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November 2021 Newsletter

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Perspectives: A Different Kind of Buyer's Remorse

By John Wingard, MD

For the past decade, my wife and I have vacationed in the mountains. We love hiking, and the cool mountains offer a respite from the sweltering Florida summers; climbing heights higher than a highway overpass in the flattest state (yes, flatter than Kansas) still provides us thrills. Last week my wife and I finally decided to buy a house in one of our favorite mountain towns. We prepared the offer and as we signed the documents we were notified the seller had accepted another offer. We were filled with regret: The house seemed perfect, even more perfect than before we were rejected. Why had we not acted more quickly?



That regret was surely in my mind when I reviewed the list of 2020 CIBMTR publications, and it undoubtedly factored in my focus on a study about patients regretting their decision to undergo allogenic HCT.

I confess I had not given much thought to this dilemma. More commonly, patients and I commiserate about a decision to not go to transplant. For some of our patients, decisional regret regarding going to transplant is also a real thing.

In a prospective study by Cusatis et al.,¹ 184 adults completed the FACT-BMT questionnaire before and at 100 days and 6 and 12 months after transplant. The FACT-BMT questionnaire measures self-reports of five dimensions of quality of life; one item asks the subject if they felt regret about having the BMT in the past 7 days. In this study, 6-8 percent of patients reported regret at one or more time points after transplant. The authors noted this is likely an underestimate. An analysis of participants who did not complete the post-transplant questionnaires indicates a higher proportion with characteristics placing them at higher risk for regret.

When adjusted for multiple variables, only the baseline pre-transplant FACT-BMT score was associated with subsequent post-HCT regret. Of note, higher baseline scores of multiple FACT-BMT subscales were associated with a lower risk of regret, but the HCT-CI score was associated with a greater likelihood of regret.

Not surprisingly, those who relapsed after transplant were more likely to experience decisional regret. The risk for regretting transplant was 17.5% greater in patients who relapsed after HCT.

Surprisingly, chronic GVHD was not associated with regret. Multiple studies have shown associations between GVHD and poorer quality of life. What is going on there? One possible clue may be how patients cope with adversity. In a study by Bishop et al.,² an examination of coping strategies used by HCT survivors indicated that certain types of coping, including positive reframing, emotional processing, and emotional expression, were associated with more psychological growth. People think, "Yeah, having GVHD sucks, but at least I did not relapse or die. Either of those would surely be worse."

It is disheartening to disappoint our patients. We are wired to help, not frustrate. Are there things we can do?

The authors suggest confirming we are offering adequate education before transplant to ensure we do our best to set expectations properly. This seems sensible and could help. The authors also suggest that regret may be caused by guilt about the impact of their illness and treatment on their spouse or other significant other. Certainly, survivors and their partners experience HCT very differently. In studies by Bishop et al.,^{3,4} significant others of HCT survivors more frequently report negative changes after transplant than their spouses / survivors, often experiencing persistent anxiety and depressive symptoms long after transplant. These significant others also report less social support, dyadic satisfaction, and spiritual well-being as well as more loneliness than survivors. In contrast to survivors, significant others reported little post-traumatic growth. Providing more support to the significant others of our patients could ease the journey for both them and the survivors.

Clearly, decisional regret is a subject that bears more reflection.

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Infection and Immune Reconstitution Working Committee

Committee Leadership

Co-Chairs:

- [Miguel-Angel Perales, MD](#), Memorial Sloan Kettering Cancer Center, New York, NY
- [Roy Chemaly, MD, MPH](#), M.D. Anderson Cancer Center, Houston, TX
- [Christopher Dandoy, MD](#), Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Scientific Director:

- [Marcie Riches, MD, MS](#), University of North Carolina Hospitals, Chapel Hill, NC

Statistical Director:

- [Michael Martens, PhD](#), CIBMTR MCW

Statistician:

- [Naya He, MPH, MS](#), CIBMTR MCW

Infection is the primary cause of non-relapse mortality in the first 100 days post-transplant, accounting for 14-27% of deaths in pediatric and adult related, unrelated, and haploidentical donor transplants.¹ Infection remains a significant cause of mortality 100 days after allogeneic transplant as well, accounting for 6-14% of deaths. In autologous transplant recipients, infection accounts for 22-28% prior to 100 days and 1-5% after 100 days. However, transplant clinicians recognize that infection accounts for significantly greater morbidity in our patients. This burden of infection and its correlation with post-transplant immune reconstitution is the focus of our committee's efforts.

Notably, the burden of COVID-19 is not reflected in these numbers, although COVID-19 remains at the forefront for all of us. The Infection and Immune Reconstitution Working Committee and the CIBMTR have reacted to the pandemic, rapidly implementing a form for data collection to assess the impact of COVID-19. The early data from the pandemic was presented at both the 2021 TCT Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR and the 2021 European Society for Blood and Marrow Transplantation Annual Meeting. This was followed by the rapid publication of one of the largest multicenter reports on the impact of COVID-19.² Ongoing analyses are underway, examining pediatric implications, race implications, the impact specifically on CAR T patients, and change over the course of the pandemic due to therapeutics and vaccines. Furthermore, members of this committee are leading the effort to prospectively assess the protection afforded to our patients following SARS-CoV-2 vaccination [[CIBMTR SC21-07 / BMT CTN 2101 COVID Observational Study](#)].

The committee recognizes that data collection for infections and immune reconstitution is complex and particularly demanding. In part, the significant effort required to document infection endpoints has contributed to underreporting biases evident in prior analyses. Given this complexity, we greatly appreciate the time data managers to share the high-quality data needed to understand and improve infection-related transplant outcomes. In addition to the data complexity, the statistical analyses are not straightforward due to the presence of multiple infections, the onset of infections at variable times following transplant, and the profound interaction between GVHD and infection. Our statisticians employ novel techniques to account for these interactions, and I refer you to a manuscript published by Soyoung Kim, PhD, in *Transplantation and Cellular Therapy* in February 2021, [Statistical Methods for Time-Dependent Variables in Hematopoietic Cell Transplantation Studies](#).

Despite the aforementioned challenges, our committee remains productive with several manuscripts published or in press, including:

- IN1701a: Goldsmith SR, Abid MB, Auletta JJ, et al. [Posttransplant cyclophosphamide is associated with increased cytomegalovirus infection: A CIBMTR analysis](#), *Blood*. 2021 Jun 10; 137(23):3291-3305. doi:10.1182/blood.2020009362. Epub 2021 Mar 3. PMC8351903.
- IN1701b: Singh AK, Dandoy C, Chen M, et al. [Post-Transplant cyclophosphamide is associated with increase in non-CMV Herpesvirus infections in acute leukemia and MDS patients](#), *Transplantation and Cellular Therapy*. In press.
- IN1701c: Mulrone CM, Bilal Abid M, Bashey A, et al. [Incidence and impact of community respiratory viral infections in post-transplant cyclophosphamide-based graft-versus-host disease prophylaxis and haploidentical stem cell transplantation](#), *British Journal of Haematology*. 2021 Jul 1; 194(1):145-157. doi:10.1111/bjh.17563. Epub 2021 Jun 14.
- Sharma A, Bhatt NS, St. Martin A, et al. [Clinical characteristics and outcomes of COVID-19 in hematopoietic stem-cell transplantation recipients: An observational cohort study](#), *The Lancet Haematology*. doi:10.1016/S2352-3026(20)30429-4. Epub 2021 Jan 19. PMC7816949.

In addition to the aforementioned COVID-19 studies, we have several other exciting studies in progress. Our first analysis using immune reconstitution data is underway. The form revisions in 2017 allowed better capture of antimicrobial prophylaxis, and a study examining this is ongoing. We have completed or nearly completed analyses examining the impact of post-transplant cyclophosphamide on bacterial and fungal infections as well as an analysis of *C. difficile* in our patients. Finally, an examination of infections following CAR T infusion is proceeding.

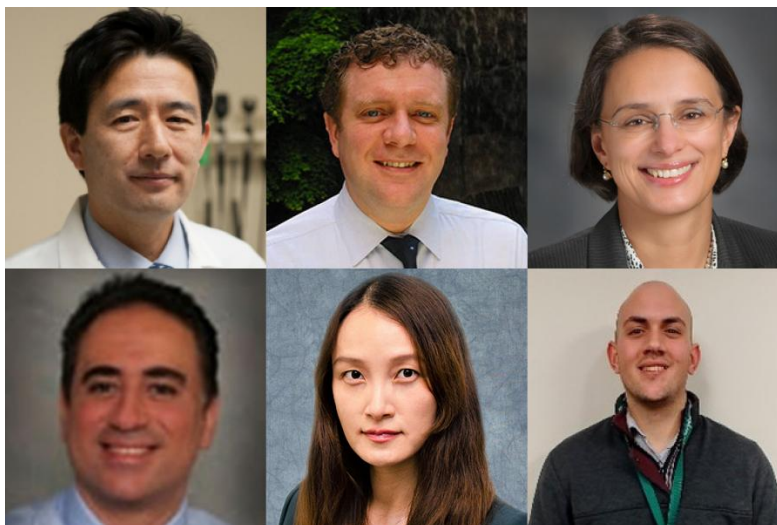
We welcome the input and participation of our working committee. The attendance to our committee continues to increase as do the number of proposals. We encourage continued participation and look forward to a robust and lively meeting at the 2022 Tandem Meetings of ASTCT & CIBMTR.

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1. Phelan R, Arora M, Chen M. [Current use and outcome of hematopoietic stem cell transplantation: CIBMTR US summary slides](#). 2020. Available at: <http://www.cibmtr.org>
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[Chronic Leukemia Working Committee](#)



Top row left to right: Ryotaro Nakamura, Bart Scott, Betul Oran

Bottom row left to right: Wael Saber, Soyoung Kim, Noel Estrada-Merly

Committee Leadership

Co-Chairs:

- [Ryotaro Nakamura, MD](#), City of Hope, Duarte, CA
- [Bart Scott, MD](#), Fred Hutchinson Cancer Research Center, Seattle, WA
- [Betul Oran, MD, MS](#), M.D. Anderson Cancer Center, Houston, TX

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The main goal of the Chronic Leukemia Working Committee is to help establish the optimal timing of HCT for patients with MDS, CML, CLL, and MPN as well as to improve HCT outcomes for such patients. As HCT is increasingly offered to older adults, many patients with a chronic myeloid / lymphoid disease are considered for HCT. During the past several years, the efforts of the committee resulted in several published manuscripts as well as both oral and poster presentations. The committee recently revised the MDS data collection forms to better capture

molecular and disease-specific data of prognostic importance. We also created a new separate series of forms for MPN disorders. In addition, these forms now also incorporate more recent novel therapies, which will help generate important future studies for the committee to pursue.

To help foster new study proposals, our committee not only provides our members with disease-specific lists of accepted studies but also with prior proposals that were not accepted and the rationale for the decision. This information allows investigators to better focus their new study proposals on concepts that are feasible and not redundant. A few of the recently published studies are described below.

CK17-02: Oran B, Ahn KW, Fretham C, et al. [Fludarabine and melphalan compared with reduced doses of busulfan and fludarabine Improves transplant outcomes in older MDS patients.](#) Transplantation and Cellular Therapy. doi:10.1016/j.jtct.2021.08.007. Epub 2021 Aug 14.

RIC regimens developed to extend the use of allogeneic HCT to older patients have resulted in encouraging outcomes. Led by Betul Oran, MD, MS, the Chronic Leukemia Working Committee compared the two most commonly used RIC regimens, intravenous fludarabine with busulfan (FluBu) and fludarabine with melphalan (FluMel), in older patients aged older than 60 with MDS. In this analysis, FluMel was associated with a reduced relapse incidence compared with FluBu although it was associated with a higher incidence of transplantation-related mortality. Because the magnitude of improvement with FluMel in RIC was greater than the improvement in treatment-related mortality with FluBu, disease-free survival was better at 1 year and beyond with FluMel compared with FluBu (48% versus 40% at 1 year [P = .02] and 35% versus 27% at 3 years [P = .01]). Overall survival was comparable in the 2 groups at 1 year but was significantly improved with FluMel compared with FluBu at 3 years (46% versus 39%; P = .03). Our results suggest FluMel is associated with superior disease-free survival compared with FluBu owing to reduced RIC in older patients with MDS patients.

CK18-01: Nazha A, Hu Z-H, Wang T, et al. [A personalized prediction model for outcomes after allogeneic hematopoietic cell transplant in patients with myelodysplastic syndromes.](#) Biology of Blood and Marrow Transplantation. 2020 Nov 1; 26(11):2139-2146. doi:10.1016/j.bbmt.2020.08.003. Epub 2020 Aug 8. PMC7609542.

Allogeneic HCT remains the only potentially curative option for MDS. Mortality after HCT is high, with deaths related to relapse or transplant-related complications. Aziz Nazha, MD, led a study identifying 1,514 MDS patients with peripheral blood samples sequenced for the presence of 129 commonly mutated genes in myeloid malignancies. A random survival forest algorithm was used to build the model identifying: age, TP53 mutations, absolute neutrophils count, cytogenetics per International Prognostic Scoring System-Revised, Karnofsky performance status, conditioning regimen, donor age, white blood cell count, hemoglobin, diagnosis of therapy-related MDS, peripheral blast percentage, mutations in RAS pathway, JAK2 mutation, number of mutations -sample, ZRSR2, and CUX1 mutations that impacted overall survival. This new model can provide survival probability at different time points that are specific (personalized) for a given patient based on the clinical and mutational variables listed above. The outcomes' probability at different time points may aid physicians and patients in their decision regarding HCT.

CK15-03: Gupta V, Kim S, Hu Z-H, et al. [Comparison of outcomes of HCT in blast phase of BCR-ABL1-MPN with de novo AML and with AML following MDS.](#) Blood Advances. 2020 Oct 13; 4(19):4748-4757. doi:10.1182/bloodadvances.2020002621. Epub 2020 Oct 2. PMC7556156.

Comparative outcomes of allogeneic HCT for *BCR-ABL1* MPNs in blast phase (MPN-BP) vs de novo AML, and AML with prior myelodysplastic syndromes (MDS; post-MDS AML), are unknown. Vikas Gupta, MD, led a study comparing HCT outcomes in 177 MPN-BP patients with 4,749 patients with de novo AML, and 1,104 patients with post-MDS AML, using multivariate regression analysis in two separate comparisons. The study showed that survival of MPN-BP after HCT is inferior to de novo AML in remission and post-MDS AML primarily due to increased relapse.

CK15-03: Gupta V, Kennedy JA, Capo-Chichi J-M, et al. [Genetic factors rather than blast reduction determine outcomes of allogeneic HCT in BCR-ABL1-negative MPN in blast phase.](#) Blood Advances. 2020 Nov 20; 4(21):5562-5573. doi:10.1182/bloodadvances.2020002727. Epub 2020 Nov 20. PMC7656913.

There is a limited understanding of the clinical and molecular factors associated with outcomes of HCT in patients with BCR-ABL1-negative myeloproliferative neoplasms in the blast phase (MPN-BP). Using the 59 of 177 MPN-BP patients with sufficient DNA for targeted next-generation sequencing of 49 genes clinically relevant in hematologic malignancies.

The study found no differences in the spectrum of gene mutations, the number of mutations, or variant allele frequency between patients undergoing HCT with PB/BM blasts <5% vs those with active leukemia. Genetic factors, namely cytogenetic alterations, and TP53 mutation status, rather than the degree of cytorreduction, predict outcomes of HCT in MPN-BP. No meaningful benefit of conventional HCT was observed in patients with MPN-BP and mutated TP53.

CK15-01: Gowin K, Ballen K, Ahn KW, et al. [Survival following allogeneic transplant in patients with myelofibrosis. Blood Advances.](#) 2020 May 12; 4(9):1965-1973. doi:10.1182/bloodadvances.2019001084. Epub 2020 May 8. PMC7218417.

Kristina Gowin, DO, MD, led this study analyzing overall survival in myelofibrosis patients treated with allogeneic HCT (551 patients) and without HCT (non-HCT) (1,377 patients). Survival analysis, stratified by the Dynamic International Prognostic Scoring System (DIPSS), revealed that the first year of treatment arm assignment, due to upfront risk of transplant-related mortality, HCT was associated with inferior overall survival compared with non-HCT. In conclusion, long-term overall survival advantage with HCT was observed for patients with Int-1 or higher risk MF but at the cost of early transplant-related mortality. The magnitude of overall survival benefit with HCT increased as DIPSS risk score increased and became apparent with longer follow-up.

Additionally, there are many ongoing studies. For MDS, our studies include the identification of germline predisposition mutations in young MDS patients (CK16-01) and the impact of donor age (CK18-03). We are also evaluating outcomes of HCT in patients with rare chronic leukemias, such as chronic neutrophilic leukemia (CK19-01b) and T-cell prolymphocytic leukemia (CK19-01a). We recently completed a project studying the impact of somatic mutations in chronic myelomonocytic leukemia (CK18-02). We are also working on myelofibrosis studies: on the development of a prognostic scoring system to predict HCT outcomes for myelofibrosis (CK17-01), and choice of conditioning regimen in MAC and RIC setting for myelofibrosis patients (CK20-01). Lastly, a recently accepted proposal evaluating the impact of donor type for myelofibrosis patients (CK21-01)

The committee welcomes new participants and new proposals. We also encourage collaboration with other committees and the use of outside data sets, which can better define the role and timing of transplantation as new non-transplan

t strategies emerge. We encourage young investigators to partake in the committee, which provides them an excellent opportunity to become familiar with novel study designs for observational research and the statistical methodologies utilized. The next in-person meeting of the Chronic Leukemia Working Committee is scheduled for February 2022 during the Tandem Meetings of ASTCT & CIBMTR in Salt Lake City, Utah. We look forward to seeing you there and welcoming new proposals.

View planned, in-progress, and completed studies and publications by visiting the [Chronic Leukemia Working Committee webpage](#).

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2022 Tandem Meetings

By Tia Houseman



The Tandem Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR (Tandem Meetings) are the combined annual meetings of the ASTCT and CIBMTR. Administrators, clinicians, data manager / clinical research professionals, fellows-in-training, investigators, laboratory technicians, MD / PhDs, nurses, nurse practitioners, pharmacists, physician assistants, and other allied health professional attendees benefit from a full scientific program that addresses the most timely issues in HCT and cellular therapy.

We are looking forward to hosting the 2022 Tandem Meetings of ASTCT & CIBMTR in-person at the Salt Palace Convention Center in Salt Lake City, Utah. To help provide a safe in-person experience, we have collaborated with CLEAR Health Pass. With CLEAR Health Pass your COVID-19 health screening is quick, easy, and secure for all on-site attendees, exhibitors, and staff. Attendees not able to travel will have access to a combination of live stream and on-demand sessions. Additionally, all registrants will have the opportunity to go back and view sessions

they may have missed during the meetings and receive continuing education credit up to 30 days following the meeting.

Scientific Program

2022 Scientific Organizing Chairs, Katharina Fleischhauer, MD, and Margaret MacMillan, MD, MSc, along with the scientific organizing committee and session chairs have assembled an excellent program. An outline of the topics is listed below. Throughout the 2022 Tandem Meetings, leading experts in the field of transplantation and cellular therapy from around the world will present the latest developments during plenary and concurrent sessions as well as via oral abstracts, posters, specialized tracks, and more.

Scientific Program Topics

- 50th anniversary of the CIBMTR: Building on the past to address the challenges of the future
- CAR T and beyond
- Cell and gene therapy -- HCT for sickle cell anemia: Donor selection, peri-transplant management and long-term follow-up -- safety focus
- The challenge of translating evidence into action in HCT
- Clonal hematopoiesis in allogeneic transplant donors: What it means, how it works, and what to do about it
- Disparities in cellular therapy
- Donor optimization
- GVHD: The next era
- Tissue stem cells, the microbiota, and GVHD
- Innate immunity: Friend and foe
- MRD and mechanisms of relapse / genetic manipulation to enhance immunotherapeutic response against myeloid malignancy
- Autologous stem cell transplantation for myeloma and lymphoma will be replaced by T-cell re-directing immunotherapies within the next 5 years – yes or no?
- Statistical issues in transplant and cellular therapy studies
- Treatment of respiratory viruses in HCT / cell therapy recipients
- Broad access to HCT worldwide: How has the WBMT advanced worldwide equity in 15 years?

Plus: Mortimer M. Bortin lecture, E. Donnell Thomas lecture, late-breaking abstracts, CIBMTR Working Committee meetings, ASTCT spotlight sessions, and Meet-the-Professor sessions, as well as industry-supported satellite symposia, product theaters, and exhibitors

Tracks

Confirmed tracks include: Administrative directors, advanced practice providers, BMT CTN coordinators, clinical research professionals / data management, clinical research professionals / data management onboarding, IT and informatics, nursing, pediatrics, and pharmacists.

Registration, Housing, and CLEAR

Registration is now open with the option to register as either an in-person attendee or virtual attendee. Once your registration is complete, you will receive information about how to book housing. In January, the Tandem Meetings will distribute information about the CLEAR Health Pass.

[REGISTER NOW](#)

Support Opportunities and Additional Information

Questions regarding support opportunities for the 2022 Tandem Meetings of ASTCT & CIBMTR may be directed to the Tandem Meetings Conference Office: TandemMeetings@mcw.edu.

We look forward to seeing you!

Follow [ASTCT](#) and [CIBMTR](#) on social media, as well as the official hashtag [#TandemMeetings22](#) for updates.

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[RCI BMT: Collaborating for the Highest-Impact Clinical Trials](#)

By Erin Leckrone, MBA

The **Resource for Clinical Investigations in Blood and Marrow Transplant** (RCI BMT) specializes in the design and oversight of transplant and cellular therapy clinical trials. Our focus is collaboration with organizations for the highest-impact clinical trials. The RCI BMT supports industry trials, academic consortium studies (BMT CTN and PTCTC), investigator-initiated studies, and studies under the oversight of the CIBMTR and NMDP/Be The Match.

Benefits of working with the RCI BMT include full-scale research operations, access to direct contact with patients and donors for research, synergies with Be The Match and Be The Match Biotherapies for end-to-end clinical trial design, operations, and logistics support. RCI BMT offerings include a built-out clinical infrastructure with a single Institutional Review Board, dedicated Data Safety Monitoring Board, master contracts, and 21 CFR 11 compliant technology.

RCI BMT currently supports a diverse portfolio of 28 active clinical studies, including 9 under investigational new drug (IND) / investigational device exception (IDE). Technology offerings include the Medidata suite of resources, including CTMS (trial management) and Rave (electronic data capture), as well as Florence eRegulatory for trial master files and site-facing electronic source binders. PROs are incorporated into 12 active protocols, many within the CIBMTR's electronic PRO system. In addition to more than 50 direct team members within project management, operations, monitoring, data management, and survey research, the RCI BMT is also supported by a robust team of physicians and experts within statistics, immunobiology, regulatory affairs, legal, and contracts. Please contact the RCI BMT for interest in future collaboration.

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[The Seminal 1102 MDS Study: Turning Evidence Into Practice](#)

By Amy Foley, MA

The BMT CTN 1102 study results were published in June,¹ showing a clear benefit of transplant and comparable quality of life for older patients with high-risk MDS over those who received standard of care therapy. Since the results were definitive, it stands to reason that referral patterns and the use of transplantation for this patient population will increase. However, study results don't necessarily translate into a change in practice (as examined for BMT CTN 0201).² That is why the BMT CTN Evidence into Practice Task Force was charged with assessing barriers to implementation, identifying key decision-makers, and disseminating the 1102 results as broadly as possible.

The task force, led by co-chairs Linda Burns, MD, and Nandita Khera, MD, MPH, took on this charge with vigor. First, they brought together a group of diverse stakeholders, including a payer representative and a patient advocate, and published a companion article to the primary results paper, addressing the challenges and opportunities in changing practice.³ They presented to patient advocacy groups, state oncology societies, and transplant teams. One such webinar, conducted in collaboration with the CIBMTR and NMDP/Be The Match, [The Case for HCT in the Treatment of MDS in Older Patients](#), is available on demand. Dr. Khera will present at the NMDP's ONE Forum this month. Additionally, the task force collaborated with others on written materials, including a [layperson summary of the results](#) written by the CIBMTR's Jen Motl, BS, RD, that the task force shared with advocacy groups on social media. The task force also supported a forthcoming article in the MDS Foundation fall newsletter, penned by 1102 Co-Chair, Ryo Nakamura, MD. From a policy perspective, the task force reached out to both ASTCT and NCCN to request an update to their practice guidelines. The task force will also collaborate with the CIBMTR and NMDP/Be The Match team that is submitting the 1102 results and other data to CMS to request that CMS cover transplantation for these patients.

Will these efforts work? The task force is hopeful their multi-pronged approach will result in more patients with high-risk MDS having access to transplant. To answer the question, they are planning a study evaluating transplant center referral volumes for MDS pre-and post-1102. Stay tuned for those results in early 2023.

P.S. For those of you who shared 1102 results with your teams, referring physicians, or others, please let us know! (@BMTCTN on Twitter; #EvidenceIntoPractice). If you'd like to request materials or speakers to share this message, please email Amy Foley at afoley@nmdp.org.

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.

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

Like us on Facebook: www.facebook.com/bmtctn

Follow us on Twitter: @BMTCTN

References

1. Nakamura R, Saber W, Martens MJ, et al. [Biologic assignment trial of reduced-intensity HCT based on donor availability in patients 50-75 years of age with advanced myelodysplastic syndrome](#). *Journal of Clinical Oncology*. 2021 Oct 20; 39(30):3328-3339. doi: 10.1200/JCO.20.03380. Epub 2021 Jun 9.
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[Carbapenems Linked with Acute GVHD in Children Who Have AML, ALL](#)

By Jennifer Motl

Elgarten et al.'s paper linking carbapenems with acute GVHD was selected as one of the top five practice-changing papers in transplant at the IDWeek conference, the premier meeting of infectious disease physicians.

Physicians should appreciate that carbapenems (meropenem, imipenem-cilastatin, and ertapenem) may increase risk of acute GVHD in children who have acute leukemia and are undergoing allogeneic HCT, according to the paper, published in the journal *Transplantation and Cellular Therapy*.

Elgarten's study included 2,550 patients, aged newborn to 21 years old, who underwent allogeneic HCT during 2004-2017. In adjusted models, carbapenems were linked with an increased risk of grade II-IV acute GVHD. Exposure to carbapenems, both before and after transplant, was problematic.

Evidence was strong. "Although retrospective analyses cannot definitively establish causality, the consistency of this association despite varying analytic approaches suggests that a causal association may exist," the authors wrote.

Citing previous studies, the authors hypothesized that carbapenems may upset the balance of flora in the microbiome and promote acute GVHD.

No link to acute GVHD was found with:

- Broad-spectrum cephalosporins (cefepime, ceftazidime, and ceftaroline)
- Aztreonam
- Antipseudomonal penicillins (piperacillin-tazobactam, ticarcillin-clavulanate)

Instead of carbapenems, researchers recommended other broad-spectrum antibiotics.

Keep in Mind

Patients who underwent an autologous HCT can still get carbapenems. Also, the study may not apply to children who have diseases other than leukemia. Finally, more studies are needed to prove causation.

Plain Language Summary

You may share a [plain-language summary](#) with patients and staff.

Reference

Elgarten CW, Li Y, Getz KD, et al. [Broad-Spectrum antibiotics and risk of graft-versus-host disease in pediatric patients undergoing transplantation for acute leukemia: Association of carbapenem use with the risk of acute graft-versus-host disease](#). *Transplantation and Cellular Therapy*. 2021 Feb 1; 27(2):177.e1-177.e8. doi: 10.1016/j.jtct.2020.10.012. Epub 2020 Dec 21. PMC7946150.

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[Immunobiology & Bioinformatics Research Team](#)

By Yung-Tsi Boion, PhD

Immunobiology & Bioinformatics Research



Newly created last fall, the Immunobiology Research and Bioinformatics Research teams joined forces under Director Yung-Tsi Bolon, PhD. Today, the team is composed of a diverse group of dedicated scientists and researchers spanning wet lab and computational backgrounds, united in the goal of saving patient lives.

On one end, the team manages the unique biorepository samples obtained from transplant patients and therapy sources and facilitates laboratory testing and quality control of the collected immunobiological data inventory. More than 250,000 pre-transplant samples from donors, recipients, and cord blood units were managed from ~200 centers, including donor centers, transplant centers, and cord blood banks. The associated immunobiology data are used in almost every CIBMTR study that explores transplant outcomes for patients, generating the knowledge we need to save and improve patient lives after transplant.

In addition to immunobiology-focused observational research conducted through the CIBMTR Immunobiology Working Committee, the team currently supports 14 BMT CTN and 3 RCI BMT clinical trial protocols and their associated correlative studies. More than 50 BMT CTN protocol-defined correlative or ancillary laboratory studies are also supported and monitored by the team. These efforts contribute to multiple research collaborations across teams both internally and externally.

Meanwhile, the team also leads bioinformatics research analyses and studies exploring the dimensions of matching (what, where, and how to match) patients and therapies using immunobiology data, whole-genome, and other omics data. These data are obtained from transplant patients and donors as well as the integration of clinical and other data from multiple platforms. Some of the omics analyses, registry and prediction modeling, and machine learning applications have contributed and continue to play a role in uncovering actionable ways that research can be put into practice. These studies and tools have been highlighted in the past and will also be shown in future editions of the [CIBMTR newsletter](#).

For example, the team created services and tools to improve the implementation of research guidelines and operational services for matching. These services and tools provide an early outlook for search prognosis and assistance in the selection of donors with HLA-B Leader assignments to facilitate the efficient selection of donors for best patient outcomes in different scenarios. More than 1,000 users in 40 countries across 6 continents accessed these tools in the first year or two of launch. In addition, more than 350 external and internal individuals utilized the Cryopreservation De-escalation COVID-19 application. The team developed and deployed this application during the pandemic for operational assessment regarding whether or not to freeze collected products ahead of shipment to transplant centers.

As an integral part of the full research and operations cycle, the Immunobiology and Bioinformatics Research team also recently welcomed three new members and looks forward to an exciting new year with the organization. Meanwhile, we also thank Alan Howard, PhD, for more than 20 years at NMDP/BTM, CIBMTR. With his retirement, a new Manager of Immunobiology Research position is anticipated to be posted soon.

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[New Self-Guided Data Manager Onboarding](#)

By Jillian Kissinger, BSN, RN

As of October 2021, CIBMTR Data Operations is pleased to offer a new self-guided onboarding option for data managers. The self-guided onboarding is a 10-week online course that is recommended for all new data managers. This course will help data managers succeed in their roles by understanding the data requirements of the CIBMTR, the functionality of the FormsNet3 application to submit data, basic information about the pathophysiology of several diseases, and key assessments used to track disease status for CIBMTR reporting. Additionally, there are two optional add-on tracks for primary data managers and cell therapy centers.

We recognize the importance of providing this education to all new data managers, which is why self-guided onboarding is available at no cost and may be accessed at any time. The course is divided into weekly schedules with eLearnings and assignments that can easily be incorporated into an organization's new hire orientation. Knowledge checks submitted along the way to ensure participants understand the presented material. Once the course is completed, data managers submit an evaluation form to provide their feedback and receive a certificate of completion.

To register for Self-Guided Data Manager Onboarding, and for more information about the course, please visit the [CIBMTR Portal page](#).

We will continue to offer the in-person onboarding option during the Tandem Meetings of ASTCT & CIBMTR each February as well as the live virtual option each September for data managers who would like additional hands-on experience. Participants should complete the self-guided onboarding prior to attending these options. For information about our in-person and virtual data manager onboarding, please visit the [CIBMTR website](#).

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[CIBMTR 2021 Facts and Figures](#)



The CIBMTR academic year [2021 Facts and Figures](#) document is now available to view on the [CIBMTR Administrative and Progress Reports webpage](#).

This document provides an annual summary of the CIBMTR's accomplishments in each research program, key publications, and high-priority initiatives.

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[SCTOD: Impact of the COVID-19 Pandemic on the Center-Specific Survival Analysis](#)

By Carol Doleysh

The SCTOD is part of the US Health Resources and Services Administration (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.

One of the important topics at the [2020 Center Outcomes Forum](#) was handling the impact of the COVID-19 pandemic in the center-specific survival analysis. Following recommendations from that meeting, recipients who developed COVID infection during their first year of follow-up were censored in the model for the 2021 analysis, which included HCTs during 2017-2019. Transplant centers were notified of this approach in May 2021. Results of the 2021 analysis are scheduled for public release in December 2021.

The CIBMTR is currently working to better understand the impact of COVID-19 on transplants performed in 2020 and is considering appropriate risk adjustments for the 2022 analysis.

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[AcCELLerate Forum, Upcoming Publications, and a New Year in the CIDR Grant](#)

By Carlos Litovich, MPH

This year's iteration of the cellular therapy meeting is a collaboration between the CIBMTR, NMDP/Be The Match, and ASTCT, titled, [AcCELLerate Forum: Creating a Sustainable Ecosystem of Cell and Gene Therapy](#). The virtual workshop is scheduled for November 18-19, 2021. This two-day, four-session forum packs an intensive agenda, coupled with ample opportunity to engage with our community and drive forward our work. The four sessions are:

- Cellular immunotherapy treatments as a standard of care: Clinical sites, professional societies, and industry collaboration to minimize redundancy
- Cellular immunotherapy reimbursement: Challenges and opportunities
- Cellular immunotherapy in the real world: Toxicity
- Future of cellular immunotherapy field

Please visit the [AcCELLerate Forum](#) webpage for more information.

In other exciting news, we recognize the work led by Mehdi Hamadani, MD, and all involved in the Cellular Immunotherapy for Cancer Working Committee study CT19-01 -- Allogeneic Transplant and CAR T Therapy After Autologous Transplant Failure in DLBCL: A Noncomparative Cohort Analysis. The important study was recently accepted for publication in *Blood Advances*. Additionally, Mazyar Shadman, MD, MPH, led the study LY20-01 - Autologous Hematopoietic Cell Transplantation versus Chimeric Antigen Receptor T-cell Therapy for Relapsed DLBCL in Partial Remission for the Lymphoma Working Committee, which was also accepted for publication in *Blood*.

As accrual nears 5,000 CAR T-cell patients, we wish to recognize the importance of our community. Without your support, including the centers that diligently submit data, we would not be able to do this great work. Thank you for your commitment!

As we start a new year in the CIDR grant, we continue to grow the CIBMTR cellular therapy database and make these data accessible to the community. We have identified the following initiatives to optimize the CIDR going into the fourth year of the grant:

- Expand data collection to solid tumors
- Complete the development of a data embargo tool to allow centers to embargo their clinical trial data for a specified time within the registry
- Expand CAR T-cell data collection in the pre-commercial setting
- Launch additional projects that include PRO collection
- Continue to collaborate on industry projects
- Develop strategies for the sustainability of the CIDR

We are excited to see our continued impact on the cellular therapy field as we continue to keep our mission at the forefront of our efforts. Again, this wouldn't be possible without your passion and commitment. Thank you!

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[Data Transformation Initiative Quarterly Community Meeting](#)

DTI continues to make large strides as we enter the final stretch of the 2021 calendar year. In September, DTI hosted its quarterly community meeting, which was attended by representatives from nearly 50 transplant centers. Participants saw a live demo of DTI's new data transfer process and had the opportunity to hear from data managers at The Ohio State University (OSU) Comprehensive Cancer Center.

Evan Morgan from OSU detailed some of the initial benefits of using the CIBMTR Reporting App. "[The CIBMTR Reporting App] integrates well into our Epic app. It streamlines CIBMTR Research ID (CRID) creation and allows for sharing demographic data," he shared. "When it comes to pulling lab values [into the 2400 and 2402], it's nice to have automation because it helps us reduce transcription error."

As we move forward, the DTI team is beginning to operationalize aspects of its work within the CIBMTR's Data Operations team. While the team continues to focus on optimizing the technology and recruiting new centers, DTI will also begin putting the data to work. To date, more than 75 people from the CIBMTR, NMDP/Be The Match, the Medical College of Wisconsin, and IQVIA have been involved in getting DTI off the ground. Their persistence, creativity, and expertise ensure that DTI is a valuable tool for transplant centers.

Sharing Your Research

By Jennifer Motl

These new plain-language summaries of CIBMTR research may help your patients:



Blood and marrow transplants (BMT) help people with advanced myelodysplastic syndromes (MDS)

Not enough people have access to life-saving transplant

Read more: [accessible](#) or [1-page version](#)



Second blood or marrow donation may have fewer cells

Some people who donate blood or marrow cells twice in 1 year may not be able to give as many cells the second time.

Read more: [accessible](#) or [1-page version](#)



Certain antibiotics linked with graft-versus-host disease

Carbapenems may seriously affect young people who have leukemia

Read more: [accessible](#) or [1-page version](#)



Young adults may need help returning to work after BMT

3 years after blood or marrow transplant, 60% of young adults are working

Read more: [accessible](#) or [1-page version](#)



More tests needed to show when BMT can help older people

Blood and marrow transplant is underused in people older than 60

Read more: [accessible](#) or [1-page version](#)

On the [Study Summaries for Patients webpage](#), you will find even more summaries.

Additional Research Datasets Available for Secondary Analysis

By Liz Siepmann

- ▶ COVID-19 Updates
- ▶ Quick Links
- ▶ Patient Resources
- ▶ Publication List
 - ▶ Publication Dataset Download
- ▶ Newsletters
- ▶ News Releases
- ▶ Slides and Reports
- ▶ Statistical Resources

Research Datasets for Secondary Analysis

The CIBMTR makes its publication analysis datasets freely available to the public for secondary analysis while safeguarding the privacy of participants and protecting confidential and proprietary data.

View the [Terms and Conditions](#).

Year	Publication	Author	Zip Download
2019	Survival outcomes of allogeneic hematopoietic cell transplants with EBV-positive or EBV-negative post-transplant lymphoproliferative disorder, a CIBMTR study.	Nalix Seema	Download
2019	Impact of cytogenetic abnormalities on outcomes of adult Philadelphia-negative acute lymphoblastic leukemia after allogeneic hematopoietic stem cell transplantation: A study by the Acute Leukemia Working Committee of the Center for International Blood and Marrow Transplant Research.	Aleksandr Lazaryan	Download
2019	Comparison of high doses of total body irradiation in myeloablative conditioning before hematopoietic cell transplantation.	Mitchell Sabloff	Download
2019	Maintenance tyrosine kinase inhibitors following allogeneic hematopoietic stem cell transplantation for chronic myelogenous leukemia: A Center for International Blood and Marrow Transplant Research Study.	Zachariah DeFilipp	Download
2019	Donor HLA-E status associates with disease-free survival and transplant-related mortality after non in vivo T cell-depleted HSCT for acute leukemia.	Chrysanthi Tsamadou	Download

In accordance with the [NIH Data Sharing Policy](#) and [NCI Cancer Moonshot Public Access and Data Sharing Policy](#), the CIBMTR is making publication analysis datasets publicly available on the [CIBMTR Research Datasets for Secondary Analysis webpage](#).

These publication analysis datasets are freely available to the public for secondary analysis. While providing these data, the CIBMTR is committed to safeguarding the privacy of participants and protecting confidential and proprietary data.

[NEW datasets are now available online.](#)

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Our Supporters

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Abbreviations

Need an acronym defined? Review our [list of common abbreviations](#).

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