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Perspectives

By Robert Soiffer, MD

Venetoclax, enasidenib, ivosidenib, gilteritinib, midostaurin, glasdegib, CPX-351, blinatumomab, inotuzumab, daratumumab, elotuzumab, panobinostat, ixazomib, ruslulinib, brentuximab, ibrutinib, idelalisib, acalabrutinib, obinutuzumab, nivolumab, pembrolizumab not to mention axicabtagene ciloleucel, lisageneicleucel (impossible to pronounce): all FDA-approved within the past six years or so to treat hematologic malignancies. With all these remarkable new agents becoming available, and with many more on the horizon, we have reason to celebrate a golden age of drug development for blood cancers. Perhaps we cannot label these products as “golden bullets,” but certainly they are changing the face of treatment and the lives of our patients.

Advances such as these inevitably bring up the question of whether hematopoietic cell transplantation will become obsolete. We can see from the annual numbers of transplants performed in the US reported to the CIBMTR that the answer to date has been “not yet.” In fact, transplantation has been steadily increasing, thanks to the recognition that it can be performed relatively safely in older patients and in recipients of haploidentical grafts. Incorporating the novel anti-cancer agents described above into a transplant regimen (either before, during, or after) is clearly where we are heading, aiming to target post-transplant relapse.
However, investigators often struggle to get hold of these agents to test in combination with transplantation. Allogeneic transplantation was typically an exclusion criterion in clinical trials of these medications to treat relapse, and the pharmaceutical industry continues to be reluctant (though the ice is breaking a bit) to test these agents to prevent relapse. The reason frequently offered is that the considerable morbidity and mortality of transplantation itself would likely obscure a drug's toxicity profile, increase the grade-5 serious adverse events attributable to the drug, and threaten FDA approval.

I certainly can appreciate pharma's stance. For nearly 50 years, transplanters have convinced their patients, their colleagues, and themselves that mortality rates of up to 30-40% were acceptable in the service of long-term cure. These percentages may be tolerable for diseases which otherwise would claim a patient's life in the near future, but when the prognosis is somewhat more favorable, mortality rates like these are unacceptable. Indeed, if allogeneic HCT were being evaluated by the FDA as a new procedure today, it might not be approved. No longer can we claim that transplantation should be held to different standards because we utilize a cellular therapy.

Several CAR T-cell constructs have been approved for non-Hodgkin lymphoma, acute lymphoblastic leukemia, and soon likely multiple myeloma. While these cellular therapies can induce considerable toxicity, non-relapse mortality rates are in the single digits, lower than most current series of allogeneic HCT. Approval of CAR T-cells would clearly have been in doubt if toxicity death rates had been substantially higher.

Although we have seen a steady decline in non-relapse mortality, we must do a better job preventing non-relapse mortality. We must work to consistently reduce such rates to less than 10%, if not less than 5%. We have heard Dr. Rick Jones from Johns Hopkins University lecture our community that rates higher than these are unacceptable, and he is, of course, correct. Whether by preventing GVHD, infection, organ toxicity, or fatal late effects, it is incumbent upon us to improve the safety of allo-transplant. The CIBMTR will play an important role by working with transplant centers to accurately catalogue causes of death so we can better devise effective interventions. If we are unsuccessful in reducing transplant-related mortality, then transplant will not, and probably should, not survive as a treatment modality.

2019 TCT | Transplantation and Cellular Therapy Meetings of ASBMT and CIBMTR

By Tia Houseman

The TCT | Transplantation & Cellular Therapy Meetings of ASBMT and CIBMTR (formerly known as BMT Tandem Meetings) is the combined annual meetings of the CIBMTR and ASBMT. This has been North America's largest international gathering of blood and marrow transplant clinicians and investigators, laboratory technicians, advanced practice professionals, transplant nurses, pharmacists, administrators, and clinical research associates since 1999.

Register and Book Housing Now
Visit the 2019 TCT Meetings of ASBMT and CIBMTR webpage to register, view the online agenda, and view additional details related to the meeting. After registering, take advantage of special conference guest room rates offered at several hotels in the TCT Meetings of ASBMT and CIBMTR housing block. All hotels within the block are located within 0.6 miles of the TCT Meetings of ASBMT and CIBMTR venues.

A Program You Won't Want to Miss
More than 3,300 leading worldwide authorities will convene in Houston, Texas, to present the latest developments in transplantation and cellular therapy at the
We invite you to join us for the Best Oral Abstract Session on Friday, February 22, in GRB-Grand Ballroom ABC and on Sunday, February 24, as we close out the meeting with Late Breaking Abstracts at the Hilton Americas Houston in Grand Ballroom A. More than 700 abstracts were submitted to this year’s meeting.

Please join us after the Best Abstracts Session on Friday afternoon as the CIBMTR Distinguished Service Award is presented to the Worldwide Network for Blood and Marrow Transplantation. Following the awards on Friday, we invite you to attend the Mortimer M. Bortin Lecture, presented by Dr. Paul Martin, and the E. Donnell Thomas Lecture, presented by Dr. Stephen Forman.

In addition to an outstanding scientific program, the 2019 meetings offer peripheral sessions for pharmacists, center administrators, coordinators, investigators, medical directors, clinical research professionals / data managers, transplant nurses, and advanced practice professionals. In addition to state-of-the-art educational offerings, industry-supported satellite sessions and product theaters will broaden the spectrum of presentations.

**Networking Opportunities**

Networking opportunities offered during the TCT Meetings of ASBMT and CIBMTR include poster sessions on Wednesday and Saturday evening in GRB-Exhibit Hall B3, the TCT Meetings of ASBMT and CIBMTR Networking Reception Thursday evening in GRB-Exhibit Hall B3, the TCT Meetings of ASBMT and CIBMTR Reception in the Hilton Americas Houston Level 4, and more.

Don’t forget to reserve your ticket to the Saturday evening TCT Meetings of ASBMT and CIBMTR Reception at the Hilton Americas-Houston to end a memorable week with colleagues and friends!

**TCT Meetings of ASBMT and CIBMTR Go Mobile!**

You can now download the official TCT Meetings of ASBMT and CIBMTR app for quick and easy access to the most current version of the schedule, venue information and more! All rooms at the George R. Brown Convention Center start with GRB within the mobile app and online agenda. If it does not have GRB, it is at the Hilton Americas Houston. Both venues are conveniently connected via a sky bridge. Watch for additional details coming via e-blast. The app is free for all attendees and with wi-fi available throughout all TCT Meetings of ASBMT and CIBMTR rooms, users can:

- View and search the meeting program schedule
- Vote / participate in interactive sessions
- Complete session surveys
- Search for speakers
- Check out who is exhibiting and find their booth on a map
- Create a personal schedule
- Message other attendees
- Access other meeting information

**Support Opportunities and Additional Information**

Questions regarding support opportunities for this year’s TCT Meetings of ASBMT and CIBMTR, may be directed to the TCT Meetings of ASBMT and CIBMTR Conference Office.

We look forward to seeing you at the Hilton Americas-Houston and George R. Brown Convention Center in Houston, Texas, February 20-24, 2019.

Join the Conversation: #TCTM19

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**Donor Health and Safety Working Committee**

**Committee Leadership**

**Co-Chairs:**

- [Michael Pulsipher, MD](#), Children’s Hospital Los Angeles (outgoing)
- [Niraj N. Shah, MD](#), National Cancer Institute
- [Galen Switzer, PhD](#), University of Pittsburgh Medical Center
- [[Jack Hsu, MD](#), University of Florida (incoming]

**Scientific Director:**
Ex-Officio Senior Advisor:
- **Dennis Confer, MD**, CIBMTR Minneapolis

Statistical Director:
- **Brent Logan, PhD**, CIBMTR Milwaukee

Statisticians:
- **Jennifer Sees, MPH**, CIBMTR Minneapolis
- **Pintip Chitphakdithai, PhD**, CIBMTR Minneapolis

The research priority of the Donor Health and Safety Working Committee, now in its thirteenth year, is to understand the impact of donation on both related and unrelated hematopoietic stem cell donors. Accordingly, outcomes from the research conducted in this committee have led to an enhanced understanding of the medical and psychosocial risks our donors undergo and identification of opportunities to improve the donor experience, safety, and overall outcomes.

Most notable in the past few years is the Related Donor Safety (RDSafe) study, which was the first large prospective study of related donors. Publications from this work to date include:


While additional data from the RDSafe study is forthcoming, the data thus far has prompted additional research questions, leading to further investigations into the donor experience, forming the basis for many of this committee’s current projects.

A particular strength of this committee has been to conduct research that may lead to truly practice changing guidelines aimed to improve the health and well-being of our donors. In this regard, a notable example of such a study looked at the impact of donor BMI on collection of GCSF mobilized PBSC from unrelated donors. This study identified there was no benefit in CD34+ yield with increasing GCSF doses in obese and morbidly obese donors and was presented at the 2018 ASH Annual Meeting as an oral abstract by Nasra Farhadfar.

Additionally, as a first for this committee, we will be looking at banked samples from healthy donors to evaluate for the presence of clonal hematopoiesis in donors and the impact on HCT outcomes. Other ongoing studies focus on the impact of the quality of bone marrow harvest on transplant outcomes and the utility of autologous blood donation in donors.

The committee would like to particularly recognize the leadership and efforts of Michael Pulsipher, MD, who co-led the RDSafe study and will be stepping down
from his tenure on the Donor Health and Safety Working Committee. We welcome Jack Hsu, MD, as the newest Chair of this committee.

View planned, in-progress, and completed studies and publications on the Donor Health and Safety Working Committee webpage. We encourage participation from the transplant community, especially new members, in ongoing studies or through the submission of new proposals.

**Regimen-Related Toxicity and Supportive Care Working Committee**

**Committee Leadership**

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The Regimen-Related Toxicity and Supportive Care Working Committee (RRTWC) seeks to mitigate morbidity and mortality. Over the past few years, the committee conducted studies that explored the impact of comorbidities on patient outcomes; comparisons of conditioning regimens; the role of supportive-care medications; and determinants of early post-transplant complications, including mortality among children requiring intensive critical care. The committee explored toxicities and transplant outcomes in different populations, from infants to older adults, and further explored the impact of conditioning and comorbidities in children.

Assessment of comorbidities is an important theme in RRT studies, as it is a recognized determinant for transplant-related mortality and overall survival. The RRTWC previously validated the hematopoietic cell transplantation-comorbidity index (HCT-CI) by Sorror and colleagues.

Recently, the committee performed a follow-up analysis of this validation study, focused on patients with non-malignant disease. This study (RT07-01b), by Thakar, Broglio, and colleagues, included more than 4,000 patients, the majority children, and it demonstrated that higher HCT-CI was associated with worse overall survival.
One exception was patients with hemoglobinopathies, for whom HCT-CI did not impact survival. This observation deserves further study, but the excellent outcome of these patients might require a larger sample size to confirm this finding. Yet, comorbidities that are used as transplant indications in case of non-malignant diseases, e.g., stroke in sickle cell, might need to be considered differently. The committee recently approved a study to evaluate each comorbidity separately in children, adolescents, and young adults to further streamline the comorbidity assessment in this population.

Conditioning regimens are another important theme for studies in RRTWC. Harris and colleagues compared busulfan / fludarabine (BuFlu) to busulfan / cyclophosphamide (BuCy) in children and demonstrated that BuFlu was more frequently utilized in more infirm patients. The results were equivalent; however, among patients with malignancies, recipients of BuFlu had a shorter post-relapse survival, likely not directly related to the choice of regimen but to patient selection. This study demonstrated that BuFlu could be utilized in this population.

Another study, done in collaboration with the BMT CTN, addressed adjusting the dose of chemotherapy used in the conditioning regimen among obese patients. The BMT CTN developed a task force to standardize this approach in the clinical trial protocols. The task force reported that dose-adjustment practices vary widely in US centers and recommended further study using the CIBMTR database.

This recommendation became a RRTWC study (RT16-01), which focused on obese patients who received an autologous transplant. This approach was intentionally designed to look at a population receiving a standard conditioning [melphalan or BEAM (carmustine, etoposide, cytarabine, melphalan)] without other risks for transplant-related mortality, such as GVHD. The study by Brunstein and colleagues demonstrated again a variability in practice related to dose adjustment, but the results showed that chemotherapy adjustment did not impact transplant outcomes. These results can be interpreted that dose adjustment is not necessary or that dose adjustment can be used to reduce exposure and cost of large doses of chemotherapy to obese patients.

Two RRTWC studies completed recently explored outcomes of myeloablative regimens. RT13-02 analyzed outcomes of patients who received higher doses of total body irradiation to assess its impact on disease relapse. RT15-02 analyzed the use of anti-convulsive medication prior to myeloablative BuCy conditioning to explore any clinical impact of the pharmacologic interaction of phenytoin and cyclophosphamide metabolism.

Improvements in supportive care and safer conditioning regimens have expanded access to transplant to older patients. The RRTWC with Muffy and colleagues concluded a study (RT12-03) that demonstrated increased use of transplant in patients older than 70 years. The number of patients older than 70 years receiving transplants for AML and MDS has increased substantially in the last decade, and outcomes are acceptable.

The same cannot be said about patients the opposite side of the age spectrum. The RRTWC performed a study to assess outcomes in the last 15 years among infants who required transplant (RT14-01). Among infants with nonmalignant disease, there was an improvement in overall survival, but unfortunately outcomes remain unchanged since 2005. Among infants with malignancy, there was no apparent improvement on outcomes during the period of the study. This could be partially explained by changes in practice related to timing of transplantation and patient selection, especially among patients with ALL. However, rates of sinusoidal obstruction syndrome are much higher in this population compared to other age groups, and that needs to be explored.

Thrombotic microangiopathy (TMA) is among transplant complications that have not been extensively studied using CIBMTR data. Changes in the forms allowed for better capture of this outcome and associated organ damage. The RT14-02 study analyzed a large population of patients to assess incidence of TMA and factors associated with this complication. It became obvious that the rates of TMA reported to the CIBMTR are lower than other series, raising a question of underreporting. Yet, the study was able to demonstrate important information related to this outcome. Additional modifications in the follow-up forms to better capture this outcome are forthcoming.

Lastly, the RRTWC conducted a study (RT14-03) to explore intensive care unit (ICU) mortality among children who received transplantation. Zinter and colleagues merged CIBMTR data with a database of pediatric ICUs (Virtual Pediatric Systems). The study is important because of this successful merger, which allowed analysis of additional variables related to ICU care not available in the CIBMTR data. The results may help transplant physicians assess children in the ICU and counsel their parents.
Moving forward, the RRTWC has a comprehensive portfolio of new studies. The major themes of approved studies include exploring individual comorbidities to optimize the utilization of the HCT-CI in different populations, studying the impact of different degrees of renal insufficiency on transplant outcomes, assessment of obesity in donors and recipients and analysis of pulmonary toxicities.

CIBMTR 2018 Annual Report

The CIBMTR 2018 Annual Report is now available to view on the Administrative and Progress Reports webpage.

This document explains who we are, what we do, how we share knowledge, how we collect and manage data, and what we will do next.

Review the electronic version to access links directly, or pick up a hard copy at the CIBMTR booth at the TCT Meetings of ASBMT and CIBMTR. Email contactus@cibmtr.org if you would like a printed copy or copies mailed to you.

Impact of Individualized Survivorship Care Plans Generated Using Data in the CIBMTR Research Database

By Linda Burns, MD

Many late complications of HCT can be prevented or their impact mitigated if detected and treated early as part of survivorship care. Guidelines to address screening and preventive care practices for HCT survivors were developed based on the literature and consensus opinion; however, research demonstrated survivors typically do not receive all of the recommended care and experience fragmented follow-up. To address these issues, the Health Services Research Program collaborated with investigators at the Fred Hutchinson Cancer Research Center (Scott Baker MD, MS, and Karen Syjala, PhD) and the Cleveland Clinic (Navneet Majhail MD, MS) to conduct a PCORI-funded multi-institutional project. This project identified and incorporated HCT patient and provider preferences for survivorship care plans into a prospective, randomized controlled trial of individualized survivorship care plans generated using data provided by transplant centers to the CIBMTR.

To identify patient and provider preferences, researchers conducted 12 focus groups with 77 participants from 4 stakeholder audiences:

1. Adult patients and caregivers
2. HCT physicians and advanced practice providers
3. HCT nurses and social workers
4. Community healthcare professionals

The survivorship care plan consisted of two parts:

1. A treatment summary either for patients and caregivers or healthcare professionals
2. Preventive care recommendations based on published guidelines for long-term HCT survivors

Patients and caregivers preferred the survivorship care plan be a single document with a glossary of medical terms in language they could understand. They wanted the treatment summary to include details about all chemotherapy and radiation therapy received, any psychosocial care, and diagnosis / complications of GVHD. Patients and caregivers felt the preventive care recommendations should include robust sections on sexual and psychosocial health and the immune system. They also suggested a space for notes to keep track of contact information for multiple specialists and healthcare providers.

Both HCT and community healthcare professionals acknowledged the patient's transition away from the transplant center is challenging. HCT providers voiced concerns that community healthcare professionals may not feel comfortable caring for HCT survivors, as did community providers, particularly as time post-completion
of training increases. In addition, community providers noted that when patients return to their care, the information they receive regarding care to be provided in the community setting is often unclear.

Researchers next tested the impact of the revised, individualized survivorship care plan in a prospective, randomized controlled trial at 17 transplant centers. Adult survivors 1-5 years post-transplantation, proficient in English, and without relapse or secondary cancers were eligible. Phone surveys assessing patient-reported outcomes were conducted at baseline and 6-months. The primary endpoint was confidence in survivorship information. Secondary endpoints included cancer and treatment distress, knowledge of transplant exposures, health care utilization, and health-related quality of life.

Of 495 patients enrolled, 458 completed a baseline survey and were randomized (231 to receive survivorship care plans and 227 to receive standard care); 200 (87%) and 199 (88%) completed the 6-month assessments, respectively. Patient characteristics were balanced in the two arms. Participants on the survivorship care plan arm reported significantly lower distress scores at 6-months and an increase in the Mental Component Summary quality of life score assessed by the SF12 Instrument. No effect was observed on the endpoint of confidence in survivorship information or other secondary outcomes. These results are being used in the next phase of research into the impact of survivorship care plans on psychosocial health, again in collaboration with the investigators at the Fred Hutchinson Cancer Research Center and Cleveland Clinic.

**Oral Abstracts at the TCT Meetings of ASBMT and CIBMTR**

Join attendees at the upcoming TCT Meetings of ASBMT and CIBMTR in Houston to hear results of two other projects performed by the Health Services Research Program this year:

1. What defines an urgent time to transplant? A National Marrow Donor Program survey of transplant physicians and search coordinators' unrelated donor selection practices (Pidal et al) in which the Histocompatibility Advisory Group conducted a national survey of donor search practices for access to allogeneic hematopoietic cell transplantation for patients with acute myeloid leukemia in the state of Virginia (Arora PC et al) conducted to generate hypotheses into differences in access to HCT by geographic and socioeconomic factors.

For more information about the Health Services Research Program, visit the Health Services Research webpage or email Lintia Burns, MD.

**SCTOD Updates**

*By Carol Daleysh*

The SCTOD is part of the US HRSA-funded C.W. Bill Young Cell Transplantation Program that collects data on all allogeneic hematopoietic cell transplants performed in the US and on transplants performed elsewhere using cellular products that originated in the US.

**Center-Specific Survival Analysis**

Outcomes reporting in allogeneic HCT is necessary to provide information requested by patients, insurers, and government agencies and to comply with current laws. The SCTOD contract requires the CIBMTR to conduct an analysis of one-year survival rates at each transplant center in the US annually. The report generated by the CIBMTR is meant to be useful as a quality improvement tool for transplant centers. The data are also available on the Be The Match Transplant Center webpage.

The 2018 Center-Specific Outcomes Report, which includes first allogeneic HCT performed between 2014 and 2016 in the US, was distributed in mid-December to center directors, payors, and FACT. The data were also updated on the Be the Match website. Additional tools accessible to transplant centers for quality improvement work include Center Performance Analytics and the Survival Calculator. Access to these is through the secure CIBMTR Portal. For additional information, contact cibmr-portalhelp@mcw.edu.

To be included in the analysis, transplant centers were required to have at least one year of follow-up on more than 90% of related and unrelated HCT recipients. View a description of the methodology used in generating this report for more information.

There have been substantial changes to the variables included in the 2018 Center-Specific Survival Analysis. Incorporating feedback from the HCT community, the
CIBMTR updated data collection forms in October 2013 and included variables believed to be important for patient and disease risk adjustment. These include zip code of residence of the recipient (for socioeconomic status adjustment) and cytogenetic and molecular markers in hematologic malignancies. The complete list of new variables tested in the 2018 analysis, and those found to be significant, can be found in the description of the methodology, specifically on pages 3 and 6 respectively. Incorporation of these variables does improve the multivariate risk adjustment model.

Center Outcomes Forum
In order to fairly address the complex issues and maintain a transparent scientific approach to center outcomes reporting, a sixth Center Outcomes Forum was held in September 2018. Participants included representatives of the HCT community, including transplant physicians and center directors, the ASBMT and its Quality Outcomes Committee, FACT, governmental funding agencies, patients, private payors, and statisticians. A summary of the meeting, including an executive summary, will be distributed to US medical directors and posted on the Center Outcomes Forum webpage. The major topics addressed at the 2018 Forum included:

- Recommendations from Pediatric Non-Malignant Disease Risk Adjustment Workgroup for new variables to incorporate in the analysis
- Recommendations from Statistical Methodology Workgroup regarding statistical modeling
- Managing the Consequences: How to improve collaboration to achieve quality improvement

10 New Patient-Level Research Summaries
The CIBMTR recently posted 10 new patient-level summaries of CIBMTR research publications on the Study Summaries for Patients webpage:

- **Chemotherapy prep for transplant works for acute leukemia, but risks of relapse are higher**
  - People with acute leukemia who got only chemo to prepare them for transplant lived almost as long as people who got chemo plus radiation, but their risks for leukemia recurrence were higher.
  - People had fewer side effects with chemo alone.

- **BMT helps some people with relapsed follicular lymphoma**
  - After 5 years, more people who got an auto transplant or matched sibling donor transplant were still alive than people who didn’t get BMT.

- **BMT helps some older people who have lymphoma**
  - Scientists say Medicare should pay for BMT for people older than 65 who have non-Hodgkin lymphoma.

- **Experimental medicine treats children with leukemia and MDS**
  - Treosulfan may be safer than a similar medicine before transplant.

- **Online tool helps predict liver problems after transplant prep**
  - Researchers at CIBMTR created a free, online VOD Risk Calculator for doctors.
  - Veno-occlusive disease (VOD) is a rare liver problem that may happen after preparation for BMT.

- **Doctors say transplants treat systemic sclerosis or scleroderma**
  - Autologous transplants help people with systemic sclerosis live longer and improve their skin, lungs and quality of life.

- **Reduced-intensity transplant prep helps young people with immune system disorders**
  - In this clinical trial, doctors treated people with 5 rare immune disorders:
    - Histiocytic lymphohistiocytosis (HLH)
    - Chronic active Epstein-Barr virus (CAEBV)
    - Chronic granulomatous disease (CGD)
    - Hyperimmunoglobulin syndrome (HIGM1)
    - Immune dysregulation, polyendocrinopathy, enteropathy and X-linked syndrome (IPEX)

- **Caregivers and patients may have PTSD after transplant**
- More caregivers than recipients reported symptoms of post-traumatic stress disorder (PTSD).
- PTSD can be treated.

- **What happens when blood cells are used instead of bone marrow in BMT for children and teens with leukemia?**
  - For children and teens with acute leukemia, researchers recommend BMT with bone marrow cells.

- **Second transplant helps some children with acute leukemia**
  - Those whose leukemia was controlled (in remission) at the time of their second BMT lived longer than those whose leukemia failed to respond to chemo.

Summaries are created through a collaborative process involving CIBMTR Consumer Advocacy Committee members, CIBMTR Medical Writers and Communications Consultant; NMDP/Be The Match Patient Education Specialists, and CIBMTR Scientific Directors. Developing these summaries is one of the main initiatives of the Consumer Advocacy Committee.

The Consumer Advocacy Committee was created in 2005 as a subcommittee of the Advisory Committee to communicate CIBMTR research results and data to the non-medical community and to provide patient and donor perspectives during the development of the CIBMTR research agenda. Many members have personal experience as a donor, recipient, or family member.

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Our Supporters
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Abbreviations
Need an acronym defined? Review our list of common abbreviations.

Last Updated: 1/26/2021 11:16 AM