



Abstract Journal

ORAL PRESENTATIONS

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20	8:15 am - 8:25 am	MISSION POSSIBLE: Examining Behaviors in Platelet Production	Administrative Management
10	8:25am - 8:35 am	Collections: A Rolling Stone Recruitment	Recruitment
13	8:35 am - 8:45 am	Adverse Reaction Due to Hemolytic Anti-IH and Subsequent Autoantibody Mimicking Anti-U	Technical/Scientific RBC
21	8:45 am - 8:55 am	Improvements in Nucleic Acid Testing: Implementing the Roche s201 TaqScreen MPX Testing Platform	Technical Donor Testing
SH	9:00 am - 9:15 am	Sol Haberman Award Winner: Cryopreservation of Peripheral Blood Progenitor Cells By Uncontrolled Rate Freezing at -95 degrees C Using Cryoprotectant Containing a Final Concentration of 5 Percent Dimethyl Sulfoxide	Sol Haberman Award Winner

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2010 Sol Haberman Award Winner

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Cryopreservation of Peripheral Blood Progenitor Cells by Uncontrolled Rate Freezing at -95 Degrees Using Cryoprotectant Containing a Final Concentration of 5 Percent Dimethyl Sulfoxide

Oral Abstract Key  (denotes Oral Presentations)

Abstract 10

RECRUITMENT

Collections: The Rolling Stone

BACKGROUND: In the past blood centers have found themselves setting collection goals in stone. After the fiscal year started there was no adjustment to the goal resulting sometimes in over collection and in others under collection. However, most centers were able to find homes for any overages and blood centers with shortages benefited from those who over collected. Times have changed and the once set in stone goals are now “rolling”.

INTRODUCTION: The days of collect it and sell it is over. The goals are now a “rolling stone” meaning they will fluctuate up and down. In order to manage the new demand presented by a continually changing market is a challenge to all blood centers. How does the fluctuation in the market affect your recruitment and collection staff? How do you keep your recruitment staff motivated and how do you keep a stable trained collections staff?

METHODS: Recruitment: We have asked recruiters to be the buffer between usage and draw, where we used to use the ad hoc market as the buffer. When we see a decrease in demand we identify the recruiter(s) to make the reduction by removing the most inefficient drives off the calendar. We keep a spreadsheet to log the reduction so at the end of the month we can calculate whether or not the recruiter met incentive guidelines by taking into account the reduction. This has been a tool that helps keep recruiters motivated in a changing environment and allows the blood center flexibility.

COLLECTION STAFF: One of the challenges in a calendar where there is a fluid goal is how to manage collection staff. If you reduce your staff to match demand and the demand unexpectedly increases it is next to impossible to ramp up your collection staff because of the time it takes to train them. In order to meet this challenge we have changed our staffing models to include 10-20% part time staff. By hiring part time it gives us the flexibility to reduce collections without having to potentially lay staff off or if we need to increase collections the ability to ramp staffing up by making part time staff full time. In other words the part time staff is the buffer for collections.

CONCLUSION: In addressing the changing demands, the tools used above have been proven effective in keeping the recruitment team motivated. Because they are not penalized for goal reduction and the earning potential remains intact they continue to be productive.

The downside to recruitment in this situation is the relationship with the sponsor groups and how to manage the messaging when removing them from the calendar. We will be working on phase two of this challenge to address the issue of sponsor group relationships.

The collection staff model has proven effective in giving the blood center flexibility to increase or decrease collections without having to fall victim to the lengthy time it takes to train a new phlebotomist.

In conclusion this model of recruitment and collections has provided the foundation for us to manage the ever changing market demands.

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Abstract 11

COLLECTION

Comparison of HemoCue® Hemoglobin Measurement to Copper Sulfate and Hematocrit

BACKGROUND: Before a blood donation, a donor's hemoglobin or hematocrit must be determined from a sample of blood taken at the time of donation. Methods to evaluate donor eligibility include specific gravity using copper sulfate, direct measurement of hemoglobin, or hematocrit or alternate approved method to rule out erroneous results that may lead to rejection of a donor. The objective of this study was to determine whether or not there is a conservative bias in the more qualitative method.

METHODS: The HemoCue® Hb301 System was piloted and validated at three blood centers. The centers were selected based on their deferral rate for hematocrit. Two centers had the highest deferral rate in the BSI system and one had the lowest. The HemoCue® Hb301 instruments were validated included testing using two different levels of liquid control material and direct comparison of hemoglobin measurements to the center's automated cell counter. Staff was trained on instrument usage and technique. Centers involved in the study tested a total of 640 donors, minimum 200 each, using the HemoCue® Hb301 System.

RESULTS: Using 2007 collection data, based on a reduction in deferral rate of 31% (from 11.67% to 8.05%) an additional 41,920 donors could meet hemoglobin eligibility criteria. Following system wide implementation there has been an overall reduction in deferral rate of 30% (from 8.36% to 5.89%). Using 2009 collection data this results in approximately 27,000 more eligible donors per year.

Abstract 11 (continued)

CONCLUSIONS: HemoCue® Hb301 System in conjunction with staff training reduced the number of deferrals for Hgb/Hct compared to the current method of using copper sulfate. Additionally, the instrument eliminates the need for copper sulfate and hematology control QC, and results in a reduction in errors by eliminating missing, incomplete or inaccurate QC for copper sulfate or hematology controls. Based on the increase of acceptable donors and potential decrease in QC errors, implementation of the HemoCue® Hb301 occurred system-wide.

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Abstract 12

ADMINISTRATIVE

Donor Service Technicians Leveraged as Ancillary Recruiters

BACKGROUND: The decline in the economy has caused the cancellation of blood drives and lower performances of historically good drives due to layoff's and poor morale. In response to this trend, weekly meetings between Donor Services Mobile management and Donor Recruitment management were instituted for brainstorming sessions. During one of these sessions, the idea of leveraging our technicians as ancillary recruiters was formed and implemented.

METHODS: The management staff (Mobiles and Recruitment) together developed a strategy to leverage technicians as ancillary recruiters. All technicians were brought in for educational sessions covering the rationale for technicians to recruit as well as how to approach a prospective donor. As part of this education, the technicians were given sample scripts and were taught to bring a sample of the current incentive to show the prospective donor. In addition, each mobile team leader was taught to send out technicians (absolute number depended on the total number of techs at the drive and the geographic range of the drive) when a drive was considered to be "failing". In our system, a drive is considered to have failed if <65% of the projected units are collected. The ancillary recruiters were allowed to recruit prospective donors for 15 minute increments, reporting back to the drive after each 15 minute increment to assist with drawing donors if needed. This strategy was primarily instituted at drives where a recruiter was not accessible, but the technicians were also given the ability to act as ancillary recruiters even when recruiters were present.

OBSERVATIONS: Since starting this program on March 1, 2009, the technicians have performed on-site recruitment at a total of 43 drives (data through November 30, 2009). As a direct result of their endeavors, 99 additional units were brought in at these 43 drives. Of the drives for which they recruited, their efforts saved 22 drives from failing.

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Abstract 13

RBC

Adverse Reaction Due to Hemolytic Anti-IH and Subsequent Autoantibody Mimicking Anti-U

BACKGROUND: Auto-anti-U is rare, but has been reported in some patients with "warm" antibody induced hemolytic anemia. Mimicking autoantibodies are antibodies with an apparent specificity that mimicks that of an alloantibody. Studies have shown 29 of 34 mimicking antibodies were in patients whose red cells carried the antigens against which the antibody is directed. Mimicking autoantibodies have been reported in many blood group systems and are often seen with concurrent depression of the corresponding red cell antigen. Transfusing Group O cells to non Group O patients may stimulate anti-IH to react at 37 C and can lead to serious problems.

CASE REPORT: A blood sample from TH, a 35 year old African American female, diagnosed with Sickle Cell Disease (SCD) was sent to the reference lab for antibody identification with a request for antigen negative units. TH had a history of warm autoantibody, anti - C, -E, -S, -K, -Fya, -Jkb, -Lea and an antibody with HTLA characteristics. Laboratory results indicated that TH was A, Ror, M+N+S-s+, K-, Le(a-b-), Fy(a-b+) and Jk(a+b-). Because of the number of antibodies in her serum, she previously received Group O antigen negative units. However, TH had an adverse reaction to the RBCs when a hemolytic Anti-IH was detected. Her hemoglobin was 5.1 g/dL and dropped to 3.8 g/dl within 2days. Haptoglobin was 55mg/dL. Serological testing on the sample received revealed the patient as A Rh pos, auto control (1+), DAT (1+w) with Anti-IgG,-C3d and anti-IgG; negative with anti-C3. The patient's serum was evaluated by hemagglutination techniques using LISS and PeG as potentiators. Reactions were observed at 37 C (1+) and indirect antiglobulin phases (3+) with screening cells and auto control 1+ with PeG. Antigen typings were reconfirmed using neocytes harvested by direct centrifugation and hypotonic wash. Antibody identification studies using selected panel cells revealed anti-Fya, anti-Lea and a cold antibody. The antibodies to Jkb, S, C, K and HTLA previously identified could not be conclusively demonstrated. A negative reaction was observed with one of the selected panel cell which was U negative. The positive DAT result with the positive autocontrol raised the possibility of an autoantibody and could be interpreted as evidence for a warm reacting autoantibody in this case. Auto anti-U was detected in an eluate prepared from TH's RBCs. Neocytes from TH were U+.

CONCLUSION: The patient had hemolysis and developed severe anemia. Because of the patient's history of transfusion reaction and hemolytic anti-IH, eight RBCs units, A1, Rh pos blood, negative for the antigens C, E,S, K, Fya, and Jkb were transfused with no apparent adverse reaction. Since TH is U+, it was not necessary to provide U negative blood for transfusion.

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Abstract 14

TECHNICAL

Cord Blood Collections: Operational Methods

BACKGROUND: A source of hematopoietic stem cells for transplantation to patients with leukemia, lymphoma and metabolic/immune disorders is umbilical cord blood. The success of the cord blood transplantation is dependent on the volume of the unit, the number of stem cells, the quality of processing/storage, and the immune matching between donor and recipient. Since immune type (HLA type) is inherited, the chance of finding an immune match is greater within one's own ethnic community. This public cord blood bank collects cord blood units from hospital-based sites as well as through remote collections. Currently, twelve collection locations are participating and the program plans to expand the number of collection sites. The collection facility selection process is based on the number of deliveries and patient population by ethnicity. The recruitment strategy is three fold: educating the public and expectant parents in the physician's offices, childbirth education classes, and presenting the cord blood program to physicians and labor and delivery nurses.

METHODS: Only low risk deliveries (vaginal or caesarean section) by the physician/nurse with no change to the delivery practice are acceptable for cord blood collection. All physicians collecting cord blood are required to successfully complete an annual competency assessment. The collection of cord blood occurs in the third stage of labor and after the infant is delivered. The umbilical vein is disinfected, then cannulated with a sterile collection bag set and the blood fills the bag facilitated by uterine contractions. This process takes less than five minutes. Third stage labor collections are recommended for the following reasons:

- Ability to collect from placentas which may become torn or fragmented on delivery.
- Not dependent on cord blood bank staff being present
- Fewer collections are lost to clotting prior to collection
- Higher hematopoietic stem cell yield per cord

Following collection, the cord blood unit is labeled and a sample of maternal blood is obtained for viral testing and HLA/genetic studies, as needed. The cord blood unit, maternal samples and forms are stored at room temperature in a secure location within the hospital until transport to the processing center.

RESULTS: Cord Blood units that meet the quality requirements of the program are listed in the National Marrow Donor Program search program. At the end of 2009 over 20,000 units have been collected, nearly 6,000 units banked, and to date over sixty umbilical cord blood units in inventory have been out sent for transplant.

CONCLUSIONS: The quality of units is continuously monitored. Quality indicators are used to track, record product loss, handle issues and provide monitoring and feedback to collectors. If an increase in contaminated/clotted product is seen, corrective action

is immediately taken. In using the protocol described, the goal to collect, process and store only those cord blood units with high cell counts has become a reality.

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Abstract 15

ADMINISTRATIVE

Quick Communication in a Laboratory Environment

BACKGROUND: As organizations grow, the ability to disseminate information and key performance indicators (KPI's) to all employees in near real-time becomes increasingly challenging. Factors such as production requirements, varied shifts and geographic constraints restrict the use of traditional business communication, such as e-mail, meetings, and memos. Instead, digital signage, a tool in which content is shown on displays with the intent of delivering that content to specific locations at specific times, may be utilized as an effective way to provide near real-time communication with laboratory personnel.

STUDY: The displays and their associated players were strategically placed within our laboratories for optimal viewing by employees. They were networked together and configured to communicate with a central server where content and queries are posted. The players update on a pre-defined interval, and show content on specific displays. As personnel perform their job duties, the need to stop to receive current information is eliminated. Instead, they need only glance at the screens to see information most important to them. For example, associates in Accessioning view a real-time RSS feed of current shipment statistics, current training requirements from HR, and KPI's of concern from the laboratory information system, while associates in the Processing Laboratory view systems validation progress, test metrics for assays, and important production announcements. In addition, the displays show content relevant to the entire organization such as changes in policy or training opportunities.

CONCLUSION: Although targeted to the laboratories, other departments have gained benefit from displaying data on the signage. Education has reported an increased attendance at training events, internal groups such as Toastmasters have reported increased enrollment, and individuals have reported an increase in overall organizational. Since we began using digital signage, our organization has gained an increased ability to quickly and efficiently distribute information to our employees. As our business units grow, alternative communication tools such as digital signage are becoming critical to our organization's success.

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Abstract 16

TECHNICAL

Development of a Molecular Beacon NAT Assay for Hepatitis A Virus

BACKGROUND: Hepatitis A virus (HAV) is a member of the Picornavirus family and is a non-enveloped single stranded RNA virus. HAV can be transmitted to susceptible individuals through blood transfusion and plasma-derived products. The purpose of this study was to develop a high throughput semi-automated molecular beacon NAT assay that could be used to screen plasma that will be used to manufacture plasma derivatives.

METHODS: Master pool samples were created by an automatic pipetting instrument used to aliquot a portion of 96 individual samples into a single master pool sample. RNA was isolated using an automatic pipetting instrument and a commercial genomic RNA isolation kit. Bovine Viral Diarrhea Virus (BVDV) was used as an internal control. The specific primer sets and molecular beacons for HAV and BVDV were placed in the amplification reactions and potential amplicons were generated via RT-PCR. Following amplification the epifluorescence of the beacons was determined using a fluorometer.

RESULTS: The developed beacon assay detected HAV levels equal to or greater than 50 IU/ml per 96 member master pool sample. The assay demonstrated 100% reproducibility using three different lots of reagents and two different technicians performing the assay. The assay demonstrated the ability to detect HAV in plasma stored at room temperature for up to 72 hours, stored at 40C for up to 7 days and stored at -300C for 30 days. The assay also demonstrated the ability to detect and identify an individual HAV positive sample within a master pool sample containing 96 individual plasma samples. The assay was not affected by different plasma additives or interfering viruses.

CONCLUSIONS: A reproducible semi-automated molecular beacon assay was developed that can be used for high throughput "in process" testing for HAV of source plasma samples. The assay meets the requirements from regulatory agencies for the screening of units that will be used to manufacture plasma derivatives.

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Abstract 17

TECHNICAL

Fetal Screen Testing - Hospital Experiences with the Fetal Screen Kit

BACKGROUND: The Hospital Relations department at Carter BloodCare offers benchmarking information to hospital transfusion services (TS) through "feedback requests". These are com-

monly in response to regulatory compliance standard revisions, operating procedure updates, and when new processes or techniques are adopted. A recent "feedback request" was prompted by an increase in false positive results using a fetal screen kit. The manufacturer indicated that the pH of the saline used for testing was likely responsible for the erroneous results. A survey was then conducted to determine if and how other transfusion services were affected by this phenomenon.

METHOD: 124 hospitals in Carter BloodCare's service area were surveyed about their experience with the fetal screen test kit.

RESULTS: A total of 48 (39%) facilities responded to this inquiry. 12 of the 48 do not perform fetal screen testing at their facility; therefore, the percentages are calculated from the 36 facilities that do perform fetal screen testing.

- Responses by Bed Size
 - Bed Size <100: 19 respondents
 - Bed Size 101-200: 6 respondents
 - Bed Size 201-300: 12 respondents
 - Bed Size 301-400: 3 respondents
 - Bed Size 401-500: 6 respondents
 - Bed Size >501: 2 respondents
- 18 (50%) respondents reported that they have seen an increase in false positive results.
- 17 (47%) respondents stated that they have not noticed an increase in false positives with the fetal screen kit.
- 5 of the 18 facilities who reported increased false positives did not contact the vendor.
- 13 of the 18 facilities reported increased false positives and contacted the vendor; they received the following responses:
 - They are working on it
 - They could not duplicate the results
 - Suggested using buffered saline
 - Let reagents come to room temp
 - Wash test cells
 - There is no problem

CONCLUSIONS: Initially the manufacturer of the fetal screen kits did not recognize the reported incidents of false positive results as a trend. However, after numerous reports of false positive results the manufacturer re-evaluated the test kit and recalled a specific lot number due to confirmed microbial contamination present in the indicator cells which could contribute to a false positive result. This study highlights the importance of reporting product issues no matter how insignificant it may seem. The manufacturer should be able to distinguish isolated incidents from larger issues necessitating a recall.

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Abstract 18

PLATELET

Increasing the Availability of HPA-1a Negative Apheresis Platelets

BACKGROUND: HPA-1a (formerly known as PLA-1) is a platelet antigen found within the platelet glycoprotein group GPIIb/IIIa. Antibody directed toward this antigen is commonly found in cases of Neonatal Alloimmune Thrombocytopenia (NAIT) and can cause platelet refractoriness in transfused patients. Our blood center currently receives 25-30 requests per year for antigen negative platelets. In order to have antigen negative platelet products readily available when needed a project was undertaken to identify HPA-1a negative platelet donors in the blood center's donor database.

METHODS: Regular apheresis platelet donors were tested using EDTA samples routinely collected at the time of donation. Testing was performed using GTI Thrombotype I™, a molecular-based assay which applies sequence-specific primers on isolated DNA to identify the donor's genotype for HPA-1a and HPA-1b. Donors with an initial negative test were retested on a 2nd donation for confirmation.

RESULTS: Initially, donors were selected for testing based upon their status as a repeat platelet donor. Testing has since been limited to male platelet donors only. At the start of this project, the blood center had only 2 donors available to support the antigen negative product requests. Products were usually not available for 2 to 4 days at best. Thus far, our testing initiative from Aug. 2008 to May 1, 2009 has yielded 37 HPA-1a negative donors; 25 of whom have been confirmed on a second sample. The summary of donors tested to find these HPA-1a negatives is shown in the table below.

HPA Donor Testing	
Total Donors Tested	1253
Total HPA-1a Negative	37
Overall Percent HPA-1a Negative	2.95

Ethnicity	# Tested	# HPA-1a Neg	% HPA-1a Neg
Caucasian	1082	33	3.05
Hispanic	66	1	1.52
African American	36	1	2.78
Asian	13	1	7.69
Native American	6	0	0
Other	5	0	0
Pacific Islander	4	0	0
Caucasian/Hispanic	2	0	0
Hispanic/Native American	1	0	0
Caucasian/Pacific Islander	1	0	0
Asian/Caucasian	1	0	0
Caucasian/Native American	1	0	0
Asian/Hispanic	1	0	0
None Designated	34	1	2.94
Totals	1253	37	2.95
			Overall % Neg

CONCLUSION: This project was implemented with the goal of having an HPA-1a negative platelet readily available when requested. Testing will remain ongoing to maintain a database of 75 to 100 confirmed donors. With this pool of donors, we will also have the ability to be more responsive to ABO and CMV status needs of patients requiring these antigen negative platelets. Efforts to coordinate the scheduling of these donors to maximize availability of product are being developed with the help of the telerecruitment and IT departments.

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Abstract 19

ADMINISTRATIVE

Lab Assistants: What Is The Impact In The Laboratory?

BACKGROUND: Laboratory Assistants (LAs) are starting to be employed more and more by Blood Banks and Laboratories throughout the nation, and can be a very important resource. LAs are able to take some of the work load off of the Medical Technologist (MTs) by answering the phone, typing/filing paper work, and other level two testing activities. Based on a full-time 40 hour work week with benefits, on average an LA makes \$14.00an hour, while a MT makes approximately \$22.00an hour. So if the lab employs a full-time position to perform the duties listed above they would spend \$560.00 per week for a LA compared to \$880 for a MT. The lab could save \$320 a week if they employed a LA over a MT. That could equate to a savings of approximately \$1,387 per month and \$16,640 per year. The goal of this study was to determine the following: Is the employment of LAs beneficial to Reference Laboratories (RLs) and/or a Transfusion Services (TSs), does employment of LAs generate cost savings and increase MTs productivity and/or time management, and will LAs help a lab run more effectively?

METHOD: A survey of 18 questions pertaining to LAs and their duties was sent out to 28 facilities across the nation. Of this group 13were TSs and 15 were RLs. The results were evaluated and analyzed.

RESULTS: 17 (61%) of the 28 facilities surveyed responded. Of those responding, only five (29%) currently employ LAs. These facilities listed LAs responsibilities as follows: answer the phones (five), receive specimens (three), and perform component manipulations (three), issue blood products (two), order supplies (five), and other various duties as assigned (five). 12 (71%) facilities do not currently employ LAs for the following reasons: there was no need for LAs (five), LAs are not cost effective (four), could not retain staff for the position (two), do not currently use LAs but would like to in the future (one).

CONCLUSION: The data suggests that currently few RLs and TSs utilize LAs. The few facilities that are using LAs are happy to have them on their staff. These facilities reported that LAs have helped free up the MTs from answering phones and many other duties. The MTs are therefore able to do more life-saving activities. LAs help to increase MT capacity and improve efficiencies in the laboratory.

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Abstract 20



ADMINISTRATIVE

MISSION POSSIBLE, Examining Behaviors in Platelet Production

HYPOTHESIS: Mission Possible team data will prove that organizational attitudes and donor complacency towards platelet collections were the primary hindrances effecting our platelet program growth.

BACKGROUND: Team was formed in early 2009 and is comprised of Directors, Managers, Supervisors, and support staff from Donor Services, Recruitment, Laboratory Manufacturing, and IT with oversight provided by a member of Executive Management. Our original goal was to investigate our platelet failures and work towards ways of mitigating a great deal of the risk and loss associated with recruiting, drawing and manufacturing this delicate and costly product.

INTRODUCTION: As we dug deeper into our organization's long established and embedded practices related to our platelet program we discovered in large part that our to then limited success with platelets could be attributed directly to cultural behaviors.

METHODS: Donor Services - Tracks and trends numerous reports and metrics and employs two donor services staff in an advisory role to evaluate performance, offer suggestion, and to report from the field any individual or group issues that may adversely affect our current platelet production program. Collect data related to successful needle in arm procedures and compared and contrasted with average machine run times, achieved split rates, and average platelet counts reinforcing the concept that more (time) is better.

IT: Developed a mean and standard deviation to more accurately measure our highest, lowest, and outlier donor deferral staff. This allowed us to look at donor deferral rates by phlebotomist number and time of day.

RECRUITMENT: Developed a tool to be utilized by Contact Center management and our Production Planning team with our Laboratory to manage our platelet donor numbers daily.

LABORATORY: Consistently compares donor projections with actual draw and hospital usage and messages outdates and export opportunities with the Contact Center daily.

OBSERVATION: Through comparison of metrics, established a direct link between procedure time and increased split rates where the difference of only 5 minutes in most cases meant he difference between a double or triple product being collected. Also able to determine truth behind rumors that staff would defer donors based on time of day. Further discovered that these individuals had numerous issues related to compliance, poor attitude, or unsuited aptitude resulting in remediation including corrective training/ coaching up to termination.

CONCLUSION: In addressing areas of concern deemed critical in our Platelet Production we have been able to seize upon an opportunity to achieve daily organizational and customer goals. Through

reports and data this team has discovered that most issues identified are more behavioral than process. By establishing goals, monitoring results, and taking immediate action we have begun to establish a corporate culture that driven by accountability and ownership.

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Abstract 21



TECHNICAL

Improvements in Nucleic Acid Testing: Implementing the Roche s201 TaqScreen MPX testing platform

BACKGROUND: Our blood center began automated nucleic acid testing in 1999 using the Roche AmpliScreen testing platform. West Nile Virus (WNV) testing using the TaqScreen assay was added in 2003. On September 1, 2009, our blood center implemented the use of Roche's s201 TaqScreen MPX Assay for NAT HIV, NAT HCV, and NAT HBV.

METHOD: Sample processing, instrumentation, staff requirements, and throughput were compared between the TaqScreen and Ampliscreen and s201 MPX TaqScreen Assay.

RESULTS: TaqScreen and Ampliscreen testing require the use of five FTEs to prepare, pool and process the testing. The s201 TaqScreen MPX Assay has reduced the staffing requirements to one FTE for all three assays. Although the size of the pools was reduced for WNV, testing is still completed more rapidly primarily due to the more advanced pooling instrumentation offered by the Hamilton Stars. The Star has a completely integrated server, which offers a better method for positive identification by eliminating all manual scanning. Prior to this server, duplicate samples or other sample problems led to manual result updating, which is time-consuming and error prone. Our new system has eliminated that need. The s201 MPX platform detects HIV-1,2+O, an improvement over the detection of HIV-1 only on the Ampliscreen assay.

Platform	TaqScreen (for WNV) and AmpliScreen (for NAT HIV-1 and NAT HCV)	S201 TaqScreen Assay (for WNV and NAT HIV, HCV, and HBV)
Assays	WNV and HIV-1/HCV	WNV, HCV, HBV, HIV-1,2 +O
Instrument for Pooling	Hamilton AT + 2	Hamilton Stars
Instrument for Processing	Cobas Amplicor Cobas Taqman	Cobas Ampliprep Cobas Taqman
FTEs Preparation /Pooling	2	N/A
FTEs Processing Completion Time	3 13 hours	1 11 hours

CONCLUSION: The implementation of the s201 TaqScreen MPX Assay has benefitted our blood center in several ways. We can perform all of the required NAT testing with fewer FTEs. Throughput is reduced and blood component availability is improved. This technology, along with the integrated servers in our new pooling instrumentation, has greatly improved our processes in the NAT lab.

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Abstract 22

TECHNICAL

Use of Segment Samples for Cryoprecipitate Component Quality Control

BACKGROUND: Within a large, multi-center blood organization, 8 centers produce pooled cryo and submit 2 units of Pooled Cryoprecipitated, AHF to the Component Quality Control (CQC) lab for monthly QC testing for Factor VIII and Fibrinogen. These units are sacrificed for QC testing. This results in a loss of product available to our customers and a loss of revenue for Blood Systems. Annually, this represents a loss of approximately \$91,200 to the organization. An evaluation was conducted to determine if segments could be a viable option for this testing.

METHODS: Monthly, during cryo production, 2 randomly selected Pooled Cryoprecipitated, AHF units were produced with segments, following center SOPs. The components and their corresponding segments were submitted to the CQC lab for 3 consecutive months from 2 different centers. Both components and segments were tested on the BCS® System, using Multifibren U for Fibrinogen testing and Factor VIII Chromogenic for testing Factor VIII.

RESULTS: Initially, a “dry run” was performed using components and segments to answer some preliminary questions regarding whether there would be enough sample in the segments to run testing in duplicate, to test the CQC lab calculations, and evaluate the correlation between instruments and segment and component results. After these answers were obtained and deemed acceptable to move forward, a % Variance study was initiated to determine the acceptable % variance between the segments and the components. As a result of this study, a 3-month pilot was conducted at 2 centers. The acceptance criteria established for each pooled component and its corresponding segment (run in duplicate and averaged) stated that agreement must be within 10% for both Fibrinogen and Factor VIII results.

CONCLUSION: 17% of the Fibrinogen and 33% of the AHF results were greater than 10% variant between the segment and the component, ranging between 11% and 24% regardless of the analyte tested. 67% of the segments demonstrated higher Fibrinogen results compared to the corresponding components, with the remaining 33% having lower Fibrinogen results. 42% of the segments demonstrated higher AHF results compared to the corresponding components. All of the segment and component results were significantly above the cut-off of 150 mg Fibrinogen and \geq 80 IU AHF. Fibrinogen results on components ranged between 169-

458 mg and segments for the same analyte ranged between 185.5-449 mg. AHF results ranged between 146-287 IU for components and between 151.5 and 266.5 IU for segments. Based on the 10% acceptable variance, the study failed. However, additional evaluation is in progress to determine whether the use of segments is still a viable option.

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Abstract 23

ADMINISTRATIVE

Centralized Document Review (Pilot Phase)

BACKGROUND: Blood Systems Inc. (BSI) is one of the nation's largest blood service providers in the country. It is made up of 14 non-profit community blood centers, United Blood Services(UBS), which provide blood, blood components and special services to patients in more than 500 hospitals in 18 states. Record review for each location is currently performed locally. The purpose of this project is to consolidate record review and potential duplicate donor analysis by centralizing equipment, software and staff resources from 14 blood centers into two sites. The objectives is to simplify and improve processes with the addition of an electronic system, as well as to reduce costs and improve consistencies.

METHOD: The development of the Centralized Document review (CDR) began with the UBS-Rio Grande blood center (namely El Paso and McAllen, TX), which at the time employed 7 FTEs to perform record review, potential duplicate donor analysis and investigations. Upgraded software/hardware was introduced to ensure transfer of documents between the Component Processing Locations (CPL) and the CDR. Additional centers were added to the pilot with parallel runs conducted prior to the live date. A Process Tracking Record was added to the pilot as a tool to measure the effectiveness of the process.

RESULTS: The total number of FTEs has decreased under the CDR Pilot from 36 FTEs to 19 FTEs. During the CDR Pilot Phase II, it was realized that unforeseen processes (documentation, labeling time, SOP and quality assurance interpretation, etc) differences existed between centers. Therefore, additional SOP revisions were necessary. Tracking of the process shows a marked improvement in the CDR meeting completion of record review for labeling per local CPL requirements.

CONCLUSION: The initial objectives of centralizing record review and potential duplicate record analysis have been met. A reduction in FTEs for record review has been accomplished and the consistencies in the review and analysis process have been improved. The CDR Pilot Phase II is anticipated to end in the first quarter 2010. Other UBS centers will be scheduled to transition their record review process to the CDR once an electronic system is implemented.

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