

## Letter from the President

More than achieving individual recognition, real leadership is about helping others achieve their goals. For example, Lance Armstrong may no longer be in contention for the yellow jersey in this year's Tour de France, but he has set his sights on helping his team to the best possible finish. FACT consists of colleagues who demonstrate such leadership every day by helping each other navigate and resolve some of the exciting, yet confusing issues in our rapidly developing field.

### Development of 5th Edition Cellular Therapy Standards

The Standards Development Steering Committee initiated the development of the 5th edition of the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration in June in Barcelona, Spain. The purpose of this meeting, led by Carolyn Taylor, PhD, Standards Chair, was to review comments and survey responses submitted by cellular therapy programs, establish overall goals for the new edition, and coordinate subcommittee activities.

The draft of the 5th edition will be available for public comment in mid-2011, with the final version being published in March 2012. Details and updates regarding the Standards development process will be provided as they become available.

We view our position as an accrediting organization as one that is responsible for educating and assisting organizations committed to quality cellular therapy product manufacturing and administration. This newsletter is just one way FACT reaches out to transplant program and bank personnel. Most of the educational information in this edition of the newsletter is not new. It can be found in FACT publications such as the Standards and Accreditation Manual and during training sessions including webinars and workshops. FACT's infrastructure is also designed to assist accredited organizations: its committees and staff are committed to assisting in any way possible. As FACT improves its technological processes, the needs of accredited organizations and inspectors are top priorities.

We encourage you to take advantage of the variety of FACT resources available to you and look forward to working with you to rise to the challenges associated with caring for our patients.

Sincerely,

**C. Fred LeMaistre, MD**

*FACT consists of colleagues helping each other navigate and resolve the exciting issues in our rapidly developing field.*

**C. Fred LeMaistre, MD**

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Editor: Kara Wacker, MBA

#### Accreditation Report

Thirteen facilities received accreditation renewal during the second quarter of 2010. The complete report of accredited organizations in the second quarter is available at [www.factwebsite.org](http://www.factwebsite.org).

Cellular Therapy Programs	Cord Blood Banks
198 Programs Registered	42 Banks Registered
182 Programs Accredited	25 Banks Accredited
16 Applications Pending	17 Applications Pending

## **FACT Website Will Bring Personalization to Inspection and Accreditation Process**

The FACTWeb Oversight Committee is working hard with you in mind to prepare to launch the new FACT website. This website will contain exciting applications that will enhance communication among FACT committees, inspectors, and organizations:

1. The personal FACTWeb profiles will deliver pertinent updates important to you straight to your inbox regarding Standards, education, and accreditation resources.
2. The historical records will track your participation in FACT inspections, educational events, and committee activities.
3. The electronic forms will enable FACT inspectors to fulfill their requirements online in real time.
4. The ASK FACT feature will enable you to ask questions or submit comments anonymously for answers from the FACT committees, and will also allow you to rate and comment on your peers' submissions.
5. The "I want to ..." search mechanism will empower you to find the information you are looking for in record time.
6. The refreshing FACT website design will make your online experience more efficient and enjoyable.

## **Do the Cellular Therapy Standards Apply to the Use of Cord Blood Units?**

The answer to this increasingly common question is **yes**. FACT separated its cord blood banking requirements into a distinct set of standards to account for the unique and inherent differences in collection, processing, storing, and releasing cord blood units. However, the Clinical Standards still apply to clinical programs and their processing facilities using cord blood.

The FACT-JACIE Cellular Therapy Standards apply to the administration of all cellular products, including cord blood, applying the clinical standards for transplantation of allogeneic or autologous cells as appropriate. Processing requirements also apply, as processing facilities play an important role in receiving a cord blood unit from a bank, storage, and performing steps such as thawing and/or washing the unit prior to administration. Accredited programs must follow the applicable requirements in the Cellular Therapy Standards when using cord blood units such as the selection of a cell source, product receipt and processing, and therapy administration.

Standards for the collection, processing, or banking of umbilical cord and placental blood cells are found in the NetCord-FACT Cord Blood Standards. Part E of these Standards emphasizes the importance of collaboration between the bank and the clinical program to ensure the proper selection and handling of these cells. Clinical programs also have a responsibility to provide the bank information regarding cell viability and engraftment.

## **ASHI Seeks Comments on 2010 Standards**

The American Society for Histocompatibility and Immunogenetics requests public comments on the proposed 2010 Standards. The redline version of the proposed 2010 Standards allows quick identification of changes. In addition, the document entitled "2010 changes to 2009 Standards" provides a side-by-side comparison of the Standards which are proposed for change as well as an explanation for each change. Please carefully consider these proposed revisions to the current standards and send your comments to Kathy Miranda at ASHI Headquarters (kmiranda@ahint.com) no later than August 27, 2010.

The ASHI Quality Assurance and Standards Committee (QAS) asks those submitting comments to remember, "First, the proposed standards may not be made more stringent based upon membership comments without a subsequent round of public comment; therefore, such comments will be deferred until the next round of revisions unless the comments are of extraordinary importance. Second, all ASHI Standards must be at least as stringent as CMS (CLIA) regulations; therefore, proposals that advocate lesser stringency cannot be considered."

## **ISBT 128 Labeling: Fitting “ALL” those Pieces into the Puzzle**

As more cellular therapy programs are fully implementing the ISBT 128 labeling technology into their systems, they are discovering just why FACT and JACIE added the following disclaimer at the end of Appendix I, Cellular Therapy Product Labeling: “Facilities registered with ICCBBA, Inc. who have fully implemented ISBT 128 labeling should follow the ISBT 128 Standard for the location of information on the label and/or the accompanying documentation.” Interpreting FACT requirements in the context of ISBT 128 labeling can be challenging.

FACT is represented on the ICCBBA Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). Realizing the limitations to the amount of text that can be printed on a label, and recognizing the significant benefits of international standardization of coding and labeling in cellular therapy, labeling and coding decisions made by the advisory group are in compliance with FACT Standards. As specific nuances are addressed in the rapidly evolving ISBT 128 database, these precise issues will be addressed by the FACT Standards and/or Accreditation Committees as appropriate.

The FACT-JACIE Standards specifically state that the location of information on the label and/or accompanying documentation as required by ISBT 128, including whether the information is affixed, attached, or accompanying the product, is compliant for facilities who are registered with ICCBBA, Inc. In addition, FACT is happy to provide more detail and clarity related to practical issues of ISBT 128 implementation as they apply to the FACT Standards. Please submit questions you have regarding compliance with FACT labeling requirements while using ISBT 128 via this newsletter’s In Your Opinion survey. For specific questions regarding coding and labeling with the ISBT 128 system, contact the ICCBBA, which is the organization charged with the international maintenance of the database.

FACT supports the international efforts to implement ISBT 128. While the Standards currently require only the use of the ISBT 128 product terminology, FACT encourages programs to fully implement the ISBT 128 technology. The CTCLAG provides several useful resources online. This is an active group that continuously updates information and makes recommendations regarding new issues. See the inset **Online ISBT 128 Resources** for more details.

### **Additives**

To encode every possible additive in every combination used by cellular therapy programs would be a nearly impossible task. While the most important anticoagulant and/or cryoprotectant may be specifically included, additional additives may be required to be included in the accompanying documentation. This is indicated on the actual label with “yes” for other additives. Because this “yes” is affixed to the product and the complete information is within the accompanying documentation, this is compliant with the FACT Standards.

### **Online ISBT 128 Resources**

There are several resources regarding ISBT 128 that are available to you online. Visit the ISBT 128 Cellular Therapy Homepage to find announcements, meeting minutes, annual reports, and more!

*Proper terminology is the only portion of the ISBT 128 Standard that is currently required of FACT-accredited programs. However, FACT encourages programs to fully implement the ISBT 128 Standard.*

*These online documents are particularly helpful:*

Standard Terminology  
Technical Specification  
Frequently Asked Questions  
Educational Materials

*Subscribe to the ICCBBA mailing list!*

## Program Relations Committee Update

The FACT Program Relations Committee was formed to assist FACT applicant and accredited organizations by assessing their needs, providing updates, and identifying and developing ongoing services. Under the leadership of Dr. Jean Sanders of Fred Hutchinson Cancer Research Center, the Program Relations Committee ensures that the organizations we serve are aware of the latest FACT information, possess the tools they need to be successful, and are encouraged to provide input into the accreditation process.



*Jean Sanders, MD*

The results of the Program Relations 2008 Needs Assessment Survey provided the committee with opportunities to work with the Training, Standards, Quality Management, Public Relations, and FACTWeb committees, as well as the FACT Board of Directors, to answer concerns and provide tools for the organizations that are currently FACT accredited or are seeking accreditation. One of the resulting benefits include the virtual roundtables which provide an interactive forum for cellular therapy programs and banks to share experiences and ask questions on a given topic.

Topics to date have featured: Time, Effort, and Resources for FACT Accreditation and Example Assessment Programs. Additional outcomes of the survey have resulted in the development of a press kit for organizations to highlight their achievement in obtaining FACT accreditation, additional tools available on the FACT web site to aid in the accreditation process, the Just the FACTs newsletter, new webinars and tutorials on topics of interest, and enhancements in training content.

In January 2010, FACT rolled out its Anniversary Program to highlight programs continuously accredited for 10 years. The Anniversary Program includes certificates for the recognized organizations, a letter of appreciation to the institutional leaders of the accredited programs, and a follow-up survey to assess program improvements since becoming accredited. The feedback from the surveys will be used to improve the process for all applicant and accredited organizations. The Program Relations Committee wants to hear from you! Provide your input and requests regarding the FACT inspection and accreditation process to Cathy Talmadge, staff liaison to the Program Relations Committee at [ctalmadge@unmc.edu](mailto:ctalmadge@unmc.edu) or 402-559-1960.

### Quality Corner

#### Training and Competency

*Lise Hernandez, RN, BSN, MPH Clinical Administrator BMT Program Roswell Park Cancer Institute in Buffalo NY*

Hematopoietic stem cell transplant recipients require specialized care from the interdisciplinary staff who provide their care and support the transplant process. These include: physicians, physician extenders, nurses, transplant coordinators, apheresis personnel, stem cell laboratory staff and all members of the transplant inpatient and outpatient hospital team. This field takes extensive and consistent training to become proficient in the specialized field. Thus, the FACT Standards were developed to ensure appropriate training and competency evaluation for transplant personnel.

As you are aware, FACT standards require that those caring for the transplant patient are adequately trained. Define what the training period will be and how the training will be fulfilled by skills necessary and number of procedures to be performed by the trainee. Maintaining competency is just as important as learning for the first time. Define how competency will be maintained. Develop a competency checklist for each discipline. Use that checklist to design an education plan which incorporates the different responsibilities and competencies into the plan; including in-services, Grand Rounds speakers, and frequent presentations.

In addition, be sure to challenge their knowledge with an occasional "what if" scenario. You can make it fun, too. Use your imagination and get the staff involved. You will be surprised at the creative ideas that come from involving the entire Team.

## Validation Studies

### A Well-Designed Procedure Makes All the Difference

Collection Facilities, Processing Facilities, and Cord Blood Banks are required to validate critical procedures; effective validation studies include several important steps. The presenters of the FACT Qualification and Validation Webinar (Dennis Gastineau, MD; Olive Sturtevant, MHP, MT(ASCP), SBB, SLS; and Michele Carbone, MS, CLS, MT(ASCP)) listed the following steps for validation studies:

1. Design and planning
2. Writing the objectives for the study
3. Performing a risk assessment of the process
4. Determining what to measure and what are acceptable outcomes
5. Having documentation in place (SOPs, worksheets, etc.)
6. Writing conclusions based on the data
7. Obtaining formal sign-offs from applicable key personnel
8. Establishing corrective actions as necessary
9. Training employees if needed
10. Reviewing and auditing the effectiveness of corrective actions

An effective validation Standard Operating Procedure (SOP) ensures validation studies follow all of these steps. It is also important to have a clearly written validation plan for individual studies to state how a specific validation will be conducted. This plan should include the following elements:

- Test parameters
- Product or unit characteristics
- Production equipment
- Acceptable results
- Variables
- Worst-case scenarios (a set of upper and lower processing limits and circumstances which pose the greatest chance of process or product failure when compared to ideal conditions)

This newsletter's Give Us the FACTs poll gives you a chance to tell us what variables you include in your validation studies. We encourage everyone to complete this anonymous poll, because the results will be used to provide facilities with ideas to incorporate into future validation studies.



## Coordinator Commentary

### We've moved. How does this affect our FACT Accreditation?

*Sarah Litel-Smith, BSMT(ASCP)*

As many of you are aware, all FACT accredited organizations are required to notify the FACT Office, in writing, of any physical relocation of facilities. What documentation will you need?

If any part of your transplant program or bank has (or will be) relocated to new physical space, you will need to submit the following information within 90 days of your move:

- 1) A description of the new facility(ies) including a floor plan and identification of the new location.
- 2) Documentation of the date the relocation occurred (or will occur) and when processes were (or will be) started at the new location.
- 3) SOPs that were created or revised as a result of the program's or bank's relocation.
- 4) Documentation of validations, revalidations, verifications, or qualifications that were performed due to the relocation. Include a schedule for completing these assessments if these assessments are not complete at the time of submission.

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

### Congratulations to our new cellular therapy inspectors!

*Hishham Abdel-Azim, MD*

Children's Hospital Los Angeles, Los Angeles, CA

*Ellen Tambini, RN, BSN, OCN*

Hackensack University Medical Center, Hackensack, NJ

## Give Us the FACTs Poll

What variables do you include when conducting the required validation studies?

### Give Us the FACTs!

*Last month's poll: What types of electronic systems does your program or bank use?*

A wide variety of systems are used by accredited programs and banks. Commercial systems, custom made databases created in standard spreadsheet software, or a combination of both are used. The FACT Standards Committee will take the wide variation of systems used into account while drafting requirements for electronic systems.

## In Your Opinion ...

What labeling requirements are difficult to comply with while using the ISBT 128 technology?

### In Your Opinion ...

*Last month's survey: How has FACT accreditation improved your program or bank over the years??*

Quality breeds success . . . FACT accreditation has given recognition to the program, allowed growth, and increased interest from other disciplines within the institution.

## FACT accreditation on agenda for Rhodes cord blood workshop!

FACT accreditation will be a topic addressed during the Cord Blood Workshop in Rhodes, Greece, on September 24-25, 2010, which is sponsored by ESH, Eurocord, Eurocord-ed, and NetCord. This technical workshop will include the FACT Standards and accreditation process; cord blood bank structures; cord blood collection, processing, and release; and the future of cord blood banking. In addition to on-site participation, registrants have the option to participate online from home or the workplace.

## Cord Blood Inspection and Accreditation Workshop to be held in conjunction with the World Cord Blood Congress!

FACT will host a Cord Blood Inspection and Accreditation Workshop on November 3, 2010 in conjunction with the World Cord Blood Congress in Marseille, France. This workshop will provide helpful tips to achieve accreditation, explain the new fourth edition NetCord-FACT Cord Blood Standards, and address topics such as common citations and international inspections. Whether you wish to become an inspector or prepare your bank for FACT accreditation, this workshop will provide you with valuable information!

### Registration Will be Opened Soon for the Following Online Events!

*Preparing for FACT Tutorial* - *Donor Evaluation Tutorial* - *Cord Blood BLA/IND Webinar*