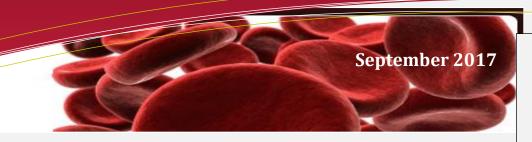
# ASBMT eNews

AMERICAN SOCIETY FOR BLOOD AND MARROW TRANSPLANTATION



## CLINICAL RESEARCH

## **Effective Transplantation Option to Matched Donor Transplant**

Children with acute leukemia who receive haploidentical hematopoietic cell transplantation (HCT) following αβ T- and B-cell depletion have similar survival outcomes as children who receive HLA-matched donor HCT, according to a study published in Blood. This clinical trial was conducted with 80 children, who received a fully myeloablative preparative regimen. Three to five days prior to transplantation, patients were given anti-Tlymphocyte globulin to prevent rejection and graft-versus-host disease. Prophylaxis was not administered after transplantation. Two of the children experienced primary graft failure; four of the patients died; and 19 patients relapsed. In addition, 24 of the patients developed grade 1-2 acute skin graft-versus-host disease

(GVHD), but none of the patients developed extensive chronic GVHD. Approximately four years after HCT, the five-year probability of survival free of chronic GVHD and relapse was 71%. The researchers determined that the total body irradiationcontaining preparative regimen was the only variable positively influencing survival without relapse or chronic GVHD. Comparing these outcomes to a study of 91 children receiving transplantation from an HLAidentical sibling or a 10/10 allelematched unrelated donor. researchers concluded that the transplantation method used for this study is a comparable alternative for children with acute leukemia in need of urgent allogeneic transplantation. More...

# **Upfront Autologous Transplant Better for Young Myeloma Patients Than Chemotherapy Regimen**

Newly diagnosed myeloma patients have a better chance of survival after upfront autologous cell transplantation than after oral chemotherapy and lenalidomide, reports a study appearing in *Leukemia*. Researchers analyzed

outcomes of 268 patients randomly assigned to receive two courses of melphalan 200 mg/m² and autologous transplantation and 261 patients who received

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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









# A WORD FROM PRESIDENT KRISHNA KOMANDURI, M.D.

Dear Colleagues:

I hope this message finds you well. As I write this, August is fading, as are the memories of time spent away from work with family over the summer. Our four kids are transitioning to

three new middle and high schools, so chaos is reigning supreme at our house as we settle into new schedules and routines.

Last month I wrote about the possibility of late summer stormy weather, and unfortunately, my column was

a little too prophetic. Hurricane Harvey rolled ashore in Corpus Christi, Texas, rapidly intensifying from a mere tropical storm to a devastating hurricane, before evolving into a significant rain and flooding event in the Houston area. I still recall witnessing firsthand the surprising and devastating effects of Tropical Storm Allison in Houston in 2001 and how the city openly embraced refugees of Hurricane Katrina in 2005. My thoughts are now with our ASBMT colleagues in Houston, their patients, families and communities as they still face the effects of this storm as I write, and as they eventually enter the long phase of recovery from a profound disaster.

With that somber caveat, I want to provide a positive update on the importance of ASBMT advocacy that I highlighted in my previous column. Just as storms can directly threaten any of us, I noted last month that changing financial climates can influence the security and sustainability of our transplant centers. This summer, the ASBMT and its partners became aware of proposed Centers for Medicare & Medicaid Services (CMS) changes in reimbursement that had the potential to severely reduce inpatient payments for transplant episodes (by as much as 70% or more).

The ASBMT, the National Marrow Donor Program (NMDP) and many of you quickly and strongly advocated against this change. Earlier this month, we were delighted to hear that our collective voices were heard, and that the proposed policy change would not go into effect. To me, this highlights perfectly the importance of a professional society, which can rapidly mobilize and advocate for the needs of its members, centers and patients. This should also provide some inspiration to those of us growing a little cynical about the power of our collective voice. I'm also happy to report that our ASBMT health policy staff, working with their NMDP colleagues, have organized our first Capitol Hill day next month. We expect that this will further help us to find our political voice to best advocate for all of you.

For me it's also grant season, which brings into focus the increasingly uncertain climate of research funding. As many ASBMT colleagues tweeted this last month, metrics of National Institutes of Health (NIH) funding continue to reach new and increasingly frustrating landmarks. For example, the median age of investigators at the time of funding of their first NIH RO1 grant has now exceeded 46 years – a startling and depressing figure. As someone who sits on a promotion and tenure committee that still holds to conventional views about the importance of NIH funding as a PI for the award of tenure, I'm increasingly concerned that the rift between expectations and reality will lead to an exodus of talented physicianscientists from our academic ranks. I know the stresses felt by many of us with established careers are greatly magnified for the junior investigators who are our future. I urge all of us, with our local and national representatives, to highlight how much more difficult this situation has become. Fortunately, the NIH has broad bipartisan support in Congress, but the challenge is proportionally increasing funding in a climate of fiscal restraint.

This week, I had the pleasure of continuing a new tradition of regular conference calls with the chairs of our ASBMT Special Interest Groups (SIGs) and senior ASBMT leaders. The goal of these calls, and our historical face-to-

# PRESIDENT'S MESSAGE (CONTINUED FROM PAGE 2)

face meeting at Tandem, is to increase the crosstalk of our increasingly productive and complex society. We hope to use these interactions to make a better Tandem meeting with an increased focus on our critical scientific plenaries, but also better communication so that members can attend sessions of interest across disciplines and SIG-directed sessions. We hope to dedicate improved infrastructure (e.g., using informatics) to enhance communications within and between SIGs, committees and task forces so involved members can better assimilate a growing number of parallel initiatives across our Society.

I'll close with noting that the ASBMT Board of Directors will also convene for its fall meeting in Chicago in early October. The Society will use this opportunity to start our process of self-reflection and strategic planning that we discussed earlier in the year. We are pleased that Michael Boo, J.D., who served as the chief strategy officer for the NMDP, will act to facilitate this strategic planning process. While we will formally survey our designated

leadership, from the Board of Directors to leaders of our SIGs, committees and task forces, we would also like to hear from our membership at large during this critical look in the mirror. In the coming months, we will tell you how to submit your thoughts on our present and future directions, as it is critical that our goals and directions directly reflect the aspirations and will of our members.

There is much more going on, and I'll look forward to continuing to update you about our many areas of progress in the coming months. At the midpoint of my term, I will note that it has been a great privilege to serve you thus far, and I look forward to a very productive fall for the Society.

As always, please feel free to contact me or your other elected representatives directly, as your feedback is essential for our collective success!

All the best.

Krishna

# **LEGISLATION & REGULATION**

# ASBMT/NMDP Legislative Day in Washington, D.C.

ASBMT will be hosting its first Legislative Day in Washington, D.C., on Thursday, Sept. 7, in partnership with the NMDP. The goal for the day will be to educate Congressional representatives on issues that affect the field of hematopoietic cell transplantation – Medicare reimbursement, physician payment and decreasing opportunities for research funding. A group of approximately 10-15 individuals have been chosen to attend, based on home locations that represent key Congressional or Senate districts.

"This has been a year of tremendous upheaval in the health policy area," said Stephanie Farnia, ASBMT Director of Health Policy and Strategic Relations. "Changes to Medicare, Medicaid, the Affordable Care Act, and the NIH budget have all been near-constant topics of conversation. This climate has underscored the need for ASBMT to have an active core set of volunteers willing to interact with their legislators about important issues that will potentially affect the field and/or the patients you all serve."

## **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, abstract submission 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).

Recognition of the effectiveness of blood and marrow transplant and cellular therapies has never been greater. Dynamic growth in the field has introduced novel and exciting approaches to treatment and care across the country and around the world. The 2018 BMT Tandem Meetings harness the latest technologies, most influential research and the brightest minds to deliver this game-changing information to you. *Join us!* 

Early registration allows you to:

- take advantage of discounted registration rates;
- make reservations at your preferred hotel; and
- purchase your ticket to the BMT Tandem Meetings reception, as space is limited.

More information on these benefits can be found on the Tandem Meetings home page.

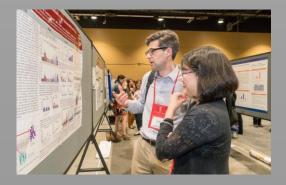


#### **Abstract Submission**

More than 100 abstracts will be selected for oral presentations during the general scientific sessions and peripheral conferences.

SUBMIT YOUR ABSTRACT

**Deadline: Oct. 3, 2017** (11:59 PM PST)



# BMT TANDEM MEETINGS (CONTINUED FROM PAGE 4)

#### ASBMT Awards to be Presented at the 2018 BMT Tandem Meetings

The ASBMT is proud to announce the names of the award recipients who will be honored at the 2018 BMT Tandem Meetings this February in Salt Lake City.

The 2018 ASBMT Lifetime Achievement Award will be presented to A. John Barrett,

M.D., chief of the Bone Marrow Stem Cell Allotransplantation Section of the Hematology Branch, National Heart Lung Blood Institute. A past president of the ASBMT, Dr. Barrett

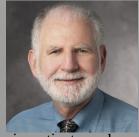


is an outstanding senior investigator with numerous contributions to research in blood and marrow transplantation for more than 30 years. Co-chair of this year's annual ASBMT-ISCT Cell Therapy Training Course, Dr. Barrett has been involved with the course since its inaugural session in 2015.

"It is important to note that his application of immune suppression to treat marrow failure disorders has been practice-changing," said Catherine Bollard, M.D., FRACP, FRCPA, of the Children's National Health System in Washington, D.C. "Furthermore, both his laboratory and clinical work in transplantation immunology have significantly contributed to the stepwise improvements in outcome, and the broadening application of allogeneic stem cell transplantation that we have witnessed particularly in the last 20 years."

Robert S. Negrin, M.D., professor of medicine and chief of the Division of Blood and

Marrow Transplantation at Stanford Medicine, was selected for the 2018 ASBMT E. Donnall Thomas Lecture. The lecture recognizes an eminent physician or



scientist, either a clinician or investigator, who has contributed meritoriously to the advancement of knowledge in blood and marrow transplantation.

A past president of ASBMT, Dr. Negrin is being honored for his exceptional contributions to the field of hematopoietic transplantation, including his profound contribution to understanding of innate and adaptive immunity and its importance in determining outcomes of allogeneic hematopoietic transplantation. His efforts to develop novel model systems and technologies, from bioluminescent imaging to novel sequencing approaches, and to apply them to studies of effector and regulatory T cells, B cells, NK cells and other immune subsets have inspired a generation of scientists. More importantly, they are advancing the possibility that targeted therapies and adoptive immunotherapy will improve outcomes related to both relapse and graft-versus-host disease. While his scientific contributions are the primary reason for this award, the ASBMT also recognizes his exceptional leadership, and his service as associate editor of *Blood* and as the founding editor of Blood Advances.

The 2018 ASBMT Public Service Awards will be presented to Jeffrey W. Chell, M.D., and Michael Boo, J.D.

Until his retirement in April of this year, Michael Boo, J.D., served as chief strategy

officer of the National Marrow Donor Program/Be The Match (NMDP), the national registry for the United States, between 2001 and 2016. His contributions included the implementation of a new strategic planning process that



helped guide substantial growth at NMDP, the development of the Center for Cord Blood in 2003, and increasing the NMDP's share of the cord blood market in the United States from 15% to over 90%. Boo also identified and launched new products and services that had significant bottom-line revenue impact and developed new relationships within the extensive NMDP

# BMT TANDEM MEETINGS (CONTINUED FROM PAGE 5)

#### **ASBMT Awards** (continued from page 5)

network of national and international partners, which improved access to cell sources and markets worldwide.

As NMDP chief executive officer and executive director of the Center for International Blood and Marrow Transplant Research, Dr.

Chell led the NMDP through a period of dramatic clinical and academic growth. Under his leadership, the Be The Match Registry has dramatically expanded, increasing the access of ASBMT and NMDP centers to unrelated donor products,



including cord blood units, from around the world.

"Dr. Chell has had transformative impact in the fields of blood and marrow transplantation and cellular immunotherapy," noted ASBMT President Krishna Komanduri, M.D. "Through efforts including his leadership of the NMDP's System Capacity Initiative, which brought together diverse stakeholders to discuss how the academic framework could support the sustainable growth of transplant centers, he helped foster the growth of academic transplant programs while always maintaining a patient-centered focus."

# LEGISLATION & REGULATION (CONTINUED FROM PAGE 3)

## **Policy Perspectives**

by Stephanie Farnia, ASBMT Director of Health Policy and Strategic Relations
Eclipses & Ellipses... that bodes well for collaboration

It has been a much busier summer in the health policy world than usual – multiple

comment periods for proposed annual policy rules from the Centers for Medicare & Medicaid (CMS), uncertainty around the Affordable Care Act repeal efforts and a couple of "out of left field" issues I'm blaming on eclipse-driven zaniness. In large part,



summer in the policy area is always reactionary – anticipating proposed rules and responding as needed when they are released – but this year felt particularly so. As we move into autumn, efforts traditionally shift to implementation of policy changes clarified in the final rules, as well as strategic planning efforts around new or continued areas of concern. I welcome that shift this year, in particular, and hope that the eclipse marked the beginning of a new cosmic alignment

that bodes well for collaboration and partnership in health care. (At this point, I'll grasp at any straws I can dream up!) There are numerous updates to share this month; I will divide them up between hematopoietic cell transplantation (HCT) and chimeric antigen receptor (CAR) T for easy future reference.

#### **Medicare and HCT**

Thanks to your outreach efforts, the HCT community was able to prevent a proposed change to the logic that CMS uses to assign claims to MS-DRGs for the **Inpatient Prospective Payment System**. The change was of a technical nature – correctly recategorizing HCT as a "non-operating room" procedure – but it would have greatly impacted the payment rates for autologous and allogeneic HCT. CMS issued the following response in the Final Rule issued in August: "We acknowledge the concerns of the

Continues on page 7

# LEGISLATION & REGULATION (CONTINUED FROM PAGE 6)

#### **Policy Perspectives** (continued from page 6)

commenters. We agree that it is important to maintain the current Pre-MDC logic for these procedures while also appropriately designating them as non-O.R. procedures. After consideration of the public comments we received, we are finalizing our proposal to change the designation for the 20 ICD 10-PCS procedure codes listed in Table 6P.4o. associated with the proposed rule and this final rule from O.R. procedures to non-O.R. procedures, effective October 1, 2017, and maintaining their assignment to the Pre-MDC MS-DRGs 014, 016, and 017 for FY 2018" (page 92 of the FY2018 Final Rule). This will sound like gibberish to many of you, but please feel good in knowing that it translates to no negative change in reimbursement.

While avoiding a loss on the MS-DRG payment was a successful demonstration of our defensive skills, there is much more to do in terms of **seeking** *improved* **reimbursement** for transplant. The National Marrow Donor Program/Be The Match has been working on that issue for several years now and is advancing legislation through Congress that asks for parity between solid organ and HCT in terms of Medicare payment policies. In an era where almost no issues have bipartisan support, this does. Please read the newsletter item on this issue and share this <u>page</u> with HCT and Government Affairs teams.

The **Quality Payment Program** (QPP), also known as MIPS or MACRA, recently held its open comment period for the second year of the program. While most HCT clinician teams will not feel a great impact from QPP in the next few years, quality-based payment programs will not be disappearing anytime soon. ASBMT submitted a brief comment letter in regard to key aspects of the proposed rule and welcomes your individual thoughts on areas for improvement as you become more involved with the program.

Finally, as we highlighted in a column a few months ago, HCT physicians will now be able to formally identify as **Hematopoietic Cell** 

Transplant and Cellular Therapy (HCTCT) physicians within the CMS system for purposes of billing. This status essentially affords you additional options for billing specialty care and will be helpful in allowing CMS to compare a true peer group when it begins evaluating cost and quality. We will issue more detail on the specific benefits of using this designation in your billing practices in a future newsletter. In the meantime, start work on signing yourself up as a HCTCT physician prior to Oct. 1. A CMS reference document can be found <a href="here">here</a> and some specific advice from a CMS representative is as follows:

"The new specialty codes will be effective October 1, 2017 and can be utilized as valid primary specialty codes or a secondary specialty code. The Provider Enrollment Chain and Ownership System (PECOS) shall make the necessary changes to recognize and use the new physician specialty codes. You can submit the CMS-855I and CMS-855O applications using the 'Undefined Physician Type' option and write in the specific specialty until the forms can be updated with the new specialty. For any "new" submissions for the C9, complete the application via PECOS or paper application. For existing providers who are currently practicing Hematopoietic Cell Transplantation and Cellular Therapy, you can submit a change of information for those providers. If a provider has more than one specialty, it can be listed as a secondary specialty. For anything related to the application submittal process, please contact your local Medicare Administrative Contractor."

(I put this in a box to give you enough room to print it, cut it out and tape it to the monitor of your program administrator's computer – advisably alongside a coffee gift card

Continues on page 8

# LEGISLATION & REGULATION (CONTINUED FROM PAGE 7)

Policy Perspectives (continued from page 7) or candy bar of choice. This is where the first ellipses come in, as the implementation of this change sounds relatively straightforward, but only time will tell...)

#### **CAR T Reimbursement Policy Updates**

As I mentioned earlier, a significant amount of my time and focus over the last few months has been shifting to CAR T – trying to understand the reimbursement models and predicted impact on centers, working on applications for new codes your teams will need in the near future, and providing input into discussions being had by payers and other national organizations. While busy, it has been a tremendously exciting time and a chance to put many of our HCT lessons to good use.

**Approval Timing and Reimbursement** 

Concerns: As most of you know, the Food and Drug Administration's approval for Novartis's CTL019 is expected sometime in September, and approval for Kite's AxiCel could come anytime before December. The treatment populations are very different between the products and have accordingly dissimilar payer implications; Kite's product will face Medicare hurdles, and Novartis will need to navigate Medicaid on a state-bystate basis. We will be sending a letter into CMS in a few weeks outlining our concerns with the expected reimbursement structure and asking them to consider payment policy alternatives where possible. The other major ellipses in this area is pricing of the products – estimates run from \$250,000 to upwards of \$650,000, all of which will have substantial repercussions for the health care system...

As some of you already know, the Institute for Clinical and Economic Review (ICER) has announced that it will be conducting an analysis of the "comparative clinical effectiveness and value" of the first two CAR T products. The process is clearly outlined on the <u>ICER</u> website and there are several opportunities for public comment. ASBMT has submitted a public comment letter, which can be read here.

Finally, the **new ICD-10-PCS code for CAR T will go into effect on Oct. 1**. We will remind you when the time comes, but please feel free to share this code with your billing teams now. Kite requested the development of these codes from CMS last winter, but new ICD-10 codes are payer- and product-agnostic, meaning the new CAR T codes 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.

XW033C3: New Technology, Introduction via <u>Peripheral</u> Vein; Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy

XW043C3: New Technology, Introduction via <u>Central</u> Vein; Engineered Autologous Chimeric Antigen Receptor T-cell Immunotherapy

And with that, a hectic summer of policy initiatives comes to a close. Next month, look for updates on ASBMT's submitted comment letters to CMS regarding the proposed Physician Fee Schedule and Outpatient Payment System rules, as well as a recap of our planned Sept. 7 ASBMT/NMDP Legislative Day.

Questions?
<a href="mailto:StephanieFarnia@asbmt.org">StephanieFarnia@asbmt.org</a>
<a href="mailto:@HCT\_Policy">@HCT\_Policy</a>

## 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.

# 4th Annual ASBMT Fall BMT Clinical Education Conference for NPs, PAs and Fellows

Registration is now open for the 4th Annual ASBMT Fall Clinical Education Conference for NPs, PAs and Fellows . . . and

space is filling up FAST! The conference will be held Oct. 26-28. 2017, at the Sheraton Hotel in Seattle.



Click here to

register. Additional information about lodging, learning objectives, and the full course schedule is provided here.

This 21/2 day program will provide clinical education for nurse practitioners, physician assistants, fellows and junior faculty caring for blood and marrow transplant patients. At the end of the course, attendees will leave with a comprehensive syllabus, a selfassessment, and a deeper understanding of the diagnostic evaluation and therapeutic treatments for acute and chronic complications of blood and marrow transplantation.

# **Highlights**

Best of Tandem" Session

Led by ASBMT president Krishna Komanduri, M.D., the "Best of Tandem" session will cover key scientific content presented at the 2017 BMT Tandem Meetings.

Pediatric Breakout Sessions

For clinicians looking for the best new information and trends in pediatrics, don't miss the pediatric breakout sessions including "Hematopoietic Stem Cell Transplantation for Pediatric Nonmalignant Disorders" with Kanwaldeep Mallhi, M.D., and "Survivorship Care for Pediatric Hematopoietic Cell Transplant Survivors" with Eric Chow, M.D., M.P.H.

View the full course brochure by clicking

#### Interested in Sponsoring?

If you are interested in becoming a sponsor for this conference, please email Angie Dahl at angiedahl@asbmt.org.

# ASSOCIATION NEWS (CONTINUED FROM PAGE 9)

#### **CRTC** Through the Eyes of an Instructor

by Carlos A. Ramos, M.D., Baylor College of Medicine

This July, I was invited to participate as an instructor in the ASBMT Clinical Research Training Course (CRTC). This

opportunity was unique for me because I attended the first CRTC in 2007 as a scholar.

This year, 12 scholars and 10 faculty members from across the transplant spectrum gathered in Charlotte, North Carolina,



to review the principles of translational and clinical research. Each scholar brought a clinical research project to present to the group, and all participants discussed and further dissected these projects in small groups that met throughout the course, with the intent of enabling each scholar to use the feedback to refine the proposed clinical trial. Throughout the course, scholars also attended short talks on clinical and statistical aspects pertaining to the field of hematopoietic stem cell transplantation, including design of clinical trials, the history of blood and marrow transplantation (BMT), choice of conditioning regimens, challenges in graftversus-host treatment, new targeted therapies, and recently developed immune cell therapies, the latter being the topic of my talk this year.

When I attended the first event in 2007, I was about to transition from being a fellow to becoming an attending physician and I had an amazing experience, with a few aspects of the course still standing out in my memory. First, I remember the thrill of having unimpeded access to leaders of the field in a collegial atmosphere. We are often told as trainees that meetings such as the American Society of Hematology are major opportunities for networking. While this may be true, a major national meeting is not necessarily an easy

occasion to strike up a conversation with people whom you have never met before. In contrast, this course provided an incredible opportunity for networking and sharing ideas. We are a small field, and I have continued to interact regularly with many of the faculty (and scholars) whom I met during the course. Many of them have contributed to my academic career progression.

Second, I recall how reassuring the course was, especially for someone who was about to take his first independent steps in the field. It was comforting to learn that grant applications are not always successful, that life can take you places other than those that may professionally make the most sense, or that one's professional path is not always as linear as one might assume by reading a CV.

Finally, free from being distracted by other duties, I was able to give my undivided attention to lectures on exciting, current topics in BMT given by leaders in the field. In the process, I learned several important aspects of clinical trial design and statistics, which are subjects seldom addressed during our clinical training in fellowship.

Being on the other side this time, I was struck by how remarkable this class of scholars was. I was extremely impressed by how they ran with our suggestions and incorporated them along with their new ideas into their initial projects. At the end of the course, the scholars presented revised versions of their clinical trials, and it was fantastic to see how much they had improved.

I thoroughly enjoyed participating in the course both as a scholar and now as faculty. Many good things have happened to me in the 10 years since I attended the course for the first time. As I mentioned to the scholars this year, I am sure this course was instrumental in many aspects of that journey.

# ASSOCIATION NEWS (CONTINUED FROM PAGE 10)

#### **Pharmacy SIG Literature Updates**

by LeAnne Kennedy, Pharm.D., BCOP, CPP, FHOPA, Chair, ASBMT Pharmacy SIG

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. Starting with this month's *ASBMT eNews*, you will receive a link to the monthly literature summaries: <a href="http://asbmt.org/about-us/special-interest-groups/pharmacy-sig#Lit">http://asbmt.org/about-us/special-interest-groups/pharmacy-sig#Lit</a>.

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.

## SIG Spotlight: Transplant Nursing Special Interest Group

by Chris Rimkus, APRN

Nursing educational sessions have been held during the Tandem Meetings since 1999. Co-chairs and Planning Committee members originated from what was previously known as the Oncology Nursing Society's (ONS) Blood and Marrow Stem Cell Transplant Special Interest Group (SIG) with strong administrative support from the national ONS. At that time, many of the co-chairs and Planning Committee members were also affiliate members of ASBMT. The nursing presence at the ASBMT Tandem Meeting grew exponentially over the years, causing the ASBMT leadership to recognize nursing as a very important player in the transplant process. In 2009, the ASBMT reached out to representation from nursing across the country to see if they would be interested and willing to start a SIG focused on nursing issues.

#### **Purpose of the Nursing SIG**

The purpose of the ASMBT Nursing SIG is to give nurses a voice in the ASBMT, allowing them to be part of the organization and planning of events and activities within the society. The Nursing SIG will be governed by a steering committee, but all members can

participate in the events and activities.

#### Membership:

- is made up of nurses and non-nurses alike and
- is free with the ASBMT membership fees- just email the membership link and you will be made a member.

#### Benefits of membership include:

- Connecting with others within your specialty
- Participating in projects
- Opportunities to participate in ASBMT initiatives or committees
- Make your voice heard on changes and needs assessment for blood and marrow transplantation (BMT) nurses

#### Planned goals for 2017-2018 include:

- Expand membership to nurses across the country, particularly staff nurses
- Collaboration with the European Blood and Marrow Transplant Group on special projects

# ASSOCIATION NEWS (CONTINUED FROM PAGE 11)

# SIG Spotlight (continued from page 11) Meet your leaders of the SIG

Current ASBMT Nursing SIG Chair: Chris Rimkus (crimkus81@hotmail.com): I have worked in BMT since 1988 and have been involved with the ASBMT Nursing SIG since its inception. I am very passionate about best practices in BMT. My hope for this SIG is that we can bring nursing together to improve practices, showing the BMT community what nursing can bring to the table to improve the day-to-day care of BMT patients. Nurses are the front line of care and have tremendous insight that can help improve quality and even affect outcomes.

Current ASBMT Co-Chair Suni Elgar (selgar@seattlecca.org): I am proud to be in my 15<sup>th</sup> year of transplant nursing. I am the manager at the Seattle Cancer Care Alliance outpatient BMT clinic. My vision for the SIG is to grow nursing representation in ASBMT by highlighting the essential components of partnership between nurses and other health care professionals in the care of BMT patients and their families

We welcome collaboration with other SIG's. Feel free to connect with any of the nursing SIG steering committee members via email – we welcome your thoughts and ideas. Our website can be found here.

#### In Memoriam - Johannes Joseph ("Jon") van Rood, Founder of Donor Associations

Professor Johannes Joseph ("Jon") van Rood, the founding father of Bone Marrow

Donors Worldwide, died July 21 in Leeuwarden, Netherlands. He was 91.

His scientific and managerial work helped to shape immunogenetics, transplantation

immunology and global cooperation in unrelated hematopoietic stem cell transplantation for 60 years.

Until the mid-1960s, transplant surgeons matched kidney donor and patient mainly by blood type. Patients had to wait until a suitable donor was found in the center where they were treated. Van Rood obtained evidence that the human leucocyte antigen (HLA) system plays an import role in the outcome of renal transplantation. Matching of the HLA-type of donor and recipients led to superior graft and patient survival. However, the number of HLA antigens was large, which made the probability of finding a donor with a matching tissue type for a particular patient low. This probability

will increase if a donor is offered to a central database of many patients in need for a transplant. For this reason, van Rood founded Eurotransplant in 1967.

He also co-founded the World Marrow Donor Association, Europdonor (now known as Matchis), the European Society for Blood and Marrow Transplantation and the European Federation for Immunogenetics.

"I have known Jon since 1983," said ASBMT Board Member James Gajewski, M.D. "I always considered him a great friend and mentor to so many of the field. His work on histocompatibility and establishing the Dutch donor registry was vital. We lost one of the great founding fathers of our field."

Van Rood received many awards including the Robert Koch Prize and the Wolf Prize in Medicine, and he was a member of the Royal Netherlands Academy of Arts and Sciences.

To read more about his life's work, <u>click</u> <u>here</u> and <u>here</u>.

# LEGISLATION & REGULATION (CONTINUED FROM PAGE 8)

#### **Help Protect Access to Life-Saving Transplants for Medicare Patients**

The National Marrow Donor Program/Be The Match, in partnership with ASBMT, has worked extensively with the Centers for Medicare & Medicaid Services (CMS) to address the serious patient access issue of inadequate reimbursement for stem cell transplant (SCT).

The current reimbursement rate for allogeneic transplants (MS-DRG 014) does not cover the true cost of SCT. The fiscal year 2018 reimbursement rate for an allogeneic transplant is almost \$65,000, which includes donor search and cell acquisition costs (approximately \$48,000 for bone marrow or peripheral blood transplant, and \$65,000 for cord blood transplant). This payment policy leaves transplant centers with very few dollars remaining to cover services, supplies, drugs, and other items for patients throughout the average 27-day post-transplant hospital stay.

These financial losses incurred by transplant

centers who treat over 1,200 Medicare patients each year could result in serious access issues for Medicare patients. Patients who are denied access to transplant will face expensive, likely futile alternative treatment options. And, in most cases, transplant is their only option for survival.

This is where the transplant community needs your help. Congressional partners are planning to propose legislation that would require CMS to align payment policy for SCT with solid organ transplant and separate donor search and acquisition costs from the MS-DRG payment.

Please contact your members of Congress today! Urge them to support legislation to reform Medicare payment policy for bone marrow, peripheral blood stem cell and cord blood transplants. Visit BeTheMatch.org/cms to submit a letter today.

# **FACT UPDATE**

## **FACT Accreditation Used as Criterion in Best Hospitals List**

U.S. News and World Report released its 2017-2018 Best Hospitals List, and FACT accreditation was again used as a ranking criterion for the cancer specialty. Since 2007, accredited programs receive a point value based on their accreditation. One point was given if accreditation was only for autologous

transplants, and two points were given if accreditation was for allogeneic transplants. All 50 hospitals with rankings in the cancer specialty have programs that are FACT-accredited. Congratulations to these programs! View the list of best hospitals in the cancer specialty.

#### **FACT Webinar: Patient-Centered Care Coordination in HCT**

Want to learn more about patient-centered care coordination in hematopoietic cell transplantation (HCT)? Join FACT for a live webinar presentation on Sept. 20 at 11 a.m. ET. Nandita Khera, M.D., M.P.H., of the Mayo Clinic Arizona, and Patricia Martin, RN, BSN, of WellPoint Inc., will explain why care coordination is important for the HCT

community. Presenters will highlight the benefits and metrics of effectiveness of care coordination, introduce the care coordination toolkit and identify the key components of the proposed framework.

View webinar details and register here.

Continues on page 14

# FACT UPDATE (CONTINUED FROM PAGE 13)

#### **FACT Webinar** (continued from page 13)

Blood Advances, a journal of the American Society of Hematology, published a manuscript authored by the webinar presenters and others titled "Patient-centered care coordination in hematopoietic cell transplantation" (Khera, Martin, et al, 2017). The article describes a care coordination framework for patients treated

with HCT within the context of coordination issues in care delivery and stakeholders involved. The article also outlines challenges, ongoing efforts to raise awareness, and potential policy changes around appropriate reimbursement to cover all aspects of care coordination. Read full article

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

FACT and JACIE published the draft 7<sup>th</sup> 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 7<sup>th</sup> edition Standards will be published in March 2018 and become effective at the end of May 2018.

## **FACT Allied Learning Center**

FACT's Allied Learning Center, a collaborative effort between FACT, AABB, ASBMT, the American Society for Apheresis, American Society of Gene and Cell Therapy, American Society for Histocompatibility and Immunogenetics, College of American Pathologists, Cord Blood Association, Food and Drug Administration, International Society for Cellular Therapy, National Marrow Donor Program/Be The Match, PACT, World Marrow Donor Association-NetCord, Save the Cord Foundation, and Society for Immunotherapy of Cancer provides a centralized resource for organizations to quickly and easily obtain

online modules applicable to their operations and training needs. The Allied Learning Center is updated quarterly with new events.

FACT encourages accredited organizations to utilize these educational activities to maintain knowledge of industry practices and regulations. Many of these sessions may be used to meet FACT requirements for continuing education. The sessions listed in the Allied Learning Center are in addition to the FACT educational program, including <u>live events</u> and <u>on-demand events</u>.

Explore the Allied Learning Center.

# CLINICAL RESEARCH (CONTINUED FROM PAGE 1)

## **Upfront Autologous Transplant** (continued from page 1)

chemotherapy and lenalidomide. Four years after treatment, survival was more likely for the transplantation recipients than the chemotherapy recipients, regardless of prognosis. Progression-free survival 1 was 42 months for transplant recipients vs. 24 months for the chemotherapy group. In addition, progression-free survival 2 was 71% for the transplant group vs. 54% for the chemotherapy cohort, and overall survival was 84% after transplantation vs. 70% following

chemotherapy and lenalidomide. Only 53% of the patients who relapsed after chemotherapy received a salvage transplant. The researchers determined that upfront autologous transplantation was more likely to reduce the risk of death than salvage autologous transplantation. The researchers concluded that these study results confirm that upfront autologous transplantation should be the standard approach for young myeloma patients. More...

#### Relapsed Aggressive B-Cell Non-Hodgkin Lymphoma and Rituximab Dosing

A long-term study comparing doses of rituximab found that there were no survival differences between standard and high doses of the drug when used with carmustine, cytarabine, etoposide and melphalan (BEAM) and autologous cell transplantation for relapsed aggressive B-cell non-Hodgkin lymphoma. The phase 2 study published in the *British Journal of Haematology* looked at data from 93 patients randomly assigned to the high- or standard-dose group. The researchers discovered that the five-year disease-free survival was 40% and the five-year overall survival was 48% with no

statistically significant differences between the two doses. Disease status and the number of prior treatments were the only factors that played a role in worse survival outcomes. Patients who had transplantation during complete remission or who received less than three prior treatments had better five-year overall survival, regardless of the rituximab dose. The researchers concluded that these study results indicate there is no advantage to using a high dose of rituximab over a standard dose. More...

## TRANSLATIONAL SCIENCE STUDIES

#### Single T-Cell Receptor Editing Treats Multiple Myeloma

A new study published in *Blood* indicates that a NY-ESO-1 T-cell receptor (TCR) single editing approach quickly produces high numbers of tumor reactive T cells, treating multiple myeloma without inducing graft-versus-host disease (GVHD). The researchers based the single editing method on disruption of the endogenous TCR  $\alpha$  chain, followed by the transfer of genes encoded for a tumor-specific TCR. Single editing allowed optimal TCR expression and preferential stem memory and central memory phenotype. Similar to unedited T cells redirected by TCR gene transfer, single

edited T cells killed NY-ESO-1<sup>pos</sup> targets. TCR transferred cells were highly alloreactive, but single edited cells had a better safety profile. As a result, when the single edited cells were infused into mice with multiple myeloma, tumor rejection occurred without GVHD. This led to higher survival rates for the mice that received the edited cells vs. those that were treated with TCR transferred cells. These study results led researchers to conclude that single TCR gene editing is a clinically feasible approach that increases the safety and efficacy of cancer adoptive immunotherapy. More...

## Researchers Develop Genetically Accurate Models of CMML and JMML

Researchers of a study appearing in *Blood* have developed genetically accurate preclinical models of chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML). Using immunocompromised mice with transgenic expression of human granulocyte-macrophage colony-stimulating factor, interleukin-3 and stem cell factor in a NOD/SCID-IL2Ry<sup>null</sup> background, researchers conducted xenotransplantation of CD34<sup>+</sup> cells, unfractionated bone marrow or peripheral blood mononuclear cells derived from 18 patients. This resulted in engraftment of CMML in the bone marrow, spleens, livers and lungs of 82 mice. Comparable results were seen with

secondary transplantation, which demonstrated the resilience of CMML grafts and confirmed that CD34<sup>+</sup> cells harbor the disease-initiating compartment in vivo. The researchers also successfully engrafted JMML primary samples into 12 mice. Engraftment of both types of leukemia led to overt phenotypic abnormalities and lethality in recipients, which facilitated evaluation of the JAD2/FLT3 inhibitor pacritinib in vivo. According to the researchers, the data from this study demonstrate that mice support the development of CMML and JMML disease-initiating and mature leukemic cells in vivo. More...

## Innate Lymphoid Cell and Interleukin-22 Deficiency Associated With GVHD

Mice with graft-versus host disease (GVHD) experience intrathymic group 3 innate lymphoid cell (ILC) loss, causing interleukin-22 (IL-22) deficiency, which worsens thymic epithelial damage. Therefore, administering IL-22 after allogeneic bone marrow transplantation can enhance thymopoiesis, reports a study from *Blood*. While mice with GVHD had depleted thymic ILCs and IL-22, mice without GVHD did not. The researchers also discovered that preventing IL-21 receptor signaling in donor T cells and the elimination of thymic ILCs improved thymopoiesis in an IL-22-dependent

manner. They also found that the thymopoietic impairment in GVHD associated with loss of ILCs could be improved by restoring IL-22 signaling. Despite uninhibited alloreactivity, exogenous IL-22 administration after transplantation led to better recovery of thymopoiesis and development of new thymusderived peripheral T cells. The researchers concluded that manipulation of the ILC-IL-22-TEC axis may be useful for improving immune reconstitution after transplantation and other T-cell deficiencies. More...

## **CALENDAR OF EVENTS**

#### SEPTEMBER

**European Society for Medical Oncology** 

ESMO 2017 Congress September 8-12 Madrid, Spain

# Canadian Blood and Marrow Transplant Group

"Pre- and Post-Transplant Issues in BMT" Themed Meeting Series September 9-10 St. John's, Newfoundland, Canada

# American Society for Histocompatibility & Immunogenetics

43<sup>rd</sup> Annual Meeting September 11-15 San Francisco, California

#### **European School of Haematology**

3<sup>rd</sup> International Conference on New Concepts in Lymphoid Malignancies September 15-17 Mandelieu, France

# **Canadian Blood and Marrow Transplant Group**

"Psychosocial Aspects of HSCT" webinar September 20

#### **ASBMT**

Corporate Council Meeting September 24-25 Fernandina Beach, Florida

#### •OCTOBER

#### **Histiocyte Society**

33<sup>rd</sup> 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

#### OCTORER

# International Society of Paediatric Oncology

49<sup>th</sup> 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

#### **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

#### November

#### **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

44<sup>th</sup> Annual Meeting March 14-16 Washington, D.C.

#### Regenerative Medicine Workshop

March 21-24 Isle of Palms, South Carolina

#### **National Comprehensive Cancer Network**

23<sup>rd</sup> Annual Conference March 22-24 Orlando, Florida