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Evaluating utility of routine ferritin testing in blood donors: A hospital-based blood donor centre experience

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Abstract

Background and Objectives: Iron deficiency (ID) poses a prevalent concern among blood donors, especially impacting young donors, premenopausal females and frequent donors. In alignment with recommendations to address ID, routine ferritin testing was implemented in a hospital-based donor centre.

Materials and Methods: Data set, encompassing 26 164 ferritin values from 16 464 blood donors over 33 months, were analysed retrospectively. Ferritin levels were assessed concerning donor characteristics such as sex, age, ethnicity and donation frequency.

Results: Ferritin testing revealed age, sex and ethnicity variations, emphasising the heightened risk of ID in young females meeting all donation criteria under 23 year of age who demonstrated the lowest mean baseline ferritin (41% [CI: 34%–48%] < 26 ng/mL; 20% [CI: 14%–25%] < 15 ng/mL). Postmenopausal females exhibited ferritin levels similar to similarly aged males. Irrespective of sex, donors showcased mean ferritin recovery within 6 months. Analysis of ferritin recovery post-donation showed a five-fold increase in risk (compared with first visit) of ID when donors return at a 2-month interval. 'Regular' donors (≥10 visits) approach a median steady ferritin level (∼30–35 ng/mL) by the sixth visit.

Conclusion: As reliance on regular blood donors increases, donation policies must strike a balance between blood centre resources and the risks posed to both regular and at-risk donors. Frequent blood donation led to donors attaining a mean steady state ferritin level above the threshold for ID. At-risk groups, particularly premenopausal females, were several times more likely to experience ID after donation but demonstrated recovery rates similar to their group's baseline levels. This valuable information informed the development of new donor deferral policies.

KEYWORDS
blood donations, donor safety, ferritin testing

This work was performed at the Department of Pathology & Laboratory Medicine, Children's Hospital Los Angeles, Los Angeles, CA.

1 | INTRODUCTION

Iron deficiency (ID) and iron deficiency anaemia (IDA) pose significant concerns in blood donors, particularly in at-risk groups such as young donors, premenopausal females, frequent donors and those with haemoglobin (Hb) values near the minimum eligibility threshold.[1] The Association for Advancement of Blood and Biotherapies (AABB) recommends proactive measures by blood collection establishments to monitor, limit, or prevent iron deficiency in donors. These measures include providing comprehensive educational materials to donors, implementing specific interventions such as donor iron supplementation, adjusting inter-donation intervals or annual donation frequency and conducting donor ferritin testing-based interventions. Additionally, post-implementation monitoring of these interventions is advised.[2]

Ferritin emerges as a superior predictor of total body iron stores compared with Hb, with decreasing ferritin levels serving as a sensitive and early indicator of iron store depletion in blood donors.[3] Donor ferritin testing, coupled with iron supplementation, has demonstrated efficacy in enhancing the recovery of Hb and iron stores, thereby reducing the incidence of pre-donation anaemia and donation deferral.[4,5] Monitoring ferritin levels and providing iron supplementation or iron status information proves effective in preventing iron deficiency in donors with continued donations.[6] Aligning with AABB recommendations, the hospital-based blood donor centre (BDC) at Children's Hospital Los Angeles, Los Angeles, CA (CHLA), initiated routine ferritin testing for all donors and implemented a ferritin-based deferral policy starting in October 2018.

However, routine donor ferritin testing poses logistical and operational challenges, consuming significant BDC resources. Meeting regulatory requirements, efficiently collecting and performing ferritin testing, communicating results with donors and implementing a ferritin-based deferral policy are among the operational challenges. Amidst the COVID-19 pandemic, with the goal of streamlining donor centre operations and enhancing efficiencies, CHLA BDC reassessed its ferritin testing strategy. This manuscript shares the experience of a hospital-based BDC in utilising routine donor ferritin testing, presents post-implementation data, and outlines the rationale for discontinuing ferritin testing.

2 | MATERIALS AND METHODS

This retrospective study at the CHLA BDC spanned 1 October 2018 to 31 July 2021, coinciding with a start and cessation of routine ferritin testing. Institutional Review Board approval was secured for privacy compliance. All successful donors meeting all donation criteria including Hb criteria were included (Hb >12.5 g/dL for females and 13.0 g/dL for males), with serum ferritin testing performed on each one of them on the specimen collected during donation. The serum ferritin testing was performed by Creative Testing Solutions (Tempe, AZ) using the Beckman Coulter (Brea, CA) AU Clinical Chemistry Analysers which utilises a latex agglutination methodology. Five single-time donors were excluded from data analyses due to having missing/aberrant recorded ages. The highest recordable ferritin level on our instruments was capped at 451 ng/mL and was used as such in the analysis.

Beginning in October 2018, CHLA BDC implemented routine ferritin testing for all allogenic and autologous whole-blood donors. Ferritin result based interventions were specifically targeted at young donors (17–22 years of age, male and female) and premenopausal adult female donors (23–50 years of age). Depending on ferritin levels, the inter-donation interval for these donors was extended. A 'low' ferritin level (13–25 ng/mL) resulted in a temporary deferral for 4 months, while a 'very low' ferritin level (≤12 ng/mL) led to a 12-month temporary deferral. Educational material on treating iron deficiency and specific instructions on using over-the-counter iron supplements were provided to these donors; no iron supplementation was offered by the CHLA BDC.

Following the discontinuation of ferritin testing in July 2021, specific interventions were introduced to limit or prevent iron deficiency in all allogenic and autologous whole-blood donors. Enhanced donor education materials and communications were provided to all donors, with a particular emphasis on iron deficiency prevention, especially for at-risk premenopausal females and frequent donors. The inter-donation interval for all young donors (17–22 years of age, male and female) was extended to 12 months (temporary deferral). Other donors were advised to limit whole blood donations to 2 times per year and platelet donations to 10 times per year with no deferral.

Data for this study was collected from the ElDorado Donor Blood Management System (Haemonetics Corp, Boston, MA). Descriptive statistics were used to represent the baseline population. Data analysis was performed using Microsoft Excel (Redmond, WA). Donor characteristics were described as means, percentages, ratios and ratios of percentages. A significance level of $p < 0.05$ was applied.

3 | RESULTS

3.1 | Demographics

Over the 2 years and 10 months study period (1 October 2018 to 31 July 2021), a total of 16 464 individual blood donors had 26 163 successful visits for whole blood donation at CHLA BDC. Ferritin testing was successfully performed on specimens collected at each visit. Females comprised 57% ($n = 9409$) of donors seen at CHLA-BDC during the study period. Detailed donor demographics for each visit by age and sex are presented in Table 1.

3.2 | Ferritin levels

Ferritin cutoffs of <26 ng/mL ('low') and ≤12 ng/mL ('very low') were utilised to categorise donors at higher risk of IDA. Data was further categorised based on these cutoffs (Table 2). Distinctions were made between 'First time' and 'Repeat' donors to account for changes in

TABLE 1 Donor demographics by age and sex.

Donor demographics	Male	Female
Ethnicity (% total donors, % 1-time donors, % repeat donors)		
African American	1.3%, 1.0%, 0.3%	1.2%, 0.9%, 0.3%
Asian	4.2%, 3.1%, 1.1%	5.1%, 3.6%, 1.5%
Asian Pacific Island	0.5%, 0.4%, 0.1%	0.6%, 0.4%, 0.2%
Caucasian	19.1%, 13.2%, 5.9%	24.6%, 17.0%, 7.6%
Hispanic	14.8%, 11.5%, 3.3%	21.8%, 16.9%, 4.9%
Native American	0.1%, 0.1%, 0.1%	0.1%, 0.1%, 0.0%
Other/not stated	2.9%, 2.1%, 0.7%	3.8%, 2.8%, 0.9%
Age groups, all donors		
17–22 year	4.4%	5.4%
23–50 year	28.9%	40.6%
≥51 year	9.5%	11.1%
Age groups, repeat donors only[a]		
17–22 year	11.3% ($n = 728$)	13.0% ($n = 886$)
23–50 year	27.4% ($n = 4758$)	28.4% ($n = 6691$)
≥51 year	32.1% ($n = 1569$)	28.5% ($n = 1832$)
Median inter-donation interval for repeat donors only,[a] months (interquartile range)		
17–22 year	6.1 (3.9–8.6)	5.3 (3.8–9.4)
23–50 year	4.9 (3.2–8.7)	6.2 (3.7–10.1)
≥51 year	5.4 (3.3–9.2)	6.2 (3.6–10.4)
Median haemoglobin at donation, g/dL (IQR)		
17–22 year	15.4 (14.8–16.0)	13.7 (13.1–14.3)
23–50 year	15.1 (14.5–15.8)	13.8 (13.2–14.4)
≥51 year	14.7 (14.1–15.3)	13.7 (13.2–14.4)
Median ferritin at donation, ng/mL (IQR)		
17–22 year	84 (56–130)	29 (18–51)
23–50 year	129 (77–208)	39 (23–66)
≥51 year	108 (58–192)	67 (38–113)

Abbreviation: IQR, interquartile range.
[a]During the study period.

TABLE 2 Ferritin levels and donor categorisation.

	Male	Female
Ferritin levels		
≤12 ng/mL	224	1256
13–25 ng/mL	941	3021
≥26–450 ng/mL	10 457	9914
≥451 ng/mL	318	32
Median ferritin at first donation for all donors,[a] ng/mL (IQR)		
17–22 year	87 (58–132), $n = 728$	30 (18–51), $n = 886$
23–50 year	137 (84–220), $n = 4758$	42 (24–70), $n = 6691$
≥51 year	117 (64–201), $n = 1569$	71 (41–118), $n = 1832$
Median ferritin for donors who visited only once,[a] ng/mL (IQR)		
17–22 year	89 (59–132), $n = 646$	30 (17–52), $n = 771$
23–50 year	146 (90–232), $n = 3454$	42 (24–71), $n = 4793$
≥51 year	129 (73–225), $n = 1065$	78 (44–123), $n = 1309$
Median ferritin at first visit for donors with at least three visits,[a] ng/mL (IQR)		
17–22 year	68 (47–134), $n = 31$	38 (28–53), $n = 28$
23–50 year	105 (61–183), $n = 673$	44 (27–70), $n = 782$
≥51 year	84 (44–162), $n = 308$	51 (33–88), $n = 248$
Median ferritin at last visit for donors with at least three visits,[a] ng/mL (IQR)		
17–22 year	46 (20–72), $n = 31$	19 (16–33), $n = 28$
23–50 year	49 (28–87), $n = 673$	26 (16–42), $n = 782$
≥51 year	49 (28–79), $n = 308$	35 (21–54), $n = 248$
Median decrease in ferritin between first and second donation for donors with two visits,[a] ng/mL (IQR)		
17–22 year	18 (4–40), $n = 82$	13 (1–19), $n = 115$
23–50 year	29 (4–60), $n = 1304$	11 (0–27), $n = 1898$
≥51 year	20 (0–49), $n = 504$	14 (1–35), $n = 523$
Median ferritin at first donation by ethnicity, ng/mL (IQR)		
African American	123 (77–212), $n = 209$	41 (24–83), $n = 199$
Asian	183 (103–312), $n = 688$	56 (32–103), $n = 839$
Asian Pacific Island	220 (133–347), $n = 82$	78 (34–120), $n = 97$
Caucasian	116 (70–185), $n = 3152$	46 (27–78), $n = 4053$
Hispanic	127 (76–203), $n = 2429$	40 (23–70), $n = 3586$
Native American	103 (72–196), $n = 24$	57 (28–81), $n = 16$
Other/not stated	132 (80–218), $n = 471$	44 (24–72), $n = 619$

Abbreviation: IQR, interquartile range.
[a]During the study period.

donor behaviour during the COVID-19 pandemic, with an increase in visits from 'Repeat' donors and a decrease in visits from donors <23 years old. Blood donation visits per year remained relatively stable at CHLA BDC during this time (Figure 1).

3.3 | Age, sex and ethnicity

Young donors (defined as 17–22 years old) trended toward lower median ferritin levels compared with donor's ≥23 years old (Figure 2 and Tables 1 and 2). Male donors exhibited equivalent to statistically higher median ferritin levels across all age groups and every visit and donation interval. Borderline inadequate haemoglobin levels in females (12.5–13.0 g/dL) at a donation showed a relative risk of a ferritin <26 ng/mL of 1.54 (1.20–1.97) at a return donation within

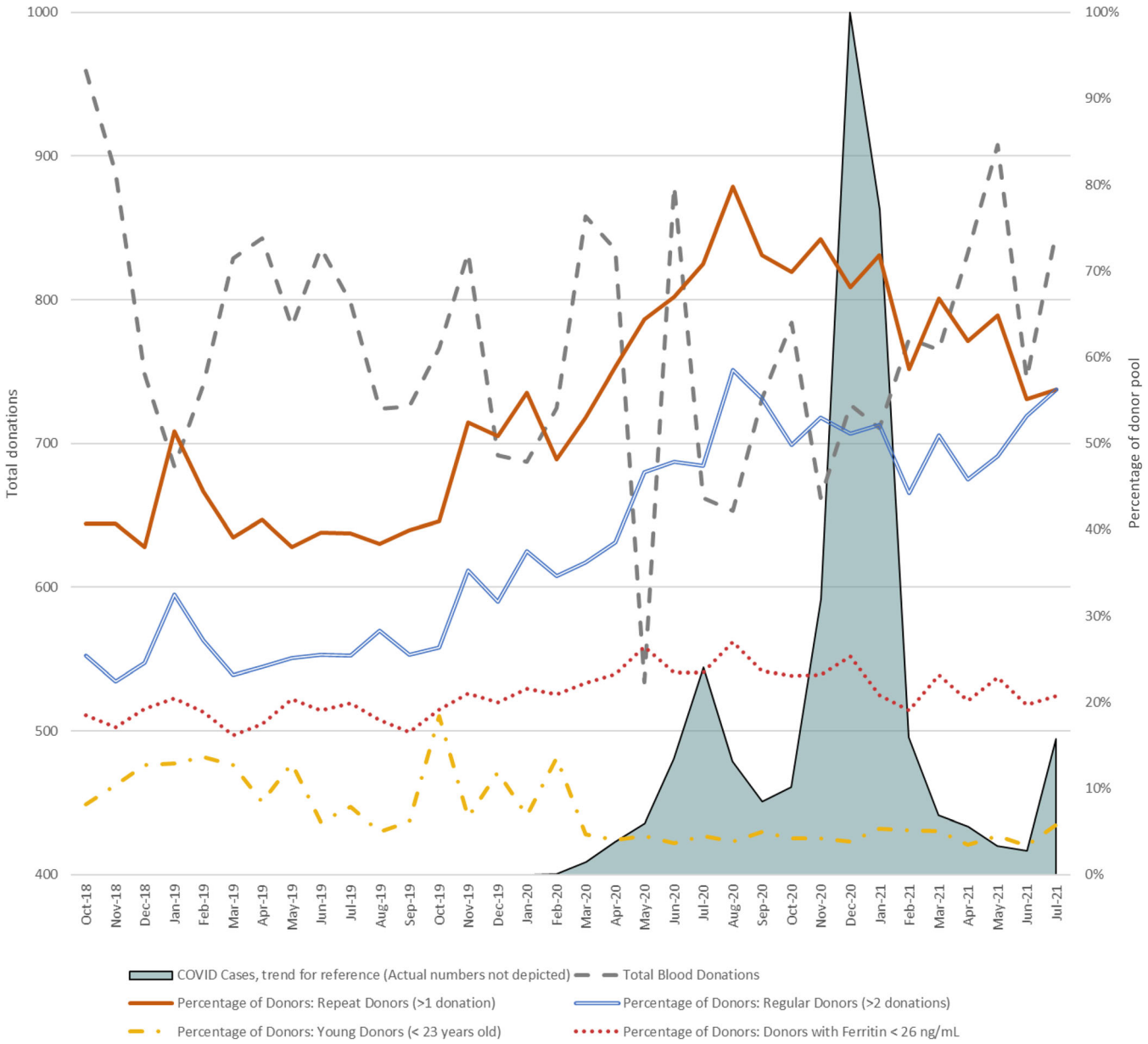

FIGURE 1 Blood donation trends during COVID-19: Trend of Children's Hospital Los Angeles, Los Angeles, CA (CHLA) blood donor centre (BDC) donation volumes and donor population during the COVID-19 pandemic, with California COVID-19 case volume data from the CDC.

6 months. Caucasian, Hispanic and Asian donors constituted the majority of whole blood donation visits as shown in Table 2.

3.4 | Donors with one visit only: Baseline ferritin data

A total of 12 038 donors (57% female) donated only once during the study period, providing baseline ferritin data. Median ferritin levels varied by sex and age (Figure 2). Young donors (17–22 years) exhibited the lowest median ferritin levels, with females showing lower levels than males. The difference between male and female ferritin levels persisted in donor's aged ≥23–50 years. However, the gap between male and female ferritin levels began to close around age 51, with overlapping baseline ferritin levels observed in their 60s.

Figure 3 illustrates the prevalence of the risk of iron deficiency in donors with only one visit. The majority of male donors (96.9% ± 0.5%, $n = 5166$) had ferritin levels ≥26 ng/mL. Approximately 60% of young female donors (17–22 years), 70% of premenopausal female donors (≥23–50 years) and 90% of postmenopausal females (≥51 years) had ferritin levels ≥26 ng/mL.

3.5 | Ferritin recovery

A total of 2356 donors (63% female) donated twice during the study period. Ferritin recovery post-donation was assessed by comparing

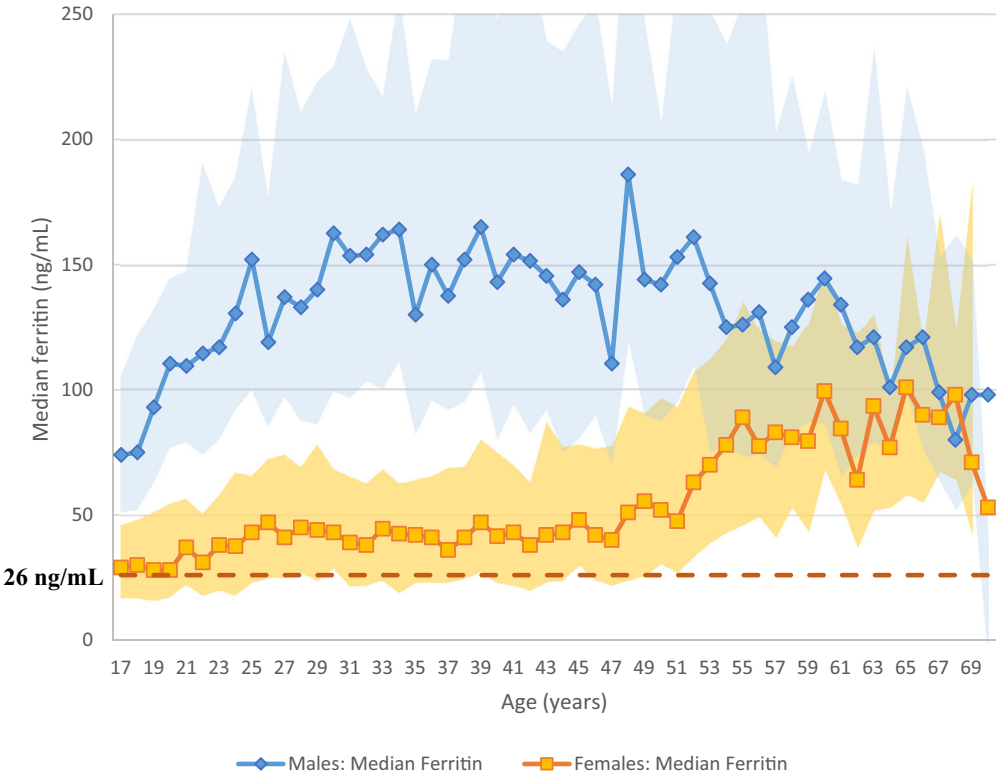

FIGURE 2 Ferritin levels for donors with one visit: Median ferritin levels by sex and age for donors with one visit, with background shadow indicating IQR. IQR, interquartile range.

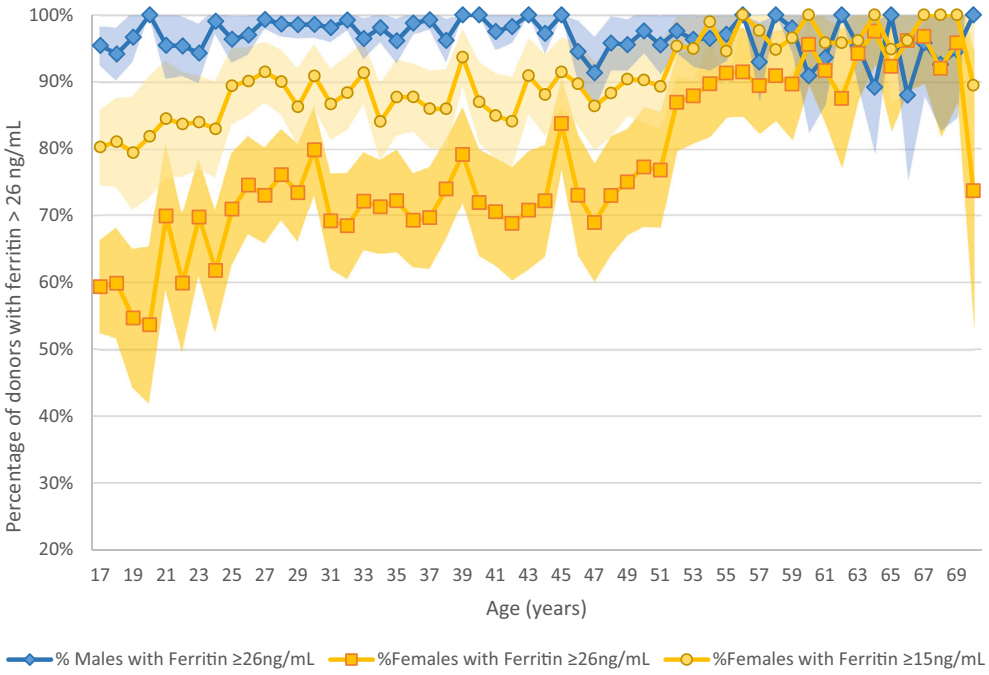

FIGURE 3 Iron deficiency risk in donors with one visit: Percentage of donors with one visit demonstrating ferritin levels ≥26 and ≥15 ng/mL for females and ≥26 ng/mL for males against age, with background shadow indicating the 95% confidence interval.

ferritin levels at the first and second visit (Table 2). Donors returning at a 2-month interval were approximately five-fold more likely to be in the lower ferritin group (<26 ng/mL) compared with donors on their first visit (Figure 4). As the donation interval increased, ferritin levels recovered and the risk of iron deficiency decreased. At a donation interval of ≥6 months, the likelihood of donors belonging to the lower ferritin group diminished to approximately one-fold risk compared with the baseline at the first visit.

3.6 | 'Regular' donors: ≥10 Visits

Eighty-nine donors (21% females) visited CHLA-BDC at least 10 times each during the study period (total 1045 successful visits). These 'regular' donors were further categorised into 'new regular' donors (started donation during the study period) and 'repeat regular' donors (had at least one previous donation at CHLA BDC before the study period). Figure 5 shows the median ferritin levels for both

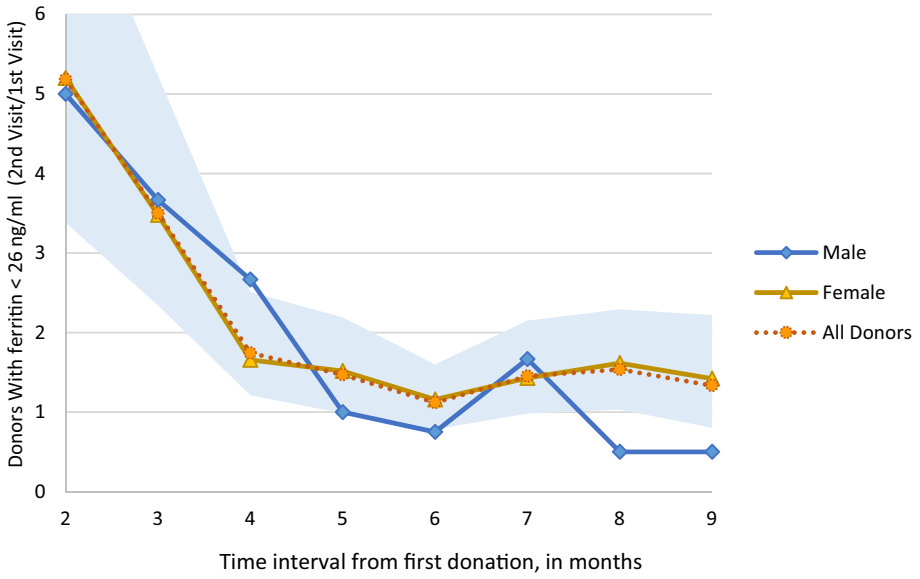

FIGURE 4 Ferritin recovery post-donation: Fold increase in proportion of donors with ferritin <26 ng/mL on their second donation over time, with background shadow showing the 95% confidence interval.

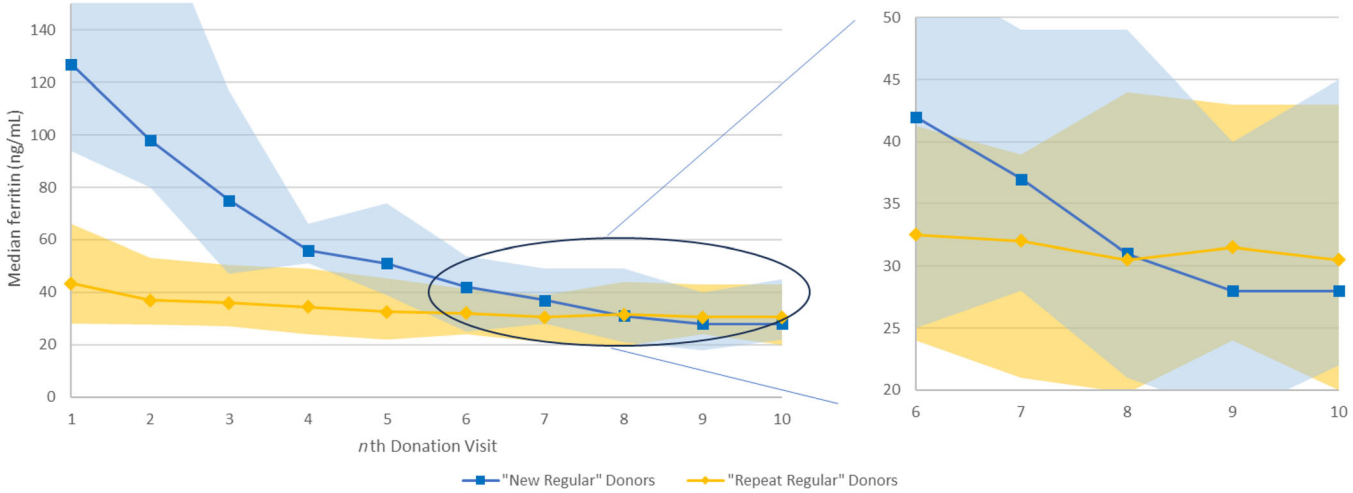

FIGURE 5 Ferritin levels for 'regular' donors: Median ferritin levels at the *n*th donation for 'new regular' and 'repeat regular' donors, with background shadow representing the IQR. A zoom-in as new regular donors approach the ferritin levels of repeat regular donors is shown. IQR, interquartile range.

groups up to 10 visits. 'New regular' donors had higher median baseline ferritin levels at their first visits during the study period compared with 'repeat regular' donors. The gap narrows, and a steady median ferritin level of ~35 ng/mL is attained by both groups around the approximately the sixth visit, with minimal further decrease in mean ferritin levels for subsequent visits (up to visit 10).

4 | DISCUSSION

Blood donor centres plays a crucial role in collecting, testing and distributing blood products to hospitals, ensuring a safe and sufficient blood supply for medical treatments and emergencies. Blood centres also have to mitigate risks such as iron depletion in donors and must achieve these goals with finite resources while preventing critical blood shortages.[7,8]

The COVID-19 pandemic significantly impacted BDC, donations decreased due to lockdowns, resources were limited and change in donor demographics were seen. A notable drop in total blood units collected, particularly from young and single-time donors, occurred at the start of the pandemic, with a sustained decrease in young donors throughout the study.[9] Despite the loss of young donors, the blood supply showed recovery due to an increase in repeat donors. A mild increase in the percentage of donors with low ferritin was observed, emphasising the importance of assessing iron deficiency risk in the changing donor landscape.

We observed that donors of Asian and Asian Pacific Islander ethnicity appeared to have higher median ferritin levels in our donor pool

(Table 2). However, the interquartile ranges (IQRs) were broader and overlapped with those of other ethnicities. The variation in ferritin levels within populations might be attributed to environmental factors.[10–16]

Sex differences in ferritin levels are pronounced, with young females identified as a high-risk category.[10,17–20] The risk was notably skewed, with the youngest females at the highest risk.[20] While premenopausal females as a larger category are generally at risk, any restrictions would constrain nearly half the donor pool; hence, we focus on the highest risk young females. Considering the decreased number of young donors due to COVID-19, their higher likelihood of being single-time donors, and the specific vulnerability of young females, a maximum donation limit of once per year was set for donors under 23 years of age. We included young males as well out of an abundance of caution and concern for the potential detrimental effects of iron deficiency in youth.[21–23]

As repeat donors became a larger fraction of the blood supply, concerns about donor iron recovery post-donation intensified.[24] Ferritin recovery was similar between sexes, with a rapid recovery before tapering toward baseline levels around 6 months (Figure 4).[4,25,26] A recommended donation limit of two times per year was established based on this data. Regular donors contributing extensively to the blood supply exhibited a steady state balance in ferritin levels after a few donations, showing stability despite the initial downwards trend observed in other studies (Figure 5).[21,27] If this vital yet at-risk group were to continue contributing, we needed to know if iron inevitably spiral ever downward or reached a steady state.[27] Fortunately, a major strength of our data comes from collected ferritin levels at every visit for our donors over a 33-month duration allowing us to readily track the ferritin levels in our regular donors.

In conclusion, our facility's extensive and long-duration ferritin testing supports, refines and expands on AABB concerns for at-risk groups.[21] Our data supports considerable baseline differences in ferritin status according to sex and age, with both sexes recovering similarly toward their baseline levels after donation.[4,25,26] Females are a particular at-risk group with young females starting with the lowest baseline ferritin levels.[10,17–20] Females with borderline low Hb at donation are at increased risk of low ferritin levels. Finally, regular donors will reach a steady state balance rather than continue to decrease in ferritin after a few donations.[27] Considering these findings, and the need to conserve our limited staffing, which was stretched thin managing the logistics of collecting and reporting ferritin results to donors, our donor centre decided to discontinue routine donor ferritin testing. While ferritin testing at every donation may provide high sensitivity for iron deficiency,[28] it may not always be practical or feasible for blood centres.[7,8] We have used these findings to tailor our donation policies that we have shared here balance blood centre resources while supporting a continued safe blood donation process for donors.

AUTHOR CONTRIBUTIONS

P.P. performed the research and wrote the first draft of the manuscript; H.H. and S.C. collected and analysed the data and reviewed and edited the manuscript; G.M. performed and supervised the research and reviewed and edited the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflicts of interest relevant to the manuscript submitted to Transfusion Medicine.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

PATIENT CONSENT STATEMENT

Patient consent was not required, as this study involved a retrospective analysis of anonymized blood donor data without any identifiable patient information.

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