May 2018 Newsletter

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Perspectives

By Robert Sciffr, MD

For >20 years, the CIBMTR and ASBMT have joined forces to hold their annual academic and organizational meetings together. The first joint ASBMT/IBMTR meeting occurred in 1995 in Keystone with about 500 participants. ASBMT and IBMTR apparently needed a little breathing room and agreed to a trial separation for a while but reunited in 1999 again in Keystone and have been going steady ever since. The two organizations initially held technically discrete meetings in one venue, one right after the other, in “tandem”, giving rise to the aptly named BMT Tandem Meetings. Most of us who attended those early meetings fondly remember the intimacy of these congresses as well as the opportunity to sneak away in the afternoon to go skiing. The membership and participation in both organizations expanded, and the meeting welcomed new attendees from other disciplines who play essential roles in our transplant teams, including nurses, physician assistants, pharmacists, administrators, donor search coordinators, nutritionists, and data professionals. We soon outgrew Keystone (much to the regret of many) and identified new venues to accommodate our swelling numbers. Registrations increased from 1,321 in 1999 to
>3,800 in 2018. Submitted scientific abstracts increased as well from 157 in 1999 to 739 this year.

More important than the size of the meeting is its scientific quality. Cutting edge basic, translational, and clinical research topics are presented in scientific symposia. Vibrant comprehensive educational sessions provide up-to-date information to guide clinical practitioners in every discipline. The disease specific Working Committees evaluate proposals from investigators throughout the world in order to develop practice changing studies leveraging the extraordinary CIBMTR Research Database and Sample Repository. Active participation in shaping these proposals is open to all attendees. The robust science presented at this year’s meeting has also prompted many biotech and pharmaceutical companies to actively engage with investigators to forge productive collaborations to develop and evaluate new therapeutics.

The success of these meetings can be credited to the remarkable dedication of the organizing committee comprised of international leaders selected by CIBMTR and ASBMT. This year, the scientific meeting was co-chaired by two of the most respected leaders in transplantation, Fred Appelbaum, MD, Fred Hutchinson Cancer Research Center, and Jerry Ritz, MD, Dana Farber Cancer Institute. Both have made indelible contributions to the field and influenced the careers of so many of our colleagues. Their insight, experience, and vision helped make this year’s meeting a rousing scientific success.

Despite the strides we have made and growth of our annual meeting, the BMT Tandem Meetings is riding off into the sunset, or at the least name is being retired. Indeed, only insiders know what “tandem” refers to. A new name has been selected that more aptly represents the breadth of our current scientific portfolio, particularly in light of the proliferation of engineered cellular therapies, including CAR T-cells, manipulated NK cells, Tregs, and viral specific T-cells. In 2019, the BMT Tandem Meetings will morph into the Transplantation and Cellular Therapy (TCT Meetings) Meetings. This may take some getting used to, and caution should be exercised as not to confuse TCT with the Transvascular Cardiovascular Therapeutics (TCT) annual meeting; the TCT in Kansas (Topeka Civic Theater); or TCT (comprised of members T.L., Comeetta, and Tiah), a Finnish rock band. I have every expectation that our TCT Meetings will continue to grow and provide the optimal venue to present and discuss the latest advances in transplantation and cellular therapy. We should all be proud of the meeting we helped create and continue to nurture.

See you in Houston, Texas, February 20-24, 2019. #TCTM19

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Steven Devine, MD, Joined NMDP/Be The Match

In March, Steven Devine, MD, joined NMDP/Be The Match as Senior Vice President and Senior Medical Director, Research Operations for the CIBMTR.

In this role, Dr. Devine serves as a critical member of the medical team and provides oversight of the CIBMTR Minneapolis research team, defining strategy and setting direction. In addition, he will have the responsibility of identifying, evaluating, and acquiring new business opportunities for the prospective clinical research program.

Before joining NMDP/Be The Match, Dr. Devine was Professor of Medicine and Director of Blood and Marrow Transplantation at Ohio State University Hospitals in Columbus, where he worked for the past 12 years. Prior to that, he held positions at Washington University in St. Louis, the University of Illinois in Chicago, and Emory University, Atlanta. He also served on the GVID Advisory Boards of Bristo-Myers Squibb and Incyte Pharmaceuticals, Kiadis Advisory Board, and Genzyme Advisory Board, as well as a member of the Boards of Directors of the National Cancer Institute (NCI) Alliance for Clinical Trials and ASBMT.

Dr. Devine brings a tremendous interest and track record in both government- and industry-sponsored BMT clinical trials. Currently he is chair of the NHLBI/NCI-sponsored BMT CTN. He also is Chair of the Transplant Committee for the Alliance, which is a member of the NCI’s National Clinical Trials Network. Dr. Devine’s CV lists 180 peer-reviewed publications and four book chapters.

Please join us in welcoming Dr. Devine.
CIBMTR is Hiring | Senior Manager Data Development

CIBMTR Milwaukee is actively recruiting an enthusiastic individual to manage the Data Development Team within Data Operations. This individual will:

- Work independently under the direction of the CIBMTR Data Operations Program Director;
- Manage the areas of data definition and development;
- Oversee training efforts, internal and external, associated with collecting high-quality data;
- Respond to clinical queries from Clinical Research Coordinators and the Audit Team;
- Collaborate with the Senior Manager of Data Capture and Senior Manager of Data Quality to ensure communication between teams;
- Work with the meeting team and oversee the agenda and implementation of the annual Data Management Meeting at the TCT Meetings;
- Collaborate with Scientific Directors and other clinical staff to coordinate clinical and operational data requirements.

The preferred individual will have clinical BMT experience as a nurse, nurse practitioner, or physician assistant.

If interested, please contact Janet Brunner-Grady, PA-C, at jgrady@mcw.edu or apply online.

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2018 BMT Tandem Meetings | Growth and Change

By Tia Houseman

We had 882 more attendees at the 2018 BMT Tandem meetings than the last time we met in Salt Lake City, 5 years ago! During Feb. 21-25, 2018, we welcomed more than 3,800 attendees from more than 40 countries. Countries with the highest representation, aside from the United States and Canada, were the United Kingdom, Netherlands, Germany, and Australia.

Those unable to travel to the BMT Tandem Meetings had the opportunity to participate via live stream and earn continuing education credits. Nearly 100 participants took advantage of this opportunity.

Program Co-Chairs Frederick Appelbaum, MD (CIBMTR), and Jerome Ritz, MD (ASBMT), along with the Scientific Organizing Committee, put together an excellent program this year of five plenary sessions and nine concurrent sessions. The meeting also included three breakfast symposia and five lunch symposia, 14 oral abstract sessions with 96 abstracts presented, nine product theaters, two poster sessions, 15 working committees, and eight Meet-the-Professor sessions. In addition to an outstanding scientific program, parallel sessions were held for clinical research professionals / data managers, BMT CTN coordinators, BMT CTN investigators, pediatrics, administrative directors, transplant nurses, pharmacists, and nurse practitioners.

Awards and Lectures

- The CIBMTR Distinguished Service Award was presented to Mahmoud Aljurf, MD, MPH, for his collaboration with his colleagues at the King Faisal Specialist Hospital and Research Centre to develop the HCT Unit. It is now one of the world's largest units for alloHCT (particularly for bone marrow failure) with current performance of 250 allogenic cases per year.
- ASBMT presented the Lifetime Achievement Award to A. John Barrett, MD, Chief of the Bone Marrow Stem Cell Allograft Transplantation Section of the Hematology Branch, National Heart Lung Blood Institute (NHLBI). As a Past President of the ASBMT, Dr. Barrett is an outstanding senior investigator with numerous contributions to BMT research for more than 30 years.
- Jeffrey W. Chell, MD, former Chief Executive Officer of NMDP and Executive Director of the CIBMTR, and Michael Boo, JD, former Chief Strategy Officer of NMDP were jointly presented with the ASBMT Public Service Award. Michael Boo identified and launched new products and services that had significant bottom-line revenue impact and developed new relationships within the extensive NMDP network of national and international partners,
which improved access to cell sources and markets worldwide. “Dr. Chell has had a transformative impact in the fields of BMT and cellular immunotherapy,” noted ASBMT President Krishna Komanduri, MD.

- Eliane Glucksman, MD, PhD, FRCP, and Emeritus Professor of Paris University, was selected for the 2018 CIBMTR Mortimer M. Borin Lecture and presented The Long Journey Toward HLA Mismatched Hematopoietic Stem Cell Transplantation.

- Robert S. Negrin, MD, 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 and presented The Ugly, The Bad and The Good of Allogeneic Transplantation.

Networking
Several networking opportunities were offered at the BMT Tandem Meetings, including two poster sessions, a networking reception in the exhibit hall, and the BMT Tandem Reception.

Growth and Change
We saw the most significant growth in meeting registrants when comparing 2017 attendance to 2018 attendance.

- The number of registrants grew by more than 350 between 2017 and 2018
- We had the second highest number of abstracts, with 739 submitted
- The number of attendees in the age group of 31-50 nearly doubled over last year
- Fellows represented 5% of the overall attendees, and 25 more than last year

To better align our name with the work we do, the BMT Tandem Meetings have been rebranded as the Transplantation and Cellular Therapy (TCT) Meetings of ASBMT and CIBMTR. This was announced during the opening remarks and displayed throughout the 2018 meeting.

See you in 2019!
Details on the 2019 TCT Meetings will be available in the months ahead. Questions regarding support opportunities at the 2019 TCT Meetings may be directed to Sherry Fisher, Director of Business Development for the CIBMTR. For general information, email TCTmeetings@mow.edu.

On behalf of the TCT Meetings Team as well as 2019 Scientific Organizing Chairs, Jane Apperley, MD, for the CIBMTR and Gay Crooks, MD, for ASBMT, we look forward to seeing you at the Hilton Americas in Houston, Texas, February 20-24, 2019.

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New VOD Risk Calculator Available

Veno-occlusive disease of the liver (VOD) is an uncommon, early complication of hematopoietic cell transplantation (HCT) that is associated with significant mortality.

The CIBMTR created a VOD Risk Calculator that provides a risk score to identify patients at high risk for VOD.


Immunobiology Working Committee

Committee Leadership

Co-Chairs:

- **Katharina Fleischauer, MD**, University Hospital Essen, Germany
- **Katharine Hsu, MD, PhD**, Memorial Sloan Kettering Cancer Center, New York, NY
- **Sophie Paczesny, MD, PhD**, Indiana University Hospital / Riley Hospital for Children, Indianapolis, IN

Scientific Directors:

- **Stephanie Lee, MD, MPH**, Fred Hutchinson Cancer Research Center, Seattle, WA
- **Stephen Spellman, MS**, CIBMTR Minneapolis

Statistical Directors:

- **Tao Wang, PhD**, CIBMTR Milwaukee

Statisticians:

- **Michael Haagenson, MS**, CIBMTR Minneapolis

The Immunobiology Working Committee (IBWC) is the largest Working Committee by study volume, and it addresses scientific questions about the association between genetic factors and successful transplantation outcomes. The committee welcomes studies that assess genes and gene products of the major histocompatibility complex, natural killer cell repertoire, cytokine / proinflammatory cytokine and immune-response determinants, minor histocompatibility loci, and other genetic factors.

The committee's studies also include comparisons of clinical outcomes from different donor types (e.g., mismatched related versus unrelated donors) and exploration of novel biostatistical and analytic approaches to investigate the impact of various HLA mismatches. In addition, the NMDP Research Sample Repository provides a unique resource for investigators conducting retrospective analyses of immune-response determinants and transplant outcomes. Currently, the Research Sample Repository contains samples from >42,000 unrelated donor / cord blood-recipient pairs and 6,300 related donor pairs for which complete clinical data have been collected and validated. Last year, the repository distributed >8,000 aliquots to investigators. Current inventory may be viewed on the Sample types and Inventory Summary webpage and requests for samples may
be submitted using the instructions on the How to Request Samples from the Research Sample Repository webpage.

For studies that examine the clinical role of the immune system in transplantation and do not require complete high-resolution HLA typing data and/or samples, the CIBMTR can provide clinical data on >46,800 HLA-identical sibling, 8,900 other-related, and 42,200 unrelated donor transplants. The IBWC currently lists 38 studies in progress, some in collaboration with other research organizations, such as the International Histocompatibility Working Group, EBMT, and Eurocord. Examples of ongoing studies include investigation of epigenetic changes prior to transplant, KIR content, algorithms for identifying non-permissive HLA mismatches, and the role of HLA-E mismatching in addition to classical studies of HLA associations with outcomes. IBWC publications may be viewed on the Immunobiology Working Committee Studies webpage.

The success of the committee depends on vibrant scientific interactions, new ideas and testable hypotheses, and participation by individuals with different perspectives and scientific backgrounds. Therefore, the IBWC encourages investigators to submit new and bold proposals. Study proposals may be submitted year-round on the How to Propose a Study webpage. Working Committee meetings convene annually at the TCT Meetings (formerly BMT Tandem Meetings), although other venues for interaction are also available. All investigators with an interest in immunology, immunobiology, and human genetics should feel welcome to become actively involved with this committee or to contact one of the chairs or a member of the scientific staff to learn more or to discuss your research ideas and proposals. We look forward to talking with you and seeing you at our next meeting.

![IBWC Members](image)

**Back row (left to right):** Sophie Paczesny, Tao Wang, Michael Haagenson, Michael Vemeiris (Past Chair, 2013-2018), and Katharina Fleischhauer; **Front row (left to right):** Katharine Hsu, Stephen Speltman and Stephanie Lee.

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**Pediatric Cancer Working Committee**

**Committee Leadership**

**Co-Chairs:**
- Parinda Mehta, MD, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH
- Angela Smith, MD, MS, University of Minnesota Blood and Marrow Transplant, Minneapolis, MN
- Gregory Yanik, MD, The University of Michigan, Ann Arbor, MI

**Scientific Directors:**
- Mary Eapen, MD, CIBMTR Milwaukee

**Statistical Director:**
- Kwang Woo Ahn, PhD, CIBMTR Milwaukee

**Statisticians:**
- Heather Tecca, MPH, CIBMTR Milwaukee
The Pediatric Cancer Working Committee (PCWC) provides scientific oversight for
studies related to HCT for childhood leukemias and other issues related to use of
HCT in children.

Autologous and allogeneic HCT are important treatment options in
multidisciplinary care for children and adolescents with cancer. As definitions of
cancer risk groups change and as new therapeutic agents are incorporated into
treatment plans, it’s essential to understand the role and timing of HCT and
outcome.

The PCWC focuses on and prioritizes transplant topics:

- Role and timing of HCT as primary pediatric cancer therapy and how to
  improve outcomes, especially by identifying risk-appropriate populations
- Identification of variables in predicting outcomes of HCT in pediatric cancers

In the last two years, the committee published three papers. One of the reports
developed a simple personalized clinical risk score for long-term survival in
children with AML and ALL. Assignment of risk score considered factors such as
age, disease status at transplantation, cytogenetic risk group, and history of
chronic GVHD. We believe assigning a personalized risk score will identify children
at higher risk for mortality who may be candidates for more aggressive
surveillance and targeted intervention.

The success of our committee depends on new ideas and testable hypotheses as
well as participation by individuals with different perspectives and scientific
backgrounds. The PCWC encourages all investigators with an interest in pediatric
cancer to propose studies, which may be submitted on the How to Propose a
Study webpage. Working Committee Chairs are available to discuss your study’s
hypothesis and feasibility prior to submission to CIBMTR.

CIBMTR Trivia
The CIBMTR represents a network of more than _____ participating centers that submit outcomes-related data for patients.

A. 350
B. 375
C. 420
D. 460

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

Team Spotlight: Data Operations Team
The Data Operations team supports the collection and management of transplant
and cellular-therapy data. It is a diversified team consisting of recipient Clinical
Research Coordinators (CRCs), Donor CRCs, Data Entry/Writing staff, Data Quality
staff, Business Product Owners, and Program Coordinators (e.g., BMT CTN studies,
corporate studies, etc.).

Recipient CRCs support data professionals at >420 CIBMTR transplant centers
worldwide, and Donor CRCs support staff responsible for reporting data at >180
donor, apheresis and collection centers.

Data Operations team members have a variety of responsibilities including
participation in the development or revision of data collection tools, electronic data-
capture systems (e.g., FormsNet3sm), data entry and imaging of paper forms,
instruction manuals, training, and e-learnings and management of data quality
programs (e.g., CPI). The Data Operations team also supports the CMS studies (e.g.,
MDM, myelofibrosis, etc.), SCTD reports (e.g., transplant center specific analysis,
center volumes), corporate studies (e.g., Kepivance, KGF, veno-occlusive disease
(VOD)), observational study requests for data discrepancies and NMDP data
requirements (e.g., donor data collection forms).

Each center is assigned to a CRC at either the Minneapolis or Milwaukee campus
of CIBMTR. CRCs answer questions not covered in the Data Management Manual
or on CIBMTR.org, and provide additional assistance answering complicated
questions.
Milwaukee Campus Data Operations Team
Front row (left to right): Janet Brunner-Grady, Mona Patel; Second row (left to right): Lawrence Stewart, Stephanie Meyers, Kavita Bhavsar; Third row (left to right): Sharon Meiers, Andrea Pope, Andrea Benoit; Fourth row (left to right): Leigh Ann Laczkowski, Amalia Hartke; Fifth row (left to right): Matthew Klein, Amy Prentice, Claudia Abel; Sixth row: Tiffany Hunt

Minneapolis Data Operations Team
Front row (left to right): Kristy Nutter, Will Affield, Bemadette Levesque, Jenny Vue, Sheryl Tasky; Second row (left to right): Marie Matlack, Monique Ammi, Brianna Schlick, Jamie Khang, Theresa Winder, Pam Lee, Kay Gardner, Angela Hauck; Third row (left to right): Connor Erickson, Lori Colt, Elliott Mitchell, Kristi Kutzner, Nicole Voit, Sue Logan, Jon Wallace, Peter Wallace, Randy Krunkkala, Amy Ewer, Jenna Tenney, Lois Horne; Not pictured: Aly Draxler, Andrea Mitsch, Christina Olson, and Tina Thole

Blood and Marrow Transplant Clinical Trials Network

By Amy Foley, MA

The BMT CTN, with its 37 Core / Consortia Centers and approximately 75 Affiliate Centers, now has enrolled >10,100 patients. The Network was established in 2001 and was renewed last year for a seven-year grant cycle by NHLBI and NCI.

Clinical Trials: Open Enrollment
The BMT CTN encourages widespread transplant community participation in clinical trials. If your center is interested in participating, visit the BMT CTN website.

There are 12 trials open to accrual and 7 in development.

BMT CTN Publications
There are 86 BMT CTN published articles, including 22 primary analyses. The following manuscripts were recently published:

- Holstein, Avet-Loiseau, Hahn et al. BMT CTN Myeloma Intergroup Workshop on Minimal Residual Disease and Immune Profiling: Summary and


- 0902: Jim, Sutton, Majhail et al. Severity, course, and predictors of sleep disruption following hematopoietic cell transplantation: A secondary date analysis from the BMT CTN 0902 trial. Bone Marrow Transplantation. 2018 Mar 7. [Epub ahead of print]


About the BMT CTN

The CIBMTR shares administration of the BMT CTN Data and Coordinating Center with National Marrow Donor Program/Be The Match® and The Emens Corporation®. Together, these three organizations support all BMT CTN activities.

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

facebook.com/bmtctn

twitter.com/bmtctn (@BMTCTN)

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Resource for Clinical Investigation in Blood and Marrow Transplantation

By Erin Lackrone

As part of clinical trial oversight, RCI BMT team members manage the collection and quality control of regulatory documents required for the conduct of clinical studies. Examples of these documents include CVs, medical licenses, training logs, and Institutional Review Board (IRB) approvals, among others. The sponsor or representative of the clinical study must store these documents, in accordance with the Code of Federal Regulations (CFR) and good clinical practice.

To facilitate efficient collection and review of these documents, RCI BMT contracted with Medidata for implementation of the Medidata Edge eTMF (electronic trial master file). This fully validated system will enable electronic storage of documents within Medidata’s clinical cloud platform and ensure compliance to 21 CFR, Part 11. The system is configurable and scalable to the existing best-practice reference model and can incorporate documents by study, institution, and country. The eTMF will integrate with the Medidata electronic database and clinical trial management system already utilized by RCI BMT.

The team is on track to complete the initial implementation of the system in May and to go live in June 2018.

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Health Services Research Update

By Linda Burns, MD; Ellen Denzen, MS; and Beth Murphy, EdC, RN

Palliative Care for HCT Patients

- The Health Services Research Program, in partnership with the ASBMT Palliative and Supportive Care Special Interest Group (SIG), is conducting phase two of the study, “Perceptions and Utilization of Palliative and Supportive Care in HCT.” This study is led by Effie Petersdorf, MD; Thomas LeBlanc, MD; and Arej El-Jawhari, MD.

- In phase one, a survey of physicians identified barriers to palliative-care use in the transplant setting, as well as concerns about patients’ perspectives on palliative care. A survey is in development to better understand transplant
patients' perspectives on palliative care. SIG members also are conducting informal polls of centers to define how palliative care is currently integrated with HCT programs. The study will include two time points to characterize patients’ perceptions throughout early transplant survivorship. This survey will be conducted in late summer 2018.

**Patient-Centered Outcomes Research (PCOR) in HCT**

- A transplant recipient, Barry Schatz, and a caregiver, Susan Kullberg, are among the steering committee members on the project, “Developing a patient-centered HCT outcomes research agenda.” PCORI funded this project and recently highlighted it in an [article](#). PCORI also invited Mr. Schatz to write about his personal experiences.
- In response to published recommendations from the Sexual Health and Relationships Working Group (Burns, et al., BBMT, 2018), a task force is forming. The task force will develop a sexual-health position paper aimed at physicians, advanced practice providers, nurses, and social workers. The task force—led by Alison Loren, MD, MS, FACP, and D. Kathryn Tiemeier, PhD, MSN—also will promote a companion, printed educational resource for HCT survivors. Linda Burns, MD, will represent the CIBMTR Health Services Research Program on the task force.

For questions about the Health Services Research Program, contact Ellen Denzen, MS, Senior Manager, Health Services Research, or visit the [Health Services Research webpage](#).

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**Study Summaries for Patients Webpage Now Easier to Navigate**

Patients and their loved ones can now more easily find research summaries of interest to them on the [Study Summaries for Patients webpage](#). Study summaries of CIBMTR research are organized by disease/condition and other transplant characteristics in an easy-to-read way. Patients and their loved ones have access to useful information that can help them talk with their doctors about treatment options.

Study summaries are created through a collaborative process involving CAC members, CIBMTR and NMDP/Be The Match Medical Writers, CIBMTR Communications Consultants, NMDP/Be The Match Patient Education Specialists, and CIBMTR Scientific Directors. Developing these summaries is one of the main initiatives of the CAC.

The CAC was created in 2005 as a subcommittee of the Advisory Committee to communicate CIBMTR research results and data to the non-medical community and to provide patients’ and donors’ perspectives during the development of the CIBMTR research agenda. Many members have personal experience as a donor, recipient, or family member.

In addition, five new patient summaries of CIBMTR publication recently were posted on the new [Study Summaries for Patients webpage](#):

- **Auto transplants are safe and effective for people with multiple myeloma and damaged kidneys**
  - Auto transplants are safe and work equally well in people with multiple myeloma and damaged kidneys.
  - The treatment can help some people stop dialysis treatments.
  - Higher doses of melphalan can improve results.

- **The number of allogeneic transplants for people age 70 years and older are increasing and outcomes are improving**
  - BMT results for older people have gotten better between 2000 and 2013.

- **A transplant from an unrelated donor can treat acute lymphoblastic leukemia**
  - New research may make it possible for more people with acute lymphoblastic leukemia (ALL) to get life-saving transplants.
  - In the past, a transplant using blood-forming cells from a sibling was the only well-tested transplant option.
  - New research shows that a transplant from an unrelated donor can help people with ALL live equally long as a transplant from a sibling.

- **After transplant, some people have problems focusing**
  - Cognitive changes after BMT may include altered attention, focus, learning, memory and thinking. Your doctor can help.

- **Donating blood-forming cells twice is safe for donors**
  - Your doctor can help you feel well during a second donation.
  - Donating twice is rare.