**Clinical Research**

**Male Unrelated Donors Increase Risk of GVHD in Study**

Recipients of male unrelated donors have a higher risk of developing graft-versus-host disease (GVHD) after allogeneic hematopoietic cell transplantation (HCT) than recipients of parous female sibling donors, reports a study from *Blood Advances*. The study consists of 2,813 patients from the Center for International Blood and Marrow Transplant Research registry who underwent T-cell replete HCT for acute myeloid leukemia, acute lymphoblastic leukemia or myelodysplastic syndrome. Researchers discovered that patients receiving male unrelated donor transplants had 1.6 times higher risk of developing grade 2 to 4 acute GVHD than parous female sibling recipients. In addition, women who received a male unrelated donor graft were more at risk for chronic GVHD than women who were parous female sibling recipients, while male recipients had similar rates of chronic GVHD regardless of the donor type. The donor type did not affect overall survival, disease-free survival, transplant-related mortality or relapse. [Read More](#)

**Older Non-Hodgkin Lymphoma Patients Can Benefit from HCT**

Medicare-age eligible non-Hodgkin lymphoma patients have similar outcomes after allogeneic hematopoietic cell transplantation as a younger cohort and should have access to the transplant procedure, according to a study appearing in *Blood Advances*. Researchers identified 1,629 patients from the Center for International Blood and Marrow Transplant Research registry undergoing first-time reduced intensity conditioning or nonmyeloablative conditioning for allogeneic HCT. Patients were divided into two groups: one group included patients at least 65 years of age, while the other group included patients ages 55 to 64. Although nonrelapse mortality was slightly higher for the older group (30% vs. 24%), relapse/progression, progression-free survival and overall survival were similar for both groups. Researchers concluded that age alone should not be a determinant for allogeneic HCT for non-Hodgkin lymphoma, and Medicare coverage should be expanded to older adults. [Read More](#)
Total Body Irradiation with Treosulfan and Fludarabine Cuts Relapse Risk

The addition of total body irradiation (TBI) to treosulfan and fludarabine transplant conditioning is effective and reduces the incidence of relapse in high-risk patients, according to a study published in Biology of Blood and Marrow Transplantation. The study included 100 patients ages 2 to 70 years with myelodysplastic syndrome (MDS)/chronic myelomonocytic leukemia or acute myeloid leukemia (AML). Patients were administered treosulfan and fludarabine alone or combined with 2Gy TBI. Patients who received TBI had a one-year overall survival of 80% compared to 69% for the non-TBI recipients. One-year relapse was 22% for the TBI recipients vs. 34% for the non-TBI patients. In addition, one-year relapse for the MDS patients was 27% with TBI and 33% without TBI, and among AML patients, relapse was 16% with TBI vs. 35% without TBI. Non-relapse mortality at six months post-transplant was 9% for both groups. These findings led researchers to conclude that conditioning with a combination of treosulfan, fludarabine and low-dose TBI is effective for high-risk patients up to 70 years of age but that the regimen had a more positive impact on AML patients than MDS patients. Read More

A WORD FROM PRESIDENT JOHN F. DIPIERGIO, M.D., PH.D.

As researchers and clinicians, our work is rooted in the public good. We get out of bed every single day not only to help patients but to literally save their lives. Our work is incredibly important for our patients because it can lead to them continuing to live an abundant, long life.

Being a part of this public-facing sector also means that we have regulations to consider in our work. These are important not only for properly regulating our field but also ensuring public and patient safety. As new policies and regulations are introduced in our field, it is incumbent on us to ensure the new framework is appropriate for the field and the work we do. We know the ins and outs of blood and marrow transplantation because we do this work every day, and it is necessary for us to actively shape the rules around the work we do.

I say all of this because Stephanie Farnia, our director of health policy and strategic relations, has been doing important work regarding reviewing and providing commentary and context on the recently released Centers for Medicare and Medicaid Services (CMS) coding recommendations. In a recent statement submitted as commentary for a CMS HCPCS meeting on May 16, she and former ASBMT president, Dr. Elizabeth J. Schpall, helped share ASBMT’s position on the recommendations and noted points where ASBMT respectfully disagrees with them. As noted in her Policy Perspective below, she and Dr. Schpall attended the meeting in person to share this feedback, and the statement is available to members and nonmembers to read as well. She will also be hosting a town hall on June 14 for ASBMT members to discuss the recommendations, ask questions and hopefully provide additional context and answers.

I would like to urge members and nonmembers to submit their commentary on these recommendations as they will greatly affect our work. ASBMT will be submitting official comments this week as the deadline for comments is this Friday, June 15. Please review the ASBMT statement on the recommendations and share your feedback with CMS.

Continues on page 3
A WORD FROM PRESIDENT JOHN F. DIPIEROSIO, M.D., PH.D.

On another note, ASBMT has a few exciting events coming up that I’d like to highlight. The first being the ASBMT Clinical Research Training Course, held in July in Park City, Utah. This is an invite-only event for up to 12 scholars to attend the course. This opportunity was created back in 2006 in an effort to help bring the principles of research from the laboratory to the clinic. We’re enormously proud of this program and our chosen scholars, and I know we’re all excited to see their work in the coming years.

The other upcoming event is our Fall Clinical Education Conference. Registration is now open for the event, so be sure to meet us in Nashville September 20-22 (as if you needed a reason to go to Nashville for the weekend). Also, be sure to note that early bird pricing is available until August 3.

We are the experts on the work we do every day, and it’s important that we actively shape the future of the field and how our patients access this care. Please consider attending the town hall this week and providing commentary by the deadline. It’s one more thing to do at the end of the day, but it is certainly time well spent.

Sincerely,

John F. DiPersio, M.D., Ph.D.
President, ASBMT

ASSOCIATION NEWS

June 2018 ASBMT Policy Town Hall

As the deadline for commentary on the new CMS recommendations nears, ASBMT will host a Town Hall on Thursday, June 14 from 11-12 p.m. CST. During the meeting, ASBMT will offer guidance, answer questions and provide feedback and insight on the proposed recommendations. Please see ASBMT’s statement on the recommendations here, which were presented at a hearing on May 16. ASBMT members can sign up for the Town Hall here. Please note that the Town Hall is open to ASBMT members only and a login is required to register.

Pharmacy SIG 2018 New Investigator Research Award Request for Letter of Intent (LOI)

ASBMT is excited to announce that we are accepting applications for the ASBMT Pharmacy SIG New Investigator Research Award. Interested applicants are required to submit a Letter of Intent (LOI). The LOI should follow the format below and will serve to permit assessment of eligibility for the award. Letters of Intent must be received by e-mail to the administrator of the grant, no later than Friday, June 29, 2018 (5:00 pm CST). For full instructions, please click here.

New ASBMT Communication: The Cellular Scoop

Starting in June, ASBMT will begin to distribute The Cellular Scoop. This bimonthly digest, delivered straight to your inbox will be the best source for the latest information on upcoming events (for both ASBMT and partner organizations), member benefits and timely industry news. The digest will have easy-to-navigate sections that point you to new and noteworthy information about ASBMT, things you may have missed and an upcoming calendar of events. Look out for the first issue later this month!
Meet the ASBMT Team

Mollie Corbett, Manager of Operations

Mollie Corbett has the pulse on everything at ASBMT. As the manager of operations, she executes the day-to-day functions and tasks for the association, always keeping an eye on the strategic plan and ensuring ASBMT meets its primary goals each year and for the next five years. She has extensive experience in healthcare association management and is excited to be a part of the ASBMT team. You will likely see her at ASBMT events and meetings as she is the person that everyone else comes to with questions. If you see her, be sure to say “hi” as she is always excited to meet the members she works for every day.

Kirk Lanzone Terry, Manager of Education

Kirk Lanzone Terry is ASBMT’s manager of education. He works closely with the education committee to execute on strategic education initiatives for the association. Most recently, he’s been heavily involved in developing the programming and content for the upcoming Fall Clinical Education Conference in Nashville. Kirk has extensive experience working with healthcare associations, both in the U.S. and internationally, and he is excited to bring his knowledge and expertise to the education sector with ASBMT. Kirk will also be a regular at upcoming ASBMT events and meetings, likely talking to speakers and ensuring the programming runs without a hitch.

Now Available: ASBMT Fall Clinical Education Conference Program Agenda

The American Society for Blood and Marrow Transplantation (ASBMT) in collaboration with The Sarah Cannon Blood Cancer Network and National Marrow Donor Program / Be The Match® is proud to announce the 5th Annual ASBMT Fall Clinical Education Conference. The conference will be held September 20-22, 2018 at the Omni Hotel in Nashville, Tenn. This multi-day conference for NPs, PAs, nurses, fellows and junior faculty will be focused on the care of blood and marrow transplant and cell therapy patients.

The three-day conference will be packed with education for the ASBMT community, including specific breakout sessions based on adult or pediatric care. Registration for the event will open shortly; please look for an email from ASBMT in the coming weeks to register to attend the conference. If you’re already planning on joining, you can book your hotel stay for the conference in advance; visit the ASBMT site for more information.

Exhibit Opportunities

With more than 200 attendees each year, we would like to invite you to participate as an exhibitor at this conference. The exhibit area will be open September 20-22 outside of where the educational presentations will take place. There will be two networking lunches as well as multiple breaks where attendees will be encouraged to visit the Exhibit Hall and network with our exhibitors. Exhibitors will also be invited to attend the conference sessions and hear talks from leaders in the field of blood and marrow transplantations and immunotherapies.

Last year we had over 20 companies exhibit at this event. If you are interested in learning more about sponsorship and exhibit opportunities, please contact Angie Dahl at adahl@asbmt.org or 312-673-4833.

Continues on page 5
June 2018 ASBMT Monthly Self-Directed Learning Quiz

On behalf of the ASBMT Committee on Education, we are pleased to continue our monthly self-directed learning quiz "Basic Principles and Practices of Hematopoietic Cell Transplantation and Cell Therapy – Question and Answer Approach" for fellows in training, highlighting HCT 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 were generated and reviewed by Syed Abutalib, M.D., Mark R. Litzow, M.D., and William A. Wood, M.D. To take this month’s quiz, click here.

Pharmacy SIG Literature Updates

For the past few years, the Pharmacy Special Interest Group (SIG) has prepared a literature update that 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.

To get the latest monthly literature summaries, go to the Pharmacy SIG page on the ASBMT website and look for the literature updates in the right-hand sidebar. 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.
**Policy Perspective**

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

We all have mental associations with summer — school being out, trips “up north” (as we like to say here in Wisconsin), ice cream, the sound of the lawn mower and so much more. My summer days center around early morning rows on Lake Mendota in Madison, Wisconsin, evening neighborhood chats after a long winter of not seeing each other and, unusually, hours crafting responses to the CMS proposed rules. Summer is rule season in the regulatory world — IPPS, OPPS, PFS, QPP (if you ever find yourself in a bizarre game of Federal Agency Wheel of Fortune, always choose a “P” for your free letter).

As noted in the [last column](#), we are preparing comments to submit to CMS before the June 25 deadline. We plan to continue our requests to CMS to reimburse for the costs of donor acquisition for HCT cases, and we are closer to choosing our preferred option among those proposed by CMS for CAR-T reimbursement. We will distribute key information the week of June 11 for your use in finalizing your own program or individual letters.

To add to the summer regulatory flurry, CMS recently issued a National Coverage Analysis for CAR-T. There are several potential concerns with this, and we plan to discuss them in a comment letter before the initial comment period ends on June 15. Please see our [ASBMT communication](#) on the issue for more details and look for more information to come. We encourage providers and centers to send in comments as well; CMS specifically noted they were undertaking the NCA process because, “To date, few Medicare patients have been studied and follow up has been limited.” Comments and clinical references on these points would be helpful.

Finally, there were two very important coding meetings that happened in May. First, the CMS HCPCS meeting was held on May 16 and included discussion of two Q codes (outpatient drug codes) for axicabtagene ciloleucel and tisagenlecleucel, respectively. ASBMT attended the meeting and [presented comments](#) encouraging CMS to separate the apheresis/cell harvest procedure, which is currently included in the coding definition, from the drug itself. ASH, the College of American Pathologists and several other commenters also attended and expressed their concerns. We are optimistic about changes being made, but we will not know the official CMS position until later this year. In the interim, we have encouraged CMS to issue guidance on the concerns we have shared with them. We will continue to track this and share more information as it becomes available. Second, Dr. EJ Shpall, a past-ASBMT president from MD Anderson Cancer Center, represented the society during our request for new CPT codes for CAR-T. We are unable to share information about the meeting until it is officially posted on the American Medical Association website, but Dr. Shpall should be commended for her great efforts in presenting this new set of therapies to the CPT Editorial Panel for review and discussion (and for sitting in the committee meetings for 15 hours before our topic was called).

This will be an intense few months of activity, and I will likely be sequestering myself for the month of June to get the NCA and IPPS comment letters completed before the next round hits in early July. Please be patient with my reply time during this period. I think Frozen’s Olaf said it best (or rather, sang it best), “When life gets rough, I like to hold on to my dream of relaxing in the summer sun just lettin’ off steam! In summer!”
FACT Update

FACT Awards First Accreditation Under the New FACT Standards for Immune Effector Cells

FACT awarded accreditation for immune effector cellular therapy under the new FACT Standards for Immune Effector Cells to The University of Texas MD Anderson CARTOX Program, directed by Elizabeth Shpall, M.D., and Sattva S. Neelapu, M.D. This is the first accreditation FACT has awarded to an immune effector cellular therapy program that is independent of a bone marrow transplant program. The program received accreditation on April 19, 2018. Read the news release View list of all FACT-accredited immune effector cellular therapy programs

FACT Webinar: ISBT 128 Labeling and Coding

Full implementation of ISBT 128 labeling and coding is required by the seventh edition of the FACT-JACIE Hematopoietic Cellular Therapy Standards, which becomes effective this month. On Thursday, June 14 at 11 a.m. ET, Dr. Phyllis I. Warkentin will discuss common questions about ISBT 128 terminology, product codes, FACT Standards and regulatory requirements. Webinar participants will have a chance to ask Dr. Warkentin questions at the end of the presentation. View meeting details and register

Seventh Edition FACT-JACIE Hematopoietic Cellular Therapy Standards Went into Effect May 30

The seventh edition of the FACT-JACIE Hematopoietic Cellular Therapy Standards became effective on May 30. As a reminder, compliance with the new requirements was required by that date. Resources for navigating the new edition of Standards are on the FACT website in the Cellular Therapy Library.

Resources include:
FACT-JACIE Hematopoietic Cell Therapy Standards, Seventh Edition
FACT-JACIE Accreditation Manual, Seventh Edition
Purchase Printed Copies
Changes to Seventh Edition FACT-JACIE Standards
FACT-JACIE Cellular Therapy Standards Crosswalk 6th to 7th Edition
FACT-JACIE Cellular Therapy Standards Crosswalk 7th to 6th Edition

A webinar presented by Dr. Paul Eldridge on how to Effectively Transition to the Seventh Edition Hematopoietic Cellular Therapy Standards, was presented on March 14. If you were unable to attend the webinar, you can purchase the recording. FACT inspectors can download the recording for free!

If you have questions related to the seventh edition FACT-JACIE Standards, contact your FACT coordinator or submit your question to askfact@unmc.edu.
**Study Looks at Skin GVHD Impact and Treatment**

Graft-versus-host disease (GVHD) targets Lgr5+ hair follicle stem cells (HFSCs), and topical ruxolitinib protects skin stem cells and maintains skin homeostasis in GVHD, reports a study appearing in *Blood*. Using mice, researchers discovered that GVHD reduced Lgr5+ HFSCs in association with impaired hair regeneration and skin wound healing after transplantation. Topical corticosteroids damaged HFSCs and failed to improve skin homeostasis, but ruxolitinib improved skin GVHD, protected Lgr5+ HFSCs and restored hair regeneration and wound healing. Read More

**miR-17-92 and Its Role in Chronic GVHD**

A *Blood* study reports that microRNA-17-92 (miR-17-92) plays a key role in the development of chronic graft-versus-host disease (GVHD). The study was conducted to determine if miR-17-92 regulates T- and B-cell responses in chronic GVHD. Researchers discovered donor T and B cells are necessary for generating scleroderma and bronchiolitis obliterans in chronic GVHD. In T cells, miR-17-92 expression improves pathogenic T helper 1 (Th1) and Th17 cell differentiation and generates follicular Th cells, germinal center (GC) B cells and plasma cells. In B cells, miR-17-92 expression produces autoantibodies and deposits immunoglobulin G in the skin. The researchers also evaluated a translational approach using antagonirs specific for either miR-17 or miR-19. Systemic administration of anti-miR-17 eliminated clinical manifestations and proteinuria incidence in recipients by inhibiting donor lymphocyte expansion, B-cell activation and GC responses. In addition, miR-17 blockade improved skin damage by reducing Th17 differentiation. These study results led researchers to conclude that miR-17-92 is required for differentiation and function of T and B cells and pharmacological inhibition of miR-17 may prevent chronic GVHD. Read More

**SCID-X1 Treatment Treats Disease and Eliminates Need for Conditioning**

Intravenous administration of foamy virus (FV) vectors effectively treats X-linked severe combined immunodeficiency disease (SCID-X1) in dogs, eliminating the need for conditioning, according to a study published in *Blood Advances*. Researchers demonstrated improved efficacy of the in vivo gene therapy by mobilization with granulocyte colony-stimulating factor and AMD3100 before injection of an optimized FV vector incorporating the human phosphoglycerate kinase enhancerless promoter. Mobilization prior to FV vector administration accelerated kinetics of CD3+ lymphocyte recovery, promoted thymopoiesis and increased immune clonal diversity. Gene-corrected T lymphocytes showed a normal CD4:CD8 ratio and a broad T-cell receptor repertoire and displayed restored γC-dependent signaling function. Treated dogs had normal primary and secondary antibody responses to bacteriophage immunization and evidence for immunoglobulin class switching. Read More
# Calendar of Events

<table>
<thead>
<tr>
<th>Month</th>
<th>Event</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td><strong>JUNE</strong></td>
<td>American Society of Clinical Oncology Annual Meeting</td>
<td>June 1-5; Chicago, Illinois</td>
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<td>American Society of Transplant Surgeons American Transplant Congress</td>
<td>June 2-6; Seattle, Washington</td>
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<td>Canadian Blood and Marrow Transplant Group Annual Conference</td>
<td>June 7-9; Ottawa, Canada</td>
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<td>Federation of Clinical Immunology Societies Annual Meeting</td>
<td>June 14-17; Chicago, Illinois</td>
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<td>European Hematology Association 23rd Congress</td>
<td>June 14-17; Stockholm, Sweden</td>
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<td>International Society for Stem Cell Research Annual Meeting</td>
<td>June 20-23; Melbourne, Australia</td>
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<td><strong>JULY</strong></td>
<td>Society for Cryobiology CRYO 2018</td>
<td>July 10-13; Madrid, Spain</td>
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<td><strong>AUGUST</strong></td>
<td>Association of Physician Assistants in Oncology 21st Annual Conference</td>
<td>August 9-12; Chicago, Illinois</td>
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<td>International Society for Experimental Hematology 47th Annual Scientific Meeting</td>
<td>August 23-26; Los Angeles, California</td>
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<td><strong>SEPTEMBER</strong></td>
<td>European School of Haematology 20th Annual John Goldman Conference on Chronic Myeloid Leukemia: Biology and Therapy</td>
<td>September 13-16; Miami, Florida</td>
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<td>World Hematology Conference</td>
<td>September 20-21; Oslo, Norway</td>
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<td>ASBMT Annual Fall Clinical Education Conference for NPs, PAs and Fellows</td>
<td>September 20-22; Nashville, Tennessee</td>
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<td>National Comprehensive Cancer Network Annual Congress: Hematologic Malignancies</td>
<td>September 21-22; New York, New York</td>
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<td>European School of Haematology 4th Annual International Conference on New Concepts in Lymphoid Malignancies</td>
<td>September 28-30; Saggart, Ireland</td>
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<td><strong>OCTOBER</strong></td>
<td>American Society for Histocompatibility &amp; Immunogenetics 44th Annual Meeting</td>
<td>October 1-5; Baltimore, Maryland</td>
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<td>ASBMT Annual Meeting</td>
<td>October 9-12; Dallas, Texas</td>
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<td>European Society for Gene &amp; Cell Therapy Annual Congress</td>
<td>October 16-19; Lausanne, Switzerland</td>
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<td>European Association of Tissue Banks 27th Congress</td>
<td>October 17-19; Lille, France</td>
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<td>European Society for Medical Oncology ESMO 2018 Congress</td>
<td>October 19-23; Munich, Germany</td>
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<td>Histioocyte Society Annual Meeting</td>
<td>October 22-23; Lisbon, Portugal</td>
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<td><strong>NOVEMBER</strong></td>
<td>Society for Immunotherapy of Cancer Annual Meeting</td>
<td>November 7-11; Washington, D.C.</td>
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<td>National Donor Marrow Program/Be The Match</td>
<td>November 9-10; Minneapolis, Minnesota</td>
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<td>International Society of Pediatric Oncology Asia Congress</td>
<td>November 23-25; Singapore</td>
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<tr>
<td><strong>2019</strong></td>
<td>ASBMT/CIBMTR Transplantation and Cellular Therapy Meetings</td>
<td>February 20-24; Houston, Texas</td>
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