Standards Development

Helen Heslop, MD
Purpose of Presentation

• Describe the Standards Development Process
• Explain the relationship among the FACT Standards
• Provide an overview of the Clinical Standards
  • Immune effector cell-specific standards will be discussed in the next session
Advantage of FACT Standards

• Cornerstone of FACT accreditation program
  • Clear list of requirements cellular therapy programs must meet
  • Accreditation activities are based upon the Standards
FACT Standards

• Evidence-based Standards:
  • Published medical literature when available
  • Accepted scientific theory and expert consensus

• Written by world-renown experts in the field, filling a variety of professional roles
  • Clinicians, laboratory scientists, technologists, quality experts

• Each edition published for public comment
  • Opportunity to provide feedback and participate in the Standards development process

• FACT Standards are not best practices
  • Define minimum requirements to reach level of quality worthy of accreditation
  • Allows flexibility in methods/processes to meet requirements
Standards Committee

• International representation
  • Hematopoietic Cellular Therapy Committee currently consists of members from 10 different countries

• World-renowned experts

• Variety of professional roles
  • Clinicians, scientists, technologists, quality experts, etc.
Factors in Standards Revision

- New developments
  - Evidence-based
- Feedback from current processes
  - Standards
  - Accreditation
- Input from related
  - Organizations
  - Individuals
Example of Different Methods to Comply with a Standard

- **Standard**: B1.2 The Clinical Program shall use cell collection and processing facilities that meet FACT Standards with respect to their interactions with the Clinical Program.

- **Ways in which this requirement could be met**:
  - Clinical program is integrated with collection and processing facilities
  - Clinical program contracts services with external collection and processing facilities that are FACT-accredited
  - Many more variations exist in FACT-accredited programs
Precedent-Setting Decisions

- Prevents inconsistent interpretation of Standards
- May require additional information
  - Standards Committee intent
  - Medical literature
  - Commonly accepted practices
- Decision is made at a global level rather than considering only an individual program
Announcements of Accreditation Committee Interpretations

- Newsletter articles
- Guidance updates
- Weekly emails
- Webinars
- Workshops
Leveraging FACT’s/HPC Transplant Field’s Expertise

- Proven standards and voluntary accreditation program
  - Forum for expert collaboration
  - Experience with drafting minimal standards and applying them to clinical and laboratory sites
  - Knowledge of cell therapy as standard of care and applying lessons learned to other specialties

- Collaboration with experts and professional societies is critical
  - Connect with specialists in various clinical areas as well as facilities manufacturing clinical research products
  - Assess relevance and usefulness of standards in new field
  - Determine necessary requirements; rely on relevant expertise for therapy-specific standards
Relationship Among Standards

- Standards that can be applied to any cell type or clinical indication and included in all other sets of Standards
- Specialized Standards for specific accreditation goals

COMMON STANDARDS FOR CELLULAR THERAPIES

Draft Immune Effector Cell Standards

Future
Scope of FACT Common Standards

- Includes basic fundamentals applicable to any cell source or therapeutic application
  - Discipline-specific or product-specific standards will be added going forward
  - Immune Effector Cell Standards first specialized requirements originating from Common Standards
- Serves as the basis for accreditation of fundamental quality requirements in cellular therapy
- Collection, processing, and/or administration of cellular therapy products from living donors intended for human administration
- Processes, facilities, personnel, and quality management programs for:
  - Minimally or more than minimally manipulated cells collected from non-hematopoietic sources (see definition at 21 CFR 1271.3(f))
  - Cells collected from hematopoietic sources and processed and administered under approved research protocols for new indications or non-homologous use (e.g., MSCs)
  - A variety of cell types, including pancreatic islets, hepatocytes, and others
Scope of FACT-JACIE Hematopoietic Cellular Therapy Standards

- Hematopoietic progenitor cells (HPC) and donor lymphocyte infusions (DLI)
- Collection of cells from marrow and peripheral blood
- Cellular processing
- Clinical administration of HPCs and DLIs from marrow, peripheral blood, and placenta/umbilical cord blood

Requires all cellular therapy programs to:

- Maintain a comprehensive Quality Management Program
- Utilize validated methods, supplies, reagents, and equipment
Scope of NetCord-FACT Cord Blood Banking Standards

• Banking of placental and umbilical cord blood for clinical use
• Screening, testing, and eligibility determination of the maternal and infant donor
• Collection of cord blood cells, regardless of methodology or site of collection
• All phases of processing, cryopreservation, storage, and distribution
• Making unit available for administration, either directly or through a registry
• Search, selection, and release processes of specific cord blood units
Clinical Program Standards
General Requirements

• Integrated medical team in geographically contiguous or proximate space and with common protocols

• Use collection and processing facilities that meet FACT Standards
  • Relationship with manufacturers is discussed in next presentation

• Abide by applicable laws and regulations

• Program Director and one other physician must be in place for at least 12 months prior to accreditation
Minimum Number of Patients

• Demonstrates program experience

• Allows program to audit processes and collect data to:
  • Perform quality management functions
  • Provide evidence of compliance with Standards

• Distinct numbers outlined for hematopoietic cellular therapy related to allogeneic/autologous, adult/pediatric, and single/multiple sites

• Currently drafted at a minimum of five for immune effector cell programs
  • Accreditation process can begin before five is reached
  • Accreditation will be awarded after five
Clinical Unit

- Designated inpatient unit that minimizes airborne microbial contamination
- Designated area for outpatient care that protects patient from transmission of infectious agents and allows for appropriate patient isolation, administration of intravenous fluids, medications, and/or blood products, and confidential examination and evaluation
Personnel Requirements

• Clinical Program Director
  – Appropriately licensed to practice medicine and be specialist certified
  – Have two years of experience as an attending physician
  – Responsible for all aspects of Clinical Program

• Attending Physicians
  – Appropriately licensed to practice medicine and specialist certified

• List of training requirements in this section

• Other requirements for mid-level practitioners, nurses, consulting physicians, and other staff
Donor Selection, Evaluation, and Management

• Applicability to a particular applicant depends on the program’s role in selection and evaluation of donors and collection

• Must have written criteria

• Informed consent

• Evaluation of the donor for suitability, or medical fitness to undergo the collection procedure

• Testing requirements

• Allogeneic donor requirements for recipient compatibility
Recipient Care

- Recipient informed consent
- Concurrent recordkeeping
- Safe administration of preparative regimens (chemotherapy and radiation therapy)
- Safe administration of cellular therapy products
- Recipient monitoring for GVHD, post-transplant vaccination schedules, discharges to facilities adequate for post-transplant care (HPC transplant-specific)
- Extracorporeal photopheresis
Clinical Research and Data Management

• Formal review of investigational treatment protocols and patient consent forms as required by applicable laws and regulations
• Disclosure of conflicts of interest in clinical research
• Collect data in CIBMTR data forms
Records

• Specific records must be maintained
  • Listed in Standard B10

• Recipient, donor, and employee records must be maintained in a confidential manner
Becoming Familiar with the Standards

• Review the information on the FACT website at www.factwebsite.org
  – Read the Standards
  – Consult the Accreditation Manual for explanations and examples
• Subscribe to and read the FACT newsletter and emails
  – Inspector trainees are already subscribed
  – If you are not receiving weekly emails from FACT, please let us know
• Ask the FACT staff questions
  – Contact information is on FACT website
Educational Opportunities

• Live events (calendar found on FACT website)
  • Workshops
  • Webinars

• Recorded events (found in Store on FACT website)
  • Recordings of past webinars
  • Tutorials
Thank You