Créer des ponts entre les communautés transfusionnelles

2024 | Saskatoon SCMT | CONGRÈS ANNUEL

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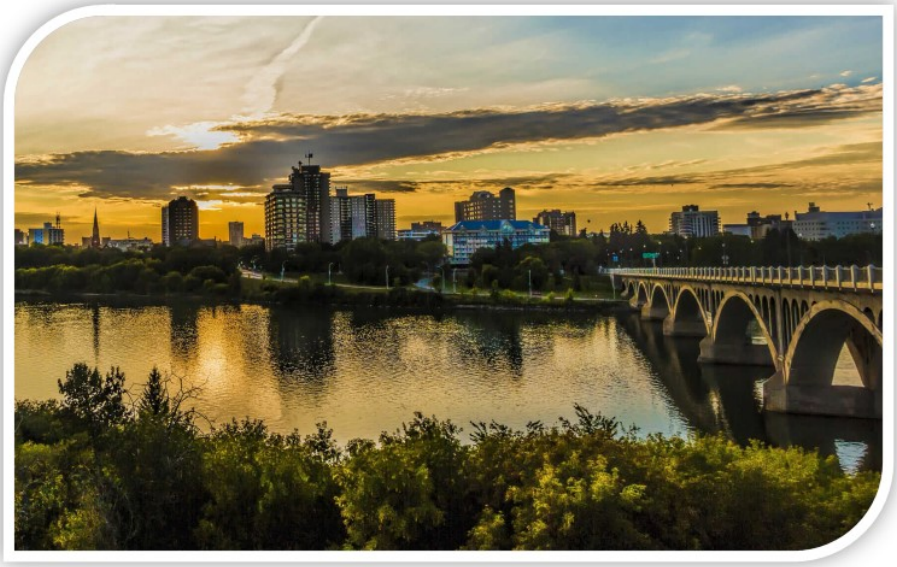

CSTM 2024

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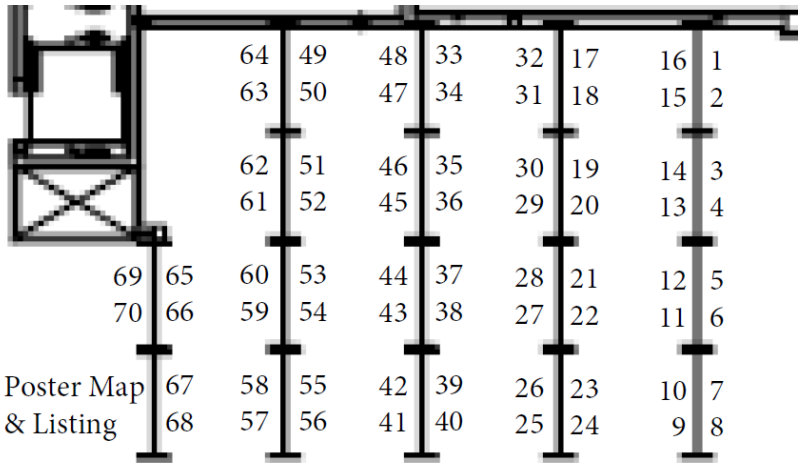

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Staphylococcal enterotoxins secreted in platelet concentrates during storage induce platelet activation and heighten Staphylococcus aureus virulence

Sylvia Ighem Chi [1] *^, Dilini Kumaran [2], Chelsea McGregor [3], Nicolas Pineault [4], Sandra Ramirez-Arcos [5]

Abstract Summary:

Introduction / Objective *Staphylococcus aureus* remains a safety threat to patients receiving platelet concentrates (PCs). Recently, we demonstrated that *S. aureus* secretes staphylococcal enterotoxins (SEs) during PC storage. SEs are superantigens that induce cytokine production and septic shock symptoms in susceptible patients. Our recent data also revealed that SEs, such as SEG and SEH, trigger pro-inflammatory cytokine release in *S. aureus* contaminated PCs. This study aimed to further investigate the relationship and effects of SEs on platelet activation and *S. aureus* virulence in a silkworm model.

Design and Methods The virulence of *S. aureus* CBS2016-05 wildtype (WT) and its derivative SE mutants [CBS2016-05Δ*seg* (Δ*seg*) and CBS2016-05ΔΔ*seg*h (ΔΔ*segh*)] were assessed using a *Bombyx mori* (silkworm) model. The lethal dose 50% (LD_{50}) was determined using 10-fold serial bacterial dilutions in insect saline (0.6% NaCl). Furthermore, silkworms were inoculated with PC-derived *S. aureus* cultures at LD_{50} concentrations to compare worm survival. In parallel, SE's ability to activate platelets was investigated by measuring CD62P (P-selectin) expression in PCs spiked with the WT and mutants at an initial concentration of 30 colony forming units (CFU)/PC bag (n=3).

Results Silkworm data showed reduced virulence (i.e., increased LD_{50}) in the mutants compared to WT [LD_{50} of ~3.31E+06 CFU/larvae (WT), ~2.30E+07 CFU/larvae (Δ*seg*) and 8.90E+07 CFU/larvae (ΔΔ*segh*)], with LD_{50} for ΔΔ*segh* being statistically different from WT ($p = 0.027$). Preliminary results of silkworms injected with *S. aureus* PC cultures resulted in decreased survival of the worms inoculated with the WT compared to the mutants: WT (27%), Δ*seg* (37%), and ΔΔ*segh* (40%). Moreover, CD62P expression was increased in WT-contaminated PCs versus non-spiked PC controls (~42.7 % vs. 12%, $p = 0.03$). Interestingly, platelet activation was significantly higher in WT than in Δ*seg* and ΔΔ*segh* spiked PCs (~42.7 % vs. 11.6 - 12.0 %, $p < 0.05$) (n=3).

Conclusions We recently demonstrated that SEs elicit elevated pro-inflammatory platelet cytokine release during PCs storage (Ighem Chi et al, Vox Sanguinis 2023;118, Suppl. 1, Pp. 45). This complementary study reveals additional biological effects of SEs including heightened *S. aureus* virulence in a silkworm

model and increased platelet activation. This information is clinically relevant for patients transfused with PC units contaminated with this bacterium.

Acknowledgements:

The authors thank volunteer blood donors and staff at the Blood4Research Facility, Vancouver (BC) for PC production. Canadian Blood Services and Health Canada provided funds. SR-A held an intramural grant from Medical Affairs and Innovation (MAI) during the development of this study, and SCI is a recipient of post-doctoral fellowship from MAI, Canadian Blood Services.

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Poster/Session Number : 1

Role of the efflux pump NorB in survival and increased quinolone resistance of Staphylococcus aureus grown in platelet concentrates

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Abstract Summary:

Introduction/Objective *Staphylococcus aureus* is a common contaminant of platelet concentrates (PCs) that poses a safety threat to transfusion patients. Transcriptome data showed that the PC storage environment heightens the expression of antibiotic resistance genes such as *norB*, which encodes for an efflux pump implicated in quinolone resistance and is negatively regulated by MgrA. NorB has also been shown to favor *S. aureus* survival in a mouse abscess model. This study **aimed** to investigate if NorB has a role in quinolone resistance and virulence in *S. aureus* grown in PCs.

Design and Methods Wild-type *S. aureus* RN6390 and derivative mutants, RN6390Δ*norB* and RN6390Δ*mgrA*, along with control strain ATCC 29213, were used in this study. Differential expression analysis of *norB* between strains grown in trypticase soy broth (TSB) and PCs were performed using RT-qPCR. Minimal Bactericidal Concentration (MBC) assays were done in TSB (37°C/static/24hrs) and PCs (22°C/agitation/24hrs) to compare resistance to ciprofloxacin and norfloxacin (n≥10). Cultures without antibiotics served as growth controls. Furthermore, *S. aureus* virulence was tested in a *Bombyx mori* (silkworm) model; the lethal dose 50% (LD50) was determined using 10-fold serial bacterial dilutions in 0.6% NaCl and compared between strains (n=3).

Results RT-qPCR data revealed upregulation of *norB* in RN6390 in PCs vs TSB (8.43-fold) and in RN6390Δ*mgrA* vs RN6390 (2.12-fold). MBCs in the ATCC strain showed increased resistance (4-64-fold) to both quinolones in PCs compared to TSB. Similarly, RN6390 and RN6390Δ*mgrA* showed increased resistance to norfloxacin in PCs vs TSB (4-16-fold). Interestingly, RN6390Δ*norB* did not grow in PCs containing norfloxacin (~70% assays). Likewise, RN6390 and RN6390Δ*norB* did not grow in PCs containing ciprofloxacin while RN6390Δ*mgrA* grew and showed 2-16-fold increased resistance to the antibiotic. Silkworm virulence assays revealed a LD_{50} of $1.02x10^4$ ($\pm 1.01x10^4$) CFU/larvae for RN6390, $3.29x10^6$ ($\pm 2.04x10^6$) CFU/larvae for RN6390Δ*norB*, and $2.85x10^5$ ($\pm 1.90x10^5$) CFU/larvae for RN6390Δ*mgrA.* The higher LD_{50} of RN6390Δ*norB* compared to RN6390 indicates virulence loss although no statistical significance was attained.

Conclusion The PC storage environment induces increased quinolone resistance in *S. aureus,* which is strain dependent. Data revealed a role of NorB in *S. aureus* virulence and survival linked to quinolone resistance when the bacterium was grown in PCs. These results indicate that NorB is part of a complex regulatory

machinery involved not only in quinolone resistance but also survival in immune challenging environments, which merits further investigation and should be considered for medical treatment of patients receiving *S. aureus* contaminated PCs.

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The authors thank the donors and netCAD Blood4Research Facility in Vancouver (British Columbia) for PC production. Canadian Blood Services and Health Canada provided funds. SR-A holds an intramural grant from Medical Affairs and Innovation (MAI), and CP is a recipient of graduate fellowship from MAI, Canadian Blood Services.

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Poster/Session Number : 2

Impact of Blood Manufacturing Methods on the Biological Age Distribution of Red Blood Cells in Stored Red Cell Concentrates

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Abstract Summary:

Red blood cell concentrates (**RCCs**), vital to transfusion therapy, consist of a heterogeneous population of red blood cells (**RBCs**) with varying biological ages. Older (**O-**) RBCs contribute to increased storage lesions, while younger (**Y-**) RBCs have enhanced post-transfusion survival. This study examined how whole blood filtration (**WBF**) and red-cell filtration (**RCF**) manufacturing methods, affect the redistribution of Y- and O-RBCs in a final RCC. We hypothesized that in the RCF method, Y-RBCs may be lost during buffy coat removal, leading to a lower Y-to-O-RBC ratio in RCF-derived RCCs compared to WBF-derived RCCs.

Twelve whole blood units were split into two halves, each undergoing either RCF or WBF processing methods. RCF involved centrifugation (3907×g for 10 min at 20°C) to compact RBCs at the bottom, leaving cell-poor plasma (**CPP**) at the top. CPP was extracted from the upper outlet, while packed RBCs were collected from the bottom outlet, and the buffy coat remained in the collection bag. Leukoreduction was performed at 20°C, followed by SAGM addition. WBF involved filtration followed by centrifugation (4552 × g for 6 min at 4°C). Plasma reach platelet and RBCs were extracted from the top outlet with SAGM added to the RBC portion. Density profiling of RBCs was conducted using Percoll® separation to determine the estimated median density (**EMD**) and proportions of biologically aged RBC subpopulations.

WBF-derived RCCs demonstrated significantly higher hemoglobin (**Hb**) levels, RBC count, and hematocrit (**HCT**) compared to RCF-derived RCCs ($p < 0.0001$). Red cell distribution width (**RDW**) was higher in WBF-derived RCCs, indicating greater variability in cell size ($p < 0.0001$). WBF-derived RCCs had higher final volume compared to RCF-derived RCCs ($p < 0.0001$). No significant difference was observed in the EMD of RCCs between the two methods. Analysis of RBC subpopulations showed variations between units, however, the ratio of Y- to O-RBCs remained consistent across all units, regardless of the method used.

Although WBF-derived RCCs had higher levels of HCT, Hb, RBC counts, and volume, the distribution of Y- and O-RBCs in RCCs was not significantly influenced by manufacturing methods, as demonstrated by consistent ratios across all units. Variations observed in the distribution of RBCs in RCCs are likely attributed to donor factors such as age and sex rather than the manufacturing method. This highlights the importance of considering donor-related factors when assessing RCC composition.

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Poster/Session Number : 3

Exploring the Impact of Gamma Irradiation on Biologically Young and Old Subpopulations of Red Blood Cells

Sanaz Hemmatibardehshahi [1] *^, Rafay Osmani [2], Mackenzie Brandon-Coatham [3], Jason Acker [4]

Abstract Summary:

Gamma irradiation of red cell concentrates (RCCs) prevents transfusion-associated graft-versus-host disease by preventing donor T-lymphocyte DNA replication; however, it can induce the generation of reactive oxygen species, leading to protein and lipid peroxidation. RCCs consist of a heterogeneous population of biologically aged red blood cells (RBCs), including young (Y-) and old (O-) RBCs. The ability of RBCs to manage oxidative stress declines with biological age. This study explored how gamma irradiation affects Y-RBC and O-RBC during hypothermic storage, hypothesizing that O-RBCs contribute to irradiation-induced lesions.

Six RCCs were pooled, and its density profiles were determined using Percoll® separation. 20 mL of Y- and O-RBCs were isolated, with Y-RBCs comprising 13.8% ± 0.07% and O-RBCs 18.5% ± 0.07% of the density spectrum. Aliquots of Y- and O-RBCs were labeled with two biotin concentrations (15 µg/mL and 48 µg/mL, respectively), and spiked back into the pooled unit before it was subsequently divided into 5 smaller RCCs. Aliquots of unseparated (U-), Y- and O-RBCs, along with RCC units, were irradiated with minimum dose of 15 Gy. Hemolysis levels, supernatant potassium (K^+) concentration, oxidative hemolysis, and p50 values were measured in RBC subpopulations before and at days 1, 7, and 14 post-gamma irradiation. Additionally, the number of biotin-labeled RBCs (BioRBCs) in RCCs was assessed using flow cytometry.

Hemolysis levels increased significantly across all RBC subpopulations post-gamma irradiation ($p < 0.0001$), with Y- and O-RBCs consistently showing higher levels than U-RBCs. Oxidative hemolysis increased across all subpopulations ($p < 0.0001$), with O-RBCs showing a more pronounced trend ($p=0.0110$). Supernatant K^+ levels correlated significantly with irradiation in Y-RBCs and U-RBCs ($p < 0.0001$), but not in O-RBCs during hypothermic storage. p50 values significantly decreased across all RBC subpopulations by day 14 ($p< 0.0001$), with Y-RBCs having the highest initial values and O-RBCs the lowest. The number of both Y- and O-BioRBCs decreased during hypothermic storage post-gamma irradiation, however no significant differences observed between them.

In summary, both hemolysis and supernatant K^+ increasing in Y- and O-RBCs following irradiation, suggests comparable membrane damage. The impaired antioxidant capacity of O-RBCs leads to a more pronounced increase in oxidative hemolysis post-gamma irradiation. Despite these differences, no significant variations in RBC survival were observed across the subpopulations, underscoring the need for further research to elucidate the complex factors influencing RBC behavior post-irradiation and during hypothermic storage.

Acknowledgements:

We are grateful to Canadian Blood Services' donors who made this research possible.

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Poster/Session Number : 4

Prolonging the circulatory half-life of C1-esterase inhibitor via albumin fusion

Sangavi Sivananthan [1] ^, Varsha Bhakta [2], Negin Chaechi Tehrani [3], William Sheffield [4] *

Abstract Summary:

Introduction: C1-esterase inhibitor (C1INH) is a plasma protein and member of the serpin superfamily of protease inhibitors. C1INH plays a crucial role in regulating vascular permeability and inflammation by inhibiting various proteolytic targets, including coagulation-related proteases such as activated plasma kallikrein (Pka) and activated Factor XII, as well as complement-related proteases such as C1s and C1r. Deficiency of C1INH leads to Hereditary Angioedema (HAE), characterized by episodic swelling that can be life-threatening, arising from unregulated Pka-mediated release of vasoactive bradykinin from kininogen. Most existing C1INH treatments exhibit short circulatory half-lives, precluding prophylactic use.

Objective: One way to address this challenge would be to extend the half-life of C1INH via albumin fusion. Our approach was to simplify recombinant C1INH by truncation and mutation and to compare it to its albumin fusion protein.

Design and methods: N-terminal hexahistidine-tagged truncated C1INH (trC1INH, C1INH lacking residues 1-97) with Mutated N-linked Glycosylation Sites (MGS) N216Q/N231Q/N330Q (H_6-trC1INH(MGS)), its murine serum albumin (MSA) fusion variant (H_6-trC1INH(MGS)-MSA), and hexahistidine-tagged MSA (H_6-MSA) were expressed in *Pichia pastoris* yeast and purified via nickel affinity chromatography. The pharmacokinetics of the three proteins were characterized in mice and H_6-trC1INH(MGS) and H_6-trC1INH(MGS)-MSA were characterized kinetically as inhibitors of Pka *in vitro*. Mice (n=6) were intravenously injected with either 50 µg H_6-trC1INH(MGS), 50 µg H_6-MSA, or 100 µg H_6-trC1INH(MGS)-MSA. Serial blood samples were collected from the tail over time, and the residual protein in plasma was detected via enzyme-linked immunosorbent assay. Terminal half-lives were determined using a two-compartment model.

Results: All results are expressed as mean ± SD. The mean terminal half-life of H_6-trC1INH(MGS)-MSA was significantly increased compared to that of H_6-trC1INH(MGS) by 3-fold (14h ± 3 and 5h ± 2, respectively), while remaining ~35% less than that of H_6-MSA (21h ± 8). The extended half-life was achieved with minimal, but significant, reduction in the mean second order rate constant of Pka inhibition of H_6-trC1INH(MGS)-MSA, by 33% relative to that of H_6-trC1INH(MGS) ($1.3x10^4$ $M^{-1}S^{-1}$ ± 0.08 and $2.01x10^4$ $M^{-1}S^{-1}$ ± 0.07).

Conclusion: Our results validate albumin fusion as a viable strategy for extending the half-life of functional C1INH and suggest that H_6-trC1INH(MGS)-MSA warrants investigation in murine models of HAE.

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Poster/Session Number : 5

Cutibacterium acnes contamination of platelet concentrates does not elicit the release and accumulation of proinflammatory factors during storage

Dilini Kumaran [1] *^, Sandra Ramirez-Arcos [2]

Abstract Summary:

Introduction/Objective The slow growing anaerobic bacterium *Cutibacterium acnes* is a common platelet concentrate (PC) contaminant incapable of proliferating in the aerobic PC storage environment. *C. acnes* contaminated PCs are often transfused as this bacterium is detected late during bacterial screening using culture methods and have been reported to cause mild adverse reactions. Activated platelets release an arsenal of proinflammatory factors (PF) including cytokines and soluble CD40 ligand (sCD40L), and elevated concentrations of these factors in PCs have been linked to reactions like febrile non hemolytic transfusion reactions (FNHTR). Since, *C. acnes* plays an immunomodulatory role in humans by eliciting PF expression, this study **aimed** to determine whether *C. acnes* could activate platelets in PCs eliciting the release of PF during storage, enhancing the risk to transfusion patients of pro-inflammatory reactions.

Methods In biological triplicates, four ABO-matched buffy coat PCs were pooled and equally split into 6 units. The units were each either inoculated with one of four *C. acnes* PC isolates (10 colony forming unit (CFU)/mL), a *Staphylococcus aureus* PC isolate (25CFU/unit, positive control), or sterile saline (negative control). The units were stored at 20-24°C with agitation for 5 days, sampled on days 0, 3 and 5, and assessed for bacterial concentration, platelet activation (CD41a–platelet marker, Annexin V and CD62p –platelet activation markers) and pro-inflammatory cytokine content (IL-1β, IL-6, IL-8, IL-10, IL-12, and TNFα) using flow cytometry, and sCD40L concentration using ELISA.

Results *C. acnes* concentrations remained stable, while *S. aureus* proliferated to a concentration of 10^8 CFU/mL by the end of storage in all PCs. *C. acnes* contaminated units did not display significant differences in the activation profile, pro-inflammatory cytokine content, or sCD40L compared to the control ($p>0.05$), while there was a significant increase ($p\leq0.05$) in activation markers and IL-8 concentration in *S. aureus* contaminated units by day 5 of storage. sCD40L concentrations were comparable in the control and *C. acnes* inoculated units during storage, while concentrations peaked significantly ($p\leq0.05$) by Day 3 and plummeted ($p\leq0.05$) on Day 5 in *S. aureus* contaminated PCs compared to the control.

Conclusion In the absence of proliferation during PC storage, *C. acnes* contamination does not promote the accumulation of PF during storage and may not enhance the risk of inflammatory reactions when transfused to patients. Residual risks can be further elucidated by assessing inflammatory response of mammalian cell lines to *C. acnes* contaminated PCs.

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Poster/Session Number : 6

Identification and Characterization of Small Molecule Drugs that Inhibit Phagocytosis

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Abstract Summary:

Immune cytopenias result from antibodies targeting hematopoietic cells, causing spleen and liver monocyte-macrophages to phagocytose opsonized blood cells through Fcγ receptor activation. Immune cytopenias include immune thrombocytopenia (ITP), autoimmune hemolytic anemia (AIHA), alloimmune hemolytic anemia, and fetal and neonatal alloimmune thrombocytopenia (FNAIT). Additional phagocytosis-inhibiting medications could be beneficial alone or with other treatments. In vitro phagocytosis inhibition was investigated on 80 drugs from a 5000-molecule library. These compounds were chosen based on previous published work. Anti-D-opsonized Rh-positive RBCs were tested for phagocytosis prevention by each compound. IVIG was used as a control inhibitor at 1 mg/mL (6.5 µM). Dose-inhibitory titration experiments determined IC50 values. To evaluate toxicity up to 250 µM, Lactate Dehydrogenase (LDH) release, MTT viability, and apoptosis were assessed in peripheral blood mononuclear cells (PBMCs), liver HEPG2 cells, and kidney HEK293 cells. Re-synthesized KB-208, with an IC50 values of 3-4 µM and minimal toxicity in all assays was selected for further evaluation. KB-208 using 2.5 mg/kg was able to ameliorate thrombocytopenia in a mouse model of ITP as well as IVIG used at ≥1000 mg/kg, with BALB/c, C57BL/6 and CD1 mice. High doses of KB-208 administered at 6 mg/kg for 60 days revealed no in vivo toxicity. KB-208 was found to inhibit anti-D opsonized RBC rosette formation at room temperature, suggesting it impacts antibody-opsonized RBC attachment to Fcγ receptors. There was no evidence that KB-208 blocked FcγR activity using monoclonal antibodies to FcγRI (CD64), FcγRII (CD32), and FcγRIII (CD16). However, KB-208 dephosphorylated heat shock protein-27 (pHSP27) in human monocytes and mouse macrophages using a human phospho-kinase array and confirmed by western blot analysis. Furthermore, KB-208 was shown to activate protein phosphatase 2A (PP2A), the natural regulator of pHSP27phoshorylation. In vitro inhibition of PP2A restored the ability of monocytes to attach to antibody-opsonized RBCs. Thus, phagocytosis inhibition may be caused by activation of PP2A resulting in dephosphorylation of pHSP27.Thus, a small molecule drug, KB-208, has been identified with low toxicity and high efficacy to reverse thrombocytopenia in mouse models of ITP. Its mechanism of action is likely indirectly having an up-regulatory effect on PP2A which results in downregulation of the serine phosphorylation of HSP27. HSP27 plays a significant role in phagocytosis by its role in cytoskeleton movement. KB-208 is a lead compound for additional pre-clinical testing in order to move it forward for eventual clinical trials.

Acknowledgements:

Canadian Blood Service (CBS) founded this project.

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Poster/Session Number : 7

Impact of Freezing Method and Number of Freeze Cycles on Plasma in vitro Quality

Roya Pasha [1] *^, Anita Howell [2], Geraldine Walsh [3], Varsha Bhakta [4], William Sheffield [5], Ken McTaggart [6]

Abstract Summary:

Introduction/Objective: Cerus' INTERCEPT Blood System for plasma pathogen reduction has been approved by Health Canada. Multiple plasmas need to be pooled to meet input volume requirements (385–650mL). Both fresh and previously frozen plasma have been used internationally as an input for pathogen inactivation, and the option to use both in Canada would allow greater production flexibility. However, treatment of previously frozen plasma requires plasma to go through two freeze/thaw cycles before transfusion. The "slow freeze" method currently used by some blood operators is known to impact labile plasma protein factors. A second freeze/thaw cycle may further reduce labile factors, a risk that might be mitigated using a "rapid freeze" method such as contact freezers.

Design and Methods: Six ABO-matched whole blood-derived plasmas were pooled, sampled, and divided into six 200 mL plasmas. Individual units underwent one or two freeze/thaw cycles using either slow freeze (SF and SF-SF; placed in ≤-18°C freezer), rapid freeze (RF and RF-RF; contact freezer, setpoint of -59°C), or combinations of both [not reported herein]. Plasma was thawed, sampled and aliquots were frozen at -80°C until tested for FVIII (labile factor), FVII (non-labile factor) and prothrombin time (PT; functional measure) on a Stago Automated Analyzer. Four replicates were performed: two group O and two non-O.

Results: All units were above the CSA Z902-20 FVIII threshold (≥0.52IU/mL) for untreated plasma. Paired t-test statistical analysis showed no significant differences between slow or rapid freezing (SF vs RF and SF-SF vs RF-RF) for all parameters tested and one or two cycles of freezing (SF vs SF-SF and RF vs RF-RF), except for FVIII (SF vs SF-SF, p=0.0130).

Table 1: Day 0 post-thaw *in vitro* quality of plasma by freezing method; mean (SD); n=4

	FVIII (IU/mL)	FVII (IU/mL)	PT (s)
SF	1.09 (0.24)	1.29 (0.08)	13.4 (0.2)
SF-SF	0.96 (0.19)	1.24 (0.07)	13.6 (0.1)
RF	1.08 (0.17)	1.26 (0.12)	13.4 (0.2)
RF-RF	1.02 (0.23)	1.24 (0.05)	13.5 (0.3)

Conclusions: This study indicates that a second slow freeze cycle can negatively impact FVIII levels, an effect which could be mitigated using rapid freezing. When determining how previously frozen plasma is

used for pathogen inactivation, freezing method should be considered to ensure clinical product requirements can still be met.

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Poster/Session Number : 8

Can DMSO-free cryosolutions better protect cord blood stem and progenitors from transient warming events (TWE)

Nicolas Pineault [1] ^, Chelsea McGregor [2] *

Abstract Summary:

Introduction/objective: Banking of cord blood units is important to collect and preserve stem cells from diverse backgrounds and hard to find HLA typing for future life-saving transplantation. We previously reported that cord blood units exposed to worse-case operational related TWE can experience close to 20% loss in product potency stressing the importance of further investigation into TWE. The aims of the present work were to develop a reliable TWE model and use it to investigate the impact of different cryoprotective solutions on stem cell grafts.

Design and methods: The TWE model was set up by exposing cord blood buffy coat samples to ambient temperature until samples warmed up to target temperatures (-120°C or, -80°C or -50°C) after which samples were returned to liquid nitrogen storage (process repeated twice). The impact of the TWEs on viability and potency of stem and progenitors were measured by cytometry (ISHAGE CD34+ counts) and colony-forming unit (CFU) assay, respectively. Pre-freeze inputs and matched samples not exposed to TWE were used as controls.

Results:

Cryovials with inserted temperature probes were used to determine the time (95% confidence interval) required for cryovials (n=5) to reach the internal target temperature of -120°C (77 secs), -80°C (170 secs) and of -50°C (399 secs). Next, we tested whether the TWE model at the target temperatures of -80°C and -120°C would recapitulate some the deleterious effects of TWE. While differences were not always significant, the recoveries of progenitor numbers (cytometry & CFU) were on average reduced by 20% (n=5), which was comparable to what was observed in whole cord blood units (*Pasha et al., Cytotherapy, 2020*). Next, we tested the impact of TWE on the potency of cord blood samples cryopreserved with 3 different cryosolutions [clinical grade DMSO/dextran control, or two new DMSO-free cryosolutions; CryoScarLess (CSL) and CryoProtectPureSTEM (CPP)]. A progressive deterioration in viability and potency was observed for all cryosolution tested with worsening TWE. However, the best post-thaw results were observed with CSL with a mean recovery of 62% of pre-freeze CFU after TWE -50°C (vs 67% without TWE), followed by DMSO (recovery 37% vs 70% without TWE), whereas CPP had the worse ($p < 0.05$, n=4) response (11% vs. 61%). Similar results were observed for the recovery of viable CD34+ cells.

Conclusions: We have set up a TWE model to test current and new CPAs for their cryoprotective properties in stem cell grafts and new therapeutic products such as CAR T cells. Using this model, we showed that the protective properties of different cryosolutions against TWE vary significantly, with the cryosolution CSL providing the best overall protection. In contrast, CPP which provides excellent protection under steady cryostorage conditions failed to protect cord progenitors from TWE.

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Poster/Session Number : 9

Comparable bacterial proliferation in red blood cell concentrates stored in DEHT/PAGGSM and DEHP/SAGM containers

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Abstract Summary:

Introduction/Objective Di(2-ethylhexyl) phthalate (DEHP) has been the plasticizer of choice for red blood cell (RBC) concentrates (RBCC) storage containers because it stabilizes RBC membranes. However, phthalates have been identified as endocrine disruptors and human carcinogens, and European regulators have mandated manufacturing blood storage containers with DEHP-free plasticizers after 2030. Consequently, our organization is investigating containers with the non-phthalate plasticizer di (2-ethylhexyl) terephthalate (DEHT) coupled with a change in additive solution from saline-adenine-glucose-mannitol (SAGM) to phosphate-adenine-glucose-guanosine-saline-mannitol (PAGGSM) to preserve RBC quality. This study **aimed** to evaluate the effect of these changes on bacterial survival/proliferation in RBCC.

Design/Methods Paired ABO-matched whole blood units were collected into DEHT/PAGGSM whole blood collection sets, pooled, and split evenly into one DEHT/PAGGSM and one DEHP/SAGM whole blood collection set. RBCCs were produced using a top/bottom buffy coat process and tested for baseline sterility prior to inoculation of the pair with either *Yersinia enterocolitica, Serratia liquefaciens,* or *Listeria monocytogenes* at ~10^2 CFU/mL or *Cutibacterium acnes* at ~10^3 CFU/mL. Spiked units were stored at 1-6°C for 43 days and sampled weekly for bacterial enumeration. The study was performed in triplicate for each species.

Results No differences in survival/growth between DEHP/SAGM and DEHT/PAGGSM RBCC were observed for *Y. enterocolitica, S. liquefaciens* and *C. acnes.* The first two species grew to 10^7 CFU/mL by day 7 of storage, and then to 10^8-10^9 CFU/mL by day 14, with no further changes until the end of storage. *C. acnes* concentration remained unchanged at 10^3 CFU/mL until day 43. Interestingly, a decline in the growth rate of *L. monocytogenes* was observed in DEHT/PAGGSM units compared to DEHP/SAGM units between days 0 and 7 of storage after which the growth rate in the DEHT/PAGGSM units increased, reaching 10^7 CFU/ml in both types of RBCC on day 43.

Conclusions Comparable bacterial survival and growth was observed between RBCC stored in DEHP/SAGM and DEHT/PAGGSM. The slower growth rate of *L. monocytogenes* observed at the beginning of RBCC storage in the DEHT/PAGGSM units may be due to differences in the plasticizer of the storage container, additive solution and/or RBCC quality, which merits further investigation. Overall, this study shows that bacterial safety risk of RBCC is not increased with the implementation of DEHT/PAGGSM storage containers.

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Poster/Session Number : 10

Investigating the quality of blood products from Canadian donors with diabetes

Elyn Rowe [1] *^, Noor Ali-Mohamad [2], Marcus Shew [3], Mindy Goldman [4], Dana Devine [5], James Johnson [6]

Abstract Summary:

Introduction/Objective: As of March 2021, individuals taking insulin to manage type 1 diabetes (T1D) are eligible to donate whole blood through Canadian Blood Services (CBS). This followed earlier policy changes allowing most individuals with type 2 diabetes (T2D) to donate. While recent studies support that donation is safe for individuals with diabetes, few have evaluated the quality of their donated blood components. Importantly, there is evidence that poor glycemic control may impact blood product characteristics. To ensure safe storage and utilization, there is a need to better understand the properties of blood products from Canadian donors with diabetes. Accordingly, our research objectives are to: 1) Screen glycemic control in CBS donors with T1D and T2D, 2) Characterize blood products – red cell concentrates and single-donor buffy coat platelets – from donors with diabetes, throughout storage.

Design and Methods: 1) CBS metadata was used to flag a subset of donors with T1D, T2D, or without self-reported diabetes. Following routine donations across Canada, CBS national testing centers shipped one tube of EDTA whole blood from flagged donors for clinical HbA1c testing. 2) Whole blood donations from donors with or without self-reported diabetes were separated into red cell concentrate (RCC), single-donor buffy coat platelet concentrate (PC, stored in plasma), and fresh frozen plasma. RCC was assessed bi-weekly over 42 days for storage hemolysis, oxidative hemolysis, ektacytometry (deformability and osmotic gradient), hematological indices, and blood gas indices. PC was assessed on days 1, 4, and 7 with CD62P flow cytometry (platelet activation and responsiveness to ADP), rotational thromboelastometry (intrinsic and extrinsic activation), hematological indices, and blood gas indices.

Results: 1) To date, N=200 (71 T1D, 86 T2D, 43 without diabetes) specimens have been screened for HbA1c. The mean HbA1c for donors with T1D was 7.22%, T2D was 7.25%, and without diabetes was 5.50%. Of all donors with diabetes, 53% had an HbA1c over the Diabetes Canada target of 7.00%. 2) Initial data from aim 2 (N=43; 2 T1D, 6 T2D, 34 without diabetes) do not suggest major clinically relevant differences in RCC or PC from donors with diabetes, though there are some notable trends with red cell hydration, storage hemolysis, and clot formation measured by rotational thromboelastometry.

Conclusions: Suboptimal glycemic control in the majority of CBS donors with diabetes could be a cause for concern for the quality of their resulting blood products. The ability to draw robust conclusions about product quality from preliminary data in aim 2 is currently limited by the current small sample size and very good

average HbA1c of the donors with diabetes to date (6.26%). Data collection for both aims is ongoing, with plans for -omics analyses on banked specimens from aim 2.

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This research would not be possible without the CBS netCAD Blood4Research center staff in Vancouver who have coordinated donor booking, collections, and whole blood processing. I would also like to thank CBS more broadly for facilitating this research and for their support. Dr. Jason Acker and his team at the University of Alberta have provided valuable insight and are currently collaborating with us on this project. Of course, I also need to thank all members of our lab for their ongoing support.

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Poster/Session Number : 11

Impact of changing from PVC-DEHP to PVC-DEHT whole blood collection sets on plasma in vitro quality

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Abstract Summary:

Background / Objective: Di(2-ethylhexyl) phthalate (DEHP) has long been used to plasticize polyvinyl chloride (PVC) blood bags. However, toxicity concerns mean upcoming regulations will ban DEHP in medical devices in Europe. European manufacturers, including those who supply bags to Canada, are developing DEHP-free blood bags. While DEHP's impact on RBCs is well known, there is little data on whether removal of DEHP will impact other WB-derived components, including plasma. This study aimed to compare *in vitro* quality of frozen plasma (FP) derived from WB collected in PVC-DEHP or PVC-di (2-ethylhexyl) terephthalate (-DEHT), a potential alternative plasticizer.

Design and Methods: In a pool and split study, approximately 480 mL of WB was collected into 500 mL prototype PVC-DEHT top/bottom WB collection sets (Macopharma REF: PRORQT4-A). On Day 0 post-collection, two ABO-matched WB units were pooled and split evenly back into one of the PVC-DEHT sets and a PVC-DEHP set (Macopharma 500 mL top/bottom set REF: LQT710X; with anticoagulant drained). After an overnight hold (18-24°C), paired WB units were processed using the same centrifugation (Hettich Roto Silenta) and extraction (Macopress Smart) programs. Plasma units were slow frozen at ≤ -18°C within 24 h of stop bleed time. FP was thawed ≥ 30 days post-collection. Aliquoted FP samples were stored in a -80°C freezer until immediately prior to testing factor levels, fibrinogen and prothrombin time (PT; Stago, STA Compact).

Results: *In vitro* quality (mean±standard deviation) for n=12 paired PVC-DEHP and PVC-DEHT FP:

- FP unit volume - DEHP: 279±15 mL *vs.* DEHT: 279±14 mL; p = 0.9544
- FVIII - DEHP: 1.07±0.26 IU/mL *vs.* DEHT: 1.07±0.25 IU/mL; p = 0.8800
- FVII - DEHP: 1.31±0.10 IU/mL *vs.* DEHT: 1.30±0.13 IU/mL; p = 0.7816
- FV - DEHP: 1.06±0.10 IU/mL *vs.* DEHT: 1.06±0.07 IU/mL; p > 0.9999
- Fibrinogen: DEHP: 2.84±0.32 g/L *vs.* DEHT: 2.86±0.31 g/L; p = 0.4783
- PT: DEHP: 13.23±0.28 s *vs.* DEHT: 13.29±0.19 s; p = 0.3877

Statistical analysis (paired t-tests, except for PT for which a non-parametric Wilcoxon matched-pairs test was used) showed no significant differences between PVC-DEHP and PVC-DEHT FP units.

Conclusions: The replacement of DEHP with DEHT plasticizer in WB collection sets does not impact the *in vitro* quality of resulting FP.

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Poster/Session Number : 12

A comparison of manual vs. automated hematocrit measurement in red blood cell concentrates in PAGGSM additive solution

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Abstract Summary:

Background / Objectives: Regulatory changes in Europe are mandating removal of di(2-ethylhexyl)phthalate (DEHP) plasticizer from blood collection and storage systems. Alternative plasticizers and additive solutions (AS) that better preserve RBC concentrates (RCCs) during storage are being explored. One promising plasticizer/AS combination is DEHT (di (2-ethylhexyl) terephthalate)/PAGGSM. The tonicity of PAGGSM could impact RBC swelling and hematocrit (Hct) measurement. This study compared Hct of DEHT-PAGGSM RCC measured manually or by an automated method.

Methods: Whole blood (WB) was collected into prototype 475 mL PVC-DEHT top/bottom WB collection sets (Macopharma REF PRORQT4-B) with CPD. RBCs were separated using one of two semi-automated component production processes: A "warm" process (n=15) in which WB was kept at room temperature and RCC separated 18-24 h post-collection; or a "cold" process (n=16) in which WB was placed at 1-6°C within 24 h of the stop bleed time and RCC separated 42-48 h post-collection. RCC in PAGGSM were stored refrigerated and sampled on day (D)1 (warm process) or 2 (cold process), D28, D36 and D43. Hct was measured using an automated Sysmex XN-1000 and a microhematocrit centrifuge (Hettich). Hemolysis was calculated using automated and manual Hct values, total hemoglobin (Hb; Sysmex XN-1000) and plasma Hb (HemoCue Plasma/Low). Paired t-tests were used to calculate statistical significance.

Results: Automated Hct (mean±SD) was slightly, but statistically significantly, lower than manual Hct on D1 (Hct = 0.62±0.02 vs. 0.65±0.02, respectively; p = < 0.0001) or D2 (Hct = 0.60±0.02 vs. 0.63±0.02, respectively; p = < 0.0001). For warm-process RCCs, automated values continued to underestimate Hct at D28 (p = 0.0001), but on D36 and D43 there were no statistically significant differences between the methods. For cold-process RCCs, the automated method overestimated Hct at D36 (p = 0.0073) and D43 (p = 0.0012). The lack of concordance between automated and manual Hct values at D1 or D2 did not significantly impact determination of hemolysis (warm-process RCCs: 0.05 ± 0.02 % with automated or manual Hct; cold-process RCCs: 0.02 ± 0.02% with automated or manual Hct).

Conclusion: Although small, potential bias in Hct determination depending on method, which we show varies during storage, should be considered when assessing alternative plasticizers/AS, particularly to ensure hemolysis calculation is not impacted.

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Poster/Session Number : 13

Converting the plasma protein product, clotting factor X, into a novel clot-dissolving agent

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Abstract Summary:

Introduction: The favoured clot-dissolving drug (i.e. thrombolytic agent) is a recombinant (r) version of tissue plasminogen activator (tPA), which activates plasminogen to plasmin, the clot-busting enzyme. However, the administration of rtPA has risk, because the high dose of rtPA required to dissolve clots causes life-threatening hemorrhage in up to 7% of patients, resulting in large part from systemic, rather than clot-localized, enzyme activity. Our lab has previously demonstrated a non-enzymatic thrombolytic function for the plasma protein clotting factor X (FX) in accelerating the generation of plasmin by tPA, and has generated a recombinant mutant to act as a replacement for rtPA. Several key characteristics are desirable: 1) a blocked active site to prevent clotting; 2) stability in plasma; and 3) accessibility of sites integral to clot-localization and thrombolysis. The hypothesis addressed here is that **the γ-carboxyglutamic acid (Gla)-domain of FX**, which is known to enable binding of FX to anionic phospholipid membranes and fibrin, **is key to localizing the thrombolytic effects of FX, facilitating enhanced safety, and that a recombinant variant of FX with thrombolytic function is superior in safety compared to rtPA.**

Methods: Wild type rFX (rFXwt) and double mutant rFX with inhibited clotting function (i) and plasmin cleavage-resistant (c) mutations (rFXic) were produced in HEK 293 cells and purified. Their plasmin-cleavage profile and prothrombin clotting times were evaluated. Calcium-dependent binding to anionic phospholipid was tested to further confirm post-translational modification and clot-localizing function of the Gla-domain. Acceleration of thrombolysis was evaluated using a plasmin-selective chromogenic substrate. Purified Gla-domainless plasma-derived FX was generated proteolytically by chymotrypsin treatment and tested in the same assays to further understand the mechanism of clot-localization.

Results: Compared to rFXwt, which was cleaved into the expected rFXβ and FXγ species by plasmin, proteolysis of rFXic was limited to production of rFXβ. This is predicted to stabilize thrombolytic activity in plasma. In contrast to rFXwt, rFXic had undetectable clotting activity in reconstituted FX-deficient plasma. Neither mutation impacted intrinsic ability to bind anionic phospholipids in a calcium-dependent manner, while removing the Gla-domain inhibited this localization ability. In preliminary efficacy tests, rFX-ic generated 10-fold more plasmin than rFXwt, indicative of thrombolytic acceleration. Calcium enhanced the

solution-phase acceleration of rtPA by rFX and protected cleavage by chymotrypsin, implicating an involvement of the calcium-binding sites of FX.

Conclusion: These data support the hypothesis that rFXic has thrombolytic activity and uses the calcium-binding Gla-domain to localize clot lysis. Next, we will assess thrombolytic efficacy *in vivo* and therapeutic safety *ex vivo*, and anticipate advocating for rFXic as both an effective and safer alternative to rtPA.

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Poster/Session Number : 14

Osmotic Variability in Red Blood Cells from Different Blood Donor Groups

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Abstract Summary:

Introduction/ Objective: Cell membrane osmotic changes are critical for red blood cell (RBC) cryopreservation, regulating the transport of water and solutes across the cell membrane during osmotic changes. A distribution of Y-RBCs (less dense/recently matured) and O-RBCs (dense/senescent) varying in teen and old blood donors. This study aimed to compare how Y-RBCs and O-RBCs from frequent and non-frequent blood donors respond to osmotic changes.

Design and Methods: Packed Red Blood Cells collected from young and senior, female and male, frequent (more than 3 times donation per year), and non-frequent (1 donation per year) donors were collected. Samples were percoll-density separated into portions of less dense / recently matured (Y-RBCs) and dense/senescent (O-RBCs). Then, samples were tested for osmotic hemolysis and deformability under an osmotic gradient (LORRCA).

Results: Y-RBCs had significantly higher elongation (EImax) values than O-RBCs at days 5 and 14 ($p \leq 0.01$) while O-RBCs were found across all days of hypothermic storage to possess significantly lower EImax results ($p \leq 0.001$). Also, Y-RBCs of frequent teen donors exhibited higher EImax compared to Y-RBCs among all donor groups ($p=0.012$). Additionally, Y-RBCs from frequent senior donors had consistently higher O-hyper values, compared to Y-RBCs, among all donors ($p=0.017$). On different testing days, the rigidity of Y-RBCs obtained from teen RCCs was significantly higher than in senior groups ($p \leq 0.05$). O-RBCs of frequent senior donors demonstrated increased resistance to osmotic hemolysis while O-RBCs from non-frequent teen donors had higher osmotic hemolysis ($p=0.029$).

Conclusions: The O-RBCs from teen donors were shown to have reduced ion channel function which may significantly contribute to the overall rigidity of these units. However, Y-RBCs from frequent senior donors have superior osmotic stability, contributing to enhanced cellular stability and functionality. In conclusion, understanding the impact of donor behavior on RBC subpopulations is crucial for optimizing the quality and functionality of blood products.

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Poster/Session Number : 15

Deep machine learning analysis of red blood cell morphological changes during hypothermic storage

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Abstract Summary:

Introduction

Morphological assessment of red blood cells (RBCs) morphology could improve clinical outcomes following blood transfusion. Deep machine learning offers the potential to quantify the morphology of large numbers of RBCs, which can overcome the limitations of traditional measurement approaches by experts that are time- and labor-intensive. This study examined RBCs morphology in the context of RBCs biological age using deep machine learning, and we hypothesized that differences in morphology may exist between male and female donors at young and senior ages during the accumulation of storage lesions.

Design and Methods

We applied machine learning to assess the morphology of RBCs subpopulations from male and female donors at the extremes of the age spectrum during long-term hypothermic storage. Blood samples from 60 healthy donors (15 teenage males, 15 teenage females, 15 senior males, 15 senior females) were collected and stored at 1 ~ 6°C for 4, 14, 28, and 42 days. RBCs samples in different subpopulations were obtained by performing a Percoll-density centrifugation method to divide red blood cell concentrates ("unseparated", U-RBCs) into less dense ("young", Y-RBCs) and more dense ("old", O-RBCs) subpopulations at each time point. Imaging flow cytometry assay was used to obtain images of RBCs (approximately 15,000 ~ 60,000 images were analyzed for each sample). After initially performing supervised learning in which the neural network learns the morphological properties of RBCs, the trained learning model with an accuracy of 84% was applied to predict the classification of unlabeled images of samples to investigate the morphology of Y- and O-RBCs over storage in the context of the donor factors age and sex.

Results

We validated our deep machine learning approach by demonstrating the morphology index of RBCs decreased with the hypothermic storage time. Teenage RBCs from female donors are less susceptible (5.56%) to storage lesions than senior RBCs from males. The morphology index of O-RBCs is higher than that of Y-RBCs and U-RBCs.

Conclusions

This work demonstrates the application of deep machine learning for classifying RBCs based on morphology. Our results reveal the effect of RBCs biological age, blood donor characteristics and hypothermic storage lesions on the morphology of RBCs, with potential implications for transfusion medicine.

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Poster/Session Number : 16

Creation of the Canadian Transfusion Trials Group: A Clinical Trials Network for Transfusion Medicine in Canada

Donald Arnold [1] *^, Jason Acker [2], Ishac Nazy [3], Keyvan Karkouti [4], Richard Cook [5], Na Li [6], Sheila O'Brien [7], Oksana Prokopchuk-Gauk [8], Nancy Robitaille [9], Nadine Shehata [10], Andrew Shih [11], Ziad Solh [12], Alan Tinmouth [13], Kathryn Webert [14], Johnathan Mack [15], Justyna Bartoszko [16], Antoine Lewin [17], Jacob Pendergrast [18], Susan Nahirniak [19], Yulia Lin [20], Michelle Zeller [21], Jeannie Callum [22]

Abstract Summary:

Introduction

The Canadian Transfusion Trials Group (CTTG) is an investigator-led national network created to accelerate relevant, high-quality clinical trials in Transfusion Medicine. The mission of the CTTG is to enable collaborative and efficient research in Transfusion Medicine in Canada. The vision is to inform best practice in Transfusion Medicine through a Canada-wide network and multi-disciplinary research partnerships. The primary objective of the CTTG is to support investigators, trainees and research staff in the design and conduct of high-impact clinical trials in Transfusion Medicine. Secondary objectives are to develop and execute innovative study designs and methodologies; to develop a shared data platform for transfusion research; to foster mentorship and training of early career investigators, medical laboratory technologists, research staff and trainees; and to integrate basic translational studies into clinical studies.

Methods

We structured CTTG to include 2 co-Directors, a Steering Committee (SC) and 6 Working Groups. The SC includes Transfusion Medicine experts with broad representation from across Canada; partners from Canadian Blood Services and Héma-Québec, academic and community hospitals; methodologists, biostatisticians, basic scientists, physicians from high blood loss specialties, patients and blood donors. The 6 CTTG working groups are dedicated to 1) evaluation of clinical trial proposals; 2) creation of a common data platform; 3) translational studies; 4) education and mentorship; 5) knowledge translation; and 6) community engagement. Each working group has a charter, a chair and vice or co-chair and 4-8 members. CTTG's stakeholders include the national blood suppliers in Canada, ministries of health from all provinces and territories, patients and blood donors.

Results

Since its inception in April 2023, the CTTG has endorsed 4 national grant proposals for randomized clinical trials (RCTs): one blood bank RCT was supported solely by CTTG, and 3 other RCTs were supported jointly

with other clinical trials networks (the Canadian Critical Care Trials Group, and the Canadian Cancer Trials Group). The blood bank RCT will evaluate sex-matched vs. sex-mismatched red blood cell transfusions in the intensive care unit. The joint RCTs will evaluate intravenous immune globin in patients with hematological malignancy, albumin in patients receiving dialysis, and platelet transfusions in critically ill patients. We will identify sentinel sites across Canada that will participate in these trials.

Conclusion

The CTTG is a network of clinical investigators, Transfusion Medicine professionals, methodologists, learners and early career investigators from across Canada that was established to facilitate and accelerate clinical trials in Transfusion Medicine. Ultimately, the CTTG will help improve transfusion practice, elevate Canada's profile as a global leader in Transfusion Medicine research through national and international collaborations, and enable career mentorship opportunities.

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Poster/Session Number : 17

Albumin Utilization and Appropriateness: A Prescriber's Perspective

Stephanie Bigsby [1] *^, Oksana Prokopchuk-Gauk [2]

Abstract Summary:

Introduction / Objective*:* Albumin is a human plasma derived protein which may be used as a therapeutic intervention. Appropriate Albumin utilization is essential to ensure patient safety and stewardship of this blood product. Recently, our province has been identified as having the highest use of Albumin per capita in comparison to other provinces. This study aims to objectively assess the practices and perspectives of our physicians as they relate to Albumin use.

Design and Methods: Survey questions were developed to explore key themes related to Albumin 5% and 25% prescription: indication for use; dosage and frequency; literature informing practice; and awareness of potential adverse reactions. Questions were administered using theREDCap online survey platform. The survey link was disseminated by email via our Health Authority – Department Heads and published within the monthly provincial Medical Association newsletter. Submissions were collected over a 4 week period. Anonymized individual responses were analysed and reported in a descriptive manner.

Results*:* A total of 43 submissions were complete and appropriate for analysis. The majority of respondents were from our two largest cities, and were from Anesthesia and internal medicine specialties. The most commonly reported indications for prescribing 5% Albumin included post-operative hypotension (50.0%) and sepsis (25.0%),neither of which are considered to be appropriate according to current clinical practice guidelines. The most commonly reported indications for 25% Albumin included hepatorenal syndrome (66.7%), paracentesis >5L (52.4%), and spontaneous bacterial peritonitis (42.9%), all of which are supported by evidence. All respondents report routinely obtaining transfusion consent; however 42.9% of respondents reported omitting discussion about adverse reactions of Albumin prior to its administration. Prescribing practices learned during residency were reported as the greatest influence on current clinician practice. Finally, grand rounds presentations or use of pre-printed order sets were reported as preferred resources for knowledge enhancement.

Conclusions: The results of this survey indicate that the majority of respondents use 5% Albumin inappropriately, while 25% Albumin is predominantly used for appropriate indications. Current Albumin prescribing practices are significantly influenced by residency training. This information can be used to inform educational resource development to optimize albumin utilization and improve patient safety.

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Poster/Session Number : 18

A streamlined approach for the identification of two rare antibodies to high prevalence Cromer antigens: anti-SERF and anti-CRAM

Melanie Bodnar [1] *^, Jacqueline Cote [2], Gerri Barr [3], Brenda Caruk [4], Susan Nahirniak [5], Candace O'Quinn [6], Aneel Noor [7], Lei Zhang [8], Marianne Stef [9], Gregory Denomme [10], Nicole Thornton [11], Celina Montemayor [12]

Abstract Summary:

Introduction:

Timely identification of antibodies to high prevalence antigens (HiPA) enables appropriate prenatal monitoring and a safe blood management plan. Rare antigen negative reagent red blood cells (RBC) may not be readily available for antibody identification, but soluble inhibitory substances can help narrow down the antibody target. While naturally occurring inhibitory substances in various fluids have long been used in blood banking, the recent availability of manufactured recombinant blood group antigens (rBGA) has expanded the toolbox. This study demonstrates how rBGA facilitated the detection of two very rare anti-Cromer antibodies and the impact on patient management.

Design and Methods:

Serologic testing was by standard hemagglutination methods. Antibody titration was performed using serial dilution of plasma in SIAT. Plasma was tested against a panel of 28 RBC negative for HiPA and treated with a battery of commercial unlicensed rBGA. Genomic DNA was isolated from WBCs for testing on the Progenika IDCoreXT assay and referred to an external lab for Sanger sequencing (SS) of the *DAF(CD55)* gene (case 1 and 2) and additional serologic testing (case 1).

Results:

Case 1 was a prenatal group O, D+ patient of Filipino descent. Case 2 was a pretransfusion sample from a group O D+ 65 yo female with variants of African descent (RHCE and Duffy) on IDCoreXT. Both samples reacted with all RBC in the HiPA negative panel including Cra-, Guti-, Zena- and Tca-. In both cases, Cromer rBGA completely inhibited antibody reactivity allowing all other clinically significant antibodies to be excluded. For case 1 SS (exons 1-10) of the *DAF(CD55)* gene revealed homozygosity for c.647C>T (*CROM*01.-12/-12*) resulting in a SERF- phenotype. The peak antibody titre (16) was reached at 13 wks gestation but the antibody became undetectable at 26 wks through to delivery at term. For case 2, SS (exons 2-10) showed homozygous c.740A>G (*CROM*01.-15/-15*) associated with a CRAM- phenotype. Plasma from Case 2 reacted with the RBC from Case 1.

Conclusions:

Two patients with rare antibodies to high prevalence Cromer antigens (anti-SERF and anti-CRAM) were identified using Cromer recombinant blood group antigen inhibition followed by *CD55(DAF)* gene sequencing. Cromer antibodies have not been associated with significant HDFN as paternally derived DAF on the placenta are thought to adsorb maternal antibodies resulting in decreased circulating antibody levels in later pregnancy as observed in this case. Neither patient required transfusion and Cromer-typed donors were not available, but extrapolation from other Cromer antibodies suggests incompatible units may be tolerated without significant hemolysis.

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Poster/Session Number : 19

Assessment of Rh D-Negative Blood Transfusions in Rh D-Positive Patients

Felicia Deng [1] *^, Nicole Gettle [2], Davinder Sidhu [3]

Abstract Summary:

Introduction: RhD-negative blood is a vital but limited resource, comprising less than 15% of the Canadian population. There is notable utilization of Rh-negative blood units however, many of which are given to Rh-positive patients. This study examines the utilization patterns of Rh-negative blood products within a health region to identify inappropriate uses and enhance blood product stewardship.

Methods: Records from Rh-positive patients who were transfused with Rh-negative blood products between July 1 and December 31, 2022 were analyzed. The hospital site, blood unit expiry dates, and patient demographics (age, sex, and phenotypic requirements) were assessed to determine the reasons for transfusion of Rh-negative blood, which were classified into appropriate or inappropriate uses. Appropriate uses included Rh-negative units given to patients with anti-D antibodies, patients with multiple phenotypic requirements for which a Rh-positive unit may not have been available, uncrossmatched females under the age of 45 and AB-positive patients given AB-negative units (given the low prevalence of type-AB blood). Transfusion of Rh-negative units that would expire within 7 days and transfusion of O-negative blood to uncrossmatched patients at rural sites with limited inventory were also considered appropriate.

Results: Among 1318 transfusions, 92% were identified as appropriate while 8% were inappropriate. Appropriate usages of Rh-negative blood were primarily due to phenotypic requirement (56% of appropriate cases) and units nearing expiry (23%). The most common reason for inappropriate transfusion of Rh-negative blood was the administration of O-negative blood to uncrossmatched females over the age of 45 (45% of inappropriate cases). At the children's hospital, inappropriate use was notably observed in uncrossmatched males (13%). No clear rationale was identified for the use of Rh-negative units in the remaining portion of inappropriate cases (42%).

Conclusions: This study highlights the need for prudent use of Rh-negative blood, especially with regard to the use of O-negative blood in uncrossmatched patients. Current guidelines, which recommend that O-negative red cells should be reserved for emergencies in females under the age of 45, should be reinforced. Strategies and educational efforts to promote the use of O-positive blood, especially for uncrossmatched males and for females over the age of 45, should be implemented to optimize blood product conservation.

Acknowledgements:

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Poster/Session Number : 20

Prevalence of West Nile Virus in Canadian Blood Donors and Assessment of Unconfirmed Positive Screening Rates

Carmen Charlton [1] *^, Kai Makowski [2], Steven Drews [3], Gordon Hawes [4], Cynthia Cranney [5], Alyssia Robinson [6], Heidi Wood [7], Mark Bigham [8], Sheila O'Brien [9]

Abstract Summary:

Introduction/Objective

West Nile Virus (WNV) is a member of the Flaviviridae family belonging to the Japanese encephalitic antigenic complex (JEAC). It is a transfusion transmittable disease, which can cause fever, headache, joint pain, rash, and diarrhea, however 70-80% of infectious are asymptomatic. We sought to examine the incidence trend of WNV NAT positivity in Canadian blood donors and examine the level of false-positive NAT screening.

Design and Methods

Our organization undertakes universal summer-fall blood donor WNV screening June-November and selective WNV screening for recent travel outside Canada the remaining months, using mini-pools of 6 by the Roche Cobas WNV NAT assay. Should a mini-pool flag positive, each sample is individually re-tested to identify the positive donation. Positive results during the summer months triggers individual testing of all donations collected the next 7 days within approximately 100 km from the site of assessed donor WNV acquisition. All WNV NAT positives from 2023 (n=13) were subsequently confirmed by two independent WNV-specific PCRs (specific for the 3' NTR and envelope regions) at the National Microbiology Laboratory.

Results

Between 2018 and 2023, no increasing trend of WNV positivity was observed over time. All travel-related winter WNV testing was negative except 3 cases in 2019 which were shown to have had recent vaccination against Japanese Encephalitis Virus (JEV), a member of the JEAC. The highest rate of WNV was in summer-fall 2018 when 9.95/100,000 donations tested positive by WNV NAT, while the lowest rate was observed in 2019 (0.25/100,000). In 2023, WNV was identified by our organization in 13 donors: 8 (61.5%) were male; 7 (53.8%) were from Ontario, (3 (42.9%) had travel history to Algonquin/Muskoka); 2 (15.4%) were from Regina, Saskatchewan (no travel history); 3 (23.1%) were from Southern Alberta; and 1 (7.7%) was from BC (travel to northwestern United States). Following WNV-specific PCR testing, 10 (76.9%) samples were confirmed to be positive for WNV. The 3 unconfirmed positive samples were collected from donors across the country (Ontario, Saskatchewan, and BC).

Summary/Conclusions

In the study period, WNV positivity was sporadic with no increasing positivity trend. Sporadic unconfirmed positives were noted across Canada. Blood operators may want to consider additional testing and donor assessment following WNV NAT positive screening results to differentiate between WNV or other JEAC viral infection, false positivity, or other confounders such as recent JEV vaccination.

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Poster/Session Number : 21

Evaluation of the New Transfusion Medicine Team on a Provincial Level

Brittani Rainkie [1] *, Shana Chiborak [2] ^

Abstract Summary:

Introduction/Objective

In 2022, Blood Management Service (BMS) was integrated into the Diagnostic Service Transfusion Medicine Team. BMS brought clinical expertise to expand project development, improve policy, and enhance patient care, which now extended beyond the confines of one health authority. This project will be evaluated from a provincially focused lens to analyze the overall impact of this transfusion medicine team and the effectiveness on enhancing best practice.

Design/Methods

In order to evaluate a change of this magnitude, several audits have been completed and others are ongoing. The goal is to evaluate the current state of transfusion practices within the regions, how this has impacted the utilization, and determine if practice changes are required. The new TM team will assess post audit findings for improved compliance, utilization, and patient outcomes. Various data tools will be used for the auditing process, based on the ability for effective data extraction at each region.

Results

Several audits have been completed and have shown areas requiring improvement in both process and compliance. Of the audits completed, recommendations are being provided to leadership with the ultimate goal of improving patient safety. Several audits are ongoing. Outcomes of one audit identified significant areas in need of improvement which will require a post recommendation audit. Significant safety issues identified include missed transfusion reactions, improper documentation, and inappropriate transfusions. Several process changes have been initiated. Early data assessment has already shown a reduction of wastage and improved compliance in the Provincial Massive Hemorrhage Protocol. One area that the TM team has focused on was increased utilization of the current blood conservation program. This has been successful in filling IV iron clinic capacity for 8 months post consolidation. Success is being quantified with pre/post parenteral iron hemoglobin values.

Conclusion

Utilizing a multidisciplinary team approach to identify areas in need of further development by means of assessment, auditing, and engagement, is important. It is not too early to say that the success that this team is seeing is only going to improve.

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Poster/Session Number : 22

Impact of Therapeutic monoclonal antibodies on timely transfusion of patients

Jacqueline Cote [1] *^, Aneel Noor [2], Wendy Lau [3], Carmela Pote [4], Albert Chang [5]

Abstract Summary:

Introduction

Haematological malignancies including myeloma use the targeted treatment with therapeutic monoclonal antibodies. Targeted therapeutic monoclonal antibody treatments continue to evolve with new monoclonal treatments for a wider range of disease. This form of treatment has been around for many years now and the interference with pre-transfusion testing is well known. Transfusion services have managed these patients as best as they can using the tools available. The critical piece of information is as always, knowledge of this form of treatment. This study looked at the impact on the turnaround times when knowledge of treatment with a targeted therapeutic monoclonal antibody was known compared to samples when this information was not known.

Design and Methods:

This is a look back study from 2022 to 2023 comparing the turnaround time for patients' who the treatment with anti-CD38 medication was known, the type and number of panels performed verses the tests performed on patients' who drug treatment was not provided.

Results:

Knowledge of therapeutic treatment with anti-CD38 or anti-CD47 drugs facilitates rapid and straight-forward serological investigation of patients. When that information is not provided transfusion service lab will perform extensive, time consuming and expensive testing to determine if the reaction is clinically significant and try to ascertain a specificity. Testing can cause delays of 4 to 8 days, increase the amount of testing performed including the use of special rare reagents. When Drug treatment is known results are available in (24hr) 1 to 2 days with little to no additional testing.

Conclusions:

Patients' drug treatment history is critical information to transfusion service, reference lab. It is recommended that transfusion service is notified of the date that treatment will begin and last date of treatment with the specified monoclonal antibody drug. Before treatments begins, following tests should be performed: ABO, Rh, Ab screen, DAT, full phenotype. When transfusion needs have been identified the

Patient's and care providers must be aware of the importance of their drug treatment history for transfusion. Transfusion service must be made aware of the therapeutic monoclonal antibody treatment to mitigate delays in provision of blood products, thus compromising patient care and safety.

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Poster/Session Number : 23

Evaluation of the cobas® DPX Duplex Hepatitis A Virus and Parvovirus B19 Nucleic Acid Test (NAT) Assay

Leisa Bruneau [1] *^, Gordon Hawes [2], Elaine Tang [3], Carmen Charlton [4], Steven Drews [5]

Abstract Summary:

Introduction/Objective

The Roche cobas® DPX assay detects parvovirus B19 (B19V) and hepatitis A virus (HAV) in donor plasma specimens and is an important safety step prior to plasma fractionation. Established thresholds for B19V were provided by Grifols (≥2,000 international units [IU]/ milliliter [mL] B19V for pools of 16) and CSL (individual B19V result is not more than 4.8 x 10^5 IU/mL). No required threshold has been established for HAV. The purpose of this evaluation is to determine the ideal operational pool size for testing B19V and HAV nucleic acid testing (NAT) using EDTA plasma specimens.

Design and Methods

Limit of detection, reproducibility and pooling studies utilized mocked-up B19V (genotypes 1 & 2) and HAV (genotypes 1a, 2a & 3a) specimens (BioQControl, Biologicals Quality Control B.V., Heiloo, the Netherlands), Somagen (LGC SERACARE, Milford, MA, USA) and anonymized COVID-19 convalescent plasma (CCP, Canadian Blood Services, Ottawa, ON, Canada). The Hamilton Microlab® STAR IVD Pipettor generated HAV and B19V specimen pools of 96, 24, and 6. Pools and individual specimens were tested using the DPX (Duplex HAV and Parvovirus B19 Nucleic Acid Test) on the cobas® 6800/8800 System. Data was collated using Excel (Microsoft, Seattle, WA, USA). General descriptive statistics, and linear regression used GraphPad Prism (Version 9.5.1, GraphPad Software, Boston, MA, USA). Limits of detection (LODs) for B19V and HAV were estimated by probit regression (MedCalc Software Ltd, Ostend, Belgium).

Results

LOD data is shown in the Table.

Table. B19V and HAV LODs for individual donor testing.

Viral target	Mean Experimental 95% Probit LOD (IU/mL)	±1 log of experimental mean (IU/mL)	Package insert 95% Probit LOD	Is Mean Experimental 95% Probit LOD within 1 log of package insert
B19V	3.7	0.37 - 37.0	13.9	Yes
HAV	2.3	0.23 - 23.0	1.1	Yes

The Roche cobas® DPX reproducible detected dilutions of B19V and NAT. Pools of 96 did not allow for reproducible detection of B19V specimens. Pools of 24 and 6 reproducibly detected B19V.

Conclusions

The Roche cobas® DPX reproducibly detects B19V and HAV near the expected LOD. In our setting, B19V and HAV NAT using pools of 24 specimens are effective.

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Poster/Session Number : 24

Donor re-entry following deferral for false reactive human immunodeficiency virus-1/2, hepatitis B virus, hepatitis C virus, syphilis and human T-cell lymphotropic virus-1/2 is effective.

Steven Drews [1] *^, Mark Bigham [2], Samra Uzicanin [3], Carmen Charlton [4], Peggy Huppe [5], Kevin MacDonald [6], Sheila O'Brien [7]

Abstract Summary:

Introduction/Objective

Our organization has a donor re-entry (DRE) program in place for unconfirmed human transmissible disease serology tests (immunodeficiency virus-1/2 [HIV-1/2], hepatitis B virus [HBV], hepatitis C virus [HCV], syphilis, syphilis and human T-cell lymphotropic virus-1/2 [HTLV-1/2) and false positive nucleic acid tests (NAT) (HIV-1/2, HBV, HCV). There is no donor re-entry process for anti-hepatitis B Core total (anti-HBc total). Implemented in 2014 (HIV, HBC and HCV) and updated in 2023 to include syphilis and HTLV-1/2, this program allows our organization to re-test donors with a specimens-only donation after a 6-month deferral period. Donors who are negative for all routinely screened transmissible disease (TD) markers are eligible to return to donate blood products.

The objective of this study is to evaluate the yield of re-entered donors for all targets and identify areas for improving program yield.

Design and Methods

Donor data were stored in an ePROGESA database (Mak-System, Brussels, Belgium). Data were collected for the period February 3, 2014-September 30, 2023. Temporary deferral codes, re-entry codes and laboratory results for donors were identified. Data analysis used GraphPad Prism 9.5.0 (GraphPad Software, Boston, MA, USA).

Results

Table. Outcomes of re-entry for donors with unconfirmed/false-positive transmissible diseases markers

Deferral targets	HIV	HBV	HCV	Syphilis	HTLV-1/2
Time frame	February 3, 2014- September 30, 2023			January 16, 2023-September 30, 2023	
# donors eligible for re-entry	2949	574	3961	1778	1377

# (%) donors who attempt re-entry[a]	839 (28%)	195 (34%)	1306 (33%)	118 (7%)	62 (5%)
# (%) tested donors re-entered [b]	497 (59%)	136 (70%)	755 (58%)	97 (82%)	32 (52%)
# (%) eligible donors who returned to donate components	405 (81%)	117 (86%)	629 (83%)	69 (71%)	20 (62%)
donation yield (donations: re-entered donor ratio)	3148 (8:1)	1313 (11:1)	5444 (9:1)	137 (2:1)	34 (2:1)

1. For HIV, HBC, and HCV, attempted re-entry was lowest for the HIV group (Fisher's exact test, p=0.0001). For syphilis and HTLV-1/2, attempted re-entry was lowest for the HTLV-1/2 group (Fisher's exact test, p< 0.0001).
2. For HIV, HBC, and HCV, successful re-entry was more likely from the HBV group (Fisher's exact test, p=0.0061). For syphilis and HTLV-1/2, re-entry was more likely from the syphilis group (Fisher's exact test, p< 0.0001).

Conclusions

Most donors (range: 52-82%) are eligible to donate after attempting re-entry and re-entering donors return appear motivated to donate. Reasons for the variability in re-entry outcomes require future study.

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Poster/Session Number : 25

Detecting hepatitis A virus in a donor specimen linked to non-fractionated plasma and cellular products: What does it mean?

Steven Drews [1] *^, Leisa Bruneau [2], Gordon Hawes [3], Elaine Tang [4], Carmen Charlton [5], Mark Bigham [6]

Abstract Summary:

Introduction/Objective

Our organization validated the Roche cobas® DPX nucleic acid test (NAT) for the detection of parvovirus B19 (B19V) and hepatitis A virus (HAV) in donor EDTA plasma. An acceptable level of HAV in plasma/blood products and the clinical relevance of an HAV NAT detection has not been defined. This presentation examines whether an HAV NAT limit of detection (LOD) of 26 IU/ml tested in specimen pools of 24 on the Roche cobas® DPX NAT would mitigate/prevent transfusion-transmitted HAV (TT-HAV) from non-fractionated blood products.

Design and Methods

The LOD of HAV in pools of 24 donor plasma specimens was determined from a prior study as 26 IU/ml. A literature review was undertaken of the general literature.

Results

A summary of relevant literature is presented in the Table.

Table. Interpreting the relevance of an HAV NAT-positive result.

Question	Supporting data	Interpretations	Key references
What is the infectious dose of HAV?	Median infectious dose not known. Proposed oral infectious (10-100 viral particles).	Infection depends on multiple recipient/donor immune factors, prior HAV vaccination or infection, and exposure viral load. Viral concentration in blood relatively low (~10^{3-5} virions/ml).	https://www.canada.ca/en/health-canada/programs/consultation-enteric-virus-drinking-water/document.html#4.2.1; doi: 10.1111/j.1537-2995.2009.02279.x.
Are there animal models of TT-HAV?	Infections of titrated HAV performed in primates.	$10^{4.5}$-fold less virus was required to infect by the IV route than by the oral route; titers estimated by tissue culture, not NAT.	doi: 10.1086/340520.
What non-fractionated blood products have been implicated in TT-HAV?	Red blood cells, platelets, frozen plasma. HAV infections irrespective of pathogen reduction.	At-risk products contain fresh plasma, and also include pathogen reduced/not pathogen reduced platelets.	doi: 10.1111/j.1537-2995.2004.04071.x; doi: 10.1111/vox.13574.

Do lookback-traceback studies identify a dose trend in TT-HAV?	No infectious dose threshold but trend to higher HAV exposure doses. High doses (200,000-3,000,000 IU/ml) more likely implicated TT-HAV.	Consider HAV dose and other factors when investigating potential TT-HAV.	doi: 10.1111/j.1537-2995.2004.04071.x; doi: 10.1111/trf.17225.

Conclusions

TT-HAV is an extremely rare event, impacted by multiple host and donor immune factors. Although an infectious dose of HAV is not well defined, TT-HAV is biased to higher HAV doses. The Roche cobas® DPX (pools of 24, LOD 26 IU/ml) will likely mitigate/prevent TT-HAV in non-fractionated blood products.

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Poster/Session Number : 26

Anti CD 38 Therapy: A “Dara”ing stepwise approach to serological problem solving

Gwen Clarke [1] *, Jennifer Duncan [2] ^, Sarah McMahon [3]

Abstract Summary:

Background: Anti CD38 antibodies are widely used therapies for malignancy. They interfere with pre transfusion serological testing by binding to CD38 on reagent and donor red blood cells (RBC). The degree of interference is variable. The DAT and antibody screen may be negative or persistently positive and panreactive. Several serological strategies for investigation of samples with anti CD38 interference have been described. Use of some may involve techniques not available at rural or remote testing sites and may be time consuming or complex to complete. We developed and evaluated a stepwise testing algorithm while trying to limit use of complex investigative tools and sample referral.

Methods: An algorithmic approach was developed and evaluated using samples from patients known to be on treatment with anti CD38 antibody therapy for whom pre transfusion testing was requested. The study involved 11 hospitals over 10 months with the numbers of tested samples in each category enumerated and the number requiring complex testing (Step 3 and beyond) determined.

Step 1: Standard antibody screen: gel screen

1a. Gel screen negative: Computer assisted crossmatch (CAC)

1b. Gel screen positive, not panreactive: gel antibody ID and serological crossmatch (XM)

Step 2: Gel screen positive, panreactive: PEG tube antibody screen (PEG)

2a. PEG negative: CAC

2b. PEG positive, not panreactive: PEG antibody ID and XM

Step 3: PEG screen panreactive: DTT-treated screening cells (DTT)

3a. DTT negative: CAC with K negative donor units

3b. DTT positive, not panreactive: DTT-treated antibody ID

Step 4: DTT positive, panreactive: Phenotype matched RBC or further investigation

A DAT was evaluated for all and if positive a serological crossmatch corresponding to the method with the negative antibody screen was used. For those where screening or ID used DTT-treated cells Kell antigen

negative RBC were selected for crossmatch.

Results: 100 test samples from 36 patients had a panreactive gel screen. Of these, 43 had a negative PEG screen and negative DAT, allowing CAC. Thirty had a negative PEG screen with positive DAT requiring PEG IAT crossmatch. Seventeen had a panreactive PEG screen with negative DTT-treated screen followed by CAC with K negative RBCs. Nine had a panreactive PEG screen, a negative DTT screen and positive DAT requiring PEG IAT crossmatch with DTT-treated cells. One had a positive screen with DTT-treated cells and required further pretransfusion investigation and phenotype matched donor RBC.

Conclusion:Using a stepwise approach to pretransfusion investigation of anti CD38 treated patients minimized the investigative steps required. 73% were evaluated with techniques readily available in laboratories with basic serological testing available. Not all patients with anti CD38 therapy require investigation with DTT-treated cells nor phenotype matching. Initial assessment with basic techniques can save time, effort and costs while optimizing safe and timely transfusion.

Acknowledgements:

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Poster/Session Number : 27

Development of A Home Transfusion Program

Alioska Escorcia [1] *^, Samantha Scime [2], Farzana Tasmin [3], Luarne Sani [4], Susanna Medic [5], Jonas Mattsson [6], Jacob Pendergrast [7], Christine Cserti-Gazdewich [8], Lani Lieberman [9]

Abstract Summary:

Purpose:

Home transfusion programs have been established in various countries. These programs are both feasible and safe with the support of inter-professional teams. Benefits of home transfusion include improved patient quality of life, prevention of nosocomial infections, reduced hospital admissions, improved patient outcomes and patient/caregiver satisfaction. Home transfusions also have the potential to reduce capacity pressures in the outpatient hospital setting. The purpose of this project was to assess the feasibility of a home transfusion program for allogeneic stem cell transplant patients at a large tertiary care academic centre.

Methods:

This project was initiated with the engagement of an interdisciplinary team, consisting of allogeneic stem cell and transfusion medicine clinicians as well as the transfusion service management team. Clinical and practice directors, as well as a policy advisor, helped to assess feasibility and confirm institutional requirements for implementation. To start, a thorough review of home transfusion standards was performed. Additionally, a comprehensive assessment of existing blood transfusion institutional policies and procedures was completed to ensure consistency across the program and identify processes that required further consideration for home transfusion. Laboratory and clinical policies and procedures were developed, outlining regulatory as well as training and competency requirements.

Results:

Review of home transfusion standards revealed requirements unique to the home transfusion setting, including home safety evaluation, ensuring the presence of an essential care partner during product administration, access to a telephone and emergency assistance, and minimum post-transfusion monitoring requirements. Criteria for patient enrolment and identification of blood products qualifying for home transfusion also needed to be clearly defined. An important consideration was limiting the distance from the hospital to the home setting as this informed the selection/validation of the transport container. Lastly, a virtual, 2-person verification of product and recipient was implemented to ensure compliance with regular blood product administration requirements.

Conclusions:

Clinical policies and procedures, as well as laboratory standard operating procedures were developed for a home transfusion program. Future work includes the assessment of patient satisfaction/outcomes and program cost benefit analysis.

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Poster/Session Number : 28

Impact of removal of deferrals for vCJD risk

Mindy Goldman [1] *^, David Mckee [2], Taraneh Monfared-Wong [3], Adrienne Alexander [4], Laura Blackadar [5], Sheila O'Brien [6]

Abstract Summary:

Introduction: Variant Creutzfeldt Jacob Disease (vCJD) was first reported in the UK in 1996, thought to be linked to epidemic bovine spongiform encephalopathy (BSE) due to change in animal feeding practices. Indefinite deferral criteria for donors who had resided in or were transfused in the UK were implemented in Sept 1999, and modified over the years to include other countries (France, Ireland, other countries in Western Europe, Saudi Arabia), different cumulative time periods (3 months for the UK, 6 months for Saudi Arabia, and 5 years for Western Europe) and at risk periods starting Jan 1, 1980 and extending to Dec 31, 1996 (UK, Saudi Arabia), and Dec 31, 2007(most of Western Europe); in total, over 70,000 donors were deferred. With the decline in vCJD cases, some deferrals were removed in Feb, 2022. After a Canadian risk model showed a risk of less than one in 16 million of vCJD transfusion transmission, remaining deferrals for the UK, Ireland, and France were removed on Nov 22, 2023. We describe efforts made to encourage previously deferred donors and people who may have self-deferred to donate.

Methods: Actions targeting previously deferred donors included removal of deferral codes to facilitate appointment booking and emails, calls, and/or automated voice calls to donors deferred from Jan 1, 2012 onwards. Marketing directed at specific organizations included outreach to embassies, selected government departments, and companies based in involved countries. General marketing included information posted on our website and social media channels, and general advertising. Clinic staff were instructed to ask first time donors if the change in criteria had motivated their donation attempt.

Results: Codes were removed from over 16,600 donors deferred from Jan 1, 2012 onwards. Over 20,000 emails were sent, and 2,000 live calls and 27,900 automated voice mails sent by Jan 22, 2024; these resulted in 752, 66, and 492 future booked appointments respectively. As of Feb 29, 2024 3,203 previously deferred donors have successfully donated. Over 600 donors deferred prior to 2012, and therefore not included in targeted recruitment efforts called the national contact centre and made a donation appointment. Over 4,400 new donors (approximately 20% of new donors) mentioned that the criteria change was partly why they donated.

Conclusions: A multi-faceted dedicated effort to encourage donation has had a major positive impact on blood availability after removal of vCJD deferral criteria.

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Poster/Session Number : 29

25 Years of changes in donor eligibility criteria: Criteria related to donor age, vital signs, and medical conditions

Mindy Goldman [1] *^, Elaine Fournier [2], Keltie Cameron-Choi [3], Patrizia Ruoso [4], Jennifer Biemans [5], Sheila O'Brien [6]

Abstract Summary:

Introduction: Criteria based on donor age, vital signs, and medical conditions have evolved substantially since Canadian Blood Services (CBS) was founded. Criteria were often based on practice, rather than evidence.

Methods: We compare 1998 and 2024 criteria manuals, review evidence used to support changes pre-implementation (Pre-I), post-implementation outcome data (Post-I) and impact on whole blood deferrals (Deferrals).

Results: Changes include:

i.) Removal of age limits of 61 for first time and 70 for repeat donors

Pre-I: US data and Canadian autologous data on reactions in older adults was used.
Post-I: No increase in faint reaction rates in older vs other donors in Canada and four other countries (BEST study).
Deferrals: In 2023, 5.5% of donors were over 70.

ii.) Removal of pulse, BP measurements and deferrals

Pre-I: A Héma-Québec study showed no increase in cardiac admissions or deaths in donors with out of range or irregular pulse allowed to donate; the AABB stated there was no evidence for BP deferrals.
Post-I: There was no increase in reactions after dropping pulse requirements and no increase in reaction rates in first time donors with out of range BP allowed to donate (2019)
Deferrals: Deferral rates decreased by approximately 0.4%.

iii.) Donors on all antihypertensives eligible, rather than just those on diuretics

Pre-I: US data and Canadian autologous data on reactions in donors on multiple medications was used.
Post-I: Reaction rates were unchanged.
Deferrals: In a 2020-2022 CBS study, 9% of all accepted donors were on antihypertensives, the

majority not exclusively on diuretics.

iv.) Deferral of all donors on insulin or with cardiac disease replaced with nuanced criteria

Pre-I: US data and Canadian autologous data on reactions was used.
Post-I: Reaction rates and cardiovascular events post-donation were unchanged.
Deferrals: Combined, there was a deferral reduction of 0.12% (2017-18, and 2021-22).

v.) Permanent deferral for most cancers replaced by a 5-year, then 1- year deferral post- curative treatment

Pre-I: Scandinavian data linkage studies showed no increase in recipient cancer risk
Post-I: Reaction rates were unchanged.
Deferrals: The deferral rate decreased by 0.2% after changing to a 5-year deferral (2015-17).

Conclusions: Re-evaluation of donor policies substantially expanded eligibility without compromising donor safety. About 10% of currently successful donors would have been deferred for these conditions by 1998 criteria.

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Poster/Session Number : 30

25 years of changes in donor eligibility: criteria related to risk of HIV, HCV and HBV

Mindy Goldman [1] *^, Elaine Fournier [2], Keltie Cameron-Choi [3], Patrizia Ruoso [4], Jennifer Biemans [5], Sheila O'Brien [6]

Abstract Summary:

Introduction: Criteria to reduce HIV, HCV, and HBV transmission risks have evolved substantially. The window period for these pathogens is under 56 days since implementation of nucleic acid testing (NAT) in 1999(HCV), 2001(HIV), and 2011(HBV).

Methods: We compared donor questionnaires and criteria from 1998 to 2024 and summarize the year criteria related to HIV and hepatitis risk were changed and deferral data from studies performed around each change.

Results: Removed questions and associated deferrals included: born, lived in, or transfused in 7 African countries with HIV variant risk (2015), born or lived in Togo or Cameroon (2018), having an HIV test in the past month (2018) and using intranasal cocaine (2022). Questions were removed about a sexual partner who: ever used illegal steroids (2014), had an unknown sexual background (2014), took clotting factor concentrates (2018), lived in 2 African countries with HIV variant risk (2018), for males, was a male or for females, had sex with another male (2022). The Confidential Unit Deferral (CUE) ballot, which allowed donors to donate but confidentially select do not use my blood, resulting in blood discard, was removed in 2015. Deferral periods were shortened from permanent to 12 months for sex with an HIV positive partner (2018), 6 months for history of hepatitis (2018) and 12 months for taking drugs or money for sex (2022). Deferral periods were shortened from 12 to 6 months for needle stick injury (2005), receiving blood (2018), and taking illegal steroids with a needle (2022). Deferrals for tattoo and piercing were shortened from 12 to 6 months (2005) and 6 to 3 months (2018), as were deferrals for electrolysis and acupuncture without a single use needle (2005, 2022). Two questions were added to assess sexual risk behaviours, replacing questions about males having sex with males (2022). The changes with the largest deferral/discard impacts were removal of the CUE ballot (0.16% of donors were having their blood discarded) and shortening of deferral periods for tattoo and piercing (deferrals reduced by 0.42% and 1.4% when moving from 12 to 6, and then 6 to 3 months, respectively).

Conclusions: Multiple changes shortened the questionnaire and expanded eligibility without compromising safety, since positive marker rates declined or were stable from 1998 to 2024.

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Poster/Session Number : 31

Adhering to International Transfusion Standards: A Retrospective Review of a Novel Laboratory Workflow for Detection of the RHCE*CeRN allele.

Kirsten Hannaford [1] *^, Sumedha Arya [2], Carmela Pote [3], Christine Franz [4], Melanie Bodnar [5], Celina Montemayor [6]

Abstract Summary:

Introduction:

The American Society of Hematology (ASH) recommends C- blood for patients with sickle cell disease (SCD) with an uncompensated *RHCE*CeRN* allele, which encodes for a partial C antigen. Because the extended red cell genotyping assay in our laboratory does not interrogate for the *RHCE*CeRN* allele, an in-house algorithm was created to identify C+ samples requiring Next Generation Sequencing (NGS) to exclude the CeRN variant. We report a retrospective review of the algorithm thirty-one months post-implementation, provide testing workflow recommendations, and estimate the prevalence of the CeRN allele in Canada.

Design and Methods:

Genotyping reports from January 2021 to July 2023 were correlated with clinical diagnoses, presence of other blood group variants, C phenotyping, and NGS results. Searches for specific text phrases from our LIS identified the samples routed through the CeRN algorithm.

Results:

Of 5959 genotyped samples, 248 C+ samples were forwarded into the CeRN workflow due to a diagnosis of hemoglobinopathy, or the presence of RHCE, Duffy or MNS variants. A total of **216** C+ heterozygous samples were identified. Of these, some had either no C phenotyping available (n=**169**) or strong C serologic phenotyping (n=**24**). The remainder (n=**23**) were referred for NGS. All but 2 C+ homozygous samples had NGS (n=**30**).

We analyzed the samples referred for NGS (n=**53**). Of the subset with a SCD diagnosis (n=**20**), 70% had concomitant presence of the Duffy GATA promoter variant, while only 10% of the samples with thalassemia (n=**21**) carried this variant. Homozygosity for C was more frequent in the thalassemia group (60%) versus patients with SCD (20%) or other diagnoses (20%).

NGS confirmed the *RHCE*CeRN* allele in 4 samples: all RhD positive and carrying the Duffy GATA mutation. The *RHCE*CeRN* heterozygous cases (n=**3**) having diagnoses of: SCD (n=**1**), sarcoidosis/ cytopenia (n=**1**) and aplastic anemia (n=**1**) were assigned a C- transfusion strategy. The homozygous *RHCE*CeRN* case (n=**1**)

was a prenatal patient with anti-RH46 who was referred to the Rare Blood Program.

Conclusions:

The data supports modification of the CeRN workflow, eliminating NGS for homozygous C+ samples in the absence of a SCD diagnosis or concomitant Duffy GATA box variant. This retrospective study reports a 1.6% prevalence of the *RHCE*CeRN* allele in C+ Canadian patient samples that qualified for our CeRN algorithm. Continued data review supports the creation of optimal, data-driven testing workflows for the diverse Canadian population.

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Poster/Session Number : 32

Characterization of Platelet Donors in the Human Leukocyte Antigen (HLA)/Human Platelet Antigen (HPA) Selected Platelet Program

QingYun Hua [1] *^, Natasha Rickards [2], Akash Gupta [3], Johnathan Mack [4], Tanya Petraszko [5], Tamiko Stewart [6], Matthew Yan [7], Matthew Seftel [8]

Abstract Summary:

Introduction/Objective:

HLA and/or HPA-selected platelets are requested for patients with platelet transfusion refractoriness secondary to HLA/HPA alloimmunization. Since 2018, the HLA/HPA selected platelet program (HSPP), part of specialized cells program of our organization, has been overseeing platelet donor HLA/HPA testing, recruitment, and provision of HLA/HPA-selected platelet units to all provinces except Quebec. Characteristics of recruited donors has not been described previously. The aim of this retrospective cohort study is to determine the age, gender, self-declared (SD) ethnicity, blood group, and geographic location of all donors tested for HLA/HPA-antigens before March 31, 2023. Additionally, we aim to evaluate the platelet donation rates amongst them.

Design and Methods:

We retrieved data on all donors typed for HLA-A, B and HPA-1 antigens between May 1, 2003 and March 31, 2023. Attributes including year of birth, gender, SD ethnicity, last donation type and province, ABO/Rh-blood group, year of testing, and total number of platelet donations were recorded.

Results:

A total of 12,289 donors were typed for HLA-A and B and/or HPA-1 from May 1, 2003 to March 31, 2023; 89% of these donors donated apheresis platelets (AP) at least once.

AP donors were predominantly of Caucasian ethnicity (71%) and male gender (84%). The second most common ethnicity was Asian (6%). The most common donor age category is 50-59 years old, accounting for 23% of donors. Ontario contained the greatest proportion of AP donors (31%). The most frequent donor blood group was A+ (37%), followed by O+ (26%). 43% donated 2-19 times, with a secondary smaller peak in the number of donors who donated more than 100 times (9%). 23% of tested donors never donated AP or only donated once.

Conclusions:

HSPP donors are predominantly Caucasian, male, older age (50-59 years old), and located in Ontario. Group A+ donors are over-represented in this program, possibly reflecting preferential whole-blood donation by group O donors. 77% are repeat AP donors, indicative of favourable donor utilization. More than half of the donors also donated non-platelet products. Further analysis of active donor pool (i.e. those who donated platelets within the last 3 years) would provide more insights into HSPP's retention rates, allowing guidance for future recruitment efforts. Our data suggest that recruitment of younger individuals and/or those with diverse ancestry may be considered to maintain support of a diverse patient population.

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Poster/Session Number : 33

1-year of ferritin testing to identify iron deficiency amongst select whole blood donors

Aditi Khandelwal [1] *^, Behr Ehsani-Moghaddam [2], Sheila O'Brien [3], Mindy Goldman [4]

Abstract Summary:

Background: A majority of regular whole blood donors are iron deficient with higher prevalence amongst female donors and those who donate frequently. Iron deficiency mitigation strategies have included a longer inter-donation interval for female donors (84 days vs. 56 days) and a higher hemoglobin threshold for male donors (130g/L vs. 125g/L). Here we present the data from first year of ferritin testing in select female whole blood donors.

Methods: Data between January 16 2023 and December 31, 2023 female donors at every 10th whole blood donation was collected. Donor demographics, donation frequency and impact on ferritin levels was collected and analyzed. Ferritin ranges were defined as low (≤24mcg/L), adequate (25-299 mcg/L) and high (≥300 mcg/L). Those with low ferritin were asked to pause donation for 6 months and consider iron supplementation.

Results: In the first year, 736,485 donors donated whole blood. Of these, 313434 were registered as female with a median age of 48 years and hemoglobin 137[131-144]g/L. 36278 were first-time donors, while 277156 were repeat donors. Of the 21753 (6.9%) who had their ferritin tested, 2686 were first-time donors and 19067 were repeat donors. The ferritin amongst first-time donors was higher at 75[IQR44-134]mcg/L compared to repeat donors at 40 [IQR 25-65]mcg/L. 8% of first-time donors had low and 5.5% had high ferritin, while 23.3% of repeats donors had low and 0.8% had a high ferritin. The median hemoglobin value for donors with low ferritin was 134[IQR 129-145] g/L and those with high ferritin was 143[IQR136-151] g/L. Ferritin levels were lower for younger donors. Ferritin levels negatively correlated with donation frequency in the repeat donors cohort. Only 8.8% of donors who made 0 – 1 donations (N=3405) had low ferritin, compared to 71.3% of those (N=11,466) who donated 4 or more times in the previous 2 years. Amongst donors who had their ferritin tested, overall 12 136 (60%) returned for a subsequent whole blood donation. The return rate was lower for those who had low ferritin (2096,39.1%), although 70% of these donors did return within 6 months.

Conclusions: Overall, 23.3% of repeat female donors have low ferritin without anaemia. Ferritin is lower amongst those with younger age and higher frequency of blood donation. Further data is required to determine impact of testing on ferritin levels for returning donors and the efficacy of personalized messaging provided to mitigate iron deficiency.

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Poster/Session Number : 34

Unforeseen Anaphylaxis to Rh Immune Globulin: A Case Report

Julie Agnew [1] *, Marissa Laureano [2] ^, Eiad Kahwash [3]

Abstract Summary:

Background:
Rh immune globulin (RhIg) is a commonly given blood product and it is typically well tolerated. Severe allergic reactions to RhIg are uncommon. We describe a serious allergic reaction to RhIg in a healthy post-partum patient who had previously received RhIg without complications.

Case Presentation:
A 30-year-old female, G3P2, presented in spontaneous labour at 37 weeks and 3 days. She had no known allergies. She was O negative and had received antenatal RhIg at 28 weeks gestation. After delivering a healthy infant who was grouped as B positive, she received a postpartum dose of RhIg. Within a few minutes of RhIg administration, she developed an urticarial rash on her arms and chest. She also experienced vomiting and swelling of the face, hands, and tongue. Her blood pressure dropped from 110/72 to 84/41. In addition, the patient experienced dyspnea and was noted to have a strong, productive cough with small amounts of thick, clear sputum.

The Critical Care Response Team was activated. She was given 50 mg of diphenhydramine and her symptoms gradually improved. She also received an H2- blocker, famotidine. Within 6 hours of receiving RhIg, her facial swelling had dissipated. Follow-up laboratory testing showed that the patient had an increased alpha-1-antitrypsin, normal C3 and C4, normal IgA, increased IgE, normal haptoglobin, normal C1 esterase inhibitor, and a normal tryptase level. The patient received acetaminophen and oxytocin on the same day, but these were felt to be unlikely triggers since they were administered several hours before the reaction.

Conclusions:
The patient experienced a probable severe allergic reaction/anaphylactic reaction to RhIg. Notably, this patient received RhIg not only antenatally with her current pregnancy, but also antenatally and postnatally with two previous pregnancies without issue. However, given the timing and her symptoms during the event, this was treated as a possible severe allergic transfusion reaction. Although adverse reactions to RhIg are rare, this patient demonstrated that it is possible even with previous exposures. This patient was advised to pursue allergy testing in the event that she needed RhIg again.

Acknowledgements:

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Poster/Session Number : 35

Mitigating Alloimmunization after a Massive Fetal-Maternal Hemorrhage: A Case Report

Muskaan Kawatra [1] *, Marissa Laureano [2] ^, Eiad Kahwash [3]

Abstract Summary:

Introduction:

Fetal-maternal hemorrhage (FMH) is the transfer of fetal blood into maternal circulation. Massive FMH is a rare event that can result in fetal demise or neonatal death. As clinical findings are often subtle and non-specific, diagnosis of FMH is difficult during prenatal care. We report a case of massive fetal-maternal hemorrhage with clinical and laboratory findings, and patient management.

Case Presentation

A 38-year-old (G1P0) female with an uncomplicated pregnancy presented at 37 weeks of gestation with decreased fetal movement. Consequently, she underwent an induction and C-section. The C-section was uneventful and there was no evidence of placental abruption. The patient was Group A negative and had no history of alloantibodies. The baby was group A positive and was found to be critically anemic with a hemoglobin of 45 g/L. The initial Kleihauer-Betke estimated the fetal bleed to be 582.5 mL and repeat testing done the same day estimated it to be 557.5 mL. Flow cytometry was requested.

The patient was treated with intramuscular (IM) Rh immune globulin (RhIG). The day after delivery, six vials of RhIG (1500 IU per vial) were administered. Two days after delivery, an additional six vials of RhIG were given without complication. Flow cytometry results became available and estimated the fetal bleed to be 256.20 mL. The patient's hemoglobin and hemolytic markers were closely monitored throughout her admission and no evidence of hemolysis was noted.

One week after the delivery, a Kleihauer-Betke test was repeated and reported a fetal bleed of 2.5 mL. Out of caution, an additional vial of RhIG was given. Surgical pathology results of the placenta demonstrated a low placental weight (below the 10^{th} percentile), which has been associated with maternal vascular disease. Slight overcoiling of the umbilical cord was also found.

Conclusions

Massive FMH is a rare, and potentially life-threatening event for a neonate. It also poses a risk to the mother due to potential red cell antigen alloimmunization. In this case, a high dose of IM RhIG given over two days was well tolerated by the patient and repeated Kleihauer-Betke testing showed a significant drop in fetal hemoglobin after RhIg was administered.

Acknowledgements:

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Poster/Session Number : 36

Optimizing Home Transfusion through Data-Driven Patient Segmentation: Assessing Needs and Resources for High-Priority Patients

Na Li [1] *^, Maryam Akbari-Moghaddama [2], Douglas Down [3], Katie Hands [4], Alyssa Ziman [5]

Abstract Summary:

Introduction/Objective: Blood transfusions have been administered in hospitals or outpatient clinics for decades. Home transfusion, introduced in 1986, has had a slow global uptake. The COVID-19 pandemic has emphasized the need for innovative and patient-centred care to provide transfusions; hence, there is renewed interest in expanding home transfusion. This study introduces a novel data-driven strategy, using machine learning over electronic health records to support optimal patient selection and resource allocation decisions for home transfusion.

Design and Methods: We proposed a three-step approach: 1) We used unsupervised ensemble clustering to separate outpatient transfusion patients into clusters based on patients' historical transfusion patterns and clinical characteristics. 2) We then established data-guided screening criteria for identifying patients who may benefit from and are suitable for home transfusions among the identified patient clusters. 3) We proposed a priority function that assigns higher priority to patients who are elderly or disabled and reside in remote locations with limited access to medical facilities, among the identified patients using the data-driven screening criteria. The proposed strategy was applied to patients who received outpatient transfusions of red blood cells (RBCs) in Hamilton, Ontario, from 2015 to 2019. The model efficacy was evaluated using discrete event simulation, assessing resource utilization in different resource- and budget-limited scenarios.

Results: We analyzed 9,724 patients who had 58,303 transfusions over five years. The ensemble clustering algorithm grouped them into four clusters: 7,707 (79.3%), 1,316 (13.5%), 421 (4.3%), and 280 (2.9%) patients. The data-guided screening criteria flagged 631 patients (6.5%) for home transfusion services, requiring a weekly average of 80 transfusion units. To meet the demand for selected patients, 40 paramedic workdays per week are required. Assuming one paramedic can administer two transfusions daily over 5 working days, eight paramedics are needed weekly to cover 100% of the home transfusion service demand. Allowing low-priority patients to receive transfusions in outpatient clinics reduces the requirement to three paramedics, serving 60% of the demand from the 631 patients, specifically for those who are elderly and reside in remote locations.

Conclusions: This study provided important evidence on patient characteristics, priorities, and resource evaluations for home transfusion, and created opportunities to refine existing transfusion programs through data-driven techniques.

Acknowledgements:

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Poster/Session Number : 37

Fibrinogen Concentrate vs. Cryoprecipitate in Adult and Pediatric Populations: A Systematic Review of RCT Data

Bonnie Liu [1] *^, Johnathan Mack [2], Shuoyan Ning [3]

Abstract Summary:

Introduction/Objective: Fibrinogen concentrate (FC) is a human blood coagulation factor indicated for the treatment of acute bleeding episodes in patients with congenital or acquired fibrinogen deficiency. Whether FC is non-inferior to cryoprecipitate (CP) for fibrinogen replacement in all clinical situations, especially among neonatal and pediatric patients, remains unclear. The goal of this systematic review is to describe the efficacy and safety of FC compared CP in adult and pediatric populations.

Design and Methods: For this systematic review, we searched MEDLINE, EMBASE, SCOPUS and Cochrane Central Register of Controlled Trials (CENTRAL) from inception to March 13, 2024 for randomized controlled trials (RCT), irrespective of blinding or language, that compared the efficacy or safety of FC to CP in adult or pediatric populations. Outcomes of interest included: mortality, frequency and volume of allogenic blood product transfusions, hemostatic efficacy, thrombotic episodes, ICU length of stay, and re-operation due to persistent bleeding.

Results:

The search strategy yielded 275 abstracts, which were reviewed independently and in duplicate by two review authors. We identified 43 abstracts that are pending full text review. Full text review and data extraction is ongoing at this time, and results will be available for CSTM 2024.

Conclusions: A systematic review of fibrinogen concentrate compared to cryoprecipitate in adult and pediatric populations is needed to inform decisions on clinical use of FC vs CP. Full results of this review are pending.

Acknowledgements:

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Poster/Session Number : 38

Effect of Room Temperature Donor Sample Storage Duration on Automated Serologic Blood Group Testing

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Abstract Summary:

Introduction/Objective:

The stability of blood samples for serologic blood group testing stored at room temperature (RT)(18-24˚C) for > 24 hours is not well characterized, with testing often recommended 'as soon as possible'. The objective of this study was to evaluate the reproducibility of serologic results from donor blood samples stored at RT for up to 72 hours.

Design and Methods:

This was a prospective cohort study. Donor samples from our collection centres and tested at our laboratories ≤24 hours of collection were included. After initial testing (Reference Time) samples were stored at RT. Testing was repeated at 2 time points from collection: (i) after 48 hours (Time 1) and (ii) after 72 hours (Time 2). Only samples with with a valid instrument interpretation were included. **Forward and reverse ABO typing, high titre anti-A/B antibody testing (HT), pool cell antibody screening, and antigen typing for RhD, weak D, Kell, Duffy (Fy) A/B, and S/s** were completed at each time point using automated methods (PK7300, PK7400, and/or NEO Iris). Agreement between Time 2 and Reference Time was evaluated using the McNemar test.

Results:

Results are summarized in Table 1. ABO, RhD, Weak D, Kell, S, s, and FyA were in agreement at all time points. HT testing was discordant in 10.8% of samples at Time 1 and 8.2% at Time 2 ($p < 0.0001$); all changed from initial negative to positive. FyB was discordant in 0.91% at Time 1, and 0.61% at Time 2 ($p=0.0313$); all changed from initial positive to negative. A variant FyB antigen, FyX (causing weak FyB expression) was identified in all 3 samples. Antibody screening was discordant in 1.17% at Time 1 and 1.43% at Time 2; all changed from positive to negative. However, confirmatory testing on initial samples indicated false-positive at Reference Time.

Conclusions:

Donor samples stored at RT for up to 72 hours provide reproducible results for automated ABO, RhD, Weak

D, Kell, FyA, S/s, and antibody screening testing. An increased proportion of donors test positive for high-titre anti-A/B antibodies when samples are stored longer than 24 hours at RT. Minimizing time to HT testing will optimize the number of donors accurately identified as 'low-titre'. Further investigation of the reproducibility of FyX variants is needed.

Table 1. Agreement in blood group serology results at Time 1 and Time 2 compared with Reference Time.

Assay	Instrument	Time 1		Time 2	
		Number tested	Percent not in agreement (N)	Number tested	Percent not in agreement (N)
ABO	PK7300				
ABO	PK7400	382	0	351	0
ABO	NEO Iris	357	0	356	0
RhD	PK7300	382	0	378	0
RhD	PK7400	382	0	372	0
RhD	NEO Iris	359	0	357	0
Weak D	NEO Iris	397	0	381	0
FyA	NEO Iris	330	0	330	0
FyB	NEO Iris	330	0.91% (3)	329	0.61% (2)
S	NEO Iris	331	0	331	0
s	NEO Iris	331	0	331	0
Kell	PK7300	382	0	382	0
Kell	PK7400	382	0	372	0
High-titre	PK7300	382	10.5%(40)	365	9.04%(33)
High-titre	PK7400	382	10.5%(41)	378	8.2%(31)
Pool cell	NEO Iris	428	1.17% (5)	421	1.43% (6)

NB: Time 1 and Time 2 sample sizes differ due to insufficient quantity, issues with control, or invalid interpretation by the instrument.

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Poster/Session Number : 39

Comparison of genotype-predicted and serologically-determined red blood cell antigen phenotypes in donors

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Abstract Summary:

Introduction and Objectives:

Serologic red blood cell (RBC) antigen phenotyping may be influenced by biologic (e.g. antigen density), pre-analytic (e.g. sample storage time), and analytic (e.g. typing reagent) factors. RBC antigen genotyping, an alternative method of predicting RBC phenotype, is less susceptible to these factors. The objective of this study is to compare the serologically-determined and genotype-predicted RBC phenotypes in donor samples tested at our organization between 2020 and 2023, and to evaluate the effect of serologic sample transport on the frequency phenotyping discrepancies.

Design and Methods:

This is a retrospective cohort study. All CBS donors with an RBC antigen genotype performed between 2020-01-01 and 2023-12-12 *and* a serologic result for **C/c**, **E/e**, **Kell (K)**, **Jka/Jkb**, **Fya/Fyb**, **or S/s** antigens were included. Donors were selected for genotyping based on self-reported ethnicity and observed phenotype (e.g. rare phenotype, 'weak' typing). Genotyping was performed using Progenika ID CORE^{XT} test kit. Results for each typing were categorized as 'concordant' if the predicted and serologic phenotypes were identical (e.g. predicted C-positive, serologically C-positive), and 'discordant' if they were not in agreement (e.g. predicted C-positive, serologically C-negative). The proportion of discordant typings were calculated overall and by city of serologic sample collection. Fisher's exact test was used to compare the rate of discordant results for samples collected in cities with and without a Donor Testing Laboratory (DTL).

Results:

A total of 4682 donors had both serologic and genotype determinations for ≥1 of the antigens of interest; 16695 individual antigens were assessed. Twenty-two discordant results were observed (0.13% of all antigens assessed) in 19 donors (0.41% of all included donors). Discordant results were observed for the following antigens: C (3), e (1), Jka (6), Jkb (4), Fyb (6), and S (2). Four of the discordant Fyb typing were explained by *GATA* box mutation and were excluded from further analysis. The distribution of discrepancies by serologic sample collection location is summarized in **Table 1**. For serologic samples collected in cities with a DTL, 0.081% of antigen typings were discordant compared with 0.10% for samples that needed to be shipped a city with a DTL (p=0.609).

Conclusions: Genotype-predicted phenotype agreed with serologic results in >99.5% of genotyped donors. Collection of the serologic sample in a city without a DTL was not associated with a significantly higher rate of antigen typing discordance. Limitations include non-random donor genotyping. The findings support the accuracy of serologic phenotyping for C/c, E/e, K, Jka/Jkb, Fya/Fyb, and S/s antigens at CBS.

Table 1. Frequency and percent of discordant predicted and serologic RBC antigen phenotypings by city of serologic sample collection.

Serologic Sample Location	Discordant Antigen Typings	Number of Antigens Tested	Percent Discordance
Vancouver	2	1451	0.14%
Edmonton	1	150	0.67%
Calgary	5	3391	0.12%
Saskatoon/Regina	0	1753	0%
Winnipeg	4	897	0.45%
Brampton	4	6530	0.061%
Ottawa	0	1426	0%
Dartmouth	2	862	0%
St. John's	0	201	0%
Other	0	30	0%
Overall	18	16691	0.13%

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Poster/Session Number : 40

Chronic Hepatitis B in Ethnically Diverse Blood Donors

Sheila O'Brien [1] *^, Behr Ehsani-Moghaddam [2], Mindy Goldman [3], Steven Drews [4]

Abstract Summary:

INTRODUCTION/OBJECTIVE An ethnically diverse donor base is desirable to increase donations with rare red cell phenotypes and to ensure adequate blood supply. Hepatitis B virus (HBV) is transmitted sexually, by blood contact, vertically from mother to child and by blood transfusion. It is sometimes occurs in immigrants from high prevalence countries. In children hepatitis B infection frequently becomes a chronic infection (95% of babies, 50% of children under 5); in adults less frequently (5 -10%). Donors are deferred for risk factors such as intravenous drug use, sexual risks and recent hepatitis, but people may be unaware of their infection, especially if infected in childhood. All blood donations are tested for HBV. If positive, the donation is discarded, and the donor is indefinitely deferred. We assessed the relationship between chronic HBV infection and ethnocultural background and material deprivation.

DESIGN AND METHODS Included were 1,539,869 first-time blood donors from April 2005 to December 2022. All donations were tested for anti-hepatitis B core antigen(anti-HBc), hepatitis B surface antigen (HBsAg) and hepatitis B nucleic acid (since 2011, prior to that supplemental testing of donations positive for anti-HBc or HBsAg). Donors who were anti-HBc reactive and HBsAg positive were considered to have chronic hepatitis B. All donors were asked to provide their ethnicity since 2020 (voluntary question). Logistic regression was fit with chronic hepatitis B as the dependent variable and age, sex, year, and neighbourhood ethnocultural composition and material deprivation quintiles as independent variables.

RESULTS Chronic hepatitis B prevalence was 47.5/100,000 (95% CI 41.5–53.5, years 2017–2022). Chronic hepatitis B prevalence was elevated in males (88.5/100,000 vs 26.6/100,000), older age groups, and those living in more materially deprived (38.2/100,000 in lowest quintile vs. 100.4/100,00 in highest quintile) and higher ethnocultural neighbourhoods (7.7/100,000 in lowest quintile vs 131.1/100,000 in highest quintile). Of 212,518 donors from 2020 to 2022 with race/ethnicity data, chronic hepatitis B prevalence was highest in East Asians (238.9/100,000 vs 7.0/100,000 in whites)

CONCLUSIONS The findings are consistent with infections in immigrants, acquired in their country of origin, in their Canadian-born children and in those with other risks. As blood donors are a low-risk population unaware of their infection and unlikely to seek testing, our results highlight the ongoing public health challenge of diagnosing chronic hepatitis B and treating it when appropriate. These results suggest that as we encourage more ethnically diverse Canadians to donate, the hepatitis B rate may also increase.

Acknowledgements:

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Poster/Session Number : 41

COVID-19 vaccination behaviour in blood donors

Sheila O'Brien [1] *^, Behr Ehsani-Moghaddam [2], Mindy Goldman [3], Lori Osmond [4], Steven Drews [5]

Abstract Summary:

INTRODUCTION/OBJECTIVE Blood donors world-wide were indispensable for monitoring anti-SARS-CoV-2 antibodies generated by infection and vaccination during the pandemic. Vaccination against SARS-CoV-2 and other seasonal infections such as influenza reduces both the incidence and severity of infections. Because winter respiratory infections can impact donor availability, it is important to understand the level of protection within the donor base. Donor vaccination behaviours are under-studied. We aimed to compare the percentage of Canadian blood donors with SARS-CoV-2 vaccination antibodies with the percentage of the general population who received at least one dose of vaccine each month during initial vaccine deployment. We also report donor attitudes towards SARS-CoV-2 vaccination.

DESIGN AND METHODS Canadian blood donors were randomly selected for SARS-CoV-2 antibody testing over 2021 (N=165,240). The percentage of donor samples with vaccination antibodies were compared with the percentage of general population who received at least one dose of vaccine in each month of 2021 except February. A random sample of Canadian blood donors were surveyed about vaccination intent and attitudes (N=4,558 participated, 30.4% response rate).

RESULTS The percentages of the general population vaccinated and donors with vaccination antibodies increased from 1% to over 90%. General population vaccination was greater early in vaccine deployment than donors ($p < 0.05$), greater in donors than the general population by mid-2021 ($p < 0.05$) but they were similar by the end of 2021. While 52.6% of surveyed donors had received vaccine in May 2021, a further 41.1% intended to when eligible. Most donors thought COVID-19 infection could be serious (83.5%) and that it was important to be vaccinated even if previously infected (77.8%).

CONCLUSIONS Early pandemic vaccine prioritization to at-risk individuals and healthcare workers gave rise to higher general population vaccination percentages, while donors had higher vaccine antibody percentages as vaccine was deployed to progressively younger age groups. This is consistent with observations of the seasonal flu shot. Since blood donors may be more willing to receive vaccination, they may be at lower risk of infection, and if they are infected may have shorter duration of illness. However, as less than a quarter of the general population had the SARS-CoV-2 booster shot in the fall of 2023, further studies of blood donor vaccination behaviour are warranted to understand to what extent donors may have reduced vaccination rates.

Acknowledgements:

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Poster/Session Number : 42

Impact of TRALI mitigation strategies on respiratory failure beyond TRALI

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Abstract Summary:

Introduction/Objectives: Transfusion related acute lung injury (TRALI) is a life-threatening complication of blood transfusion associated with significant morbidity and mortality. From 2005-2009, policy and production changes were made at Canadian Blood Services to reduce the risk of TRALI among transfusion recipients. Whether these changes have led to respiratory failure above and beyond TRALI is unclear.

Design and Methods: This is a retrospective cohort study evaluating the adult in-patients (age ≥ 18 years) who received 1 or more plasma and/or platelet transfusion(s) between 2005 and 2012. Due to the complexity of changes made by the blood supplier, this study was divided into two efficacy questions (examining patients who received platelets alone and plasma alone) and a single policy (examining patients who received either product). Local inventory analyses and discussions with the blood supplier guided the selection of TRALI implementation date changes. We performed univariate and multivariate logistic regression analyses adjusting for key covariates. Primary outcome was respiratory failure, as defined using Canadian Classification of Health Interventions (CCI) codes. Baseline respiratory failure prior to transfusion and respiratory failure post transfusion were able to be captured using timing of CCI codes.

Results: During the study period, we identified 4892, 4532, and 15439 in-patient hospital admissions that were included for the plasma only, platelet only, and policy questions, respectively. Baseline respiratory failure was higher in the post TRALI implementation study time periods for the platelet only (50.1% vs 26.9%) and policy questions (54.3% vs 44.8%) compared with the plasma only question (40.0% vs 40.2%). In unadjusted analyses, respiratory failure post transfusion was higher for plasma only (8.1% vs 5.9%), platelet only (4.7% vs 2.6%), and policy (10.4% vs 8.3%) analyses. Multivariate analysis demonstrated no change in respiratory failure comparing post-TRALI changes to pre-TRALI changes for all analyses. For the platelet only analysis, odds ratio [OR] 1.162, 95% confidence interval [CI] 0.795-1.698, p = 0.438; for plasma only analysis, OR 1.159, 95% CI 0.582-2.309, p = 0.674; for the policy analysis, OR 1.151, 95% CI 0.900-1.472, p = 0.263.

Conclusions: TRALI mitigation strategies were not associated with reduced risk of respiratory failure above and beyond TRALI.

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Poster/Session Number : 43

Albumin Utilization and Appropriateness: A Provincial Healthcare Quality Improvement Project

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Abstract Summary:

Introduction/Objective: There are a limited number of evidence-based indications for albumin use in clinical care. Recently published audits of intravenous albumin utilization have identified the majority of albumin administered is for inappropriate or non-evidence-based indications. In the 2021/2022 fiscal year, our province was found to have the highest rate of albumin use per capita in Canada. Therefore, the primary objective of this study was to determine the local distribution of albumin use and its appropriateness.

Design and Methods: A multi-center retrospective chart audit was conducted on all patients who received albumin 5% and/or 25% transfusions in five hospital sites from two large urban centers (Centre 1 and Centre 2) between January 1 and February 28, 2023. The audit was completed by two individuals who collected data including patient demographics, the documented albumin dose and indication for use, prescriber specialty, and adverse reactions. Use was classified as appropriate if it was given for an evidence-based indication as listed in Transfusion Ontario's *Bloody Easy 5*. Data was merged for comparative statistical analysis.

Results: A total of 1235 albumin orders for 411 patients were reviewed; 661 orders were from hospitals in Centre 1 and 574 orders were from Centre 2. Overall, we identified that 91.0% of albumin 25% orders and 63.2% of albumin 5% orders were prescribed for inappropriate indications. Assessing each centre individually, only 6.6% of albumin 25% orders at Centre 1 and 11.8% at Centre 2 were found to be appropriate. Albumin 5% use was appropriate in 21.3% of orders at Centre 1 and 70.3% at Centre 2. General Internal Medicine physicians ordered albumin more frequently than any other specialty, encompassing 40.5% of albumin 25% orders and 25.1% of albumin 5% orders. One adverse transfusion event was reported during the study period.

Conclusions: Our study confirms that the majority of albumin transfused in our province is for inappropriate indications, with Center 1 identified to have a greater rate of inappropriate albumin use. This audit identifies that development and implementation of strategies are required to improve albumin use appropriateness to reduce albumin utilization and patient exposure to an unnecessary treatment.

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Poster/Session Number : 44

Physician Blood Transfusion Orders and Compliance with the Standards: Results of a Single-Centre Audit

Heather Panchuk [1] *^, Oksana Prokopchuk-Gauk [2], Sarah Tehseen [3], Sheila Harding [4]

Abstract Summary:

Introduction: Blood transfusion is the most common medical procedure in hospitalized patients. Documentation of a comprehensive transfusion order is an essential means of communication about patient care from the most responsible practitioner to nursing staff and the transfusion medicine laboratory. Otherwise, incomplete orders may expose the patient to potential risks of administration errors and adverse transfusion reaction. To underscore the importance of transfusion orders, lab accreditation standards require clear documentation of a comprehensive transfusion order, including a specified rate or duration of blood infusion. In preparation for an upcoming lab accreditation visit, we completed an audit of physician blood transfusion orders at our centre to assess compliance with accreditation requirements.

Methods: Nursing and clerical staff from inpatient and outpatient areas of 5 transfusing facilities within our centre were notified of this planned audit prior to its initiation. Blood transfusion order copies submitted by fax to the Transfusion Medicine Lab (alongside the Blood Product Request Form) between February 1-28, 2023 were included in this retrospective audit. Our Transfusion Safety Officer reviewed all submitted orders for completeness, in accordance with the *Canadian Society of Transfusion Medicine (CSTM) Standards for Hospital Transfusion Services, 5.9.1.4*.

Results: A total of 213 physician orders for transfusion were received and reviewed during our study period; the majority were hand-written (without use of a pre-printed order set). All orders reviewed included required patient demographics. The clinical indication for transfusion was absent in 124 (67%) orders. The date of transfusion was not specified in 188 (88%). All orders included the blood component or product to be given; however, the dose was not specified in 12 (6%) orders. The rate of blood administration was not specified in 167 (78%) orders. Overall, none of the orders audited included all information required to be considered complete.

Conclusion: The clinical indication for transfusion, date of transfusion and rate of administration were absent from most blood transfusion orders audited during our study period. All physician orders were missing at least one requirement for completeness. These results highlight the need to develop and implement strategies to optimize blood transfusion order completeness and compliance with lab standards, and may include physician education, revision of existing paper-based pre-printed order sets, expansion of pre-printed order set use to all patient care areas, and implementation of an electronic order entry system.

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Poster/Session Number : 45

Red Cell Antigen Genotypes and Variants in a National Sample of Blood Donors in Canada

Sheharyar Raza [1] *^, Thomas Sierocinski [2], Celina Montemayor [3]

Abstract Summary:

Background: Red cell antigens vary across individuals and incompatible transfusions can lead to alloimmunization with adverse clinical outcomes. Antigen genotyping is increasingly cost-effective and can provide valuable information for antigen matching, particularly for antigen variants. We sought to report the distribution of red cell antigens and predictors of antigen variants in our sample of blood donors.

Design and Methods: We retrospectively analyzed all donors who had red cell genotyping performed using the Grifols ID CORE XT platform between May 1, 2018, and December 31, 2023 (n = 5 years), including the Rare Blood Donor program database. Ethnoracial grouping was obtained from self-identification during electronic questionnaire at the time of donation. Logistic regression was used to explore predictors of the presence of *RHCE* variants among donors.

Results: Overall, 4228 donors were identified in the red cell genotype database with one-third of donors carrying at least one variant allele. The most prevalent ethnoracial groups in the database were White (35%), Black (27%), and Indigenous (20%). Variant alleles were most often reported among donors of African (94%), Arabic (39%), and "Other" (35%) groupings. Across predicted phenotypes, variants were more often reported among those who were Fya-, Fyb-, C-, S-, E-, Jka-, e+, and s+. Logistic regression model showed significant associations between *RHCE* variant presence and a predicted C-, E-, c+, e+, Fya-, Fyb-, S- phenotype, and with self-identified ethnoracial grouping (all $p < 0.01$). When tested separately for predicting the presence of *RHCE* variants, models including only self-identified ethnoracial group performed similarly to models including only predicted antigen phenotypes.

Conclusions: Our population of genotyped blood donors carries significant antigenic diversity and prevalence of variant antigens. An awareness of these patterns might inform donor recruitment initiatives, reflexive genotype testing, and nuanced risk discussions with patients receiving transfusion therapy.

Acknowledgements:

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Poster/Session Number : 46

Pre-donation blood pressure testing does not help predict risk of vasovagal reactions in apheresis plasma donors

Kaye Romans [1] *^, Aditi Khandelwal [2], Mindy Goldman [3], Sheila O'Brien [4]

Abstract Summary:

Introduction: Historically, blood pressure (BP) measurements have been required to determine whether apheresis plasma donors can safely donate. Donors were accepted if systolic BP was between 90 to 180 mm Hg and diastolic BP was between 50 to 100 mm Hg. The utility of deferral for out-of-range BP to mitigate vasovagal reactions has not been well-studied in plasma donors.

Design and Methods: A pragmatic observational study was conducted at one Plasma Donor Centre from August to December 2023. With donor consent, donor age, gender, weight, height, pre-donation BP, plasma collection volume and occurrence of vasovagal reactions (VVR) were recorded at each donation attempt. Donors proceeded with their donation regardless of their BP values. Currently, 500mL of saline is given to those donating over 550mL of plasma. The percentage of total blood volume (%TBV) was calculated for each donor. Data was analyzed using Proc Genmod of SAS program, descriptive statistics were obtained followed by an association analysis and a logistic regression model.

Results: A total of 4,040 donations occurred during the study period with 1,857 (46.0%) donations by female donors, 288 (7.13%) by first-time donors, a majority (64.0%) donating 12 – 15.9% TBV and 83.8% received saline infusions. Amongst 118 donors who had out of range pre-donation BP, 63 had low BP. None of the donors with out-of-range blood pressure reported experiencing a vasovagal reaction. There were 27 VVR reported and all of these donors had a BP value within the previously defined range. VVR were more common in first time donors (27.8 per 1,000 donations) compared to repeat donors (5.06 per 1,000 donations), among female (9.69 per 1,000 donations) compared to male (4.12 per 1,000 donations) donors and in those who did not receive saline. Younger age, first-time donor status, lower %TBV collected, lower TBV and absence of saline administration were associated with VVR occurrence ($P < 0.01$). The logistic regression model indicated that the odds ratio for not experiencing a VVR with saline administration vs without was 15.2.

Conclusions: Pre-donation BP measurement is not a reliable predictor of vasovagal adverse events in plasma donors. BP as a determinant of plasma donor eligibility may lead to unnecessary deferrals. To reduce the incidence of vasovagal reactions in plasma donors, other evidence-based mitigation strategies should be considered such as water, salty snacks, applied muscle tension and saline administration.

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Kaye Romans [1] *^, Canadian Blood Services,

Aditi Khandelwal [2], Canadian Blood Services, MD

Mindy Goldman [3], Canadian Blood Services, Ottawa ON Canada, MD

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Poster/Session Number : 47

Can A Pop-Up Stop a TACO? A Best Practice Advisory Alert as an Electronic Decision Support Tool to Mitigate the Occurrence of Transfusion Associated Circulatory Overload

Lianne Rotin [1] *^, Farzana Tasmin [2], Rita Ieshu [3], Michal Jamorski [4], Christine Cserti-Gazdewich [5]

Abstract Summary:

Introduction:

Transfusion-associated circulatory overload (TACO) occurs in 1-10% of transfusion exposures, with 20% requiring disposition escalations. The elderly, patients with cardiac and renal impairment, and those with volume-overload are disproportionately affected. Restrictive transfusion thresholds, slow transfusion rates, and diuretics in susceptible patients may prevent TACO, but the onus is on the transfusing clinician to pre-emptively identify at-risk patients and enact appropriate mitigation strategies.

Objective:

To reduce TACO rates at our institution by implementing a health information system (HIS) Best Practice Advisory (BPA) as a clinical decision support (CDS) tool to provide transfusion recommendations for at-risk patients.

Methods:

A BPA was designed to screen patient charts for TACO risk factors (age >60, history of heart failure, acute/chronic renal failure, and/or diuretic use) at time of transfusion ordering. If risks were detected, an alert featuring TACO mitigation strategies was generated **(Figure)**. This BPA was implemented at the time of transition from our previous HIS (Quadramed), which lacked CDS tools for transfusion ordering, to our current HIS (Epic). Transfusion reactions reported by clinicians before (from 2010-01-01 to 2022-06-03) and after Epic/BPA implementation (2022-06-04 to 2023-07-07) were investigated, classified, and tallied by the hospital transfusion service. TACO was concluded in the framework of existing definitions, with inclusion of high-suspicion cases lacking alternative explanations. The Z-test was used to compare TACO rates and frequencies before and after BPA implementation.

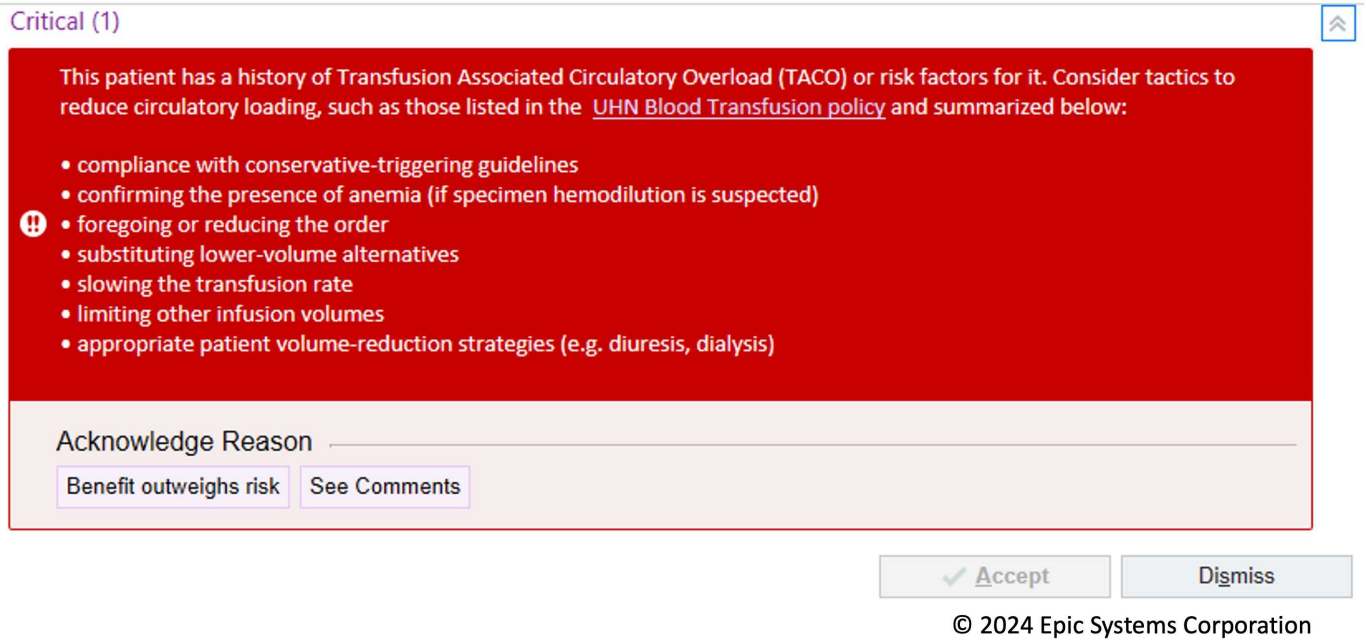
Results:

In the pre-Epic era, TACO represented 406/4208 transfusion reactions (9.6%) over 4537 days, with steady annualized TACO rates over this period. TACO represented 17/325 transfusion reactions (5.2%) in the first 398 days post-Epic/BPA implementation, with 516 BPA alerts fired. This 46% decrease in TACO as a proportion of reported transfusion reactions was statistically significant (z=2.64, p=0.0083). TACO frequency also decreased by 52%, from 1 every 11.2 days to 1 every 23.4 days pre- to post-Epic/BPA, while background transfusion reaction rates were unchanged (every 1.1 vs 1.2 days), suggesting that decreased TACO frequency did not result from decreased overall reaction reporting (z=3.20, p=0.0014).

Conclusions:

TACO rates decreased in overall frequency and relative to other reaction types at our institution following implementation of a TACO-focused BPA, highlighting the utility of this CDS tool. BPAs may have applications in transfusion medicine beyond TACO prevention, though caution must be taken not to induce alert fatigue.

Figure: Epic BPA alert



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Poster/Session Number : 48

Room-temperature phase change material configuration validation for platelet and plasma protein product transport

Ana Simonette Salaveria [1] *^, Anne Burry [2], Bruce W Lyon [3], Heather Blain [4], Healther Malcolm [5], Ryan Holman [6], Susan Nahirniak [7]

Abstract Summary:

Background: Cold transport of red cells and other blood products is well-understood but room temperature (RT) transport for platelets and plasma protein products (PPP) remains problematic. We have no provincial standardized transport methods for these products. Platelets can be transported for a maximum of 24 hours without agitation at 20-24°C while RT PPPs require 2-25°C transport. This experiment aims to validate phase change material (PCM) configurations for transporting platelets and PPP at RT.

Methods: We manipulated three variables: PCM configuration, product load, and incubation temperature. Two 22C Akku 2L Delta T (large PCMs) or two stacks of 22C TempShell Frame and 22C TempShell Element (ring stack PCM) placed inside 20L Blueline Transport containers comprised the different container configurations. Bubble wrap or RT-incubated Cryopak Flexible Ice Blankets were packing materials. Load variations were either minimum (one unit of platelets or one box of 100 mL albumin) or maximum (25 boxes of 100 mL albumin for large PCMs, 12 boxes for ring stacks, or 3 units of platelets for both). Large PCMs and ring stacks were tested in four external temperatures: -28°C, 4°C, 20-25°C (RT), and 37°C. Logtags were placed inside containers on top of the product to record every 10 minutes for 20-24 hours. Data are plotted as line graphs and compared using linear regression.

Results: Large PCMs charged to 20°C kept PPPs and platelets within 20-24°C for >24 hours at RT, 1-3 hours at 4°C, one hour at -28°C, and 24 hours at 37°C. Ring stacks at 18-20°C kept PPPs within 20-24°C for a maximum of 3 hours at RT, < 2 hours at 4C, and 10 minutes at -28°C. Large plate PCMs were easier to charge, dissipated heat slower, and displayed temperature more accurately than ring stacks. Charging PCMs to 18-20°C inside a 4°C fridge drove products below 20°C. Temperature variation within the lab made it difficult to charge the PCMs at 20°C consistently and pushed 50% of RT incubations out of range during maximum load testing.

Conclusion: Ring stacks were deemed inadequate but large PCMs showed the greatest promise in meeting

requirements at maintaining room temperatures of 20-24°C for at least 24 hours. However, it was evident that charging PCMs to 20°C and maintaining an appropriate ambient temperature in our laboratories and courier vehicles will be factors that require tight controls to ensure standards are met.

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Ana Simonette Salaveria [1] *^, University Of Alberta,

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Bruce W Lyon [3], Alberta Precision Laboratories, MLT

Heather Blain [4], Alberta Precision Laboratories,

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Poster/Session Number : 49

Confirming the Burden of Non-Reportable Transfusion Reactions to Blood Components - Evaluation of a Sentinel Site Model and Canadian Applicability

Joanne Nixon [1], Melanie St John [2], Fahad Kabir [3], Nour Alhomsi [4], Nancy Heddle [5], Andrew Shih [6] * ^

Abstract Summary:

Introduction:

Hospitals throughout Canada submit "reportable" adverse transfusion reactions (R-ATRs) to the national hemovigilance program (Transfusion Transmitted Injuries Surveillance System; TTISS). "Non-reportable" reactions (NR-ATRs) include: delayed serological, minor allergic, and febrile non-hemolytic. In 2006, the Ministry of Health funded implementation of a sentinel site model (SSM), with 4 hospital groups (28 hospitals) representing 33% of transfusion activity, to additionally capture NR-ATRs. This study compared sentinel to non-sentinel site performance and evaluated productivity of sentinel site hospitals, to inform the burden of NR-ATRs and potential SSM implementation in other Canadian jurisdictions.

Design and Methods:

We included R-ATRs and NR-ATRs to blood components reported: 1) from 2016-2020, 2) with a severity grade of 1-3, and 3) and imputability of the ATR to transfusion as possible, probable, and definite. Blood component transfusion activity was obtained from Canadian Blood Services; and national activity with ATR rates from national the TTISS report. Blood products were not assessed given lack of utilization data. The descriptive analysis compared sentinel and non-sentinel site R-ATRs; and sentinel site R-ATRs and NR-ATRs in total and by site blood component transfusion activity.

Results:

All hospitals reported 984 R-ATRs: 432 (44%) and 552 (56%) R-ATRs occurred in sentinel and non-sentinel sites respectively, both reported 13% of R-ATRs as life-threatening (grade 3 severity), and sentinel sites reported lower R-ATRs of "not determined" severity (0% vs 4%). Sentinel sites captured 2,075 NR-ATRs, extrapolating that 6,350 NR-ATRs would occur.

We observed that in sentinel sites with over 10,000 units transfused/year, 97% and 98% of R-ATRs and NR-ATRs are captured respectively. Sentinel sites submitted 30 NR-ATRs as severe (grade 2 severity), primarily at sites with the highest transfusion activity, that TTISS would not have captured without the SSM. As our region accounts for 40% of Canadian transfusion activity, the burden of NR-ATRs can be extrapolated to be

15,700 in Canada.

Conclusion:

The value of hemovigilance including surveillance of all reactions is to detect signals affecting transfusion safety. Severity levels of R-ATR between sentinel and non-sentinel sites were similar suggesting consistency of reporting between the two hospital groups and supporting the feasibility of the SSM to capture the burden of NR-ATRs including severe NR-ATRs that would otherwise be missed. Higher reporting yields occur for hospitals with higher transfusion activity, potentially informing implementation of the SSMs in jurisdictions seeking to confirm the burden of NR-ATRs in their hemovigilance programs.

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Poster/Session Number : 50

Pathogen inactivated platelets in pediatrics: a single-centre audit of platelet transfusions

Ingrid Tam [1] *^, Roxane Labelle [2], Brittany Armitage [3], Elaine Leung [4]

Abstract Summary:

Introduction/objective

Platelet transfusions are used to treat or prevent bleeding in patients with decreased or dysfunctional platelets. Pathogen inactivation of platelets offers an improved safety profile and are released earlier in their shelf life when compared to untreated platelets. However, despite similar bleeding outcomes, adult patients transfused with pathogen inactivated platelets have lower platelet count increments, increased number of platelet transfusions, and heightened risk of platelet refractoriness. There are limited studies that include pediatric patients. Canadian Blood Services implemented Cerus INTERCEPT Pathogen Inactivation Technology for the manufacturing of pooled platelets psoralen-treated (PPPT) in January 2022.

At our organization, PPPT became available for transfusion in January 2022. The objective of this study was to investigate the difference between transfusion with PPPT compared to untreated platelets in a pediatric hospital setting.

Design and methods

We conducted a retrospective review of all platelet transfusions occurring between January 1, 2021 to December 31, 2022, that covers the period of one year prior to and one year following the implementation of PPPT. Platelet transfusions were characterized based on the method of collection (apheresis or pooled), and pathogen-inactivated (PI) or untreated. Platelet counts were collected at different timepoints, with a pre-transfusion count measured within 24 hours before transfusion, and post-transfusion counts measured within 24 hours and/or 24-48 hours after transfusion. Adverse transfusion events were collected over the same period.

Results

In total, 1536 transfusions in 240 unique pediatric patients were included. Compared to untreated platelets

(n = 1308), transfusion with PI platelets (n = 228) was associated with a statistically significantly lower 24-hour platelet increment (mean PI = 21.9, untreated = 34.4, p=0.0000003) and 48-hour platelet increment (mean PI = 10.28, untreated = 18.70, p=0.007). Whether platelets were pooled or apheresis had no significant impact on 24-hour platelet increment. PI platelets were associated with less overall transfusion reactions. Repeat transfusion within 24 hours occurred in 42% of transfusions with PI platelets compared to 29% with untreated platelets.

Conclusions

Overall, the results align with several previously published studies in adults and builds on the limited number of previous studies in pediatric patients. Transfusion with PPPT is associated with a lower platelet increment at 24 hours and at 48 hours, which may lead to an increased rate of repeat transfusions. Decreased overall transfusion reactions were observed with PI platelets. Further study is warranted to fully characterize PI platelet transfusions in pediatrics.

Acknowledgements:

Ingrid Tam [1] *^, Department Of Pathology And Lab Medicine, University Of Saskatchewan; Saskatchewan Health Authority, Saskatoon, SK,

Roxane Labelle [2], Children's Hospital of Eastern Ontario,

Brittany Armitage [3], Children's Hospital of Eastern Ontario,

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Poster/Session Number : 51

Is being Greedy actually a bad thing? A review of rule in and rule out criteria for transfusion medicine antibody investigations

Adela Vasilache [1] *^, Bruce Lyon [2], Jennifer Duke [3], Kristy Schmitt [4], Penelipe Harder [5], Susan Nahirniak [6], Gwen Clarke [7]

Abstract Summary:

Introduction and Purpose: Rule-in and rule-out criteria are critical to confidently identify blood group antibodies to avoid a potentially fatal transfusion reaction. Sources disagree on the minimal criteria needed to confirm specificity. We compared different rule-in and rule-out criteria sets, comparing accuracy, testing time, and reagent resources.

Methods: The two rule-out criteria differed in the use of the patient's phenotype. Three rule-in criteria differed by the number of exclusion cells used-one, two, or three. These were further subdivided into two categories each; a) required the set amount of needed inclusion cells per suspected antibody and b) allowed the same inclusion cells to rule-in more than one antibody (i.e. Greedy method). Rule-in and rule-out criteria were mixed and matched into sets. For accuracy comparisons, the probabilities of the identified antibodies were calculated for each set of criteria. For comparisons of time and resources needed, the number of additional exclusion and inclusion cells required were recorded. The number of donor units screened for crossmatch compatibility was calculated.

Results: 75 antibody investigations were re-evaluated. Ten had single specificities so were not applicable for any criteria sets that included the Greedy method. Rule-in criteria results are seen in Table 1 and rule-out criteria results are seen in Table 2.

	Average number of additional exclusion cells	**Average testing time (min)**	**Average number of donor units screened**
Without phenotype	2.2	33	39.8
With phenotype	2.04	30.6	30.6

Table 1: Summary of rule-in criteria results.

	Average number of additional inclusion cells	**Average testing time (min)**	**Average antibody probabilities**
One inclusion cell	0.23	3.4	0.0569
One inclusion cell + Greedy	0	0	0.163
Two inclusion cells	0.92	13.8	0.0306
Two inclusion cells + Greedy	0.12	1.8	0.154
Three inclusion cells	1.64	24.6	0.0142
Three inclusion cells + Greedy	0.43	6.5	0.142

Table 2: Summary of rule-out criteria results.

Discussion: The number of inclusion cells needed per antibody has the greatest impact on antibody probability. Use of the same inclusion cells for two or more antibodies was not justified due to the poor probability values ($p>0.05$). Use of two inclusion cells yielded sufficient probability values for accuracy without utilizing as many resources as using more. Addition of the phenotype for rule-out saved time and reagents while maintaining accurate results.

Acknowledgements:

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Jennifer Duke [3], Alberta Precision Labs,

Kristy Schmitt [4], Alberta Precision Labs,

Penelipe Harder [5], Alberta Precision Labs,

Susan Nahirniak [6], Alberta Precision Laboratories, MD, FRCPC

Gwen Clarke [7], University Of Alberta , MD

Poster/Session Number : 52

The Clinician's Role: A Rapid Scoping Review of Health System and Policy Implications of Immune Globulin Prescription and Management

Umair Majid [1] *, Quinn Grundy [2], Kelly Holloway [3] ^

Abstract Summary:

Introduction / Objective:

Immune globulin (Ig) is a critical treatment option for managing immunodeficiency disorders and neuropathic conditions. This rapid scoping review analyzed the existing literature on clinician experiences related to the prescription and management of Ig, underlining its implications for healthcare systems and policy-making. The presentation will explore patterns in clinical practice, challenges within the healthcare system and care provision, and the educational requirements of healthcare providers.

Design and Methods:

Through a systematic approach, we conducted a rapid scoping review to identify literature on the experiences and perspectives of clinicians about the prescription and administration of Ig for immunodeficiencies and neuropathies. Our research encompassed primary and secondary empirical studies without geographical limitations. We ran our search strategy in PubMed, Embase, PsycINFO, the Social Sciences Citation Index, and CINAHL to ensure a thorough investigation.

Results:

This review analyzed 23 studies organized into four key themes. First, there was a disparity in the knowledge and awareness of Ig treatment among clinicians, varying by location and medical specialty. There were also disparities in the dosing, methods of administration, and duration of Ig therapy across different specialties and countries. Second, the review delved into why clinicians preferred subcutaneous Ig (SCIg) over intravenous Ig (IVIg), citing factors such as ease of use. Third, the review shed light on the difference in perception between physicians and patients regarding the treatment decision-making process, with physicians viewing it as a collaborative effort and patients feeling decisions were predominantly physician-driven. Lastly, the socio-political and economic influences on the rising demand for Ig will be discussed.

Conclusions:

This rapid scoping review explored the clinicians' experiences and perspectives with Ig therapy, highlighting implications for healthcare systems and policy-making. The findings emphasize the need for dedicated research and a cohesive, evidence-informed strategy toward the administration and prescription of Ig therapy.

Acknowledgements:

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Quinn Grundy [2], University of Toronto,

Kelly Holloway [3] ^, Canadian Blood Services, PhD

Poster/Session Number : 53

New plasma donors: a qualitative study of retention

Kelly Holloway [1] ^, Morgan Seeley [2] *

Abstract Summary:

Introduction/Objective: Retaining new source plasma donors in voluntary non-remunerated settings is imperative to meeting demand for plasma-derived therapeutic products. Studies on plasma donation have largely focused on the experiences and perspectives of whole-blood donors who transition to plasma donation. Little attention has been given to new plasma donors with a long-lapsed or no prior whole blood donation history. The objective of this study is to understand the factors impacting the intentions of new plasma donors to make future donations and develop a habit of plasma donation.

Design and Methods: This study is a sociological investigation of the experiences of new plasma donors at three Canadian Blood Services source plasma collection centers. Data from 46 individual semi-structured interviews with new plasma donors were coded using NVivo software and analyzed using thematic analysis.

Results: The majority of new plasma donors express their intention to donate in the future, citing multiple reasons. Positive donation experiences and an ongoing desire to help others through plasma donation serve as key motivators for subsequent donation practices. New plasma donors construct their motivations for future donation in relation to others. They are encouraged by positive interactions with staff at the donation center and perceive the donation process as an opportunity to strengthen existing relationships and expand their social network. New plasma donors express a desire to receive more information about the impact of their donations, particularly regarding the recipients of plasma products. Moreover, they suggest greater access to social support and efforts to enhance opportunities to build connections with others through plasma donation, which they believe would reinforce their commitment to future donation practices. Despite their intentions to continue donating, few new plasma donors establish a consistent donation routine or commit to a fixed donation schedule. Instead, they set goals or flexible plans for donation.

Conclusions: Our study highlights the significant role of the plasma donation experience in influencing new plasma donors' intentions to make subsequent donations. Blood services should enhance donor retention by building upon the relationships that donors establish with staff and other donors and emphasizing the stories of recipients to provide donors with a sense of connection though a clear understanding of their impact on others. Additionally, blood operators should support new donors in establishing goals and/or flexible donation habits that are aligned with insights into how donors incorporate donation into their complex lives.

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Kelly Holloway [1]^, Canadian Blood Services, PhD

Morgan Seeley [2]*, Canadian Blood Services, PhD

Poster/Session Number : 54

Outreach strategies for a diverse stem cell registry

Kelly Holloway [1] *^, Jennie Haw [2]

Abstract Summary:

Introduction/Objective: Patients with certain hematological, immunological, or metabolic conditions can be treated with hematopoietic stem cell transplantation; stem cell transplants can treat over 80 diseases and disorders. Stem cell registries struggle to recruit committed stem cell donors, particularly from targeted demographics such as underrepresented racialized communities. The objective of this study is to examine recruitment materials and outreach strategies to increase stem cell awareness and registration among underrepresented racialized Canadians, aged 17-35.

Design and Methods: Focus groups were conducted with young adults ages 17-35 who self-identify as BIPOC/racialized to explore their views of the blood service, stem cell donation, promotional materials related to the stem cell registry, and community-led outreach strategies. Data analysis was conducted using thematic analysis and informed by interpretive grounded theory. NVivo 12, qualitative data analysis software was be used in data analysis. All interview transcripts were de-identified and uploaded to NVivo. Our organization Research Ethics Board approved this study.

Results: Five focus groups were conducted with a total of 17 participants. Focus group participants' views on the blood operator were related to the blood operator's overall lack of engagement with their community. While participants saw the blood operator as serving an important need, to collect and distribute blood, they were not sure about how donation fit into the healthcare system, the need for stem cell donations, or the importance of donations from racialized communities. Most had not donated because of a lack of awareness of the blood service, screening criteria, no centre in their neighborhood, and their community had not been engaged. Half the participants registered concerns when asked about their opinion of the blood operator, stemming from 1, the belief that screening criteria were discriminatory toward racialized and sexual and gender minorities, and 2, the blood operator wasn't visible in their community. They felt materials promoting the stem cell registry in Canada needed to clarify what stem cell donation is and why racialized communities matter. Further, that these materials should be more sensitive to representation of racialized communities. Finally, outreach events should be tailored to the communities' needs and interests.

Conclusions: Our study found that knowledge of stem cell donation, messaging to promote stem cell donation, and strategies to register donors from underrepresented racialized communities are inter-connected, and partnership with underrepresented racialized communities is required to create materials and strategies that are relevant and meaningful to them.

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Kelly Holloway [1] *^, Canadian Blood Services, PhD

Jennie Haw [2], Canadian Blood Services, PhD

Poster/Session Number : 55

Beyond Diagnosis and Treatment: A Qualitative Study of Immune Globulin Recipients' Experiences and Engagement in the Health System

Umair Majid [1] *, Quinn Grundy [2], Stephanie Kelly [3], Kelly Holloway [4] ^

Abstract Summary:

Introduction / Objective:

Human plasma is an essential source of over 25 therapeutic proteins, treating various conditions, from bleeding and clotting disorders to immunological and metabolic abnormalities. Leading the charge among these plasma-derived treatments is immune globulin (Ig), which has witnessed a significant uptick in usage due to its broadening scope in medical care. This surge in demand for Ig accentuates the growing necessity for plasma donations, underlining its indispensable place in the medical landscape. In Canada, initiatives to improve plasma self-sufficiency have resulted in the formation of centres for plasma collection. Studies on plasma donation have revealed that donors are primarily driven by the wish to contribute to the national plasma inventory and possess a keen interest in learning about the beneficiaries of their donations. This research seeks to bridge the gap between plasma donors and recipients by exploring the experiences of Ig recipients within the Canadian health system, focusing on their understanding and involvement in the decision-making and dissemination of Ig.

Design and Methods:

This investigation engaged 23 Ig recipients in Canada via two phases of interviews. The first set of interviews concentrated on the individuals' experiences with their treatments, illuminating their understanding of their health conditions, the effects of Ig therapy, and the obstacles encountered in managing their conditions. The follow-up interviews, which are the primary focus of this presentation, explored their engagement with the blood system responsible for collecting plasma and managing the dissemination of plasma products, as situated within the broader Canadian health system. These interviews discussed participants' awareness of the donation system and decision-making about Ig products, their interactions with healthcare professionals, and their involvement in patient advocacy organizations.

Results:

We found a spectrum of engagement among the recipients, from those who primarily wish to ensure the

continuity of their treatment without deeper involvement in Ig decision-making to a smaller group desiring an active role in Ig decision-making and dissemination. The majority focused their time and attention on understanding the nature of their illness and the implications of their treatment on their life. While information about their illness and Ig was accessible through various channels – such as healthcare providers and patient advocacy organizations – the onus falls on recipients to proactively seek out the information they desired, a task not all are equipped or have the capacity to undertake due to constraints in knowledge, time, or energy.

Conclusions:

This study discussed two groups of Ig recipients. The first group, representing the majority, sought information to better understand their illness and its treatment. The second group, representing a minority, desired information that equipped them with the knowledge to engage in Ig decision-making and dissemination.

Acknowledgements:

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Stephanie Kelly [3], Canadian Blood Services,

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Poster/Session Number : 56

Relationship of Isohemagglutinin Titres and Reverse Grouping in Renal Transplant Patients

Sebastian Vuong [1] *^, Shuoyan Ning [2], Nadia Gabarin [3], Zofia Kelly [4]

Abstract Summary:

Introduction/Objective:

Titres of anti-A and anti-B are evaluated in various clinical circumstances including incompatible platelet transfusion, hematopoietic stem cell transplantation and ABO incompatible organ transplantation. In immunology, isohemagglutinin titres are used as an alternative to evaluating vaccine response during the work-up of primary immunodeficiency disorders (PID) with cutoffs of anti-A ≤1:16 and anti-B ≤1:8 suggesting impaired humoral function. At our institution, we have seen increased requests for isohemagglutinin titres over the past year for this purpose. Given that antibody titration is labour intensive and prone to inter-technologist variability, we sought to evaluate reverse grouping as a surrogate marker for isohemagglutinin titres.

Design/Methods:

Reverse grouping and isohemagglutinin titre results from 2017-2022 were obtained from potential renal transplant patients in Hamilton. Patients were predominantly group B and O transplant recipients with A2 donors given that ABO-incompatible transplantation is more common in these recipient-donor combinations. Reverse grouping was performed by automated tube method using A1 and B reagent red cells with reaction strength graded from negative to 4+ at room temperature (RT) and anti-human globulin (AHG) phase. Antibody titration was performed by tube technique and reported as the reciprocal of the highest dilution with 1+ agglutination. Results were obtained manually from electronic medical records.

Results:

There were 223 group B and O patients with anti-A (RT+AHG) titres, 23 group A and O patients with anti-B (RT) titres, 22 group A and O patients with anti-B (AHG) titres, and 39 group O patients with anti-A (RT+AHG) titres. Overall, higher titres were associated with stronger reactivity on reverse grouping. However, the relationship between titres and strength of reverse grouping varied based on RT versus AHG phase and ABO blood groups of the patients analyzed, precluding the ability of reverse grouping to reliably predict titers. Titres as low as 2 can demonstrate strong (4+) reactivity while titres as high as 1024 can demonstrate weak (1+) reactivity. Among group B and O renal transplant patients (for whom the most data is available), negative reactivity on reverse grouping consistently captured patients with anti-A titres of 1:16 or less. The

probabilities of capturing anti-A titres of 1:16 or less with a weak (1+) reverse grouping were 95% and 79% for RT and AHG phase, respectively.

Conclusions:

Reverse grouping cannot be used as a reliable overall surrogate for isohemagglutinin titres based on a population of renal transplant patients. However, our data suggests that negative reactivity on reverse grouping may be used to predict titres of ≤1:16 which, in the context of PID, are cutoffs used for diagnosis. Given this narrow predictive capability, there is limited utility for laboratory practice. Additional studies in more generalizable populations may provide further insight.

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Poster/Session Number : 57

Implementing an Electronic Provincial Immune Globulin Utilization Database

Laura Aseltine [1] *^, Rebecca Barty [2], Donna Berta [3], Alison Wendt [4]

Abstract Summary:

Introduction/Objective

Use of Immune Globulin (IG), specifically Intravenous Immune Globulin and Subcutaneous Immune Globulin, increases at an average rate of 8% yearly [1]. Following the Auditor General's 2020 recommendations, a provincial blood coordinating office (PBCO) developed a central repository to electronically collect hospital IG data. Continuous audit data will identify IG use, inform future utilization criteria revisions, determine compliance with utilization criteria, and forecast demand in the event of an IG shortage.

Design/Methods

Research Electronic Data Capture (REDCap)[2] was used to electronically collect, analyze, and export data, aligning with the current paper-based form submitted to Transfusion Medicine Laboratories (TML) to prescribe IG. Personal health information is not captured in REDCap; each patient is identified with an anonymized number. Database allows for back entry of historical IG data. Functionally was piloted by one site. Hospital participation is voluntary with IG data entered manually or uploaded electronically. To encourage participation, the database features; training guides/videos for data entry, automated order expiry alerts (six month and one year), built-in dose calculator, and templated reports to support process enhancements in TML.

Results

On February 14, 2024, a provincial invitation to participate in IG data entry was disseminated.

- Volunteer pilot site entered 571 IG requests representing 306 unique patients.
- Effective March 15, 2024, 22 hospitals have agreed to participate, providing 588 additional IG requests representing 145 unique patients (historical and real time data)
- 22 participating hospitals denote approximately 25% of provincial IG use in FY 2022/23.
- Preliminary data analysis identifies opportunities for improvement with dosing by adjusted body weight for all patients, updates in utilization criteria, and demand forecasting.

Conclusions

In the context of human health resource constraints impacting laboratories, early findings demonstrate the

appeal and necessity of an electronic provincial IG database with swift uptake by hospitals. Ongoing evaluation of data by stakeholders aligns with the revision of provincial IG utilization criteria, supporting IG utilization monitoring for trends and forecasting. The PBCO persists in its commitment to engage hospitals to participate in IG data entry.

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Poster/Session Number : 58

Determining the Impact of Current Canadian Stem Cell Registry Policy on Donor Availability via Dynamic Registry Simulation

John Blake [1] *^, Kathy Ganz [2], Matthew Seftel [3], David Allan [4]

Abstract Summary:

Background and Objectives: When a hematopoietic stem cell registry size is constrained by limits on recruiting, as in Canada, identifying the right person to recruit is a critical determinant of effectiveness. The aim of this study is to evaluate the impact of changes to donor recruitment effort, within ethnic groups, on the matching effectiveness of the Canadian registry as it evolves over time.

Materials and Methods: Simulation methods are applied to create a cohort of 25,000 donor recruits over a ten-year time horizon. New recruits are added to the registry each year, while some existing donors "age-out" upon reaching their 36th birthday. In a similar fashion, simulated patient lists are created. At the end of each simulated year, simulated patients are matched against the simulated registry.

Results: There are increased matches in non-Caucasian populations when ethnically diverse registrants are preferentially recruited, but there are larger decreases in the number of matches for Caucasian patients. Additionally, ethnic communities that have limited registrants in the Canadian registry in 2021 do not benefit from increased recruiting efforts as much as communities with a larger initial number of registrants.

Conclusion: Preferentially recruiting from non-Caucasian populations reduces the number of matches from Canadian sources, since increases in non-Caucasian populations will not fully counterbalance decreases to Caucasian patient matches. Nevertheless, more than 80% of all matches are for Caucasian patients, regardless of the donor recruiting effort within ethnic groups. We conclude that Canadian patients will need to draw on international sources for stem cell donations as the Canadian registry becomes more diverse.

Acknowledgements:

John Blake [1] *^, Canadian Blood Services, PhD

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Matthew Seftel [3], Canadian Blood Services, MD

David Allan [4], Canadian Blood Services, MD

Poster/Session Number : 59

Cost Analysis: IVIg Administration in Chronic gMG Patient Populations Across Canada

Maxime Boutin-Caron [1] * ^

Abstract Summary:

Introduction:

Since 2010, immunoglobulins (Ig) utilization rate has doubled internationally (NAC & CBS, 2020). Despite efforts since 2018 to make Canada self-sufficient in Ig inventory management, the COVID-19 pandemic emphasized the need to reach this goal (NAC & CBS, 2020). Immunology and neurology are the two most prevalent medical sub-specialties for Ig treatments, neurology being the one that uses the highest volume of Ig products administered to patients in some provinces (INSPQ, 2023).

In neurology, generalized myasthenia gravis (gMG) represents the second largest patient population receiving IVIg (INSPQ, 2023). Although various strategies may be implemented to reduce IVIg usage rates in Canada, each province has the mandate of managing its own Ig stocks. As such, there may be disparities between provinces in Ig inventory management initiatives.

To inform decision-makers on how to prioritize IVIg usage and establish clear policies to maximize Ig availability to treat patients, clear financial data should be available. Publications have compared treatment costs between IVIg and SCIg (Ritchie et al., 2022), others have retrospectively assessed the costs of IVIg usage (Murphy et al., 2019) over a period of time. However, no systematic pan-Canadian cost assessment of IVIg administration in the hospital ambulatory care setting has been performed.

Method:

To estimate the cost of hospital ambulatory care IVIg administration, the gMG patient population was selected. From January to March 2024, clinician salaries, medical equipment and hospital overhead costs were compiled for all Canadian provinces and territories. A baseline scenario of chronic gMG patient treatment cycles was established and costs were calculated to compare all health jurisdictions in the country. In addition to direct costs such as salaries and medical supplies, indirect costs such as indirect salaries, energy and infrastructure costs were factored into the final calculations.

Results:

Salary differences, mainly nursing, and infrastructure costs were the two main elements affecting the IVIg administration cost between provinces. Yearly IVIg treatment costs in hospital ambulatory care settings for

one chronic gMG patient may be upward of $9,000 in certain parts of Canada.

Discussion:

With the availability of alternative treatments to cyclical hospital-based IVIg therapies for chronic gMG patients (CADTH, 2023; CADTH, 2020), health authorities and decision-makers could reallocate significant budgets and move closer to Ig products self-sustainability should they offering this type of treatments in the community. Non-public healthcare patient support programs (PSP) would also further decrease the financial burden of gMG treatments on public healthcare networks.

Acknowledgements:

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Maxime Boutin-Caron [1] *^, Maxime B. Caron, Consultant, RN, M.Sc., CNN(C), C.Adm.

Poster/Session Number : 60

Simulation Modelling to Inform Group O Negative Red Blood Cell Inventory Management

Jasdeep Dhahan [1] *^, Alexander Rutherford [2], Doug Morrison [3], Andrew Shih [4], John Blake [5], Deb McDonald [6], Robby Chen [7], Lillian Hao [8]

Abstract Summary:

Introduction / Objective - O negative individuals comprise 6-7% of the population, yet O negative demand exceeds 12% of transfusions. There is concern over the sustainability of the O negative blood supply. Red blood cells are perishable and managing these stocks in our province, and other regions of Canada, with remote hospitals is challenging. Demand must be satisfied without wasting this precious resource. Challenges in inventory management is due in part to lack of data but is also highly influenced by human factors. We believe that transfusion medicine technologists, often responsible for managing inventory day-to-day, are key to understanding the human factors of ordering. We are developing a simulation model of a network of hospital blood banks that accounts for human factors with the intent to inform O negative red blood cell inventory management.

Design and Methods - We interviewed transfusion laboratory technologists from all health authorities and a Canadian Blood Services Distributions lead in our province. We found five themes that affected technologist decision-making on red blood cell inventory management, key challenges for O-negative red blood cells, and identified the top inventory management strategies used by technologists. These results and near real-time inventory data from the Transparent Blood Inventory dashboard are being used to inform a discrete-event simulation model that we are building.

Results – Most blood bank models in literature do not account for human factors. Our qualitative work identified some human factors to inform a hospital blood bank model that reflects real-work practices. Our simulation model was built to include min-max ordering policies, compatible substitutions with priority for shortdated group O red blood cells, uncertainty of transport, and redistribution of O negative red blood cells. Our model is validated against real-world data using key performance indicators identified by technologists. This model can be used to test what-if scenarios to inform inventory management.

Conclusions – The next step will be to extend our model to include a redistribution network of hospitals. We will test strategies for equitably balancing the risk of shortages against the potential for wastage or the practice of using O negative red blood cells for non O negative patients to avoid expiry. Results will improve the sustainability of the national O negative blood supply and safeguard the altruistic contributions of donors, while bridging the gap in knowledge about the human factors in the inventory management.

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Lillian Hao [8], BC Provincal Health Services Authority,

Poster/Session Number : 61

Vein to Vein... to Vein? Traceability Logistic Challenges in a Novel Organ Donor Transfusion-for-Graft-Rejuvenation Protocol

Luarne Sani [1] *^, Alioska Escorcia [2], Erin Winter [3], Beth Paltser [4], Markus Selzner [5], Matthew Seftel [6], Farzana Tasmin [7], Susanna Medic [8], Christine Cserti-Gazdewich [9], Jacob Pendergrast [10], Lani Lieberman [11]

Abstract Summary:

Introduction / Objective

Transfusion support for solid organ transplant patients requires several logistical, regulatory, and legal considerations. This project involved the transfusion service's support of a novel method for organ donor retrieval. Specifically, the lab's ability to meet CSA standards and the Krever recommendation were challenged due to the need to identify a recipient of a transfusion in the event of a lookback event while balancing the privacy and legal obligations of the provincial anonymous organ donor program. The clinical situation involved leaving organs within a deceased donor and using transfusion to rejuvenate the organs for retrieval for subsequent donation.

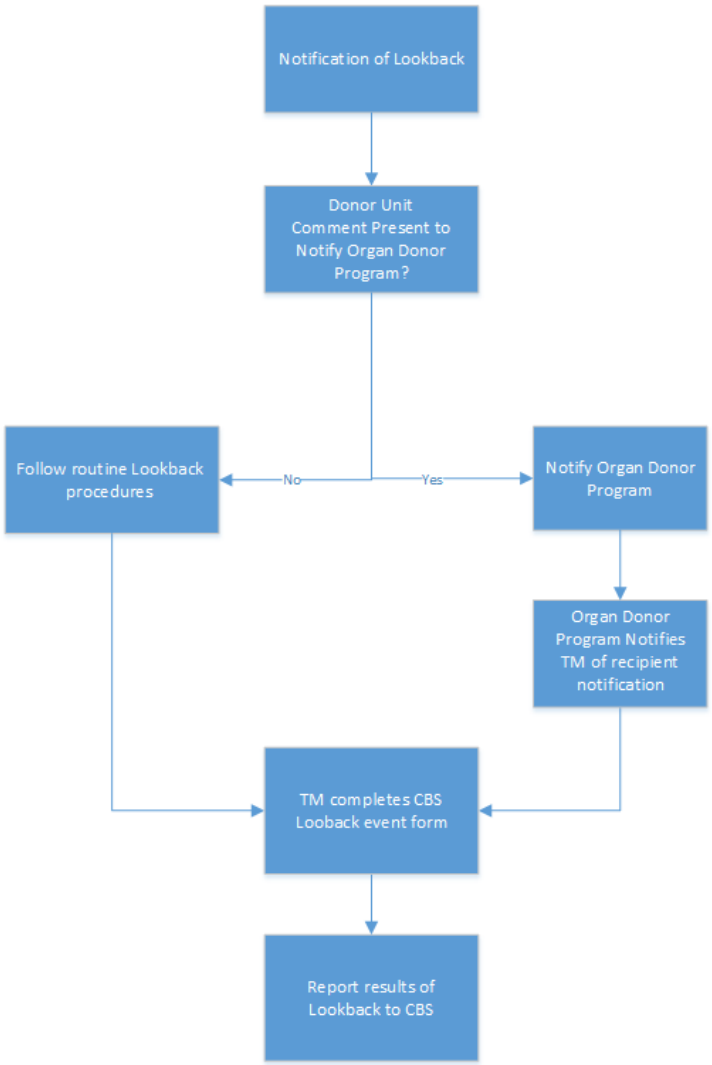
Design and Methods

The logistical challenge was presented to the transfusion medicine (TM) laboratory Medical Director and manager. A meeting with a multidisciplinary group was organized including the transplant surgeon, the TM Medical Director, provincial donor program team members, and TM management. Key issues discussed included (1) Legal and privacy issues related to inputting transfusion data about the donor organs and the potential to link to the recipients; (2) identifying the final recipient(s) of the transfused organ(s) if a lookback was issued; (3) the need for in-date group and screens for the donor.

A medical director from Canadian Blood Services (CBS) reviewed the appropriate reporting requirements needed in this situation.

Results

A process involving the transfusion medicine laboratory and the provincial organ program was developed and is under review. An acceptable documentation practice is still under review by CBS.



Conclusions

This case highlighted how new procedures can impact established processes. Balancing requirements mandated by CSA standards and the Krever report, as well as legal and privacy obligations of external parties present challenges when reviewing and documenting lookback events. This case highlighted the impact of transfusions beyond recipients in the laboratory or hospital information system.

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Poster/Session Number : 62

Nurse-administered SCIg at Infusion Centers is a Viable Alternative to IVIg in Antibody Deficiency

Adil Adatia [1] *, Pranavi Thota [2] ^

Abstract Summary:

Primary and secondary antibody deficiencies (PAD and SAD) are amongst the most prevalent immunodeficiency syndromes, often necessitating life-long immune globulin therapy (IRT). Both intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg) have demonstrated efficacy in managing PAD and SAD. Comparative analyses between these two treatments are limited to nurse-administered IVIg versus home therapy with self-administered SCIg. Nurse-administered SCIg, however, has some advantages in both modalities, such as the reduced risk of systemic reactions associated with SC dosing and the nursing support associated with IV therapy. The feasibility of implementing nurse-administered SCIg programs within hospital infusion clinics facing increasing patient volumes across Canada has not been studied.

This cross-sectional study aimed to assess the viability and resource utilization of nurse-administered SCIg in patients with PAD/SAD. SCIg was infused by nursing staff into the abdomen by pump using quadrifurcated needle sets. Information on infusion duration, time in the infusion chair, direct nursing time, and treatment satisfaction using the Life Quality Index (LQI) were collected. LQI is a 15-question instrument with scores 1 to 7 (higher is better) that assesses three domains: treatment interference, therapy-related problems, and therapy setting. Time measures for each patient were expressed as minutes/month to account for the more frequent dosing of SCIg compared to IVIg. All subjects provided written informed consent.

There were 11 SCIg patients included in the study. Mean age was 64 years, and 9/11 were female. SCIg patients were receiving treatment q14 days. Median (IQR) times per month for infusion, use of infusion chair, and direct nursing contact were 156 (76), 216 (83), and 92 (42) min, respectively. Median durations per month collected from 2 IVIg patients for comparison were 179.5 (18), 221.5 (4), and 72 (10) min, respectively. Average SCIg LQI scores (SD) were 5.3/7 (2.2), 5.0/7 (2.0), and 6.1 (1.6) for treatment interference, therapy-related problems, and therapy settings, respectively.

The infusion clinic and nursing time needed to provide SCIg at a hospital infusion clinic is comparable to that needed for IVIg. Patient reported favourable treatment satisfaction with nurse-administered SCIg, particularly regarding the treatment setting. Nurse-administered SCIg may thus be a useful treatment modality for well-selected patients such as older adults.

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Poster/Session Number : 63

Scoping review of genomics in clinical care and research: considerations for blood operators

Jennie Haw [1] ^, Nev Perera [2] *, Christy Simpson [3], Terrie Butler-Foster [4], Gwen Clarke [5], Kelly Holloway [6], Poojan Joshi [7], Celina Montemayor [8], Kieran O'Doherty [9], Kathleen Hammond [10]

Abstract Summary:

Introduction Genetic sequencing of blood antigens enables blood operators to provide enhanced matches and improve patient outcomes. Advancements in genomics make possible the sequencing of many more donors. Limited research exists on the social, ethical, and legal considerations for genomics and blood donation; however, there is extensive literature on genomics in clinical care and research. A scoping review of the social, ethical, and legal literatures on genomics, clinical care and research was conducted to help inform blood operators given the potential for expanding genomic sequencing. This presentation reports results of the legal literature scoping review.

Design and Methods – Applying Arksey & O'Malley's framework, we conducted an electronic database search (CanLII, Westlaw, Quicklaw, and HeinOnline) using the following key words: (genom* OR genetic) AND (sequenc*) AND (blood OR hematolog* OR hemo*) AND (bioethic* OR ethic). Inclusion criteria were English language articles published from 2008-present; mention of donors, research, research participants; human genetics; and legal standards and principles. Exclusion criteria were articles focused solely on commercial direct-to-consumer genetic testing. The initial search resulted in 1058 articles and 194 were included and uploaded to Covidence after title review. Following removal of duplicates and title and abstract review, 75 articles were included for full text review. A framework for analysis was developed and thematic analysis was conducted to identify areas of debate or concern regarding genomics in clinical care and research.

Results – Areas of legal debate or concern regarding genomics in clinical care or research include the following. First, as research shifts towards using previously collected genetic data, the status of research participants may become less clear, directly impacting their autonomy and privacy rights. Second, there are mixed concerns regarding the adequacy of current informed consent processes, particularly broad consent models that may not meet legal requirements in all jurisdictions. Third, issues related to data ownership were prevalent, with some jurisdictions denying peoples' property rights to their tissue. Fourth, issues of data ownership and governance for Indigenous communities require careful attention given historical instances of exploitation concerning genetic data. Lastly, distinctions between genetic data for clinical, compared to research purposes were made, as avenues for legal recourse for addressing lack of consent differ for each.

Conclusions – Legal scholarship on genomics in clinical care and research has identified several issues that

require further attention. The relevance and transferability of legal questions, concerns, and recommendations in health-related fields to blood donation requires ongoing discussion and consultation.

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Poster/Session Number : 64

Analysis of participant responses to the 2023 IQMH educational survey on blood regulations: A comprehensive review

Chang Keun Lee [1] *^, Laura Aseltine [2], Melanie Tokessy [3], Akash Gupta [4], Hakan Buyukdere [5], Xiaodong Qi [6]

Abstract Summary:

Introduction / Objective

Effective blood regulations are paramount to safeguarding Canadian blood donors and recipients of transfusions. The regulations describe the regulatory requirements for establishments engaged in the collection, processing, storage, and distribution of all blood products. As an essential component of its annual education survey, the Institute for Quality Management in Healthcare (IQMH) administered three case studies centred on blood storage, distribution, and reporting to Health Canada, serving to assess the comprehension and implementation of regulations across blood banks of diverse proficiency levels.

Design and Methods

The survey was distributed to 151 participants, with a voluntary response rate of 74.2% (n=112). Among respondents, 59 were categorized as 'Advanced', with antibody identification licensure, while 53 were classified as 'Basic', with antibody screening licensure. A review conducted by the Transfusion Medicine scientific committee focused on five questions that failed to achieve 80% consensus. To assess comprehension levels, responses were segmented into the aforementioned categories. Discordance rates were calculated by taking the sum of the percentages of responses that differed from the recommended answer.

Results

- Five out of the total 10 questions in the survey that did not reach 80% consensus:
  - 1 out of 2 – storage-related
  - 1 out of 4 – distribution-related
  - 3 out of 4 – reporting-related
- Discordance rates for each discordant response were calculated as 72%, 31%, 53%, 49%, and 38%, respectively.
- The calculated discordance rates for 'Advanced' participants were slightly or moderately lower than that of 'Basic' participants in the five reviewed questions.

Conclusions

Since the inception of the Blood Regulations in 2014, there has been a noticeable absence of formal educational initiatives for hospital laboratories or centres in interpreting these regulations. This educational survey has revealed a significant discordance rate in laboratory comprehension of the requirements in the Blood Regulations. While some of the participants categorized as "Advanced' are likely registered establishments with Health Canada, and thus possess a deeper understanding of the regulations, the majority of participants in this category are not registered establishments. Surprisingly, despite this distinction, the performance of 'Advanced' participants did not surpass that of the 'Basic' participants. This underscores the urgent need for enhanced formal education and/or awareness campaigns to ensure a consistent and accurate application of the regulations, and the proper reporting of errors and accidents to Health Canada.

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Hakan Buyukdere [5], The Ottawa Hospital/EORLA lab, MD

Xiaodong Qi [6], Mackenzie Health, MLT

Poster/Session Number : 65

How to Succeed as a Transfusion Practitioner – Developing the Handbook

Crystal Brunk [1] *, Clare O'Reilly [2] ^, Tara Winckler [3], Liana Perruzza [4]

Abstract Summary:

Introduction: Transfusion practitioners support the development and implementation of transfusion medicine best practices. They can have various professional backgrounds and outside of transfusion medicine knowledge they need an assortment of specialized skills in order to succeed in the role. Historically there have been few tools created specifically for the education and training of individuals holding this unique role.

Methods: A working group was formed consisting of three transfusion practitioners at various stages in their careers. The objective of the group was to develop a tool that would facilitate success in a transfusion practitioner role regardless of baseline level of experience or professional background. It was determined that the project scope would include resources for obtaining transfusion medicine foundational knowledge, tools needed to succeed in the role, and skills required for the role with resources to develop them. Out of project scope would be creation of foundational knowledge content, and the development of specific protocols or standard operating procedures. A literature review was conducted to determine what resources already existed both provincially and nationally. After reviewing the available resources in combination with the roles and responsibilities of transfusion practitioners in the province a content list was generated. Working group members assimilated the required content from local, national, and international sources. Once drafted the tool's content was validated by local technical, nursing, and medical resource groups.

Results: A handbook was developed that covers the following topics: Transfusion Practitioner Roles and Responsibilities, Foundational Knowledge, Courses and Training, Local Committees and Professional Organizations/Memberships, The Canadian Blood System, Provincial Blood Coordinating Offices, Transfusion Medicine Standards and Regulations, Guidance on Navigating Accreditation and Inspections, Blood Utilization and Patient Blood Management, Hemovigilance, and Specialized Skills. The handbook was posted on the provincial blood coordinating office website on August 1, 2023 and as of December 31, 2023 has received a total of 113 views. The handbook has been viewed by people from seven Canadian provinces and from five different countries.

Conclusions: The Transfusion Practitioner Handbook is now available as a recourse for current and future transfusion practitioners. It is being used provincially as a tool for new transfusion practitioners and by others in the transfusion medicine field to support on-going education and training.

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Liana Perruzza [4], PHSA, RN

Poster/Session Number : 66

How an Internal Audit Program Informs Provincial Quality Initiatives in Transfusion Medicine

Heather Malcolm [1] *^, Agnieszka Frankiw [2], Joanna McCarthy [3], Susan Nahirniak [4]

Abstract Summary:

Introduction

Provincial accreditation standards and the Health Canada Blood Regulations require a robust internal audit system to verify compliance with requirements. Dedicated Transfusion Medicine (TM) Quality staff developed an internal audit program and schedule for our provincial TM program to identify areas of noncompliance and opportunities for improvement.

Design

Blood storage audits and thawing plasma audits were conducted by Operations staff and reviewed by Quality. Each zone performed immediate corrective actions. Zonal results were compiled in an Excel spreadsheet by regulation/provincial standard as percent compliant. This provincial summary identified common areas of conformance. Medical leadership determined that quality improvement preventative initiatives would be developed and implemented for areas that were less than 75% compliant with the goal of achieving at least 90% in all areas by 2028.

Results

Immediate areas of focus identified:

- documentation standards and complete/correct records (33-72%; n=6)
- follow up of equipment problems and repair, including out of range temperatures (17 – 67%; n=8)
- standard operating procedures (33-66%; n=4)
- training documentation, including procedure sign off (0=73%;n=16)

To address these issues the following initiatives are underway: development of an online good documentation practices training session and competency, standardization of equipment document suite, development of an online nonconforming event training session and competency, and implementation of a read and sign process to allow staff reading of approved procedures prior to implementation date.

Conclusions

Internal audit result review allows a provincial program to develop and implement quality improvement

initiatives that focus on preventative action to comply with regulatory and accreditation standards. Using percent compliance as the metric is an easy way to monitor effectiveness of the initiatives.

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Heather Malcolm [1] *^, Alberta Precision Laboratories, MLT BSc

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Joanna McCarthy [3], Alberta Precision Labs, MLT

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Poster/Session Number : 67

Provincial Transfusion Medicine Program Approach to Preparing Annual Health Canada Report

Heather Malcolm [1] *^, Agnieszka Frankiw [2], Joanna McCarthy [3], Susan Nahirniak [4]

Abstract Summary:

Introduction

Health Canada Blood Regulations (Section 108) requires that each establishment prepares an annual report summarizing all of the errors and accident reports including analysis of the investigations. Our Transfusion Medicine (TM) program includes 3 registered establishments and 106 non registered facilities. The Quality department has 5 dedicated staff to support the TM program. The majority of front-line staff are cross trained in multiple laboratory disciplines (including diagnostic imaging in many rural locations) and do not have the resources or knowledge to prepare reports at the facility level.

All TM errors and accidents are reported in an online portal by front line staff. The system allows for investigation documentation, categorization and communication with impacted parties. Operations staff perform the immediate investigations and in consultation with medical staff (and quality staff if required), determine if the Health Canada Blood Regulations apply so that appropriate action is taken. Quality staff perform a secondary review and ensure all reports submitted are categorized correctly and generate a report from the system. These quarterly reports are reviewed and then combined to form the report for the provincial program.

Design

Quarterly, reports categorized as Blood Components and Products are reviewed by Quality staff to ensure proper categorization. The reports to appear on the Health Canada report are further tagged with additional information to assist with preparation of the analysis of the investigations as required by the Blood Regulations. The functionality of the online portal/reporting system allows for ongoing trending on a customizable dashboard and presented graphically.

Results

Quarterly reports are reviewed by the program Discipline Council and User Group committees and then combined to create the annual report. Consistent categorization and adding tags has allowed for more robust analysis of trending and recurring issues and informs program quality improvement initiatives. In 2023, this review has allowed focus on the out of hospital transport conditions which has impacted 27 facilities which

resulted in implementation of logtag monitors and a QI project for transport box evaluations.

Conclusions

Identifying trends and recurring issues as a program allows for standardized approaches within the program to address issues. Preparing an annual report for the entire program allows the expertise to be centralized and focused but still able to support staff at the facility level.

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Poster/Session Number : 68

Centralized Screening of IVIg for Central Nervous System Conditions - One Year Post-Implementation

Mandy Feng [1] ^, Kristin Rosinski [2] *, Aimee Beauchamp [3]

Abstract Summary:

Introduction

The Provincial Blood Coordinating Office (PBCO) collaborates with provincial stakeholders and facilitates initiatives as well as the advancement of transfusion medicine practices.

Since 2000, PBCO focused on appropriate utilization of Intravenous Immune Globulin (IVIg). One of the initiatives is maintaining a screening programs with expert panel members, to ensure appropriateness of use and optimal patient care. Centralized screening for Rheumatology conditions began in 2008, and Peripheral Nervous System conditions in 2013. In 2023, PBCO implemented the same practice for Centralized Nervous System conditions with the goal of creating a succinct, yet comprehensive neurology program.

Design and Methods

Using clinical research to create recommendations, conditions were segregated by appropriateness, and screened based on 3 categories:

- *Conditionally Approved*: Clinical research proves that IVIg is likely an appropriate treatment; whereby the hospital site is to review and approve up to 3 courses of treatment, in line with the recommendations. All future requests are screened by a member of the Neurology Panel.
- *Only in Exceptional Circumstances* (or not listed): Clinical research suggests that IVIg may be an appropriate treatment; case dependent. All requests are screened by a member of the Neurology Panel.
- *Not Indicated*: Requests should be denied at the health authority. Exceptional circumstances may result in a discussion between the ordering physician and a member of the Neurology Panel.

All cases reviewed diagnosis, dosing, consultation letters and treatment questionnaires. Patient management was compared to Provincial recommendations. A letter was sent to the ordering physician with the results of the review and treatment recommendations, as well as a decision on the IVIg request, including dosing details.

Every 6 months, all cases are reviewed again by a panel of Central Nervous System experts, each with different focus of study. Challenging cases provoked further follow up and recommendations from the

broader panel.

Results

In the first year of the program:

- 94 first time requests were received of which 3 cases came to the panel.
- 91 renewal requests were reviewed by the panel
    - 53 cases recommended to trial a decreased dose
        - 11 of these cases recommended to also trial an alternate immunotherapy
- 31 cases recommended to continue with current therapy

Countless provider-to-provider consults were had, information sessions shared, and clinical and technical resources created to ensure ease of access and understanding.

Conclusion

IVIg may be effective in the management of some CNS inflammatory conditions. Using a physician-led utilization program in our province with targeted education to ordering physicians promotes best practice, and surely assists in the overall utilization of IVIg. Lessons learned from the first year of screening will inform future versions of the provincial recommendations.

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Kristin Rosinski [2] *, BC PBCO, MLT

Aimee Beauchamp [3], BC Provincial Blood Coordinating Office, BComm

Poster/Session Number : 69

Pediatric Transfusion Camp: Applying Kern's Six-Step Approach to Curriculum Development to create and implement a national pediatric transfusion medicine curriculum

Ines Zuna [1] *^, Lani Lieberman [2], Teresa Skelton [3], Suzanne Beno [4], Sophie Chargé [5], Casey Kapitany [6], Richard Haspel [7], Catharine Walsh [8], Yulia Lin [9], Jeffrey Bone [10]

Abstract Summary:

Introduction

Pediatric transfusion medicine (TM) knowledge is a known gap among Canadian trainees in pediatric specialties, and there is need to improve clinician understanding. Pediatric physiology and response to illness and trauma differs from the adult, and there is an increased incidence of transfusion reactions in this population. *Transfusion Camp* is a Canada wide TM curriculum currently provided to non-TM trainees, with most content tailored to adult patients. This project adapts the successful *Transfusion Camp's* content and team-based learning (TBL) structure for the pediatric patient using Kern's six-step approach to curriculum development.

Design and Methods

Pediatric *Transfusion Camp* involves nationwide engagement of multi-disciplinary experts for content creation, delivery, and assessment design. The first group of learners include Canadian pediatric anesthesiology and pediatric subspecialty trainees in hematology-oncology. Each participant will attend two in-person or virtual pediatric-focused TM days, with additional two optional days, and will be assessed with self-reported surveys, and a paired pre- and post-test comparison. Course modification occurs in three domains:

1. Didactic content: Adding evidence-based pediatric TM content to current *Transfusion Camp* curriculum
2. TBL: Designing pediatric specific cases with content experts
3. Knowledge testing: Adapting the BEST-TEST 3, an internationally validated pediatric transfusion assessment, to Pediatric *Transfusion Camp* topics and validating the assessment through Rasch analysis

Results

Kern's six-step curriculum approach shapes Pediatric *Transfusion Camp*. A Delphi panel of pediatric experts identified 31 core TM topics for general and subspecialty pediatric trainees, comprising the curriculum

blueprint and Kern's Step 3 (Goals & Objectives). Step 4 (Educational Strategies) involves content experts in the creation of lectures and TBL seminars on topics including platelet refractoriness, perioperative management, and massive hemorrhage protocol. Each of the 21-questions in the BEST-TEST 3 were analyzed for application to blueprint topics, contributing to Step 6 (Evaluation & Feedback). Of the 21 questions, 16 are slated to be part of the pre- and post-test. Additional multiple-choice questions aligning with Delphi topics and Pediatric *Transfusion Camp* cases were developed through rigorous process in pedagogical design.

Conclusion

Launching in September 2024, the inaugural Pediatric *Transfusion Camp* curriculum aims to equip Canadian trainees with a strong foundation in pediatric TM knowledge and clinical application. Kern's six-step curriculum approach aligns pediatric TM learning objectives, content, and assessment. Though the initial cohort will be comprised of pediatric anesthesiology and hematology-oncology fellows in Toronto and Vancouver, the goal is to expand access to all Canadian pediatric subspecialty trainees in the future.

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Poster/Session Number : 70

Isohemagglutinin titres: A comparison of pathogen reduced pooled platelets manufactured with platelet additive solution versus untreated pooled platelets

Melanie Bodnar [1] *^, Dora Lopes-Carvalho [2], Tammy Ison [3], Behr Ehsani-Moghaddam [4], Cindy Lever [5], Ilona Resz [6], Mei Yiep [7], Shuoyan Ning [8], Michelle Zeller [9], Charles Musuka [10]

Abstract Summary:

Introduction:

Limitations in platelet inventory necessitate the use of ABO-incompatible (ABOi) platelets for transfusion with possible risk of an acute hemolytic transfusion reaction due to the presence of high titre (HT) isohemagglutinins (ISO). Pooled platelets psoralen-treated (PPPT) are manufactured following the division of 7 donor buffy coats in a platelet additive solution (PAS). The PAS:plasma ratio of 60:40 provides a dilutional effect on ISO levels. The purpose of this study is to compare the proportion of PPPT that test ISO HT positive versus untreated 4 donor platelet pools without PAS (UPP).

Methods:

Component-based ISO titration was performed on 1001 UPP (Nov 8 2022-Feb 8 2023) and 1019 PPPT (Jun 1 2023-Aug 31 2023) followed by testing of 834 additional group O PPPT (Sept 1 2023- Jan 19 2024) to refine the HT rate estimate. All testing was performed at a single laboratory by a manual immediate spin tube method using an aliquot of platelet supernatant diluted 1:50 with saline tested separately against A1 and B cells. Agglutination with either/both A1 and B cell(s) constituted a positive HT result. The proportion of components with HT results were compared for PPPT vs UPP. Statistical analysis was performed using SAS with p-values calculated using the Chi-Square method.

Results:

Of 1019 PPPT in PAS, 3 (0.29%) tested HT positive and all were group O. By comparison, 64/1001 (6.4%) UPP were HT positive (p value < 0.0001). The rate of HT positivity by ABO blood group for PPPT vs UPP: Group O 3/559 (0.54%) vs 53/496 (10.6%) (p value < 0.0001); Group A 0/439 (0%) vs 9/468 (1.9%); Group B 0/21 (0%) vs 2/37 (5.4%). For group A and B platelets, the relatively low rate of HT positive events in both UPP and PPPT precluded meaningful statistical comparison. Testing of 834 additional group O PPPT yielded 6 HT positive components for a total of 9/1393 (0.65%) HT positive group O PPPT (99% CI 0.23-1.43%).

Conclusions:

Greater than 99% of pathogen reduced pooled platelets in PAS have low isohemagglutinin titres using a common component-based testing assay. For PPPT, none of the group A or B tested HT positive with 0.65% positivity in group O. The significant reduction in HT positive pooled platelet components with this new manufacturing method confers a greater safety profile when ABO incompatible platelet transfusion cannot be avoided. These findings may impact hospital decisions around inventory management, platelet selection and titre testing.

Acknowledgements:

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Poster/Session Number : S1A

Implementation of sexual risk behaviour donor screening in Canada

Mindy Goldman [1] *^, Antoine Lewin [2], Christian Renaud [3], Sheila O'Brien [4]

Abstract Summary:

Introduction: In 2022 Canadian Blood Services and Héma-Québec removed the three month deferral for men who have sex with men and adopted gender neutral criteria assessing sexual risk behaviours in all donors. We assessed the impact of these changes on the safety and adequacy of the blood supply, one year post-implementation at Canadian Blood Services and 9 months post-implementation at Héma-Québec.

Methods: All allogeneic donors are asked if they have had a new partner or more than one sexual partner in the last 3 months. Donors answering yes to either question are asked if they had anal sex in the last 3 months; if yes, they are deferred for 3 months. We followed HIV rates before and after the criteria change and interviewed HIV positive donors. We assessed the number of donors answering yes to the new questions and the number deferred by age, gender, and donation status. Data on donors, donations, transmissible disease markers and deferrals were extracted from our epidemiology databases. Source plasma donors were not included. Comparisons were made using the Chi square test.

Results: There were three HIV positive donations out of 990,291 donations pre-implementation and four out of 929,384 post-implementation (0.30/100,000 vs 0.43/100,000, p=0.72). All post-implementation HIV positive donors were male, Canadian Blood Services' donors in Ontario. One was non-compliant with multiple criteria. No risk factors were identified in the other three positive donors, although one had English comprehension difficulties. 2.9% of donors answered yes to a new partner and/or more than one partner; the percentage answering yes to a new partner was higher than more than one partner (2.6% vs 1.2%, p< 0.0001). On implementation, 0.15% of donors were deferred for a new partner and/or more than one partner and anal sex. Deferral rates were highest in first time, younger donors, with similar rates in males and females, and have decreased to 0.06% one year post-implementation.

Conclusions: Implementation of sexual risk behavior donor screening resulted in unchanged HIV rates and a manageable impact on blood availability. Gender-neutral criteria have also simplified screening for trans donors. After over 30 years, we are no longer asking donors about their sexual orientation, increasing the inclusiveness in our donor base.

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Poster/Session Number : S1B

Understanding priorities and barriers to donation for communities of African and South Asian ancestry

Jennie Haw [1] *^, Poojan Joshi [2], Joyeuse Senga [3], Biba Tinga [4], Kelly Holloway [5]

Abstract Summary:

Introduction: To better meet the needs of a genetically diverse population and maintain long-term sustainability of the blood supply, many blood operators must increase the diversity of their donor pool. This presentation reports results from two qualitative case studies examining barriers to donation for communities of African ancestry and South Asian ancestry in Canada. We aimed to understand priorities for each community and how these inform barriers to donation.

Methods: Informed by community-based research methodology, we conducted two related qualitative case studies with communities of African ancestry (CS1) and communities of South Asian ancestry (CS2). Sickle Cell Disease Association of Canada (SCDAC) was the community partner for CS1; Sikh Nation and Sant Nirankari Mission were community partners for CS2. Semi-structured interviews were completed with 10 key informants in each community who identified as a leader, for a total of 20. Interviews were conducted from Dec/22-Mar/23, audio-recorded with participant's consent and transcribed. Participants had the option to review their transcript for accuracy. Data were uploaded to *NVivo 12* and thematic analysis was conducted.

Results: For CS1, community priorities included: healthcare disparities for people with sickle cell disease, inequitable healthcare services, gun violence, Islamophobia, and job security and employment equity. For CS2, community concerns included: economic concerns, challenges with healthcare systems, inadequate housing, immigration policy, declining quality of education, health challenges post-covid 19, and Islamophobia.

Key informants in both communities spoke extensively about experiences of systemic racism both at the personal and community levels in their everyday lives; however, mistrust was a barrier to donation for CS1 but not CS2. Deferral criteria were a barrier for both communities; however, results suggest that the impact on the communities differed. Another notable difference was the level of engagement with blood operators. For key informants in CS1, engagement with blood operators was minimal; however, key informants of South Asian ancestry described more extensive engagement with blood operators, which they often initiated and maintained.

Conclusion: Results suggest that barriers to donation differ for different racialized communities, and these are informed by community concerns, histories, and experiences with healthcare and state systems. Barriers

to donation should be understood within the context of each community's experiences of systemic racism more broadly beyond the donation context.

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Poster/Session Number : S1C

Cost-Effectiveness Analysis of Efgartigimod Versus Chronic Intravenous Immunoglobulin (IVIg) for Treatment of Acetylcholine Receptor Antibody Positive (AChR-Ab+) Generalized Myasthenia Gravis (gMG) in Canada

Jason Locklin [1], Angela Genge [2], Cynthia Z. Qi [3], Allen Zhou [4], Roger Kaprielian [5], David Garcia [6], Jason Locklin [7] * ^

Abstract Summary:

Introduction / Objective

Efgartigimod is a first-in-class human IgG1 antibody Fc fragment approved by Health Canada in 2023 for acetylcholine receptor antibody positive (AChR-Ab+) generalized myasthenia gravis (gMG). Efgartigimod is expected to be used among patients with AChR-Ab+ gMG whose symptoms persist despite current treatment (CT) and to primarily displace chronic intravenous immunoglobulin (IVIg) in clinical practice.

The objective of this study was to assess the cost-effectiveness of efgartigimod versus chronic IVIg for adults with AChR-Ab+ gMG.

Design and Methods

A Markov model was developed to estimate costs and benefits (measured as quality-adjusted-life-years [QALYs]) of efgartigimod and chronic IVIg for patients with AChR-Ab+ gMG in Canada. The analysis was conducted from the Canadian publicly funded healthcare system perspective over a lifetime horizon. The model comprised 6 health states: MG-ADL < 5, MG-ADL 5–7, MG-ADL 8–9, MG-ADL ≥10, myasthenic crisis, or death. Health state transition probabilities were estimated using data from the ADAPT and ADAPT+ studies, plus a network meta-analysis that compared efgartigimod against chronic IVIg. Utility values were obtained from the MyRealWorld MG study. Modeled costs included treatment and administration, disease monitoring, complications from chronic use of corticosteroids, exacerbation and crisis management, adverse event, and end-of-life care. Patients receiving efgartigimod or chronic IVIg with MG-ADL ≥5 and who did not die/discontinue were assumed to receive the treatment every 4 weeks or every 3 weeks over the lifetime horizon.

Results

Over a lifetime horizon, efgartigimod and chronic IVIg were predicted to have total discounted QALYs of 16.80 and 13.35, and total discounted costs of $1,913,294 and $2,263,906, respectively. Compared to chronic IVIg, efgartigimod incremental QALYs were 3.45 and cost savings was $350,311.

Conclusions

Efgartigimod provides greater benefit at lower costs than chronic IVIg for patients with AChR-Ab+ gMG whose symptoms persist despite treatment with CT in Canada. Limitations include model assumptions on treatment utilization and limited public evidence on chronic IVIg efficacy.

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Poster/Session Number : S1D

Isohemagglutinin Titration in Pooled and Apheresis Platelets

QingYun Hua [1] *^, Bruce Lyon [2], Jennifer Duke [3], Amanda Felske [4], Karen Hobbs [5], Ryan Holman [6], Ghazala Radwi [7], Davinder Sidhu [8], Gwen Clarke [9], Susan Nahirniak [10]

Abstract Summary:

Introduction/Objective:

Platelet inventory constraints necessitate ABO-incompatible platelet transfusion. Many labs minimize the hemolytic risk by confirming low titre (LT) donor isohemagglutinins prior to crossing ABO groups. This process is time consuming and costly. The advent of Pathogen-reduced platelets (PRP) in platelet additive solutions (PAS) should dilute plasma and decrease high titer isohemagglutinins (HT). We determined the proportion of HT platelets and incompatible transfusions to reassess the need for titres following introduction of PRP/PAS.

Design and Methods:

Our titre method is a manual tube (1:50) dilution of platelet supernatant tested with A1/B red cells. Testing included 49,058 pooled and 11,738 apheresis platelets over 4 years from 44 sites. The HT proportion was determined along with the rate of out-of-group transfusions and hemolytic reactions. The impact of PAS dilution was estimated. PRP testing was performed by Quidel Ortho automated gel.

Results:

60,796 platelet units were tested. Group O pooled and group B apheresis platelets had HT in 6.6% and 5.7% respectively. Whereas group O apheresis and group B pooled platelets had HT in 5.1% and 3.5%, respectively. Group A pooled and apheresis platelets included 2% with HT. Approximately 25% of platelets transfused were ABO incompatible and no hemolytic reactions were reported. 5,208 platelet units (8.6% of total platelet inventory) were discarded due to outdate. Out of the discarded units, 1-2% were designated HT which is slightly higher than the expected 0.5% if they were deemed equivalent to LT.

Based on the proportions of PAS-E and plasma for PRP platelets, plasma from each donor comprises 11ml (6% of total volume) vs a minimum of 20 mL and up to 257mL per donor in untreated pools. This indicates that PAS-E will dilute residual plasma by at least 50%. Preliminary testing of 20 PRP components did not identify HT units.

Conclusions:

Our data supports cessation of titre testing for transfusable platelet units to prevent hemolysis from passive

isohemagglutinins. Prospective monitoring of Immune globulin hemolysis secondary to passively acquired antibodies demonstrates rates of 3-4% which has been considered clinically acceptable. Using this as a comparator, our demonstrated baseline high of 6.6% in untreated pools would come below this following PAS suspension. Removal of HT designations will also improve inventory management and reduce platelet wastage.

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Poster/Session Number : S1E

Monoclonal anti-D induces low efficiency trogocytosis: Implications for the prevention of Hemolytic disease of the fetus and newborn (HDFN).

Yoelys Cruz Leal [1] *^, Lazaro Gil Gonzalez [2], Peter A.A Norris [3], Alan Lazarus [4]

Abstract Summary:

Abstract

Introduction/Objective

Hemolytic disease of the fetus and newborn (HDFN) is an alloimmune condition provoked by maternal IgG that crosses the placenta and causes fetal red blood cell (RBC) destruction. Donor-derived Rhesus Immune Globulin (RhIG) is the only licensed option available to prevent HDFN through a phenomenon called antibody-mediated immune suppression (AMIS). The mechanism as to how RhIG induces AMIS is poorly understood and this has hampered the successful development of monoclonal antibodies to replace RhIG. Our recent murine data suggests that trogocytosis-induced antigen loss could play a central role in AMIS induction. The present work aims to compare the ability of anti-D monoclonal antibody, clinically assessed, to promote in vitro trogocytosis under AMIS conditions compared with RhIg.

Design and Methods

RhD^+human RBCs (RBCs) were fluorescently labeled with PKH67 and sensitized with different concentrations of RhIG (WinRho, SDF) or the IgG1 BRAD5 monoclonal anti-D antibody. Sensitized vs non-sensitized RBCs were incubated with or without THP-1-CD16A macrophages for 30 min and 3 hours. Fluorescent RBCs were recovered, macrophages washed, and remaining RBCs lysed. The ability of BRAD5 vs RhIG to induce RBC membrane fluorescence loss and RBC membrane transfer to the macrophages (ie., trogocytosis) as well as phagocytosis were evaluated. Median fluorescence intensity (MFI) of PKH67 on the RBC recovered, the percentage of $PKH67^+$ macrophages, as well as their PKH67 MFI, were determined by flow cytometry. Confocal cell microscopy to visualize the interaction between macrophages and anti-D sensitized RBCs was performed.

Results

We observed that RBCs sensitized with ≥110 ng/mL of RhIG showed significant phagocytosis while lower concentrations primarily demonstrated significant trogocytosis-driven antigen loss. As the theoretical plasma concentration of anti-D in patients administered RhIG is below 100 ng/mL, our findings indicate that trogocytosis is the probable in vivo mechanism under AMIS conditions. In the case of BRAD5, this antibody, like RhIg, was capable of inducing both phagocytosis and trogocytosis. However, much higher concentrations

of BRAD5 were necessary to achieve a comparable degree of trogocytosis as compared to RhIg.

Conclusions

This work demonstrates that RhIG has the capacity to induce trogocytosis at clinically relevant concentrations, with minimal to no phagocytosis. Conversely, the BRAD5 monoclonal antibody although capable of trogocytosis, was over ten times less efficient than RhIG, mirroring its poorer efficacy in prior clinical studies for preventing RhD alloimmunization.

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Poster/Session Number : S2A

Towards Safer Transfusion Therapies: The Role of Non-Inflammatory Fcγ Receptor 1 Blockade

Yaima Tundidor Cabado [1] * ^

Abstract Summary:

Introduction: The ongoing need to reduce reliance on intravenous immunoglobulin (IVIg) in treating autoimmune and inflammatory diseases calls for novel, targeted therapeutic strategies. Given the adverse events linked with Fcγ receptor (FcγR) III blockade, this study investigates the therapeutic potential of targeting FcγRI, demonstrated herein to be non-inflammatory, offering a more specific and safer alternative to the generalized action of IVIg.

Objective: This work aims to develop an in vivo anti-FcγRI therapy as a more focused and safer alternative to both IVIg therapy and FcγRIII blockade, with potential implications for improving patient outcomes and quality of life.

Design and Methods: From a phage display library, novel anti-human FcγRI antibodies were selected based on their high affinity and specificity for FcγRI. These antibodies were characterized for their ability to block Fc-FcγRI interactions using a human macrophage cell line and to prevent macrophage-mediated phagocytosis of sensitized red blood cells. The inflammatory nature of anti-FcγRI antibodies, compared to those engaging FcγRIII, was assessed through temperature changes and cytokine responses in FcγR-humanized mice, as well as in C57BL/6 and BALB/c mice, providing a comprehensive safety profile.

Results: We developed five novel anti-human FcγRI antibodies, each demonstrating a significant ability to inhibit FcγRI-mediated phagocytosis in vitro, without eliciting adverse inflammatory responses in vivo. Notably, anti-FcγRI administration did not result in the temperature changes or inflammatory responses observed with anti-FcγRIII, highlighting the non-inflammatory benefits of FcγRI targeting.

Conclusions: Our findings support the development of anti-FcγRI antibodies as a promising, non-inflammatory therapeutic approach for transfusion medicine. This strategy not only has the potential to reduce the dependency on IVIg but also offers a safer and more specific method for modulating the immune response in patients.

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Vivarium.

Yaima Tundidor Cabado [1]*^, Innovation And Portfolio Management/Canadian Blood Services, PhD

Poster/Session Number : S2B

Quantifying residual red blood cells in platelet and plasma components: Flow cytometry and a visual inspection tool support implementation of pathogen inactivation

Brankica Culibrk [1] *, Anita Howell [2], Geraldine Walsh [3] ^, Peter Schubert [4], Ken McTaggart [5]

Abstract Summary:

Introduction / Objective: Platelet concentrates (PC) and plasma components may contain low numbers of residual RBCs (rRBCs). INTERCEPT Blood System (Cerus Corporation) pathogen inactivation (PI) requires that input components have rRBC counts < 4 x 10^6/mL. However, counting rRBCs is challenging and there is no consensus method. To support implementation of PI to produce apheresis and pooled platelets, psoralen treated, we developed a flow cytometry assay to count rRBCs and a visual inspection tool (VIT) to assess suitability of PCs for PI treatment.

Design and Methods: The flow cytometry protocol was based on the BD Leucocount Kit and used Trucount Tubes, which contain a known number of fluorescent beads, to determine absolute cell counts. PCs or plasma were diluted 10X in PBS and added (20 µL) to Trucount tubes. RBCs were labelled with CD235a (glycophorin A)-PE, diluted with 1 mL PBS and acquired (stopping collection: 2,500 beads) on a BD FACS Canto II (FACSDiva Software v8.0.1). A gating strategy based on glycophorin A-positive events was used to ensure only RBCs were counted. To develop the VIT, PCs were spiked with known RBC concentrations (1 x 10^6 rRBC/mL; 4 x 10^6 rRBC/mL; and 6 x 10^6 rRBC/mL), photographed and colour-true prints were generated. The VIT was validated using PCs spiked with known rRBC counts and determining pass or fail against the 4 x 10^6 rRBC/mL limit.

Results: The flow cytometry assay was linear up to 1,500 RBC events, beyond which it undercounted rRBC. Within- and across-run measurements of assay precision resulted in intra-assay CVs of 2.55-3.36% (n = 5 samples; 9 runs on each) and inter-assay CVs of 2.02-5.12% (n = 5 replicate samples counted in independent runs). Spiking apheresis PCs with between 0 and 6 x 10^6 rRBC/mL demonstrated the assay's accuracy (correlation coefficient 0.9997). Validation of the VIT by 10 or more users confirmed it could distinguish whether spiked units failed against the 4 x 10^6 rRBC/mL limit.

Conclusions: The flow cytometry assay is suitable to count rRBCs in PCs and plasma. The VIT is implemented and being used operationally to determine the suitability of PCs intended for PI treatment.

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Poster/Session Number : S2C

Comparative Analysis of Osmotic Characteristics and Post-Deglycerolization Survival in Biologically-Aged RBC Subpopulations

Sanaz Hemmatibardehshahi [1] *^, Andrew Holt [2], Jason Acker [3]

Abstract Summary:

Cryopreservation is a crucial long-term strategy for maintaining the quality of red blood cells (RBC) used for clinical and industrial purposes. However, it can induce osmotic stresses, leading to a 15-20% loss of RBCs during cryoprotectant addition/removal and freezing/thawing. This study investigated how biological aging influences RBC osmotic characteristics. We hypothesized that old RBCs (O-RBCs) would exhibit diminished osmotic features compared to young RBCs (Y-RBCs), contributing to their loss during cryopreservation.

Seven RCCs were pooled and the density profile was determined using Percoll® separation. 20 mL of Y-RBCs (13.18% ± 0.07) and O-RBCs (10.08% ± 0.07) at the extremes of the density spectrum, were isolated. The hydraulic conductivity (*Lp*) and solute permeability (*Ps*) of unseparated RBCs (U-RBCs), Y-RBCs, and O-RBCs were measured using stopped-flow spectroscopy. Osmoscan parameters (Ohyper, EImax, EIhyper) of RBC subpopulations were measured using a laser ektocytometer. Osmotic fragility and osmotic hemolysis of RBC subpopulations were measured. Aliquots of Y- and O-RBCs were labeled with two biotin concentrations (15 µg/mL and 48 µg/mL, respectively) and spiked back into the pooled unit. The pooled units were split into five units and underwent cryopreservation using a high glycerol/slow-cooling method. The numbers of BioRBCs were assessed following deglycerolization at three different time points (1, 7, and 14 days), using flow cytometry.

O-RBCs demonstrated significantly higher *Lp* values than Y-RBCs across NaCl solutions, with U-RBCs having the lowest *Lp* value ($p < 0.0001$). O-RBCs had the highest *Ps* during deglycerolization ($p = 0.0020$). O-RBCs exhibited the highest rigidity (KEI) ($p < 0.0001$) along with the lowest Ohyper, EImax, and EIhyper followed by U-RBCs and Y-RBCs having the highest ($p < 0.0001$). Osmotic hemolysis and osmotic fragility results demonstrated that O-RBCs exhibited superior tolerance to hypotonic solutions than Y- and U-RBCs across various osmolalities ($p< 0.05$). The number of both O-BioRBCs and Y-BioRBCs dropped post-deglycerolization by day 14 of hypothermic storage with no significant differences between subpopulations.

Despite the superior osmotic characteristics of Y-RBCs, their advantages did not translate into improved post-deglycerolization survival. Using a high glycerol/slow-cooling method may have favored O-RBC preservation, indicating the need for further exploring cryopreservation techniques tailored to specific RBC characteristics. These findings highlighted significant variations in osmotic characteristics among RBC subpopulations, laying the groundwork for future research on cryopreservation and post-transfusion survival

of RBC subpopulations.

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Poster/Session Number : S2D

Red Cell Genotyping Genomics Development Program Year 1 Progress Report: a Focus on Gender-Inclusive Blood Group Sequencing.

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Abstract Summary:

Introduction: A Next Generation Sequencing (NGS) Program was established to enhance molecular immunohematology testing services in Canada, with two concurrent arms: (1)laboratory assay development, and (2)social sciences, ethics, and legal considerations. Setup of a genomics physical laboratory infrastructure, bioinformatic capabilities, and recruitment of key staff expertise were completed the first year. Program goals include development and optimization of an enrichment blood group NGS test, in alignment with the organization's DEI and reconciliation values.

Sex chromosome ploidy, often determined by a person's gender or sex assigned at birth (SAAB), is regularly used for identity check in high-throughput genomic assays, and is critical for precise interpretation of phenotypes encoded in the X and Y chromosomes. For blood typing applications, this includes the *XG*, *CD99*, *XK* and *GATA1* genes. However, gender and SAAB are not only inexact proxies for sex chromosome ploidy, but their use raises important inclusivity considerations.

Since no blood group antigens are currently known to be encoded by the Y chromosome, an NGS blood group enrichment assay was designed with probe targets limited to relevant X chromosome and pseudoautosomal regions. To improve existing data QC and support gender-inclusive practices, we developed an objective analytic strategy that is independent of gender/SAAB information.

Methods: An enrichment probe panel was designed to capture all relevant blood group determining genomic regions, including exons, flanking sequences, and non-coding regulatory sites. Genomic DNA of 18 calibration samples, 96 test samples with known XY ploidy by real-time PCR, and 14 well-characterized panel cell samples with known Xg^a phenotype, were subjected to library preparation, enrichment, and short-read NGS. Calibration samples included known XX, XY, XO, XXXXY, XXXX, XXY, XXYY and XYY ploidies. GATK and mosdepth were used for read alignment, variant calling, and coverage estimation. A linear regression model was derived from the calibration set coverage data.

Results: Leave-one-out cross validation of the ploidy estimation tool with the calibration samples provided an $R^2 = 0.992$ and a mean standard error = 0.07 between observed and predicted values. The correlation of the copy number of X quantified by real-time PCR and by NGS was 0.93 for our test set (n=96). We predicted Xg(a+), Xg(a-), CD99-high, and CD99-low phenotypes in the 14 panel cell samples, using our sex

chromosome ploidy estimation and the GATA-binding regulatory site (rs311103) zygosity. Xg^{a} phenotype prediction accuracy and precision were 0.9 and 0.75 respectively; 4 samples were appropriately flagged for phasing ambiguity. One discordance was further investigated with Whole Genome Sequencing.

Conclusions: We present a novel analytic tool for precise quantification of blood-group related sex chromosome regions in a custom NGS enrichment panel. This novel approach supports gender inclusive practices for donors and patients.

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Poster/Session Number : S2E

Platelet Transfusion Refractoriness Due to Anti-CD36 and Challenges of Importing CD36 Negative Platelets

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Abstract Summary:

INTRODUCTION

CD36 (GPIV) is a glycoprotein expressed on white cells, red blood cells and platelets and plays an important role in regulating immune response. CD36 deficiency is more frequently found in the Black and Asian populations and is rare in Caucasians. Anti-CD36 antibodies have been reported in cases of fetal and neonatal alloimmune thrombocytopenia (FNAIT) and platelet transfusion refractoriness. CD36 has also recently been recognized as a red cell antigen by ISBT and antibodies may cause interference in a red cell antibody screen. Identification of an anti-CD36 antibody requires specialized platelet testing and patients may subsequently require CD36 negative platelets for future transfusion support. This case describes the laboratory investigation of CD36 alloimmunization and the complex process involved to import suitable platelets from an international blood bank.

METHODS

Samples were received for platelet alloimmunization testing from a 5-year-old female of African (Cameroon) descent diagnosed with AML. During her chemotherapy cycles, transfusions with random donor platelets failed to yield adequate platelet increments (post-transfusion increments < 5).

PakLx (werfen) kit was used for the detection of IgG antibodies against HPA-1-5 and GPIV and the LABScreen Single Antigen (One Lambda) kit was used to detect the presence of HLA Class I antibodies. Confirmatory testing, by Platelet Antibody Bead Array (PABA) assay, was referred to the Versiti WI – Platelet and Neutrophil Immunology Laboratory.

RESULTS

Anti-CD36 (MFI=4028) was detected by PakLx. Multiple Class I HLA antibodies (cPRA=68%) were detected by LABScreen Single Antigen kit. Anti-CD36 was confirmed by PABA by Versiti.

To meet the patient's transfusion requirements, a CD36 deficient donor, who was also an HLA-permissive match, was identified from Versiti Blood Centre of Wisconsin. The platelet import process involved the coordination of the donor's availability with the patient's anticipated transfusion needs. Other factors for

consideration included irradiation requirements, unit availability after donation, airline carrier used for shipment, flight schedules, custom and import documentation, and contingency plans due to collection/transport delays.

An adequate platelet increment was achieved from transfusion of apheresis platelets acquired from the CD36 deficient Wisconsin donor.

Pre Platelet Count	Post Platelet Count (within 24 hrs)
< 1	73
14	56
5	51
15	59

CONCLUSION

This case highlights the important clinical impacts of anti-CD36 and the logistics that are required to import international platelets. Anti-CD36 antibodies can be clinically significant and may not be detected without specialized testing. Despite the complex process to import the CD36 deficient platelets, but through the coordinated efforts with Versiti BCW, adequate platelet increments were achieved leading to effective patient care/outcome.

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