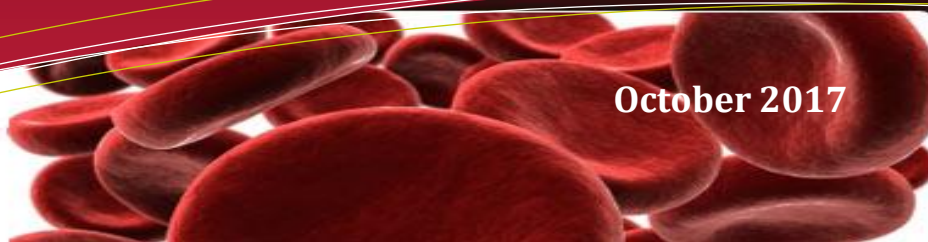


ASBMT eNews

AMERICAN SOCIETY FOR BLOOD AND MARROW TRANSPLANTATION



October 2017

CLINICAL RESEARCH

IgM Memory B Cell Maturation Block Causes Post-Transplant-Deficient Humoral Immunity

Deficient humoral immunity after allogeneic hematopoietic cell transplantation (HCT) is attributed to an IgM memory B cell maturation block, according to a study appearing in *Biology of Blood and Marrow Transplantation*. For the study, researchers assessed long-term B cell immune reconstitution by evaluating humoral immune reconstitution in 71 pediatric recipients of allogeneic HCT. Among the findings, tetanus toxoid antibody levels were normal one year after transplant, but antipolysaccharide carbohydrate antibodies remained at a low level for as long as five years post-transplant. In addition, naïve B cell counts returned to a normal level within six months of HCT.

However, deficient IgM memory B cell counts continued for up to two years, and insufficient switched memory B cells stabilized within one year of transplant. While this was associated with CD4⁺ T-cell immune reconstitution as soon as six months post-transplant, there was no correlation with IgM memory B cells at any point, suggesting that allogeneic HCT recipients have impaired antibody immune reconstitution mostly attributed to IgM memory B cell maturation block. The study also examined the effects of total body irradiation, chronic graft-versus-host disease and cord blood on humoral immune reconstitution.

[More...](#)

More Older Patients Receiving Allogeneic HCT

Since 2000, the number of people aged 70 and older who have received allogeneic hematopoietic cell transplantation has increased, improving the number of older people who survive hematologic malignancies, reports a study from *Blood*. Researchers examined data from 1,106 patients over the age of 69 who received transplants

between 2000 and 2013. The number of elderly transplant recipients accounted for .1% of all transplants in 2000 and 3.85% in 2013. Researchers also discovered that two-year overall and progression-free survival after transplant increased for this

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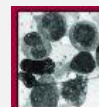
BMT Tandem Meetings

February 21-25, 2018
Salt Lake City, Utah

Comprehensive Update on Blood and Marrow Transplantation

Early Registration & Abstract Deadline: October 3, 2017

• Laboratory Research • Clinical Investigations • Patient Care



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A WORD FROM PRESIDENT KRISHNA KOMANDURI, M.D.

Shelter From the Storm

Dear Colleagues:

While there is much ASBMT news to report, I'm going to deviate from the usual business of speaking about Society priorities and accomplishments in this column. The reason for that is that the last several weeks have been anything but ordinary.



I am writing this at the end of September, which has been an unexpectedly tumultuous month. Two months ago, I wrote about storm clouds, but could not have imagined when I wrote about my visit to the National Hurricane Center that Miami would soon be in the sights of a potentially fearsome storm. Just weeks after the torrential rains and catastrophic flooding in Houston, much of Florida saw itself in the path of a category 5 hurricane. As Irma intensified and seemed to lock its sights onto southern Florida, our program and our staff braced for both the clinical and personal impacts of the storm. Many, like my family, who resided in mandatory evacuation zones, faced anticipatory school closings and were forced to flee our homes due to the threats from wind and possible storm surge. Given that our life's work is caring for the sick at their most vulnerable, others knew that their families would have to be without them during a difficult time as they stayed at the bedside providing patient care.

By the time the storm made landfall, the eye had veered west (as a reminder about the still significant limitations of even the most sophisticated big data predictions) and Miami was hit by "just" category 1- and 2-sustained winds. Still, the devastation was significant, though fortunately mostly to trees, fences and power lines rather than critical structures like buildings and houses. Furthermore, the path of impact was wide given the immense size of the storm, and most of the residents of our region lost power; at our house, we lost all cellular

phone and wired internet services. Three weeks later, life has (mostly) returned to normal, albeit punctuated by the persistent sounds of chainsaws and with maimed trees, dramatically decreased shade canopies and large piles of browning debris, serving as stark reminders of what we faced not long ago.

Still, this experience was not entirely negative. The storm served as a reminder of how fortunate we are to be members of a genuinely special community. I cannot count the number of heartfelt messages I received from ASBMT friends and colleagues who reached out. Many offered not only their sincere concern but even refuge in their own homes. Several medical directors of transplant programs contacted me in advance, expressing concern about our patients and offering patient care assistance if our unit became impossible to occupy after the storm. Fortunately, our inpatients remained entirely well thanks to the incredible efforts by dedicated members of "ride-out" teams, who willingly stayed with transplant recipients rather than their own family members.

Our medical school and hospital administrators took the remarkable step to house family members of staff who could not evacuate, including pets who could not be left alone in the uncertainty of the storm. Even after our medical school ceased normal clinical operations, our transplant staff continued to voluntarily work to operate scaled-down emergency clinics and to finish collections on patients and donors who had already started mobilization. All of this proved inspiring and uplifting to me and to our deserving and vulnerable patients.

While their conduct was nothing less than remarkable, the challenges faced by the staff of our stem cell transplant program paled in comparison to those faced by patients who were about to undergo or had recently received transplants. As I could not help but consider the

Continues on page 3

PRESIDENT'S MESSAGE (CONTINUED FROM PAGE 2)

needs of my own family, the importance of community and support for our patients came into sharp relief. The complexity of the pre-transplant process (from donor selection in the allogeneic setting to mobilization and collection in our autologous recipients) was dramatically increased by our inability to operate normal clinics, perform apheresis and obtain unrelated donor products with roads and airports closed or inaccessible. Despite challenges, we came together as a team and kept everyone safe.

Most of us take for granted continuous mobile communications, internet access, the availability of 24-hour pharmacies, weekend clinics, near-immediate blood product availability and other realities that did not exist in most of southern Florida communities for over a week. Irma (and Harvey before her) should remind us all that the least fortunate of our patients cannot take any of these factors for granted even in fair weather, due to limitations in finances, transportation or caregiver access. Despite the unpleasantness of the past weeks,

what most of us faced is nothing like the silent struggles of our patients and their loved ones.

These recent experiences reaffirm for me how lucky we are to be part of such a special community – dedicated not only to the care of our vulnerable patients, but to each other. Those of us in Houston and Miami will tell all of you to take life a bit less for granted, to review and polish your disaster plans and (most importantly) to give extra thanks for the well-being of your family and your co-workers. I am so grateful all of you were there for me, my colleagues and our patients. Those of us affected sincerely hope we don't have to return the favor anytime soon, but know that we will if ever needed. I am so proud and thankful to help govern a society so ingrained with camaraderie and altruism.

Until next month, I wish all of you clear skies and happy days!

Krishna



Irma's aftermath, Palmetto, Florida

BMT TANDEM MEETINGS

BMT Tandem Meetings

February 21-25, 2018
Salt Lake City, Utah



Registration Now Open for the 2018 BMT Tandem Meetings

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

Online registration and housing reservations are now open for the [2018 BMT Tandem Meetings](#). Innovative educational sessions and related conferences will provide tools to improve your skills, broaden your knowledge base and help you lead the future of blood and marrow transplantation (BMT).



Travel Grants

ASBMT will present 20 \$500 travel grants to U.S./Canada-based fellows and two \$750 travel grants to international fellows to attend the 2018 BMT Tandem Meetings. **ASBMT Travel Grant applications must be completed and submitted by Nov. 15, 2017.** You are welcome to complete an application in advance of receiving information on the status of your submitted 2018 BMT Tandem Meetings abstract. ASBMT will identify applicants who have an accepted abstract before selecting travel grant recipients. For more information, [click here](#).

Celebrating 25 Proud Years of ASBMT

Do you know what happens in 2018? The ASBMT will celebrate its 25th anniversary!

Drop by the ASBMT booth at the 2018 BMT Tandem Meetings to walk down memory lane and revisit all the accomplishments ASBMT has brought about since 1993. There will also be a plenary celebration which will include presentations about the Society's beginnings, critical advances in clinical research and transplantation immunology, and a brief look into the future.



LEGISLATION & REGULATION

Policy Perspectives

by Stephanie Farnia, ASBMT Director of Health Policy and Strategic Relations

September was an enormously busy month for ASBMT policy activities. Comment letters were submitted to the Centers for Medicare and Medicaid Services (CMS), we hosted our first Hill Day, spoke with our industry partners at the Corporate Council event and continued to work our way through the wacky world of reimbursement coding.



New CAR-T code alert

Two new ICD-10-PCS codes for chimeric antigen receptor T-cell therapy (CAR-T) went into effect as of Oct. 1. The new ICD-10 codes are *payer and product agnostic*, meaning the new CAR-T code can be used with all payers and for all CAR-T products. Caveat: check with your commercial payers in terms of their use and acceptance of this code, as always. We are encouraging providers to use this code with any inpatient CAR-T treatment episode, regardless of whether it is part of a trial or with an approved product.

XW033C3: *New Technology, Introduction via Peripheral Vein; Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy*

XW043C3: *New Technology, Introduction via Central Vein; Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy*

More codes to come: In the month of October, ASBMT will be releasing a document that outlines the analysis we have performed, with the help of Nimitt Consulting, to identify the CPT and revenue codes that can be used to bill outpatient services, physician service and/or used for internal cost accounting practices in relation to the provision of CAR-T. Keep an eye out for an email blast noting that the document is available. We are also hard at work on the coding applications we will need to secure new codes for those areas where gaps have been identified.

Comment letters to CMS

A number of comment letters were submitted to CMS in the last few weeks. All of the letters are available in their entirety on the ASBMT [website](#); quick highlights are below.

Outpatient Prospective Payment System: CMS made a proposal to adjust a status indicator for the 38205, peripheral blood stem cell harvesting for allogeneic transplant, simply as part of a routine housekeeping effort. There are unintended billing implications for this, which we outline in the [letter](#). Additionally, we asked CMS to consider creating Comprehensive Ambulatory Payment Classifications (C-APCs) for Autologous HCT, Donor Lymphocyte Infusion and HPC Boost. As these C-APC request changes were not proposed by CMS, they have a slim chance of being finalized in the rule but may be taken up as off-cycle work by CMS for next year. Finally, we repeated our request that CMS find a way to pay separately for donor cell acquisition costs.

Physician Fee Schedule (PFS): The PFS rule is considered one of the most important policy pieces of the year for physician groups that practice primarily in the clinic setting, as it governs which codes will be paid, at what rate and in which combination. While it is less immediately important for most of you in tertiary health systems, the ASBMT works with the American Society of Hematology, the American Society of Clinical Oncology and other societies to monitor downstream impact to your ability to bill the appropriate RVUs for your patient care encounters and demonstrate the required productivity levels to your financial team. Our [comment letter](#) this year included our concerns with proposed changes to the series of bone marrow aspiration codes, as well as apheresis and chemotherapy codes, and also encouraged CMS to continue its efforts to pay for more telehealth services. James Gajewski, M.D.,

Continues on page 6

LEGISLATION & REGULATION (CONTINUED FROM PAGE 5)

Policy Perspectives (continued from page 5)

performed the lion's share of the work in analyzing the proposed rule and sharing his perspective on the proposed changes with the other partner societies.

CAR-T: There was not a proposed rule issued by CMS in relation to payment policy for CAR-T, but we felt it was crucially important to create a problem statement [letter](#), outlining the concerns we anticipate in the first year of using Food and Drug Administration-approved commercial products in the Medicare population. This is the longest of the letters by far – grab a cup of coffee first – but is important in understanding potential impact to your facilities. This is a public document and can be shared with financial staff at your facilities.

Legislative advocacy in Washington

Partnering with the National Marrow Donor Program/Be the Match Payer and Public Policy team, the ASBMT hosted its first true Hill Day on Sept. 7. As mentioned elsewhere in this newsletter, we were lucky enough to have 11 representatives from across the country join us to meet with Congressional members and staffers to talk about the need for improved research funding and appropriate reimbursement for HCT in the Medicare population. Throughout the day, we put a special focus on discussion of draft legislation being circulated by the NMDP that would require CMS to pay donor acquisition costs separately from reimbursing the cost of the patient's hospital stay. So far, the bill has to your government affairs teams or bipartisan support

and the NMDP team is seeking a legislative vehicle to attach it to for passage this fall. We will keep you informed as that develops and may ask for outreach elected representatives. A tremendous thank you goes to the advocates who found time in their schedules to join us on the Hill, the NMDP team for their partnership and Kathleen Lester of Lester Health Law, who performed the intensive planning and coordination of our time in Washington.

ACA repeal efforts

As all of you well know, the efforts to try to repeal the Affordable Care Act (ACA) continued in September with the Graham-Cassidy bill. The ASBMT [continues to oppose](#) any legislation that greatly reduces access to insurance coverage and care, threatens Medicaid funding and/or creates systems in which individuals face steep insurance penalties for pre-existing conditions. It is unlikely these efforts to undermine the ACA will cease, though they may shift into more regulatory efforts that impact the way the law is moved through the annual appropriations and rule-making cycles. We will continue to monitor these efforts and speak up when needed. I greatly appreciate the ongoing willingness of many of you to speak up and advocate on behalf of the patients and families you treat.

Here's hoping October brings more time for thoughtful work on all of our respective projects, as well as a bit of time for caramel apples, Halloween costumes and walks in the park before the snow flies. Questions?

StephanieFarnia@asbmt.org @HCT_Policy

ASBMT Goes to Washington!

ASBMT hosted its first Legislative Day in Washington, D.C., on Thursday, Sept. 7, in partnership with the National Marrow Donor Program. The goal for the day was to educate Congressional representatives on issues that affect the field of hematopoietic cell transplantation – Medicare reimbursement, physician payment and research funding.

A group of 11 ASBMT representatives were

chosen to attend, based on home locations that represent key Congressional or Senate districts.

Edward Peres, M.D., Henry Ford, Detroit
Dianna Howard, M.D., Wake Forest, Winston-Salem
Fred LeMaistre, M.D., Sarah Cannon, Nashville

Continues on page 7

LEGISLATION & REGULATION (CONTINUED FROM PAGE 6)

ASBMT Goes to Washington (continued from page 6)

Corey Cutler M.D., Dana Farber, Boston

Sue Coolidge, C.M.A., Seidman Cancer Center, Cleveland

Rebecca Tombleson, Pharm.D., Moffitt, Tampa

John DiPersio, M.D., Washington University School of Medicine, St. Louis

Clint Divine, University of Kansas, Kansas City

Navneet Majhail, M.D., Cleveland Clinic, Cleveland

James Gajewski, M.D., ASBMT Practice Policy Consultant, Portland

Reagan Cussimanio, University of Kansas, Kansas City



Dr. Peres (left) and Dr. Howard spoke to legislators about Medicare reimbursement and federal funding for research.

During the course of the day, BMT representatives visited nearly 30 legislators' offices. Those more experienced at meeting with lawmakers were paired with first-timers.

"I was very encouraged by our visit with the Congressional offices regarding our effort to improve CMS reimbursement models for stem cell transplant for Medicare beneficiaries," said John DiPersio, M.D., ASBMT's president-elect. "I left Washington with the sense that we

communicated our issues clearly and that we were met by bipartisan support for our proposals. I was most encouraged by the fact that both the House and Senate were working on separate bills that would respond to our needs and recommendations further reducing the risk of limiting access of Medicare beneficiaries for life-saving stem cell transplant procedures."

"It was truly a great day," said Corey Cutler, M.D. "I actually felt we were doing something for the greater good that day."

Although Dr. Cutler originally met only with Senate staffers, he did bump into Sen. Elizabeth Warren at the airport.

"I told her that I was *JUST IN* her office," said Dr. Cutler. "That got me 30 seconds of her time, so I could tell her the abbreviated pitch, and of course, I got a selfie!"

"We also reminded all House and Senate staffers that we met with that maintaining NIH funding is absolutely essential for continued progress in our efforts to better understand the biology of cancer and those treatments that will prolong life and the quality of our patients' lives," said Dr. DiPersio.

"Overall the visit was extremely productive and I was pleased to see the bipartisan support on the issues we discussed, which was very encouraging," said Clint L. Divine, M.B.A., M.S.M.

More photos from the day-long excursion were posted to ASBMT's [Facebook](#) and [Twitter](#) pages. To see them, scroll until you see posts from Sept. 7.



Dr. Cutler and Sen. Elizabeth Warren during his visit to Washington, D.C.

ASSOCIATION NEWS

ASBMT New Investigator Awards

The ASBMT is now accepting applications for the 2018 New Investigator Awards.

The ASBMT New Investigator Awards are designed to encourage clinical or laboratory research by young investigators in the blood and marrow transplantation (BMT) field. The award is \$30,000 per year, typically for two years, and is preferably used to support the investigator's salary for his or her research effort. Alternatively, the award may be used for direct support of research costs.

Applicants are required to submit the New Investigator Award application, a curriculum vitae that adheres to the National Institutes of Health (NIH) Biographical Sketch format, a list of other support that also adheres to the

NIH format, a letter of recommendation from the applicant's sponsor/mentor (two pages maximum) and a description of the proposed research (four pages maximum).

New Investigator Award applications will be evaluated for:

- Scientific merit within the BMT field
- Significance and anticipated overall impact of the potential findings to the BMT field
- Institutional environment
- Training record of the sponsor/mentor

Deadline to apply is Oct. 16. For full details including eligibility requirements, please [click here](#).

ASBMT Fall BMT Clinical Education Conference This Month

Featuring Best of Tandem

The fourth annual ASBMT Fall BMT Clinical Education Conference for NPs, PAs and Fellows will take place Oct. 26-28 in Seattle. This two-and-a-half-day continuing medical education program will update nurse practitioners (NPs), physician assistants (PAs), fellows and junior faculty on key findings presented at the annual BMT Tandem Meetings, as well as other timely and highly relevant research and clinical care topics in the field of blood and marrow transplantation (BMT).

Through lecture and case-based presentations, specialists in the field will discuss current treatment challenges faced by clinicians involved in the care of both adult and pediatric transplant patients. The conference will also feature ample opportunity for interactive discussion and question-and-answer sessions.

[View meeting details and register online.](#)

Registration for this conference is currently full, however, you can easily add yourself to the waitlist.



ASSOCIATION NEWS (CONTINUED FROM PAGE 8)

ASBMT Meets with Industry Leaders at Corporate Council Meeting

ASBMT leadership and past presidents met in late September with industry and blood and marrow transplantation (BMT) thought leaders at the ASBMT Corporate Council meeting. Some of the Council's objectives are to establish meaningful dialogue between industry leaders, health care providers and the ASBMT's leaders. Headed by Armand Keating, M.D., the Council aims to share information, advice and assistance to address specific BMT issues.

The Council is about problem solving. Corporate Council members come away from meetings armed with information and council based on the experiences of their peers, who have addressed similar challenges and succeeded. Plus, the open discussion of emerging trends will keep Council members ahead of the curve and able to anticipate future challenges.

This year's Corporate Council consists of:

- Actinium Pharmaceuticals
- Amgen, Inc.
- Bristol-Myers Squibb Company
- Celgene Corporation
- Chimerix
- Gilead Sciences
- Incyte
- Jazz Pharmaceuticals
- Juno Therapeutics
- Kite Pharma



- Merck & Co., Inc.
- Millennium: The Takeda Oncology Company
- OTTR
- Pharmacyclics
- Sanofi Genzyme

During this year's meeting, discussions focused on the challenges of supportive care after stem cell transplantation, the role of immune Cell-Based Therapies, Engineered T Cell Therapy, as well as ASBMT's efforts to improve access and referral for BMT. An overview of health policy issues was also presented by ASBMT Director of Health Policy and Strategic Relations Stephanie Farnia.

Companies seeking information on the Corporate Council should contact Angie Dahl at AngieDahl@asbmt.org.

Pharmacy SIG Literature Updates

For the past few years, the Pharmacy Special Interest Group (SIG) has been preparing a literature update which is shared with our SIG members. Members of the Pharmacy SIG Communications Committee review key journals monthly to identify important articles related to stem cell transplantation. The pharmacists then

summarize the article's key highlights deemed important for the practice of stem cell transplantation. Your transplant pharmacist may have passed this monthly summary to you in the past, however, the leadership of ASBMT feels that this is a great service that should be shared with all ASBMT members.

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ASSOCIATION NEWS (CONTINUED FROM PAGE 9)

Pharmacy SIG Literature Updates (continued from page 9)

To get the latest monthly literature summaries, [click here](#). We hope that you will enjoy reading them and if you have any

comments, feel free to contact the Pharmacy SIG by emailing ASBMTPharmacySIG@gmail.com.

UASLP Honors Guillermo J. Ruiz-Argüelles, M.D.

The Universidad Autónoma de San Luis Potosí (UASLP) in Mexico recently honored ASBMT member Guillermo J. Ruiz-Argüelles, M.D., with the honorary title, “Doctor Honoris Causa” for his service as a prominent hematologist, a specialist in bone marrow transplantation “and, above all, a distinguished humanist.”

Dr. Ruiz-Argüelles serves on the steering committee for ASBMT’s HCT Value and Health Economics Special Interest Group.

When accepting his award in an auditorium filled with students dressed in white coats, Dr. Ruiz Argüelles said that everything he has been able to accomplish in medicine was

because “he always stood on the shoulders of giants,” including his father and many of his teachers.

To read more, [click here](#).



Dr. Ruiz-Argüelles (right) accepts his award.

NEWS FROM THE NMDP

Setting a Patient-Centered Outcomes Research Agenda in HCT: Priorities in Education, Care Delivery and Financial Burden

Attend this webinar on Oct. 18 from 2-3 p.m. CT to learn about the National Marrow Donor Program (NMDP)/Be The Match efforts to engage a broad community of researchers, patients and caregivers to develop a research agenda in patient-centered outcomes of

hematopoietic cell transplantation, hear the findings of three working groups focused on education, care delivery and financial burden, and learn next steps of this initiative. [View details and register](#).

Symposium: Bridging Treatment to Transplant and Current Advances

Join us on Oct. 21 in New York City for a symposium focusing on the growing number of patients and providers seeking hematopoietic cell transplantation (HCT) as a cure for malignant and non-malignant disorders. In this symposium, experts will

discuss HCT as a first line treatment and how to break down barriers and leverage research advances to support their patients from initial treatment through post-transplant care. [Register online to attend the symposium](#).

FACT UPDATE

FACT Cellular Therapy Inspection and Accreditation Workshop 2018 BMT Tandem Meetings – Feb. 20

The blood and marrow transplant field has been a leader in voluntarily improving quality. Currently, accredited clinical programs are adapting to new FACT standards and procedural changes to the accreditation process. This workshop will provide background on these changes. Topics of the morning workshop sessions include how to effectively transition to the 7th Edition Hematopoietic Cellular Therapy Standards, Center for International Blood and Marrow Transplant Research 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 new inspector training

track includes sessions regarding the FACT accreditation process, 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 the FACT common citations 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.](#)

FACT-ASBMT Quality Boot Camp 2018 BMT Tandem Meetings – Feb. 21

Join us for the FACT-ASBMT Quality Boot Camp at the 2018 BMT Tandem Meetings on Feb. 21 in Salt Lake City, Utah. This year's boot camp will focus on topics identified by programs and FACT as challenging. The boot camp will strengthen quality assurance activities through an in-person workshop. Members of the FACT Quality Committee and the ASBMT Administrative Directors Special Interest Group's Quality Working Group

encourage you in the months leading up to the BMT Tandem Meetings to review your quality program and identify its 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. Check the [FACT educational calendar](#) for registration details coming soon.

FACT Announces New Strategic Plan

Every three years, FACT goes through a dynamic process to review our strategic plan and to make modifications to enhance our vision, our strategies and our goals. We have focused the last nine months on understanding the critical external forces that motivate us and, at the same time, stay committed to

strengthening operations and adjusting the organization's direction in response to a changing environment. There have been multiple revisions to the strategies and goals; however, our mission, our vision and our values have remained unchanged.

View the [2017-2020 FACT Strategic Plan](#).

FACT UPDATE (CONTINUED FROM PAGE 11)

FACT and JACIE Reviewing Public Comments on Draft 7th Edition Standards

FACT and JACIE published the draft 7th edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* for inspection and public comment from May through July 2017. Over 70 respondents submitted more than 600 comments on the draft. This stakeholder participation benefits the Standards by

confirming agreement with the requirements, improving clarity and providing helpful guidance information.

The Standards Committee is currently reviewing the comments and incorporating edits as appropriate. The final version of the 7th edition Standards will be published in March 2018 and becomes effective at the end of May 2018.

Immune Effector Cellular Therapy Resources

The main objective of FACT's Immune Effector Cellular Therapy Standards is to promote quality practice in immune effector cellular therapy administration. FACT is committed to supporting efforts to make quality immune effector cellular therapy accessible to patients much like it did for blood and marrow transplantation and cord blood banking. Several

resources are available to assist with understanding immune effector cells and implementing FACT Standards. Resources include FACT Standards for Immune Effector Cellular Therapy, educational on-demand webinars, frequently asked questions and FACT workshop presentations.

[View all resources on the FACT Website.](#)

CLINICAL RESEARCH (CONTINUED FROM PAGE 1)

More Older Patients Receiving Allogeneic HCT (continued from page 1)

population: overall survival was 26% prior to 2008 and 39% for the 2008-2013 time period. In addition, progression-free survival improved from 22% to 32%. According to the study, transplant-related mortality remained steady over the decade, ranging from 33% to 35%.

In addition, morbidity was associated with umbilical cord blood grafts and myeloablative conditioning. The researchers concluded that transplantation should be considered for patients over the age of 69 with hematologic malignancies. [More...](#)

Combination Therapy Prevents GVHD and Late Non-Relapse Mortality

According to phase II trial results published in *Bone Marrow Transplantation*, a combination of thymoglobulin, tacrolimus and sirolimus is effective at preventing severe chronic graft-versus-host disease (GVHD) and late non-relapse mortality. The combination therapy was tested on 47 patients to prevent acute and chronic GVHD after unrelated allogeneic hematopoietic cell transplantation (HCT). Approximately four years after HCT, the

incidence of severe chronic GVHD was 6.4%, while the overall incidence of chronic GVHD was 44.7%. In addition, non-relapse mortality was nearly 28%, disease relapse was 30%, progression-free survival was 42% and overall survival was 47%. At the last follow-up, 20 patients were still alive and disease-free, but four of these patients continued to require systemic immune suppression. [More...](#)

TRANSLATIONAL SCIENCE STUDIES

Lower ILC Levels and IL-22 Production Linked to Thymic Epithelial Damage

Mice with graft-versus-host disease (GVHD) have lower thymic innate lymphoid cell levels (ILCs) and production of interleukin-22 (IL-22), which exacerbates thymic epithelial damage. Therefore, administering IL-22 after transplant can improve thymopoiesis, reports a study from *Blood*. Researchers discovered that GVHD is caused by depleted intrathymic group 3 ILCs, which is necessary for thymic regeneration. GVHD mice experienced thymic ILC3 loss, which led to deficient intrathymic

IL-22, unlike mice without GVHD. This inhibited thymic epithelial cell protection and impaired thymopoiesis recovery. However, preventing IL-21 receptor signaling in donor T cells and thymic ILC elimination improved thymopoiesis in an IL-22-dependent-manner. Consequently, restoring IL-22 signaling improved thymopoietic impairment, and administering IL-22 post-transplant enhanced thymopoiesis recovery and new thymus-derived peripheral T cell development. [More...](#)

IAPs Provide Protection From GVHD

Inhibitors of apoptosis protein (IAP) expression in host mice decreases the occurrence of graft-versus-host disease (GVHD), and IAP expression in nonhematopoietic host target tissue mitigates GVHD damage, according to a study appearing in *Blood Advances*. This study examined the role of IAPs in immunity regulation, using both chemical and genetic approaches, in mouse models of allogeneic bone marrow transplantation. The researchers discovered that the second mitochondria-derived activator of caspase mimetic AT-406, a small-molecule pan-IAP inhibitor, worsened GVHD. To explore the role of different IAPs in host and donor cellular compartments, researchers used mice with X-linked IAP and cellular IAP deficiency. They learned that donor T cells from these mice had

the same GVHD severity and allogeneic responses as B6 wild-type T cells (B6-WT). However, when used as recipient mice, both X-linked IAP and cellular IAP deficiencies resulted in increased mortality from GVHD, compared with B6-WT mice. Bone marrow chimera studies indicated that both types of deficiency in host nonhematopoietic target cells exacerbates GVHD, unlike that in host hematopoietic-derived cells. Intestinal epithelial cells from IAP-deficient mice showed lower levels of antiapoptotic proteins as well as autophagy-related protein LC3 after allogeneic transplantation. These study results led researchers to conclude that IAPs protect host mice from GVHD gastrointestinal damage. [More...](#)

Endothelial Damage Predicts Acute GVHD

Endothelial damage is worse in patients with acute graft-versus-host disease (GVHD), and corresponding elevated levels of Von Willebrand factor (VWF) and TNF receptor 1 (TNFR1) are strong predictors that a patient will develop the disease, according to a study published in *Bone Marrow Transplantation*. For the study, researchers conducted in vitro experiments, exposing endothelial cells to serum from 31 patients with acute GVHD and 13 patients without it. They measured for the presence of VWF and platelet adhesion, as well as activation of intracellular signaling proteins. Plasma levels

of VWF, ADAMTS-13, TNFR1, soluble vascular cell adhesion molecule 1 and soluble intercellular adhesion molecule 1 were also measured. Results showed a marked proinflammatory and prothrombotic phenotype in endothelial cells in association with acute GVHD. In addition, levels of VWF and TNFR1 that were above normal seven days after transplantation were able to predict that approximately 90% of patients with these elevated levels would develop acute GVHD. [More...](#)

CALENDAR OF EVENTS

•OCTOBER

Histiocyte Society
33rd Annual Meeting
October 3-4
Singapore

American Association of Tissue Banks
41st Annual Meeting
October 3-6
Orlando, Florida

National Comprehensive Cancer Network
12th Annual Congress: Hematologic Malignancies
October 6-7
San Francisco, California

AABB
Annual Meeting
October 7-10
San Diego, California

International Society of Paediatric Oncology
49th Congress
October 12-15
Washington, D.C.

European Society for Gene & Cell Therapy
Annual Congress
October 17-20
Berlin, Germany

Canadian Blood and Marrow Transplant Group
"Ocular Chronic GVHD" webinar
October 18

Association of Community Cancer Centers
34th National Oncology Conference
October 18-20
Nashville, Tennessee

•OCTOBER

European Association of Tissue Banks
26th Congress
October 18-20
Treviso, Italy

ISCT-ASBMT
Cell Therapy Training Course
October 23-27
Seattle, Washington

ASBMT
4th Annual BMT Clinical Education Conference for NPs, PAs and Fellows
October 26-28
Seattle, Washington

•NOVEMBER

Society for Immunotherapy of Cancer
Annual Meeting
November 8-12
National Harbor, Maryland

National Donor Marrow Program/Be The Match
Council Meeting
November 10-11
Minneapolis, Minnesota

Canadian Blood and Marrow Transplant Group
"Quality and Accreditation" webinar
November 15

Memorial Sloan Kettering
Clinical Application of CAR T Cells
November 16-17
New York, New York

European Society for Medical Oncology
Asia Congress
November 17-19
Singapore

•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.

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

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