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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Summary and Recommendations of the 2021 Center Outcomes Forum Held on November 12, 2021

Executive Summary

The 2021 Center Outcomes Forum was held on November 12, 2021. The CIBMTR® (Center for International Blood and Marrow Transplant Research) invited representatives of the hematopoietic cell transplantation (HCT) community, the American Society for Transplantation and Cellular Therapy (ASTCT) Quality Outcomes Committee, Foundation for the Accreditation of Cellular Therapy (FACT), National Marrow Donor Program (NMDP), governmental funding agencies, patients, private payers, and statisticians. Discussion focused on if CIBMTR can adequately adjust for the impact of the SARS-CoV-2 / COVID-19 (COVID) pandemic in the Center-Specific Survival Analysis.

The main discussion and recommendations are briefly summarized in the following pages. Recommendations regarding COVID risk adjustment include:

- Make additional attempts to improve completeness of reporting of the 'COVID Approach Variables' from US centers, including through circulation of the summary of this Center Outcomes Forum.
- Inform centers to prioritize collection of 'COVID Approach Variables' for allogeneic recipients.
- Analyze completeness of reporting of 'COVID Approach Variables' and whether these data affect outcomes at centers with a high completeness of reporting. These analyses will inform use of the 'COVID Approach Variables' for the 2022 Center-Specific Survival Analysis.
- Re-assess geographic and time-dependent COVID impacts on HCT centers for 2020 recipients.
- Describe the impact of the pandemic on HCT practice changes and evaluate the completeness of the 'COVID Approach Variables' for use in risk adjustment modeling.
- Prepare a base model using patient-, disease- and transplant-related factors similar to the 2021 Center-Specific Survival Analysis censoring for COVID infection.
- Examine time-fixed and time-varying COVID effects (including calendar time, geographic COVID-incidence and death rates) on outcomes within the first year after HCT as well as possible interactions with COVID effect modifiers as an extension of the base model.
- Examine impact of individual center-reported COVID-approach variables on HCT outcomes if data completeness is sufficient.
- Use results of exploratory analysis to inform the final risk adjustment modeling approach for 2022, which should include the existing pseudo-value risk-adjustment model if possible.
- Evaluate whether a carve-out period is necessary to handle COVID impacts.
- Examine the assumption that censoring for COVID infections is independent of outcomes, by modeling the likelihood of COVID infection as a function of baseline and post-HCT variables.

- Evaluate whether censoring at COVID infection within the first year after HCT has differential effects on HCT center outcomes.
- Develop guidance documents for report stakeholders describing the final approach to the analysis, limitations, and interpretation of results.
- Address the limitations related to the impact of the COVID pandemic on the results and appropriate interpretation in the final Center-Specific Survival Report.
- Increase communications about the Center-Specific Survival Analysis during the next year, specific to changes related to the COVID pandemic to include:
    - Reminders for centers about the importance of COVID-specific data for risk adjustment
    - Planned approach to risk adjustment and results of analyses that will be used to inform the final methodology
    - Updated limitations for the Center-Specific Survival Analysis and implications for interpretation and use of the analyses

Introduction

To increase transparency and understanding of center outcomes reporting in HCT, CIBMTR began in 2008 to hold biannual Center Outcomes Forums. CIBMTR invites representatives of the HCT community, including transplant physicians and center directors, the ASTCT, FACT, governmental funding agencies, patients, private payers, and statisticians. The purpose is to review the current approach to center-specific outcomes reporting and to provide meaningful recommendations for future reports. Summaries of these meetings are available at http://www.cibmtr.org/Meetings/Materials/CSOAForum.

An off-cycle Center Outcomes Forum was held on November 12, 2021, to discuss risk adjustment for the impact of the COVID pandemic in the Center-Specific Survival Analysis. Participants included a broad range of invited stakeholder participants (Appendix A) and working group members (Appendix B) who presented recommendations. A summary of the group discussion and recommendations from this meeting follows.

Background

HCT recipients infected with COVID have been reported to have higher mortality rates than the general population (including Shah et al, JCI 2020; Altuna et al BMT 2020; Sharma, AK et al Lancet Haematology 2021). The COVID pandemic has therefore had **direct** negative effects on outcomes of HCT recipients. In addition, changes in HCT and centers' standard practices and procedures in response to the pandemic may have **indirect** effects on HCT outcomes and may not be equally distributed across all US HCT centers. CIBMTR must carefully consider the ways these direct and indirect factors, largely beyond the control of HCT centers, may influence HCT outcomes, and whether they can be adequately incorporated into the Center-Specific Survival Analysis to create a fair and unbiased representation of center outcomes.

Based on Recommendations provided at the Center Outcomes Forum in 2020, CIBMTR censored allogeneic HCT recipients who developed COVID infection, as reported to the CIBMTR by centers, within the first year after HCT for the 2021 Center-Specific Survival Report. Additionally, CIBMTR tested for time-varying COVID effects on one-year survival in the analysis, as described below.

The 2021 Center-Specific Survival Report included patients who received a first allogeneic HCT between January 1, 2017 and December 31, 2019. The effect of the COVID pandemic on these patients was

limited to their HCT follow-up in the first year. The 2022 Center-Specific Survival Report will include patients who received HCT in 2020, during the pandemic, and therefore these recipients may have been affected differently than those transplanted in 2019. The purpose of the Center Outcomes Forum was to make recommendations for consideration for the 2022 Center-Specific Survival Report.

Overview of 2021 Center-Specific Survival Report

An important function of the Center Outcomes Forum is to review the Center-Specific Survival Analysis and provide recommendations for improvement. It is essential that CIBMTR continue to collect relevant and updated patient, disease and transplant characteristics for use in the risk-adjustment models. Additionally, because this publicly available report has high impact for the HCT community, it is important to review the statistical modeling methodology to maintain accountability and transparency. Details about the report methodology, including modeling to test for COVID impacts, can be found on the CIBMTR website. The 2021 Center-Specific Survival Report was reviewed, as was progress on accomplishing the main recommendations from the 2020 Center Outcomes Forum.

The 2021 analysis and report included more than 25,100 patients at 173 US centers who received a first allogeneic HCT between January 1, 2017, and December 31, 2019. The 2021 model is similar to 2020, except for the following:

- Recipient age grouping was adjusted in the younger groups to represent pediatric and adult cases more clearly.
- Therapy-related MDS was not included in the model this year as it was not statistically significant.
- Therapy-related AML and multiple myeloma ISS stage at diagnosis were statistically significant and included in the model this year.
- Recipients of allogeneic HCT who developed COVID as reported by the centers were censored at the date of reported infection.

Recommendations from the 2020 Center Outcomes Forum have been addressed:

- CIBMTR should expedite data collection efforts for allogeneic HCT recipients from 2019 to facilitate preliminary modeling to understand the impact of the COVID pandemic on outcomes of allogeneic HCT. **Done.**
- Develop a modeling approach to test the impact of COVID on outcomes for recipients of HCT in 2019 and implement that approach in early 2021. **Done for 2021; pending for 2022**.
- Use the results of the preliminary modeling for impact of COVID to design, as needed, a modified pseudo-value modeling approach for the Center-Specific Survival Analysis for the cohort of patients transplanted in 2017-2019. **Done.**
- Develop communications for use across all relevant stakeholder groups regarding plans for the Center-Specific Survival Analysis in 2021 and subsequent years to address COVID. **Done for 2021; pending for 2022.**
- Continue to collaborate with the Scientific Registry of Transplant Recipients (SRTR) and other organizations involved in public outcomes reporting to explore if other organizations are making assessments of the impact of COVID on general acute care for geographic areas to inform this effort. **Done for 2021; ongoing.**

Summary of Center-Specific Survival Analysis 2021

Recommended changes were discussed at the 2020 Center Outcomes Forum. Changes in the 2021 Report:

- Censored for COVID infection at date of reported infection
- Time-varying COVID effects were NOT significant
- Therapy-related MDS was not significant
- Therapy-related AML, MM ISS stage at diagnosis were significant
- Individual centers' data are available on the CIBMTR Portal

2022 Center-Specific Survival Analysis – Proposed Plan

CIBMTR created a small group of physicians and statisticians (see Appendix B) to develop a proposal to address COVID related impacts on the Center-Specific Survival Analysis for discussion at the 2021 Center Outcomes Forum that:

- Leverages the results from the analysis conducted in 2021 to develop an approach to subsequent analyses that address all relevant COVID impacts for recipients of HCT in 2020; and
- Acknowledges many more factors may impact outcomes for HCT performed in 2020 and the approach will need to re-analyze factors tested in the 2021 analysis and develop appropriate methods to adjust for COVID-related impacts in the 2022 analysis and beyond.

Data Available for Use

Background

- The following data are currently being collected by CIBMTR and may be useful for risk-adjustment:
    - Data available for all HCT recipients:
        - Transplant Essential Data (TED) Forms (2400, 2450)
            - Data available beginning May 2020
                - Pre-HCT COVID infection, and related hospitalization or mechanical ventilation (no dates) (pre-TED)
                - Development of COVID since last report and date (post-TED)
                - COVID as primary or contributing cause of death (collected on Post-TED and Death Form (2900))
                - Although these data could be reported as of May 2020, these data are available for nearly all patients since the beginning of the pandemic.
            - Data available beginning 10/29/2021
                - Includes information on hospitalization and use of mechanical ventilation resulting from COVID infection
                - Includes information on vaccination status before and after transplant
    - Data available for some HCT recipients:
        - Comprehensive Report Forms (2100, 2149, 2900) – This information is available on the subset of patients selected for the CRF reporting track
            - Data available beginning 3/27/2020
            - Respiratory Virus Post-Infusion (2149): Collects detailed infection information for COVID
                - Diagnostic information

        - Symptoms to assess severity
        - Treatment information
        - Outcome of infection
      - Cause of death information
    - 'COVID Approach Variables' – This information was collected on a supplemental data form beginning August 2020 for patients whose HCT was after March 1, 2020:
      - Was the HCT impacted for a reason related to the COVID pandemic? [Y or N]
      - Is the HCT date different than the originally intended date? [Provide intended date]
      - Is the donor different than the originally intended donor? [Provide intended donor]
      - Was the product thawed from a cryopreserved state before infusion? [Y or N]
      - Is the product type different than originally intended? [Provide original product type]
      - Did the preparative regimen change from the original intended plan? [Y or N]
      - Did the GVHD prophylaxis change from the original intended plan? [Y or N]
- Importantly, CIBMTR routinely collects information about the HCT **as performed** (donor, HLA match, product details including cryopreservation, preparative and GVHD prophylaxis regimens), and these variables will continue to be used in the standard risk adjustment model.
- Collection of the 'COVID Approach Variables' can inform whether changes in how HCT were performed **may have varied by time period and geographic region**, and therefore may have had **differential impacts on HCT centers**.
- Although completeness of reporting for standard data collection instruments is very high, **there has been variability in reporting of 'COVID Approach Variables' despite numerous reminders for centers**. As of November 2021, as many as 30% of allogeneic HCT performed in 2020 do not have information about whether the pandemic affected the transplant approach . **Additionally, the distribution of data completeness across centers is not random.** This variability in reporting may limit the ability to use this information for risk adjustment for recipients of HCT in 2020.

Discussion

Discussion focused on whether there are additional sources of information about COVID that could be used by CIBMTR for risk adjustment, or if there are additional data elements related to COVID that should be incorporated into data collection forms for future use.

- It was acknowledged that CIBMTR is a unique resource; and it does not appear that other organizations have collected relevant information specifically for HCT recipients that could be used by CIBMTR.
- No new sources of publicly available COVID-related data that could be used to inform the Center-Specific Survival Analysis were identified.
  - For instance, no authoritative source of information about adherence with public health recommendations (such as mask use), which may affect COVID or other respiratory infection rates, is available.

- There were suggestions about information CIBMTR could test in its analyses for 2022:
    - Consider looking at month-to-month transplant rates for centers by geographic regions. Changes in volumes may be a surrogate for COVID impacts on centers resources during the pandemic. Unfortunately, monthly volume at HCT centers is relatively small and inherently variable which will make trend analysis challenging for most centers.
    - Consider whether the distance between patients' residence and the HCT center has differential impact on outcomes. Although this has been tested in the past, access to post-transplant care during the pandemic may have varied by distance from the center.
    - Vaccination Status for recipients, as available
    - Consider whether long-hauler COVID syndrome affected HCT outcomes.
        - CIBMTR is not capturing sufficient data that would allow this to be addressed systematically.
        - A multi-center study would be the best approach.
        - There are data to suggest those who develop COVID and recover can proceed to HCT without concern.
    - There was further discussion about the importance of collecting information about changes in donor, graft type, preparative regimen or GVHD prophylaxis. As well, delays in transplant may have resulted in later stage disease at HCT for some patients. Since centers routinely report the disease status at transplant, it is already included in the risk adjustment model.
- Regarding completeness of data reporting:
    - Challenges to data reporting include staff reductions and hiring freezes at transplant centers and the questions about COVID impact ('COVID Approach Variables') are not easily answered by a data manager. Incomplete data for the 'COVID Approach Variables' may not be random and may be associated with staffing shortages or other effects of the pandemic.
    - Suggestions were made to make the process of submitting the COVID impact spreadsheet more user friendly, possibly by putting in FormsNet3.

Recommendations

- Make additional attempts to improve completeness of reporting of the 'COVID Approach Variables' from US centers, including through circulation of the summary of this Center Outcomes Forum.
- Inform centers to prioritize collection of 'COVID Approach Variables' for allogeneic recipients.
- Analyze completeness of reporting of 'COVID Approach Variables' and whether these data affect outcomes at centers with a high completeness of reporting. These analyses will inform use of the 'COVID Approach Variables' for the 2022 Center-Specific Survival Analysis.
- Re-assess geographic and time-dependent COVID impacts on HCT centers for 2020 recipients.

Proposed Analysis Plan 2022

Background

The Center-Specific Survival Analysis plan in 2021 included patients transplanted in 2019 whose post-transplant care may have been affected by COVID. These impacts were tested in the model as described above, and after censoring for COVID infections reported to CIBMTR, did not significantly affect the risk adjustment. However, patients who received HCT in 2020 will be included in the upcoming analysis, and

their pre-HCT, transplant AND post-HCT experience may all have been affected **by changes in care related to the pandemic**. Therefore, the approach to the analysis performed this year to include these patients may require modification. Proposed analyses to address these impacts is the main focus of this Center Outcomes Forum.

- 2022 Center-Specific Survival Analysis Overview of Analysis Plan
    - Includes first allogeneic HCT recipients 1/1/2018 – 12/31/2020
    - CIBMTR plans to conduct exploratory analyses of potential impact of the COVID pandemic on practice changes and HCT outcomes in the first year after HCT
        - Exploratory analyses will focus on
            - Patients as the unit of analysis, as opposed to focusing on centers as is done for the final Center-Specific Survival Analysis.
            - Broad impacts during the pandemic, including timing
            - Differential effects across centers based on local variation reflected in COVID incidence/impact
        - If observed, can CIBMTR account for these differential effects by adjusting for measured practice changes attributed to COVID pandemic?
        - COVID infection in HCT recipients, and its impact on survival will NOT be the focus of the analysis, as CIBMTR intends to censor recipients at the time of COVID infection as reported by the centers
        - Censoring for COVID infection in the analysis assumes that COVID infection is an independent censoring mechanism; this assumption will be assessed by modeling the likelihood of a COVID infection as a function of baseline and post HCT patient characteristics
    - Results of exploratory analyses will guide formal approach for the 2022 Center-Specific Survival Analysis
- Proposed Analysis Process
    - Exploratory Analysis 1: Examine impact of pandemic on HCT practice changes. *[Details of the exploratory analyses are included in the posted meeting slides.]* These analyses are largely descriptive.
        - Assess the completeness of 'COVID Approach Variables' by calendar time and by HCT center.
        - Assess accuracy by comparing center reported use of cryopreservation with NMDP URD policy by time period.
        - Describe the distribution of 'COVID Approach Variables' overall and by quarters of calendar year 2020.
        - Examine variability by center.
        - Correlate reported changes in COVID approach with geographic incidence rates at HCT centers in 2 weeks preceding HCT.
    - Exploratory Analysis 2: Examine whether COVID infection is an independent censoring mechanism and estimate the incidence of COVID infection in this cohort.
        - Model the likelihood of COVID infection as a function of baseline and post HCT patient characteristics, to determine whether COVID incidence is associated with factors such as GVHD or if it is an independent censoring mechanism.
    - Exploratory Analysis 3: Examine impact of geographic COVID incidence and time period on post-HCT survival.
        - Prepare "base model" using variables as in the 2021 Center-Specific Survival Analysis with Cox regression to handle time-varying COVID effects.

        - Patient-level analysis with censoring for COVID infection after HCT
        - Examine COVID time-fixed effects – cut points to categorize data will include those used in 2021 analysis AND will be re-assessed based on updated data
            - History of pre-HCT COVID infection
            - Date of HCT relative to pandemic time periods
            - Average geographic COVID infection rates over 2-week periods preceding the HCT based on zip code of HCT center
            - Average geographic COVID death rates over 2-week periods preceding the HCT based on zip code of HCT center
        - Examine COVID time-varying effects - cut points to categorize data will include those used in 2021 analysis AND will be re-assessed based on updated data
            - Follow-up calendar time period for 2020 and 2021
            - Average geographic COVID infection rates over 2-week periods preceding the HCT based on zip code of HCT center
            - Average geographic COVID death rates over 2-week periods preceding the HCT based on zip code of HCT center
        - Examine interactions with COVID effect modifiers of interest (each time varying)
            - Time period after HCT (0-100d, 101d-180d, 6mos-1year)
            - History of acute GVHD grades II-IV
            - History of chronic GVHD
        - Examine interaction between COVID incidence rates and calendar time periods to determine whether impact of variation in COVID incidence is limited to certain periods that may best be handled by a time-period exclusion/"carve out" from the Center-Specific Survival Analysis.
    - Exploratory Analysis 4: Examine impact of COVID-associated practice changes on post-HCT survival using 'COVID Approach Variables'.
        - Use model developed Exploratory Analysis 3 to account for the direct impact of COVID incidence and time period effects.
        - Depending upon results obtained in Exploratory Analysis 1, add 'COVID Approach Variables' to the model to examine the impact of COVID approach changes.
        - Determine whether adjustment for 'COVID Approach Variables' makes the COVID incidence and other time-varying effects no longer significant. If this occurs, it indicates that any COVID incidence effect acts primarily through changes to COVID approaches, and that adjustment for COVID approach variables only would be adequate. Elimination of time-varying effects, if no longer significant after adjustment for COVID approach variables, would simplify the modeling approach to risk adjustment.
    - Based on results of exploratory analyses, recommend the approach to the 2022 Center-Specific Survival Analysis. Options include:
        - Use the current pseudo-value logistic regression approach with censoring patients experiencing COVID within one year post HCT, and additional adjustment for baseline COVID variables ('COVID Approach Variables') if only baseline COVID-related factors are important in the model.
        - Use a carve-out/exclusion period if COVID impact seems transient or limited to specific time periods (e.g., if the biggest or only impact is during the early period of the pandemic).

- If time-dependent COVID variables are needed in the risk-adjustment model, develop and propose a new modeling approach/framework to account for these effects.
- Examine robustness of CSA conclusions both with and without censoring for COVID infection.
- If censoring for COVID infection is not appropriate due to association with baseline or post HCT patient factors and a high incidence rate, develop and propose a new modeling approach/framework to account for this.

Discussion

- The current Center-Specific Survival Analysis model accounts for patient-, disease- and transplant-related baseline variables and therefore adjusts for the HCT risk "as delivered." Changes in how HCT were delivered in 2020 because of the pandemic, and the potential impact of these changes on outcomes, can be **indirectly** assessed using time-varying geographic effects, or using information about changes in approach as **directly** reported by HCT centers. These changes are important for risk adjustment **if** they are differential between HCT centers. Post-HCT complications can also be modeled using time-dependent variables. Unfortunately, time varying effects introduce complexity to the current logistic regression models supporting the Center-Specific Survival Analysis.
- There was general agreement with the proposed analysis process and recognition of potential limitations.
- Concern was raised that censoring at infection may remove a disproportionate selection of patients with specific patient risk factors or complications post-HCT that may skew results. There may be an ascertainment bias in testing and detecting COVID infection in patients with certain characteristics, including GVHD, relapse or other complications. This could inappropriately advantage centers whose patients differentially develop complications like GVHD that influence COVID infection rates and outcome and become "masked" through censoring at COVID infection. Results could be compared with and without censoring to determine if there is an impact. CIBMTR could also compare patients with existing data about characteristics of those that do/do not get COVID in the first year after HCT to understand the magnitude of problem.
- There was general consensus to carefully examine the first 3-4 months of the pandemic for impact on HCT practices and outcomes. In general, HCT teams were most impacted by sudden changes related to the pandemic, and thereafter adapted more consistently. However, although all transplant centers were impacted during the pandemic, the effects varied over time and geographic location. It should not be assumed that these affects will cancel out on average. Patterns of patients' adaptations to the pandemic, including their presentations for post-HCT surveillance are likely much more difficult to assess.
- CIBMTR will consider a "carve-out" period based on the analysis results. If the impact of the pandemic is substantial for the entire network in a certain period, such as the first several months, it may make sense to exclude/carve out that time period from the analysis. This is the approach that was taken by the SRTR. There may not be sufficient data to do this by center or geographic region.
- It will be important for payers and other stakeholders to carefully consider use of the report, regardless of the final modeling approach taken by CIBMTR. CIBMTR has a commitment to

produce a high-quality, reliable, unbiased and equitable Center-Specific Survival Analysis. While acknowledging limitations, there has been a high degree of confidence from the HCT community that the report was measuring actual center performance. CIBMTR will prepare the most accurate report possible with a reasonable level of confidence in the results accounting for pandemic-related changes. However, in the next few years, it is recommended that payers carefully consider how they use the report in the setting of uncertainty about fully measuring and adjusting center performance for pandemic-related changes.

- Similarly, changes in reporting of outcomes and performance to the public may require modification to explain changes related to the COVID pandemic and limitations.

Recommendations

- Describe the impact of the pandemic on HCT practice changes and evaluate the completeness of the 'COVID Approach Variables' for use in risk adjustment modeling.
- Prepare a base model using patient-, disease- and transplant-related factors similar to the 2021 Center-Specific Survival Analysis censoring for COVID infection.
- Examine time-fixed and time-varying COVID effects (including calendar time, geographic COVID-incidence and death rates) on outcomes within the first year after HCT as well as possible interactions with COVID effect modifiers as an extension of the base model.
- Examine impact of individual center-reported COVID-approach variables on HCT outcomes if data completeness is sufficient.
- Use results of exploratory analysis to inform the final risk adjustment modeling approach for 2022, which should include the existing pseudo-value risk-adjustment model if possible.
- Evaluate whether a carve-out period is necessary to handle COVID impacts.
- Examine the assumption that censoring for COVID infections is independent of outcomes, by modeling the likelihood of COVID infection as a function of baseline and post-HCT variables.
- Evaluate whether censoring at COVID infection within the first year after HCT has differential effects on HCT center outcomes.
- Develop guidance documents for report stakeholders describing the final approach to the analysis, limitations, and interpretation of results.

Limitations of Analysis Plan

Background

CIBMTR and the HCT community recognize existing limitations of risk-adjustment modeling for the Center-Specific Survival Analysis. Among these, availability and completeness of data for specific risk factors related to the COVID pandemic may represent the greatest challenge to CIBMTR's ability to produce a report that represents a fair, unbiased assessment of centers' performance for allogeneic HCT recipient.

- Potential limitations include:
    - 'COVID Approach Variables' (discussed above)
        - Information collected by CIBMTR may not fully represent COVID patient experience/outcomes.
        - Completeness of data submitted by centers is variable within and across centers. Missing date is potentially non-random and associated with degree of COVID impact on centers.

        - As previously discussed, censoring for COVID infection may not be appropriate if it is found to be associated with baseline or post-HCT patient factors.
        - Accuracy and representativeness across centers.
    - Adjustment based on publicly available geographic COVID incidence and mortality data may not fully remove differential changes/impacts across centers or geographic regions
    - If CIBMTR adopts a new modeling framework, lack of familiarity with the modeling framework could lead to lower acceptance by the HCT community
    - There may be limitations unique to pediatric centers, particularly related to delays in HCT for "elective" non-malignant indications (e.g., thalassemia, Fanconi anemia) or outcomes such as graft failure related to use of cryopreserved products for these indications

Discussion

- It is important to recognize that the Center-Specific Survival Analysis has a profound impact on transplant centers.
- A fundamental assumption related to fair, equitable analysis is results that are unbiased and appropriately adjusted for effects that could be differential across centers.
- It is not possible to quantitatively address increased uncertainty of data not directly captured.
- CIBMTR should consider how it can accommodate the uncertainty/limitations related to the impacts of the COVID pandemic beyond the direct impacts of COVID infection on HCT outcomes in the first year after HCT, which are anticipated to be handled by censoring for COVID infection.
    - Changing the confidence interval (CI) from 95% to 99% may accommodate additional uncertainties as fewer transplant centers would fall outside the CI.
    - Add qualifying language about cautious interpretation of the results and educate stakeholder groups about limitations.
    - Exclude a time period from the analysis similar to that used by SRTR for solid organ recipients.
- There was a suggestion to collaborate with other organizations, such as the FACT Quality Committee or ASTCT Payer Relations Committee, to prepare a recommendations paper regarding interpretation and use of the results over the next three to four years.

Recommendations

- Address the limitations related to the uncertainty of adequately adjusting for the impact of the COVID pandemic on the results and appropriate interpretation in the final Center-Specific Survival Report.

Communication Plans with Stakeholders

Background

The Center-Specific Survival Analysis has become generally accepted and understood by US centers and other stakeholders. The Center Outcomes Forum is one venue for communication about the Center-Specific Survival Analysis and planning for future analyses. CIBMTR has increased communication efforts with centers in the last 18 months about changes in the analysis, through publications, increased email communication with center directors, and engagement with FACT and ASTCT. As changes related to the COVID pandemic are likely to have increased impact on the Center-Specific Survival Analysis in 2022, additional communication opportunities should be undertaken.

- Planned communication with stakeholders includes:
    - Updates for HRSA during quarterly Contract Officer Representative meetings, as well as planned meetings to discuss CIBMTR's approach to the Center-Specific Survival Analysis, results of planned preliminary analysis and resulting methodologic approach.
    - Periodic reminders for transplant centers about the importance of reporting COVID infections pre- and post-HCT.
    - Encourage timely completion of the supplemental COVID data collection worksheet by transplant centers, emphasizing the importance of these data in the 2022 Center-Specific Survival Analysis risk adjustment, especially for HCT in 2020.
    - Post and distribute the 2021 Center Outcomes Forum summary and action items for centers.
    - Develop communication materials for payers.
    - Give presentations at the 2022 Tandem Meetings, including the Center Administrators session and possibly a meeting with payers to provide education and receive feedback on CIBMTR's plans.

Discussion

- The Center Administrators meeting at Tandem is a forum to educate center administrators, who are generally responsible for centers' quality.
- CIBMTR should consider partnering with ASTCT to communicate with payers at Tandem to clarify additional limitations related to the COVID pandemic.
- CIBMTR should consider partnering with ASTCT Quality Outcomes Committee and with FACT on other opportunities to educate stakeholders.

Recommendations

- Increase communications about the Center-Specific Survival Analysis during the next year, specific to changes related to the COVID pandemic to include:
    - Reminders for centers about the importance of COVID-specific data for risk adjustment
    - Planned approach to risk adjustment and results of analyses that will be used to inform the final methodology
    - Updated limitations for the Center-Specific Survival Analysis and implications for interpretation and use of the analyses

Appendix A: Attendees of 2021 Center Outcomes Forum

Name	Organization	Representation
Kwang Woo Ahn, PhD	CIBMTR	CIBMTR PhD
Jack Aiello, EE, MS	CIBMTR Consumer Advocacy Committee	Patient Advocate
Jeffery Auletta, MD	CIBMTR	CIBMTR Scientific Director
Jenni Bloomquist, BA, MS	CIBMTR	MSP Staff
Anthony Bonagura, MD	Optum Health Services	Payer
Sharniece Covill, BS	CIBMTR	MKE Staff
Christopher Dandoy, MD	Cincinnati Children's Hospital	ASTCT QOC/Adult
Steven Devine, MD	NMDP/Be The Match	CIBMTR Scientific Director
Clint Divine, MBA, MSM	University of Kansas	Center Admin
Carol Doleysh	CIBMTR	MKE Staff
Theresa Hahn, PhD	Roswell Park Cancer Institute	HCT Center-Adult
Michael Heim, MS	CIBMTR	MKE Staff
Mary Horowitz, MD, MS	CIBMTR	CIBMTR Scientific Director
Dianna Howard, MD	Wake Forest Baptist Health	HCT Center-Adult
Samantha Jaglowski, MD, MPH	Ohio State Medical Center	ASTCT QOC/Adult
Leslie Lehmann, MD	Dana-Farber Cancer Institute	CSA Research TF
Marilyn Levi, MD	Health Resources & Services Administration	Gov't staff (HRSA)
Brent Logan, PhD	CIBMTR	CIBMTR PhD Statistician
Sue Logan, BS	CIBMTR	MSP Staff
Navneet Majhail, MD, MS	Sarah Cannon	ASTCT QOC/Adult
Richard Maziarz, MD	Oregon Health & Science University	HCT Center-Adult
Christa Meyer, MS	CIBMTR	MSP Staff
Brandon Nuechterlein	Children's Hospital Colorado	Patient Advocate
Kristin Page, MD	Duke University	HCT Center-Peds
Miguel-Angel Perales, MD	Memorial Sloan Kettering	HCT Center-Adult
Waleska Perez, MPH	CIBMTR	MKE Staff
Ronald Potts, MD	Interlink Health Services	Payer
Jaime Preussler, MS	CIBMTR	MSP Staff
J. Douglas Rizzo, MD, MS	CIBMTR	CIBMTR Scientific Director
Mary Senneka	NMDP/Be The Match	MSP Staff
Akshay Sharma, MD	St. Jude Children's Research Hospital	CSA Research TF
Bronwen Shaw, MD, PhD	CIBMTR	CIBMTR Scientific Director
Nawraz Shawir, MBBS	Health Resources & Services Administration	Gov't staff (HRSA)
Gregory Sides, BS	CIBMTR	MSP Staff
Stephen Spellman, MBS	CIBMTR	MSP Staff
Andrew St. Martin, MS	CIBMTR	MKE Staff
Keith Stockerl-Goldstein, MD	Barnes Jewish Hospital	HCT Center-Adult
Jesse Troy, PhD, MPH	Duke University	PhD Stat
Edmund Waller, MD, PhD	Emory University Hospital	HCT Ctr-Adult
Julie Walz	Humana	Payer

Name	Organization	Representation
Michelle Williams, RN	BCBSA	Payer
John Wingard, MD	University of Florida	HCT Center-Adult
William Wood, MD, MPH	University of North Carolina	HCT Center-Adult
Mei-Jie Zhang, PhD	CIBMTR	CIBMTR PhD Statistician

Appendix B: Working Group Members

Name	Organization	Representation
John Wingard, MD (moderator)	University of Florida	HCT Center-Adult
Kwang Woo Ahn, PhD	CIBMTR	CIBMTR PhD Statistician
Jeffrey Auletta, MD	CIBMTR	CIBMTR Scientific Director
Christopher Dandoy, MD	Cincinnati Children's Hospital	ASTCT QOC/HCT Center-Peds
Michael Heim, MS	CIBMTR	MKE Staff
Brent Logan, PhD	CIBMTR	CIBMTR PhD Statistician
Navneet Majhail, MD, MS	Sarah Cannon	HCT Center-Adult
Miguel-Angel Perales, MD	Memorial Sloan Kettering	HCT Center-Adult
Marcie Riches, MD, MS	University of North Carolina	HCT Center-Adult
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