International Bone Marrow Transplant Registry / Autologous Blood & Marrow Transplant Registry

IBMTR/ABMTR newsletter

Volume 9 Issue 2 January 2003

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Therapy of acute graft-versus-host disease

By Angelo M Carella, G Beltrami, PR Scalzulli and MT Corsetti

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The management of acute and chronic graft-versus-host disease (GVHD) is a continuing problem for transplant experts. Therapy generally involves the same agents as used for prophylaxis (glucocorticoids, cyclosporine and antithymocyte globulin [ATG]). Corticosteroids are the backbone of most treatment regimens for acute GVHD. Some transplant centers begin with relatively low corticosteroid doses for patients presenting with limited skin disease. High-dose glucocorticoid therapy is usually administered to patients with systemic involvement or severe skin manifestations. A common dose is methylprednisolone 2–2.5 mg/kg/day. Since use of high-dose corticosteroids increases the risk of opportunistic infections, concomitant prophylactic antibiotic, antiviral, and antifungal therapy is recommended.

Unfortunately, fewer than 50% of patients developing significant acute GVHD show durable improvement after initial treatment. Corticosteroid-resistant acute GVHD is extremely difficult to manage and is associated with high morbidity and mortality. One commonly used salvage drug is ATG. However, ATG has not been shown to be significantly more effective than cyclosporine or methylprednisolone.[1]

Similar to cyclosporine, FK506 has efficacy in treatment of acute GVHD. However, the response rate for patients with steroid-refractory acute GVHD is generally less than 10–20%.[2]

Mycophenolate mofetil (MMF) is an antiproliferative agent that interrupts the late stage of the immune response signaling sequence at the time of DNA synthesis. Interest in MMF in the blood and marrow transplant setting has been heightened by promising results seen in studies of a canine transplant model using a non-myeloablative conditioning regimen followed by post-graft immunosuppression with cyclosporine 30 mg/kg/d plus MMF 20 mg/kg/d. MMF used as prophylaxis decreases the incidence of acute GVHD and the use of corticosteroids. When used to treat acute GVHD, MMF resulted in a one-grade improvement in most patients with acute GVHD (71%), higher than seen in controls (43%).[3] Of note, the MMF

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"Keystone" Synonymous with Tandem BMT Meetings

By D'Etta Waldoch, CMP

Associate Director, International Programs, IBMTR/ABMTR

Are you going to the Keystone Meeting? Isn't that the ASBMT Meeting? I thought it was the IBMTR/ABMTR Meeting!! What meeting ARE we going to January 30–February 3, 2003?

To put the brakes on all the confusion – it is called the "2003 Tandem BMT Meetings". And yes, it is the IBMTR/ABMTR Meeting and yes, it is also the ASBMT Meeting. Since 1995, these two organizations in blood and marrow transplantation have been meeting "in tandem" – one meeting after the other – to afford reduced travel costs, less disruption in professional schedules and more interaction with a wider circle of colleagues for the 60–70% of participants who attend both meetings in a single week. What a concept! The Tandem BMT Meetings are planned each year by a joint scientific organizing committee, who work cooperatively to avoid overlap of topics and invited speakers. In addition, industry-supported satellite

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The Blood and Marrow Transplant Clinical Trials Network (BMT-CTN)

By Christopher Bredeson, MD, MSc, FRCPC

Assistant Scientific Director, IBMTR/ABMTR

As noted by Julie Vose and Lisa Filipovich in this edition of the Newsletter, the IBMTR/ABMTR, in collaboration with colleagues at the National Marrow Donor Program (NMDP) and the EMMES Corporation, has been working hard on the new NIH-funded BMT-CTN. The importance to this effort of existing Registry resources supported by the contributions of our member centers cannot be overstated. IBMTR/ABMTR data and statistical capabilities greatly enhance our ability to design protocols and plan trials and are an invaluable asset for the activities of the BMT-CTN. The Statistical Center once again expresses its appreciation to everyone who participates in our activities. The following overview outlines the structure of the BMT-CTN, defines the important role for non-Core centers, summarizes the first 2 protocols that are being developed, including information on Investigators'

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Perspectives

Julie M. Vose, MD
ABMTR Executive Committee Chair
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Although clinical and translational research in the field of autologous transplantation has been ongoing for over two decades, trial results evaluating large numbers of patients were previously difficult to identify in the literature. The ABMTR was originally conceived in the late 1980s by the collaboration of top transplant physicians and centers to address this lack of analyzable data. This network allowed accumulation of a large amount of retrospective and subsequently prospective data from patients undergoing autologous transplantation at many transplant centers. Important studies evaluating various aspects of autologous transplantation for Hodgkin disease, non-Hodgkin lymphoma, breast cancer, various leukemias, and, more recently non-malignant diseases have been published in peer-reviewed journals based on this vast effort. In addition to disease-based research, studies evaluating graft effects, preparative regimens, and quality of life have also formed an important focus of ABMTR research.

The ABMTR has now accomplished the collection of more than 22,000 reports of patients receiving autologous transplantation for various malignancies and other conditions since data collection began in 1989. During 2001, 521 reports for patients undergoing autologous transplantation for Hodgkin's disease, 1465 reports for non-Hodgkin's lymphoma receiving autologous transplantation, and 1647 reports from multiple myeloma/plasma cell dyscrasia patients' autotransplants were received by the Registry. This large accumulation of data has allowed the ABMTR to analyze important transplantation questions of common and rare diseases for which transplantation is offered.
In addition to the important research accomplishments leading to abstract presentations and publication in peer-reviewed journals, the ABMTR provides invaluable information to patients, physicians, and healthcare agencies interested in transplantation. During 2001, information on various aspects of transplantation was provided for over 1100 requests to the ABMTR/IBMTR.

Over the past year, the IBMTR/ABMTR, in collaboration with the National Marrow Donor Program and EMMES Corporation was awarded a five-year NIH grant to coordinate the newly established Blood and Marrow Transplant Clinical Research Network (BMT/CTN). This consortium has established a Data Coordinating Center for the network of 16 transplant centers, which will be performing prospective clinical trials focusing on various aspects of hematopoietic stem cell transplantation and supportive care. This important effort will soon initiate the first approved clinical trials in the network addressing these issues. Without the strong leadership of the IBMTR/ABMTR, this important collaboration would not have been possible.

The information provided by ABMTR data analysis as well as the important results of prospective clinical trials from the BMT - CTN could shape the future of transplantation clinical care and research. It is my pleasure to continue as the Chair of the Executive Committee for ABMTR during this exciting transition toward the future of transplantation.

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regimen also resulted in a significant reduction in the doses of prednisolone required, which likely contributed to the decreased morbidity observed in MMF-treated patients.

MMF has also been used in some patients with treatment-refractory acute and chronic GVHD. In a study by Abhyankar and colleagues, patients with steroid-resistant GVHD were given MMF monotherapy at 2 g/d for adults and 600 mg/m^2 in children for a median of 25 days. Only two of the seven (29%) patients had a complete or partial response.[4]

Investigational and experimental therapies in acute GVHD

Antilymphocyte monoclonal antibody therapies have had mixed results in steroid-refractory GVHD. These include IL-1 receptor antibody, TNF-α antibody, and IL-2 receptor antibody. Antin and coworkers[5] conducted a phase I/II trial to evaluate the effectiveness of an IL-1 receptor antagonist in 16 patients with steroid-resistant GVHD. Improvement was noted in the skin (8/14), GI tract (9/11), and liver (2/11). In 24 patients with resistant grade III–IV GVHD given anti-TNF-α, there were no complete responses, but 17 patients had a partial response. Herve *et al*.[6] reported the efficacy of IL-2 receptor antibody (IgG1 murine monoclonal antibody) in patients with steroid-resistant GVHD. Twenty-nine of 58 patients (50%) had complete resolution of GVHD. Anasetti and coworkers[7] reported similar results. Humanized anti-TAC (IL-2 receptor antibody) is now available. In a study of 20 patients with steroid-refractory GVHD, improvement was noted in eight patients.

Pentostatin is known to decrease lymphocyte numbers and function. At Johns Hopkins Hospital, Margolis *et al*.[8] have investigated pentostatin for treatment of GVHD. Nine patients with steroid refractory GVHD received salvage therapy with pentostatin. Many of the patients had also failed salvage with daclizumab and infliximab. Four patients achieved a complete response and two a partial response.

Recently, Anasetti *et al*. found that treatment with anti-CD3 F(ab')$_2$ can selectively induce apoptosis of donor T cells that recognize a recipient alloantigen in mice, thereby preventing GVHD (personal communication). The selective elimination of antigen-activated T cells by non-FcR-binding anti-CD3 antibodies could serve as an ideal strategy to prevent GVHD and allograft rejection or to treat autoimmune disorders. They tested HuM291 for its immunosuppressive activity in a Phase I study of acute GVHD therapy. Eighteen patients with grade III–IV acute GVHD who were refractory to 2 mg/kg MP plus cyclosporine or tacrolimus, received HuM291: 3 at 0.25 mg/m^2 q.o.d. x 7 doses, 3 at 1.0 mg/m^2 q.o.d. x 7 doses and 12 at 3.0 mg/m^2 x 1 dose.

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Perspectives

Alexandra H. Filipovich, MD
IBMTR Executive Committee Chair
Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA

The past year, which has brought such a painful rise in tensions around the globe, has also seen advances in crosscultural and multiinstitutional cooperation in clinical research that should ultimately benefit our patients undergoing innovative cellular therapies. The IBMTR and ABMTR have played a leading role in this effort through several new initiatives. These include the establishment of a Clinical Trials Network in North America and the convening of an international review panel to critique and guide future endeavors of the IBMTR/ABMTR upon the eve of its successful renewal of funding from the NIH. The IBMTR/ABMTR database continues to grow with over 15,000 new cases reported in 2001 and the total number of cases rising to 165,000 cases.

The Blood and Marrow Clinical Trials Network (CTN) represents a new venture funded by the National Heart and Blood Institute (NHLBI) and the National Cancer Institute (NCI) under a grant awarded to three collaborating insitutions: the IBMTR/ABMTR, the National Marrow Donor Program (NMDP) and the EMMES Corporation, a private enterprise specializing in data management and trial monitoring. The role of the IBMTR/ABMTR is to provide scientific leadership and spearhead study design and statistical analysis. In the first year of funding the CTN identified the 16 Core Clinical Centers and Steering Committee, developed standard definitions and operating procedures, and proposed three clinical protocols. The first protocols to be implemented include:

1) a randomized study of fungal prophylaxis (Voriconazole vs. Fluconazole) for prevention of deep-seated fungal infections
2) comparison of autologous transplantation vs. autotransplantation followed by non-myleoablative allogeneic transplantation for multiple myeloma
3) a comparison of bone marrow versus peripheral blood as a stem cell source for unrelated donor transplantation.

Open meetings to encourage participation from the BMT community will be held at the 2002 ASH and 2003Tandem BMT meetings.

The meeting of the review panel to assist strategic planning of IBMTR/ABMTR activities took place on October 21, 2002 in Milwaukee, Wisconsin. Thirty-seven participants representing a broad range of scientific, administrative and "consumer" constituencies spent the day identifying current strengths and deficits of the IBMTR and developing priorities for programmatic change and future scientific emphases.

Two major logistical improvements were favored.

- First, a strong effort should continue to simplify data reporting by developing a set of common data elements to be used by the many different agencies and registries that collect data, implementation of web-based data entry and data sharing among registries.
- Second, exploration into establishing a tissue repository (DNA and RNA) that would be linked to clinical data should move forward. This would allow evaluation of biologic and genetic factors and their effect on clinical outcomes of BMT across multiple institutions and transplant approaches.

Three major scientific themes for ongoing and future IBMTR/ABMTR studies were identified.

- First, there is a continuing need to provide descriptive analyses of BMT outcomes in rare diseases, principally genetic disorders of childhood, e.g. congenital anemias and neutropenias, immunodeficiencies and other inborn errors of metabolism. Ideally, when disease specific registries already exist, e.g. Diamond-Blackfan Registry, the IBMTR should try to partner with these groups to establish the role of BMT in the broader context of the natural histories of the disorders. Long-term follow-up of disease-specific endpoints, such as cognitive development or risk of future malignancies, should be planned prospectively. These goals will require development of new strategies to capture data, likely requiring direct future contact with affected individuals.
- The second focus area was the study of late effects of BMT during the prolonged period of survival afforded to patients who, otherwise, would have died. Again, additional strategies to maintain access to survivors over many years, including obtaining appropriate, IRB sanctioned, informed consent at the time of BMT to allow direct future contact will be required.
- The third scientific theme was the immunology of BMT: the interplay of GVHD, GVL, and immune reconstitution. An effort to focus on such issues was recommended. This effort could include new retrospective studies, e.g. of potential risk factors for GVHD which have not been extensively analyzed in the past, such as HLA C mismatch or cytokine polymorphisms. Future data collection may need to pay specific attention to late infectious complications, linked to biologic assays of immune recovery that could be supported at collaborating institutions with new or independent funding.

Overall, the review committee enthusiastically agreed that the IBMTR/ABMTR should continue to do what it does best – outcomes research. More rapid assessment of developing technologies impacting the field was encouraged, and will become an emphasis at the face to face meetings of the disease-oriented Working Committees held annually at the Tandem Meetings and in interval communications to committee members throughout the year. Further development and dissemination of biostatistical expertise was also endorsed.

The next steps in the strategic planning process involve presentations and discussions with the IBMTR/ABMTR Executive Committees at the 2002 ASH meeting, and with the full Advisory Committee in Keystone, 2003. All of us at the Executive Committee welcome queries and suggestions from members regarding these efforts at any time, and thank you for ongoing support in improving your Registry.

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Manifestations of GVHD improved in all 18 patients. Five patients whose EBV titer rose above 1000 copies per ml after HuM291 were treated with one or more doses of the B cell-specific CD20 antibody, rituximab. EBV became undetectable and overt lymphoma did not occur. Further studies are ongoing to determine a potential role of HuM291 for primary or secondary GVHD therapy.

Alemtuzumab targets the CD52 antigen and is effective in the prevention of acute GVHD;[9] however, no results have been reported using this drug to treat pre-existing acute GVHD.

The induction of acute GVHD requires host antigens to be presented to donor T-cells by antigen-presenting cells (APCs), such as dendritic cells (DCs). Recent evidence has suggested that only host APCs can interact with donor T-cells in the induction of GVHD. Because CD52 has been reported to be expressed on monocyte-derived DCs,[9] we reasoned that alemtuzumab might have a direct effect on DCs, in addition to donor T-cells, not only for GVHD prevention but also for the treatment of acute GVHD. We therefore assessed the effect of alemtuzumab in three patients with liver and gastrointestinal (GI) grade III acute GVHD, refractory to conventional immunosuppressive therapy.

The first patient, a 53-year-old woman with high-risk chronic myeloid leukemia (CML), received non-myeloablative allografting from an HLA-identical sibling. Despite GVHD prophylaxis with cyclosporine, the patient developed grade III acute GVHD. At 65 days post-engraftment, cyclosporine was stopped and alemtuzumab treatment was initiated. Liver enzymes and bilirubin levels reduced in the 2 weeks following the last dose of alemtuzumab, and GI acute GVHD resolved 1 week later (Figure 1). The second patient, a 46-year-old man with high-risk CML, received a myeloablative allograft from an HLA-identical sibling with cyclosporine for GVHD prophylaxis. At 27 days post-transplant, grade III acute GVHD developed that progressed despite treatment with high-dose methylprednisolone. After treatment with 73 mg alemtuzumab in total, complete regression of GI and liver acute GVHD was observed. The third patient, a 44-year-old woman with relapsed low-grade non-Hodgkin's lymphoma, received a reduced intensity allograft from a HLA-identical sibling with methotrexate and cyclosporine as GVHD prophylaxis. Grade I acute GVHD developed and, despite an increase in cyclosporine dose, progressed to grade III acute GVHD. Treatment with methylprednisolone 2 mg/kg/d was given for 6 days, during which time the bilirubin increased from 4.1 mg/dl to 23.7 mg/dl. Alemtuzumab treatment was initiated and rapidly reduced bilirubin and liver enzymes to normal levels. Skin GVHD also disappeared, but grade I GI GVHD persisted.

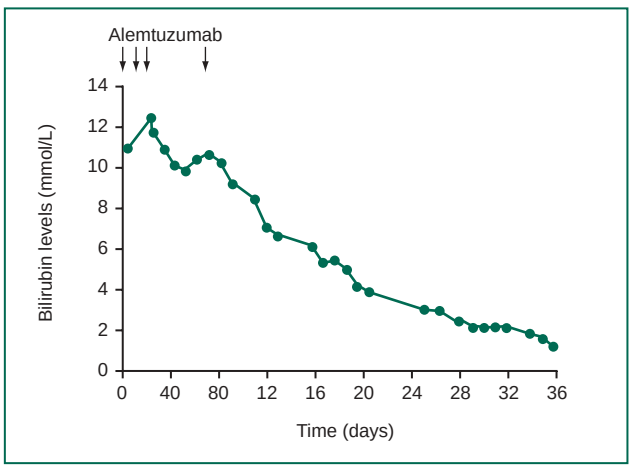

Figure 1. Impact of alemtuzumab on bilirubin levels in Patient 1

In summary, in all three patients, acute GVHD rapidly responded to alemtuzumab. All patients maintained complete chimerism during and after alemtuzumab therapy. All patients tolerated the alemtuzumab infusion with mild side effects, such as rigor/chills, fever and headache. Neutropenia and thrombocytopenia were seen in two patients. In all patients, CMV reactivation was observed and successfully treated with ganciclovir ± foscarnet. Additional study of this agent seems warranted.

In summary

The poor prognosis of steroid-refractory GVHD patients and the lack of effective standard therapies have engendered enthusiasm for studies of newer agents. However, the lack of uniform criteria for steroid-refractoriness and of response of GVHD to therapy is probably reflected in the wide range of reported response rates with older agents and mandates that the true efficacy of these agents be properly evaluated in randomized controlled studies.

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IBMTR/ABMTR Data Management Update

By Diane J. Knutson

Senior Research Associate, IBMTR/ABMTR

Excerpts from the soon-to-be-released 2002 Core Insert Manual

Registering or Research Team?

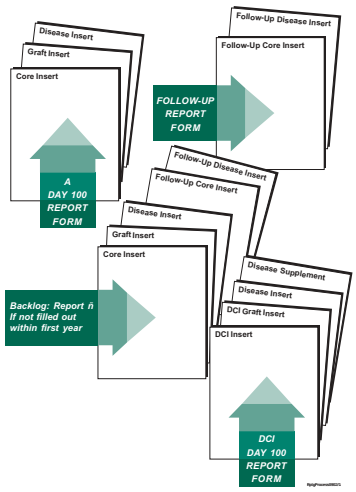
'Registering only' Teams complete TED and TEDFU Forms and comprehensive Report Forms only if voluntarily participating in a special study. Research Teams submit comprehensive Day-100 Report Forms and Follow-up Report Forms as requested via the Pre-Reg reply or for special study requests of previously exempt Forms.

What is a Report Form?

Day-100 Report Form = Core Insert + Graft Insert + Disease Insert (Disease Inserts not available for a particular diagnosis will become due when released.)

Follow-Up Report Form = Core Follow-up Insert + Disease Follow-up Insert

Note: if a subsequent transplant is performed for a different diagnosis from the first transplant, continue to submit the Disease Insert from the diagnosis of the first transplant, not the new diagnosis.



Supply of Report Forms:

- Download from www.ibmtr.org. Check website periodically for updated versions (version date is located in lower right corner of all Forms).
- Request paper copies via the Fax Order Form.
- Stemsoft software- submit Report Forms via disk.

Basic reporting "rules"

- The Registry assigns team number. Your Team assigns IUBMID number.
- Use ink, any color but black or red.
- Make sure answers are readable (large and neat).
- Use abbreviations cautiously (TX = treatment? Texas? transplant?).
- Common options are listed as tick boxes. Review the list before using the "other specify" option.
- Record data in the most specific question possible (e.g. CMV-Ipn belongs in Ipn rather than Infections – site lungs).
- Team number and IUBMID number must appear at the top of one side of each page (stickers or stamps are acceptable).
- Label attachments with the corresponding Insert name, page and question number, as well as Team and IUBMID number.
- Keep a copy of the Report Form for your files. If a paper copy is submitted to the Registry, the copy must have back-to back pages. Single-sided Report Forms are unacceptable.

Report Form cut-off dates

Reporting periods for Registration and Report Forms are the same. Pre-Reg/MTED or TED should have the same cut-off as the Day-100 Report Form.** TEDFU corresponds to Follow-up Report Forms.

**As the Form title implies, the cut-off is Day-100, unless the patient receives a reportable subsequent transplant or infusion of donor cellular therapy less than 100 days from the previous infusion or if the recipient expires before Day-100. Please see timeline examples.

Date of Report (DOR)

The date the Form is deemed accurate, complete and ready to send is the DOR. It will not be Day-100 unless you actually fill out the Form and all the inserts, checking for accuracy/completeness, and send the Form on Day-100. DOR links all the pieces that make up a Report Form; therefore the Core Insert, Graft Insert and Disease Insert (or CoreFU and Disease FU) must have the same DOR even if not completed on the same date.

Missing Data

If the pre-printed answers on the Report Form do not allow for "unknown," we expect that generally these data should be available to you. Exceptions should be noted in the margin rather than leaving the question blank. A letter of explanation would be required if a question was universally unable to be answered. If a "yes" answer leads into a box with a series of "yes/no" tick boxes, all must be answered "yes" or "no." Blank boxes will generate an error message.

Tip: use a light color highlighter to identify questions that require further investigation to prevent overlooking them.

Unit of Measure

Do not modify units or the number of pre-printed boxes available on the Report Form. Convert your data to the options available before answering. Ask your laboratory or transplant physician for assistance. If you believe there is a unit error, please contact us and send an example from the patient chart that highlights the error.

Dates

Review the chronology of dates before submitting the Form. Please use a copy of the sample timeline to help identify the

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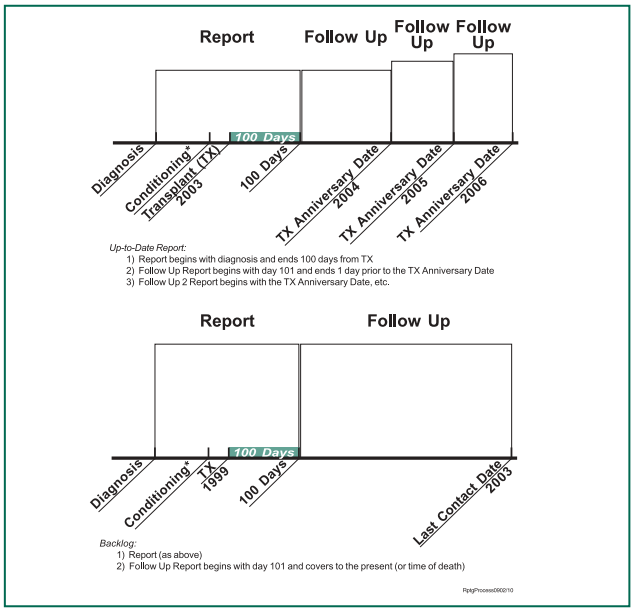

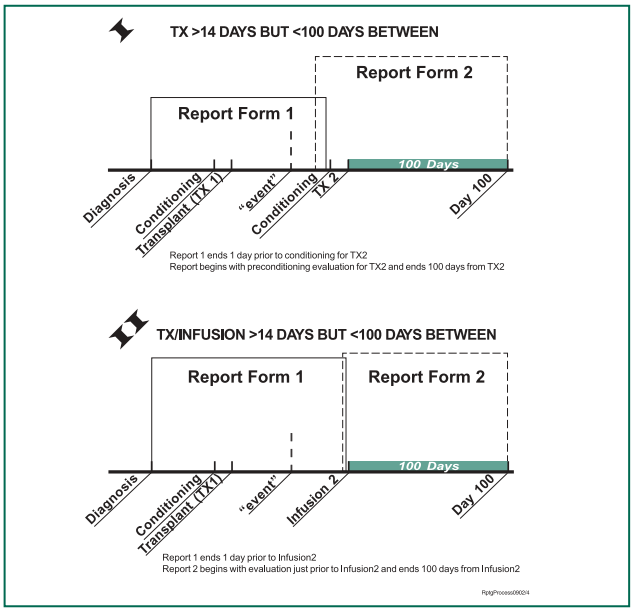

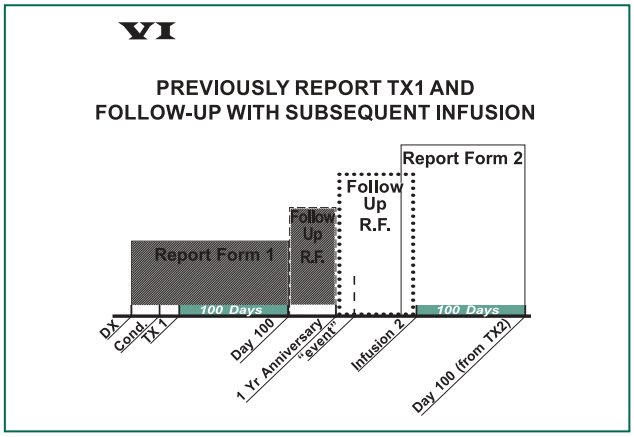

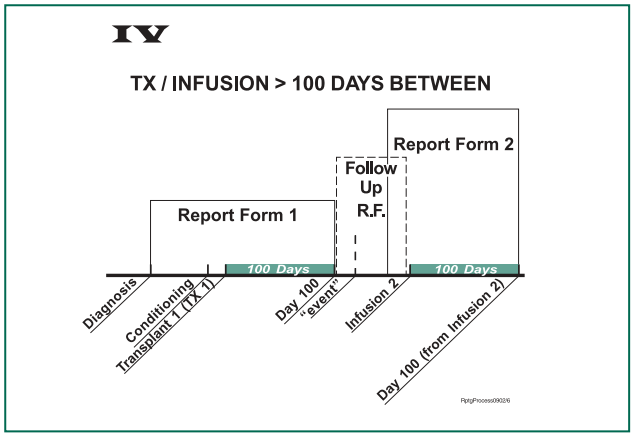

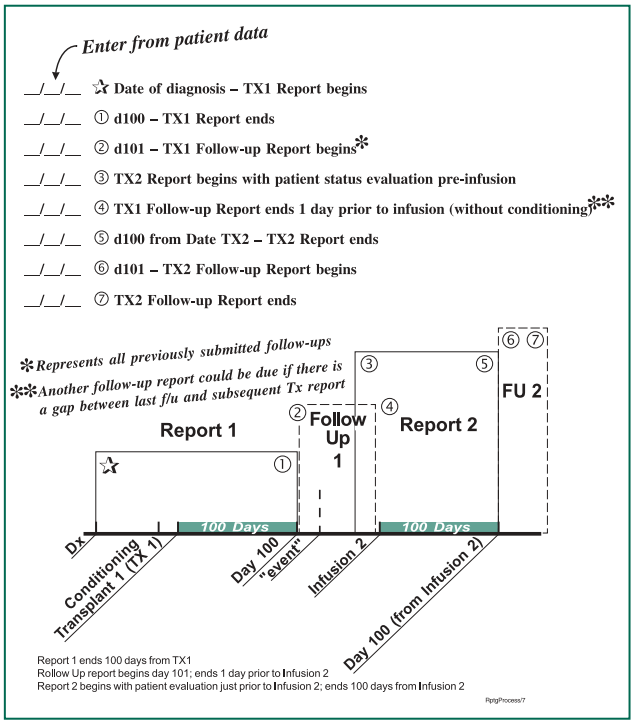

order of events and which Report Form they belong to as well as which section of the Report Form (e.g. do not report Pre-conditioning/pre-TX data in the post section).

Error Corrections and Error Reports

If you found an error, send the correction by whatever means is easiest for you. Include Team #, IUBMID #, DOB, dateTX, Form name, DOR and indicate the correction was "unrequested" (as it was not requested by the Registry). Do NOT include the patient's name, as we are no longer able to accept names for identification according to governmental regulations.

When a Report Form is processed our Data Entry Specialist may identify errors, e.g. missing fields, date sequence errors, etc., which will be noted on Report Notes. Before the Report Form is added to our database, our computer performs additional data consistency checks. Periodically these errors will be compiled into an Error Report and sent for corrections. If there is any error that you do not understand, please contact us.

Clinical Research Associates Return to Milwaukee

By D'Etta Waldoch, CMP

Associate Director, International Programs and Diane J Knutson, BS, Senior Research Associate, IBMTR/ABMTR

After last year's Fall Clinical Research Associates' Data Management Meeting, which came to a final conclusion right around the infamous date of September 11th, we wondered if we could get folks to return to Milwaukee in 2002 – see sidebar story. As it turned out, the 2002 conference was our most successful yet! (and the 2001 conference was also pretty darn good, if you were wondering).

An afternoon workshop on the Basics of Clinical Research, hosted by the Medical College of Wisconsin Clinical Trials Office, kicked off the conference on Friday, September 20th. Pizza and networking opportunities were on the social agenda that evening, during a welcome reception hosted by Dr Mary Horowitz and Registry staff. Participants always seem happy to put a name with a face, meet new colleagues and greet old friends.

Saturday's sessions focused on the basics of reporting and overcoming obstacles to follow-up reporting. Roundtable sessions were led by a former BMT patient, a BMT staff nurse and clinical research professionals from centers with over 90% compliance for follow-up reporting. Topics included successful approaches to staying in touch with your BMT patients.

Sunday's approach to research took a 360-degree turn, as Statistical Center staff presented how to complete a research project from initial idea to poster presentation. Participants were encouraged to have an idea in mind as they learned to formulate a hypothesis, choose an appropriate type of study and apply appropriate statistical techniques to their project. Examples of inappropriate use of statistics were also provided. Potential research projects were discussed and we hope to see a number of these completed studies submitted to the Clinical Research Associates Conference in Keystone in early 2003.

Post-conference evaluations were extremely positive, citing a new awareness and appreciation for the entire process of clinical research, from both those who are directly involved in research projects to those who support others in their institution by working with the raw data rather than the end points. Continuing education credits for allied health professionals attending the Fall Conference were awarded by the Medical College of Wisconsin.

NIA technique ("Through Movement We Find Health") exercise classes were offered at the end of the day on Friday and Sunday to rejuvenate the body, along with the mind. NIA allows participants to reap the rewards of moving at their own level of intensity, making each workout a personal accomplishment. Black-belt instructor, Barb Wesson, explains the theory of NIA is to provide time to slow down and become calm, giving the nervous system and whole body a chance to recharge and energetically realign. NIA classes received very favorable reviews and consideration is being given to adding NIA to the agenda for the next data management meetings at Keystone Resort this winter. More information available at www.nia-nia.com.

Keep your eye on the web site at: www.ibmtr.org for update information on our Clinical Research Associates' Data Management Conference at the 2003 Tandem BMT Meetings in Keystone, Colorado. January 30 will feature introductory sessions for first-timers, January 31 is all about in-depth topics on what's new in transplant and how it relates to reporting, and February 1 highlights special topics on research, expanding on the agenda from the 2002 Fall meeting. We look forward to seeing you in Keystone – unless of course, you want to wait until next Fall for another great weekend in Milwaukee!

Hanne Baekgaard Laursen of Copenhagen and Anne-Maree Johnston of Camperdown, Australia expected to travel home from Milwaukee on 9/11/01. When they arrived at the gate for their flight to Toronto, they were less than amused by a television showing jets crashing into buildings. They remember thinking how it was very inappropriate and in poor taste to show that in an airport! When the volume was turned up moments later, to everyone's horror, they realized the scenes were real and right now! Needless to say, the flight was grounded and the women weren't going anywhere anytime soon. According to Hanne, when news of the Pentagon bombing was announced it all became completely surreal, and people immediately began to bond with one another. One woman in the boarding area was frantic as she repeatedly tried to get through on a cell phone, demanding, "Is Pat at the Pentagon today?". Everyone held their breath until she finally received the answer. Cheers rang out and strangers smiled through their tears – whoever he was, Pat was NOT at the Pentagon!

A call back to IBMTR headquarters sent staff into motion and within an hour, Hanne and Anne-Maree were whisked away from the airport, which was quickly being evacuated, and reinstated into their hotel rooms. Dr Mary Horowitz instructed the hotel that the IBMTR would cover the expenses for those who were stranded in Milwaukee after attending the 2001 Fall Data Management Conference. Hanne – always one to find a positive spin on a negative situation – cited an unexpected bonus of having lunch at the hotel right next to former President George Bush (Senior) and his wife Barbara, who were among those grounded in Milwaukee when air traffic across the country was suspended. Hanne's eyes twinkled, recalling how everyone at her table overheard the ex-president phone home to let his son know he was alright! Anne-Maree called her 80-year-old mother in Australia to let her know she was safe. Trying to be inconspicuous, she also mentioned that she had lunch next to a famous American, who's name starts with "B". Her mother quickly perked up – Bing Crosby???

While all this was going on, Diane Knutson of the IBMTR became worried about Hanne and the others because she hadn't yet heard that they were still in Milwaukee and safe. Diane was amused when she learned via email from Hanne's office that they already knew she was OK, and hoped that her time was being well-spent – so, Hanne dutifully went out shopping for new golf shoes for her boss!

Not to be stopped in her tracks, Hanne bravely returned to Milwaukee one year later for the 2002 Fall Data Management Conference and to concentrate on being a tourist. She came back recounting some unforgettable tales, but also thanking IBMTR/ABMTR staff for their assistance in helping her and others feel safe during an unforgettable time of tragedy and terror the previous year.

International Bone Marrow Transplant Registry / Autologous Blood & Marrow Transplant Registry
IBMTR/ABMTR newsletter
Volume 9 Issue 2 January 2003

Scientific Review of IBMTR/ABMTR Programs

by Mary M. Horowitz MD, MS
IBMTR/ABMTR Scientific Director
Robert A. Uihlein Professor of Medicine
Medical College of Wisconsin, Milwaukee, WI, USA

Major support for IBMTR/ABMTR research activities is provided through a Cooperative Agreement (U24) with the U.S. National Institutes of Health (NIH). Three NIH Institutes (the National Cancer Institute, the National Heart Lung and Blood Institute and the National Institute for Allergy and Infectious Disease) jointly fund this program. The U24 grant mechanism is designed to fund programs that serve as a resource to enhance scientific activities in the biomedical community. This past summer, the NIH favorably reviewed the IBMTR/ABMTR's application for another five years of funding; the new award will provide funds for the period March 2002–February 2008.

As the next five-year grant cycle begins, the IBMTR and ABMTR Executive Committees have initiated a comprehensive assessment of IBMTR/ABMTR activities to determine how we can best fulfill our responsibility as a resource to the blood and marrow transplant (BMT) community. This assessment began with an all-day Forum on Current and Future IBMTR/ABMTR Activities held in Milwaukee, WI, on October 21, 2002. Participants included many Executive Committee and Working Committee members, external scientific reviewers from diverse fields, representatives from NIH, and key Statistical Center staff. The purpose of the Forum was to review past, current and planned activities of the IBMTR/ABMTR and to make recommendations to be considered by the Executive Committees in developing a five-year strategic plan.

In advance of the one-day meeting, participants received written background materials and were asked to write a short critique, focusing on ways in which the IBMTR/ABMTR might better serve the BMT community. Participants were asked to be candid with their feedback, comments and critiques.

The Forum began with a brief overview of the IBMTR/ABMTR by Statistical Center personnel and an open question and answer session. This was followed by presentations from several participants on the challenges and opportunities facing the field of hematopoietic stem cell therapy. Discussion of the strengths and weaknesses of IBMTR/ABMTR outcomes analyses, clinical trial support and potential new areas of activity followed. Small breakout groups then discussed five key areas brought up during the day:

- Long-term follow-up studies – how can the IBMTR/ABMTR do a better job in assessing late complications of transplantation; how can we assist centers in maintaining follow-up on BMT recipients? How can we minimize reporting burdens for centers as the number of long-term survivors increases?
- Linking clinical data with biologic material – should the IBMTR/ABMTR establish a tissue repository to link with Registry data?
- Uniformity of data reporting – how can the IBMTR/ABMTR play a role in developing consensus on common data elements for assessing BMT outcome? How can the IBMTR/ABMTR facilitate dialogue among national and international groups involved in clinical data collection related to BMT to develop a set of common data elements?
- Immunobiological studies – how can the IBMTR/ABMTR better use its resources to address issues of transplant biology?
- Rare diseases – can the IBMTR/ABMTR increase its collaboration with disease-oriented groups to better assess the role of transplantation in rare diseases?

The Forum provided many suggestions for both improving current operations and productivity and for expanding into new areas (see article by Dr. Filipovich on page 3). The recommendations will be summarized and presented to the Executive Committees at their next meeting in December. A presentation to the general membership will follow at the Tandem BMT meetings in Keystone. Many aspects of the Forum's recommendations will also be discussed at individual Working Committee meetings in Keystone.

Important decisions about future IBMTR/ABMTR activities will be made over the next few months. As we embark on this strategic planning effort, we welcome your input. Please consider sharing your own ideas on how the IBMTR/ABMTR can better serve your needs and the needs of the BMT community, either by writing to the Statistical Center directly (ibmtr@mcw.edu) or by participating in discussions at the Tandem BMT Meetings.

Waldoch – continued from page 1

sessions are offered to broaden the spectrum of state-of-the-art offerings. Take a look at this year's agenda! Does it get any better than that?

Yes! In addition to an outstanding scientific program, the 2003 Tandem BMT Meetings offer peripheral sessions for BMT pharmacists, BMT center administrators and medical directors, clinical research associates and data managers working with the IBMTR/ABMTR, and nurses interested in the BMT Special Interest Group of the Oncology Nursing Society (ONS).

Want to know more? Check out the meeting link on our Web site at www.ibmtr.org. Attendees can review the entire meeting agenda and register right there, on-line. You can also arrange for housing by downloading the Keystone housing form and faxing it directly to Keystone – or call to make your reservation using the phone number provided. There is even a link to Keystone's web site where you can find out about upcoming winter activities and attractions.

Trouble with your computer? Call Patty Vespalec at the IBMTR/ABMTR Statistical Center at 414-456-4261 to get registration forms faxed or mailed to you.

We are delighted that at the time of the Early Registration Deadline (October 21), more than 600 people had already registered for the 2003 conference. As of January 10, we have more than 1,100 registered. Abstract submissions came in at a record number of more than 260 entered online this year. This is one year you won't want to be left out in the cold alone – come to Keystone with the rest of us!

Bredeson continued from page 1

Meetings for this trial, and introduces the next studies under development. More information about any of these items is available at the Network's website: www.bmtctn.net.

Strengthening Existing Relationships and Forging New Links: The Structure of the BMT-CTN

The BMT-CTN consists of 3 components: the Data Coordinating Center (DCC), Core Clinical Centers and Non-core Clinical Centers. Figure 1 outlines the interacting / overlapping relationship of the 3 organizations that partner to form the DCC. With Dr. Mary Horowitz as the PI, the IBMTR joined with the NMDP (Dr. Dennis Confer Co-PI) and the EMMES Corporation (Dr. Shelly Carter Co-PI) in applying to form the DCC. As can be seen in the figure, each organization brings both shared and unique skills that are vital to the overall success of the network. The primary goal of the DCC is to facilitate the development and execution of clinical trials based on the proposals and protocol ideas approved by the BMT-CTN Steering Committee.

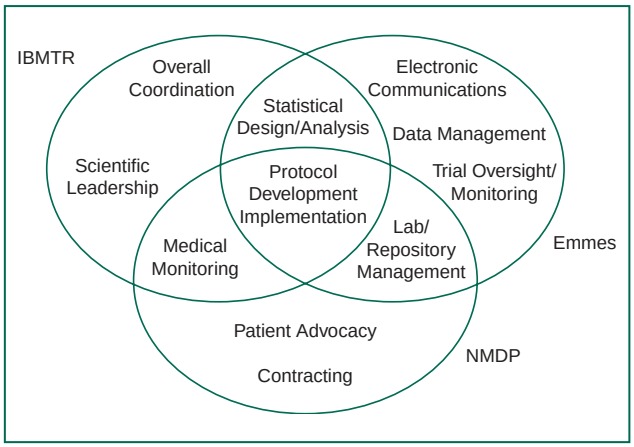

Figure 1. Relationships and responsibilities within the BMT-CTN Data and Coordinating Center

Table 1 lists the 16 BMT-CTN Core Clinical Centers and the PI for each site. Each Core Center brings its expertise to the BMT-CTN through representation on the BMT-CTN Steering Committee. Additionally, each center has committed to enrolling patients on trials developed by the group. While some of these centers have worked together previously, the close and on going collaboration of these centers since the inception of the BMT-CTN has facilitated the rapid progress made since last fall.

While the 16 Core Centers perform a significant number of transplants each year, for many protocols it is expected that participation of other interested non-Core Centers will be essential to enable timely study accrual. To participate as a non-Core Center, a site must meet minimum criteria of being either an NMDP-approved or FACT accredited transplant center. Beyond this, consideration of inclusion of individual non-Core Centers will be made based on targeted sample sizes, accrual timelines and technical requirements of the protocol in addition to other considerations such as ease of study implementation and available resources. An application for participation is available on the BMT-CTN website. The DCC looks forward to facilitating involvement of non-Core Centers in the initial BMT-CTN protocols discussed below.

Study Funding

Each study will be supported at participating sites with a per patient payment based on the complexity of the trial, number of research related investigations, shipping of samples, length of case report form, required PI effort, etc. IRB submission fees will be covered if this is part of the institution's standard procedure. One time start up costs for some reagents, shipping materials etc. may also be part of a site's study budget.

Table 1. Core Clinical Centers and Site Principal Investigators

Case Western Reserve (consortium)	Hillard Lazarus
City of Hope	Steve Forman
Dana Farber Cancer Institute	Joseph Antin
Duke University (pediatrics)	Joanne Kurtzberg
Fred Hutchinson Cancer Research Center	Fred Appelbaum
Johns Hopkins University	Richard Jones
Memorial Sloan-Kettering Cancer Center	Richard O'Reilly
Pediatric Blood and Marrow Consortium	Alan Gamis
Stanford University Medical Center	Robert Negrin
University of California San Diego/SCRIPPS (consortium)	Edward Ball
University of Florida	John Wingard (Chair, Steering Committee)
University of Michigan	James Ferrara
University of Minnesota	Dan Weisdorf (Chair-elect, Steering Committee)
University of Nebraska	Julie Vose
University of Pennsylvania	Ed Stadtmauer
University of Texas M. D. Anderson Cancer Center	Sergio Giralt

The First Studies

At its first meeting in November 2001, the Steering Committee identified 2 studies for initial implementation. Each study was assigned to a Protocol Team consisting of representatives from the Steering Committee, an MD protocol officer and 2 PhD statisticians from the DCC, a non-Core Center representative, NHLBI and NCI representatives and other DCC staff. The protocols were chosen on the basis of scientific merit, relevance to the BMT community, willingness of Core Centers to participate and feasibility.

The first study "A Prospective Randomized Double-blinded Trial of Fluconazole vs. Voriconazole for Prevention of Invasive Fungal Infections in Allogeneic Blood & Marrow Transplant Patients" is chaired by Dr John Wingard and Dr Thomas Walsh (Figure 2). The primary objective of this study is to compare the fungal-free survival of the 2 groups at 180 days posttransplant. This study highlights the goal of the BMT-CTN, which is to identify high priority questions in BMT and address them in a timely manner, i.e. definitively addressing the role of voriconazole early in its product life cycle. In addition to the committed participation of the Core Clinical Centers, this study will require non-Core Centers to achieve its accrual goal of 850 patients over 3 years.

The second study under development will evaluate strategies to improve on the outcome of autologous transplantation for multiple myeloma. The protocol team is co-chaired by Dr. David Maloney and Dr. Firoozeh Sahebi. The protocol team is working to define the arms of a phase 3 trial based on biologic assignment to an

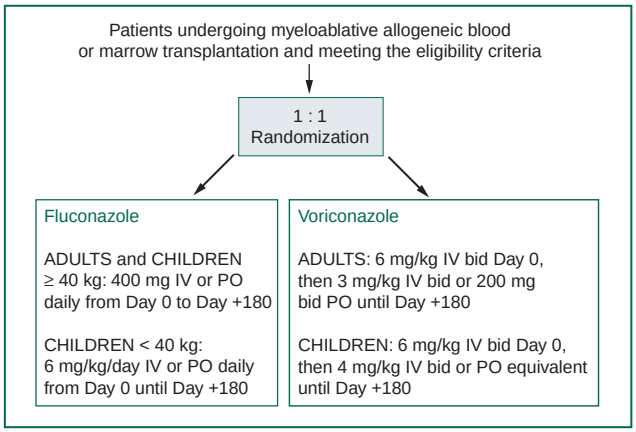

Figure 2. A prospective randomized double-blinded trial of fluconazole vs. voriconazole for prevention of invasive fungal infections in allogeneic blood & marrow transplant patients

autologous followed by allogeneic NST transplant for patients with an HLA-identical sibling versus an alternate strategy for those without a sibling donor. It is expected that the final design of this trial will be complete in time for an Investigators' Meeting coincident with the Keystone Tandem BMT Meetings in January 2003. It is expected that this trial will require active participation of a significant number of non-Core sites to meet accrual goals. Protocol development can be followed and commented on at the BMT-CTN website.

Investigators' Meetings Planned for Fungal and Myeloma Protocols

The next step towards opening these 2 protocols will be informational investigators' meetings. The first of these meetings will be held just prior to the start of 2002 ASH meeting in Philadelphia on December 5, 2002 from 6:00 p.m. until 9:00 p.m. At this meeting, sites that are committed to participating as well as other potentially interested sites will be able to hear an overview of the BMT-CTN's structure and activities and an overview of the fungal protocol. The location of the meeting will be posted on the BMT-CTN website as soon as this information is available. Subsequently, a pair of meetings will be held in concert with the 2003 Tandem BMT Meetings in Keystone. In addition to a review of the BMT-CTN and overview of the protocol for investigators, these meetings will include a session for study coordinators on protocol specific issues such as sample collection and shipping, case report forms, data collection and web-based electronic submission. At the time of preparation of this newsletter, the MM protocol meeting will be held January 30, 2003 from 2:00 p.m. until 5:00 p.m. The Fungal Prophylaxis protocol meeting also on January 30, 2003 follows from 5:45 p.m. until 8:30 p.m. Details regarding the meeting rooms will be available soon. It is hoped that interested sites will take the opportunity to have their coordinators attend these sessions as part of a broader opportunity for them to attend other components of the Tandem meeting such as the Data Managers meetings, the Pharmacy meeting or the main scientific program.

Communicating with the BMT-CTN

To facilitate information dissemination, for the exchange of ideas and to solicit interested non-Core sites, the BMT-CTN has established a public website (www.bmtctn.net). Here interested individuals can find background on the BMT-CTN, information on upcoming meetings, protocols under development and, as completed, the BMT-CTN Manual of Procedures and other publications. The Network also welcomes your ideas and input.

Next Trials

While the BMT-CTN looks forward to opening its first 2 trials, we are actively developing the next series of trials. The first is a randomized trial of bone marrow versus peripheral blood grafts in the unrelated donor setting, done in collaboration with the NMDP. Two other non-myeloablative transplant trials are also being drafted, one in follicular lymphoma and the other in Hodgkin's lymphoma. It is hoped that these will be ready for roll out by early summer 2003.

IBMTR/ABMTR studies disparity in survival by race after HLA-identical sibling hematopoietic stem cell transplantation

By Fausto R. Loberiza, Jr., MD, MS

Assistant Scientific Director, IBMTR/ABMTR

Differences in healthcare access, utilization, and outcome among racial or ethnic groups are documented in a wide variety of medical and surgical settings in the USA. African-Americans, for instance, are less likely to undergo some medical procedures, including bone marrow transplantation, and have lower long-term survival than Caucasians after treatment for many types of cancer, including leukemia. The IBMTR/ABMTR recently completed a study examining discrepancies in survival by race after HLA-identical sibling transplantation for acute or chronic leukemia. The study determined survival rates at three different time points (1985–1989, 1990–1994, and 1995–1999) among Caucasians, African-Americans, Hispanics and Asians. Whereas biological factors may account for most survival discrepancies among racial groups, socioeconomic, psychosocial, and cultural factors may also play a role. Additional studies examining these issues are planned. Investigators interested in participating are asked to contact Fausto R. Loberiza, Jr., MD, MS, at 414-456-8325 or at faustol@mcw.edu.

Derek S Serna, a 2nd year medical student at the Medical College of Wisconsin, will present this study during the 44th Annual Meeting of the American Society of Hematology in Philadelphia on December 2002. Other co-authors are: Mei-jie Zhang PhD, K Scott Baker MD, Mary Eapen MBBS, MS, Mary M Horowitz MD, MS, John P Klein PhD, Stephanie J Lee MD, MPH, J Douglas Rizzo MD, and Fausto R Loberiza Jr MD, MS.

This study represents a new area of IBMTR/ABMTR investigation focussing on non-traditional variables that affect the outcomes of stem cell transplantation. A new Health Services Working Committee will be soon formed and will welcome study proposals integrating non-clinical variables with traditional patient, disease, and transplant-related variables. Study design and statistical methodological issues that utilize the Registry data are also encouraged and will be processed through this committee. Persons interested in this type of research are also invited to contact Dr Loberiza.

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