What's on the Horizon?
The Future of Transfusion Medicine
And Cellular Therapy

Our 2018 BBANYS Annual Meeting has several different tracks. On Friday we offer an afternoon of presentations on donor related topics. This session is being held at the New York Blood Center at 310 E. 67th Street, New York, NY from 12:00 to 4:30 p.m.

On Saturday there will be 3 different tracks – Scientific/Clinical, Management/Technical and Cellular Therapy. These sessions are being held at NYU Langone Medical Center at 550 First Avenue, New York, NY.

Below are descriptions of the presentations including learning objectives. See the Schedule at a Glance for more information.

Friday, June 8, 2018

New York Blood Center at 310 E. 67th Street, New York, NY

12:15 - 1:15 a.m. - Auditorium, First Floor
Iron Depletion in Blood Donors: What Do We Know and What Can We Do About It?
Speaker: Bryan R. Spencer, PhD
Description: Recent research shows that many blood donors, especially repeat donors, have intermediate or advanced iron depletion. This talk will review the impact of blood donation on blood donor iron status, whether young donors are more likely to be iron depleted than older donors, and what measures are available to protect donors against iron depletion.
Objectives: 1. Summarize the prevalence of iron depletion in blood donors and the casual role of blood donation. 2. Evaluate available evidence regarding risk for iron depletion in high school age donors compared to older donors. 3. Review available measures to mitigate iron depletion and the potential impact on blood availability and donor iron status.

1:15 - 2:15 p.m. - Auditorium, First Floor
Donor and Component Testing
Speaker: Donna Strauss, MS
Description: Overview of required tests performed for donor qualification, product qualification and tests performed for quality control of blood products.

Objectives: 1. Describe current donor testing algorithms. 2. Discuss quality control performed on blood products. 3. Outline the current challenges of pathogen inactivation of single donor platelets.

2:30 - 3:30 p.m. - Auditorium, First Floor
Donor Qualification and Selection
Speaker: Eric Senaldi, MD
Description: This presentation will include a discussion of safety concerns for donors and patients. Changes in criteria for donor eligibility and differing criteria based on the type of donation will also be reviewed.
Objectives: 1. Describe how donor selection impacts patient safety. 2. Review eligibility criteria designed for patient safety. 3. Review eligibility criteria designed for donor safety.

3:30 p.m. - 4:30 p.m. - Auditorium, First Floor
Donor Notification, Lookback and Post Transfusion Adverse Events
Speaker: Alexandra Jimenez, MD
Description: Blood donations and transfusions can sometimes bring about events that require additional actions on the part of donation centers and hospital blood banks. In addition to providing a learning experience to any participant, this session will be a review of important aspects of the blood collection and donation process that will assist in maintaining proficiency.
Objectives: 1. Review how donors are notified and counseled about unacceptable test results on their donation. 2. Explain the hospital's roll in the various Lookback procedures. 3. Discuss the process for investigation of suspected infectious disease transmissions.

Saturday, June 9, 2018

NYU Langone Medical Center at 550 First Avenue, New York, NY.

Keynote Speaker

8:10 - 9:10 a.m. - Farkas Auditorium (Main Level)

Keynote: The Future of Stem Cell Therapies, What Every Transfusion Medicine Specialist Needs to Know
Speaker: Zbigniew "Ziggy" M. Szczepiorkowski, MD, PhD, FCAP
Description: The specialists in transfusion medicine have been active participants in the introduction of stem cell therapies into clinical practice. This rapidly growing field offers a plethora of new opportunities as well as challenges to our approach to hemotherapy of the future. This presentation will focus on the introduction of different sources of hematopoietic stem cells into daily practice as well as the development of new trends. We will review how advances in the stem cell field may affect our daily practice and attempt to foretell the next developments including in vitro manufacturing of blood components.
Objectives: 1. Describe current applications of stem cells in daily applications in transfusion medicine. 2. Identify trends in the use of stem cells. 3. Describe challenges and opportunities of wider introduction of stem cell derived cellular therapy products.

Track A: Scientific and Clinical Track

9:10 - 9:55 a.m. - Farkas Auditorium (Main Level)

Record Keeping in the Electronic Age
Speaker: Suzanne Butch, MLS(ASCP)^{CM}, SBB^{CM}, DLM^{CM}, Theresa Downs, MT(ASCP)SBB
Description: What are the challenges of record keeping in the electronic world? This session will present the requirements for document control and record keeping, provide some ideas and examples on how to manage a flexible system where both paper and electronic documents and records are created and stored in an organized easy-to-control fashion, and give tips on ways to accommodate those records that are still (and may always be) on paper.
Objectives: 1. Define the requirements for document control and record keeping. 2. Develop a process for document control and record keeping. 3. Discuss methods of overcoming the challenges of maintaining electronic and paper documents and records

10:25 - 11:10 a.m. - Farkas Auditorium (Main Level)

What's a Blood Banker to do? Options for Compliance with the FDA's Draft Guidance to Mitigate Against Bacteria in Platelets
Speaker: Jessica Jacobson, MD
Description: Discussion of the March 2016 FDA Draft Guidance on "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" and the anticipated options which may be included in the next version of the Draft Guidelines based on evidence published since 2016.
Objectives: 1. Describe the existing FDA approved options for mitigating against the risk of bacteria in platelets. 2. Discuss what the FDA is considering as additional options for mitigating against the risk of bacteria in platelets.

11:10 - 11:55 a.m. - Farkas Auditorium (Main Level)

Effective Auditing: Do's and Don'ts
Speakers: Suzanne Butch, MLS(ASCP)^{CM}, SBB^{CM}, DLM^{CM}, Theresa Downs, MT(ASCP)SBB
Description: Are you wondering how to meet auditing requirements efficiently and effectively? This session will present an audit format, schedule, audit topics and the do's and don'ts of auditing in the transfusion service, Stem Cell Processing and Donor Centers.
Objectives: 1. Define an audit. 2. Select audits to ensure compliance with regulations. 3. List three do's and don'ts for auditing.

1:25 - 2:10 p.m. - Farkas Auditorium (Main Level)

Oral Abstract Presentations:

Pre-operative Anemia Management Program Reduces Blood Transfusion in Elective Cardiac Surgical Patients
Presented by: Christine Cahill, MS, BSN, RN

The Little Hospital that Could: Building a Nationally Recognized Patient Blood Management Program
Presented by: Robert Raggi, MD, JD

A Multidisciplinary Pilot Program to Reduce Redundant Laboratory Sampling in an Adult Medical Intensive Care Unit
Presented by: Christine Cahill, MS, BSN, RN

Transfusion Associated Platelet Refractoriness in a 5 Month Old Hypoplastic Left Heart Patient
Presented by: Amy Schmidt, MD, PhD

2:10 - 2:55 p.m. - Farkas Auditorium (Main Level)
Grow it Yourself: Planting a Patient Blood Management Program at Your Institution
Speaker: Himani V. Bhatt, DO, MPA
Description: Patient Blood Management (PBM) is a significant quality and patient safety initiative that many providers are interested in. Attention to transfusion strategies and anemia management have become important in managing patients and many hospital systems have taken a multimodal approach to taking care of the patient.
Objectives: 1. Identify components of a Patient Blood Management (PBM) program. 2. Identify methods to obtain support for a PBM program. 3. List common challenges faced when starting a PBM program.

3:25 - 4:10 p.m. - Farkas Auditorium (Main Level)

Platelet Transfusion Practices in Critically Ill Children
Speaker: Marianne Nellis, MD, MS
Description: This session will evaluate the factors that influence the decision to transfuse platelets and transfusion outcomes in critically ill children.
Objectives: 1. Review the current guidelines with relevant evidence for platelet transfusions in critically ill children. 2. Discuss results from recent large observational cohort study that includes indications, thresholds and outcomes.

4:10 - 4:55 p.m. – Farkas Auditorium (Main Level)

Red Blood Cell Transfusion in Sickle Cell Disease: What Do We Know About Alloimmunization?
Speaker: Sally A. Campbell-Lee, MD
Description: Red Blood Cell (RBC) transfusion is an important tool in the treatment of patients with sickle cell disease (SCD) including use for the complications of stroke, acute chest syndrome and multi-organ failure. However utilization of this treatment is often limited by RBC alloimmunization. This lecture will review current indications for RBC transfusion as well as the latest concepts in the understanding of component, donor and recipient factors in the development of alloimmunization.
Objectives: 1. Describe the current indications for RBC transfusions in SCD. 2. Discuss the component, donor and recipient factors that have been studied which impact the development of RBC alloimmunization.

Track B: Management/Technical Track:

9:10 - 11:55 a.m. - Alumni Hall B (Main Level)

Better Together: Immunohematology and Genomics
Speaker: Christine Lomas-Francis, MSc, FIBMS; Sunitha Vege, MS
Description: This presentation will demonstrate, through case studies, the power of combining DNA analysis with hemagglutination. The value of the use of multiple serological techniques and directed DNA-based assays for resolution of complex antibody investigations and antigen typing discrepancies

will be discussed. Understanding their potential will allow the strategic use of resources to aid in clinical decision-making. Audience participation will be encouraged to share approaches to problem solving. **Objectives:** 1. Describe the use of advanced serological techniques, including enzymes and chemicals, and DNA-based testing as tools for complex antibody identification and for resolving antigen typing discrepancies. 2. Illustrate through case studies the combined power of serology and DNA testing methods in transfusion medicine.

1:25 - 4:55 p.m. - Alumni Hall B (Main Level)

Competency: Past, Present, Future
Speakers: Kathleen M. Crowley, MLS(ASCP)^{CM}, SBB^{CM}; Jennifer Dikeman, MS, MT(ASCP); Tanya Hamilton, MS, MT(ASCP), CQA(ASQ)
Description: This will be an interactive program designed to help the participants develop their own competency program. The first half of the program will be didactic, discussing competency, training and regulatory requirements. Each attendee is asked to bring their facility competency program to be used in the second half of the program, working in small group sessions.
Objectives: 1. Define competency. 2. Explain the difference between training vs. competency. 3. Create a competency program for one's own facility.

Track C: Cellular Therapy Track

9:15: – 9:45 a.m. - Alumni Hall A (Downstairs)

Adoptive Therapy with Viral Specific T cells: From Donor Derived to Off the Shelf Therapies
Speaker: Susan Prockop, MD
Description: In this presentation I will discuss the history and recent advances made in the field of adoptive T cell therapy. A brief introduction will explain the range of currently available T cell therapies. These therapies include use of expanded populations of naturally occurring T cells that are now being developed for off-the-shelf-use. The enrichment of specificity and depletion of allo-reactivity is demonstrated by how these cells behave in vivo. Open questions remain including how to optimize expansion of T cells and augment their in vivo efficacy and whether the production can be effectively scaled up. The ability to translate these successes with both T cell receptor targeted and CAR targeted T cell therapies into solid tumors has been slow to develop. Adoptive T cell therapy is rapidly expanding and there are over 300 trials on clinical trials.gov.
Objectives: 1. Discuss the approaches to making viral specific T cells. 2. List the advantages and disadvantages of donor derived vs. off the shelf adoptive T cell therapies.

10:00 a.m. - 10:30 a.m. - Alumni Hall A (Downstairs)

CD19 CAR T Cells in Hematologic Malignancies
Speaker: Jae Park, MD
Description: In the last several years, we have observed emergence of several promising immunotherapeutic approaches in solid and hematologic malignancies. One approach involved a genetic modification of patient's own T cells to express a chimeric antigen receptor (CAR) targeting a tumor specific antigen. A CAR is a recombinant receptor construct composed of an antibody-derived single-chain variable fragment (scFv), linked to intracellular T-cell signaling domains of the T-cell receptor, thereby redirecting T-cell specificity to the tumor in an HLA-independent manner. We and others have demonstrated that treatment of patients with CD19 targeted CAR T cells induce 80-90% complete response rates in patents with relapsed or refractory B cell acute lymphoblastic leukemia (ALL) and 50-60% response rates in patients with diffuse large B cell lymphoma (DLBCL), leading to approval of several CD19 CAR T cells for relapsed or refractory ALL and DLBCL. CD19 CAR T cell therapy is

associated with unique set of side effects, mainly cytokine release syndrome (CRS) and neurological symptoms. In the presentation, we will discuss the updated clinical data of CD19 CAR T cells in ALL and DLBCL as well as approaches to potentially minimize the predictable CRS and neurological toxicities.
Objectives: 1. Identify key features of the mechanism of action of CD19 CAR T cells in leukemia and lymphoma. 2. Discuss the key toxicities associated with CD19 CAR T cells.

10:30 - 11:00 a.m. - Alumni Hall A (Downstairs)

Pancreatic Islet Cells: Clinical Use and Processing
Speaker: Beth Schrope, MD, PhD
Description: Allogenic and autologous transplantation of human pancreatic islet cells will be reviewed, including indications for the procedures, islet processing techniques and results.
Objectives: 1. List the indications for autologous and allogeneic pancreatic islet cell transplantation. 2. Describe techniques used for islet isolation. 3. Discuss the results of allogeneic and autologous pancreatic islet cell transplantation.

11:00 - 11:30 a.m. - Alumni Hall A (Downstairs)

Process Validation and Root Cause Analysis in the Cellular Therapy Laboratory
Speaker: Ronit Slotky, PhD, MSc; Ljiljana V. Vasovic, MD
Description: Cellular therapy laboratory Good Manufacturing Practice (GMP) requires a robust Quality Management System (QMS). Process validation and error management are essential for maintaining GMP and serve as fundamental Quality Assurance (QA) and Quality Control (QC) tools. Process validation demonstrates that requirements for a specific application or intended use have been met, and provides assurance that new or changed processes and procedures are capable of consistently meeting specified requirements before implementation. Root Cause Analysis (RCA) is a systematic approach designed to identify the causes of errors, non-conformances, deviations and adverse events. This session will review the requirements of a good validation plan and effective RCA, and will provide essential tools for putting together process validations and Corrective Action Preventive Action (CAPA).
Objectives: 1. Explain why Root Cause Analysis (RCA) is needed for a successful Corrective and Preventive Action (CAPA), review diagnostic tools for RCA and describe the benefits of "Hard on the problem soft on the person" RCA style. 2. Define Qualification, Verification and Validation, and discuss their differences and similarities, share validation examples, and provide essential tools for good validation plans.

11:30 a.m. - 12:00 p.m. - Alumni Hall A (Downstairs)

Overlapping Issues Between Transfusion Medicine and Cellular Therapy Labs
Speaker: Laura Vesneske, MT(ASCP)
Description: This session will address the challenges of communication, shared resources, and testing between the HPC lab and Blood Bank.
Objectives: 1. Discuss notification of ABO type change. 2. Discuss receipt of HPC products on off shift in the blood bank. 3. Discuss sharing of staff resources.

1:30- 2:00 p.m. - Alumni Hall A (Downstairs)

Out of "Site", but not Out of Mind: Cellular Therapy Laboratory Functions That Occur Off-site
Speakers: Jo-ann Tonon, (ASCP)SBB, Rona Singer Weinberg, PhD

Description: This session will address the use of off-site laboratories for manufacturing and storage of cellular therapy products. Off-Site contract Cellular Therapy Manufacturing labs provide a solution for providing patients with cutting-edge cellular therapy technologies without the necessity of maintaining on-site laboratories. Contract laboratory staff are highly trained professionals that can perform standard and research protocols efficiently and according to specifications provided by hospitals, investigators, and/or pharmaceutical companies. In addition, contract laboratories provide quality and regulatory oversight and maintain all relevant accreditations thus providing outstanding service and safety economically. The challenge of finding additional space for cryopreserved cellular therapy products with a high transplant volume in a busy metropolitan center necessitates the need to find off site storage.
Objectives: 1. Describe how contract cellular therapy labs provide services to patients. 2. List factors to consider in selection of an offsite facility. 3. Describe how to perform initial and ongoing qualification of an offsite storage facility.

2:00 - 2:45 p.m. - Alumni Hall A (Downstairs)

Panel: Standardization in the Cellular Therapy Laboratory
Panel Members: Michael Ancharski, BS, ASCPCM; Scott T. Avecilla, MD, PhD; Nita Patel, SH(ASCP); Ronit Slotky, PhD, MSc; Laura Vesneske, MT(ASCP)
Description: This session will address topics in cellular therapy laboratory practice that are not currently standardized and are not dictated by regulation or accrediting body standards. Different approaches at different institutions will be discussed and analyzed.
Objectives: 1. Recognize the utility of standardizing cellular therapy practices to reduce variability among institutions. 2. Identify potential process improvements in their current practice for standardization based on panel discussion topics. 3. Apply the standardized practices developed from the panel discussion to their current methodologies.

2:45 - 3:40 p.m. - Alumni Hall A (Downstairs)

Cellular Therapy Round Table Discussion
Discussion Leaders: Michael Ancharski, BS, ASCPCM; Scott Avecilla, MD, PhD; Melissa Cushing, MD; Nita Patel; Ronit Slotky, PhD, MSc; Yvette Tanhehco, PhD, MD, MS;
Jo-ann Tonon, (ASCP)SBB; Laura Vesneske, MT(ASCP); & Rona Singer Weinberg, PhD
Description: This session will address complicated and difficult case scenarios involving cellular therapy products in a small group environment. The focus will be on new and evolving methods, products, and regulations.
Objectives: 1. Explain how to introduce new cellular therapy products and cellular therapy clinical trials into a CT Lab. 2. Discuss how to educate and train employees completely new to the field. 3. Explain an approach to comply with new regulations and standards in the CT Lab.

4:10 - 4:55 p.m. - Alumni Hall A (Downstairs)
The Meaning of GMP: Busting Some Myths
Speakers: Yen-Michael S. Hsu, MD, PhD; Lee McDonald, PhD
Description: Laboratory work in a mixed blood bank/cellular therapy laboratory crosses several compliance standards and FDA regulations. The newest cellular therapies such as CAR-T cells are “more-than-minimally manipulated”, and require processing work in compliance with Good Manufacturing Practice (GMP) regulations. This presentation will explain the purpose and meaning of GMP, and how its controls of processes, products, incoming materials and QA/QC practices work together to ensure manufacturing of quality products meeting pre-defined criteria. Chimeric Antigen Receptor (CAR) T cell product has been the new corner stone for personalized cell therapy approved by FDA recently. The current good manufacturing practice (cGMP) is the critical element for the successful production of these novel cell therapy products used in the human clinical trial. There has been an observed exponential

growth of cell therapy based trials in the US and globally. This second half of the presentation will discuss the overall journey of establishing a cGMP laboratory at an academic institution and new categories of cGMP cell therapy products to be evaluated.
Objectives: 1. Explain the purpose, meaning and basic elements of GMP. 2. Contrast GMP with blood bank laboratory controls. 3. Describe the cGMP CT laboratory's role during the development of cell therapy product manufacturing.

Please visit bbanys.org for registration information.