Center for International Blood and Marrow Transplant Research

Sharing knowledge.....

.......Sharing hope
The CIBMTR Grew Out of Two Important Collaborative Efforts in BMT

- International Bone Marrow Transplant Registry (IBMTR)
- National Marrow Donor Program (NMDP)
IBMTR

Æ Voluntary outcomes registry established in 1970
≠ 2 years after the first successful HCTs
≠ At a time when there were ~12 transplant centers, < 50 transplants a year worldwide

Æ Maintained a database of clinical information on recipients of autologous and allogeneic hematopoietic stem cell transplants in ~450 centers in 47 countries

Æ Provided scientific and statistical support for analyzing those data
NMDP

Æ 1986 – U.S. government appropriated funds to establish the National Bone Marrow Donor Registry (Donor Panel)

Æ 1988 – U.S. Organ Transplant Amendments Act – mandated collecting outcome data (Recipient Registry); also collects donor outcomes

Æ ~150 transplant centers and 90 donor centers

Æ Repository with matched recipient/donor blood samples
CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH

Æ Established July 2004

Æ A research collaboration between the International Bone Marrow Transplant Registry and the National Marrow Donor Program to support clinical research in BMT & related fields

≠ All of the former IBMTR
≠ Research Operations Department of NMDP
135 staff including, 6 PhD statisticians, 14 MS statisticians, 11 MD-MS faculty;
Active program of statistical methodology research specifically focused on transplant outcomes in addition to supporting clinical studies
CIBMTR
270,000 Cases Registered, 1984-2008
450 Publications

**Year**

- '84
- '86
- '88
- '90
- '92
- '94
- '96
- '98
- '00
- '02
- '04
- '06
- '08

**Transplants**

- Autologous
- Allogeneic

**Topics**

- QOL, Long-term Follow-up
- Multicenter Clinical Trials
- Immunobiology*
- Technology Assessment
- Prognostic factors
- Descriptive

*SCTOD Repository - Related donor-recipient pairs
*NMDP Repository - Specimens for >13,000 unrelated donor-recip pairs

270,000 Cases Registered, 1984-2008

450 Publications
CIBMTR SCIENTIFIC ACTIVITIES

Observational Research
- Clinical outcomes
- Immunobiology
- Health Services

Statistical Methodology

Prospective Clinical Trial Support
- BMT CTN
- RCI BMT
CW Bill Young Cell Transplantation Program

Æ Established by legislation passed in 2005
Æ Successor to National Bone Marrow Donor Registry (contract held by NMDP since 1987)
Æ 5 components:
  ≠ Bone Marrow Coordinating Center
  ≠ Cord Blood Coordinating Center
  ≠ Single Point of Access/Office of Patient Advocacy
  ≠ Cord Blood Banks
  ≠ Stem Cell Therapeutic Outcomes Database
Under the Contract, SCTOD will-

- **Collect data (and specimens)**
  - ALL allogeneic hematopoietic cell transplants (HCTs) with a recipient or donor from the U.S.
  - Related donor-recipient repository
  - Other cellular therapies
  - Quality of life data
  - Secure, efficient electronic data capture system

- **Analyze data**
  - Center-specific outcomes for U.S. transplant centers
  - Perform analyses of optimal size for the adult donor registry and cord blood unit inventory
  - Conduct and support other research using the data collected under the contract

- **Disseminate data**
  - Within the Program
  - To the scientific and medical community
  - To patients, families and the public
Data Collected

TED-level data

- All allogeneic US HCT recipients
- All autologous HCT recip in US w consent or “center agreement”
- Approved by OMB for SCTOD
- Includes basic demographic, comorbid, HLA, disease, transplant, and outcome data
- Time to complete 30 – 120 min
TED-level INSTRUMENTS

- Unique ID
- Pre-TED
- Post-TED
- Death Form
- HLA form
- Infectious Disease Marker
- Infusion form
- Timeline: Pre, 100 days, 6 mos, 1 year and annually
  - Overdue 30-60 +days after due
Data Collected

- Comprehensive Report Form
  - Randomized selection based on TED level data
  - Detailed demographic, disease, transplant and outcomes data
  - Typically used for research studies
  - Completed at pre-HCT, 100 d, 6 mos, 1 year and annually
    - Overdue 30 – 60 + days after due
  - Generally 6-8 hours to complete
DATA COLLECTION FOR CIBMTR

*Harmonized form replacing NMDP and IBMTR Report Forms
Current/Future Data Flow

Transplant Essential Data Form

Non-US; US Auto

US Related*; Unrelated**

Mandatory

Voluntary

AGNIS - A Growable Network Information System: Collaboration with NIH Bioinformatics

Single CIBMTR Database (Research Database)

Comprehensive Report Forms

Voluntary

Expanded MED-A

MED-B

EBMT

Eurocord

AP BMT Group

*Donor outcomes routinely collected
**Donor outcomes to be collected on subset
What is NOT collected!

Æ Every Grade 3-5 AE

≠ Limited AE collected, not real time

Æ Detailed infection data

Æ Details of graft processing

Æ Detailed additive data

≠ Manufacturer, expiration date, lot number, etc
## Infusion Form Example

14. Were anticoagulants added to the product during collection?

1. ☐ yes
2. ☐ no

Specify anticoagulant(s):

15. Acid citrate dextrose (ACD)
   1. ☐ yes
   2. ☐ no

16. Citrate phosphate dextrose (CPD)
   1. ☐ yes
   2. ☐ no

17. Heparin
   1. ☐ yes
   2. ☐ no

18. Other anticoagulant
   1. ☐ yes
   2. ☐ no

19. Specify other anticoagulant: ____________
Systems to Handle Data

Æ Inputs
- Paper forms (< 10%)
- Electronic
  - Forms Net 2.0
    - Direct web-based data entry
  - AGNIS automated data

Æ Outputs
- Direct printing from Forms Net
- Electronic output of data file
- AGNIS
ROLE OF OBSERVATIONAL DATABASE IN CLINICAL RESEARCH

- Analyze trends
- Descriptive studies
- Identify factors associated with outcome
  - Clinical
  - Center-specific
  - Socioeconomic
  - Biologic/genomic
- Assess treatments / strategies
  - Donor selection
- Study late effects
- Analyze access / utilization
- Design / Interpret / Facilitate clinical trials
Limitations of Observational Data Collection

- Prospective vs real-time
  - Data collection
  - Interval-based reporting
- Focused on outcomes and research, not surveillance and adverse events
- Data elements relevant to broad picture
- Limited resources for data collection and submission
Questions?

Æ Data collection instruments
≠ www.cibmtr.org/DATA/Data_Mgmt_Forms/index.html

Æ AGNIS
≠ www.agnis.net

Æ FormsNet 2.0
≠ www.cibmtr.org/DATA/data_idx