

Harmonising Standards in SCT: An Update on AHCTA Initiatives

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Advancing Transfusion and
Cellular Therapies Worldwide

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cellular therapy accreditation**

Original Mission

AHCTA members commit themselves to the harmonisation of their respective standards with the objective of creating a single set of quality, safety and professional requirements for cellular therapy including haematopoietic stem cell (HSC) transplantation.

WBMT Mission of AHCTA

Function is to recommend to the Executive Committee policies, programs, or actions in the area of any/all issues pertaining to regulatory and accreditation matters, practices and codes with both inter- and intra-national implications. This involves all aspects of cellular therapy (or stem cell transplant) procedures related to Recipient, Donor, Graft Processing. The committee will coordinate efforts with the Dissemination and Education Standing Committee activities where applicable.

Member Organizations

- AABB
- Asia Pacific Blood and Marrow Transplantation Group
- American Society for Blood & Marrow Transplantation
- Eastern Mediterranean Blood and Marrow Transplantation
- European Federation for Immunogenetics
- European Group for Blood & Marrow Transplantation
- Foundation for the Accreditation of Cellular Therapy
- International NETCORD Foundation
- International Society of Blood Transfusion
- International Society for Cellular Therapy (Europe)
- Joint Accreditation Committee ISCT (Europe)-EBMT
- National Marrow Donor Program
- World Marrow Donor Association

Projects to date

- Position Paper, “Towards a Global Standard for Donation, Collection, Testing, Processing, Storage, and Distribution of Allogeneic HSC and Related Cellular Therapies”
- Comparison of Cellular Therapy Standards “crosswalk”
- Survey on country specific import/export requirements (through WMDA)
 - Posted on WMDA web site
- Resources Compendium on web site



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Documents

Title	Updated	Link
Mission statement		
Towards a Global Standard for Donation, Procurement, Testing, and Distribution of HSC and Related Cellular Therapies Position Paper (revised 27 May 2008)	27-05-2008	

Comparison of Cellular Therapy Standards

Crosswalk documents.

Note: These crosswalks were prepared for the purpose of providing basic information on organizational activities for global comparison and gap analysis. They are NOT intended to be used as a reference or source document and are not endorsed by any of the participating organizations. All standards are undergoing revision at the time of web posting. Efforts will be made to update the information as soon as possible. Users are directed to each organization's standards and accreditation policies for reference and the crosswalk should not take the place of a thorough line-by-line review of the Standards.

1 Donor standards	29-10-2010	
2 Background etc	03-01-2009	
3 Regulation & Inspection	13-09-2010	
4 Quality Management standards	03-01-2009	
5 Cell Collection standards	03-01-2009	
6 Labelling & Coding	07-06-2010	
7 Cell Processing	03-01-2009	

Surveys

Import & Export Requirements



This [import- and export survey](#) was originally started in 2003. In 2009 WMDA began updating the data and you are invited to participate [here](#).

Comparison of Inspection Processes

The tables are populated with data from the FACT-JACIE (4th ed.), Netcord-FACT (4th ed.), WMDA and AABB (4th ed.)

Definitions	Abbreviation
WMDA 208	W
FACT-JACIE 4th Ed	F-J
Netcord-FACT 4th Ed	NC-F
AABB 4 Ed	AA
Y	years

REQUIREMENTS	W	F-J	NC-F	AA
Facilities Inspected & Accredited				
Clinical Facility(ies) (Performing infusions)		X		
Adult		X		
Pediatric		X		
Both		X		
Collection Facility(ies) or Sites		X	X	X
Processing Facilities(ies)		X	X	X
Cord Blood Bank			X	X
Unrelated donor Registry	X			
Categories of Accreditation				
Autologous Cellular Therapy Products		X		X
Allogeneic Cellular Therapy Products		X		X
Both Autologous and Allogeneic Products		X		X
Cord Blood	X		X	X
Unrelated	X		X	X
Directed donor			X	X
Autologous			X	X
Nature of Inspection				

Resources



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Resources

This is a compendium of resources prepared by the organisations collaborating within AHCTA. Each organisation is responsible for the contents of their materials.

Last updated: 19 July 2010

Assessment/Inspection Tools

- AABB**
 - AABB Information (*member access restricted*)
 - AABB Assessment tool (*member access restricted*)
- FACT**
 - FACT-JACIE Cellular Therapy Accreditation Manual (*Free*)
- JACIE**
 - Inspection Checklist (*look for JACIE Inspection Checklist 4th ed ver [X].xls*)
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)
- NETCORD**
 - Netcord-FACT Cord Blood Accreditation Manual (*Free*)
- WMDA**
 - WMDA Accreditation Handbook

Educational programs

- AABB**
 - AABB Resources (*some member restricted/discounted*)
 - Circular of Information
 - Learning Centre
- FACT**
 - FACT Inspector Training Webinars (*Free to inspectors, for sale to non-inspectors*)
 - FACT Tutorials (*Free to inspectors, for sale to non-inspectors*)
 - Donor History Questionnaire
 - FDA Cellular Therapy Liaison Meetings (2005-2009)
- ICCBBA (cellular therapy)**
 - ISBT 128 Information
- ISCT**
 - ISCT Resources (*some member restricted/discounted*)
 - Laboratory Resources
- JACIE**
 - Link to Events
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)

Quality Plan Information

- AABB**
 - Quality Plan Publications
- FACT**
 - Quality Management Webinar Series
- JACIE**
 - Quality Management Guide (2008)
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)

Publications (books, videos, slide sets)

- AABB**
 - Publication (book) on Methods
 - Publication (book) on Stem Cell Transplant
 - Quality Plan Publications
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)
- Product Assistance for Cellular Therapies (FACT)**
 - Cell Therapy: cGMP Facilities and Manufacturing

Sample procedures

- AABB**
 - AABB Commendable practices
- ISCT**
 - Laboratory resources (*Free*)
- JACIE**
 - Quality Management Guide (2008)
 - Sample Quality Management Materials
 - Suggested list of Policies and Standard Operational Procedures (SOPs)
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)
- Product Assistance for Cellular Therapies (FACT)**
 - SOP Requests

Standards

- AABB**
- ASHI**
- EFI**
- FACT/JACIE**
- ICCBBA (cellular therapy)**
- NETCORD**
- NMDP**
- WMDA**

Other resources

- ISSCR International Society for Stem Cell Research (ISSCR)**
 - International, national and local regulations, guidelines and resources
- National Marrow Donor Programme**
 - NMDP network website (*requires login*)
- NMDP Radiation Injury Treatment Network**

Organisations & Associations

- American Association of Blood Banks
- American Society for Blood & Marrow Transplantation
- Asia Pacific Blood and Marrow Transplantation Group
- European Federation for Immunogenetics
- European Group for Blood & Marrow Transplantation
- Foundation for the Accreditation of Cellular Therapy
- International NETCORD Foundation
- Joint Accreditation Committee (ISCT (Europe)-EBMT)
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Current Project

- Scope: To develop a consensus or guidance on minimal qualifications for training of staff who collect HPC (A) and HPC (CB) products
 - Focus on international audience
 - Developing countries
 - New programs in underserved areas
- Survey posted and distributed
 - AHCTA and participating organizations
 - Closes February 28, 2011
 - 400 responses to date
 - http://www.surveymonkey.com/s/AHCTA_Survey

Why? Training is first step in developing a program

- All accrediting programs require adequate training and documentation for collection staff
- Different countries
 - Varying requirements
 - Array of “titles” and qualifications
- Novel mechanisms for training and documentation needed
- Will focus on HPC, Apheresis and HPC, Cord Blood
 - May consider BM at later time
- **Benefits:**
 - Learn from one another
 - Maximize limited resources
 - Avoid “reinventing the wheel”
 - Increase likelihood of compliance

Aligns with Mission of WBMT

Promote excellence in stem cell transplantation and cellular therapy including stem cell donation on a global scale



AHCTA Focus Thus Far

- Providing variety of resources to developing countries and SCT programs
- Providing consensus documents
 - Serve as resource and points to consider
 - Posted on www.ahcta.org
 - Current project – training of collection staff
 - Survey may provide examples of compliance for staff training
 - Drafting of Consensus Paper

How it works

- Standing monthly conference calls
 - Access number +/- Go To Meeting
- Representative and alternate from each organization
- Keep agenda focused
 - Occasionally “recruit” volunteers
 - It only takes a spark –editors easier to find than drafters
 - Sometimes people like to be asked
 - Subgroup works on crosswalk (separate calls)
- AABB supports conference calls
 - Some participants use skype
 - Use Google docs for document collaboration
- Open to creative use of new technologies

Challenges

- Some participants use Skype to access call in number
 - Connection quality varies
 - Saves cost of international dialing
 - When webinar in use (via Go To Meeting), some may have trouble with access
 - Permits all to view same document
- Access issues with Google
 - Employer restricted – some blocked
 - Two people can edit at once – no version control
- Global timing issues
 - Time inconvenient for most

Other Hurdles

- Everyone is overbooked
 - Rely on volunteer time from volunteers already volunteering for sponsoring organization
 - Project must be valuable to community
- Getting the word out
 - Do the people that would most benefit from AHCTA initiatives know it exists?
 - How do we expand knowledge base of people who know about the resources?

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