CIBMTR Working Committees in the Spotlight

The 17 Working Committees of the CIBMTR provide scientific oversight for the use of CIBMTR data and statistical resources. Working Committee responsibilities include:

- designing and conducting studies relevant to their subject area and involving CIBMTR data, statistical resources, networks and/or centers;
- considering proposals to use CIBMTR data for studies pertinent to their subject area;
- periodically assessing and revising relevant sections of CIBMTR data collection forms;
- planning and conducting workshops at CIBMTR meetings.

Working Committees have responsibility for setting priorities for observational studies using CIBMTR's large clinical databases. These observational studies are a core activity of the CIBMTR. For a full listing of the 17 Working Committees and their leadership, point your browser to [http://www.cibmtr.org/COMMITTEES/working_committees_idx.html](http://www.cibmtr.org/COMMITTEES/working_committees_idx.html).

We'll be highlighting the work of these Working Committees in upcoming Newsletters. We begin with the Acute Leukemia and Health Services & Psychosocial Research Working Committees in this issue.

Acute Leukemia Working Committee

The Acute Leukemia Working Committee (ALWC) focuses on hematopoietic stem cell transplantation (HCT) for the acute leukemias and myelodysplastic syndromes (MDS). The committee was one of the first established and has been among the most productive. The Committee's prior and ongoing studies address a wide range of issues related to HCT for patients with all phases of acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL) and MDS.

The ALWC is led by 3 co-chairs: Armand Keating, MD (Princess Margaret Hospital, Toronto); Jorge Sierra, MD (Hospital Sant Pau, Barcelona); Martin S. Tallman, MD (Northwestern Memorial Hospital, Chicago). The Scientific Director is Daniel Weisdorf, MD. CIBMTR Statisticians are Mei-Jie Zhang, PhD and Waleska S. Pérez, MPH.

Each year the Working Group begins 2-3 new projects (and tries to complete 2-3 ongoing projects). The current portfolio of studies includes:

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<th>Project Number</th>
<th>Principal Investigator(s)</th>
<th>Title</th>
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The ALWC’s major research focus is in defining the optimal role of transplantation both in frequent and rare indications. Regarding the latter, registry studies are particularly helpful. Recently, many Committee proposals have focused on transplantation for AML and ALL patients with high risk disease (relapsed and refractory AML, high-risk karyotype and older adults), novel transplant strategies (non-myeloablative transplantation and umbilical cord blood transplantation), and comparisons with conventional chemotherapy. The Committee has encouraged and taken advantage of important collaborations with other groups and institutions to enable comparative studies to be completed drawing on databases from the CALGB, MD Anderson Cancer Center, City of Hope, Fred Hutchinson Research Cancer Center, the International MDS Risk Analysis Workshop (IMRAW) group, the German AML Intergroup and the NMDP (well before the affiliation).

The following section summarizes the current ALWC research activities:

**LK01-02** Treatment of relapsed and refractory AML: Outcomes after HCT and salvage chemotherapy (Study Chair: Marcos de Lima, MD Anderson Cancer Center, Houston, TX, USA; Status: Analysis). This project compares overall survival of patients with relapsed or primary refractory AML treated with allogeneic HCT (CIBMTR) with that of patients treated with chemotherapy alone (MD Anderson Cancer Center).

**LK02-02** Allogeneic HCT for the treatment of therapy-related MDS and AML (Study Chair: Mark Litzow, Mayo Clinic, Rochester, MN, USA; Status: Data File Preparation). This project analyzes outcomes and factors associated with prognosis following transplantation for therapy-related MDS and AML.

**R02-05** Unrelated donor HCT in AML and ALL patients who fail an autologous transplant (Study Chair: James Foran, University of Alabama at Birmingham, Birmingham, AL, USA; Status: Protocol Development). This project will examine patients receiving unrelated donor HCT relapsing after a previous autograft for ALL or AML and attempt to identify patients likely to have the best outcome.

**R02-09** Evaluation of donor leukocyte infusions (DLI) to treat relapsed hematologic malignancies after related and unrelated donor myeloablative HCT (Study Chair: Alison Loren, University of Pennsylvania Cancer Center, Philadelphia, PA, USA; Status: Protocol Development). The value of related and unrelated donor DLI in treatment of acute leukemia relapsed after allografting will be examined, including the impact of disease status, timing and dose response.

**LK03-03** Outcome of HCT in patients with active leukemia at the time of transplant (Study Chair: Michel Duval, Hôpital Sainte-Justine, Montreal, Quebec, Canada; Status: Data File Preparation). This project evaluates the results of patients undergoing allogeneic HCT for refractory acute leukemia.

**R03-50** Allogeneic HCT from unrelated donors for Ph-negative ALL (Study Chair: David Marks, Bristol Children’s Hospital, Bristol, United Kingdom; Status: Data File Preparation). This project proposes to analyze the outcomes of adults with Philadelphia chromosome-negative ALL who have an unrelated donor HCT performed in first complete remission.

**LK04-01** Comparison of autologous and allogeneic HCT for patients with acute promyelocytic (APL) in second complete remission (Study Chair: More Rubinger, CancerCare Manitoba, Winnipeg, Canada; Status: Protocol Development). This project analyzes outcome of patients with APL in second complete remission including details of molecular remission prior to transplant.

**LK04-02/R02-14/GV01-01** Comparison of ablative vs. non-myeloablative allogeneic HCT for AML or MDS (Study Chairs: Selina Luger, University of Pennsylvania, Philadelphia, PA, USA; Michael Pulsipher, University of Utah School of Medicine/Primary Children’s Medical Center, Salt Lake City, UT, USA; Olle Ringdén, Karolinska Institute-Huddinge Hospital, Huddinge, Sweden; Status: Data File Preparation). This revised project incorporates elements of three previous projects comparing the outcomes using non-myeloablative or reduced intensity vs. myeloablative conditioning in patients ≥ 18 years of age.

**LK04-03** Autologous vs HLA-identical sibling transplant for AML (Study Chair: Armand Keating, Princess Margaret Hospital, Toronto, Ontario, Canada; Status: Data File Preparation). This analysis will assess the relative efficacy of allogeneic and peripheral blood autografts for AML in first complete remission.

**LK05-01** Outcome of allogeneic HCT in AML with adverse-risk karyotype with myeloablative conditioning using matched continued on page 3
June 7th and 8th of this year, a number of leading investigators in HCT, as well as experts in hematologic malignancies and related diseases, will convene in Ann Arbor, Michigan for a State of the Science Symposium. This is the second State of the Science Symposium dedicated to hematopoietic stem cell transplantation issues. The first, held 5 years ago, developed the blue print for the initial Blood and Marrow Transplant Clinical Trials Network (BMT CTN) studies and served as a roadmap for the successful 5 year continuation of the BMT CTN grant.

The work for this Symposium began almost a year ago when Dr. James Ferrara assigned 12 Committee Chairs the task of recruiting thought leaders in their areas to discuss, through face to face meetings, conference calls and email discussions, the “most compelling questions to be answered in the next 5 years by the BMT CTN.” The committees were also charged with proposing ways to answer those questions and identifying barriers to overcome.

The twelve areas of discussion will be

1. optimal donors and graft sources
2. regimen-related toxicity
3. graft-versus-host disease
4. infection and immune reconstitution
5. late effects and quality of life
6. pediatrics
7. leukemia
8. multiple myeloma
9. lymphomas
10. non-malignant diseases
11. gene and cell therapy
12. optimal trial designs

This meeting offers wonderful opportunities for all persons interested in the field. For fellows in training and junior faculty, it is a chance to hear many of the most established researchers define the problems of transplantation today as well as potential solutions. This may serve as a catalyst for them to develop a field of interest in their own careers.

For established transplant clinicians and researchers, it is an opportunity to provide feedback to the Committees and even challenge their conclusions and recommendations in order to make the final product more reflective of the “spirit of our field.”

Finally, for allied health care personnel, it will provide an intensive review of where we stand today, where we want to be five years from now and how we propose to get there.

In short, I invite all of you to “block the dates” of June 7th and 8th and find time to join us in Ann Arbor. Make your voices heard so that the roadmap that we lay out for the next five years in transplant research represents the needs of our large transplant community.

Mark Your Calendars!
Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
State of the Science Symposium
June 7th & 8th, 2007
Ann Arbor, MI
For more information: www.cibmtr.org/MEETINGS/soss_2007.html

CIBMTR scoring system to predict the outcome after allogeneic HCT for AML (Study Chair: Jorge Sierra, Hospital de la Santa Creu i Sant Pau. Autonomous, University of Barcelona. Spain; Status: Protocol Development). This project proposes to identify the factors that will impact leukemia-free survival after allogeneic HCT following myeloablative conditioning as treatment for primary AML. Based on the identified factors, a scoring system predicting transplant outcomes will be generated.

Assessment of allogeneic HCT in older patients with MDS and NHL (Study Chairs: Brian McClune, University of Minnesota, MN, USA; Sergio Giralt, MD Anderson Cancer Center, Houston, TX, USA; Status: Protocol Development). This project proposes to examine post-HCT outcomes in older (vs. younger) patients undergoing allografting in order to evaluate patient, disease and treatment factors that will modify transplant outcomes.

We encourage all members of the HCT community to actively participate in our Committee to generate new proposals or participate in the design and conduct of our studies. To submit a proposal, see www.cibmtr.org/SERVICES/observational_research_idx.html. We are particularly enthusiastic about stimulating the participation of young investigators. The next ALWC meeting will be held in February 2008 at the BMT Tandem Meetings in San Diego, California.
BMT Tandem Meetings – The challenges that come with success

By D’Etta Waldoch, CMP

2007 BMT Tandem Meetings
An unprecedented 1,862 attendees from 39 countries filled the Keystone Conference Center, Lodge and Inn beyond capacity for the 2007 BMT Tandem Meetings, Feb 8-12, to present the latest developments in blood and marrow transplantation. The 2007 agenda included 6 plenary sessions, 11 concurrent sessions, 3 workshops, 78 oral abstracts, 3 poster sessions and 12 satellite symposia.

More than 450 abstracts were submitted by investigators from 31 countries, representing a 31% increase over the 349 submitted for our previous meeting in Keystone. Visit www.cibmtr.org to view abstracts, which are indexed and accessible online, or to purchase audio CDs, MP3 files or CD-ROM recordings of the 2007 BMT Tandem sessions.

New in 2007, conference evaluations and transcripts for continuing medical education (CME) or allied health professionals’ contact hours were available online. Visit the CIBMTR Web site to print out your CME transcript, if you have not already done so (registration ID required). Additional questions about CME transcripts may be directed to info@condorregistration.com (256-852-4490).

Over the past 30 years, Keystone Resort became a traditional venue for BMT-related meetings, including the Tandem Meetings since 1995. Many who returned year after year even referred to the “BMT Tandem Meetings” as the “Keystone Meetings.” Early conferences were attended by fewer than 500 worldwide transplant experts, but annually the Tandem Meetings have grown in size, breadth and content. Keystone’s expansion of the Conference Center in the summer of 2000 provided space for additional workshops and peripheral conferences to be added to the overall Tandem Meetings agenda. In 2007, however, filled to the summit, it became clear it was finally time to accept that the BMT Tandem Meetings had outgrown the option of returning to Keystone Resort.

2008 BMT Tandem Meetings
Upon bidding a fond farewell to Keystone, a much warmer breeze beckons as we set our sails for San Diego and the Manchester Grand Hyatt for the 2008 BMT Tandem Meetings, February 13-17. Scientific Program Chairs for 2008 are Drs. Stella Davies for CIBMTR and Marcel van den Brink, MD for ASBMT.

In addition to five days of scientific and clinical meetings related sessions include: BMT CTN Steering Committee, FACT Training Workshops, Clinical Research Professionals’ Data Management Conference, BMT Center Administrative Directors Conference, BMT Pharmacists Conference, Transplant Nurses Conference and the BMT Center Medical Directors Conference.

Sessions targeted primarily to pediatric transplantation will be held February 14.

Detailed information about the 2008 BMT Tandem Meetings will be continuously updated on the CIBMTR (www.cibmtr.org) and ASBMT (www.asbmt.org) Web sites. Online conference registration, hotel reservations and the abstract submission program (deadline October 8, 2007) should be available in August. Check back periodically for updates to the provisional agenda.

For general information, please e-mail D’Etta Waldoch, CMP at the conference office at dettawaldoch@cs.com.

Questions regarding support opportunities at the 2008 BMT Tandem Meetings may be directed to Sherry Fisher at slifisher@mcw.edu.

Fall Meeting update

By Diane Knutson

With the merging of CIBMTR and NMDP data collection systems slated for July 2007, training is more important than ever before. Plans are underway for centers to receive informational materials in May to assist in understanding the new Stem Cell Therapeutic Outcomes Database (SCTOD) contract, the new Harmonized Report Forms and new data management processes. A variety of media, including CD’s, conference calls, an updated Data Management Manual, information accessible directly from FormsNet™ 2.0, CIBMTR Web site updates and, of course, our meetings will be used to inform every center about the new forms and processes. A survey has been sent to transplant centers to evaluate their training needs. Areas highlighted in the survey were: location/date of future Fall Meetings; interest in attending certification training or testing from groups like ACRP or SOCRA; forums to discuss good practices, successful implementation of data management departments and topics for workshops. We welcome suggestions anytime and use them for developing our training programs. Thank you to everyone who has provided feedback on the evaluations and surveys.
FormsNet™ 2.0

By Ken Bengtsson
Bioinformatics, National Marrow Donor Program®, Minneapolis, MN, USA

FormsNet™ 2.0 is an exciting new tool that will be used to capture both the standard outcomes dataset required by the Health Resources and Services Administration (HRSA) for the Stem Cell Therapeutic Outcomes Database (SCTOD, see CIBMTR Newsletter; Volume 12, Issue 2, December 2006) and the CIBMTR research dataset from transplant centers. FormsNet™ 2.0 will be implemented in July 2007. At that time, centers will be able to submit data on paper, via StemSoft Software Inc., or directly using the web-based FormsNet™ 2.0. StemSoft customers will use FormsNet for data entry with their software pulling their data back into their local StemSoft database.

The purpose of the application is to minimize the reporting burden on centers by providing a user friendly interface with simple data entry, easy correction of errors and lists of forms that are due. What’s so good about FormsNet™ 2.0?

Features of FormsNet™ 2.0 include:
- Web-based application with easy, secure access
- Real time:
  - Form submission
  - List of forms that are due
  - Validation and error correction/override
  - Saves incomplete forms to be completed later
  - Secure - SecurID® RSA token, ID and PIN required
  - Query and reporting tools
  - Data entry does not require the use of a mouse
  - Completed forms available in PDF format for printing and viewing

FormsNet™ 2.0 will provide bi-directional communication between centers, including handling notifications for expected or missing data. FormsNet™ 2.0 will have automated validation checks within and between forms, automatically generated error reports, field-level audit trails, review functions for center supervisors, electronic signature capability, and the flexibility to add additional features. A programmed query system and interactive data exchange capabilities with centers will be available. FormsNet™ 2.0 will accommodate pre-programmed queries for outcomes reporting to all appropriate users and, eventually, allow for the generation of customized reports.

Benefits of using FormsNet™ 2.0 versus paper

- FormsNet™ 2.0:
  - Manages form tracking/status
  - Instant validation and error correction/override
  - Faster form submission
  - Eases Continuous Process Improvement (CPI) compliance
  - Option to print clean PDF copy once complete
  - Security
- Paper:
  - Manual form tracking/status
  - Increased likelihood of errors and manual corrections
  - Faxed copies are hard to read
  - Mailed forms can be lost and are not secure

How does AGNIS fit in?

To address the problem of redundant data entry, a data exchange system called AGNIS (A Growable Network Information System) is being developed that will allow data sharing from diverse database systems without manual re-entry into a specific electronic interface. Centers may then collect their own data in the way that works best for them and share it with others that also link to AGNIS, enabling an “enter once, use often” capability.

AGNIS will allow centers and networks to electronically share HCT data from local systems with other centers, registries, and networks through a single software link.

AGNIS is a public system for the electronic exchange of clinical network data, an open source, peer-to-peer messaging service. Because it is open source, third-party developers, such as StemSoft Software Inc., will be able to integrate AGNIS-like services into their software, allowing centers to continue using their systems and reducing centers’ submission burden.

The software is currently in the development stage and will be released to the public in October 2007.
Harmonized Forms

By Diane Knutson & Marie Matlack

The CIBMTR was awarded the contract for the Stem Cell Therapeutic Outcomes Database (SCTOD) which is a component of the C. W. Bill Young Cell Transplantation Program. The SCTOD is charged with collecting outcome data on all allogeneic hematopoietic stem cell transplants where either the donor or the recipient resides in the United States.

To meet the reporting requirements of the SCTOD, the CIBMTR in conjunction with the NMDP and EBMTR have revised the Transplant Essential Data (TED) Forms. The revised Forms have new names, Pre-TED and Post-TED, which will replace the existing Pre-Reg, MTED, TED-01, and TEDFU-01 Forms. The CIBMTR has also worked with the NMDP to harmonize the research Report Forms. All of the new forms will be released in July 2007.

There are several exciting changes that will be occurring with the release of the new forms:

- Centers providing data on paper forms will submit them to one site for data entry (Transplant Centers will be assigned to either the Milwaukee or Minneapolis Campus).
- Data may be submitted electronically.
  - Via FormsNet 2.0, which includes an interface with Stem Soft (see Page 5)
  - There will be one comprehensive Forms Due Report.
- Reporting time points will be the same for the Post-TED and the Harmonized Research Report Forms (100 days, 6 months and annually).
- There will be a combined Continuous Process Improvement (CPI) Program and a combined Audit Program.
- Recipient registration:
  - Transplant centers will acquire a unique recipient ID number (“Universal ID #” or “CIBMTR recipient ID”).
  - All transplant recipients will be registered prior to transplantation.
  - Recipient will retain the unique ID number if they transfer to another transplant center.
- New “TC”/“Team Number” codes will be assigned to each transplant center (“CIBMTR Center #”).

The CIBMTR and NMDP are collaboratively working to meet the challenges and requirements of the new SCTOD contract. The two campuses are developing integrated internal processes to create streamlined and efficient collection and data management. The changes that are occurring will provide complete, quality data that will enhance research opportunities for the transplant community.

When the new H-Forms are released, there will be one system for both organizations. A packet of materials describing the new process will be arriving at Transplant Centers in May 2007.

Financial burden of HCT.

The HSWC has faced special challenges. Perhaps all committees secretly believe this, but many of the critical variables that would be valuable for our studies (income, education, occupation, health insurance status etc) are blank on submitted Report Forms, therefore missing in the CIBMTR database. We speculate that these data are not easily available to data managers. Zip code allows some estimation of socioeconomic status and is a common surrogate used in large population studies. For a period of time, the CIBMTR was not capturing patient zip code, although this oversight has since been rectified. We also discovered that many coordinators were listing the zip code of the transplant center, rather than patients’ home addresses. To try to improve collection of socio-economic data, the committee has created a self-reported patient form to allow patients to provide the information directly. These forms will be available in July 2007, and we hope will help teams improve their reporting of these variables.

The HSWC often finds itself grappling with research questions and types of data that require creative approaches to study design and data collection, which leads to lively debates during our committee meetings. For example, how does one quantify the barriers to optimal posttransplant care when there are likely to be financial, cultural, language and social factors for certain populations?

Finally, the HSWC Co-Chairs and Scientific Directors (along with the Co-Chairs of the Late Effects Working Group (John Wingard, Brian Bolwell and Gerard Socie) have helped CIBMTR develop a plan to collect quality of life data from allogeneic transplant recipients. Collection of quality of life data is required for the Stem Cell Therapeutic Outcomes Database (SCTOD) of the C. W. Bill Young Transplantation Program (see CIBMTR Newsletter, Volume 12, Issue 2, December 2006). The plan was presented to Health Resources and Services Administration (HRSA) in April and suggests collection of a core set of instruments on a subset of patients at 3 time points: prior to transplantation, at 1 year and 3 years posttransplant. Data collection will begin at highly committed centers with existing infrastructure. Posttransplant information will be collected centrally with data reported back to the centers. There are many details including selection of centers, compensation to centers, IRB approvals, etc. that must be considered before this plan can be fully implemented. However, there are obvious benefits to the HSWC from this legislative mandate, in that we would have a wealth of data to address scientific questions relevant to the “psychosocial” component of our committee name.

If you are interested in health policy and psychosocial issues, then the HSWC should definitely be on your list of “must attend” events at our next CIBMTR meeting in San Diego. Concept sheets can be submitted throughout the year so distinguish yourself and submit one earlier than the day before the deadline. For submitting a proposal, see www.cibmtr.org/SERVICES/observational_research_idx.html. You can contact any of the Chairs or Scientific Directors to help you as you develop projects.
How to Handle NMDP Report Forms until July 2007
For the past 12 years the CIBMTR has accepted copies of NMDP Report Forms to help reduce the data submission burden on participating centers. Now we have taken it one step further and made the process even more efficient. It is no longer necessary to:
• make copies of the NMDP Report Forms (also subsequent Follow-up Report Forms),
• complete a CIBMTR Graft Insert ,
• submit them to CIBMTR.
Any NMDP recipient record with a Day-100 Report Form or Follow-Up Report Form ‘due’ on the most recent CIBMTR ‘Request for Patient Data,’ that has a completed NMDP form is now ‘exempt’ from submitting these ‘due’ forms. Please communicate this to CIBMTR by writing NMDP RID (Recipient ID #) on CIBMTR ‘Request for Patient Data’.
Between now and July 2007, all recipients with an NMDP donor still need to be registered with CIBMTR. In the box at the bottom of the Pre-Registration form (see below), check “No Report Form due” and write the NMDP RID in the empty space available. If your center registers patients with CIBMTR electronically instead of on paper forms, please submit a list of IUBMIDs and corresponding RIDs to CIBMTR.
After CIBMTR confirms that the Report Forms are up-to-date, the recipient record will be marked as “exempt” in the CIBMTR database. This exemption will expire in July 2007 when reporting shifts for all centers to the new CIBMTR Harmonized Report Forms (H-Forms).
No changes in data submission until July 2007
All other data submission processes at CIBMTR (and NMDP) remain unchanged until July 2007. This includes the CIBMTR data submission process for:
• registration (TED) data;
• autologous donor research;
• related donor research.

Foundation and corporate support of the CIBMTR
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