CIBMTR 2021
What your work makes possible
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WHO WE ARE - MORE THAN A DATABASE

Scientific and Statistical Expertise

Large Network of Clinical Centers

Unique and Extensive Clinical Database

CIBMTR RESEARCH
Impact of COVID-19 on CIBMTR activities in 2020

- Fewer procedures
- Staffing impacts
- Data collection, CPI and audit
- COVID-19 data collection
- Impact to research studies, including consenting patients to the research database and sample repository
- Center specific analysis
- CIBMTR studies
Data professional impacts

• At most centers, data professionals worked off-site to maintain social distancing and avoid exposure to COVID-19
• In many cases, data professionals may not have routine access to the EMR and other essential systems remotely
• Data professionals subject to furlough because of economic effects on health systems
Adapting to COVID-19 – Addressing Reduced Center Capacities

• Recognizing this potential more limited capacity for data reporting at centers
  – Continuous Process Improvement was suspended: no penalties for delayed submission during the crisis
  – Extended the cut-off for forms reimbursement

• On-site audits were cancelled
  – Remote auditing did happen at a few health systems
  – Centralized data audit continued
Adapting to COVID-19 – Collecting COVID data

• Multiple rapid changes to CIBMTR forms which data managers needed to react to (March):
  – The Post-HCT Follow-up Data Form (2100) and Cellular Therapy Essential Data Follow-up Data Form (4100) were updated to include a new organism option for COVID-19 (SARS-CoV-2). The updated option is located in the “Infection” section of each of these forms; F2100 R5 (Q429) and F4100 R5 (Q181)
  – The current option value “Coronavirus” was updated to “Coronavirus (excluding COVID-19 (SARS-CoV-2))”. The additional instructional text was added to further clarify this option should NOT be selected if the organism is COVID-19.
Adapting to COVID-19 – Collecting COVID data

• In May:
  – The Post-TED Form (2450) was updated to add
    • Option for COVID-19 (SARS-CoV-2) as both a primary and contributing cause of death
    • Question to capture if the recipient developed COVID-19 (SARS-CoV-2) since the date of last report
  – The Death Data Form (2900) has been modified to capture COVID-19 (SARS-CoV-2) as both a primary and contributing cause of death
• Both the Pre-TED Form (2400) and the Cellular Therapy Essential Data Pre-Infusion Form (4000) were modified to add three additional questions to capture COVID-19 (SARS-CoV-2) infection prior to the start of the preparative regimen / infusion

88. Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of the preparative regimen / infusion?
   - Yes – Go to question 89
   - No – Go to question 91

89. Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?
   - Yes
   - No

90. Was mechanical ventilation given for COVID-19 (SARS-CoV-2) infection?
   - Yes
   - No
COVID Data Collection

• Form 2149 (Respiratory Virus Post-Infusion Form) was quickly adjusted to be appropriate for data collection
  – Existing form used in the BMT CTN 18-01 study
• Initially submitted though ServiceNow
• Added to FormsNet in May
• Triggered from the infection question on TED/CRF
  – Can be requested at any time by the site (‘on demand’)
• Two time points: “Initial” and “Follow-up”
  – If the infection is captured as “improved” or “ongoing” in question 41 on “Initial” submission, an additional “Follow-up” 2149 comes due
Adapting to COVID-19 – Clinical Trials

- RCI BMT and BMT CTN trials significantly affected
  - Accrual temporarily suspended for 7 trials; accrual restricted to certain graft types or certain centers at 2 others
  - On-site monitoring suspended – remote monitoring being considered
  - Many scheduled visits will be done by telemedicine - some functional assessments (e.g. 6-minute walk test) being adapted to be done at home
  - Required many communications with study teams, NIH, DSMB, IRB and centers
  - Data systems amended to collect information on COVID-19 and its impact (whether related to direct infection/exposure to restricted access to medical centers)
What are the research impacts?

• Research office/Institutional Review Boards have:
  – Suspended human subjects research that is not interventional (and potentially of benefit to the patient)
  – Limited patient accrual to patients without standard of care options
    • Phase I or II trials, patients with refractory disease

• Observational research often deemed non-essential
  – Even if considered “minimal risk” and consent processes are embedded in routine consent for HCT
Consent Issue and Impact on Research

• Some centers have prohibited all non-interventional research in an effort to minimize patient and staff contact and potential exposure

• Would have a negative effect on CIBMTR’s ability to understand the effect of the pandemic on HCT and CT patients
  – Without consent, we can still collect HCT data but only for government reporting purposes

• We believe the research restriction should not apply to CIBMTR
  – Consent can be obtained by the clinician consenting the patient to HCT or CT and data can be reported later
  – NO VISITS OR ASSESSMENTS REQUIRED THAT ARE NOT STANDARD OF CARE

• Encourage centers to consent patients even if data reporting is delayed
  – ASTCT Position Statement shared with centers’ IRBs
  – Reminders to centers regarding reporting obligations and importance of research
Has COVID-19 changed how HCT is performed?

- Acquisition and cryopreservation of donated stem cell product before initiation of preparative regimen
- Decreasing availability of BM rather than PBSC
- Lung spirometry often deferred for infectious risk
- Drug shortages may impact preparative regimens
- Delayed allogeneic HCT for non-malignant or chronic disease
- Many programs are restricting transplants to inpatient only
- Patient follow-up has often been converted to virtual
Potential Impacts to SCTOD Reports

• Center Specific Survival Analysis – highest impact report
  – Incidence of COVID-19 infection and treatment resource availability is variable
    • By location of center, residence of patient
  – Impact of COVID-19 infection on HCT outcomes
  – Delays or changes in HCT procedure may impact outcomes
    • PBSC vs BM/cryopreservation/ RIC vs MAC
      – Lack of spirometry affects calculation of HCT-comorbidity index

• Additional data collection to understand these factors
  – Complicated to collect the information
  – Collected through the CIBMTR portal
Adapting to COVID-19 – Addressing Reduced Center Capacities: new CRIDs generated
Adapting to COVID-19 – Addressing Reduced Center Capacities: number of forms submitted
COVID Data Collection: 1150 reports as of January 5

https://www.cibmtr.org/Covid19/Pages/default.aspx

Cellular Therapy Type:
- Allogeneic Transplant: 31 (2.71%)
- Autologous Transplant: 574 (50.13%)
- Pending: 510 (44.54%)
- Autologous Cell Therapy: 87
- Allogeneic Cell Therapy: 93

Age at Infection:
- <20: 93
- 20-29: 66
- 30-39: 87
- 40-49: 136
- 50-59: 204
- 60-69: 302
- >=70: 120
- Pending: 137

CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH
COVID Data Collection: 1150 reports as of January 5
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Number of COVID-19 Infections: 1,150
Number of Centers Reporting: 188 (155 US, 33 non-US)
Adapting to COVID-19 – Continuing CIBMTR Scientific Activities

• All data collection/center support systems were fully operational
• All CIBMTR staff worked remotely since mid-March
  – Maintaining appropriate privacy and security procedures

• Working Committee activities are proceeding
  – Continue previously established timelines for ongoing studies but understand that PIs and Scientific Directors may be less available
  – New studies approved following Transplant and Cellular Therapy meetings will start - reserve hours for COVID-19-related activities
CIBMTR COVID-19 data collection

- A paper describing the outcomes for the first 318 patients was accepted for publication in Lancet Hematology in December
  - Disease severity was mild in 49% of patients, while severe disease requiring mechanical ventilation occurred in 14%
  - The overall probability of survival was 68% at 30 days after the diagnosis of COVID-19 for both alloHCT and autoHCT recipients.
  - **Age over 50 years** (hazard ratio [HR] 2.53; 95% confidence interval [CI] 1.16-5.52), **male sex** (HR 3.53; 95% CI 1.44-8.67), and development of **COVID-19 within 12 months of transplant** (HR 2.67; 95% CI 1.33-5.36) were associated with a higher risk of mortality due to COVID-19 among alloHCT recipients

- Huge thanks to everyone in CIBMTR and in the centers who have contributed to this remarkable effort!
Studies relevant to COVID-19 done quickly!

• Impact of cryopreservation
  – Three separate analyses done and submitted/published

• Impact of Tociluzimab
  – possible treatment for COVID-19 lung disease

• Outcomes related to COVID-19 infection
  – Paper describing the outcomes for the first 318 patients accepted for publication in Lancet Hematology in December
CIBMTR Number of Patients Registered, 1970-2020

*Includes CAR-T and genetically modified products

(Data are incomplete for 2020)
Number of CAR T-cell Infusions: 2016-2020 (3,488 patients and 3,665 infusions)

Data Incomplete for 2019 & 2020
Prior HCT to CAR T-cell by Indication: 2017-2020

Acute Lymphoblastic Leukemia

- 2017: 100%
- 2018: 90%
- 2019: 80%
- 2020: 70%

Non Hodgkin Lymphoma

- 2017: 100%
- 2018: 90%
- 2019: 80%
- 2020: 70%

Legend:
- No Prior HCT
- Prior AutoHCT
- Prior AlloHCT
Collecting clinical outcomes data worldwide for 45 years
6 major areas of research activity
15 Scientific Working Committees

44 HCT global experts chair committees in their field – thousands participate

- 59 publications in 2020
- >2,800 worldwide researchers
- 36 presentations this year
- >154 ongoing studies
Peer-Reviewed Publications 2004-2020
44,454 adult unrelated recipient/donor pairs
10,117 adult related recipient/donor pairs
5,182 recipient/cord pairs
24,974 samples distributed to investigators

>2.9 million samples
Blood and Marrow Transplant Clinical Trials Network (BMT CTN)

>13,200 patients enrolled on BMT CTN trials since 2003
Renewed for 4th, 7-year cycle

2020: 8 publications

>460,000 research sample repository

53 clinical trials
• 5 studies in active follow-up or analysis

• 12 studies enrolling patients
  • Includes 4 INDs and 1 IDE
  • Over 1,400 patients and donors accrued in 2020

• 4 studies in development
Developing tools – from the data you provide

- **Survival Calculator - 1 Year**
  - Calculates probability of 1-year survival after allogeneic transplantation for individual patients
  - More than 2300 distinct users in 2020
- **Disease Risk Index (DRI) Calculator**
  - A validated tool to categorize groups of patients undergoing allogeneic HCT for hematologic malignancy by disease risk
  - 6,429 unique pageviews in 2020
- **VOD Calculator**
  - Calculates a risk score to identify patients at high risk for developing veno-occlusive disease within 100 days of allogeneic transplant
  - Approximately 1,864 unique users in 2020
1. Note that center grouping of users had not been uniformly tracked in QlikView prior to 2018 but had been at portal level within Google Analytics.
CIBMTR

The Future

Everyone has a donor

Data transformation

Gene Therapy

PROs

Data sharing
INNOVATIONS

Data transformation

Data sharing

Patient-reported outcomes

New website

How we get data

How we use and share data
Data Transformation Initiative

- Enhancing/simplifying processes throughout the data lifecycle
  - Partnered with IQVIA
- Year 1 focused on data acquisition
  - Meet the data where it resides, such as an EMR or a research database
  - Enlist data standards according to how data is structured to collect it
  - Enlist technical standards (e.g. LOINC, SNOMED, etc.) to move the data to CIBMTR
  - Minimize center level effort required to use the prototype
- Pilot prototype now complete! Thank you to the centers that participated!!
- Being rolled out to multiple additional centers
Data sharing

• More ‘pre-prepared’ data available
  – Standard, regularly updated dataset
  – Publicly available dataset (posted after paper is published)

• An important upcoming focus of data transformation
  – CIBMTR data: all in one place
  – Novel analytic tools and methods
Routine Patient-Reported Outcomes (PRO) collection

Watch Deb Mattila’s presentation on Feb 2 at 11.30 CT
Routine Patient-Reported Outcomes (PRO) collection

**ELIGIBLE PATIENTS IDENTIFIED BY SITE**

As of Dec 15, sites have identified 60 eligible patients

- 20 from Texas Transplant Institute
- 31 from Cleveland Clinic Foundation
- 9 from Stanford Health Care

**PATIENT CONTACT AND ACCRUAL UPDATE**

As of Dec 15, the Survey Research Group has attempted outreach with 60 patients

- 6 Approaching
- 16 Enrolled
- 31 Unreachable/Lost to Follow-up
- 7 Declined
CIBMTR Website: Overview and Updated Timing

Project Purpose:
1. Develop a website that supports mobile devices and employs modern website best practices;
2. Establish an easy-to-use navigation for users to access the rich repository of information;
3. Create a website featuring customized content for unique target audiences.

Project Timeline: Note: Project was delayed due to COVID-19 pandemic.

- Completed Digital Assessment: March 2020
- Content Inventory / Sitemap Development / Design: January - June 2021
- Development and Deployment: Early 2022
CIBMTR Website: Digital Assessment

• **Research included:**
  – Google Analytics
  – Keyword information
  – User interviews
  – Employee survey
  – Competitive site analysis

• **Audiences:**
  – *Primary:* Data managers, investigators
  – *Secondary:* Corporations, patients
  – *Tertiary:* Employees

• **Key takeaways:**
  – Search function
  – Better organization
  – High-level summaries
  – Quick links
  – More images, less text
  – Reduce clicks to access information

• **Next steps:**
  – Content inventory
  – New sitemap
TOGETHER, WE CAN MEET THE CHALLENGE
ONLINE RESOURCES

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