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RESEARCH ARTICLE

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Source plasma deferral trends: A 3-year analysis of 255 centers in the United States

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Abstract

Background: Plasma contains many important proteins of therapeutic interest including albumin, clotting factors, and antibodies. Source plasma (SP) is in great demand particularly due to a shortage of immunoglobulin. To better understand how to increase supply, we examined SP donor deferrals for the previous 3 years.

Study design: This is a description of donor deferrals at 255 plasma donation centers in the United States for April 1, 2017 to March 31, 2020.

Results: A total of 4 587 923 events were evaluated for the 3-year period 2017-2020. There were 873 227 deferrals analyzed for 2017-2018, 1 765 582 in 2018-2019, and 1 949 114 for 2019-2020. The most common deferral each year was for unacceptable blood pressure (BP) or pulse which comprised 27.9%, 28.2%, and 28.3% of deferrals in 2017-2018, 2018-2019, and 2019-2020, respectively. The second most common cause of deferral was for unacceptable hematocrit which comprised 14.1% of deferrals in 2017-2018, and 16.0% in 2018-2019 and 2019-2020. The majority of these deferred donors had low hematocrits and were predominately (~80%) female. Deferral for unacceptable total protein comprised a smaller percentage (~4%) of deferrals.

Discussion: Most donor deferrals were due to unacceptable screening results, particularly high BP, elevated pulse, low protein, and low hematocrit. Although rates of deferrals in other categories have been slightly increasing over time, they comprise a small percentage. Donor education regarding healthy lifestyle choices may improve overall donor health, decrease deferrals, and increase SP supply.

KEYWORDS

donor deferral, donor adverse event, John Wiley, plasma, source plasma

1 | INTRODUCTION

Plasma contains many important proteins including albumin, blood clotting factors, and antibodies.[1] The majority of plasma collected for fractionation is collected in the United States. According to the Plasma Protein Therapeutics Association (PPTA), approximately 53 million liters of plasma was collected in the United States in 2019.[2] More than 20 different therapeutic plasma proteins are purified from collected plasma via a multi-step process including

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precipitations and/or chromatographic steps. Notably, the demand for pharmaceutical plasma products, particularly intravenous immunoglobulin (IVIG) products, has been increasing at the rate of 3% to 8% per year.[1-4]

Plasma that is manufactured into protein products is categorized as either source or recovered. Source plasma (SP) is derived from donors who donate just plasma via plasmapheresis and are compensated for their time. SP consists of 625 to 800 mL per donation in the United States.[3] Recovered plasma is derived from whole blood donations and typically ranges from 100 to 160 mL.[3] Approximately 87% of plasma used to produce fractionation products is derived from SP.[3,5] During SP donation, the donor's blood is centrifuged to separate the components based upon density. The plasma is collected sterilely into a bottle and the remaining components are returned to the donor with the addition of normal saline. Donors can donate SP more frequently than recovered plasma because cellular components are returned to the donor. A donor can donate SP twice in a 7-day period with at least 48 hours between donations. In the United States, donors at collection centers operated by for-profit companies are paid/compensated for their time.

TABLE 1 Selected causes for deferral in 2017-2020

Deferral	2017-2018 (%)	2018-2019 (%)	2019-2020 (%)
Blood pressure/pulse unacceptable	27.9	28.2	28.3
Hematocrit unacceptable	14.1	16.0	16.0
Temperature unacceptable	6.8	5.2	3.9
Non-reportable reaction	4.4	4.4	8.3
Cell loss	3.4	3.2	3.0
Total protein unacceptably low	2.2	2.7	2.6
Tattoo	1.5	1.5	1.5
Total protein unacceptably high	1.4	1.4	1.5
Poor veins	1.2	1.1	1.0
CDCS match	0.9	1.0	1.1
Medical history unacceptable—PERMANENT	0.9	0.9	0.8
Unacceptable address check deferral	0.9	0.8	0.9
Indirect antiglobulin test positive	0.3	0.1	0.1
Medical history unacceptable—TEMPORARY	0.8	1.0	1.1
No proof of address	0.7	0.5	0.6
Lipemic plasma	0.6	0.9	1.3
Medications—TEMPORARY	0.5	0.6	0.6
Unacceptable weight	0.5	0.6	0.7
Piercing	0.5	0.6	0.7
Incarcerated >3 days	0.4	0.4	0.4
Unreliable answers	0.4	0.4	0.4
Pregnancy	0.3	0.3	0.3
Unacceptable behavior	0.2	0.3	0.2
Prior pheresis problems	0.1	0.2	0.1
Rest veins	0.1	0.2	0.2
Medications—PERMANENT	0.1	0.1	0.2
NDDR reject	0.1	0.1	0.1
Under influence of alcohol/drugs	0.1	0.1	0.1
Seizure	<0.1	<0.1	<0.1
Male to male sex	<0.1	<0.1	<0.1
Syphilis or gonorrhea history	<0.1	<0.1	<0.1
Whole blood/platelet donation	<0.1	<0.1	<0.1

Abbreviations: CDCS, cross donation check system; NDDR, national donor deferral registry.

Donors are screened at the time of donation using questionnaires and are also medically assessed with a limited physical examination which is performed initially and annually. Additionally, the donors have protein electrophoresis and syphilis testing performed at their first donation and every 4 months thereafter. Each donor is considered a new (applicant) donor if there is a lapse of 6 months or more since their last donation. After two successful donations with acceptable test results, a donor is considered a qualified donor. Only units from qualified donors are acceptable for fractionation into injectable therapeutics.

Each donor's total protein and hemoglobin are quantitated at the collection center for each donation. Each plasma donation is then tested in a central laboratory for infectious disease markers: hepatitis B virus (HBV) surface antigen and deoxyribonucleic acid (DNA), hepatitis C virus (HCV) antibodies and ribonucleic acid (RNA), human immunodeficiency virus (HIV) antibodies and RNA, as well as in process testing for hepatitis A RNA and parvovirus B19 DNA.

Thus, the safety of plasma and its derivatives relies on donor selection and testing as well as on efficient pathogen inactivation steps in the processing of the final pooled product and pharmacovigilance. Importantly, there has not been any reported transmission of infectious blood borne diseases via plasma derivatives since 1994.[6,7] Several studies of blood donor deferrals have shown that donor deferral results in possibly losing a donor and that the longer a deferral, the higher the chances are of the donor not returning.[8-15] We examined SP donor deferrals for the previous 3 years at 255 plasma donation centers in the United States. While there have been numerous reports of deferral data in blood donors, this is the first comprehensive report of deferral patterns in SP donors.

2 | MATERIALS AND METHODS

Since this was a description of SP donor deferrals, an electronic query of the NexLynk DMS (Oracle-based) database using SQL code to find the number of deferrals applied to donors was performed across 255 plasma donation centers in the United States for 1 April 2017 to 31 March 2020. Each year was analyzed as 1 April to 31 March of the following year. All donors were applicants or qualified by the Plasma Protein Therapeutics Association's (PPTA) International Quality Plasma Program (IQPP) process. Data were analyzed using Microsoft Excel and SPSS Statistics.

3 | RESULTS

Data from a total of 255 SP donation sites was examined. All sites were from one company and spanned across the

TABLE 2 Screening deferrals for 2017-2020

Deferral	2017-2018 (%)	2018-2019 (%)	2019-2020 (%)
Pulse high	21.3	21.2	20.7
Hematocrit female low	9.4	10.9	10.9
Temperature high	6.5	4.9	3.6
BP-DIA high	5.0	5.3	5.7
Hematocrit male high	2.4	2.4	2.3
Hematocrit male low	2.3	2.6	2.7
BP-SYS high	1.3	1.4	1.6
Total protein male high	1.0	1.0	1.1
Total protein female low	1.1	1.4	1.3
Total protein male low	1.1	1.4	1.3
Weight low	0.4	0.5	0.5
Total protein female high	0.4	0.4	0.5
Temperature low	0.3	0.3	0.2
BP-SYS low	0.2	0.2	0.2
Weight high	0.1	0.1	0.2
Hematocrit female high	0.1	0.1	0.1
BP-DIA low	0.1	0.1	0.1
Pulse low	<0.1	<0.1	<0.1

Abbreviations: BP, blood pressure; DIA, diastolic; SYS, systolic.

United States. All centers operated in accordance with Food and Drug Administration (FDA) regulations and Plasma Protein Therapeutics Association (PPTA) industry voluntary standards. A total of 4 587 923 deferral events were evaluated for the 3-year period 1 April 2017 to 31 March 2020. There were 873 227 deferrals analyzed for 2017-2018, 1 765 582 in 2018-2019, and 1 949 114 for 2019-2020. The deferral events comprised 6.3% of total donations in 2017-2018, 10.6% of total donations in 2018-2019, and 10.8% of total donations in 2019-2020. Selected causes for deferral and their overall percentage of total deferrals in 2017-2020 are given in Table 1. Deferrals for vital signs, hematocrit, and protein are given in Table 2 and Figure 1. The most common deferral each year was for unacceptable blood pressure (BP) or pulse which comprised 27.9% (243938), 28.2% (497467), and 28.3% (551959) of deferrals in 2017-2018, 2018-2019, and 2019-2020, respectively. The majority of these deferred donors (20.7%-21.3%) had a high pulse (above 100 beats/min). The next most common causes of deferral were low hematocrit in females, high temperature, and high diastolic BP (>100 mmHg). High systolic BP (>180 mmHg) comprised a much lower percentage of donor deferrals. Low pulse, low systolic BP, and low diastolic BP were less common causes of donor deferral and together comprised only ~0.3% of donor deferrals.

The second most common cause of deferral was for unacceptable hematocrit which comprised 14.1% (123 402), 16.0% (282 875), and 16.0% (312 563) of deferrals in 2017-2018, 2018-2019, and 2019-2020, respectively. The majority of these deferred donors had low hematocrits and were predominately (~80%) female. Notably, deferred male donors were nearly evenly split between deferrals for high and low hematocrits (Table 2). Deferral for unacceptable

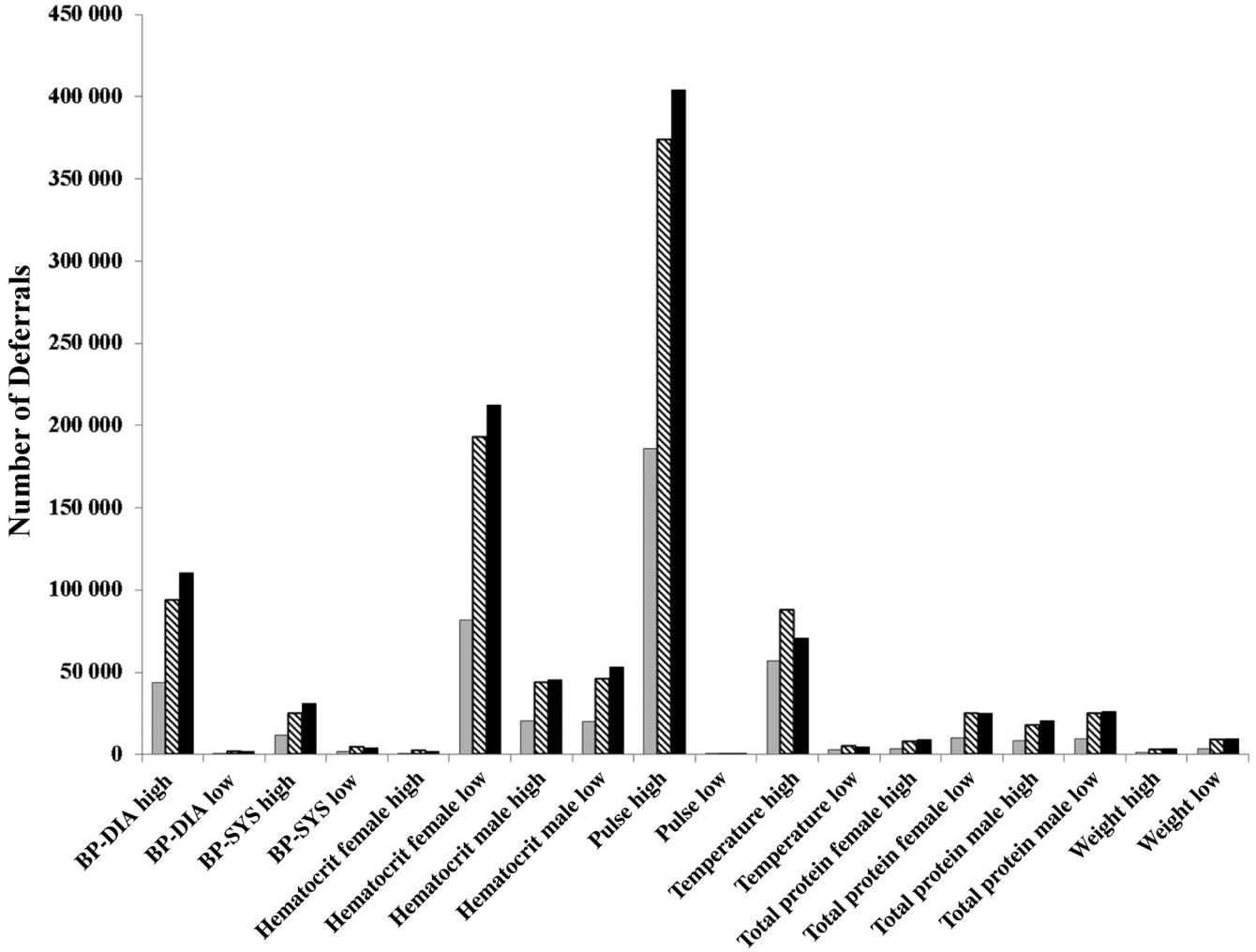

FIGURE 1 Screening donor deferrals. The absolute number of deferrals across all 255 donor centers are depicted in this bar graph. The vertical axis depicts the number of donor deferrals and the horizontal axis describes the reason for deferral. High pulse represents the largest number of deferrals, followed by low female hematocrit and high diastolic BP. Grey bars represent 2017-2018, diagonal lines represent 2018-2019, and black bars represent 2019-2020. BP, blood pressure; SYS, systolic; DIA, diastolic

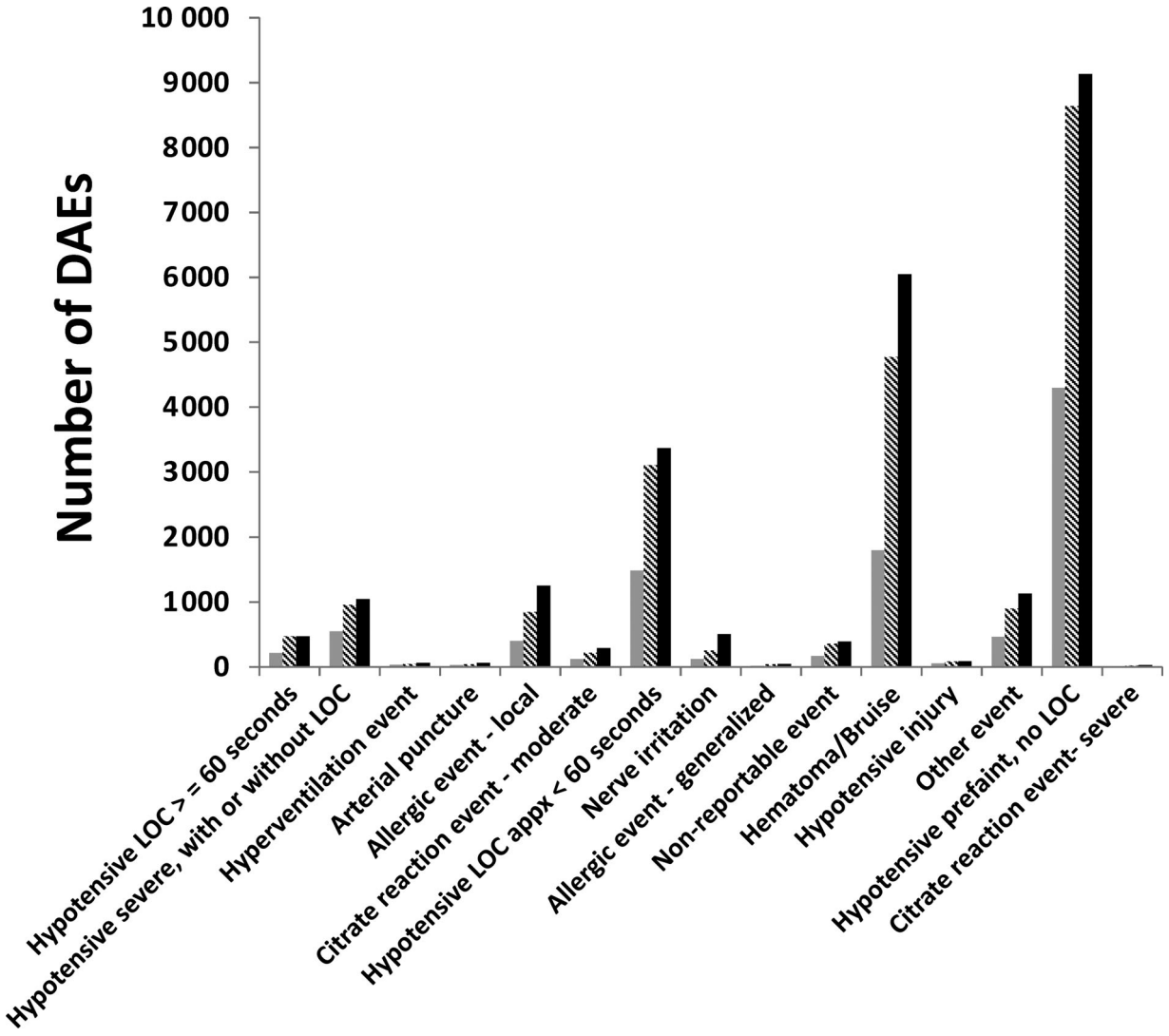

FIGURE 2 Donor adverse events. The most common types of DAEs between 2017 and 2020 are shown in the graph. The most common type of DAE was hypotensive prefaint reactions with no loss of consciousness. Grey bars represent 2017-2018, diagonal lines represent 2018-2019, and black bars represent 2019-2020. DAE, Donor adverse events; LOC, loss of consciousness

total protein results comprised a smaller percentage of deferrals [3.6% (32055) 2017-2018, 4.1% (73636) 2018-2019, and 4.1% (81196) 2019-2020]. Most of these deferrals were for low protein (<6.0 g/dL). The relative proportion of donors deferred for unacceptable temperature steadily declined from 6.8% (59566) in 2017-2018 to 5.2% (92358) in 2018-2019 and finally to 3.9% (75232) in 2019-2020. The number of donors deferred for unacceptable weight was low (<1%) for all years examined. More donors were deferred for elevated weight (>400 lb) than for low weight (<110 lb). These trends in screening deferrals were similar across nearly all 255 donor centers including new centers (defined as less than 1 year old).

Deferrals for piercings (0.5%-0.7%), tattoos (1.5%), and incarceration (0.4%) were essentially steady across the 3 years. Notably, deferrals for lipemic plasma increased from 0.6% in 2017-2018 to 0.9% in 2018-2019, to 1.3% in 2019-2020. In 2017-2018, 1.7% of deferrals were for unacceptable medical history (temporary and permanent) compared to 1.9% in 2018-2019 and 2019-2020. A small portion of donors were deferred across the 3-year period for requiring insulin to treat diabetes [776 (0.1%) in 2017-2018; 1703 (0.1%) in 2018-2019; and 1526 (0.1%) in 2019-2020].

Deferral for non-reportable (ie, minor) reactions increased from 4.4% in 2017-2018 and 2018-2019 to 8.3% in 2019-2020. Non-reportable reactions are reactions that the donors have that do not meet the criteria for a donor adverse event (DAE). According to the PPTA International Quality Plasma Program (IQPP) standards, there was a total of 9795 reportable DAEs in 2017-2018, 20 851 in 2018-2019, and 24 048 in 2019-2020. The likely causes

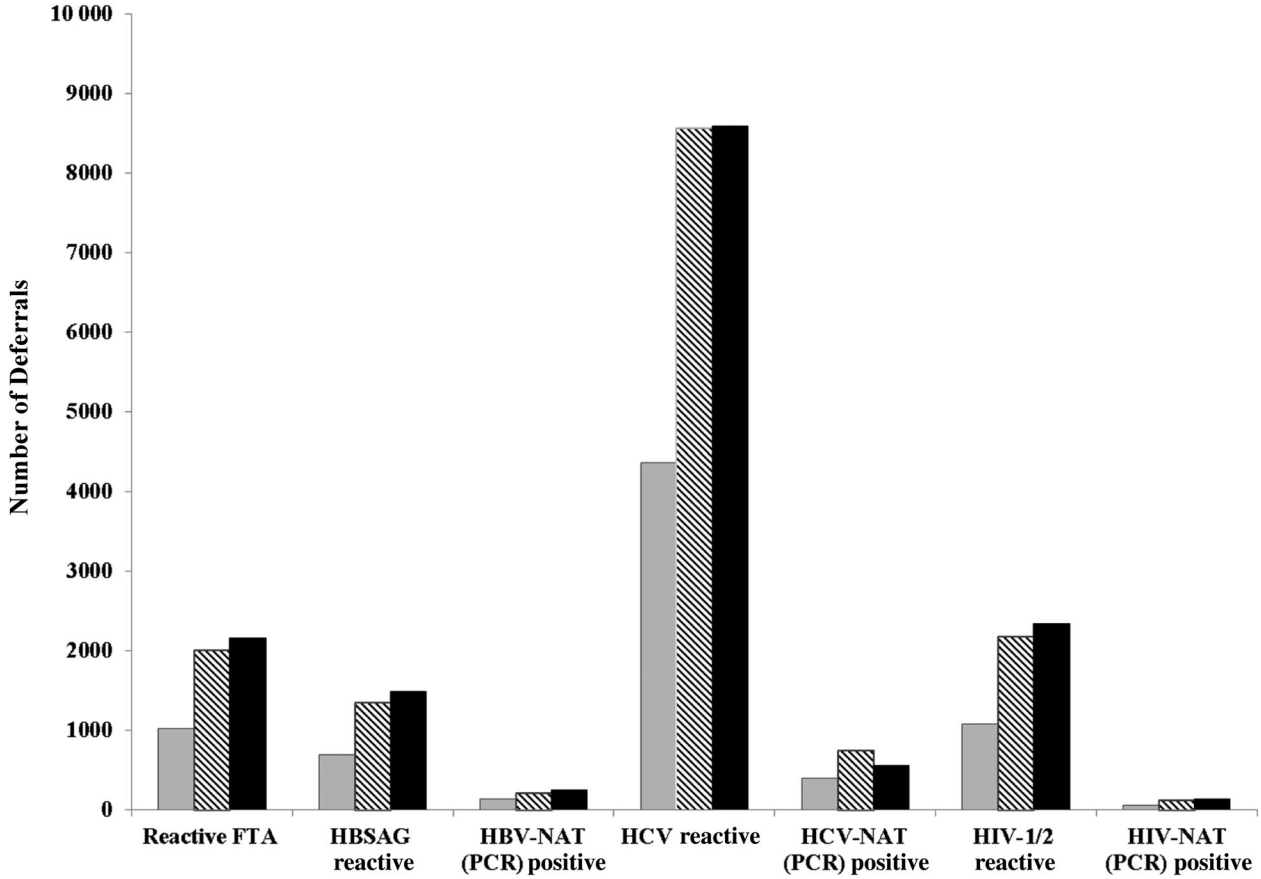

FIGURE 3 Infectious disease testing. The absolute numbers of positive infectious disease tests for each respective year are shown in the bar graph. The HCV antibody testing was positive more frequently as compared to other tests followed by HIV 1/2 antibody and FTA tests. Grey bars represent 2017-2018, diagonal lines represent 2018-2019, and black bars represent 2019-2020. FTA, fluorescent treponemal antibody; HBSAG, hepatitis B surface antigen; NAT, nucleic acid test; PCR, polymerase chain reaction

TABLE 3 Infectious disease markers

Infectious marker	2017-2018	2018-2019	2019-2020
HCV Ab	4356	8561	8593
HIV 1/2 Ab	1081	2181	2341
FTA	1017	2014	2152
HBV sAg	685	1354	1485
HCV NAT	398	750	553
HBV NAT	137	221	242
HIV NAT	58	120	129

Abbreviations: Ab, antibody; FTA, fluorescent treponemal antibody absorption test; NAT, nucleic acid testing (PCR); sAg, surface antigen.

of the increased number of DAEs resulting in deferral were an increase in donor collections and adoption of a new donor adverse event reporting standard required by PPTA. The most common DAEs in all 3 years were hypotensive (presyncope) reactions with no loss of consciousness (LOC), followed by hematomas/bruises, and hypotensive reactions with LOC <60 seconds (Figure 2). Figure 2 depicts some of the more common causes of reportable DAEs.

Other causes of donor deferrals included unacceptable address check, no proof of address, and poor veins. Donors deferred for a history of seizures comprised a small number of deferrals (~0.1%) as did syphilis or gonorrhea history. Moreover, a small number of donors were deferred for being under the influence of alcohol or drugs (~0.1%) all 3 years. Approximately 0.2% of donors were deferred each year for unacceptable behavior. Lastly, some donors (~0.4% each year) were deferred for unreliable answers, which is cause for permanent deferral.

Donor deferrals for positive infectious disease markers remained steady over the 3-year period (Figure 3 and Table 3). A total of 7732 (0.9%) donor deferrals in 2017-2018, 15 201 (0.9%) in 2018-2019, and 15 495 (0.8%) in 2019-2020 were for positive infectious disease markers. Most donors were deferred for positive hepatitis C virus (HCV) antibodies followed by human immunodeficiency virus (HIV) 1/2 antibody positivity and reactive fluorescent

treponemal antibody (FTA) test. Notably, there were 2706 deferrals in 2017-2018, 5369 deferrals in 2018-2019, and 5947 deferrals in 2019-2020 for positive serologic test for syphilis (STS) screening results. Less than half of these deferrals were associated with a positive FTA test result (1107 in 2017-2018; 2014 in 2018-2019; and 2152 in 2019-2020).

Every 4 months, donors are tested with protein electrophoresis. The number of donor deferrals associated with failed protein electrophoresis results increased from 2017 to 2020. In 2017-2018, there was a total of 6460 (0.7%) deferrals. In 2018-2019 there was a total of 12 059 (0.7%) deferrals, and in 2019-2020, there was a total of 24 243 (1.2%) deferrals. The most likely cause for this increase in deferrals between 2018-2019 and 2919-20 was a change in the testing method. The most common cause of a donor failed protein electrophoresis was low albumin.

The majority of SP donors are not whole blood or blood center donors of platelets. In 2017-2018, 869 (<0.1%) donors were deferred for previous whole blood or platelet donation. In 2018-2019, 1550 (<0.1%) of donors were deferred, and in 2019-2020, 1411 (<0.1%) of donors were deferred for previous platelet or whole blood donation.

4 | DISCUSSION

In this study, the majority of donor events were for failed vital signs (BP, pulse) or hematocrit or total protein. Elevated pulse above 100 bpm was the single largest deferral reason followed by low hematocrit, and elevated BP (Tables 1, 2, and Figure 1). Most of the deferral percentages have remained essentially constant over the past 3 years.

Less information has been published to date on SP donation than on whole blood donation. This leaves comparison of donor deferrals to those published by blood donation centers such as the American Red Cross (ARC). In this study, 0.1% of all donations (not all deferrals as has been discussed earlier) in 2017-2018 and 1.7% in 2018-2019 and 2019-2020 resulted in deferral for unacceptable hematocrit as compared to 7.7% at the ARC.[16] Similar to what was observed at the SP donor centers, the majority of those donors deferred for unacceptable hemoglobin were women. Women of child bearing age are more likely to have lower hematocrits due to menstruation. The difference in hematocrit deferrals may relate to the fact iron deficiency is found in more frequently in whole blood donors and is not found in frequent SP donors.[17]

Notably, a lower absolute number and percentage of donors at the ARC were deferred for unacceptable BP or pulse (BP: 48777 deferrals, 0.64%; pulse: 30806 deferrals, 0.41%)[16] as compared to the SP centers (1.7% of all donations deferred for unacceptable BP/pulse in 2017-2018, 3.0% in 2018-2019, and 3.1% in 2019-2020). The ARC data also reflects higher deferrals for Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD) risk factors as compared to the SP donor centers. This difference likely reflects the difference in the age and travel history of donors at these two types of centers. The mean age of donors in 2017-2018 was 33.5 ± 11.3 y/o, in 2018-2019 was 33.7 ± 11.4 y/o, and in 2019-2020 was 34.3 ± 11.5 y/o. uring this time, CSL Plasma did not accept new donors older than 65 or established donors older than 74.

A more recent study by Sapiano et al. examined data from the National Blood Collection and Utilization Survey (NBCUS).[18] This study analyzed the number of blood donors and deferrals within the United States. They found that deferral for low hemoglobin/hematocrit comprised ~44% of all deferrals in 2017 and ~52% of deferrals in 2015.[18] Notably, ~80% of those with low hemoglobin/hematocrit were women. This is a much higher percentage of overall deferrals than what was observed for low hematocrit at the SP donor centers (14.1%-16.0%).[18] However, the predominance of women having lower hemoglobin/hematocrit was a common observation between these two studies. The larger percentage of deferrals for low hematocrit at blood donor centers may be attributed to the fact that the donors are donating whole blood containing red blood cells (RBCs) and that donors at the SP centers are overall losing minimal RBCs.[17,19,20] Sapiano et al. also observed a large proportion (20.5% in 2017 and 26.7% in 2015) of deferrals for pulse and/or BP.[18] This similar to what was observed in this study (27.9%-28.2%). The deferral rate for tattoos and piercings in the NBCUS study was 2.4% in 2017 and 2.6% in 2015[18] which is slightly higher than was observed in this study (~1.7%). A small percentage of donors were deferred across the 3-year period for positive infectious disease markers. As shown in Figure 3, the most common infectious disease marker was HCV antibody.

As shown in Table 3, deferrals for HIV 1/2 Ab were ~ 10-fold higher than deferrals for HIV NAT and deferrals for HCV Ab were also ~10-fold higher than deferrals for HCV NAT. This is most likely due to applicant donors who are either on highly active antiretroviral therapy (HAART) therapy or who have been treated for HCV infection. The donor questionnaire addresses both of these and donors should be screened out if they answer honestly; however, this is not always the case. Additionally, many donors who have received treatment for HCV believe that they have been cured of HCV and can donate, which is also not true. Moreover, donors who are on pre-exposure prophylaxis (PrEP) for HIV prevention are also excluded from donating.

In an effort to increase the number of available blood and plasma donors, the FDA lowered several of the deferral periods for donors in May 2020. Several areas of change most pertinent to SP centers was the decrease of the deferral for tattoo or piercing from 1 year to 3 months as well as the change in deferral for men who have sex with men (MSM) from 1 year after the last contact to 3 months.[21,22] At our plasma centers, these deferrals are 4 months due to European regulations, but it has impacted deferrals. An analysis of the 2020-21 data will be necessary to quantify this change.

Schreiber et al. recently analyzed 1.1 million SP donors that made 12 183 182 donations over a 4-month period.[23] They found that the DAE rate was 15.85 per 10 000 donations.[23] In our study, the rate of DAEs was 6.97 per 10 000 donations in 2017-2018, 14.84 per 10 000 donations in 2018-2019, and 13.38 per 10 000 donations in 2019-2020. Thus, the rate of DAEs in our study was slighter lower than those reported by Schreiber et al.; however, not all DAEs result in deferral and we are only reporting cases where donors were deferred due to an adverse event. Similar to our study, the most common DAEs observed were hypotensive (8.32 per 10 000) and phlebotomy (5.91 per 10 000) related.[23] Together, these two categories comprised ~90% of all DAEs.

In the IMPACT trial, Hartmann et al. analyzed the effect of two different nomograms for donating plasma on repeat donation rate and deferral rates.[15] In one arm, donors donated plasma based upon a weight-based nomogram, which is standard for SP donation, and in another arm, the donor height, weight, and hematocrit were used to determine a plasma donation volume. The number of repeat donations was essentially the same in both arms as was the number of deferrals.[15] There were 798 donors with at least one deferral in this study. A total of 376 donors from the weight-based arm were deferred as compared to 422 donors from the other arm.[15] Thus, there did not appear to be an increase in hypotensive DAEs. Additionally, there were no statistically significant differences in deferrals for vital signs, protein, or hematocrit between donors in the two arms.[15] This study, indicates that donor weight, height, and hematocrit may be able to be used to generate a personalized amount of plasma for each donor to donate and that some donors may be able to donate larger amounts of plasma safely.

Over the 3 years presented here, donor deferrals were relatively the same as a percentage of total deferrals in several areas including tattoos, piercings, incarceration, elevated pulse, elevated systolic or diastolic BP, and unacceptable medical history to name a few. There was an increase over the years in deferrals for lipemic plasma, non-reportable reactions, and DAEs. These increases were most likely secondary to increased number of plasma collections, changes in testing methodology, and adoption of new DAE reporting standards. Additionally, the increases in deferrals may also be due to a decrease in overall health of the general population as has been described in some public health studies.[24-26]

Many deferral causes in this study comprised only a small percentage of the total deferrals and would not represent a suitable starting target for further action. The largest change in donor deferrals will result from focusing on significant deferral causes, particularly the screening tests such as BP, pulse, and hematocrit. By decreasing overall donor deferrals, more donors would be eligible to donate and less donors would be lost due to the deferral and dropping out of the program. Loss of donors due to deferrals, even short deferrals, can add up to a significant loss of donors and potential SP collection.[8-15] This study ended as the pandemic began. It will be of interest to determine in the future how deferrals were impacted by COVID-19.

5 | CONCLUSIONS

There is an increased demand for plasma to be manufactured into plasma derived medicinal products such as IVIG, albumin, and clotting factors. In this study, we sought to better understand the causes and causes of donor deferrals at our SP centers across the United States. By understanding the deferral data, our hope is to modify policies or institute donor education so as to increase overall donation and decrease deferrals.

From this study, it is apparent that donor suitability as defined by pulse, BP, total protein and hematocrit are four areas for focus. We carefully screen donors to ensure it is safe for both the donor (hematocrit, BP, pulse) and recipient (infectious diseases). The system is effective as witnessed by our deferrals for these issues as well as the fact that overall rates of positive infectious disease markers are low. Donors deferred for BP, pulse, hematocrit, and infectious disease testing positivity are directed to follow-up with health care practitioners in the community. The donor deferral process presents an opportunity to educate donors on health screening and healthier lifestyle. A concerted effort to increase overall donor health would likely result in a win-win situation for the donors, the community, and patients who need the plasma products. Due to the large number of deferrals related to cardiovascular health (unacceptable BP and pulse), SP collectors may be in a unique position to help improve donor health by partnering with local clinics or hospitals to provide donors more information about access to health care.

CONFLICT OF INTEREST

All of the authors are employees of CSL Plasma.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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