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Perspectives

By Robert Soiffer, MD

I had my right hip replaced a few months ago. The cartilage there was essentially gone, and the bone on bone apposition led to my hobbling around. I wish I could say this developed because of my elite athletic activities. Alas, I cannot say this was a consequence of multiple marathons, IRONMAN competitions, or mountain climbing in the Himalayas. It probably cannot even be attributed to wild dancing at the TCT Meetings of ASTCT and CIBMTR (formerly BMT Tandem Meetings) parties. I think I must chalk my joint deterioration up to age. Getting older is a fact of life, one that is hard to escape, but a fact we must all address. This is no less



true in the field of transplantation and cellular therapies. At our center, we are performing transplants in patients well into their 70s, and several centers go beyond that age. Today, most Americans (not all) are aware of the importance of diet, exercise, and smoking avoidance, and many senior citizens are quite fit. We have all heard that 60 is the new 40 and 70 the new 50, etc. Social Security actuarial tables indicate that a 72-year-old woman has a median life expectancy of more than 15 additional years, so it is no wonder they are often offered potentially life-saving / extending cellular therapies. This is a remarkable evolution in our field. Most of us (particularly the "senior" citizens among us) remember when a

patient above age 35 or 40 would never have been considered a candidate for BMT. With reduced intensity conditioning and improved supportive care, upper age limits have continuously been raised, and results have been gratifying for many patients.

Now this does not mean that every septuagenarian with a blood cancer should have a transplant. There is a wide variation in functional capacity in this population, and many patients who appear fit superficially can face significant problems, particularly with GVHD, tolerability of immune suppressive medication, and consequences of altered drug metabolism. We need to have a more refined understanding of how older patients will handle transplant, rather than simply assessing crude tests like Karnofsky scores. At our center, Dr. Gregory Abel partnered with our geriatric colleagues to study older individuals with hematologic malignancies receiving conventional non-transplant therapy. They identified that activity of daily living dependency, cognitive impairment, and reduced gait speed are all associated with inferior survival. Small functional studies were also reported in older transplant recipients. Now the CIBMTR through the BMT CTN (1704) is undertaking a comprehensive effort to tackle this issue with the prospective CHARM (Composite Health Assessment Risk Model) study. At baseline, standardized Geriatric Assessment tools incorporating subject reported data and bedside testing will be collected. HCT-Comorbidity Index scores will be assigned. and C-reactive protein and albumin will be measured locally. Serial measures at 3, 6, and 12 months for frailty, skilled facility admission, and quality of life using PROMIS measures for physical function, depression, and anxiety will be determined. As many as 1,100 older patients will be accrued over 3 years. The study is scheduled to begin shortly, and I encourage all centers to participate if possible. Data gathered through this effort will be invaluable in helping us set expectations for patients, counsel wisely as to treatment options, and obtain critical biologic insights.

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Health Services and International Studies Working Committee



Nandita Khera, MD, MPH



Shahrukh K. Hashmi, MD, MPH



William Wood, MD, MPH

In 2013, the CIBMTR's Health Policy / Psychosocial Issues WC and the International Studies WC merged to form the Health Services and International Studies (HSIS) WC. The goal of this committee is to help improve the practice and outcomes of HCT through health services research worldwide. This committee brings together an enthusiastic and diverse global group of HCT investigators representing varied clinical and research backgrounds. One of the current co-chairs works for an international transplant center, which helps to evaluate studies in developing countries. This committee's study portfolio includes population-based studies seeking to better understand health disparities in access to and outcomes of HCT, practice patterns in HCT, and the impact of HCT-related variables and social determinants on outcomes other than survival, such as costs and health care utilization. To complete some of these studies, the committee not only queries the CIBMTR database but also links it to other large databases both within and outside the US. In addition, the WC strives to ensure quality registry data by understanding gaps in follow-up and lead efforts to improve international data collection. To help tackle an important issue pertaining to outcomes, healthcare delivery or global health research within the arena of HCT, attend the TCT Meetings of ASTCT and CIBMTR in February 2020 to see this committee in action.

In the last 5 years, the committee published 12 papers, which can be viewed on the HSIS WC website.

The current HSIS WC portfolio contains 7 active studies:

- HS14-01 Investigating clinical outcomes and inpatient health care resource utilization of hematopoietic cell transplantation for children with acute leukemia
- HS15-01 Who is lost to follow-up in the Center for International Blood and Marrow Transplant Research (CIBMTR) registry?
- HS15-02 Impact of socioeconomic status on pediatric stem cell transplant outcomes
- HS16-01 Trends in utilization and outcomes of autologous and allogeneic hematopoietic cell transplantation in racial and ethnic minorities
- HS16-02 The impact of marital status on hematopoietic stem cell transplant recipient outcomes: A surrogate for consistent caregiver
- HS16-03 Relationship of race / ethnicity and survival after single and double umbilical cord blood transplantation
- HS17-01 Association of community health status and center survival for alloHCT

For more information about these studies, visit the HSIS WC webpage.

The strength of the HSIS WC is its collaboration with many societies and organizations in areas of health policy, health care delivery, and global health. The HSIS WC works closely with the CIBMTR Health Services Research Program operated by NMDP/Be The Match's Patient and Health Professional Services department. The Health Services Research Program typically conducts investigator-initiated studies that require expertise and resources beyond those usually needed for CIBMTR studies. Recently the HSIS WC partnered with the Brazilian Society of Stem Cell Transplantation to perform joint studies pertaining to HCT-related health services in Brazil. Other international collaborations are also ongoing. Investigators, from both within the US and globally, are highly encouraged to consider proposing studies to committee, especially those which can help achieve worldwide impact.

Committee Leadership

Co-Chairs:

Nandita Khera, MD, MPH, Mayo Clinic Arizona and Phoenix Children's Hospital, Phoenix, AZ

<u>Shahrukh K. Hashmi</u>, MD, MPH, King Faisal Specialist Hospital, Riyadh, Saudi Arabia

William Wood, MD, MPH, University of North Carolina, Chapel Hill, NC

Scientific Director:

Wael Saber, MD, MS

Statisticians:

<u>Ruta Brazauskas,</u> PhD <u>Naya He,</u> MPH, MS

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BMT CTN Publishes >100 Manuscripts

By Amy Foley, MA

The BMT CTN, with its 38 Core / Consortia Centers and approximately 75 Affiliate Centers, has now enrolled more than 10,700 patients. The Network was established in 2001 and is currently in its fourth grant cycle funded by the NHLBI and NCI.

BMT Clinical Trials:

The BMT CTN encourages widespread transplant community participation in all of its clinical trials. There are 10 trials open and 1 released to centers:

Rare and Non-Malignant Diseases

- 1502 CHAMP: Haplo HCT for Severe Aplastic Anemia
- 1503 STRIDE2: BMT vs. Standard of Care for Sickle Cell Disease
- 1507 Haplo HCT for Sickle Cell Disease

GVHD / Microbiome and immune Reconstitution

 1703 PROGRESS III: PTCy vs. Tacrolimus / Methotrexate for GVHD Prophylaxis

- 1801 Mi-Immune: Microbiome and Immune Reconstitution in Cellular Therapies and HCT (companion study to 1703)
- Two additional GVHD treatment studies are in development

HCT Donor Source

• 1702 Outcomes of Alternative Donor Allogeneic HCT

Prognostic Assessment for Older Patients

 1704 CHARM: Composite Health Assessment Model for Older Adults (mentioned in <u>Perspectives</u> above)

Leukemia, Lymphoma, and Myeloma Maintenance Therapy

- Alliance A051301 (BMT CTN 1201): DLBCL
- 1506 FLT3+ AML
- ECOG-ACRIN EA4151 (BMT CTN 1601): Mantle Cell Lymphoma
- SWOG S1803 (BMT CTN 1706): Multiple Myeloma

Cellular Therapies

 4 studies in development: NK Cell (1), CAR T Cell (2), and HIV-Specific T Cell (1)

If your center is interested in participating, please visit the **BMT CTN website**.

BMT CTN Publications

There are 102 BMT CTN published articles, including 28 primary analyses. The following manuscripts were recently published:

- **Bolaños-Meade et al. Three prophylaxis regimens (tacrollmus, mycophenolate mofetil, and cyclophosphamide; tacrollmus, methotrexate, and boftezomib; or tacrollmus, methotrexate, and maraviroc) versus tacrollmus and methotrexate for prevention of graft-versus-host disease with haemopoletic cell transplantation with reduced-intensity conditioning: A randomised Phase 2 trial with a non-randomised contemporaneous control group (BMT CTN 1203). Lancet Haematology. 2019 Mar 1; 6(3):e132-e143. https://www.ncbi.nlm.nih.gov/pubmed/30824040
- Levis et al. FET3 Inhibitor maintenance after allogeneic transplantation: is a placebo-controlled, randomized trial ethical? Journal of Clinical Oncology. 2019 Jul 1;37(19):1604-1607. Epub 2019 Apr 29. https://www.ncbi.nlm.nih.gov/pubmed/31034300
- Gooptu et al. Effect of sirolimus on immune reconstitution following myeloablative allogeneic stem-cell transplantation: An ancillary analysis of a randomized controlled trial comparing tacrolimus / sirolimus with tacrolimus / methotrexate (Blood and Marrow Transplant Clinical Trials Network / BMT CTN 0402). Biology of Blood and Marrow Transplantation. 2019 Jul 1. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/31271885
- **Ambinder et al. Allogenete hematopolette cell transplant for HIV patients with hematologic malignancies: The BMT CTN-0903 / AMC-080 trial.
 Biology of Blood and Marrow Transplantation. 2019 Jul 4. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/31279752

About the BMT CTN

The CIBMTR shares administration of the BMT CTN Data and Coordinating Center with NMDP/Be The Match and The Emmes Company. Together, these three organizations support all BMT CTN activities. The BMT CTN Steering Committee is currently under the leadership of Chair Rick Jones, MD (Johns Hopkins). Helen Heslop, MD (Baylor College of Medicine), is Chair-Elect, and Ed Stadtmauer, MD (University of Pennsylvania), is Vice-Chair.

To receive up-to-date information about BMT CTN studies, meetings, and news:



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^{**} indicates a BMT CTN primary results publication



The TCT | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR are the combined annual meetings of the ASTCT and CIBMTR. This has been North America's largest international gathering of blood and marrow transplant clinicians and investigators, laboratory technicians, advanced practice professionals, transplant nurses, pharmacists, administrators, and clinical research associates since 1999.

Global leaders in the field of transplantation and cellular therapy will present the latest developments February 19-23, 2020, during the TCT Meetings of ASTCT and CIBMTR at the World Center Marriott in Orlando, Florida. The scientific program will consist of 6 plenary sessions, 9 concurrent sessions, 96 oral abstracts, and 2 poster sessions.

NEW THIS YEAR! An additional plenary session has been added to Wednesday evening.

Scientific Program Toples and Special Sessions Include:

- Immunotherapy
- Alternative donor transplant
- Survivorship care in transplantation and cellular therapy
- · GVHD, health economics in BMT and CAR-T
- · Post-transplant relapse and infection
- · Barriers to transplantation and cellular therapy beyond HLA
- · International access to HCT drugs
- · Advances in microbiome
- CAR-T

The TCT Meetings of ASTCT and CIBMTR will also include the Mortimer M. Bortin Lecture, E. Donnell Thomas Lecture, Late Breaking Abstracts, CIBMTR Working Committee Meetings, ASTCT Special Interest Groups, and Meet-the-Professor Luncheon Sessions. Along with these state-of-the-art educational offerings, industry-supported satellite sessions, product theaters, and exhibitors will broaden the spectrum of presentations even further.

Parallel Sessions

In addition to an outstanding scientific program, the 2020 meetings offer parallel sessions for advanced practitioners, TCT pharmacists, center administrators, clinical research professionals / data managers, coordinators, electronic medical record and HCT software vendors, IT practitioners, IT decision makers, IT stakeholders, informaticians, investigators, medical directors, and transplant nurses.

Abstracts, Registration, and Housing

The abstract submission site will open in August with a deadline of October 3. Online registration and housing will open in early September. After registering, take advantage of special conference guest room rates offered at 1 of 8 hotels in the TCT Meetings of ASTCT and CIBMTR housing block. Don't forget to reserve your ticket to the Saturday evening TCT Meetings of ASTCT and CIBMTR Reception to end a memorable week with colleagues and friends!

Support Opportunities and Additional Information

Questions regarding support opportunities at the 2020 TCT Meetings of ASTCT and CIBMTR may be directed to the TCT Meetings of ASTCT and CIBMTR Conference Office: TCTMeetings@mcw.edu.

We look forward to seeing you in Orlando, Florida!

Join the Conversation: #TCTM20

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By Angela Hauck and Elleen Tuschi

Can you believe we have been using ServiceNow for 2 months to transform our operational productivity? The CIBMTR uses the ServiceNow Incident Management application to deliver a more transparent, flexible, and service-oriented experience for centers. The launch was successful with more than 2,700 tickets submitted. To date, we have closed 92% of our tickets.

Our goal is to increase customer satisfaction with a streamlined channel for support and the ability to grow with the organization. We have learned a lot over the past 10 weeks and are working on the next phase in which we will add more enhancements – such as optimal data retrieval as well as key performance indicators, metrics, and digital workflows – for the user and internal staff.

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SCTOD Center Outcomes Forum: TestIng Center Effects and Machine Learning Methods

By Carol Doleysh

The SCTOD is part of the HRSA-funded C.W. Bill Young Cell Transplantation Program that collects data on all allogeneic HCTs performed in the US and on transplants done elsewhere using cellular products that originated in the US.

Center Outcomes Forum

Preliminary recommendations from the Statistical Methodology Working Group about testing center effects and machine learning methods were presented at the 2018 Center Outcomes Forum. Final recommendations were added to Appendix C of the meeting summary. Complete materials are now available on the CIBMTR website.

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Five New Summaries for Patients

The CIBMTR recently revised the patient summary template to increase interest, engagement, and readability. Take a look at the new template by clicking on the summaries listed below.

Share the 5 new patient-friendly summaries of CIMBTR publications with your patients. Watch for new summaries on the <u>Study Summaries for Patients webpage</u>:



Patients, families and caregivers need transplant info

Blood and marrow transplant (BMT) is a highly complex treatment that can affect health for years afterward.

Read more



Medicines keep away both GVHD and cancer

Three medicines given after BMT work best, according to a clinical trial.

Read more



Better transplant strategies needed for bables

Transplant may cure disease but has side effects.

Read more



BMT may protect IQ in children with sickle cell disease

Blood or marrow transplant from an unrelated donor may preserve intelligence in children with sickle cell disease.

Read more



Doctors recommend a single autologous blood or marrow transplant followed by only lenalidomide maintenance, instead of more intensive treatments.

Read more

Summaries are created through a collaborative process. Each quarter, members of the CIBMTR's <u>Consumer Advocacy Committee</u> (CAC) select studies. A team from the CIBMTR and NMDP/Be The Match writes, reviews, designs, posts, and promotes the summaries; team members include a Medical Writer, a Senior Patient Education Specialist, Scientific Directors, and a Communications Specialist.

The CAC was created in 2005 to communicate CIBMTR research to the public and to provide patient and donor perspectives during the development of the CIBMTR research agenda. Many CAC members have personal experience as a donor, recipient, or family member.

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Mary Horowitz, MD, MS; Receives Aplastic Anemia & MDS International Foundation's First Lifetime Achievement in Science Award

By Liz Siepmann

The <u>Aplastic Anemia & MDS International Foundation</u> (AAMDSIF), the world's leading non-profit health organization dedicated to serving patients afflicted with bone marrow failure disease, presented its first Lifetime Achievement in Science Award to CIBMTR Chief Scientific Director, Mary Horowitz, MD, MS, at the Foundation's 35th Anniversary Luncheon and Awards Program on May 18, 2019. Dr. Horowitz was honored for the significant impact her work has had on stem cell transplant and hematologic malignancy practice worldwide.

Congratulations, Dr. Horowitz, on this honor!



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CIBMTR Senior Scientific Director to Present at 10 Summit

By Liz Siepmann

The Immuno-Oncology (IO) Summit will take place Aug. 5-9, 2019, in Boston, MA. CIBMTR Senior Scientific Director Marcelo Pasquini, MD, MS, will present "Patient Outcomes Tracking through Registries: Understanding the Role in Adoptive Cell Therapies, Present and Future" on Wednesday, Aug. 7 from 3-3:30 p.m.

Dr. Pasquini will discuss how the CIBMTR is partnering with Be The Match Biotherapies® to drive standardization across the cell therapy industry, including the registration and tracking of patient outcomes of adoptive cell therapies worldwide. The CIBMTR has built a Cellular Therapy Registry that accurately captures the nature, sequence, and effects of modern cellular therapies, including CAR-T cells. From this vantage point, the CIBMTR has a unique window into the adoptive cell therapy industry and evidence showing how such a database can be utilized to advance both academic research and industry research and development.

Learn more about this presentation by visiting the IO Summit website.

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CIBMTR Trivia

The CIBMTR represents a large network of centers that submit data for patients. Approximately how many centers submit their data?

A. 460

B. 550

C. 420

D. 390

<u>Enter your answer online</u>. If you answer correctly, you will be entered into a drawing to win a CIBMTR prize.

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Abbreviations

Need an acronym defined? Review our list of common abbreviations.

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CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program®/Be The Match® and the Medical College of Wisconsin

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