

Letter from the President

This edition of "Just the FACTs" describes some changes that are very important to FACT. We are proud to highlight FACTweb, a cellular therapy community portal. FACTWeb connects stakeholders in cellular therapy from around the globe in a dynamic, virtual environment of effective accreditation services, exciting educational opportunities, and real-time communication. In order to best support our role as the premier organization in cell therapy standard development, accreditation, and education, we recognized the need to develop the requisite infrastructure in information technology. I hope you will enjoy becoming acquainted with FACTWeb and exploring its potential to help you with the important work that you do.

Another change that is even more vital to our mission is the announcement of the Fifth Edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration. Dr. Carolyn Keever-Taylor chaired the Standards Committee that has updated, and, where needed, changed our accreditation standards to keep pace with changes in cellular therapy leading to improved patient outcomes. The product that is the result of this international effort is without question our best work. Dr. Keever-Taylor, her dedicated subcommittee chairs and committee members, and all of you who submitted the more than 800 comments to improve these standards deserve our deepest gratitude.

This newsletter is my last as President of FACT and thus marks another change which itself is trivial by comparison. For the last fifteen years I have been privileged to work with you in an effort to facilitate progress in the most exciting field in medicine while assuring the best possible outcomes for patients. What is not trivial is that the sum of your efforts has clearly helped write the history of our generation in cellular therapy. Dr. Helen Heslop will be assuming the role of President and we have an unbelievably talented and dedicated board. With such gifted leaders and committed membership, our future appears even more exciting than our past. I will remain on the board as immediate past president during Dr. Heslop's tenure but I want to take this opportunity to thank you for your support of FACT, but even more importantly to thank you for what you do everyday for the patients we all serve.

Sincerely,

C. Fred LeMaistre, MD

Few will have the greatness to bend history itself; but each of us can work to change a small portion of events, and in the total of all those acts will be written the history of this generation.

Robert F. Kennedy

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Editor: Kara Wacker, MBA, RAC

Accreditation Report

Seventeen blood and marrow transplant programs received accreditation renewal during the third quarter of 2011. The [complete report of accredited organizations](#) in the third quarter is available at www.factwebsite.org.

Cellular Therapy Programs	Cord Blood Banks
196 Programs Registered	52 Banks Registered
186 Programs Accredited	30 Banks Accredited
10 Applications Pending	22 Applications Pending

Cellular Therapy Programs Recognized for 10 Years of Continuous FACT Accreditation

In 2011, 27 cellular therapy programs achieved 10 years of continuous FACT accreditation. The FACT [Program Relations Committee](#), under the leadership of Jean Sanders, invites everyone to join them in congratulating these 27 programs. As part of the celebration of their achievement, the programs were asked to respond to a survey that addressed the impact of FACT accreditation and provided an opportunity to provide feedback regarding challenges of accreditation. The survey results indicate that a strong majority of the respondents feel that FACT accreditation has had a significant to major impact on their program. The respondents unanimously agreed that FACT accreditation has positively impacted quality within their program. Peer perception, attitude of the affiliated institution towards the program, insurance reimbursements, number of transplants performed, and participation in clinical trials have also been positively impacted by FACT accreditation.

Challenges identified included the time and resources required to maintain accreditation, keeping current with the standards, and reviewing, revising, and organizing documents to ensure compliance. FACT will use the feedback received to develop tips and tools to manage the challenges as well as assess the process to see where changes may be appropriate.

What They Have to Share With You

Programs achieving 10 years of continuous FACT accreditation share their thoughts on FACT accreditation.

“FACT accreditation has a positive impact on the quality of the program and forces a program to uphold the highest standards.”

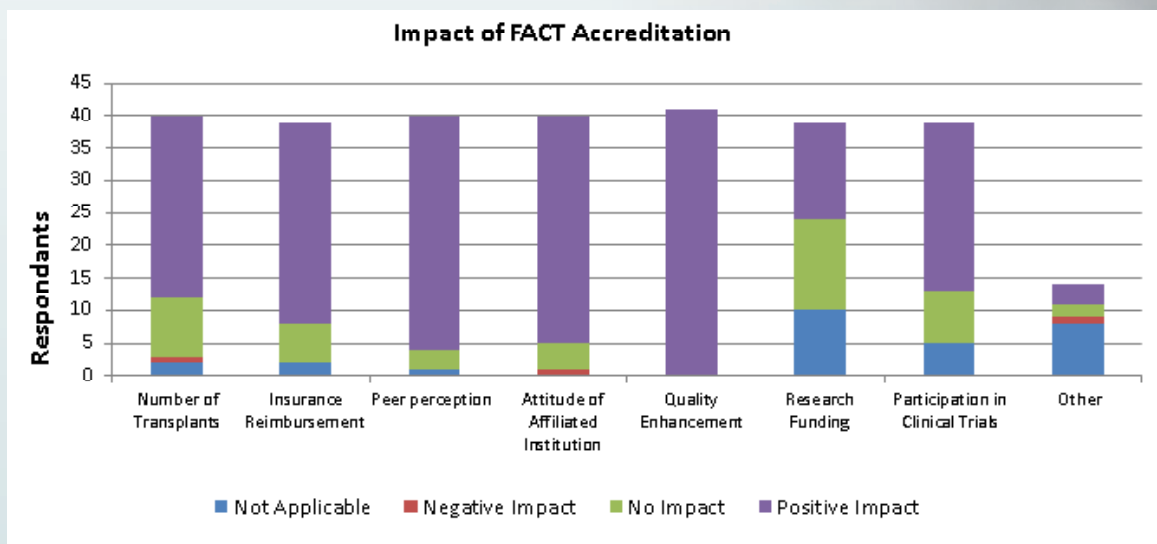
“The accreditation reviews are informative and provide opportunities/suggestions for improvement. It is helpful to have knowledgeable outsiders give constructive feedback on established programs.”

“It’s worth the effort. It keeps everyone current on policies and procedures and also causes much needed communication between all aspects of the transplant program.”

“The work in maintaining the level of the program is a continuous one, rather than simple preparation for the accreditation review.”

“FACT accreditation is a great way to routinely critically evaluate your processes, to look for places for improvement. The institution also recognizes the benefits of this accreditation, and as such the process is useful in negotiating for financial support for changes required by FACT.”

“It is essential and is a powerful tool in facilitating program quality, cohesion and forward progress.”



Programs with 10 Years of Accreditation

Adult and Pediatric Allogeneic and Autologous Programs

University of Colorado Denver Blood and Marrow Transplant Program University of Colorado Hospital and The Children's Hospital

The University of Nebraska Medical Center Hematopoietic Cell Transplantation Program

Virginia Commonwealth University Medical Center, Massey Cancer Center, Bone Marrow Transplant Program

Medical College of Wisconsin Blood and Marrow Transplant Program Children's Hospital of Wisconsin and Froedtert Hospital

Indiana University Bone Marrow and Stem Cell Transplantation Program

Vanderbilt University Medical Center and Nashville Veterans Administration Medical Center

Blood and Marrow Transplantation Program of Mayo Clinic, Nemours Children's Clinic, and Wolfson Children's Hospital

Penn State Milton S. Hershey Medical Center Bone Marrow Transplant Program

University of Michigan Blood and Marrow Transplant Program

University of Wisconsin Madison Hematopoietic Stem Cell Program

The OU Medical Center Blood and Marrow Transplant Program

The Blood and Marrow Transplantation Program of the Holden Comprehensive Cancer Center at the University of Iowa

The Johns Hopkins Bone Marrow Transplantation Program

University of Illinois Medical Center at Chicago Stem Cell and Bone Marrow Transplant Program

Adult Allogeneic and Autologous Programs

Wake Forest University Baptist Medical Center

The Blood and Marrow Transplant Group of Georgia at Northside Hospital

Beth Israel Deaconess Medical Center

Emory University Hospital Bone Marrow and Stem Cell Transplant Center

Intermountain Blood and Marrow Transplant Program

Northwestern Memorial Hospital Hematopoietic Stem Cell Transplant Program

Adult Autologous Programs

St. Luke's Mountain States Tumor Institute Blood and Marrow Transplant Program

USC Norris Cancer Hospital

Boston Medical Center Autologous Stem Cell Transplant Program

NorthShore University Health System Hematopoietic Progenitor Cell Clinical Program

INOVA Fairfax Hospital / Fairfax Stem Cell Transplant Program

The Blood and Marrow Transplant Program of the Cancer Centers of the Carolinas

Independent Collection and Processing Facilities

Jackson Memorial Hospital Transfusion Medicine Services

Congratulations!

Coordinator Commentary

Maintaining FACT Accreditation: Interim Reports

Sarah Litel-Smith, BSMT(ASCP)

FACT-accredited organizations are required to comply with current FACT Standards and policies, notify the FACT office of significant changes (e.g., relocations, change in Directors, etc.), and complete and submit the Interim Report Form in a timely manner. The FACT office will send each FACT-accredited organization the Interim Report Form with pre-printed information. Each organization is required to review and complete the Interim Report Form within 90 days, making corrections or additions as necessary.

The following supporting documentation will also need to be submitted with the Interim Report Form:

- Copies of current Joint Commission, HFAP, DNV, or equivalent, certification
- ASHI certification for facilities performing HLA testing
- A complete patient list (no names) for the past 12 month period from the date of accreditation to the anniversary date
- Documentation of eligibility for directors, attending physicians, and mid-level practitioners that have joined the organization since it was accredited
- Documentation, if requested, noting correction of deficiencies and/or implementation of a change required by the Accreditation Committee during the formal accreditation process

If you have any questions, please be sure to contact your FACT Accreditation Coordinator or the FACT Office at 402-559-1950.

Cord Blood Standards Development Begins

The Cord Blood Standards Steering Committee initiated development of the 5th edition NetCord-FACT International Standards for Cord Blood Collection, Processing, and Release for Administration in Rome, Italy on October 24th and 25th, 2011. The Steering Committee reviewed experiences with the 4th edition Standards, feedback received via the Cord Blood Standards Survey, new regulatory requirements, and current scientific data.

The 5th edition Cord Blood Standards is scheduled for publication on July 1, 2013 with an effective date of September 29, 2013.

The committee will accept feedback via the [Cord Blood Standards Survey](#) until December 31, 2011 and appreciates any comments that could be used to update the Standards.

Coming Soon: The 5th Edition Cellular Therapy Standards!

The 5th edition FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration is nearing completion. The following are important dates for cellular therapy programs to remember:

5th Edition Publication Date: March 1, 2012

The final version of the 5th edition Cellular Therapy Standards will be officially published on March 1, 2012. This includes the Accreditation Manual and associated documents.

5th Edition Effective Date: May 31, 2012

The 5th edition Cellular Therapy Standards will be effective on May 31, 2012. All documentation beginning on this date must demonstrate that your program is in compliance with the 5th edition.

Deadline for 4th Edition Checklist: February 29, 2012

Programs wishing to be inspected under the 4th edition must submit their checklist before the 5th edition publication date.

Deadline for 4th edition On-site Inspections: May 30, 2012

Programs wishing to be inspected under the 4th edition must be inspected before the 5th edition effective date.

Quality Corner

Principles of Organizational Quality Management: A Business Perspective

Jill Hempel, MS, ASQ-CMQ/OE

Maintaining quality in cellular therapy organizations to achieve positive patient outcomes is of utmost importance, especially for the patients and families involved in the procedures. Another purpose of quality is to achieve success from a business perspective. The following directional principles developed by West and Cianfrani (2005) help personnel from all areas of a cellular therapy organization provide focus on what to do to improve the overall outcomes not only of the patients, but also of the organization as a whole.

Focus on Patients (Customers): Focusing on meeting customers' needs and expectations is essential for organizational success, as they are the source of the need for services and revenue generation. Measuring customer satisfaction and acting upon this information allows an organization to determine and prioritize changes for improvement.

Focus on Social Responsibility: Personnel, patients, and society at large may all have a stake in the organization's performance. Focusing on these stakeholders and their expectations is important for the organization to be sustainable.

Focus on Results: Organizations need to achieve good performance results to maintain viability in the future. Positive patient outcomes, patient satisfaction, quality improvement, environmental performance, and financial performance are key areas to generate positive results.

Focus on Agility: Organizations need to be flexible and have rapid responses to organizational and external changes. The organization must also develop a mindset that agility and change are good things. Determining the critical external and internal forces is essential to developing plans to meet these potential changes with positive results.

Focus on the Future: Long-range planning, understanding needed core competencies, and establishing plans to meet future needs allows an organization to better control its own destiny.

Congratulations to our new inspectors!

Cord Blood Bank Inspectors

Kathleen Sazama, MD

LifeCord Cord Blood Bank

Julia Walker, BSMT(ASCP)CLS

The University of Texas MD Anderson Cancer Center

Bart Vandekerckhove, MD, PhD

Navelstrengbloedbank Rode Kruis-Vlaanderen

Elizabeth Semple, PhD

Cells for Life Cord Blood Institute Inc.

Cellular Therapy Inspectors

Elie Richa, MD

University of Chicago Medical Center

Become an inspector!

Transition to Online Accreditation

Ramona Repaczki-Jones, MSE

Frequently Asked Questions Provide Another Source of Information

Due to the popularity of the [ASK FACT](#) button on the FACT website, a substantial list of [frequently asked questions](#) (FAQ) is now available to accredited and applied organizations. These FAQs are another source of information covering topics related to accreditation, standards, inspectors, education, and FACTWeb.

Visit Us During the FACTWeb Drop-in Sessions at the 2012 BMT Tandem Meetings

The FACTWeb Oversight Committee is hosting drop-in sessions in San Diego during the 2012 BMT Tandem Meetings on February 1, 2012 from 12 noon to 2 pm and on February 4, 2012 from 9 am to 11 am.

These drop-in sessions are FREE and are an opportunity to ask the committee specific questions about the new online accreditation portal and request demonstration of specific modules. To ensure adequate room sizes and resources, registration is encouraged. Open registration will be announced via email and the FACT website.

Participants at FACTWeb User Feedback Meetings Invited to Provide More Input

Following the successful FACTWeb User Feedback Meetings conducted this past year, the FACTWeb Oversight Committee will invite participants to serve as testers of the FACTWeb accreditation portal. The committee appreciates the valuable suggestions and comments participants provide and is reliant on web testers to identify successful and unsuccessful experiences using FACTWeb. Testing will occur from January 16, 2012 to January 25, 2012.

FACT Website Wins Best in Class Award

The Interactive Media Council, Inc. awarded FACT a “Best in Class” Interactive Media Award for its redesigned website.

The “Best in Class” award is the highest honor bestowed by the Interactive Media Awards. Websites are judged on design, content, feature functionality, and usability as well as on standards compliance and cross browser compatibility. The [FACT website](#) received a score of 483 out of 500. There were 139 entries submitted under the ‘Healthcare’ category in the 2011 award year and 13 websites won Best in Class.

The Interactive Media Council, Inc. is a nonprofit organization of leading web designers, developers, programmers, advertisers, and other web-related professionals. The competition is designed to elevate the standards of excellence on the Internet and offer winners a boost in marketing and exposure.

“FACT is excited to have won the ‘Best in Class’ Interactive Media Award for its website redesign. The interactive project was a successful collaboration among various stakeholders located across the globe. FACT’s staff and a group of dedicated volunteers spent tireless hours reviewing content and testing the system,” said Ramona Repaczki-Jones, FACT’s Information Technology Manager.

ISCT Leads Inaugural Reimbursement Roundtable

On September 14, 2011, the International Society for Cellular Therapy (ISCT) led a roundtable with major US payors, healthcare providers, and industry to initiate a collaboration to address cell therapy product reimbursement.

The interest of many insured U.S. citizens was represented by participation of payor organizations including Anthem Blue Cross Blue Shield, LifeTrac, and OptumHealth.

Ed Horwitz, M.D., PHD, stated that, "this latest initiative reinforces ISCT's strategic commitment to build the necessary alignment with academia, industry and other stakeholders to expedite the development and maturation of the field and ultimately bring cell therapy treatments to patients faster." For more details, read the [full press release](#).

FDA Approves First Cord Blood BLA

The United States Food and Drug Administration (FDA) requires all cord blood units distributed after October 20, 2011 to be distributed under an approved Biologics License Application (BLA) or Investigational New Drug (IND) application. On November 10, 2011, the FDA approved the BLA for HEMACORD, cord blood units manufactured by the New York Blood Center, Inc. HEMACORD is indicated for use in hematopoietic stem cell transplantation procedures in patients with disorders affecting the hematopoietic (blood forming) system. See the [FDA press release](#) for full details.

Transplant Indications Broadened Under NMDP IND!

The FDA is allowing the NMDP to broaden the indications under its 10-CBA IND protocol to enable transplant centers to use unlicensed cord blood units under this IND when a transplant "Is indicated in conjunction with an appropriate preparative regimen for use in hematopoietic stem cell transplantation procedures for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment."

Transplant centers should review the full [NMDP Network Announcement](#) dated 10/24/11 for further instructions.

ASHI Harmonization Working Group Achieves Publication

In early 2010, The American Society of Histocompatibility and Immunogenetics (ASHI) formed the Harmonization of Histocompatibility Typing Terms Working Group with members representing clinical, registry, and histocompatibility organizations, including FACT, to harmonize histocompatibility typing terms. The goal was to define a consensual language for laboratories, physicians, and registries to communicate histocompatibility typing information. The Working Group defined terms for HLA typing resolution, HLA matching, and a format for reporting HLA assignments. In addition, definitions of verification typing and extended typing were addressed.

The 2011 article *Definitions of histocompatibility typing terms* was published in *Blood* ([doi: 10.1182/blood-2011-05-353490](https://doi.org/10.1182/blood-2011-05-353490)) and *Human Immunology* ([doi: 10.1016/j.humimm.2011.06.002](https://doi.org/10.1016/j.humimm.2011.06.002)).

JUST^{THE} **FALL 2011**
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Visit the FACT booth at the ASH Annual Meeting and Exhibition!

December 10-13, 2011

San Diego, California

Exhibitor Booth #1617

Visit with FACT staff, ask questions, and obtain information regarding upcoming educational events, how to become an inspector, and the online FACTWeb accreditation portal!

FACT Workshops to Unveil the FACTWeb Accreditation Portal!

The 2012 FACT workshops will buzz with excitement this year as we unveil the NEW online accreditation portal, FACTWeb, and give participants an opportunity to practice using the system! All FACT inspectors and personnel responsible for coordinating FACT inspections are strongly encouraged to attend.

The following workshops are open for registration:

Cellular Therapy Inspection and Accreditation Workshop

San Diego, CA on January 31, 2012

In conjunction with the BMT Tandem Meetings

Two tracks are available: The FACTWeb track and the Introduction to Cellular Therapy track. FACTWeb Track attendees must bring a laptop to use during the FACTWeb exercises.

Cellular Therapy Collection Workshop

Atlanta, GA on April 10, 2012

In conjunction with the ASFA Annual Meeting

This workshop will be a FULL day in 2012! The workshop will begin at 8 am this year in order to provide attendees practice using the FACTWeb accreditation portal. Attendees must bring a laptop to use during the FACTWeb exercises.

Cellular Therapy Inspection and Accreditation Workshop

Seattle, WA on June 5, 2012

In conjunction with the ISCT Annual Meeting

Two tracks are available: The FACTWeb track and the Introduction to Cellular Therapy track. FACTWeb Track attendees must bring a laptop to use during the FACTWeb exercises.

The **FACTWeb Track** provides detailed information and practice with FACT's new online accreditation portal. All FACT inspectors and personnel responsible for coordinating FACT inspections are strongly encouraged to attend. FACTWeb ATTENDEES MUST BRING A LAPTOP TO USE DURING THE FACTWeb EXERCISES.

The **Introduction to Cellular Therapy Inspections Track** provides introductory information related to the inspection of clinical, collection, processing, and quality management functions within a cellular therapy program. Registrants who are new to the FACT inspection and accreditation process, such as new personnel and organizations seeking initial accreditation, are encouraged to attend.

*Stay tuned for details of the Cord Blood Inspection and Accreditation Workshop
June 2012 at the Cord Blood Symposium in San Francisco, California*

Visit the FACT store for educational recordings of webinars, tutorials, and virtual roundtables!

Attention Laboratory Medical Directors!

Do you feel like you were thrown into a management role, expected to "learn as you go?" The CAP's [LMD AP3](#) is designed to provide pathologists with the education and practical skills essential to excellent performance as a laboratory medical director. Training covers the latest regulatory and compliance expectations, as well as the leadership and management skills for quality operations and patient care. The next program is April 19-20, 2012 in Chicago, Illinois

See other related opportunities by logging into FACTWeb and selecting "Related Opportunities"