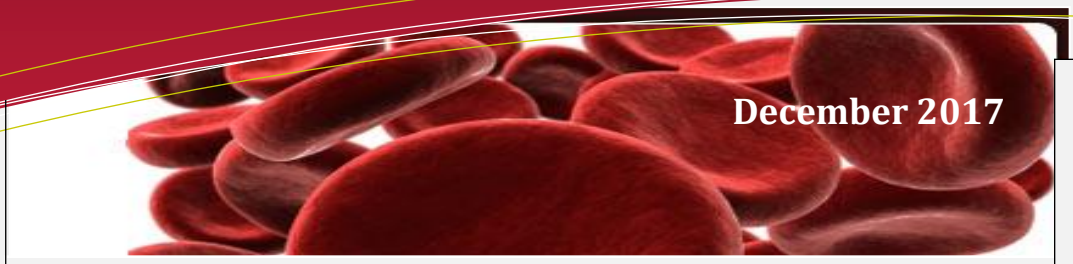
# ASBMT eNews

AMERICAN SOCIETY FOR BLOOD AND MARROW TRANSPLANTATION



December 2017


## CLINICAL RESEARCH

### Safety of Natural Killer Cell Infusions for Leukemia Relapse and Viral Infections

High doses of natural killer (NK) cells expanded ex vivo can be safely infused into patients after allogeneic hematopoietic cell transplantation, improving NK-cell function and decreasing occurrences of relapse and viral infections, reports a phase 1 clinical trial published in *Blood*. Eleven leukemia patients each received a dose of NK cells two days prior to transplantation, as well as one week and four weeks after transplantation. There were no adverse reactions to the infusions, including dose-limiting toxicities. Although seven of the patients developed grade 1-2 acute graft-versus-host disease, none of the patients developed grade 3-4 acute GVHD nor chronic GVHD. In addition, there were only minor viral complications. One patient died and one patient relapsed, but all the surviving patients were in remission more than one year after transplant and had superior quantity, phenotype and function of NK-cell reconstitution compared to leukemia patients who did not receive NK cells. More...

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# A Word From President Krishna Komanduri, M.D.

Dear Colleagues,

As I write this, I am honestly amazed at how 2017 has flown by. This column will mark my last of the calendar year, and as you read this those of you who will not be providing vital clinical care over the holidays will likely be thinking ahead to some well-deserved time with your loved ones over the winter break. Like me, you'll also be contemplating resolutions for the new year that we hope will persist at least into springtime.

When I last wrote, the ASBMT was about to conduct two events that highlight to me the vitality and critical efforts of the Society. The first was the biennial Cell Therapy Training Course conducted in collaboration with the ISCT and the second was our Annual Fall Clinical Education Conference. These events were held during the same October week in Seattle, thanks to efforts of our colleagues at the Hutch. Both the training course and the education meeting were spectacular successes. I was privileged to participate in both meetings and remain extraordinarily grateful for the efforts of the dedicated chairs, and for the time and energy invested by the many ASBMT members who presented to the receptive audiences in both venues. Already, plans are underway to consider how to continue our success with the ASBMT/ISCT 2019 Cell Therapy Training Course and the 2018 Fall Education Conference.

I noted last month the approval of a second transformative CAR-T therapy (Yescarta for CD19+ lymphomas failing prior therapies) and continued to highlight the many ASBMT efforts to ensure patient access and sustainable success of cellular immunotherapies, including autologous engineered T cell therapy. The ASBMT continues to be a leader in advancing the regulatory and reporting framework that will be needed to track clinical activity and obtain reimbursement for these therapies. For example, the Society is leading efforts to develop codes (e.g., CPT codes to designate efforts to prepare and infuse engineered T cell products) needed to ensure tracking and reimbursement of efforts. Since prices could not be anticipated prior to FDA approvals, and since reimbursement frameworks for public and private payers follow approval, we are closely monitoring issues of access and reimbursement critical to the cell therapy centers and patients who are at the core of our membership and mission.

One issue of immediate concern is the lack of a suitable Medicare reimbursement model for inpatient care of patients for older patients, who are expected to constitute a significant fraction of patients eligible to receive and likely to benefit from CD19-directed CAR-T therapies for lymphoma. Medicare reimbursement models struggle to adjust to new technologies used in the inpatient (MS-DRG) setting and adjustment to reimbursement rates can lag years behind introduction of new technologies. Due to the unique aspects of CAR-T, in that it is a new therapy with high cost but potentially significant benefit, we are concerned that the delay in the usual Medicare reimbursement adjustment processes will create financial barriers to care in the short-term. Our advocacy in this arena has included direct comments to the Centers for Medicare and Medicaid Services (CMS) to ensure adequate reimbursement that will be needed to provide access to patients at great need for these therapies. In November, I along with Stephanie Farnia our health policy director and others met with senior officials in the Center for Medicare and Medicaid Innovation (CMMI) to discuss these concerns. Critically, it is not our role to comment on or defend pricing of these products, but to ensure that the provision of these therapies in the transplant and cell therapy centers we represent

*Continues on page 3*

## PRESIDENT'S MESSAGE (CONTINUED FROM PAGE 2)

is both viable and sustainable from a clinical and financial perspective, irrespective of care setting. We will continue to address all aspects of these developing therapies, including advancing the science, clinical care and health economics framework needed to ensure there short and long-term success.

As the year ends, I want to remind all of you to vote in the ASBMT elections for new officers (including our 2020-2021 President!) and to finalize your plans to attend the 2018 Tandem Meetings in Salt Lake City. I'm excited to report that at this early stage that advance registrations are running ahead of the record pace of the last two meetings, which reflects the vitality of our field and the outstanding program that Jerry Ritz and Fred Appelbaum (ASBMT and CIBMTR meeting co-chairs) have put together. I look forward to the incredible scientific and clinical exchange that will occur in February.

Finally, I want to thank all of you for your support, feedback and efforts on behalf of the Society in 2017. I wish each of you a very happy and restful holiday season, and hope that the new year is filled with personal and professional success, good health and joy for you and your loved ones. I will give thanks over this holiday for the great privilege of leading this Society, and to seeing and interacting directly with many of you in 2018.

*Krishna*

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## CLINICAL RESEARCH (CONTINUED FROM PAGE 1)

### Third-Party Virus-Specific T Cells Used to Treat Viral Infections

Researchers have discovered that third-party virus-specific T cells can be used to safely treat some patients with resistant viral infections after allogeneic hematopoietic cell transplantation and have long-term benefits, according to a study published in *Blood Advances*. This clinical trial included 30 patients with either cytomegalovirus (CMV), Epstein-Barr virus or adenovirus after standard therapy. Patients were administered infusions of partially HLA-matched, third-party, ex vivo-expanded virus-specific T cells anytime between one month and one year after transplant. For one year, researchers monitored patient safety, viral dynamics and immune recovery. The infusions were safe and well tolerated, and acute graft-versus-host disease occurred in only two patients. At the end of the year, the overall response rate was 93%. Most patients had viral control, but five of the patients required the reintroduction of antiviral therapy after the final infusion. Of those with viral control, CMV-specific T-cell immunity increased as did $CD8^+$ terminal effector cells. PD-1 expression was elevated on $CD8^+$ lymphocytes before third-party T cells were infused and remained high at the time of viral control. More...

## CLINICAL RESEARCH (CONTINUED FROM PAGE 3)

### Bortezomib Maintenance Therapy After Tandem Autologous/Allogeneic Transplantation

New study findings suggest that bortezomib maintenance therapy after tandem autologous/allogeneic hematopoietic cell transplantation improves survival for newly diagnosed high-risk multiple myeloma patients. The study appearing in *Blood Advances* included 31 patients, 26 of whom received an HLA-matched allogeneic transplantation approximately two months after an autologous transplant. Among the transplant recipients, 21 patients received one of two bortezomib doses every two weeks for nine months. According to the findings for 24 newly diagnosed high-risk patients, 71% had two-year progression-free survival, 52% had four- year progression-free survival,75% had two-year overall survival and 61% had four-year overall survival. In addition, the seven other patients, who had relapsed or persistent disease, had two-year and four-year progression-free survival of 14%, two-year progression-free survival of 43% and four-year progression-free survival of 29%. The researchers concluded that bortezomib maintenance therapy benefits may prevent multiple myeloma from progressing until a graft-versus-myeloma effect can be achieved but that the same benefit does not apply to patients who previously had unsuccessful therapy. More...

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## ASSOCIATION NEWS

### DiPersio Receives NCI Outstanding Investigator Award

*By Julia Evangelou Strait*

ASBMT President-Elect John F. DiPersio, M.D., Ph.D., of Washington University School of Medicine in St. Louis, has received a $6 million outstanding investigator award from the National Cancer Institute (NCI) of the National Institutes of Health (NIH) to support research aimed at improving therapies for leukemia.

Dr. DiPersio, the Virginia E. and Sam J. Golman Professor of Medicine in Oncology, is also deputy director of Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine. He is a leading expert in understanding and treating leukemia, a cancer of the blood-forming cells in the bone marrow. Along with chemotherapy, the standard of care for leukemia is a stem cell transplant, commonly referred to as a bone marrow transplant.

Dr. DiPersio (right) speaks with fellow oncologist Armin Ghobadi, M.D.

"One of our major goals is to optimize stem cell transplantation — both in making the process of donating stem cells faster and more efficient and in finding ways to control the potentially damaging side effects of the transplant," Dr. DiPersio said. "A stem cell transplant is often the only curative therapy for these types of blood cancers. But the transplant itself can be life-threatening if the donor's stem cells begin to attack the patient's vital organs. If we can control and prevent these side effects, it could have a significant impact on patients."

# ASSOCIATION NEWS (CONTINUED FROM PAGE 6)

## Plesca Chosen as Inaugural ASBMT Pharmacy SIG New Investigator Award Recipient

Dragos Plesca, Pharm.D., Ph.D., BCOP, will be honored with the very first ASBMT Pharmacy Special Interest Group (SIG) New Investigator Award at the BMT Tandem Meetings February in Salt Lake City.

Pharmacy resident program director at the Carolinas Medical Center and Levine Cancer Institute in Charlotte, North Carolina, Dr. Plesca's project title is "Acquired immunity in multiple myeloma patients undergoing maintenance therapy post autologous stem cell transplantation." His research will be fully funded in the amount of $25,000 per year for two years, and is sponsored by Takeda Oncology.

"This award will offer the opportunity to gain invaluable knowledge in the humoral and acquired immunity of multiple myeloma patients undergoing maintenance therapy post-transplantation, and at the same time will promote involvement in clinical and translational research by new pharmacist investigators," said Dr. Plesca.

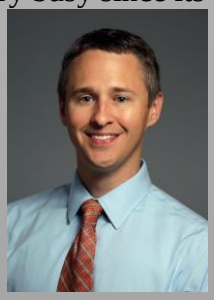
As the PGY2 Oncology Pharmacy Residency Program Director and member of the PGY1 Pharmacy Residency Advisory Committee, he mentors trainees as well as new practitioners in various research studies aimed at improving the outcomes of patients with cancer. He has served as the chair of the ASBMT Pharmacy SIG Research Subcommittee in the past, and is planning to continue dedicating time and effort to promoting research initiatives in the field of cellular therapy and stem cell transplantation by both junior and senior pharmacy practitioners.

*This is the first time the ASBMT Pharmacy SIG has given this New Investigator Award. The winners of the ASBMT New Investigator Awards, given annually for nearly 10 years, will be announced in the coming months.*

## SIG Spotlight: Palliative and Supportive Care Special Interest Group

*By Thomas LeBlanc, M.D., Co-Chair*

The Palliative and Supportive Care Special Interest Group (SIG) has been very busy since its recent transition from being a "task force" to an official special interest group.



Several of our members presented at the 2017 Tandem Meeting's Presidential Plenary Session on palliative care, a well-attended session that generated great interest in the topic and in our emerging SIG.

As the SIG has grown and developed, we have recognized the need for more data to guide our work and our practice. This led to the development of a national survey study to better understand transplant clinicians' practices regarding palliative care and yield actionable data to guide future SIG efforts. This work was done with the support of the ASBMT and in partnership with the National Marrow Donor Program.

In total, nearly 300 transplant physicians nationwide completed the survey, and we learned several important things about knowledge, perceptions, attitudes, access and use of palliative care services. This work was accepted for poster presentation at the 2017 American Society of Hematology meeting in Atlanta, and manuscript writing is currently underway.

Next, we will develop a patient and caregiver survey in partnership with the NMDP to help us better understand the perspectives of patients and families regarding palliative care. Key areas of focus for the future include educational outreach about palliative care and ongoing research about

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## ASSOCIATION NEWS (CONTINUED FROM PAGE 5)

### SIG Spotlight (continued from page 5)

the unique palliative care needs our patients and families face in hematopoietic cell transplantation.

Continuing in this theme, several of our members will be presenting at the 2018 BMT Tandem Meetings, including a session on palliative care at the BMT Clinical Education Conference for NPs, PAs, fellows and junior faculty.

If you are interested in joining the SIG, or if you'd like to know more, click here.

### Voting for ASBMT Officers and Directors Begins Soon

The annual online election of ASBMT officers and directors will begin very soon. Qualified members will receive voting instructions via email. Please plan to participate in this important process.

### Special Session at ASH - Hematologic Response to Mass Casualty Radiological Disasters

The Radiation Injury Treatment Network (RITN) was asked to do a special session at the 59th American Society of Hematology (ASH) Annual Meeting & Exposition in Atlanta this month. The session, "Hematologic Response to Mass Casualty Radiological Disasters" will be held Dec. 10 from 9:30 a.m. to 11 a.m.

The panel discussion will cover existing preparations for mass casualty radiological disasters that affect the United States and how the hematology and oncology community will be brought to bear to assist. The sessions will begin with a description of the disaster scenario, its complications and the resulting surge in medical care that will impact the entire nation (this can be applied to any nation in the world, and an international radiological connection will be included). The scenario will be followed by a brief overview of the RITN including the preparedness efforts to date as well as description of resulting resources available to the hematology/oncology community.

Dennis L. Confer, M.D., chief medical officer, National Marrow Donor Program, associate scientific director, Center for International Blood and Marrow Transplant Research, will lead the discussion. For more information about the session, visit here.

### Visit ASBMT at ASH

Do you plan to attend the 59th American Society of Hematology (ASH) Annual Meeting & Exposition in Atlanta Dec. 9-12? If you do, please drop by booth #1947 in the exhibit hall to meet friendly representatives from ASBMT.

### Dr. Stephanie Lee Elected Vice President of American Society of Hematology

*By Molly McElroy*

The American Society of Hematology (ASH) has elected Stephanie Lee, M.D., M.P.H., a member of the Clinical Research Division at Fred Hutchinson Cancer Research Center, to be its vice president.

The one-year term will begin after the 2017 ASH Annual Meeting Dec. 9–12 in Atlanta. It will be followed by successive one-year terms as president-elect and then as president. ASH announced the news Nov. 1.

Lee will be the first Fred Hutch faculty member to serve on the ASH Executive Committee since Hutch bone marrow transplant pioneer and Nobel laureate E. Donnall Thomas, M.D., served as president in 1988.

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# ASSOCIATION NEWS (CONTINUED FROM PAGE 6)

## Lee Elected Vice President (continued from page 6)

"We are thrilled by Dr. Lee's accomplishment and the role she will have in leading our field," said Gary Gilliland, M.D., Ph.D., president and director of Fred Hutch. "It is particularly notable that she is the first Hutch member to be elected president of ASH since Don Thomas."

Dr. Lee has been a member of ASH for 22 years, and during that time she has served in various leadership roles, most recently as ASH secretary. She previously chaired the ASH Scholar Awards Program Study Section.

To read this story in its entirety, visit here.

## ASBMT Self-Directed Learning Quiz

On behalf of the ASBMT Committee on Education we are pleased to introduce "Basic Principles and Practices of Hematopoietic Cell Transplantation and Cell Therapy – Question and Answer Approach," a new self-directed learning quiz highlighting hematopoietic cell transplant and cell therapy topics. Answers to each question appear with evidence-based "non-exhaustive" peer-review commentary. Our aim is to provide you with a credible and freely available educational resource. Questions generated and reviewed by Syed Abutalib, MD, Mark R. Litzow, MD, and William A. Wood, MD.

To see this month's quiz, click here.

## 2018 Fundamentals of HCT Training Course

The Fundamentals of HCT Training Course will be held Saturday, March 24 from 1 p.m. to 6 p.m. and Sunday, March 25 from 8 a.m. to 1 p.m. at the fourth HOPA Annual Conference at the Denver Convention Center and Hyatt Regency Denver.

Details will be available soon here.

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# BMT TANDEM MEETINGS

## 2018 BMT Tandem Meetings

Salt Palace Convention Center
Salt Lake City, Utah
Feb. 21–25, 2018

## Poster Presenters: New for 2018, Share Your Research Using PosterCast!

Are you presenting a poster at the 2018 BMT Tandem Meetings? ASBMT invites you to communicate your data using PosterCast, a free smartphone app that will let meeting attendees stream a succinct audio explanation of your poster as they view it. PosterCast streaming is especially valuable during viewing hours, when posters are unattended by presenters.

In early 2018, ASBMT will email you a unique key that will allow you to quickly and easily create and upload a three-minute audio description of your poster. At the meeting, attendees will be able to scan a barcode on your poster and listen to your description. It's like using a self-guided audio tour at an art museum. You can learn more about PosterCast at postercast.com.

## BMT Tandem Meetings (continued from page 7)

**Attend the 2018 BMT Tandem Meetings Virtually!**

If you can't get away to the 2018 BMT Tandem Meetings in Salt Lake City – but don't want to miss out on things your colleagues are experiencing – there is a way to participate VIRTUALLY.

Once again, you can actively participate in several of the sessions right from your computer – without getting on a plane. This year, however, we will be using a different platform – without avatars. You will still see what the "in-person" attendees are seeing and hear what they are hearing in real time.

Participants will have access to presentation slides and live audio, including an interactive chat platform for questions and answers through session moderators. Select plenary sessions, concurrent sessions and symposia are included in the offering.

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## Legislation & Regulation

**Policy Perspectives**

*By Stephanie Farnia, ASBMT Director of Health Policy and Strategic Relations*

"Winter is coming…" I have never seen "Game of Thrones," but I am told this phrase is an ominous bit of foreshadowing. In the slightly less bloody realm of health care policy, winter is instead a brief and welcome respite from the Medicare rule-making cycles that dominate the calendar between April and November. It also affords a bit of time to reflect on accomplishments of the year to date, prioritize issues left undone and start to develop plans to tackle those concerns.

My primary regret in the close of this year is having had to tell many of you that certain issues – of real importance to your programs – need to wait in queue behind other matters; as someone that has long asked members of the transplant community to consider problems of access and reimbursement, it is painful to know that not all can be addressed simultaneously. 2017 was the year of CAR-T from the reimbursement perspective, and my hope is that 2018 allows me to re-integrate HCT concerns into the working agenda.

There are a number of significant updates since late October. Each of the following items and issues deserves its own long form discussion, but due to the constraints of the space time continuum, brevity will have to suffice.

**Hematopoietic Cell Transplantation**

- **HR 4215**: The National Marrow Donor Program (NMDP)/Be The Match has successfully introduced legislation in the House of Representatives that would require the Centers for Medicare & Medicaid Services (CMS) to pay for HCT donor acquisition costs in the same way they utilize for solid organ transplant. The simple version of this is essentially pass-through payment of

*Continues on page 9*

## LEGISLATION & REGULATION (CONTINUED FROM PAGE 8)

**Policy Perspectives (continued from page 8)**

donor costs, calculated on a center-specific 'reasonable cost' basis each year. Now that legislation has been introduced, it is crucial to contact offices and ask them to move this forward. Please see the NMDP/Be The Match page on this issue for more information.

- **Medicare Coverage of HCT for Lymphoma**: As many of you know, there is no clear national Medicare coverage policy for lymphoma, leaving each center to attempt to try to gain coverage for individual patients when needed. The ASBMT and NMDP have been working on this jointly for the past several years. In July, Dr. Komanduri was asked to present to a group of Medicare Administrative Contractor (MAC) medical directors and shared information on the need for HCT as an option to treat lymphoma. In October, one regional contractor – National Government Services (NGS) – issued a Local Coverage Article supporting the use of HCT for certain lymphoma diagnoses. Please share with your financial teams, as the information is new and may not have been highlighted in contractor communications. For those of you outside of the NGS area, this is a great resource to utilize when requesting approval of patient cases through your own MAC. Resources: NGS Article A52879 and detail on the codes included on this NMDP/Be The Match reference sheet.
- **Medicare Coverage of Leukemia Codes**: The current National Coverage Determination (NCD) for HCT provides coverage for "…leukemia, leukemia in remission…" This phrasing implies coverage for individuals with leukemia, regardless of disease state, i.e. leukemia (without having achieved remission) and leukemia in remission. However, all coverage *language* is translated into *billing codes* for the purposes of claims processing, and the intent of the language may not always be retained in this process. In this case, when the diagnosis code set for the covered indications were converted from ICD-9 to ICD-10, an overly limited list of codes was created and programmed into the Medicare Code Editor. These edits resulted in denials when a patient claim was submitted with a code that read "leukemia, not in remission/without having achieved remission," despite the broader allowance that the NCD language allows. The ASBMT and NMDP approached CMS about this issue in 2016, at which time the Coverage and Analysis Group said they would take it into consideration for future updates. In early November, CMS published a summary of changes to coverage coding tables that went into effect at the beginning of the 2018 fiscal year (Oct. 1, 2017) and included updates to the coding table for the Stem Cell Transplantation NCD (110.23). The updates clarified that codes for leukemia subtypes not having achieved remission are covered and also added codes for polycythemia vera and CLL BCR/ABL-positive. As with all things on the CMS website, it is a bit complicated to get to the reference documents for these issues. Start with the MLN Matters article (MLN10086), click on the link to the NCD spreadsheets at the end of the bulleted list of changes, open the zip file and look for the spreadsheet corresponding to NCD 110.23. There are several tabs that allow you to then look more closely at CMS's interpretation of the codes which should be allowed to pass through the code editor.

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## LEGISLATION & REGULATION (CONTINUED FROM PAGE 9)

**Policy Perspectives** **(continued from page 9)**

**CAR-T**

- The ASBMT Recommended Coding Guidance document can be found on the website. Thank you to the 300+ of you that joined us on our recent webinar to explain this effort.
- The Novartis product, Kymriah, was granted a Q code by CMS that can be used in the outpatient setting for provision of the product. Note that the code includes payment for leukapheresis.
- Two additional letters were submitted to CMS and the Center for Medicare & Medicaid Innovation (CMMI) requesting new solutions to the reimbursement issues associated with the provision of CAR-T to Medicare beneficiaries in the inpatient setting. Copies of the letters can be found on the Advocacy Archive page and are considered to be public documents. ASBMT representatives met with CMMI staff on Nov. 27 to discuss the potential for a model that would allow for site-neutral separate payment for CAR-T products. More discussion will be forthcoming.
- While we are not at liberty to discuss details, the ASBMT has submitted requests to the American Medical Association for new CPT codes to describe the procedural aspects of CAR-T. Presentation of the applications will take place in early February. The codes would not be effective until 2020 due to the coding approval and update cycle.

**CMS Rule Making**

As it is the holiday season, I will give you the gift of not discussing the finalized CMS rules for the Quality Payment Program, the Physician Fee Schedule and the Outpatient Prospective Payment System until January.

For those of you that will be attending the American Society of Hematology meeting, I'll keep an eye out for you. I will never be as Twitter-prolific (Twitterific?) as @BldCancerDoc or @DrMiguelPerales, but I will share key reimbursement and policy information as I can. @HCT_Policy

I have greatly enjoyed my first full year with the ASBMT, and I am thankful for the first-hand view into the passion and commitment you bring to your work. I wish all of you a peaceful holiday season and will look forward to more partnerships on these issues in 2018.

## FACT UPDATE

**Prepare for the 7th Edition Hematopoietic Cellular Therapy Standards**

The Foundation for the Accreditation of Cellular Therapy (FACT) is preparing for the 7th edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, and we are here to help you do the same! Several upcoming events will provide information regarding changes made and how to comply. The 7th edition will be published on March 1, 2018, and will become effective on May 30, 2018. At that time, FACT will also publish minimal changes to the FACT Immune Effector Cell Standards, Version 1.1, in an effort to provide consistency and transparency among all sets of FACT Standards.

The following workshops will extensively discuss changes to the 7th edition:

Cellular Therapy Inspection & Accreditation Workshop at the BMT Tandem Meetings
Cellular Therapy Collection Workshop at the ASFA Annual Meeting
Cellular Therapy Inspection & Accreditation Workshop at the ISCT Annual Meeting

# FACT UPDATE (CONTINUED FROM PAGE 10)

## Now Available: Example Documents for Immune Effector Cellular Therapy Programs

Several examples of educational content, guidelines, and forms for immune effector cellular (IEC) therapy programs are available on the FACT website. These documents are to enhance understanding of processes that must be formalized and documented in a program, and may also serve as a resource as programs formalize their IEC-related processes. These documents are only examples of implementing aspects of an IEC program, and FACT does not require that these specific documents be used. View the example documents.

## Read the *Just the FACTs* Newsletter

The *Just the FACTs* newsletter, 2017 Volume 2, is now available online for you to read, review and search articles within volumes and over time. The *Just the FACTs* newsletter has become a trusted resource for our constituents, and its online capabilities make it even more useful.

Articles in this volume include:

- FACT Announces 2017-2020 Strategic Plan
- Many New Developments in FACT Standards Development Activities
- Inspection of Fixed or Non-Fixed Cord Blood Collection Sites? That is the Question for FACT
- We are a FACT-Accredited Transplant Program Providing Immune Effector Cellular Therapy
- Michele Sugrue Outlines Her Recipe for Successfully Performing FACT Inspections
- Many more!

## WMDA-NetCord Webinar: Manual and Automated Methods for Thawing of Cord Blood

**Rescheduled for Wednesday, March 21, 2018**

This WMDA-NetCord webinar is scheduled for Wednesday, March 21, 2018, at 11 a.m. EDT, 3 p.m. GMT. Cellular therapy departments must thaw cord blood units, and they often use very different processes from the procedures outlined by the cord blood bank providing the unit. These SOPs are sent by the cord blood bank and are not always adapted to the disposals and reagents used by the department who then thaw the units. Diane Fournier, Ph.D., of Héma-Québec, and Roger Horton, Ph.D., of The Anthony Nolan Cord Blood Bank, will discuss manual and automatic thawing methods used by different departments for thawing of these units, and what can be done to improve recovery of the cells. Also, a multi-center study for harmonization of post thaw analysis of CD34 and CD45 cells will be presented. View meeting details and register here.

## Feedback Requested Regarding NetCord-FACT Standards

Clinical programs often receive cord blood units from FACT–NetCord accredited banks. FACT and WMDA-NetCord invite you to complete a short survey focused on general concepts of interest regarding the NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration. The results of this survey will be reported to the Standards Steering Committee for review and consideration as it begins to draft the next edition. Your input helps maintain the clarity, usefulness, and relevance of the Standards. Responses will be accepted through Dec. 29, 2017. The 7th edition is scheduled for publication in October 2019. Complete the survey.

# FACT UPDATE (CONTINUED FROM PAGE 11)

## FACT Events at the 2018 BMT Tandem Meetings

FACT will host several popular events at the 2018 BMT Tandem Meetings in Salt Lake City. Join us for this educational programming to gain well-rounded knowledge about the FACT Standards and accreditation process.

### Cellular Therapy Inspection and Accreditation Workshop – Feb. 20

The blood and marrow transplant field has been a leader in voluntarily improving quality, and accredited Clinical Programs are currently adapting to several new FACT Standards and procedural changes to the accreditation process. This workshop will provide background on these changes. The morning workshop sessions include major topics such as how to effectively transition to the 7th Edition Hematopoietic Cellular Therapy Standards, CIBMTR data audits, clinical outcomes including center reported causes of low survival and the accreditation of immune effector cellular therapy programs.

The afternoon session includes two different tracks: New Inspector Training Orientation and Common Citations. The Inspector Training track includes sessions on the FACT accreditation process, what documents to review before an inspection, the ins and outs of performing an onsite inspection, how to conduct an exit interview, and finally, how to make your case via the inspection report. The Common Citations track will review recent deficiencies and corrections related to commonly cited Standards in the areas of quality management, personnel, and donor information and consent to donate. Sessions are accompanied by exercises and group discussions to practically apply lecture concepts to real-world experiences.

Note: Inspector trainees are required to attend the New Inspector Training Orientation Track.

View meeting details and register here.

### Cellular Therapy Leadership Course 101 – Feb. 20

Do you want to improve your leadership skills? Everyone wins when leaders get better, and this half-day course is designed for that outcome. The course is open to anyone who has (or aspires to) a leadership position in cell therapy – whether you direct a transplant center or laboratory, lead a cell collection service or cord blood bank, head a staff of nurses or transplant coordinators, hold an office or board position in a volunteer organization, chair a committee, or have any position in which you are expected to motivate and lead a team. View meeting details and register here.

### Cellular Therapy Advanced Leadership Course 201 – Feb. 20

If you completed FACT's Cell Therapy Leadership 101 course previously and want more, the 201 course is for you. This advanced workshop drills deeper into organizational development and leadership skills. Participants in the prerequisite Cell Therapy Leadership 101 course in the morning also are eligible to register for the 201 course in the afternoon. View meeting details and register here.

### FACT-ASBMT Quality Boot Camp – Feb. 21

Join us for the FACT-ASBMT Quality Boot Camp at the 2018 BMT Tandem Meetings on Feb. 21 in Salt Lake City. This year's boot camp will focus on topics identified by programs and FACT as challenging. The boot camp will strengthen your quality assurance activities through an in-person workshop. Members of the FACT Quality Committee and the ASBMT Administrative Directors SIG Quality Working Group encourage you in the months leading up to the BMT Tandem Meetings to review your quality program and identify strengths and weaknesses. Quality experts will present concepts and lead roundtables that provide participants an opportunity to ask questions and help each other reach their goals during the boot camp. View meeting details and register here.

# TRANSLATIONAL SCIENCE STUDIES

## Tregs and Tcons Cure Mice of Leukemia

Regulatory T-cells (Tregs) that are expanded following a specific protocol can cure acute leukemia in the absence of graft-versus-host disease, according to study findings published in *Biology of Blood and Marrow Transplantation*. Researchers performed six clinical-grade separation procedures then used high-dose interleukin-2, anti-CD3/anti-CD28 TCR stimulation and rapamycin to expand regulatory T cells. The expansion process occurred over 19 days and resulted in a median of 8.5-fold expansion. During the culture period, FOXP3 expression remained stable but CD127 decreased. In addition, the in vitro suppression assay showed Mixed Lymphocytes Reaction inhibition, and in vitro amplification did not cause any karyotypic modification. To evaluate the bifunctional axis of graft-versus-host disease (GVHD) and graft-versus-leukemia effect, researchers tested expanded Tregs and conventional T cells (Tcons) in mice with leukemia. All the mice were cured of leukemia and survived without GVHD. The researchers concluded that patients with high-risk and/or relapsed/refractory leukemia may benefit from high doses of Tregs and Tcons. More...

## 5-lipoxygenase/Leukotriene $B_4$ Axis Linked to GVHD Prevention

The axis of the enzyme 5-lipoxygenase (5-LO) and leukotriene $B_4$ ($LTB_4$) plays a key role in the development of graft-versus-host disease (GVHD), reports a study from *The Journal of Experimental Medicine*. Researchers transplanted 5-LO-deficient leukocytes into mice and studied the pharmacologic effect of 5-LO inhibition by zileuton and $LTB_4$ inhibition by CP-105,696. They discovered that there was an increase in nuclear 5-LO expression in splenocytes, indicating there was enzyme activation after GVHD. Treatment with either zileuton or CP-105,696 achieved the same results: prolonged survival, reduced GVHD scores, diminished intestinal and liver injury, decreased levels of serum and hepatic $LTB_4$, inhibition of leukocyte recruitment and decreased production of cytokines and chemokines. In addition, chimerism and graft-versus-leukemia were unaffected. These study findings suggest that the 5-LO/$LTB_4$ axis could be a target for the development of GVHD therapies. More...

## Reviving Aging Cells With Young Endothelial Cells

Young endothelial cells transplanted into mice revived aged hematopoietic cell function, according to a study appearing in a recent issue of *The Journal of Clinical Investigation*. For the study, researchers cocultured hematopoietic stem and progenitor cells and endothelial cells ex vivo and infused endothelial cells into mice after myelosuppressive injury to demonstrate that aged endothelial cells damage the repopulating activity of young hematopoietic stem cells and have a myeloid bias. However, the researchers discovered that young endothelial cells restored the repopulating capacity of aged hematopoietic stem cells but were unable to reverse myeloid bias. Infusing the young endothelial cells into older mice enhanced hematopoietic recovery after myelosuppressive injury and restored endogenous hematopoietic stem cells. Coinfusion of young endothelial cells improved engraftment and overall survival in lethally irradiated mice by reducing damage to the bone marrow vascular microenvironment. The researchers concluded that these study findings show that there is potential for endothelial cell therapies to improve engraftment and hematopoietic recovery in elderly patients after myelosuppressive treatments. More...

# Calendar of Events

## •December

**American Society of Hematology**
Annual Meeting
December 9-12
Atlanta, Georgia

## •January

**Cell & Gene Therapy World**
January 22-25
Miami, Florida

## •February

**BMT Tandem Meetings**
Combined ASBMT and CIBMTR Annual Meetings
February 21-25
Salt Lake City, Utah

## •March

**European School of Haematology**
Clinical Updates on CLL and Indolent Lymphoma
March 2-4
Paris, France

**European School of Haematology**
4th International Conference on Hematologic Malignancies at Older Age: Biology and Therapy
March 9-11
Mandelieu, France

**Association of Community Cancer Centers**
44th Annual Meeting
March 14-16
Washington, D.C.

## •March

**Regenerative Medicine Workshop**
March 21-24
Isle of Palms, South Carolina

**National Comprehensive Cancer Network**
23rd Annual Conference
March 22-24
Orlando, Florida

**ASBMT/NMDP**
Fundamentals of HCT Training Course
March 24-25
Denver, Colorado

## •April

**American Association for Cancer Research**
Annual Meeting
April 14-18
Chicago, Illinois

**European School of Haematology**
6th International Conference on Myelodysplastic Syndromes
April 26-28
Mandelieu, France

## •May

**The American Society of Pediatric Hematology/Oncology**
Annual Conference
May 2-5
Pittsburgh, Pennsylvania

## •May

**International Society for Cellular Therapy**
Annual Meeting
May 2-5
Montreal, Canada

**European School of Haematology**
Clinical Updates on Acute Leukemias
May 4-6
Budapest, Hungary

**American Association of Immunologists**
Annual Meeting
May 4-8
Austin, Texas

**American Society of Gene and Cell Therapy**
Annual Meeting
May 16-19
Chicago, Illinois

**Oncology Nursing Society**
43rd Annual Congress
May 17-20
Washington, D.C.

**International Society for Biological and Environmental Repositories**
Annual Meeting
May 20-24
Dallas, Texas


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