6th EDITION OF FACT-JACIE STANDARDS

Sections CM and C

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JACIE joint accreditation committee

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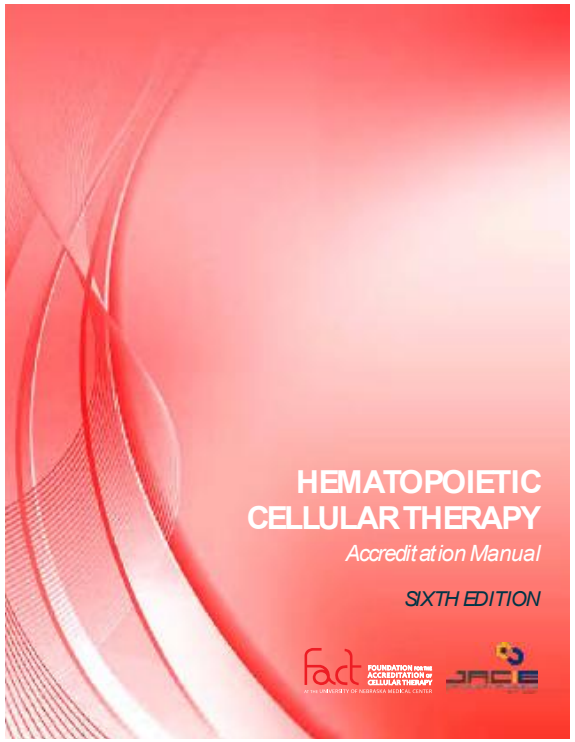
6th edition


HEMATOPOIETIC
CELLULAR THERAPY
Accreditation Manual
SIXTH EDITION

6th EDITION

PUBLIC CONSULTATION

- 90 meetings
- 900+ hours of work by volunteers
- Number of public comments: 1,563 (94% increase from 5th Edition)
- Number of contributors: 180 individuals and groups (117% increase from 5th Edition)
- Number of countries represented: 15 (Increase of 7 from previous year)

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SCOPE

6TH EDITION

- INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

5TH EDITION

- INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

Clinical	Collection Marrow	Collection Apheresis	Processing
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Marrow Collection Facility	C2 Apheresis Collection Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	CM4 Quality Management	C4 Quality Management	D4 Quality Management
B5 Policies and Procedures	CM5 Policies and Procedures	C5 Policies and Procedures	D5 Policies and Procedures
B6 Allogeneic and Autologous Donor Selection, Evaluation, and Management	CM6 Allogeneic and Autologous Donor Evaluation and Management	C6 Allogeneic and Autologous Donor Evaluation and Management	D6 Equipment, Supplies, and Reagents
B7 Recipient Care	CM7 Coding and Labeling of Cellular Therapy Products	C7 Coding and Labeling of Cellular Therapy Products	D7 Coding and Labeling of Cellular Therapy Products
B8 Clinical Research	CM8 Process Controls	C8 Process Controls	D8 Process Controls
B9 Data Management	CM9 Cellular Therapy Product Storage	C9 Cellular Therapy Product Storage	D9 Cellular Therapy Product Storage
	CM10 Cellular Therapy Product Transportation and Shipping	C10 Cellular Therapy Product Transportation and Shipping	D10 Cellular Therapy Product Transportation and Shipping
			D11 Distribution and Receipt
			D12 Disposal
B10 Records	CM11 Records	C11 Records	D13 Records
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	

MAIN ISSUES

1. HLA typing laboratory accreditation
2. Stability studies
3. Deviation management
4. Minimum number of marrow collection procedures
5. Continuing education
6. Accreditation for chimerism testing
7. ISBT 128 implementation
8. Central venous catheter placement
9. Qualification of facilities prior to distribution
10. Clinical outcome requirements

Special Request for Public Comments: Evaluating One-Year Survival in FACT-JACIE Standards

posted 10 Nov 2014 03:07 by Eoin McGrath [updated 10 Nov 2014 03:07]

FACT and JACIE are finalizing the sixth edition of the FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. Based on public comments and strategic initiatives, an additional standard is proposed:

> *"The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data. If expected one-year survival outcome is not met, the Clinical Program shall submit a corrective action plan."*

The FACT-JACIE Standards already require internal outcome analyses. With the introduction of published comparative national and international data, Clinical Programs have additional resources to evaluate their one-year survival rates and improve upon them when they fall below expected ranges. Note that this standard is written with "should," signifying that it is a recommendation. If a Clinical Program does not meet expected outcomes, accreditation will not be withheld but the program will be required to submit a corrective action plan for achieving expected one-year survival.

The proposed Standard, general principles and limitations, proposed implementation process, and instructions for submitting comments are described in the official Request for Public Review and Comment: One-Year Survival for Allogeneic Transplant Requirements. We strongly encourage review of this document to gain a full understanding.

Access the online comment form at www.surveymonkey.com/s/clinicaloutcomes.

Common standards

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- "Product" =
- "Cellular therapy product"

- Quality Management Supervisor = Quality Manager

General points

Communication

- Communication between all involved parties is essential for the success of the program
- Lies at the very heart of FACT-JACIE philosophy
- Distinguishes FACT-JACIE from most regulatory / accreditation / certification requirements
- Look for evidence of active and regular communication

DOCUMENT MANAGEMENT

- Reference to a current version of orders, worksheets, reports, labels, and forms.
- There shall be policies and procedures for development, approval, implementation, review, revision, and archival of all critical documents.
- Agreements shall be dated and reviewed on a regular basis.

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DONOR ADVOCATE

- A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.

Bone Marrow Transplantation (2014), 1–4
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www.nature.com/bmt

ORIGINAL ARTICLE

The impact of improved JACIE standards on the care of related BM and PBSC donors

C Anthias[1,2], ME Ethell[3], MN Potter[2], A Madrigal[1,2] and BE Shaw[1,2,3]

Discrepancies exist between the care of unrelated donors (UDs) and related donors (RDs), particularly regarding medical suitability criteria, consenting procedures and donor follow-up. Changes to the most recent JACIE standards have addressed these issues. We studied 208 RDs who underwent PBSC or BM donation in a single centre during 2004–2013 to determine the impact of regulatory changes on donor care, and assessed the safety and efficacy of stem cell donation in donors not meeting UD medical suitability criteria. We observed significant improvements in donor consenting procedures ($P=0.003$) and donor follow-up ($P=0.007$) after stipulations in these areas were introduced. We saw a higher incidence of serious adverse events (SAEs) in RDs not meeting UD suitability criteria ($P=0.018$), and a higher incidence of SAEs in donors ≥60 years ($P=0.020$). Haematopoietic progenitor cell donation is less safe in RDs who do not meet UD criteria for medical suitability. Although changes to JACIE standards have improved practice, development of specific medical suitability for RDs and guidelines around 'grey areas' where risks to a donor are unclear or theoretical, will be important in improving RD safety and standardising practice.

Bone Marrow Transplantation advance online publication, 10 November 2014; doi:10.1038/bmt.2014.260

PREGNANCY TEST

- A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

NOW INCLUDED IN PART C

- SOP for Administration of blood products.
- All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- Review and approval of the validation plan, results, and conclusion by the Facility Director or designee and the Quality Manager or designee.
- The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

EDUCATION

- 10 hours per annum
- Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and apheresis.

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MANAGE ERRORS, DEVIATIONS

- Changes to a process shall include evaluation of risk to confirm that they do not create an adverse impact anywhere in the operation and shall be validated or verified as appropriate.
- An approved validation plan, including conditions to be validated.
- All investigation reports shall be reviewed in a timely manner by the Processing Facility Director, Medical Director, or designee and the Quality Manager.
- Investigations shall identify the root cause and a plan for short- and long-term corrective actions as warranted.
- Follow-up audits of the effectiveness of corrective actions shall be performed in a timeframe as indicated in the investigative report.

MANAGE ERRORS, DEVIATIONS

- Documentation shall include a description of the event, the involved individuals and/or cellular therapy products, when the event occurred, when and to whom the event was reported, and the immediate actions taken.
- Cumulative files of errors, accidents, biological product deviations, serious adverse events, and complaints shall be maintained.
- Cumulative files shall include written investigation reports containing conclusions, follow-up, corrective actions, and a link to the record(s) of the involved cellular therapy products.

RELATED DONORS

- Family members and legally authorized representatives should not serve as interpreters or translators.
- Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.
- Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

RELATED DONORS

- CM/C6.1: Written criteria for donor evaluation and management

- CM/C6.2 : Donor information and consent
  CM/C6.2.6.1: Consent obtained by a licensed healthcare professional that is different from the primary healthcare professional overseeing care of the recipient
  CM/C6.2.1.3: Rights of the donor or authorized representative to review the results of testing
  CM6.2.3: Family members and legally authorized representatives should not serve as translators

CM/C6.3 : Suitability for cell collection
  CM/C6.3.3: Pregnancy testing
  CM/C6.3.4: Choice of laboratory for donor testing

CM/C6.4 : Additional requirements

RELATED DONORS

DONOR ADVOCATE

- A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms as defined by applicable laws.

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New standards

PART CM

- CM2.3.1 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

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PART CM SOPS

- CM5.1.5 Prevention of mix-ups and cross-contamination.
- CM5.1.12 Hygiene and use of personal protective attire.
- CM5.1.13 Emergency and disaster plan related to the marrow collection procedure.

PART CM

- CM6.3.5 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- CM6.3.6 There shall be a written order from a physician specifying, at a minimum, timing and goals of collection.
- CM7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."
- CM8.15.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.
- CM9.1 Marrow Collection Facilities shall control storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of products.

PART C

- C2.1.2 There shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination in outpatient units where collection is performed.
- C4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.

PART C

BACKUP COVERAGE OF STAFF (CM3.3.2, C3.4.1, D3.4.1)

- Facilities were often found to have minimal staff that was only sufficient should no staff members be absent.
- To provide sufficient coverage should staff members become unavailable, facilities must have a minimum of one designated trained individual with an identified trained backup.

PART C

- C4.13.1 Qualification plans shall be reviewed and approved by the Apheresis Collection Facility Director or designee.
- C4.14.2 Each validation shall include:
- C4.14.2.1 An approved validation plan, including conditions to be validated.
- C4.14.2.2 Acceptance criteria.
- C4.14.2.3 Data collection.
- C4.14.2.4 Evaluation of data.
- C4.14.2.5 Summary of results.
- C4.14.2.6 Review and approval of the validation plan, results, and conclusion by the Apheresis Collection Facility Director or designee and the Quality Manager or designee.

PART C SOPS

- C5.1.4 Management of donors who require central venous access.
- C5.1.6 Administration of blood products.
- C5.1.7 Prevention of mix-ups and cross-contamination.
- C5.1.15 Recalls of equipment, supplies, and reagents.
- C5.1.17 Hygiene and use of personal protective attire.

PART C

- C6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.
- C7.4.6 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, "For Nonclinical Use Only."

PART C

- C8.3 Equipment shall be inspected for cleanliness prior to each use and verified to be in compliance with the maintenance schedule daily prior to use. Equipment shall also be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.
- C8.3.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.
- C8.3.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.
- C8.16.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

PART C

ECP

- C8.17 There shall be a policy addressing safe administration of ECP.
- C8.17.1 Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe administration of ECP.
- C8.17.2 The ECP procedure shall be performed according to written standard operating procedures of the facility performing the procedure appropriate for the clinical condition of the patient.
- C8.17.3 A final report of the details of ECP administered shall be documented in the patient's medical record.

PART C

- C11.6.5 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.
- C11.6.9.4 System assignment of unique identifiers.

Changed Standards

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CORD BLOOD

- Cord blood units that have not been red cell reduced prior to cryopreservation shall be washed prior to administration.
- Cord blood units that have been red cell reduced prior to cryopreservation should be diluted or washed prior to administration.

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CHECKING DRUGS & PATIENT ID

- Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified people shall verify and document the drug and dose in the bag or pill against the orders and the protocol, and the identity of the patient to receive the therapy.

STORAGE IN CF

- Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

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TRANSPORT

- The cellular therapy product shall be transported and/or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.
- Cellular therapy products that are transported and/or shipped from the collection site to the Processing Facility shall be transported and/or shipped in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.

CF DIRECTOR EXPERIENCE

- The Apheresis Collection Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within the accreditation cycle.

STAFFING

- The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one designated trained individual with an identified trained backup to maintain sufficient coverage.

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TIME TO ENGRAFTMENT

- For HPC products intended for hematopoietic reconstitution, time to engraftment following product administration measured by ANC and platelet count shall be analyzed.

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URGENT MEDICAL NEED

- Cellular therapy products that do not meet allogeneic donor eligibility requirements, or for which allogeneic donor eligibility determination is not yet complete, shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient's physician and the Processing Facility Medical Director or other designated physician.

RETURNED PRODUCTS

- When cellular therapy products are returned to the Processing Facility after distribution for administration, there shall be documentation in the Processing Facility records of the events requiring return, the temporary storage temperature when at the clinical facility, the results of inspection upon return, and subsequent action taken to protect product safety and viability.

Labels

CELLULAR THERAPY PRODUCT LABELING

6th	6th	6th	6th	6th	5th	5th	5th	5th	5th
Element	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration	Element	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration
Unique numeric or alphanumeric identifier	AF	AF	AF	AF	Unique numeric or alphanumeric identifier	AF	AF	AF	AF
Proper name of product	AF	AF	AF	AF	Proper name of product	AF	AF	AF	AF
Product attributes			AC	AC	Product modifiers	AF		AF	AF
					Product attributes (manipulations)			AC	AC
Recipient name and/or identifier		AT	AT	AT	Recipient name and identifier (if applicable)	AF	AT	AT	AT
Identity and address of collection facility or donor registry		AT	AC	AC	Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC	Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT	Approximate volume		AT	AT	AT
Name and quantity of anticoagulant and other additives		AC	AC	AC	Name and volume or concentration of anticoagulant and other additives		AT	AT	AT

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CELLULAR THERAPY PRODUCT LABELING

6th edition					5th edition				
Donor identifier and (if applicable) name		AT	AT	AT	Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature range		AT	AT	AT	Recommended storage temperature range		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see CM7.4.2, C7.4.2, D7.4.2).		AT	AT	AT	Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4).		AT	AT	AT
As applicable:					If applicable:				
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT	Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"		AT	AT	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT	Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT	Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT
Identity and address of processing and distribution facility(ies)			AC	AC	Identity and address of processing and distribution facility(ies)			AC	AC
Statement "Do Not Irradiate"			AT	AT	Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AC	AC	Expiration Date (if applicable)			AT	AT
Expiration Time (if applicable)			AC	AC	Expiration Time (if applicable)			AC	AT
ABO and Rh of donor (if applicable)			AC	AC	ABO and Rh of donor (if applicable)			AC	AC

CELLULAR THERAPY PRODUCT LABELING

6th edition					5th edition				
RBC compatibility determination (if applicable)				AC	RBC compatibility testing results (if applicable)				AC
					Statement "Properly Identify Intended Recipient and Product"				AT
Statement indicating that leukoreduction filters shall not be used.				AT	Statement indicating that leukoreduction filters should not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT	Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
					Statement "For Use By Intended Recipient Only" (if for allogeneic recipient)				AT
					Statement "For Nonclinical Use Only" (if applicable)				AT
Date of distribution				AC	Date of distribution				AC

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CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING AND TRANSPORT ON PUBLIC ROADS

6th edition					5th edition		
Element	Inner container document	Outer container label			Element	Inner container document	Outer container label
Date of distribution	AC	AC			Date of distribution and time, if appropriate	AC	AF
Time of distribution, if appropriate	AC	AC					

Removed standards

5th edtion Standards not included in the 6th edition

PART CM: TESTING

REMOVED

- CM6.3.9 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- CM6.3.10 A red cell antibody screen shall be performed on allogeneic recipients.
- CM7.3.2 Marrow Collection Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the cellular therapy product.

PART C:

REMOVED

- C4.3.3 A description of minimal trainer qualifications and a uniform plan for staff training.
- C4.4 The Quality Management Plan shall include, or summarize and reference, policies and procedures for development, approval, validation, implementation, review, revision, and archival for all critical processes, policies, and procedures

PART C:

REMOVED

- C4.10.1.7 Follow-up for effectiveness of corrective action.
- C4.10.5 Deviations from Standard Operating Procedures shall be documented.
- C4.10.5.2 Unplanned deviations and associated corrective actions shall be reviewed by the Apheresis Collection Facility Director or designee.
- C4.10.6 There shall be a defined process improvement plan that includes policies or procedures for the recognition and investigation of the cause of all issues that require corrective action.

PART C:

REMOVED

- C5.1.3 Donor treatment.
- C5.1.16 Facility management and monitoring.
- C6.4.1 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.
- C6.4.2 A red cell antibody screen shall be performed on allogeneic recipients.
- C7.3.2 Apheresis Collection Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the cellular therapy product.
- C11.1.2.1 If records are maintained in more than one location, there shall be a system to ensure prompt identification, location, and retrieval of all records.

FACT-JACIE 6th Edition

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