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Abstract Journal

2023 SOL HABERMAN AWARD WINNER

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ImpactLife

TITLE: Testing Allogeneic Blood Donors with Unexpected Antibodies for Improved Utilization of Red Blood Cell Inventory

ABSTRACT:

Donor red blood cell units that have been labeled as having an antibody are difficult to utilize. Depending on blood center policy, they may even be immediately discarded. There are limited hospitals that will accept red blood cell units labeled with an antibody, and there are limited patients able to receive them. A study was performed to determine if there is a way to test these donors that better represents the amount of antibody that is actually present in the red blood cell units. It was found that a considerable proportion of these red blood cell units could be labeled for general inventory when using an alternate testing procedure.

INTRODUCTION:

Current FDA regulations and AABB standards require all allogeneic blood donors be screened for unexpected antibodies in their plasma.[1,2] If a donor is found to have a positive antibody screen, an antibody identification must be performed if any red blood cell units are going to be labeled. The red blood cell unit(s) must be labeled with the specificity of the antibody. All other blood products from the donation, such as plasma and platelets, are discarded. Utilization of red blood cell units labeled with an antibody can be difficult, as many hospitals do not accept them. Depending on blood center policies, these units may be discarded before an identification is performed. The following data was collected at a community-based blood center.

Antibody detection testing is performed at an offsite testing facility using an automated instrumentation method. If a positive result is obtained, the blood center Reference Laboratory is alerted so they can perform an antibody screen and, if needed, identification. Current procedures require testing be performed in the column agglutination method, also known as gel. Reference Lab testing is done on plasma from a retention EDTA tube collected at the time of donation.

Red blood cell units have almost all plasma removed, as well as an additive solution added, further diluting any residual plasma. Testing from a retention tube is not representative of how much antibody is present in a red blood cell unit. Using a modified testing procedure on units with positive antibody screens could positively impact blood inventory levels, which are constantly low. If testing is performed using the red blood cell unit segment supernatant instead of the retention tube plasma, and/or a less sensitive testing method is used, some of these red blood cell units might demonstrate a negative antibody screen and be labeled for general inventory. A less sensitive testing method would eliminate enhancing weaker antibodies with a titer of less than one and deemed not clinically significant.[3] A study was conducted to determine what proportion of red blood cell units containing unexpected antibodies could be saved for general inventory if these testing changes were to be implemented.

MATERIALS AND METHODS:

All whole blood collections with positive antibody screens over a two-month period were tested. An antibody screen was performed off the retention tube plasma in both gel method and tube method. The tube method used a 30-minute incubation at 37°C with no enhancement media, followed by the indirect antiglobulin test (IAT). This will be referred to as the 30-minute saline method.

A titration was performed on all retention tubes with positive 30-minute saline screens. The titrations used a serial dilution of the plasma and were tested at 30-minute saline IAT in tube. The indicator cell used was a homozygous cell, with the exception of samples with anti-K or anti-Kpa where a heterozygous cell was used. If a donor had multiple antibody specificities, the indicator cell was positive for all antigens to which they had antibodies. The titer was recorded as the reciprocal of the highest dilution yielding a 1+ or stronger reaction macroscopically.

Four segments were taken off the red blood cell units of each product being tested. The segment contents were emptied into a test tube and spun down to separate and harvest the supernatant. An antibody screen was performed using the segment supernatant in gel method on all samples. An antibody screen was performed using the segment supernatant in the 30-minute saline method for all donors that had a positive 30-minute saline screen using the retention tube plasma.

RESULTS:

Data was collected from testing results over a two-month period, for a total of 86 products tested. A range of 13 different antibody specificities were identified, with some samples having multiple specificities present. The distribution was as follows: 22 anti-K, 22 anti-E, 17 anti-D, 15 anti -M, 7 anti-C, 5 anti-c, 3 anti-Jk^a, 2 anti-Fy^a, 1 anti-e, 1 anti-Kp^a, 1 anti-S, 1 anti-Le^a, and 1 antibody of undetermined specificity.

A 30-minute saline screen was performed on the retention tube plasma on all 86 samples. A negative screen was obtained on 21 of the samples, and the remaining had positive screens. (Table I) All samples with a negative 30-minute saline screen had a titer of less than one. A titration was performed on all 65 of the retention tubes with a positive 30-minute saline screen. The titers ranged from 1 to 128, with 44 (67%) of the samples having a titer of 4 or less.(Table II)

A gel screen was performed on the red blood cell unit segment supernatant from 77 of the 86 donors. Nine could not be retrieved for testing. A negative screen was obtained on 36 of the samples, and 41 had positive screens.(Table I)

A 30-minute saline screen was performed on the red blood cell unit segment supernatant on 59 of the 65 products with positive 30-minute saline screen off the retention tube. A negative screen was obtained on 28 of the samples, and 31 had positive screens. Overall, 49 (57%) had a negative 30min saline screen on the retention tube plasma or on the red blood cell unit segment supernatant.

Table I. Retention Tube Plasma and Segment Supernatant Screen Results

Result	Retention Tube 30 min Saline Screen	Segment Supernatant Gel Screen	Segment Supernatant 30 min Saline Screen
Negative	21 (24%)	36 (47%)	28 (47%)
Positive	65 (76%)	41 (53%)	31 (53%)

Table II. Titer Results									
Titer	<1	1	2	4	8	16	32	64	128
Number of donors	21 (24%)	12 (14%)	17 (20%)	15 (17%)	10 (12%)	3 (3%)	3 (3%)	3 (3%)	3 (3%)

DISCUSSION:

In this study, a considerable proportion of red blood cell units did not have a clinically significant level of antibody detected.[3] Almost one fourth (24%) of products tested had a titer of less than one when testing plasma from the retention tube. Additionally, more than half (57%) the red blood cell units had a titer of less than one when testing was also done using the supernatant from the unit segments.

The number of red blood cell units returned to general inventory will vary depending on a blood center's collection numbers and current testing procedures. One study performed over a 4.5-year period, using data from four separate blood centers, found that 0.77% of their donors had a positive red blood cell alloantibody screen.[4] According to this study, 439 red blood cell products per 100,000 whole blood collections could be returned in general inventory.

This study demonstrates there is less antibody present in the red blood cell unit than the donor retention tube. Comparable results were found in a separate study where alloantibodies were undetectable in 28% of the donor segment supernatants, and all antibody titers decreased in segment samples compared to the donor specimen.[5]

Changing the process in which these products are tested could greatly impact utilization of these red blood cell units. In a two-month period, 49 red blood cell units would have been added to general inventory and not labeled as having an antibody if 30-minute saline testing was performed on the supernatant from the red blood cell unit segments. Annualized, approximately 294 red blood cell units at this facility could avoid being labeled with an antibody and instead be added to general inventory.

Blood donor centers will likely see a financial impact as well. More of these units being labeled for general inventory will mean more being available for distribution, instead of being disposed of when hospitals will not accept them. Less technologist time will be spent identifying antibodies on these donors, since about half of the products will have a negative antibody screen when using the least sensitive method.

SUMMARY:

Red blood cell units that are labeled with an antibody are difficult for blood centers to distribute. Many of the units end up being discarded due to the lack of hospitals that accept these units. This study tested if there was a better way to test donors with a positive antibody screen that may lead to fewer units needing to be labeled as having an antibody.

When a less sensitive testing method was performed on the red blood cell unit segment supernatant, more than half of the donors tested had a negative antibody screen. These units would not need to be labeled as having an antibody and could be added to general inventory.

Red blood cell units from donors with a positive antibody screen can be better utilized if testing procedures are modified to better represent the amount of antibody that is in the red blood cell unit.

This modification will lead to more blood being readily available on the shelves, which is significant during a time when blood shortages are a constant reality.

REFERENCES:

1. Title 21 C.F.R. 606.151(d)

2. AABB. Testing of Donor Blood. In: Standards for Blood Banks and Transfusion Services. 33rd ed. Bethesda, MD: AABB; 2022:34-35.

3. Cohn CS, Delaney M, Johnson ST, Katz LM. Test Methods. In: Technical Manual. 20th ed. Bethesda, MD: AABB; 2020:392-392.

4. Karafin MS, Tan S, Tormey CA, et al. Prevalence and risk factors for RBC alloantibodies in blood donors in the recipient epidemiology and Donor Evaluation study-III (REDS-III). Transfusion. 2018;59(1):217-225.

5. Hill EA, Bryant BJ. Comparison of antibody titers in donor specimens and associated AS-1 leukoreduced donor units. Transfusion. 2013;54(6):1580-1584.

2023 | **Oral & Poster** Abstracts

The following Abstracts were submitted for review by the South Central Association of Blood Banks Program Committee Chairs and were selected in either ORAL or POSTER categories for the 2023 Abstract Journal. All Oral Abstracts presented at the 2023 SCABB Annual Meeting & Exhibit Show in Denver, Colorado.

Presenting	Time	Abstract #	Abstract Title	Abstract Authors	Type	Category
6/7/2023	10:50 AM	**Sol Haberman Award Winner**	Testing Allogeneic Blood Donors with Unexpected Antibodies for Improved Utilization of Red Blood Cell Inventory	D. Zeman, MLS(ASCP)SBB	ORAL	T/S
		1	Improving Team Member Engagement and Process Improvement Using Employee-led Performance Improvement Committee (EPIC)	Mingmar Sherpa, DCLS, MLS (ASCP), SBB (ASCP), Vitalant; Steve Armstrong, DHA, MLS(AMT), SBB(ASCP), FACHE, Vitalant, Laurie Sutor, MD, Carter Blood Care	POSTER	ADMIN
		2	Utilizing Historical Antigen Negative Data to Optimize Antigen Testing Algorithms	Michael Gannett MLS (ASCP) SBB, OneBlood, Orlando, Claribel Resto, MHSc (ASCP) SBB, OneBlood, Fort Lauderdale	POSTER	T/S
		3	Anti-c Identified in a Patient with a Previously Unreported RHCE Allele, RHCE*ceVS.03-DIIIa(2-3)	K. Bowman, KL. Billingsley, C. Williford, C. Steinmetz, J. Gardner, M. Kalvelage	POSTER	T/S
6/8/2023	12:20 PM	4	Implementation of a Molecular Genotyping Protocol for Patients with Warm Autoantibodies	Dorothy Blake[1], William S Crews Jr.[1], Sandy Wortman1, Laurie Sutor[1,2], LeeAnn Walker[3], Sarah Burnett-Greenup[3] 1Carter BloodCare, Bedford, TX 2University of Texas Southwestern Medical Center in Dallas, TX 3 University of Texas Medical Branch, Galveston, TX	ORAL	T/S
6/7/2023	12:05 PM	5	Aliquoting Cryoperserved Red Cell Units	Dave Sawh, OneBlood Inc.	ORAL	T/S
6/8/2023	11:05 AM	6	The Science...or Not Behind Deferrals of Blood Donors With a History of Cancer	Richard R. Gammon[1],8 Courtney Hopkins[2,8] Gagan Mathur[3,8] Susan N. Rossmann[4,8] Merlyn Sayers[5,6,8] Todd Straus[7,8] [1].OneBlood, Scientific, Medical, Technical Direction, Orlando, Florida 2.Vitalent, Corporate Medical Affairs, Charleston, South Carolina 3.University of California Irvine, Orange, CA 4.Gulf Coast Regional Blood Center, Houston, Texas 5.Carter Blood Care, Bedford, Texas 6.University of Texas Southwestern Medical Center, Dallas, Texas 7.The Community Blood Center, Appleton, Wisconsin 8.Donor Cancer Deferral Workgroup, America's Blood Centers, Washington, D.C.	ORAL	T/S
		7	Donor with Rare Polymorphisms Results in Multiple RBC Genotype Discrepancies	K. Bowman, KL. Billingsley, M. Kalvelage; LifeShare Blood Center	POSTER	T/S
6/7/2023	2:05 PM	8	Cost Effectiveness of Allogeneic Adsorption versus Soluble Recombinant Blood Group Protein	Katherine Dovydaitis BB(ASCP)[CM], Tara Francis SBB(ASCP)[CM], Cody Riebel BB (ASCP)[CM], Michael Gannett MLS(ASCP) SBB[CM], Richard Gammon, MD, OneBlood, Inc.	ORAL	T/S
		9	Evaluation of DNA Quality Using Aged EDTA Samples	K. Bowman, KL. Billingsley, C. Cheney, M. Kalvelage LifeShare Blood Center	POSTER	T/S
		10	In Vitro and In Vivo Plasma Quality Collected via the Rika Plasma Donation System	Taylor Barrett, Annette Feussner, Kati Dawson, Alice Chen, Toby L. Simon	POSTER	T/S

Abstract #1 | POSTER

TITLE: Improving Team Member Engagement and Process Improvement Using Employee-led Performance Improvement Committee (EPIC)

AUTHOR(S): M Sherpa[1], S Armstrong[1], L Sutor[2]

1. Vitalant, Scottsdale, AZ, USA

2. Carter BloodCare, Bedford, TX, USA

BACKGROUND:

An organization-wide employee engagement survey demonstrated team members wanted to be more involved in decision making processes and have improved two-way communication with leadership. With that in mind, the Employee-led Performance Improvement Committee (EPIC) was implemented at the three reference labs (RL) and one hospital transfusion service (TS) in the NE Division. These committees allow for improvements with communications, enhanced process improvement, and provides each team member with an active process to have their laboratory improvement ideas discussed and implemented.

METHOD:

EPIC is a team member only committee that strives for the improvement of Refence Laboratories and Transfusion Services (RLTS). EPIC's goal is to be a progressive committee of peers that any team member below the supervisor level may attend to provide their solutions for concerns, process improvement ideas, and workplace suggestions. EPIC is designed to provide a pathway for team members to be heard and develop action plans ensuring their ideas are implemented. The key elements of the committee's success are: 1) All team members below the supervisory level are considered part of EPIC; 2) The EPIC monthly meetings are held in person, virtually, or asynchronously; 3) Ideas and suggestions are presented by the team members to the committee; 4) Meeting agendas, minutes, and attendee list are created after each meeting; 5) Anything discussed by the EPIC committee, must conclude with an action plan prior to implementation and submitted in an SBAR (Situation, Background, Assessment, Recommendation) format to leadership for approval; 6) Management approval of all SBARs is necessary to ensure the committee's solutions do not conflict with policies, procedures, or regulations; 7) The EPIC chairperson is elected to a one-year term, so that experience of committee leadership is shared among the team members.

RESULTS/FINDINGS:

In the first three months of EPIC's implementation, the TS submitted ten SBARs. Each IRL submitted at least one SBAR, with a total of five. The SBARs that have been submitted ranged from improving the workspace to changing laboratory processes. Among the SBARs submitted by IRL, 80% (4/5) were approved by leadership team and 75% (3/4) of the approved were successfully executed. Similarly, 40% (4/10) of the SBARs submitted by TS were approved. The remaining 60% (6/10) SBARs were returned to the team for further clarification and revision.Staff participation in monthly EPIC meeting was tracked. More than 90% of the IRL staff participated in each meeting. TS had a 30% and 45% participation in the first two months.

As of writing this abstract, we have not measured improvements in morale among staff or process change effectiveness post execution of process improvement ideas. However, positive feedbacks have been received from discussion with several staff participating in the EPIC.

CONCLUSION

EPIC has been a great success and we have already received several positive feedbacks from staff. Staff have been very excited and appreciative of EPIC, as they get to express their ideas and bring those ideas to fruition. Furthermore, it has helped identify project champions and provided an opportunity to identify new leaders. While there was an initial learning curve as the team became self-directed and managed, it quickly became apparent that EPIC filled a need. Implementation of EPIC has changed the effectiveness of communication and collaboration between and among the IRL and TS teams that depend on each other to provide quality patient care.

Abstract #2 | POSTER

AUTHOR(S): M Gannett, C Resto, OneBlood, Inc.

Utilizing Historical Antigen Negative Data to Optimize Antigen Testing Algorithms

BACKGROUND/CASE STUDY

To provide antigen negative RBCs to patients with antibodies or those with phenomatch transfusion requirements requires extensive screening of donors and management of test results to ensure that blood is available. Our blood center tests a large number of donors for the C, E, c, e, and K antigens. Therefore, we sought to optimize our testing algorithm by evaluating our usage.

STUDY DESIGN/METHOD

The usage of antigen negative RBCs was evaluated for an 11-month period and grouped by RH category as either R_1R_1, R_2R_2, R_0R_0, or rr. K– requirements were also evaluated separately. Requests of single RH antigen negative blood was excluded from the study. Antigen negative orders as well as blood crossmatched for patients with antibodies and/or who had phenomatch transfusion requirements were considered. Additionally, we evaluated our automated antigen testing results for one year and two weeks of donation data to determine the number of RBC units that could be labeled based on historical antigen typing according to the FDA guidance. All analysis was performed using the R statistical programing language.

Table

Phenotype	Average Weekly Demand	Hx Supply vs Demand*
R_1R_1	93	769%
R_2R_2	36	278%
R_0R_0	273	79%
rr	94	766%
K–	690	496%

*Hx Supply are units able to be labeled as historically antigen negative

RESULTS/FINDINGS

Approximately 16,000 antigen negative orders and 20,000 RBCs issued from our laboratories during the 11-month period of time were evaluated. The table displays the average weekly demand and compares that with the supply of units that could be labeled as historically antigen negative. It was found that the number of units that could be labeled based on historical antigen results exceeded the weekly demand for all categories except for R_0R_0, therefore the supply of R_0R_0 blood requires testing of current donations to meet the demands. The subsequent category with the least historical supply compared to demand was R_2R_2 units.

CONCLUSIONS

By reviewing the supply and demand data an updated algorithm was identified. This algorithm focused on obtaining a second typing on donors who are R_1R_1, R_2R_2, R_0R_0, or rr so subsequent donations can be labeled as antigen negative based on historical typing. Donors who are historically R_0R_0 and R_2R_2 will be prioritized for testing a second time as will all donors of African descent to ensure that the demand for R_0R_0 blood can be met. A daily limit will be applied to all other testing of new donors according to demand projections. Overall, we have identified that we can reduce our testing by approximately 73% while meeting the demand to provide antigen negative blood components. The reduction in testing is expected to significantly decrease the overall testing costs to approximately 27% of the original algorithm. This would not be possible without the ability to label blood products with historical antigen results.

Abstract #3 | POSTER

TITLE: Anti-c identified in a patient with a previously unreported RHCE allele, RHCE*ceVS.03-DIIIa(2-3)

AUTHORS: K. Bowman, KL. Billingsley, C. Williford, C. Steinmetz, J. Gardner - LifeShare Blood Center

BACKGROUND/CASE STUDIES:

A 36 year old African American female complaining of abdominal pain with no known transfusion history was referred to the Immunohematology Reference Laboratory (IRL) for antibody identification. Initial serologic testing by the referring facility and the IRL demonstrated anti-c with a negative auto control and DAT (polyspecific). The RBC phenotype appeared to be D+, C+, E-, c-, with 1+ weak mixed field reactivity noted with the e typing. Given the questionable transfusion history the sample was referred for genotyping and clarification of patient's RBC phenotype.

STUDY DESIGN/METHODS:

Serologic evaluation included tube testing using Gamma LO-ION™ and PeG™ enhancements' (Immucor, Inc., Norcross, GA), as well as solid phase testing with Immucor Galileo Echo® Capture-R Ready-ID (Immucor, Inc.). RBC antigen types were confirmed with licensed antisera. DNA was extracted using the QIAcube (Qiagen, Germantown, MD) and analyzed using the IDCore^{XT} assay (Progenika Grifols, Emeryville, CA), a multiplex sequence specific primer (SSP) testing platform. RHCE genotyping was resolved using next-generation sequencing of the RH proximal promoter, exons 1-10, portions of introns 2-3, and cDNA cloning and Sanger sequencing of RHCE exons 3-9 (Grifols IH, San Marcos, TX).

RESULTS/FINDINGS:

The IDCore^{XT} assay yielded "Unknown" results for the RHCE genotype with an otherwise unremarkable RBC genotype. The sample was referred to Grifols IH, San Marcos, TX for investigation. Sequencing studies determined the RHD genotype to be RHD/RHD*DIIIa-ceVS.03 (4-7) and the RHCE genotype to be RHCE*CeRN/RHCE*ceVS.03-DIIIa(2-3). It does not appear that allele RHCE*ceVS.03-DIIIa(2-3) has been previously reported, therefore the predicted phenotype partial C, E-, c-, weak partial e, VS+, V-, hrB+, hrS+ is uncertain, but is consistent with the reported anti-c as well as the serologic typings performed on this sample.

CONCLUSIONS:

Anti-c was identified in a patient with RHD genotype, RHD/RHD*DIIIa-ceVS.03(4-7) and RHCE genotype, RHCE*CeRN/RHCE*ceVS.03-DIIIa(2-3). The patient was scheduled for surgery and two c-E- crossmatch compatible units were provided.

Abstract #4 | ORAL

TITLE: Implementation of a Molecular Genotyping Protocol for Patients with Warm Autoantibodies

AUTHOR(S): D Blake[1], W.S. Crews Jr.[1], S Wortman[1], L Sutor[1,2], L Walker[3], S Burnett-Greenup[3]

1.Carter BloodCare, Bedford, TX; **2.**University of Texas Southwestern Medical Center in Dallas, TX; **3.** University of Texas Medical Branch, Galveston, TX

BACKGROUND:

Warm autoantibodies (WAA) in patient samples cause delay and additional expenses when determining product suitability through traditional testing. In 2013, our Immunohematology Reference Laboratory (IRL) introduced a modified testing protocol for WAA patients that provides prophylactic phenotypically matched red blood cells (RBC) for qualifying patients with a molecular genotype. Patients subsequently referred to the IRL with WAA history, after initial visit, are investigated using either the traditional protocol (TP) or molecular protocol (MP). MP was only performed when antibody screen and DAT were reactive.

STUDY DESIGN/METHODS:

Retrospective record review was performed for IRL samples referred from 2004-2020. Referrals, alloantibodies, gender, and age were recorded. Additionally, the number of common clinically significant antigens needed to supply phenotypically matched RBCs for each patient was also recorded for the MP group. To analyze charges and time testing, 300 patients were randomly selected, and testing performed in each protocol was estimated. Initial investigations included Direct Antiglobulin Tests (DAT) (Polyspecific, IgG, and Complement), six antibody identification panels, one elution study, one red cell treatment, and one differential adsorption. TP included DATs, four antibody identification panels, one elution study, and one differential adsorption. MP included DATs and one antibody identification panel using both LISS and PEG enhancements.

RESULTS/FINDINGS:

Analysis of charges and time spent on IRL testing determined there were savings at two or more referrals. Overall, 219/300 (73%) of patients met or exceeded the number of referrals for savings. Table 1 shows further analysis between the two groups. Demographics were similar while statistically significant ($p<0.001$) differences were seen in both time and antigen typing required.

CONCLUSION:

The MP is effective in saving time and charges on WAA investigations for referring hospitals and the IRL after two visits. In this group, additional charges for molecular genotyping and providing phenotypically matched RBCs were not statistically significant and provides additional benefits to patients. Implementing a MP should be considered if equipped with acceptable inventory.

Table 1: Comparison of Traditional Protocol and Molecular Protocol

	TP n=150	MP n=150	p value
Male	31.3% (n=47)	34.7% (n=52)	.539[2]
Female	68.7% (n=103)	65.3% (n=98)	
Mean Age	59.6	64.5	.287[1]
Alloantibody present	Yes 48.7% (n=73)	Yes 50.7% (n=76)	.729[2]
	No 51.3% (n=77)	No 49.3% (n=74)	
Average number of referrals	4.5	4.3	.796[1]
Average Charges	1222.58	1269.78	.107[1]
Average time (min)	264	156	<.001[1]
Average antigen typing required	1.3	4.1	<.001[1]

[1] t-test

[2] Chi square (gender): X^2 (1, N = 300) = 0.3769

[2]Chi square (alloantibody): X^2 (3, N = 300) = 0.12

Abstract #5 | ORAL

TITLE: **Aliquoting Cryopreserved Red Cell Units**

AUTHOR: D Sawh, MBA, SBB, OneBlood, Inc.

BACKGROUND/CASE STUDIES:

In a previous case submitted to the Immunohematology Reference Lab, a pediatric patient requiring extremely rare Inb negative red blood cells (RBCs) was admitted to a local hospital. Due to the rarity of this blood type, only frozen RBCs were available at the time. In accordance to the patient's age and weight, the volume of RBCs required for transfusion was approximately 100mL per transfusion. To prevent wastage of these rare RBCs and to ensure continued availability of blood, the frozen units were thawed and aliquoted into portions. The process of aliquoting frozen units was further investigated to determine its effect on RBC recovery.

STUDY DESIGN/METHODS:

A total of 4 units were cryopreserved and processed during the trial. The cryopreserved RBC units were thawed at 37 oC. A transfer bag was sterile connected to the container to split the unit into halves; one half of the unit (Bag B) was returned to the freezer for at least 24 hours while the other half (Bag A) was deglycerolized using the COBE 2991 cell processor. The vendor protocol for High-Glycerol Deglycerolization was modified to compensate for the lower volume of RBCs. The modified protocol eliminated one cycle from the RBCs and one from the 1.6% NaCl. After processing, the unit was evaluated for RBC percent recovery and hemolysis using the vendor provided hemoglobin color comparator, which measures hemoglobin on a scale of 1-8, with 1-4 being an acceptable level of percent free hemoglobin (25-150 mg).

RESULTS/FINDINGS:

The average percent recovery for all aliquots processed was 81% which met the standard expectation of 80% for quality control. The average percent recovery for Bag A was 82%, whereas Bag B had a percent recovery of 81%. The hemolysis level for each bag was measured using the vendor's "Free Hemoglobin Visual Comparator".

Unit #	Initial Blood Volume (mL)	Pre Hct (%)	Unit Aliquot	Hgb Level	Final Hct (%)	Final Blood Volume (mL)	% Recovery
1	257	63	A	2	71	91	80
			B	2	79	81	79
2	351	60	A	3	65	117	72
			B	3	66	121	75
3	330	54	A	2	72	109	88
			B	2	69	114	88
4	304	57	A	2	74	103	88
			B	2	72	95	80
Average	311	59	A		71	105	82
			B		72	103	81

Conclusion: The average percent recovery exceeded the 80% mark for standard quality control. The result from the "Free Hemoglobin Visual Comparator" indicates that there was no increase in RBC hemolysis due to the modified procedure, in either Bag A or Bag B.

CONCLUSION:

The average percent recovery exceeded the 80% mark for standard quality control. The result from the "Free Hemoglobin Visual Comparator" indicates that there was no increase in RBC hemolysis due to the modified procedure, in either Bag A or Bag B. The difference in average percent recovery between Bags A and B was 1%, showing the thawing and re-freezing process did not negatively affect the RBC percent recovery or create an increase in hemolysis.

These results exhibit that this procedure can be seen as a viable option for prolonging rare RBCs availability and with further examination could be added to standard operating procedures.

Abstract #6 | ORAL

TITLE: **The Science…or Not Behind Deferrals of Blood Donors With a History of Cancer**

AUTHOR(S): R Gammon[1,8],C Hopkins[2,8],G Mathur[3,8],S.N. Rossmann[4,8],M Sayers[5,6,8],T Straus[7,8]

1.OneBlood, Scientific, Medical, Technical Direction, Orlando, Florida; **2.**Vitalent, Corporate Medical Affairs, Charleston, South Carolina; **3.**University of California Irvine, Orange, CA; **4**.Gulf Coast Regional Blood Center, Houston, Texas; **5.**Carter Blood Care, Bedford, Texas; **6.**University of Texas Southwestern Medical Center, Dallas, Texas; **7.**The Community Blood Center, Appleton, Wisconsin; **8.**Donor Cancer Deferral Workgroup, America's Blood Centers, Washington, D.C.

BACKGROUND/CASE STUDIES:

In the United States (US), the Food and Drug Administration and Association for the Advancement of Blood and Biotherapies allow blood centers to screen and defer donors with a history of cancer based upon the discretion of their medical directors (MD).

RESULTS/FINDINGS:

Responses were received from 37 (79%) centers. There were no permanent deferrals for benign lesions and for donors with a history of carcinoma or sarcoma who had completed treatment. Donors with a history of leukemia or lymphoma were only accepted if the diagnosis occurred prior to age 18. Donors with a myelodysplastic or myeloproliferative syndrome were deferred permanently at 32 (86.5%) of centers with only 1 (2.7%) accepting with no deferral. Handling of donors with high white blood cell counts (WBC) varied with 8 (21.6%) not notifying the donor to 11 (29.7%) notifying donors at WBC counts of 12,000-16,000/uL. Donors with cancer who were not in active treatment (i.e. prostate cancer) were subject to a variety of deferrals. Blood center response to post-donation reports of cancer ranged from no action because the donor remains eligible 5 (13.5%) to donor deferral 20 (54.0%). Regarding the prevalence of donors deferred for cancer 17 (45.9%) respondents stated it was 1-5% of all donors and the remainder 20 (54.1%) did not know. Literature review yielded no evidence of transfusion transmitted cancer.

CONCLUSIONS:

Cancer deferral policies vary widely among blood centers in North America, and are not generally based on evidence, but on some aspects of the precautionary principle. There is no published evidence that any of the wide range of deferral decisions that physicians make for individuals successfully treated for malignancy place those individuals at risk for morbidity. As the blood donor population ages and with increased risks of malignancy, this precautionary approach may cause further reductions in the available donor pool.

Type of Cancer	Accept- No Deferral Number (Percent)*	Maximum Deferral Number (Percent)
Skin cancers- Squamous and Basal Cell	27 (73.0%)	Permanent 2 (5.4%)
Solid tumors – Carcinomas and Sarcomas	5 (13.5%)	Five Years 4 (10.8%)
Leukemias and Lymphomas	2 (5.4%)	Permanent 28 (75.7%)
Elevated WBC Counts	20 (54.1%)	Permanent 2 (11.8%)
Cancer but No Active Treatment	12 (32.4%)	Permanent 9 (24.3%)

*Other category not shown

Abstract #7 | POSTER

TITLE: Donor With Rare Polymorphisms Results in Multiple RBC Genotype Discrepancies

AUTHOR(S): K Bowman, KL Billingsley, M Kalvelage - LifeShare Blood Center

BACKGROUND:

Advances in molecular technology and the ability to genotype patients and donors is slowly replacing serologic phenotyping in Immunohematology Reference Laboratories (IRL) around the world. Like serology, genotyping has limitations that must be considered even when using licensed methodologies. Manufacturers caution false negative results may be obtained when unexpected rare mutations affect primer or probe binding resulting in allele dropout or failed amplification. These rare outcomes may go unrecognized without additional serologic or molecular confirmation.

METHODS:

RBC genotyping was performed on a self-identified Hispanic donor. DNA was extracted using the QIAcube (Qiagen, Germantown, MD) and analyzed using the IDCoreXT assay (Grifols, Emeryville, CA), a multiplex sequence specific primer (SSP) testing platform. RBC antigen types were confirmed with licensed anti-Jk^{a} (Immucor, Norcross, GA) and donor derived anti-Yt^{a}. Discrepancies were resolved by Sanger sequencing (Grifols IH, San Marcos, TX).

RESULTS:

Routine genotyping identified this donor as *JK*B/JK*B* and *YT*B/YT*B* with a predicted phenotype of Jk(a-b+) and Yt(a-b+). However, serological confirmation determined the donor to be Jk(a+) and Yt(a+). Sequencing of JK exons 4–11 revealed a genotype of *JK*A(588A)/JK*B* with a predicted phenotype of Jk(a+b+). The predicted Jk(a-) phenotype by the IDCore^{XT} assay was due to a drop-out artifact caused by a polymorphism within the forward primer site of the *JK*A* allele at position IVS8-38. Sequencing of *YT* exons 2–5 revealed a genotype of *YT*A(1775G)/YT*B(1431T)* with a predicted phenotype of Yt(a+b+). Although the genotype of allele YT*A(1775G) has not been reported, Yt(a+) seems probable since allele *YT*B(1775G)* encodes a Yt(b+) phenotype.

In this case, the predicted Yt(a-) phenotype was due to a drop-out artifact caused by a polymorphism in the reverse primer site at position IVS2+33 of the *YT*A* allele. These two mutations caused impaired amplification of both alleles, interpreted by the ID Core^{XT} BIDS software as the absence of the *JK*A* and *YT*A* alleles.

CONCLUSION:

Genotyping, when used in conjunction with serology, has become an essential tool in the IRL. Commercial molecular assays allow for testing of multiple blood group antigens on multiple samples in a relatively short time. It is helpful in predicting phenotypes of patients recently transfused, those with a positive DAT (IgG), and in cases where serologic typing reagents are not available or are unreliable. Genotyping is essential for resolution of weak and variant antigens that may not be detected with routine serologic methods. Although SSP genotyping assays continue to improve, this case illustrates why it should not replace serology as the sole means of RBC antigen characterization.

Abstract #8 | ORAL

TITLE: Cost Effectiveness of Allogeneic Adsorption Versus Soluble Recombinant Blood Group Protein

AUTHOR: K Dovydaitis, BB(ASCP)CM, T Francis, SBB(ASCP)CM, C Riebel, BB(ASCP)^{CM}, M Gannett, MLS(ASCP)SBB^{CM}, Richard Gammon, MD, OneBlood, Inc.

BACKGROUND/CASE STUDIES:

Immunohematology Reference Laboratories (IRL) often receive samples for antibody identification (ABID) that include a historical antibody which interferes with the exclusion of new underlying alloantibodies. The laboratory's ability to quickly identify or exclude additional antibodies is important for patient care. A common approach to removing interfering antibody is through allogeneic adsorption (ADS). A newer approach to this scenario is the use of soluble recombinant blood group antigen (rBGA). Soluble rBGA works by neutralizing antibodies to the corresponding antigen. Both methods are effective, but multiple factors can be considered when deciding which to use. This study compared the time and cost needed to resolve cases using rBGA versus ADS.

STUDY DESIGN/METHODS:

Seven staff members were timed while performing antibody neutralization using one rBGA to yield a volume of neutralized plasma for a 6-cell selected panel (including controls) tested at Gel-indirect antiglobulin test (IAT). Seven staff members were also timed for setup of one ADS using 1 ml of untreated red blood cells (RBC) to yield a volume of plasma for parallel testing at Gel-IAT. Total set up time for each method was averaged. Steps for rBGA neutralization include: preparation of supplies, mixing, centrifuging, and pipetting. Steps for ADS setup include: cutting segments, washing RBC, packing RBC, and removing saline supernatant. For both rBGA and ADS, the setup time was recorded until the start of the incubation (INC) period. Estimated times were used for antigen typing of ADS RBC, packing ADS RBC, and testing of plasma to calculate a total time for each method. The cost of technical time was calculated using $40 US dollars (USD) per hour. Commercial vendor prices were used to calculate reagent costs for each method. Cost of the rBGA reagent was calculated using the price for one vial of rBGA and dividing the amount needed to yield six tests. The cost of one ADS RBC aliquot was calculated by dividing the cost of one RBC donor unit by the volume assuming a unit is 300mL. The price of antisera for phenotyping the ADS RBC unit was also incorporated into the reagent cost.

RESULTS/FINDINGS: The table summarizes the average time and cost for each method and to test a 6-cell panel.

Method	Setup	Antigen confirmation*	INC	Packing ADS RBC*	Testing Panel*	Total	Reagent USD	Technical USD	Total USD
rBGA	10′	NA	30′	NA	30′	70′	$18	$47	$65
ADS	25′	20′	60′	10′	30′	145′	$33	$97	$130

(′)- minutes, * - estimated

CONCLUSION:

The overall cost to perform rBGA neutralization was $65 USD less than the cost to perform a single ADS. The average time for rBGA method was 75 minutes less than the ADS method. Both methods allow for the exclusion or identification of underlying alloantibodies. However, in this study, the use of rBGA had a lower cost and used less time to resolve cases with antibodies that can be neutralized using rBGA.

Abstract #9 | POSTER

TITLE: Evaluation of DNA Quality Using Aged EDTA Samples

AUTHOR(S): K. Bowman, KL. Billingsley, C. Cheney, M. Kalvelage - LifeShare Blood Center

BACKGROUND/CASE STUDIES:

Most Immunohematology, specifically RBC and platelet, genotyping assays recommend using a DNA concentrations of greater than or equal to 10ng/ul with a purity absorbance (A260/A280) ratio of 1.6 to 2.2. To ensure this outcome, DNA extraction is commonly performed on EDTA whole blood specimens less than seven days old. Unfortunately, there are situations when fresh samples are not available and are received outside this preferred time. Use of these older samples for extraction could have multiple benefits for the patient and the laboratory including fewer patient phlebotomies, reduction in turnaround times and fewer canceled or postponed surgeries and/or other transfusion dependent procedures.

STUDY DESIGN/METHODS:

This two-year retrospective study evaluated 22 EDTA whole blood specimens received with collection dates ranging from eight to 30 days. DNA was extracted using the QIAcube (Qiagen, Germantown, MD) and the purity and concentration of each determined using spectrophotometric technology (NanoDrop LITE, Thermo Scientific). All samples were analyzed using one of two FDA licensed RBC genotyping assays, Immucor's BioArray™ PreciseType HEA BeadChip Test (Immucor Inc. Atlanta, GA) or Grifols' Progenika IDCORE^{XT} Kit (Grifols, Emeryville, CA).

RESULTS/FINDINGS:

All 22 samples tested had acceptable DNA concentrations with a minimum of 20.1 ng/ul and a maximum of 253.2ng/ul. While one sample was lower than the minimum DNA (A260/A280) absorbance ratio of 1.6 at 1.1, all yielded acceptable reportable genotyping results.

CONCLUSIONS:

While fresh samples, less than seven days old, are preferred for DNA extraction older samples can yield acceptable DNA for use with most RBC / platelet genotyping assays. Viable DNA was extracted from specimens older than the recommended guidelines by as much as three weeks. The option to use these samples for genotyping is cost effective and beneficial for the patient, the testing laboratory and the transfusing facility. Using older samples reduces patient phlebotomies, testing delays and lessens the need to postpone or reschedule transfusion dependent procedures including surgeries.

Abstract #10 | POSTER

TITLE: In Vitro and In Vivo Plasma Quality Collected via the Rika Plasma Donation System

AUTHOR(S): T Barrett,[1] A Feussner,[2] K Dawson,[2] A Chen,[1] T Simon[2]

AFFILIATIONS:

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2. CSL Plasma, Boca Raton, United States

3. Research and Clinical Bioanalytics, CSL Behring Innovation GmbH, Marburg, Germany

PURPOSE:

Source plasma is an essential resource utilized in the manufacture of plasma-derived medicinal products. The Rika Plasma Donation System (Terumo BCT, Inc., Lakewood, CO) is a new plasmapheresis device for the collection of source plasma that applies continuous flow technology to efficiently collect plasma while limiting the extracorporeal volume. This study confirms the characteristics of the plasma collected on the Rika system using pooled whole blood units (in vitro) are comparable to expected results based on past collections (in vivo).

METHODS:

The in vitro quality of the plasma collected on the Rika system was evaluated based on common proteins purified out of plasma using pooled whole blood units (Terumo BCT) and plasma collected from donor runs (CSL Behring). The pooled individual type-matched whole blood units were collected in 4% sodium citrate solution to maintain an anticoagulant ratio of 1:16. Blood pools were held in incubator shakers set to 37 °C representing body temperature with circulation. The system was tested under two different test conditions: Normal (N=6) and Worse Case (N=18). Normal conditions were performed at approximately 20 °C with no intended operator intervention. Worse-case conditions were performed at 30 °C at maximum flow rate and targeting the highest collection volume in the smallest donor blood volume maximizing re-centrifugation of blood. The operator also induced 6 pauses during the procedure changing flow dynamics. The donor connected in vivo results were generated from 105 unique participants in a previously published clinical study evaluating the Rika system. A total of 33 mini pools, each containing 36 unique donor samples, were created to simulate the fractionation manufacturing process, and then assessed for plasma quality. Both the in vitro and in vivo results were analyzed using traditional descriptive statistics, including mean and standard deviation (SD).

RESULTS:

While there are limitations on how well the human body can be simulated in the lab environment, the in vitro and in vivo results produced by the separate laboratories are similar (Table). The Normal, Worst Case, and Donor Connected Minipools all report total protein measurements >50 g/L and Factor VIII content >0.7 IU/mL (or >70%) indicating good manufacturing practice per the European Pharmacopoeia, a commonly used standard for source plasma.

CONCLUSIONS:

The characterization results generated in vivo confirms the in vitro predicate work and performance of the plasmapheresis device. This data further supports that the Rika Plasma Donation System offers an effective alternative to the currently marketed devices for the collection of source plasma

Table. Characterization of Plasma collected *In Vitro* and *In Vivo*

Analyte	In Vitro[1]		In Vivo[2]
	Normal Plasma Bottle (N=6)	Worst Case Plasma Bottle (N=18)	Minipool Plasma (N= 33)
Alpha-1 Antitrypsin (mg/dL)	105 ± 6	109 ± 8	150 ± 6
Albumin (g/dL)	3.8 ± 0.2	3.8 ± 0.1	2.9 ± .01
Apolipoprotein A1 (mg/dL)	128 ± 8	137 ± 10	118 ± 5
Activated Partial Thromboplastin Time (s)	25 ± 1.0	25 ± 1.1	30 ± 1.3
C1 Esterase Inhibitor (mg/dL)	24 ± 1	22 ± 1	30 ± 1
Factor VIII (%)	105 ± 12	115 ± 19	112 ± 7
Factor IX (%)	95 ± 8	94 ± 8	107 ± 4
Fibrinogen (mg/dL)	318 ± 11	334 ± 34	305 ± 15
Immunoglobulin G (mg/dL)	787 ± 81	861 ± 74	614 ± 27
Prothrombin Fragment 1+2 (pmol/L)	187 ± 31	165 ± 70	147 ± 12
Prothrombin Time (s)	13 ± 0.4	13 ± 0.4	11 ± 0.3
Total Protein (g/L)	58 ± 3	62 ± 2	55 ± 2

Results are mean ± standard deviation. [1]Bioanalysis performed by laboratory A. [2]Bioanalysis performed by laboratory B.

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