Q&A: References and Data Supporting the Management of Risk for Iron Deficiency in Female Donors

The following is provided to assist blood establishments considering the proposed strategies for blood collection from female donors with a hemoglobin (HB) level of 12.0 – <12.5 g/dL.

Management of risk for iron deficiency in female donors with HB levels of 12.0 - <12.5 g/dL using extended deferral without ferritin testing

Q: Why is 6 months the suggested deferral period in the “No Ferritin Testing” algorithm?

A: The REDS-III HEIRS Study\(^1\) showed that for donors not taking iron, on average the recovery to pre-donation ferritin levels took longer than the 168-day follow-up. Recovery of hemoglobin was highly variable and 2.5 to 5 times longer on average for donors not taking iron, compared to those randomized to take iron, who recovered in a month.

Q: Why is the recommended dosing for iron supplements 18-38 mg/day?

A: The REDS-III HEIRS study used 38 mg/day, and the STRIDE Study\(^2\) found equivalent efficacy of 19 and 38 mg/day doses in protecting against iron deficiency. Multivitamins with iron might have 18 mg in them and separate iron supplements might have about 38 mg elemental iron.

Q: Why suggest iron supplements for only 8 weeks, isn’t longer better?

A: Donors randomized to take iron in the REDS-III HEIRS study took 38 mg of iron daily for 24 weeks of observation, and the investigators found that nearly 90% of the benefit of taking iron occurred during the first 8 weeks.\(^3\) It is assumed that donor compliance might be higher if the period for which they are asked to take iron is shorter, but that was not assessed in the study.

Q: Isn’t a shorter deferral period between donations acceptable if the donors take iron?

A: HEIRS found that while hemoglobin recovery was estimated to occur within the current interdonation interval for those taking iron, recovery of ferritin was slower (median of 76 days). In STRIDE, those assigned to 19 or 38 mg of iron daily reduced their odds of ferritin < 26 or < 12 ng/mL by 80% but did not reduce those odds to zero; e.g., at the end of the study, more than 30% of those taking iron had ferritin < 26 ng/mL. Encouragement of iron consumption for female donors does not ensure compliance (and it is anticipated that some donors will choose not to take iron), the tracking of which could be operationally cumbersome. A 6-month deferral in the absence of ferritin monitoring accommodates the variable and often lengthy recovery periods for hemoglobin and ferritin for many donors. For centers that choose to evaluate donor compliance with an iron supplementation regimen, a deferral period shorter than 6 months may be worked into the protocol at an appropriate stage.
Management of risk for iron deficiency in female donors with HB levels of 12.0 - <12.5 g/dL using ferritin testing

Q: Why is 16 weeks the suggested deferral period for women with a ferritin level < 26 g/dL in the “Ferritin Testing” algorithm?

A: The REDS-III HEIRS Study found that while hemoglobin recovery was estimated to occur within the current interdonation interval for those taking iron, recovery of ferritin was slower (median of 76 days). Some of the female donors with ferritin < 26 ng/mL will have absent iron stores (indicated by a ferritin level < 12 ng/mL). The goal would be to replete them beyond their pre-donation level, optimally to > 26 ng/mL. A longer interval than the current 8-week donation interval would be indicated for that. The assumption is that many donors receiving a letter reporting their low ferritin results would, in fact, be responsive to the message and either delay their next donation or purchase and take iron, or both. STRIDE found that 70% of donors receiving such a letter responded with one or both measures.4

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Q: What proportion of female donors should I expect to have a ferritin level < 26 ng/ml?

A: Based on the REDS-II RISE study5,6, simulations using REDS-II donation data and RISE data7 and unpublished data from Blood Systems Incorporated, blood establishments might expect half or more of their female donors with Hb < 12.5 g/dL to have a ferritin level < 26 ng/mL.

Q: Above what ferritin level should donors be advised to stop taking iron supplements?

A: Some donors with a high enough ferritin level will not need to take iron supplements. It is up to the blood establishment’s medical director to determine at what ferritin level a donor is no longer encouraged to take iron supplements. That level might vary according to individual donor characteristics, donation behavior and assay used.
References


