveness has been evaluated.

Screening for serum/plasma ferritin

Ferritin is a more sensitive test for identifying iron deficiency compared to hemoglobin. However, ferritin testing may result in deferral of half of the frequent donors, as suggested by the RISE study, and would negatively impact the donor pool.¹² Screening of blood donors at first and every tenth donation thereafter with serum/plasma ferritin was implemented in Denmark in 2012. Testing was conducted more frequently if hemoglobin or ferritin levels were abnormal at previous donation. Overall, 1.5% of male and 43% of female donors had ferritin levels of <15ug/L and would have required deferral.²⁸ However, the effectiveness of this deferral in mitigating iron deficiency in blood donors is questionable. No studies have reported the impact of screening with ferritin without supportive iron supplementation.

Donation frequency and inter-donation intervals

The AABB guidelines allow blood donors to donate blood every eight weeks in the US. Simon et al. agreed with this recommendation for men but suggested that menstruating women should be limited to one or two donations per year due to their higher incidence of iron deficiency.⁸ This study also

reported that donors become significantly more iron deficient with each increase in donation frequency.^{8,24} Similar findings were reported by other investigators,^{20,25} including the RISE study, which concluded that the number of donations was the strongest predictor of iron deficiency. Frequent donors that donated blood less than four times in the last two years were 5.3 times more likely to be iron deficient and those that donated seven to nine times were 13.9 times more likely to be iron deficient compared to first time donors.^{24,12}

Blood donors in the United Kingdom and several other European countries can donate blood every 12 weeks if they are male and every 16 weeks if they are female, and their minimal acceptable levels of hemoglobin are also higher than acceptable levels in U.S (12.5 g/dL for women and 13.5 g/dL for men).^{32,33} Donors in New Zealand can donate up to four times a year.³⁴ The RISE study looked extensively at the inter-donation intervals and reported that an interval of less than 14 weeks was significantly related to higher likelihood of AIS or IDE than donating after 14 weeks.¹² The results of this study suggest that it takes at least three months and maybe longer to replenish the iron lost in a whole blood donation. There are no studies that compare the impact of donor frequencies and inter-donation variation worldwide.

Education and iron supplementation

Iron supplements are available over the counter and are generally recommended for people that have decreased ferritin levels. Simon et al. reported that female blood donors that take iron supplements had significantly higher iron stores than those that do not take them (p=0.002).⁸ This was true even if the supplements were not taken regularly. It was recommended that menstruating women that donated more than three times a year should consistently take iron supplements.⁸ Similar findings were reported by Mast and colleagues in a recent randomized blinded placebo-controlled clinical trial where frequent blood donors were randomized into five groups: iron status informational letter, two different doses of iron supplements, placebo, or no information.²⁷ The results of this study indicated that the mean ferritin level increased by 10.3 ng/mL in the educational information group, 18.3 ng/mL in the low dose supplement group, and by 16.7 ng/mL in the higher dose supplement group (p<0.0001). There was a 70% decline (p<0.002) in the proportion of subjects with iron deficiency (ferritin <12 ng/mL) due to iron therapy. The iron status of those in the placebo group or ones that did not receive any intervention either got worse or remained unchanged.²⁷ These results indicate that low dose iron therapy is more effective than educational information, but both result in improvement of iron status of blood donors. Several other studies have findings that support iron supplementation in blood donors.^{12,35-38}

DISCUSSION AND RECOMMENDATIONS

Iron deficiency anemia is one of the major causes of blood donor deferral.²⁴ Based on current guidelines, persons with iron deficiency can continue to donate until they become anemic.

The US national blood supply is dependent on donors who repeatedly donate blood to fulfill the transfusion needs of the population. It is generally believed by donor centers that re-

recruitment of new donors is more cost-effective than managing iron deficiency in existing donors.¹⁶ However, despite recruitment efforts, 70% of donors are repeat donors;³⁹ and therefore, are at risk for iron deficiency. The increasing prevalence of iron deficiency in donors suggests that current blood donation guidelines have failed to protect donors. Some interventions that were considered in various studies to manage iron deficiency in donors include screening with serum/plasma ferritin, limiting donation frequency and/or inter-donation intervals, and supplementation of lost iron at each donation.

Determining the iron status of blood donors before every donation using ferritin testing would be ideal. However, assay performance as well as the defined reference ranges for the diagnosis of iron deficiency vary by testing methodology and populations. Other barriers to screening donors using ferritin testing, besides assay characteristics, may include expense of testing, instrumentation requirements, and operational resources. A point of care test that can be performed to obtain quick results, especially for mobile donor settings, would be best for donor testing, but such a test is not available at this time. There are also several unanswered questions, such as frequency of testing, type of test to be utilized, and counseling regarding iron deficiency. In the current environment, deferral of every donor with decreased ferritin would negatively impact the donor pool and may result in decreased availability of blood for those who need it. Screening using ferritin would only be helpful if a low ferritin level triggers an intervention to address the iron deficiency such as an educational intervention or iron replacement therapy.

Based on a literature review, it is clear that an inter-donation interval of eight weeks is not adequate to replenish iron stores. Guidelines from other countries include donation intervals from 12-16 weeks, but there are no studies to show that this practice is effective in reducing iron deficiency in donors.

There is a concern by some in the blood bank community that offering oral iron replacement tablets to blood donors after each successful donation would be risky for a donor who had undiagnosed hereditary hemochromatosis. In hemochromatosis, there is an increased absorption of iron which can lead to iron overload.⁴⁰ Although the effects of giving low dose iron replacement tablets to blood donors with hemochromatosis has not been studied, it has been postulated that these donors might absorb more iron than necessary from the tablets. Therefore, if a donor center chooses to give or recommend iron replacement for blood donors, it would be important to initially screen each donor with a one-time ferritin test so those with undiagnosed hemochromatosis or iron overload could be identified and deemed ineligible for iron replacement therapy.

After considering all the available interventions to mitigate iron deficiency in blood donors, iron replacement makes sense. It is imperative that the iron loss from donation is replaced to negate the effect of the blood donation. Therefore, 19 mg iron replacement therapy, which is proven to be 70% effective in reducing iron deficiency,²⁷ should be provided to every donor for 60 days or eight weeks so they have the opportunity to

replace the lost iron before they are eligible to donate again. A one-time serum ferritin test to evaluate the donor's iron status should be performed, so donors with increased iron stores can be deferred from this therapy and referred to their physicians for follow-up, and those with decreased iron stores could be alerted via a follow-up letter. The letter would also serve as an educational tool that would strongly encourage donors to take iron supplements if needed or to be evaluated by their physicians if they have increased iron stores.

A combined intervention of screening, iron replacement, and education will be more effective in addressing iron deficiency than any single intervention. We urge the FDA and AABB to include this approach in their guidelines and to encourage continuous evaluation of iron status in blood donors.

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