Letter from the President

This newsletter is a celebration of sorts. First, it recognizes cellular therapy programs that have maintained ten or more years of continuous FACT accreditation. To remain dedicated and committed to continuously improving processes for the betterment of patients for a decade or more is a remarkable achievement. In the past ten years, FACT has published four editions of the Cellular Therapy Standards and has participated with several collaborative organizations and committees in addressing standards related to cell therapy. Remaining aware of and adapting to new accreditation requirements and industry-wide publications, such as the Circular of Information and ISBT 128 terminology, is a major but worthy endeavor. The programs highlighted in this newsletter deserve not only recognition for their accomplishments but our thanks. Through their commitment to quality, they have helped improve the FACT accreditation process. Some of their words of wisdom are included to provide helpful advice to their fellow accredited organizations.

We also salute three outgoing Board members who received Outstanding Achievement Service Awards. Over the years, the FACT Board of Directors has been filled with experts in our field whose passion for improving patient care is inspiring. The Board members highlighted in this letter are transformational leaders who have helped shaped FACT into the influential and dynamic organization it is today. While we are sure to miss their leadership at the Board level, we will continue to tap their expertise on behalf of FACT for years to come. With the changes in membership, the current FACT Board of Directors is planning a strategic retreat in May, which will be an opportunity to celebrate FACT’s success and create plans to carry that success into the future.

Sincerely,

C. Fred LeMaistre, MD
Programs Recognized for Ten or More Years of Continuous FACT Accreditation

The FACT Program Relations Committee, led by Dr. Jean Sanders, congratulates 44 cellular therapy programs that have maintained their FACT accreditation continuously for ten or more years. To celebrate this achievement, the committee sent a survey to these programs to assess the impact of FACT accreditation. Programs indicated that FACT accreditation has had an overall positive impact. See the graph titled Impact of FACT Accreditation for details regarding the impact of FACT accreditation.

When asked what challenges programs have faced concerning accreditation, the most commonly mentioned items were the effort required to prepare for and maintain accreditation; lack of commitment from the affiliated institution for resources, personnel, and funds; and keeping up with the Standards and documentation requirements as they have changed over the years. FACT will use this feedback in future publications to provide tips on how to manage these challenges.

Programs with 10+ Years of Accreditation

Adult and Pediatric Autologous and Allogeneic Programs

Barbara Ann Karmanos Cancer Center Blood and Marrow Stem Cell Transplant Program
Blood and Marrow Transplant Program of UCSD/Sharp LLC and Rady Children’s Hospital of San Diego
H. Lee Moffitt Cancer Center & Research Institute Blood and Marrow Transplant Program
Hackensack University Medical Center Blood and Marrow Transplantation Program
Northwest Marrow Transplant Program at Oregon Health & Science University, Legacy Good Samaritan Hospital and Medical Center and Doernbecher Children’s Hospital
Oncology Group and Fort Sanders Regional Medical Center
Seattle Cancer Care Alliance
Shands Hospital at the University of Florida
Stanford University Medical Center Blood and Marrow Transplant Program
Strong Memorial Hospital Blood and Marrow Transplant Program
Texas Transplant Institute
Tufts Medical Center Bone Marrow and Hematopoietic Stem Cell Transplant Program
University of Alabama Adult and Pediatric Bone Marrow Transplantation and Cell Therapy Program
University of Chicago Stem Cell Transplant Program
University of Louisville Blood and Marrow Transplant Program
University Medical Center/Arizona Cancer Center Blood and Marrow Transplantation Program
University of Minnesota Blood and Marrow Transplant Program
University of Texas MD Anderson Cancer Center Department of Stem Cell Transplantation and Cellular Therapy
University of Utah Stem Cell Transplant and Myeloma Program

Adult Autologous and Allogeneic Programs

Adult Hematopoietic Stem Cell Transplant Program, Dana-Farber Cancer Institute/Brigham and Women’s Hospital
Baylor University Medical Center
Cancer Institute of New Jersey Robert Wood Johnson University Hospital Blood and Marrow Transplant Program
Christiana Care Health Services
Coleman Foundation Blood and Marrow Transplant Center at Rush University Medical Center
Words of Wisdom from Accredited Programs

While challenges were identified, the majority of programs felt that the benefits of FACT accreditation were worth the effort. The following are their perspectives regarding FACT accreditation:

“Maintaining a highly functioning quality program requires significant effort, but FACT provides the framework to make this successful.”

“We have received support and guidance for creating and maintaining standard operating procedures to promote excellent quality care.”

“The amount of time required for the application and pre-FACT preparation at larger centers is resource intensive.”

“Accreditation is a process best to not aim high to start with but rather meet the standards and then slowly build on them - do not commit to things just to finalize a checklist but build a sustainable platform.”

“It is challenging to meet the requirements of the FACT standards with a small program and limited resources. Try to organize your program so that one undertaking can meet many of the standards.”

“Make [FACT accreditation] a high priority and every staff member should participate; partner with the institutional QI department and engage more people outside of the program.”

“Having physicians from our program involved as FACT inspectors has greatly increased their understanding and commitment to our preparedness.”
FACT Extends Outstanding Achievement Service Awards to Outgoing Board Members

FACT has benefited from the outstanding leadership of three outgoing Board Members who participated in their last Board of Directors meeting on February 23, 2010. Each contributed to FACT via countless hours as Board Members, committee chairs and members, inspectors, and personnel at accredited institutions. Board President, Dr. Fred LeMaistre, acknowledged each of them and provided them with Outstanding Achievement Service Awards.

Frank Smith, MD
Board of Directors: 2001-2009
Other previous and current appointments:
- Treasurer
- Executive Committee

Helen Heslop, MD
Board of Directors: 2001 - 2009
Other previous and current appointments:
- Vice President
- Executive Committee
- Chair, Professional Relations Standards Committee

Nancy H. Collins, PhD
Board of Directors: 1996 - 2009
Other previous and current appointments:
- Chair, Cellular Therapy Standards
- Chair, Cord Blood Standards
- Cellular Therapy and Cord Blood Accreditation Committees

The goal of the inspector handbook is to strengthen and continue FACT’s tradition of developing effective, positive, and collegial inspectors.

Third Edition FACT Inspector Handbook Provided to Inspectors

FACT updated its FACT Inspector Handbook in January 2010 to encompass feedback and experiences gained by FACT inspectors and organizations that have been inspected. The handbook passes on the guidelines and wisdom that inspectors and accredited programs and banks have developed since the inception of FACT.

The Inspector Handbook is intended to provide tips to inspectors in an easy-to-read guide that can accompany them on inspections. The goal of the handbook is to strengthen and continue FACT’s tradition of developing effective, positive, and collegial inspectors to better the field.
Don’t Let Your Accreditation Lapse!
Follow the Inspection and Accreditation Timeline

Remember to follow the Cellular Therapy or Cord Blood Inspection and Accreditation Timeline to ensure your organization maintains continuous FACT accreditation. FACT created this timeline to assist organizations with knowing when to submit what in a manner that will ensure they are reviewed by the Accreditation Committee prior to expiration of accreditation. Cathy Matuella, FACT Accreditation Coordinator, reminds organizations that the day of inspection is not the date of accreditation; rather, the day the Accreditation Committee awards accreditation is the accreditation date. Therefore, organizations are encouraged to submit their pre-inspection submissions nine months prior to expiration with the goal of being inspected six months prior to expiration. Failure to follow the timeline places organizations at risk of being removed from the FACT website.

The following timelines are available on the FACT website for reference while completing the inspection and accreditation process:

- Cellular Therapy Initial Accreditation Timeline
- Cellular Therapy Renewal Accreditation Timeline
- Cord Blood Initial Accreditation Timeline
- Cord Blood Renewal Accreditation Timeline

A Note from the FACT Cord Blood Accreditation Committee

Linda Cave, Cord Blood Accreditation Committee Staff Liaison, encourages all cord blood banks to continue to make improvements in their Quality Management (QM) programs and to remain current in today’s ever changing cord blood banking field. QM requirements, specifically the QM Plan and validation studies, are commonly cited during inspections.

Coordinator Commentary
Shipping and Transportation
Sarah Litel Smith, BSMT(ASCP)

The terms shipping and transportation are often used interchangeably as both terms refer to the movement of products between or within facilities. FACT differentiates between the terms based on how the product is moved.

According to FACT definitions, movement between or within facilities is:

- **Shipping** if the product/unit leaves the control of trained personnel of either the organization it came from or is going to.
- **Transporting** if the product/unit does not leave the control of trained personnel of either the organization it came from or is going to.

So, while both shipping and transportation refer to the movement of products between or within facilities, the difference lies in whether or not a product leaves the control of trained personnel. For example; if a product is sent by taxi, a courier not trained by the organization, FedEx, USPS, or UPS, it is being shipped, whether it is going to another facility that is an integral part of the organization or it is going to an unrelated organization. However, when a product is going from the Processing Facility (located on- or off-site) to the patient’s bedside and the processing technologist is taking the product, it is being transported.

As a friendly reminder, a policy or procedure, applicable for each facility (i.e. the sending and receiving facilities), that addresses shipping and/or transportation is required by FACT.
Circular of Information for the Use of Cellular Therapy Products Published

The Circular of Information for the Use of Cellular Therapy Products (Circular) was published in February 2010 and is intended to be an extension of the cellular product label. As an extension of container labels, each processing/issuing facility has the option and is encouraged to provide more facility or product specific information in the space provided in the Circular. The organizations involved in writing the Circular limited the scope to minimally manipulated cellular products such as peripheral blood progenitor cells, bone marrow, cord blood, and leukocytes. The group recognizes the fact that there are other cellular products which could not be adequately covered in the Circular. The electronic version of the Circular has been enhanced to allow for addition of facility-specific information at the end of the document.

2009 ASHI Standards Available

The 2009 ASHI Standards were approved by CMS and are available to the FACT community on the ASHI website. Cellular therapy programs and cord blood banks are suggested to review the requirements and discuss any that are pertinent to their operations with their HLA testing laboratories to ensure their current agreements are appropriate and that all parties are in compliance with applicable requirements.

ASHI Harmonization Group Includes FACT and other Standards-Setting Organizations and Registries

The American Society for Histocompatibility and Immunogenetics (ASHI) created a harmonization group to clarify HLA-related terminology and promote communication between standards-setting organizations (including FACT) and registries. This group is a result of feedback provided to ASHI regarding the need to communicate with related organizations that may be affected by its standards. FACT thanks ASHI for creating this group and acknowledges FACT-accredited organizations who provided feedback regarding the worthy endeavor for harmonization.

Upcoming Meetings Related to Cellular Therapy

The following meetings will contain exciting, pertinent information related to cellular therapy. Participation is encouraged. (Note: FACT workshops require separate registration.)

16th Annual ISCT Meeting
May 22-26, 2010
Philadelphia, Pennsylvania

2010 ASFA Annual Meeting
May 26-29, 2010
New Orleans, Louisiana

Annual International Umbilical Cord Blood Transplantation Symposium
June 3-6, 2010
San Francisco, California

FDA Cord Blood Workshop Discusses Pathway to Licensure

The FDA, with AABB, FACT, and other organizations, hosted a workshop on March 8-9, 2010 to discuss the pathway to cord blood licensure or Investigational New Drug (IND) approval. Participants from around the world represented cord blood banks, registries, transplant physicians, and other stakeholders. Presentations from the FDA, cord blood banks, and physicians provided explanations and recommendations regarding the FDA licensure guidance and draft IND guidance, with considerable time reserved for question and answer sessions. The insightful information from these sessions is under review by the FACT Professional Relations Committee, which intends to provide accredited and applicant cord blood banks a detailed synopsis of this valuable knowledge.

Biologics License Applications (BLA) and INDs are due to the FDA by October 2011. Cord blood banks are urged to begin preparations for submissions.
Congratulations to New Active FACT Inspectors!

Becoming an active FACT inspector requires considerable time and effort on a voluntary basis. FACT thanks and congratulates the following individuals who completed their first official FACT inspection in the first quarter of 2010:

**Cellular Therapy Inspectors**
- Sergio Giralt, MD  *Clinical*
- Shakila Khan, MD  *Clinical*
- Mitchell Cairo, MD  *Clinical*
- Patricia Shi, MD  *Apheresis Collection*
- Mary Mooney, MSHA, MT(AMT)  *Processing*
- Elzbieta Smogorzewska, PhD, MSc, CLS  *Processing*

**Cord Blood Inspectors**
*Also a current Cellular Therapy Inspector*
- Helen Heslop, MD*
- Chitra Hosing, MD*
- Abba Zubair, MD, PhD*
- Tiziana Bonfini, MD
- Michael Mueller - Steinhardt, MD
- Michele Carbone, MS, CLS, MT(ASCP)*

New Approach to Updating Inspection-Related Documents

FACT continuously improves its inspection-related documents to ensure they remain complete and accurate as improvements are made to the inspection and accreditation process. Because updates to these documents may occur while an organization is in the middle of the process, FACT will now post updates to these documents on a quarterly basis and announce them in the Just the FACTs newsletter. Furthermore, the effective dates and revisions will be included on the website. This change is intended to assist organizations with keeping up with necessary changes to the FACT process. The following are documents that have been updated since the last newsletter:

- Cellular Therapy Initial Accreditation Timeline
- Cellular Therapy Renewal Accreditation Timeline
- Cellular Therapy Inspection Checklist
- Cord Blood Initial Accreditation Timeline
- Cord Blood Renewal Accreditation Timeline

Quality Corner: Outcome Analysis

*Jill Hempel, MS, ASQ-CMQ/OE*

Outcome analysis is a formal assessment and focuses on the results of therapy. Analyzing patient outcomes requires thoughtful planning, data collection, evaluation, investigation, and follow-up. In order to meet these aspects of outcome analysis, the Plan, Do, Study, Act (PDSA) cycle can be utilized to streamline the process of analyzing outcomes:

**Step 1: Plan** Plan the test or assessment, including a plan for collecting data. State the objective of the assessment. Make predictions about what will happen and why.

**Step 2: Do** Execute the test or assessment. Document problems and unexpected observations. Begin analysis of the data.

**Step 3: Study** Complete a thorough analysis of the data. Compare the data to your predictions. Summarize and reflect on what was learned.

**Step 4: Act** Refine the change, based on what was learned from the test. Determine what modifications should be made, if any. Prepare a plan for the next test.

Since the outcomes analysis process is not linear, it allows for several tests of change before the expected outcome is achieved to ensure optimal outcomes are the result. The PDSA cycle is a simple but effective process for analysis and action that accelerates improvement, and captures the core philosophy of continual improvement.
Give Us the FACTs Poll

What types of electronic systems does your program or bank use?

Give Us the FACTs!

In Your Opinion . . .

How has FACT accreditation improved your program or bank over the years?

In Your Opinion . . .

Last month’s poll: How does your organization train personnel to obtain donor medical history?

We did not receive any answers to this question . . . one reason may be because training personnel to obtain donor medical history is a difficult task compounded by the fact that staff turnover is common. The FACT Training and Development Committee plans to create a tutorial on this topic in Fall 2010 as a resource for personnel training.

Time is Running Out! Register Today for Upcoming FACT Workshops!

Cellular Therapy Workshop at the ISCT Annual Meeting
May 23, 2010 from 8 am to 5 pm in Philadelphia, PA

A new focused track will include information on storage, release, and distribution; process controls; labeling; and quality management issues unique to Processing Facilities!

Collection Workshop at the ASFA Annual Meeting
May 25, 2010 from 12 pm to 5 pm in New Orleans, LA

Now open to Collection Facilities as well as inspectors! In addition to general inspection and accreditation process information, special sessions will address quality management from a collection perspective and distribution from a Collection Facility.

Cord Blood Workshop at the International Umbilical Cord Blood Transplantation Symposium
June 6, 2010 from 8 am to 5 pm in San Francisco, CA

Register today to learn about the new fourth edition Cord Blood Standards, inspection of various cord blood banking structures, required interactions between a cord blood bank and a clinical program, and more!

Note: Separate registration for FACT workshops is required.

Example Assessment Programs the Topic of the Next FACT Virtual Roundtable
June 11, 2010 at 1 pm ET

Register today to learn about the quality assessment programs at accredited cellular therapy programs and cord blood banks! This virtual roundtable will conclude the QM Series Module 2: Quality Assessment Activities.