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C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

C.2.1 CIBMTR PUBLIC INTERNET PRESENCE

C.2.1.a Public Site

The CIBMTR website (cibmtr.org) is unrestricted and provides information about the CIBMTR and its research. It supports the Working Committees and BMT CTN through information about how to submit a proposal, access to a listing and summaries of all studies in process, and access to a summary of all CIBMTR publications. The website facilitates data and information requests, and it provides access to all current and past data collections forms, training manuals, and videos as well as other materials for both investigators and data professionals. The website information is, in part, supported by DISCO, which maintains data on more than 670 studies, more than 800 publications (since 1972), and 1,545 authors and their institutions at time of publication. In 2014, the CIBMTR public website had approximately 368,000 unique page views.

• CIBMTR Rebranding. In 2014, the CIBMTR updated the public site with a new look and feel to reflect branding more closely aligned with both MCW and NMDP and to promote usability among its stakeholders. The rebranded website was launched in July and received favorable feedback.

• Disease Risk Index Assignment Tool. By the end of December 2014, the CIBMTR plans to launch a Disease Risk Index Assignment Tool for use by clinicians and researchers. It was created to provide a robust and flexible tool that can be used for prognostication and the analysis and interpretation of retrospective data. The Disease Risk Index can also be used for the stratification of patients entering prospective HCT clinical trials. At present, this index applies only to adult patients with hematologic malignancies; it is NOT intended to give an accurate prognosis for individual patients.

An Advisory Team meets regularly to review the site and plan updates. Web content is assigned to appropriate subject matter experts and content leads to ensure accuracy.

C.2.1.b Collaborative Site

The Collaborative site (collaborate.cibmtr.org) uses the SharePoint Enterprise Collaboration platform to promote cooperative work among CIBMTR staff members and provides a communication platform for specific studies and initiatives. This site is secured by username and password, and user-specific security credentials are assigned.

The CIBMTR uses the site for storing and sharing protocol and consent documents, donor / recipient tracking tools, confidential committee information, data, manuscript drafts, and other relevant information. While only two Working Committees currently use the Collaborate site on a regular basis, it is available to all for sharing information.

C.2.1.c Portal Site

• Data Back to Center. The DBtC application provides users the ability to download CIBMTR TED level data variables. The data have been validated and processed in the Research Database and are reviewed and refreshed quarterly. Legacy IBMTR data is available for download as far back as 1964, and some legacy NMDP data is available as far back as 1987. These data can be downloaded by authorized users of a transplant center in a comma-separated value format. Between January 1 and December 1, 2014, 951 unique, non-CIBMTR visitors viewed 2,332 DBtC pages and downloaded data 486 times.
  oIn 2013, DBtC access was extended to two cooperative registry groups (Asia-Pacific Blood and Marrow Transplant Group & Canadian Blood and Marrow Transplant Group) to obtain data submitted to CIBMTR by their transplant center members. Access to a transplant center's data is only provided in cases where the transplant center has signed a data transmission / sharing agreement form with their respective registry. In 2014, the CIBMTR continued discussion with other international registries to put in place formal agreements to use CIBMTR data as their primary data source.
  oIn July 2014, DBtC underwent major enhancement to include all pre-TED and post-TED form version 4 changes introduced in FormsNet3 during the Forms Revision release in 2013.

• Center Volumes Report. The Center Volumes Report allows centers to preview; correct, if necessary; and approve center volume data published annually to the HRSA Blood Cell Transplant website (http://bloodcell.transplant.hrsa.gov). Under contract to HRSA as part of the C.W. Bill Young Transplantation Program, the CIBMTR provides information regarding transplants performed at US transplant centers. The CIBMTR uses the portal site to give centers access to the Center Volumes Report and to display and download the previous five years (2009-2013) of volume data as well as the current year under review (2013). For 2013, 59 of 215 centers have submitted approval to publish their center volume data, and we anticipate the number of centers that agree to have their data published will increase significantly. During 2014, there were 5,081 pages viewed by 707 unique, external visitors to the portal site, and, of those, 1,668 views were of the Center Volumes Report.

• Patient One-Year Survival Calculator – Allogeneic Transplants. In July, the CIBMTR launched the Patient One-Year Survival Calculator for Allogeneic Transplants by deploying the calculator to the portal site for access by medical directors. The intent of this online survival calculator is to provide centers with a tool to predict one year survival for individual allogeneic HCT recipients. Data taken from the CIBMTR Center-Specific Survival Report for 2013 is used to calculate the "expected" probability of one-year survival for individual recipients of first allogeneic HCT in the US. Patient, disease, and transplant characteristics of alloHCT recipients at US HCT centers between 2009 and 2011 are used to generate these estimates. The calculator will be updated annually to reflect new information contained in the center outcomes analysis.

C.2.2 BE THE MATCH INTERNET PRESENCE

The Be The Match Internet Presence consists of two websites, one designed for the public and the other for professionals. CIBMTR data and research findings are presented on both websites.

C.2.2.a BeTheMatch.org

BeTheMatch.org is designed for patients and families, donors, and supporters. It incorporates personal stories of donors and recipients, opportunities for support, and detailed information about transplantation written for the public. The website provides scientific information in lay terms related to specific diseases, various treatment options, the process of transplantation, and life after transplant. It also addresses concerns related to specific populations, including children and caregivers.

C.2.2.b BeTheMatchClinical.org

BeTheMatchClinical.org is designed for clinicians, network participants, payors, and bioinformatics professionals. For clinicians, the website provides access to evidence-based tools, clinical guidelines, presentation slides, outcomes data, and education courses on HCT. The website also provides information specific to types of network participants: transplant centers, donor centers, apheresis and collection centers, and cord blood banks. For payors, BeTheMatchClinical.org offers information to help individuals understand BMT, determine coverage, and answer employer and patient questions. For individuals interested in bioinformatics, the website provides resources and access to expertise for immunogenetic-focused research and operational bioinformatics as well as frequently used HLA tools.

C.2.3 HRSA BLOOD CELL TRANSPLANT WEBSITE

HRSA's Blood Cell Transplant website (bloodcell.transplant.hrsa.gov) provides information for the public, physicians, and other constituents. It incorporates transplant resources, donor information, and cord blood information as well as research, data, and outcomes. CIBMTR data and research findings are incorporated in numerous ways, including through CIBMTR-created reports:
• US Survival Report;
• Transplant Data by US Center Report;
• Transplant Data by Disease Report.

C.3 TECHNOLOGIES OR TECHNIQUES

C.3.1 STATISTICAL TECHNIQUES AND METHODOLOGY

The CIBMTR has developed and evaluated the statistical models used in HCT research through its relationship with the MCW Division of Biostatistics faculty, which has substantial collective experience in assessing the unique problems associated with HCT research. This year, these faculty members published the following statistical techniques and methodology:
• Comparison of cumulative incidence functions with early or late weightings and with an R-CIFsmry package;
• Application of a symbolic covariance matrix for interval-valued variables to principal component analysis;
• Use of a revised Fisher model on the analysis of quantitative trait loci with multiple alleles.

CIBMTR MS-level statisticians also develop statistical techniques based on HCT research. In 2014, Zhen-Huan Hu developed a set of SAS Macros for generating survival analysis reports for lifetime data with or without competing risks.

C.3.2 HLA TYPING AND MATCHING

Based on the findings of numerous large, contemporary retrospective studies and comprehensive reviews, overall survival is increased and transplant-related mortality reduced when recipients of unrelated donor HCTs are evaluated and matched at high resolution for HLA-A, B, C, and DRB1 (8/8 matched). When multiple equivalently matched unrelated donors are available, the consideration of addition HLA loci and non-HLA factors may be used to prioritize the final donor selection. A recent CIBMTR study (Pidala et. al. Blood 2014) demonstrated that selection of 8/8 matched donors with T cell epitope permissive HLA-DPB1 mismatches leads to improved overall survival and reduced transplant-related mortality in comparison to those with non-permissive mismatches.

Umbilical cord blood transplants expand access to patients unable to find a suitable unrelated adult donor due to a traditionally lower threshold of HLA match. The recipient and cord blood units should at minimum be typed at HLA-A and B at intermediate resolution (or higher) and HLA-DRB1 typed at high resolution by DNA-based methods. A recently published CIBMTR retrospective study (Eapen et. al. Blood 2014) supports the consideration of high resolution matching at HLA-A, B, C, and DRB1 to maximize graft success and minimize risks of non-relapse mortality. The study also found that the impacts of HLA matching were not offset by increasing cell dose beyond the minimal recommended total nucleated cell dose of ≥ 3x10^7/kg.

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period?

No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

File uploaded: U24.CIBMTR.C5.pdf

C.5b Resource Sharing

C.5b.1 Research Database

The CIBMTR collects data for approximately 20,500 new transplant recipients annually as well as a continually increasing volume of follow-up data on previously reported recipients and donors. These data are maintained in the Research Database, which now contains information on more than 390,000 transplant recipients going back to transplants performed in 1968. Data and information from the Research Database are shared in a variety of ways (**Table C.5b.A**), and the Coordinating Center takes care to ensure shared data are appropriately utilized and interpreted (**Section B.2.2 Scientific Resource Utilization Program**).

Table. C.5b.A Utilization of CIBMTR Research Database-related resources accessible through the CIBMTR website, January 1 - December 1, 2014

	Total N*
Information Request Service	**462**
CIBMTR Webpages	
Data Management Manual	45,464
Data Collection Forms	38,036
Web-based US Transplant Reports	21,477
Data Management Training and Reference	14,125
Summary Slides	8,618
Publication List	2,877
Annual BMT Tandem Meetings Working Committee and Data Management Meetings Materials	1,313
Working Committee Studies Lists	1,269
Statistical Resources	1,258
Patient Resources	758
Procedures and Progress Reports	714
Newsletter	483
Data Back to Centers Application	469
CIBMTR Webpages TOTAL	**136,861**
Other CIBMTR Research Database-Related Resources	
External Webpages	
HRSA US Survival Report	
HRSA Transplant Data by US Center Report	
HRSA Transplant Data by Disease Report	
Be The Match US Center Listing Report	
Resources Available to CIBMTR Transplant-Center Members	
Annual Report on Transplant Survival Rates	
Survival Outcomes Calculator (available to physicians only)	
FormsNet Data-Back-to Centers Application	
Resources Available upon Request	
Report of Survival Statistics for BMT	
US Center Volumes Dataset	

C.5b.1.a Information Request Service

The CIBMTR aims to provide maximum access to the data it collects and generally responds to information requests within two days. Information requests can be submitted at www.cibmtr.org and bloodcell.transplant.hrsa.gov as well as by mail, fax, and phone. These requests often come from physicians and patients seeking information about transplant outcomes. For the conduct of clinical trials, researchers request data for multiple purposes, including evaluation of potentially eligible patients or centers, review of current transplant practices and therapies for protocol development, and assessment of accrual patterns and barriers during the conduct of the trial. **Table C.5b.B** summarizes the information requests submitted to the CIBMTR in 2014.

Table C5b.B. Data Requests Addressed by the CIBMTR January 1 – December 1, 2014

Type of organization	Number of Requests
Physician/Researcher	324
Pharmaceutical/Biotech Company	43
Patient or Relative	23
Patient Advocacy Group	46
Market Research Firm	18
Federal Government Agency	2
State Government Agency	0
Insurance Company	0
Medical Society	0
Student	3
News Media	3
Law Firm	0
Cord Blood Bank	0
TOTAL	**462**

C.5b.1.b CIBMTR Research Database-Related Webpages within the CIBMTR Website

The CIBMTR provides data and information from the Research Database on the CIBMTR website in a variety of formats.

- **Data Management Manual** (45,464 unique page views). A comprehensive reference document for completing the TED forms and CRFs. The manual also details SCTOD reporting requirements, describes protocols and the consent process, and includes downloadable versions of essential forms.
- **Data Collection Forms** (38,036 unique page views). Provides access to current and retired versions of the forms used by the CIBMTR to collect standard data elements for all transplant recipients.
- **Web-based US Transplant Reports** (21,477 unique page views). Directs users to the Be The Match US Center Listing Report and the following customizable reports of patient survival and transplant available through the HRSA Website:
    - Disease-specific survival estimates at 100-days, 1 year, and 3 years post-HCT (estimates are also available by patient age, patient gender, patient race, or cell source);
    - The number of bone marrow and cord blood transplants performed at a specific transplant center;

  - The number of bone marrow and cord blood transplants reported for a specific disease (also available by patient age, patient gender, patient race, cell source, and the year when the transplant was performed).
- **Data Management Training and Reference** (14,125 unique page views). Provides access to a wide variety of CIBMTR data management training and reference materials.
- **Summary Slides** (8,618 unique page views). Includes charts and figures summarizing current uses and outcomes of alloHCT and autoHCT.
- **Publication List** (2,877 unique page views). Searchable descriptive list of more than 800 peer-reviewed scientific journal publications resulting from the use of CIBMTR data and statistical resources.
- **Annual BMT Tandem Meetings Working Committee and Data Management Meetings Materials** (1,313 unique page views). Provides access to agendas, handouts, and educational materials from specific meetings at the BMT Tandem Meetings:
  - Working Committee Meetings;
  - Clinical Research Professionals / Data Management Conferences.
- **Working Committee Studies Lists** (1,269 unique page views). A summary of the planned, in-progress, and recently published CIBMTR clinical outcomes studies for each Working Committee.
- **Statistical Resources** (1,258 unique page views). Provides access to resources offered through the unique partnership between the CIBMTR and MCW Division of Biostatistics, including biostatistical publications and a series of statistical lectures targeted at basic and clinical investigators.
- **Patient Resources** (758 unique page views). Includes:
  - Post-transplant care recommendations for adult and pediatric autoHCT and alloHCT recipients available to help patients and clinicians understand and plan for the specialized care of transplant recipients;
  - Patient-level summaries of CIBMTR research articles.
- **Procedures and Progress Reports** (714 unique page views). Provides access to the CIBMTR's annual Progress Report, annual Summary of Accomplishments, and Manual of Operations.
- **Newsletter** (483 unique page views). Published at least twice per year. Articles feature updates on Working Committees, the SCTOD, data management and collection, and noteworthy events in the HCT community.
- **Data Back to Centers Application** (469 unique page views). Links to the FormsNet DBtC application that provides CIBMTR member centers the ability to retrieve all the TED-level (and TED-level equivalent) data their center has reported to the CIBMTR.

C.5b.1.c External webpages presenting data summaries prepared using the CIBMTR Research Database

- **HRSA US Survival Report.** Disease-specific post-HCT survival estimates by the length of time after transplant: 100 days, 1 year, and 3 years. Survival estimates are also available by patient age, patient gender, patient race, or cell source.
- **HRSA Transplant Data by US Center Report.** The number of bone marrow and cord blood transplants performed at a specific transplant center.
- **HRSA Transplant Data by Disease Report.** The number of bone marrow and cord blood transplants reported for a specific disease. Totals are also available by patient age, patient gender, patient race, cell source, and the year when the transplant was performed.
- **Be The Match US Center Listing Report.** Transplant center specific information about facilities, personnel, diseases treated, cost, and transplant experience, including the number of transplants performed and survival rates by age, disease type, and disease stage.

C.5b.1.d Data Resources Available to CIBMTR Transplant Center Members

- **Annual Report on Transplant Survival Rates.** A comprehensive summary of the web-based US transplants reports available through the HRSA website distributed annually to each US CIBMTR-reporting center.
- **Survival Outcomes Calculator (available to physicians only).** Computes one-year survival rate estimates based on user-selected critical patient-, disease-, and transplant-related factors known to affect transplant outcomes.
- **FormsNet Data-Back-to Centers Application.** A web-based application that provides centers the ability to retrieve all the TED-level (and TED-level equivalent) data their center has reported to the CIBMTR.

C.5b.1.e Other CIBMTR Data Resources Available to Physicians and Researchers upon Request (and to Corporations through the CIBMTR Corporate Membership Program)

- **Report of Survival Statistics for BMT**. A highly detailed report on survival statistics that describes use and outcome of autoHCT and alloHCT in the more than 500 centers who have participated in the CIBMTR.
- **US Center Volumes Dataset**. Center-specific pre-transplant patient-, disease-, and transplant-related characteristics data for nearly all allogeneic and a majority of autologous hematopoietic stem cell transplants performed in the US between 2008 and 2012.

C.5b.2 Research Repository

The CIBMTR provides access to more than 1.8 million sample aliquots available through the Research Repository, including pre-transplant related and unrelated donor / recipient (or cord blood) pairs as well as recipient blood samples for investigative use. The Research Repository also provides a unique resource to investigators for retrospective analysis of immune response determinants and transplant outcomes.

The Research Repository currently houses more than 31,000 cases for which samples from both the transplant donor and recipient are available and complete clinical data have been collected and verified. The majority of the samples have complete high resolution data available for HLA-A, B, C, DRB1/3/4/5, DQ, and DP loci. In addition, the Research Repository contains research samples from approximately 3,500 related transplant pairs.

In 2014, the CIBMTR distributed 8,313 research samples in support of various studies, and 20 manuscripts utilizing research samples and immunobiology clinical outcomes data were published, which is almost twice as many manuscripts as published last year (**Figure C.5b.A**).

Figure C.5b.A. CIBMTR Publications Utilizing Immunobiology Research Samples and Clinical Outcomes Data