

Letter from the President

After our pre-inspection meeting at a recent FACT inspection, our team went to dinner. One of the topics for discussion was summer vacations and a member of our team volunteered that because of the limited professional time allowed by her facility, she was using personal vacation time to participate in the inspection we were conducting. As I questioned her sacrifice of vacation time to participate in a FACT survey, she made it clear how committed she was to helping our colleagues. Her story is not unique.

As the eyes and ears of FACT, our inspectors are critical to FACT's mission of improving the quality of cellular therapy. While conducting inspections can sometimes seem to be a thankless job, FACT does not take our inspectors for granted. We understand many of our inspectors not only use personal time to prepare for on-site inspections, but also take personal vacation days to conduct the inspections. Such dedication to their colleagues and the patients they serve is honorable, impressive, and a driving force in FACT's success.

We attempt to express our gratitude through a variety of ways, such as providing free access to education and recognizing exceptional efforts. These small acts of appreciation can in no way adequately equal the commitments FACT inspectors make. Yet our inspectors continue to quietly fulfill their responsibilities and for that we are grateful. Please tell us if you know of an outstanding effort made by one of our inspectors and share any ideas you have about how to express our appreciation to these outstanding individuals.

Sincerely,

C. Fred LeMaistre, MD

Such dedication is honorable, impressive, and a driving force in FACT's success.

Volunteers to Be Selected for Committee Appointments

The FACT Board of Directors thanks everyone for the tremendous response from volunteers interested in serving on FACT committees. Over 100 individuals expressed willingness to serve on one or more committees. As a peer-driven organization that conducts its business through volunteers, active involvement in FACT committees ensures the inspection and accreditation process reflects the needs and desires of the field. The open positions will be filled this summer, and selected members will be notified.

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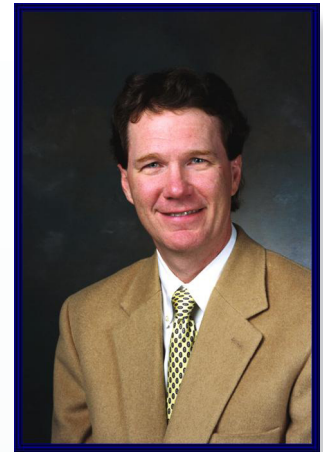
Accreditation Report

One new blood and marrow transplant program earned accreditation and ten additional organizations received accreditation renewal during the second quarter of 2011. The [complete report of accredited organizations](#) in the second quarter is available at www.factwebsite.org.

Cellular Therapy Programs	Cord Blood Banks
198 Programs Registered	47 Banks Registered
186 Programs Accredited	30 Banks Accredited
12 Applications Pending	17 Applications Pending

Inspector Spotlight: Frank Smith, MD

Frank Smith, MD, of Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Medicine, has performed FACT inspections for 12 years and is often complimented for his effectiveness as an inspection team leader. What makes him a successful inspector? He would summarize his approach into four categories: organization, communication, taking care of people, and managing expectations.



Organization

Dr. Smith takes his role as Team Leader seriously – he understands the importance of making the inspection process efficient for both inspectors and applicants. He accomplishes this with extensive preparation before the on-site inspection.

One of his claims to fame as a FACT inspector is his pre-inspection team teleconference. After the inspection date is determined and the inspection team receives the organization's pre-inspection submission, Dr. Smith's assistant sets up a teleconference for the inspection team approximately one month from the inspection date. The pre-inspection teleconference is typically organized as follows:

- Confirmation that all team members received their inspection binders
- Review of the proposed agenda
- Major concerns, missing information, or needed follow-up from the applicant
- Assignment of a team member to contact the applicant to discuss the proposed agenda

Dr. Smith also takes care to organize his inspection binder and notes. He offers to clinical inspectors this helpful tip: to prepare for the data audit portion of the clinical inspection, decide which data points you plan to audit and then transfer the data from the submitted TED forms to the data audit worksheets before the inspection. This results in less flipping through voluminous amounts of paper the day of the inspection, because you will only have to find those data points in the primary source data.

Communication

Communication among inspection team members and with the applicant is key to a good working relationship. In addition to the pre-inspection teleconference, Dr. Smith makes himself available and tells his team members that they may call him if any issues come up while they are preparing for the inspection. He arranges for the inspection team to meet the night before the inspection for dinner or for breakfast on the inspection day.

During the day of the inspection, he reiterates the importance of the working lunch. He spends about 30 minutes discussing with his inspection team issues, themes, and patterns discovered during the morning portion of the inspection. He also assesses what information is missing so that it can be requested immediately after the working lunch. The team rejoins briefly before the exit interview so that they can provide each other a summary of what they've found and have an opportunity to quietly organize.

Communication with the applicant is also critical. Introductions at the beginning of the day ensure everyone has a chance to meet and gain an understanding of each other's roles. Dr. Smith always tells the Clinical Program Director before the inspection starts that if significant issues are found, he may request a private meeting with the Director. He also communicates with the Clinical Program Director regarding the progress that is being made and a tentative time for the exit interview.

Taking Care of People

Dr. Smith believes it is the Team Leader's responsibility to set the tone of the inspection. Team Leaders must be organized, polite, and helpful to reduce anxiety. Through this behavior, everyone will understand that the FACT

inspection and accreditation process is intended to be a professional and collegial activity meant to raise everyone's quality of processes. Everyone improves and learns as a result of inspections, including the inspectors themselves, and both inspectors and applicants should try to enjoy the inspection day. Humor is a great way to diffuse tension.

To Dr. Smith, it's often the little things that count. For example, he puts forth great effort to ensure transportation to and from the airport, hotel, and inspection site for the inspection team is organized and that everyone knows where they need to be and when. He prefers to use a rental car or taxi cab to get to and from the applicant's facilities rather than an escort from the applicant to avoid a potentially awkward situation if the inspection results are poor.

Managing Expectations

While Dr. Smith bases his inspection philosophy on being collegial, he does not shy away from the obvious reality that on-site inspections are hard work. So that everything goes well and that the inspection is thorough and fair, he makes sure everyone knows what is expected of him or her.

For inspection teams, he demonstrates through example that preparation is crucial. While it is understood that FACT inspectors are busy volunteers, the last thing an inspector should do is wait to prepare until the flight to the inspection. He also asks the inspectors to complete their inspection reports before returning home if possible. If the team inspected a large and/or complex program, he will even ask the team to stay an extra night to complete the report. He notes that memories of inspection findings are not like wine – they do not get better with age.

At the time the applicant is given the proposed inspection agenda, Dr. Smith ensures applicants are given clear instructions regarding what they must contribute in order to conduct an efficient inspection. The following instructions are given during the first contact between an inspection team member (as chosen during the pre-inspection team teleconference) and the applicant's contact person, which allows the applicants a few weeks to prepare:

- A dedicated, knowledgeable person from the program must be assigned to each inspector for the whole inspection day. Clinical inspectors need two dedicated individuals: one who is familiar with the medical records and quality management documents to help the inspector find the information and one who can retrieve documents requested throughout the day.
- Documentation should be assembled in the order of the inspection checklist. Primary source data for the data audit should be in the order requested.
- If electronic records are used, the applicant should print out the required pages. Inspectors should not be expected to find electronic records themselves.
- The applicant must be prepared to give an approximately 10 minute overview of its program at the beginning of the day. Dr. Smith especially likes to know the history of the program, how many transplants are performed, and if there is any research focus.

On the day of the inspection, Dr. Smith explains to the applicant that the role of the inspectors is to be the eyes and ears of FACT. No accreditation decision is made until the report is reviewed by the Accreditation Committee. He also uses humor to warn everyone that inspectors will appear to be from Missouri (the "Show-Me" state): applicant personnel will hear the inspectors say "show me" frequently throughout the inspection.

Dr. Smith believes that the training that inspectors receive plays a major role in the success of the inspectors. He credits much of his knowledge to his trainer, Dr. Fred LeMaistre, who he refers to as, "the master of organization, communication, and thoughtfulness." In turn, he enthusiastically shares his wisdom to help other inspectors. We hope his insights into the inspection process are helpful to both inspectors and applicants as they prepare for upcoming FACT inspections.

FACT Inspectors Complete Impressive Number of Inspections in 2010

FACT is extremely proud of its inspectorate and wishes to convey its thanks to everyone who has volunteered their time and expertise to prepare for and travel to on-site inspections. FACT inspections occur continuously throughout the year, and it is important to periodically take a moment to express gratitude to these individuals and reflect on their accomplishments.

FACT inspectors completed **72** inspections in 2010. This includes review of pre-inspection submissions, preparation of personal and professional responsibilities, travel, performance of an on-site inspection, and completion of inspection reports. This is a busy group of leaders in cellular therapy and cord blood banking who take time out of their busy schedules to help their peers increase the quality of care provided to patients around the world.

Thank you, and keep up the good work!

Inspector Recognition Program

While individuals serve as FACT inspectors on a volunteer basis, FACT does provide these small tokens of appreciation in an effort to recognize our exceptional inspectors:

- When FACT receives positive comments about inspectors via the Inspection Evaluation forms or any other modes of feedback, a letter recognizing the inspector's achievements is sent to the named inspector with a FACT gift.
- Periodically, inspectors who have performed frequent inspections are recognized in the Just the FACTs newsletter.
- Inspectors attending in-person FACT workshops receive a certificate recognizing their volunteer efforts and the number of FACT inspections performed.
- When requested, FACT generates special letters detailing the contributions of inspectors and/or committee members for their volunteer work with FACT to use for tenure and promotions, enhancing their CV, and other personal and professional pursuits. If you are ever in need of a letter of recommendation, please feel free to contact the FACT office.

Congratulations to our new inspectors!

Marta Torrabadella-Reynoso, MD

Barcelona Cord Blood Bank
Cord Blood Inspector

David Ford, MSc

Cord & Marrow Transplant Program Centre for Children's
Cancer & Blood Disorders
Cellular Therapy Inspector

Thank you to Dr. William Tse

Inspectors are asked to perform two inspections per year, and Dr. Tse, of Children's Memorial Hospital Stem Cell Transplant Program went above and beyond by performing three inspections in 2010. Thank you for your dedication!

FACT Accreditation a Criterion for the U.S. News & World Report's Best Hospitals List Again

FACT accreditation was again included in the *U.S. News & World Report* methodology for its Best Hospitals list in the Cancer category. Programs accredited for only autologous transplantation received one full point, and programs accredited for allogeneic transplantation or both allogeneic and autologous transplantation received two full points. A complete list of the Best Hospitals can be found on the [U.S. News & World Report website](#). Congratulations to the FACT-accredited programs that were included in this list!

FACT Invited to Write Article Answering, "What is Cellular Therapy?"

Dr. Phyllis Warkentin, FACT Chief Medical Officer, was invited to author a column entitled, "[What is Cellular Therapy?](#)" for the Michigan-based magazine, CoSozo. This article is intended for readers who are unfamiliar with cellular therapy and its uses. It provides a well-rounded perspective of the history and future of this important field.

CoSozo publishes health and wellness publications encompassing all aspects of health and wellness from conventional to alternative, environmental, financial, and legal. One of its primary interests is providing quality information to readers about a variety of approaches to health and wellness and area experts that can assist them with their health challenges and wellness goals.

Coordinator Commentary

Helpful Hints from the FACT Accreditation Coordinators

Sarah Litel-Smith, BSMT(ASCP)

- Physician training, competency, and knowledge requirements often change with each new edition of Standards. Please remember to review and update the terminology in your documentation of physician training, competency, and knowledge. The 5th Edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration* will include changes in the required areas of competency.
- Distribution includes the transfer of products from the Collection Facility to the Processing Facility, from the Collection Facility directly to the Clinical Program, and from the Processing Facility to the Clinical Program. All requirements related to distribution apply to both Collection and Processing Facilities.
- While labels require version control, individual labels do not need to contain the version number. The version number may be on the template sheet or roll of labels.

Be sure to contact your FACT Accreditation Coordinator if you have any questions.

Transformation to Online Accreditation

Ramona Repaczki-Jones, MSE

FACTWeb Development Update

Three successful FACTWeb User Feedback Sessions took place during the last six months with over 75 participants from cellular therapy and cord blood bank organizations. During these sessions, we presented an overview of the FACTWeb Accreditation Portal and gathered information on the needs of future users of the system. The feedback was reviewed by the FACTWeb Oversight Committee chaired by Mark Litzow, MD. Useful features and functionality came out of these meetings for both applicants and inspectors. The user feedback participants, together with the FACTWeb Oversight Committee, will begin testing the FACTWeb accreditation portal in the fall of 2011, prior to release on March 1, 2012.

Website Statistics

The FACT Website, released in September 2010, is experiencing impressive web activity, averaging 166 visitors per day. The traffic is directed to the FACT website by the following sources:

- 29% from search engines
- 45% from referring websites
- 26% from direct visits

From April 1, 2011 to July 15, 2011, the 17,547 visits to the FACT website came from the following countries:

1. United States
2. Canada
3. Italy
4. Australia
5. United Kingdom
6. Greece
7. India
8. Mexico
9. France
10. Germany

ASK FACT

The ASK FACT button on the FACT website, located on all pages, has been a very popular feature. Visitors ask various questions related to FACT accreditation, standards, education, FACTWeb, and inspector-related topics. A summary of the questions and answers will be published on the FACT website with a rating/comment mechanism to determine how useful the information is to the web visitors.

Congratulations to Nancy Edger Hall, the winner of FACT's Facebook drawing!

FACT's Facebook page has reached over 100 fans, and Nancy is the lucky recipient of a free webinar or tutorial of her choice! Encourage your colleagues to ["like" our page](#) today!

Quality Corner

Self-Assessments in Preparation for a FACT Inspection

“...The readiness is all.” (Hamlet, V ii, 234-237)

Jill Hempel, MS, ASQ-CMQ/OE

A self-assessment in preparation for a FACT inspection is a retrospective review of activities in an organization to determine if they are performed according to written procedures and follow FACT Standards. It is essentially a large-scale internal audit of compliance to the Standards. Objectives for conducting self-assessments in preparation for a FACT inspection include:

- Determine the current state of readiness of the organization to undergo a FACT inspection.
- Adopt a method of ensuring continuous readiness for FACT inspection.
- Identify areas for improvement within the organization.
- Create methods for increasing communication in the various facilities of the organization.

These objectives will help to determine whether the work performed by the organization is in compliance with the FACT Standards. The self-assessments also help verify that policies and procedures are properly implemented. For example, the FACT Standards specify that processing worksheets must be completed concurrently with the processing procedure; a self-assessment will uncover if that is truly taking place. These internal self-assessments confirm whether or not personnel comply with SOPs. Just like audits conducted as part of the Quality Management Plan, these self-assessments can follow the “Plan-Do-Check-Act” (PDCA) Cycle, and include documentation for self-assessment performance, reporting, corrective action, follow-up, and closure.

Self-assessments prior to a FACT inspection should reduce anxiety of the organization’s personnel during preparation for the actual inspection. The entire FACT inspection experience should be demystified, allowing the organization and its personnel to feel confident and ready to proudly show FACT inspectors their processes.

Mark Your Calendars for the 5th Edition Cellular Therapy Standards

The 5th edition of the *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*, along with its accompanying Accreditation Manual, is scheduled for publication on March 1, 2012. Cellular therapy programs must be in compliance with the new edition by May 30, 2012.

FACT will contact organizations whose inspection and accreditation process will be beginning around this time as a reminder and to work with them to ensure their accreditation does not expire.

The 5th edition Cellular Therapy Standards will be released at the same time as the new FACTWeb online accreditation portal.

Three FACT Workshops are Open for Registration!

September 14, 2011

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the ISCT North American Regional Meeting in Charlottesville, Virginia.

This training workshop is designed to explain the requirements for FACT accreditation of cellular therapy programs. The Processing Track focuses on Processing Facility requirements. The Overall Cellular Therapy Program Track provides introductory information on inspections of clinical, collection, processing, and quality management functions.

October 26, 2011

Cord Blood Inspection and Accreditation Workshop

in conjunction with the World Cord Blood Congress in Rome, Italy.

This training workshop is designed to explain the requirements for FACT accreditation of cord blood banks. Preliminary agenda items include cord blood donor and unit testing; validation studies; controlling collection supplies and reagents; and cord blood search, selection, and release.

January 31, 2012

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the BMT Tandem Meetings in San Diego, California.

Two tracks are available to registrants:

- 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.

Save the date for the following workshops:

April 10, 2012

Cellular Therapy Collection Workshop

in conjunction with the ASFA Annual Meeting in Atlanta, Georgia.

June 5, 2012

Cellular Therapy Inspection and Accreditation Workshop

in conjunction with the ISCT Annual Meeting in Seattle, Washington.