

FREQUENTLY ASKED QUESTIONS: FACT and COVID-19

March 13, 2020. Updated April 8, 2020; April 21, 2020, May 6, 2020, May 22, 2020

Updated May 22, 2020

1. What are the updated recommendations for cryopreservation of bone marrow and peripheral blood grafts for transplantation?

NMDP/Be The Match announced in its May 19, 2020 Network News that the requirement to cryopreserve products in response to the COVID-19 pandemic has been adjusted based on results from their research recently posted on line in [Biology of Blood and Marrow Transplantation](#). Using data from the CIBMTR observational database, Mary Eapen et. al. found that patients transplanted for severe aplastic anemia had a higher rate of graft failure at one year and an inferior overall survival rate at one year when the graft had been cryopreserved than if it had been administered fresh. These findings differ from results of prior studies of patients receiving cryopreserved grafts for hematologic malignancies. These data support the use of non-cryopreserved grafts for patients with severe aplastic anemia whenever possible.

2. Is FACT going to conduct virtual inspections during the pandemic?

FACT has received numerous inquiries about the possibility of virtual inspections. How accredited facilities can be assessed between on-site visits is being discussed frequently. FACT does require Annual Reports from accredited facilities, and facilities are continuing to submit information despite the pandemic. FACT will be surveying programs to determine if some are able to submit documents in advance of the deadline in preparation for an inspection.

FACT is not currently planning to conduct a virtual inspection in lieu of an on-site visit. In addition to all usual issues involved with a virtual inspection, an important consideration is the availability of volunteer inspectors who may have competing responsibilities in their own institutions during this time. We will be assessing the availability of our volunteer inspectors. We also realize there may be additional potential options, and we will continue to pursue these new ideas. We will continue to update our accredited programs and volunteers as new information is available.

Updated May 6, 2020

1. Since our accreditation timeline has changed, when will our Annual and Renewal Reports be due? How much data is expected for these reports - 12 months or 18 months?

The due dates for your Program's reports depends upon where you are in the accreditation cycle.

If you are currently between the awarded accreditation and your Annual Report, your Annual Report will be due 18 months from the date of the awarded accreditation. In this case, your Annual Report should include 18 months of data, i.e., since your awarded accreditation date.

If your program has already submitted the Annual Report, your next Report is the Renewal Report which will be due 18 months after your Annual Report. In this case, your Renewal Report should contain 18 months of data, i.e., all data since your Annual Report.

2. Are we required to wait the entire 18 months to complete these reports or can we submit the information early?

FACT staff are currently working remotely and are able to receive and review your reports. FACT encourages you to submit the reports as early as your local circumstances allow.

As time permits, FACT Accreditation Coordinators may offer individual Programs the option to submit information ahead of usual due dates. If you want to start on your reports early, contact your FACT Coordinator to open your application in the FACT Accreditation Portal.

3. Is there any specific guidance for autologous transplant patients, specifically about screening for COVID-19, documentation of screening, sedation, and other issues?

For documentation of screening of autologous transplant patients prior to transplant, prior to collection of the hematopoietic cellular therapy product, or prior to a clinic or apheresis visit, FACT recommends this documentation follow routine medical record documentation practices. There may be specific institutional screening policies that should also be followed. Programs that want to implement enhanced screening for COVID-19 prior to collection of autologous HCT/Ps should follow FDA recommendation to include questions whether in the previous 28 days, the patient/donor has:

- Cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or
- Been diagnosed with or suspected of having COVID19 infection.

For specific guidance about sedation, medications, consideration for delay of transplant, or other clinical issues, refer to the recently updated ASTCT Interim Guidelines for COVID-19 Management in Hematopoietic Cell Transplant and Cellular Therapy Patients at [http://astct.informz.net/z/cjUucD9taT0yMTQzNjc4JnA9MSZ1PTUxNTU4MzAzMCZsaT0xOTc3OTg5Nw/index.html ;!!JkUDQA!bcHjooAv-726AebrD0ocS0THJGL8EfNT4y5OmrBHIOD-H0mqf4e3OjEBjrjsb5n0\\$](http://astct.informz.net/z/cjUucD9taT0yMTQzNjc4JnA9MSZ1PTUxNTU4MzAzMCZsaT0xOTc3OTg5Nw/index.html ;!!JkUDQA!bcHjooAv-726AebrD0ocS0THJGL8EfNT4y5OmrBHIOD-H0mqf4e3OjEBjrjsb5n0$).

Updated April 21, 2020

1. HPC products destined for our clinical program are being cryopreserved at the collection center or occasionally by a third party facility due to COVID-19 travel restrictions and other concerns. Is our program expected to have written agreements in place to be in compliance with standards B4.6.1 and D12.1.1?

Presumably these products are unrelated donor products facilitated by a donor registry. Most likely, any single program will receive only one such product from a specific collection site or cryopreservation facility. This makes it impractical to have an individual written agreement in place with each collection or cryopreservation facility. FACT would consider these services of cryopreservation and shipment to be an extension of the program's written agreement with the Donor Registry.

2. When our laboratory cryopreserves an unrelated donor product for another transplant center, what records should we include with the shipment?

FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Seventh Edition, require [D13.5.2] the Processing Facility to

provide “a copy of all records relating to the collection, processing, and storage procedures performed related to the safety, purity, or potency of the cellular therapy product”. This would include at a minimum, the volume, total nucleated cell count, cell viability, CD34+ and CD3+ cell counts if performed, microbial culture results, testing, processing, and cryopreservation methods, identification and quantification of additives and cryoprotectants, and the freezing curve. The Processing Facility records should also identify any other facility participating in the collection or processing, and the extent of its responsibility [D13.5.3].

In addition, the Donor Registry will provide registry-specific product analysis forms and potentially, additional data forms related to collection, processing, or storage that should be included with the product shipment. Data required will include identifiers for the donor and recipient, collection date, and product characteristics, including anticoagulants, additives, and the results of all testing performed.

If the Collection Center or Laboratory providing products to an accredited Clinical Program is not FACT or JACIE accredited, the Clinical Program may have to specifically request processing information, including the data listed above.

Laboratories undertaking cryopreservation for another transplant program should obtain recipient information necessary to perform the optimal pre-cryopreservation processing. Particularly in the case of bone marrow products, documentation of the donor and recipient ABO group is critical to ensure red cell reduction strategies are used prior to cryopreservation in the case of incompatibility.

3. When we anticipate our on-site inspection will be scheduled, we are not certain we will be able to allow FACT inspectors in our Facility because of COVID-19 concerns for travel and exposure of staff. Can we request a virtual inspection?

FACT does not intend to schedule or perform on-site inspections until it is safe to do so. If necessary, further adjustments will be made to the timelines. Through annual reporting, there are processes in place to assess programs between on-site inspections. FACT is not currently planning to perform virtual inspections in lieu of the on-site visit.

4. So that we can prepare now and keep appropriate records, are there details available about the information to be required on our Annual Report related to COVID-19?

The templates for the Annual Report are under development. Information to be requested will include at a minimum:

- Was there any relocation of services for inpatient or outpatient care? If yes, submit your risk assessment of the move, including ensuring adequate space and protection from airborne microbial contamination and provision of adequate medications, blood products, and other critical services.
- Did your program make changes in the number of types of transplants performed during the pandemic?
- Were there staff changes or shortages experienced on your transplant service?
- How did your program manage COVID-19 infection in your transplant patients – were patients managed on the transplant unit or transferred to other appropriate quarantine space? Did you provide physician or nurse support or training in the event of patient transfer?

- Were COVID-19 issues incorporated into your quality management meetings?
- Was there a relocation of the apheresis collection service, a need to change apheresis providers, or disruption in service?
- Was your apheresis service involved in the collection of convalescent plasma? Did this affect your ability to collect apheresis products for your transplant patients?
- Was there relocation of the processing facility or disruption in its ability to meet the needs of the clinical program?
- Was there a disruption in your ability to provide marrow collection services? If yes, what alternatives were employed to meet patient needs?
- Are any of the relocations expected to be permanent?
- Describe any telemedicine initiatives in your BMT program.

Updated April 8, 2020

1. Is the extension of our accreditation expiration date a permanent change or will our next accreditation cycle be shortened?

The six-month extension in expiration date represents a permanent change to your program's accreditation date and will be added to your current accreditation cycle. Your next accreditation cycle will be a full three years.

2. When will we get an updated Accreditation Certificate listing the new expiration date?

FACT will send new Accreditation Certificates to all accredited organizations after scheduling of on-site inspections has resumed and extended timelines have been confirmed. If circumstances necessitate further delays, adjustments will be made to timelines. If a certificate is needed sooner, the Program Director should contact the FACT Accreditation Coordinator.

The official list of FACT-accredited organizations and the services for which each is accredited is available at www.factwebsite.org.

3. Is there an update to allogeneic donor screening and testing requirements for HCT/Ps? Should these donors be routinely tested for COVID-19?

FDA continues to work with CDC and other federal and international agencies to monitor the evolving coronavirus pandemic. In Guidance issued April 1, 2020, FDA continues to recommend the routine screening measures already in place for evaluating potential HCT/P donors for clinical evidence of infection and to consider additional information related to COVID-19. This would include whether the potential donor had, in the previous 28 days, been diagnosed with or suspected of having COVID-19 infection or had had close contact with individuals diagnosed with or suspected of having COVID-19 infection.

At this time, FDA does not recommend laboratory testing of asymptomatic HCT/P donors for COVID-19.

4. Our BMT Program is accredited for Immune Effector Cells. An Infectious Disease physician in our institution is considering opening a trial to treat patients with COVID-19 using an investigational cellular therapy product. The product is manufactured as an “off the shelf” product by a third-party manufacturer. The patients will not be transplant patients and will not be treated on the transplant unit. Does this trial fall under our HCT accreditation?

In this scenario, the accredited program has no responsibility for procurement of the starting material or for manufacturing or administering the product. Among the many models of immune effector cell program structure, this would be considered to be a cellular therapy trial within the same institution, but not a part of the accredited program. The trial does not affect the BMT Program accreditation, even though the program is accredited for immune effector cells.

However, the FACT Standards for Immune Effector Cells are relevant to this sort of clinical trial. FACT recommends that physicians utilizing cellular therapies outside of the BMT unit consult and follow these Standards to the extent possible. In particular, aspects of quality management such as SOPs, training, appropriate facilities for the population being treated, good documentation practices, management of occurrences and adverse events, data management, and follow - up of clinical outcomes could contribute to the safe administration of these products. Transplant physicians with expertise in immune effector cells and their toxicities could offer valuable consultation.

- Data management: CIBMTR through its Cellular Immunotherapy Data Resource may be interested in capturing these cellular therapy product infusions.
- Some patients with severe COVID-19 have been reported to have a cytokine release syndrome, a disorder with which physicians utilizing immune effector cells have familiarity.

5. What can we do if an allogeneic donor is suddenly unavailable for an urgent transplant?

The National Marrow Donor Program/BeTheMatch is currently requiring that all unrelated donor products be cryopreserved and shipped to the Transplant Center prior to initiating the recipient’s preparative regimen. Many transplant centers have begun this practice for related donors also. CIBMTR is currently analyzing data on the relative efficacy of fresh and cryopreserved grafts, with results expected soon. At least two experts have volunteered to assist if a facility is unfamiliar with cryopreservation of allogeneic marrow products. Their contact information is available at <http://www.aabb.org/advocacy/regulatorygovernment/Documents/Cryopreservation-of-Allogeneic-HPC-Marrow-Products.pdf>. Additionally, [FACT Consulting](#) is available. FACT-accredited facilities must follow all relevant standards related to change control for a new procedure, process validation, and personnel training.

If an alternative donor is not readily available, some programs are considering the use of cord blood grafts. Cord blood units are readily available for use, do not raise infectious disease questions related to coronavirus, and can be shipped without travel restrictions. NMDP/Be The Match has a Cord Blood Consultative Service for CB unit selection and is offering cord blood units from network banks for practice to programs unfamiliar with thawing and washing procedures. In addition, a presentation on thawing practices is available from NMDP/Be The Match: [Cord Blood Thawing Methods](#).

6. Our Apheresis Department is developing workflows and protocols to facilitate virtual visits. Does FACT have any position on telemedicine in Apheresis?

Telemedicine is being implemented in many areas of medicine. Due to the COVID-19 pandemic, interest has grown rapidly to minimize the risk of transmission of infectious diseases between patients and medical staff, to reduce the need to travel for care, to preserve supplies of personal protective equipment, and to increase flexibility of the workforce. Telemedicine could also facilitate specialty care to patients who otherwise lack access due to geographic isolation or limited mobility. There are many HIPAA-compliant and suitable platforms and formats available to facilitate these visits. Many institutions have secure platforms for telemedicine embedded into the EMR. Laws, regulations, and institutional policies are variable across state and national boundaries. Although concerns related to reimbursement have been limiting, the Centers for Medicare & Medicaid Services (CMS) has recently expanded telehealth coverage and access by waiving certain requirements during this public health emergency.

While FACT has no standard that explicitly cites telemedicine, many Standards would apply to the application of these technologies in an accredited apheresis facility. These would include, but not be limited to, the responsibility to abide by applicable laws and regulations (C1.3), maintenance of a comprehensive system of document control (C4.5), policies and standard operating procedures to manage occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints) (C4.10), qualification of critical vendors and equipment (C4.13), electronic records (C11.7), policies and standard operating procedures addressing critical aspects of operations and management (C5.1), and staff training (C5.5). Standards related to donor and recipient confidentiality and issues of consent require particular attention when these actions occur in the telemedicine environment.

Published March 13, 2020

1. Our on-site inspection was just postponed because of travel restrictions due to COVID-19. What happens if our accreditation expires?

No accreditation will lapse due to delays and postponements related to COVID-19. All currently accredited organizations will automatically receive a six-month extension of this accreditation cycle. This date will be further extended if circumstances require that action. New accreditation certificates will be provided.

The FACT website is the official source of the list of accredited organizations. Currently accredited organizations in the process of renewal or due for renewal will remain listed on the website during this period.

2. When will our inspection be rescheduled?

We will not be rescheduling on-site inspections until there is more information available about the timeline of this pandemic, when inspectors will be available and able to travel, and when sites will be ready to host visitors and an on-site inspection.

3. When our inspection is rescheduled, will we have the same inspection team?

FACT will make every effort to realign the same inspection team with the applicant program. This is especially important to inspectors who may have already been prepared for the inspection.

4. We are in the middle of the renewal process. What should we do?

To the extent possible, you should continue to submit documents and respond to Requests for Information (RFI) sent to you from your Accreditation Coordinator. FACT Accreditation Coordinators are available by phone or email to assist you. FACT understands that staff shortages and other demands during this COVID-19 pandemic may limit your ability to follow the usual timeline. Extensions of deadlines for response will be granted by your coordinator as needed on a case-by case basis.

5. What will happen to our accreditation if our allogeneic transplant numbers fall below the minimum requirement in 2020 because our resources were stretched to accommodate COVID-19 issues?

Clinical treatment decisions, the availability of medications, donors, cellular therapy products, and clinical trials may each affect the number of stem cell transplant patients during the COVID-19 pandemic. FACT will make every effort to work with your program and make accreditation decisions on a case-by-case basis, in a reasoned and fair manner.

6. We may need to temporarily relocate our transplant patients due to COVID-19. What will FACT require us to submit related to relocation?

FACT is aware that health care facilities may face significant challenges in meeting the needs of all patients during this pandemic. Both inpatient and outpatient settings may be affected. Temporary relocations of cellular therapy patients based on institutional needs related to COVID-19 do not require immediate reporting to FACT. A description of the activities and the facilities utilized will be requested at the time of the Program's Annual Report to FACT.

FACT expects that any temporary relocation of cellular therapy recipients or shifts in models of delivery of care should be undertaken to the extent possible using your Quality Plan and Clinical Standards as a guide. Considerations include a risk assessment of the alternate location, ensuring the facility is in an appropriate location with adequate space and protection from airborne microbial contamination, and that there is availability of appropriate medications, blood products, trained health care professionals, and additional care as required by these patients.

7. What are the expectations of FACT related to deviations?

To the extent possible, management of deviations should follow usual quality management processes. Planned deviations from standard processes should be approved by the appropriate director or medical director, reviewed by the quality manager, and performed and documented in the usual manner. Unplanned deviations should be documented, investigated, reported, and a corrective action plan developed if appropriate, using the mechanisms described in your Quality Management Plan.

8. How will FACT be treating care adjustments related to COVID-19?

Specific patient care recommendations are outside of the scope of FACT Standards. However, our parent society, the American Society for Transplantation and Cellular Therapy (ASTCT) and its Infectious Disease Special Interest Group have developed interim guidelines for COVID-19 management of HCT and cellular therapy patients. These will be updated as new information becomes available related to epidemiology, clinical outcomes, and efficacy of drug therapies: <https://www.astct.org/connect/astct-response-to-covid-19>

EBMT has also published guidelines:

<https://www.ebmt.org/ebmt/news/coronavirus-disease-covid-19-updated-ebmt-recommendations-8th-march-2020>

The American Society of Clinical Oncology (ASCO) has also developed useful clinical guidelines related to caring for cancer patients in the context of the coronavirus pandemic:

<https://www.asco.org/asco-coronavirus-information?cid=DM4750&bid=39975269>

In addition, FACT's global partner The World Marrow Donor Association (WMDA) has provided blood and donor guidelines and resources for cord blood banking:

- [Cord Blood Support Service](#)
- [Information specified per country \(on restrictions on import/export\)](#)
- [Donor suitability criteria](#)
- [European Centre for Disease Prevention and Control](#)

Numerous other resources are available, including the [World Health Organization](#) and the [Centers for Disease Control and Prevention](#).

9. How should we screen donors for allogeneic transplant?

The potential risk of transmission of COVID-19 by blood or cellular therapy product infusion is unknown; however, respiratory viruses are not generally known to be transmitted by blood transfusion. Programs considering enhanced screening of potential donors should consult FDA guidance to provide donor education, encourage self-deferral as appropriate, and manage post-donation information about COVID-19. This includes considering deferral of donors who have traveled to areas with COVID-19 outbreaks, lived with individuals diagnosed with COVID-19, or have themselves been diagnosed with or suspected of having COVID-19 infection. Based on limited information, deferral should last 28 days after resolution of symptoms or after return from an outbreak area. FDA will update these recommendations as more information becomes available.

- <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-blood-establishments-regarding-novel-coronavirus-outbreak>
- <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-or-cellular-or-tissue-based-product-hctp-establishments>

Due to the uncertainty of the situation and the potential for additional travel bans, NMDP/Be The Match strongly recommends cryopreservation of adult donor products to allow for delivery of the product to the transplant facility prior to starting a recipient's preparative regimen. Neither testing of donor products nor quarantine is currently recommended by NMDP or FDA.

<https://network.bethematchclinical.org/news/nmdp/be-the-match-response-to-covid-19/>