KABB
Newsletter

Summer 2020

CHANNELS

INTERVIEW WITH A BOARD MEMBER

We would like to introduce Angie McCowan-Bailey. Angie is on the board of directors for KABB. She has served as the president, treasurer and secretary in the past, and now she is part of the registration committee. Angie's family includes her husband Brian, and her children Cameron (23 years old) and Courtney (20 years old). Spending time, including playing games with her family and traveling to the beach, is how she would choose to spend her free time. Angie has a pet Lionhead rabbit named Sawyer who is 7 years old and a Maltipoo named Pearl who is 13 yrs. old.

Growing up, Angie and her older sister Lisa spent a lot of time in the laboratory waiting for their mother to get off work. Their familiarity with the laboratory led to a legacy of Medical Laboratory Scientists (MLS), which includes her mother Gilda, her sister Lisa and now her daughter Courtney who will graduate from Western Kentucky University as a Medical Laboratory Scientist.

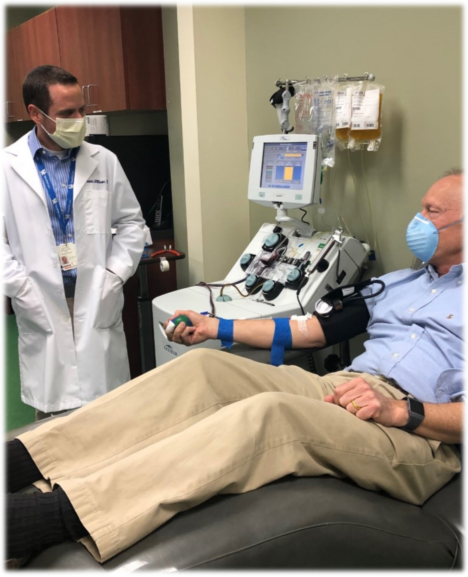
Angie would encourage others interested in pursuing Laboratory Science that there will be a career waiting for you right after graduation. She also recommends Laboratory Science as an undergraduate steppingstone to further your career if wanted. She has seen Laboratory Scientists go back to school and become a Physician's Assistant, Physician, Dentist and Surgeon. Angie's own career was influenced by her mother and her previous supervisor, Marcella Baker, whose knowledge of Medical Laboratory Science and Blood Bank encouraged her own pursuits.

Angie graduated from the University of Kentucky in 1991. She spent her first few years on the graveyard shift working in her hometown at Baptist Health Corbin, but she has spent the majority of her career serving our Veterans at the VA Hospital in Lexington, KY as the Transfusion Medicine and Tissue Bank Supervisor. Angie gets satisfaction in knowing that she is providing safe blood/blood products for our Veterans. The evolution of Blood Banking is exciting as changes allow for more automation, molecular testing and streamlining of processes to allow for electronic crossmatching.

Thank you so much Angie for sharing more about yourself with the members of KABB!

INSIDE THIS ISSUE

COVID-19 CONVALESCENT PLASMA



Dennis Williams, MD (Medical Director, Kentucky Blood Center)

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is responsible COVID-19, has disrupted all of our lives. While the mortality rate is significantly less than its predecessors, its global transmission is unprecedented. This can be partially attributed to the high number of asymptomatic and mildly symptomatic individuals; the virus is easily spread by those who don't even realize they have it. So while the mortality rate and prevalence of severe disease among those infected may pale in comparison to previous outbreaks, the total number of patients infected brings the number of life threatening cases to potentially overwhelming levels.

As this is a novel virus, no specific therapeutic agents or vaccines are available. The FDA recently issued an emergency investigational new drug protocol (eIND) for the use of COVID-19 convalescent plasma (CCP) as treatment in patients with severe or life-threatening disease. CCP is plasma from individuals who have recovered from COVID-19 and have antibodies to the virus in their blood. Infusing the plasma from recovered individuals to treat those with the disease is not a new concept. It was used to treat patients during the 1918 Spanish flu epidemic. The idea is to transfer passive immunity to the patient. Limited data shows treating COVID-19 patients with CCP may be beneficial to their outcome.

"Infusing the plasma from recovered individuals to treat those with the disease is not a new concept."

ANNUAL MEETING

Traditionally, the KABB annual meeting is held in August. As with many events, the COVID-19 pandemic has led to the cancellation of the annual meeting. This decision was made following the guidelines provided by the CDC to ensure the safety of the attendees and our community at large. We hope everyone will continue to participate in KABB through our website and Facebook page. We hope to have the meeting in 2021 and we look forward to seeing you there.

The FDA has set criteria for donor eligibility to donate convalescent plasma. First, these potential donors must meet all regular FDA donor eligibility requirements for blood donation and/or plasma donation by apheresis. Second, the donors must have laboratory proof of previous infection, either through a positive diagnostic test (i.e. NP swab) at the time of illness or a positive serologic test for antibodies after recovery. Third, the donor must be recovered, defined as 14 days after complete resolution of symptoms with a negative COVID-19 test result, or 28 days after complete resolution of symptoms, with no COVID-19 testing required. Fourth, the donor should have no risk for HLA antibodies in order to decrease the risk of Transfusion Related Acute Lung Injury (TRALI). For this reason, male donors and female donors without a history of pregnancy are preferred; female donors with a history of pregnancy require HLA antibody testing. Last, titers of neutralizing antibodies should be tested for if available, and samples stored for future testing if not available.

Kentucky Blood Center was one of the first in the country to begin collecting convalescent plasma from recovered COVID-19 patients just three days after the eIND was issued by the FDA. Since that time, plasma has been collected from more than 55 recovered COVID-19 patients. The first transfusion recipient from local donation was recently released from the hospital after a lengthy stay that included an extended period of critical care.

Hospitals have been critical in helping find recovered COVID-19 patients to make the plasma donations. Kentucky Blood Center fully vetted the potential donors, completed the pre-donation screening and collected the plasma. Most donors are able to donate enough plasma to help two patients. Kentucky Blood Center has developed a registry for recovered COVID-19 patients wishing to donate plasma and urges anyone who believes they may have been infected to register. When reliable FDA approved antibody testing becomes available, those donors can be contacted for screening. While the success of an experimental treatment like this will not be known for some time, history indicates it is a promising treatment option when there are no other known therapies available.

ANIMALS NEED BLOOD TOO

Leah Rucker, MLS (ASCP)CM (VA Medical Center, Lexington, KY)

Animals have assisted in the development of Blood Banking over the course of history. In return, blood banking technology has been used to save the animals we love through transfusion. The first successful blood transfusion was performed by physician Richard Lower between dogs in England in 1665. Blood transfusion history is older than the United States! Dr. Lower successfully transfused blood from a lamb to a human just 2 years later in France. As one might expect, however, transfusion reactions led to the discontinuation of this practice 10 years later.

Of course human blood groups include A, B, AB and O. Cats also have A, B and AB blood groups, but cats do not have group O blood. The most common type in cats is group A. At least 8 blood groups have been identified in dogs. Horses have over 30 blood groups!

While blood banking isn't something considered in general veterinary practice, there are specialized diagnostic laboratories across the United States. Of the specialized animal laboratories, The Equine Blood Testing Laboratory is located in Kentucky . Everyday, the animals we love receive life saving transfusions. These transfusions rely on donations from healthy dogs, cats and even horses.

One dog's blood donation can save four other dogs. One cat's donation can save up to two cats. Some veterinarians may even keep a donor animal around the office in case of an emergency. Blood from cats is consistently critically low in supply, so a transfusion may result in high vet bills. In 2014, the life of a cat in Florida was saved when transfused with blood from a canine donor!

Cats and dogs who donate blood must meet specifications to keep themselves and the recipient healthy. They must be up to date on all vaccinations, must meet weight and age requirements, and above all must not be stressed by a visit to the veterinarian for the donation. Instead of T-shirts and Little Debbie cakes, dogs and cats receive lots of love and treats when they donate. They also often get free bloodwork from some veterinarians.

Talk with your pet's veterinarian if you'd like more information about how your pet can save lives through blood donation.

TEST YOUR KNOWLEDGE

1. This parasite causes Chagas disease. Testing is performed on blood donor's once in the donor's lifetime.
2. This "compound antigen" is present when a person inherits an allele of the *RHCE* gene that codes for both the c and e antigens.
3. This reagent dissolves disulfide bonds and removes CD38 from the RBC surface.
4. This set of quality regulations must be followed by every clinical laboratory in the United States.
5. These antibody coated red cells are used as QC to ensure AHG reagent was added and is working properly.
6. Red cells frozen in glycerol have an expiration of _____ from collection.
7. This test using acid is used to screen maternal blood samples for the presence of fetal cells .
8. This commercial product can be used to adsorb IgM antibodies from patient plasma.
9. Antigens in this HLA blood group system are destroyed by Ficin and corresponding antibodies can be neutralized using AB pooled plasma.
10. This reagent is used by laboratories to remove IgG antibodies from the surface of RBCs. It is usually used for phenotyping.

Answers on page 5

VALIDATIONS

Kim Turner, MSQA, MT(ASCP), CQA(ASQ) , (Kentucky Blood Center VP, Quality and Regulatory Affairs)

A validation provides a high degree of assurance that a specific process will consistently produce an outcome meeting the predetermined specifications and quality attributes. The purpose of a validation is to verify that all elements of the process, which includes the SOPs, equipment, software, personnel training and workflow, function individually as expected, but also work in tandem to produce the expected results in your facility with your personnel.

Whenever a new process/procedure or a modification to a current process/procedure is going to be made, an assessment needs to be performed to determine if the new process or modification has the ability to affect the quality, safety, potency, purity or identity of a product or service, or the safety or well-being of a donor/patient. If so, then a validation needs to be performed. There are many different types of validations. They can include equipment, reagents, software, processes, and procedures. The scope of a validation varies depending on the multitude of the change.

When performing validations, it is best to start with a validation plan. Validation plans can be a formal or an informal document depending on your organization; they may vary depending on the type of validation. A plan is the roadmap to follow during the validation; it allows subject matter experts from all affected departments a chance to provide input to the process. This ensures the validation is performed in the best way to meet your organization's needs and the regulatory requirements.

VALIDATION PLAN COMPONENTS:

PURPOSE- What is the goal of this validation? Why are you doing it (ie. cost savings measure, replacement of broken/outdated equipment, increase throughput/turnaround time, etc.)? Include any information that will help the reviewers understand why this validation is being performed.

DESCRIPTION- Describe the equipment and the procedure being validated. What does it do? What it is used for?

INSTALLATION QUALIFICATIONS (IQ)- Review the Operator's manual for the equipment and include all steps recommended by the manufacturer for the installation. Developing a checklist is a good way to make sure all actions are planned, accomplished, and documented.

Examples of IQ: Compare container contents to invoice. Are all parts accounted for? Are any parts damaged? Physical space needed for new equipment? Environmental requirements? Warranty information? Correct Power supply available? Who will install?

OPERATIONAL QUALIFICATIONS (OQ)-OQ indicates items to be checked for proper operation of the equipment. OQ serves as a detailed review of hardware or software startup, operation, maintenance, cleaning and safety procedures. These items can be included in the checklist above or as a separate document. The main idea is to get it documented in order to have an organized plan for when the validation is performed.

Examples of OQ: Calibration requirements? Maintenance requirements? Supplies used in the operation of the equipment? Temperature controls? CO2 controls? Display units and signaling LEDs? Does your new equipment operate as describe in the Operator's manual?

PERFORMANCE QUALIFICATIONS (PQ)-PQ verifies and documents that the equipment is working with reproducible results within a specific working range in your laboratory with your personnel. During this phase, the new equipment should be operated as it will be used in the real world workflow.

Examples of PQ: Determine the accuracy, precision, analytical sensitivity, analytical specificity, and reportable range; Interfering substances? (Refer to 42 CFR 493.1253 for guidance) Equipment limits? Operating parameters? Sampling plan -number of samples to have a level of confidence in the new process, over the range of the instrument, under the same conditions and in the same workflow as real world samples

VALIDATION PLAN COMPONENTS *cont.*

STAFF TRAINING- How will the staff be trained on the new piece of equipment/procedure? With a Training document or memo? Will it be Self-training, Instructor training, Computer training, Demonstration/ Observation training?

DOCUMENTS- Determine if new documents need to be developed or current documents need to be modified.

Examples of Documents to consider: SOPs, Training plans, Competencies, forms, etc.

REQUALIFICATION CRITERIA- Requalification of equipment is required upon major maintenance or repair, equipment modification, and equipment relocation. Again, any change that has the ability to affect the quality, safety, potency, purity or identity of a product or service, or the safety or well-being of a donor/patient needs to be revalidated.

TIMELINE WITH RESOURCES-A timeline, with resources needed, is a good tool for management to determine the impact a validation will have on the organization and to determine if the organization can proceed with the validation as proposed.

Examples of Resources: Personnel (time needed to perform the testing, review the results, develop or modify documents, train the staff, etc.), supplies, reagents, etc.

ACCEPTANCE CRITERIA-In indicate the outcome that must be demonstrated to ensure validation is completed and successful. The process must consistently produce an acceptable product or output that meets the manufacturer's specifications, current good manufacturing practices, and accepted industry standards. This criteria needs to be defined in the validation plan.

TEST YOUR KNOWLEDGE ANSWERS

1. *Trypanosoma cruzi (T. cruzi)*
2. f [RH6] antigen
3. Dithiothreitol (DTT)
4. Clinical Laboratory Improvement Amendments (CLIA)
5. Check Cells/Coombs control cells
6. Ten years
7. Kleihauer-Betke (K-B) Test
8. Rabbit Erythrocyte Stroma (RESt)
9. Chido/Rogers blood group system
10. EDTA Glycine-Acid (EGA)

SOURCES FOR FREE CONTINUING EDUCATION:

BB GUY PODCASTS: https://www.bbguy.org/podcast/

ARUP LABORATORIES : https://www.aruplab.com/education/webinars

CAP: https://learn.cap.org/lms/lab

CDC: https://www.cdc.gov/cecredit/

IMMUCOR: https://immucor.knowledgeanywhere.com/

MEDTRAINING: https://medtraining.org/

ON COURSE LEARNING: https://www.continuingeducation.com/laboratory-technology/courses/free

ORTHO ON DEMAND: https://www.orthoclinicaldiagnostics.com/en-us/home/learning

SYSMEX: https://www.sysmex.com/us/en/Education/Pages/Training-and-Education.aspx

AMERICAN RARE DONOR PROGRAM (ARDP)

Heather Caudill, MLS(ASCP)CM, (QA Specialist II, Kentucky Blood Center Lexington, KY)

The American Rare Donor Program (ARDP) was founded in 1998 as a collaboration of the American Red Cross and the American Association of Blood Banks. ARDP is managed by the American Red Cross in Philadelphia, PA, where they maintain a national database of over 80,000 donors with "rare blood types" This allows rare blood to be located in a timely fashion, whether it be from a previously donated unit or by recruiting a donor to donate when the need a rises. Each year, AABB accredited Immunohematology Reference Laboratories are required by AABB standards to screen at least 1,000 donors for high incidence antigens or for a full phenotype to identify rare donors and to submit at least 10 donors to the ARDP each year.

If a donor is identified as being rare, they will be asked for permission to submit their information to ARDP. Once that permission is received, the identifying facility will submit the donor to ARDP and the donor will receive a welcome packet which includes a card with the donor's phenotype printed. If a need arises for the rare donor's type, ARDP sends requests to all of their members in hopes of finding a unit somewhere in the country. Occasionally, it may be necessary to recruit the rare donor to donate in order to fill the request.

Every day the ARDP receives requests for rare units and forwards those requests along to their members. With the help of the ARDP, finding units across the country is easier and more efficient than trying to locate them individually. The ARDP is fills 94-95% of the requests they receive annually, therefore, it is fairly rare to have a need go unfulfilled. Having a national database allows the ARDP to quickly identify which donors will meet a request, and expedites the recruitment of those donors if necessary.

Donors who have a rare blood type are encouraged to donate regularly so that the blood is available when the need arises. Often, rare donations are separated from the general red cell population and held aside for patients who have a special need. If necessary, rare red cell donations can be frozen in glycerol and kept frozen for up to 10 years to ensure that the product will be available when the need arises. Often rare donors are encouraged to have their family members be tested as well since their siblings or parents may also meet the requirements for rarity.

ARDP RARE REQUIREMENTS:

HIGH PREVALENCE ANTIGEN NEGATIVE– The donor must be negative for an antigen that occurs in less than 1 in 1000 donors.

IgA DEFICIENT– Donor must have an IgA level of <0.05mg/dL tested on samples from two separate draw dates.

MULTIPLE COMMON ANTIGEN NEGATIVE-The donor must meet the following criteria:

- Donors must be group O or group A unless they are of African descent.

AND

- Negative for 2 Rh antigens (R1R1, R2R2, R0R0, or rr), K-, Fy(a-) or Fy(b-), Jk(a-) or Jk(b-), AND S- or s-

OR

- R1R1, R2R2, or rr, AND K- and Fy(a-b-).

KABB 2020 MEMBERSHIP FORM

Name and Credentials (MD, SBB, MLS, MLT, RN): _____

Affiliation (Hospital, Blood Center., Company) _____

Street Address: _____

City, State and Zip Code: _____

Phone Number: _____

Email Address: _____

2020 Dues: $10.00 for Professional Membership

$5.00 for Student Membership

Make checks payable to Kentucky Association of Blood Banks

Remit Payment to: Angie McCowan-Bailey
320 Southbrook Dr.
Nicholasville, KY 40356

Would you like to:

- ☐ Participate in the Newsletter Committee
- ☐ Submit an article for the *CHANNELS* Newsletter
- ☐ Hold an office
- ☐ Be a speaker
- ☐ Participate in another committee
- ☐ _____

CONNECT WITH US!

Visit us at: www.kyassociationofbloodbanks.wordpress.com

Or on Facebook: Kentucky Association of Blood Banks—KABB

CHANNELS

Channels is the official newsletter of the Kentucky Association of Blood Banks, and as such is an publication that serves Kentucky and the surrounding areas. The mission of this newsletter is to provide information, education and a means of collaboration among those who practice transfusion medicine. Your input helps us accomplish this mission and make the newsletter more meaningful to the reader.

Please send any feedback or contributions to:
ajclark2382@gmail.com

KABB OFFICERS & COMMITTEES

PRESIDENT:
Steve Schwarze, PhD, MLS(ASCP) SBB
IMMEDIATE PAST PRESIDENT:
Elpido Pena, MD
SECRETARY:
Dennis Williams, MD
TREASURER:
Leonard Boral, MD
EDUCATION COMMITTEE CHAIR:
Julie O'Brien, MT (ASCP)
MEMBERSHIP COMMITTEE CHAIR:
Jennifer Jenkins, MPH, MT(ASCP)
WEBSITE COMMITTEE CHAIR:
Denise Smith, MT (ASCP)
NEWSLETTER COMMITTEE CHAIR:
Amanda Clark, MLS(ASCP)
STUDENT COMMITTEE CHAIR:
Donna Ratliff, MT(ASCP)
AUDIOVISUAL COMMITTEE CHAIR:
Kathy Evans, MT(ASCP), SBB

CHANNELS NEWSLETTER
Kentucky Blood Center
ATTN: Amanda Clark
3121 Beaumont Centre Circle
Lexington, KY 40513

E-mail:
ajclark2382@gmail.com

PLEASE PLACE STAMP HERE