



- Mr. Eoin McGrath, BA
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- EBMT Employee





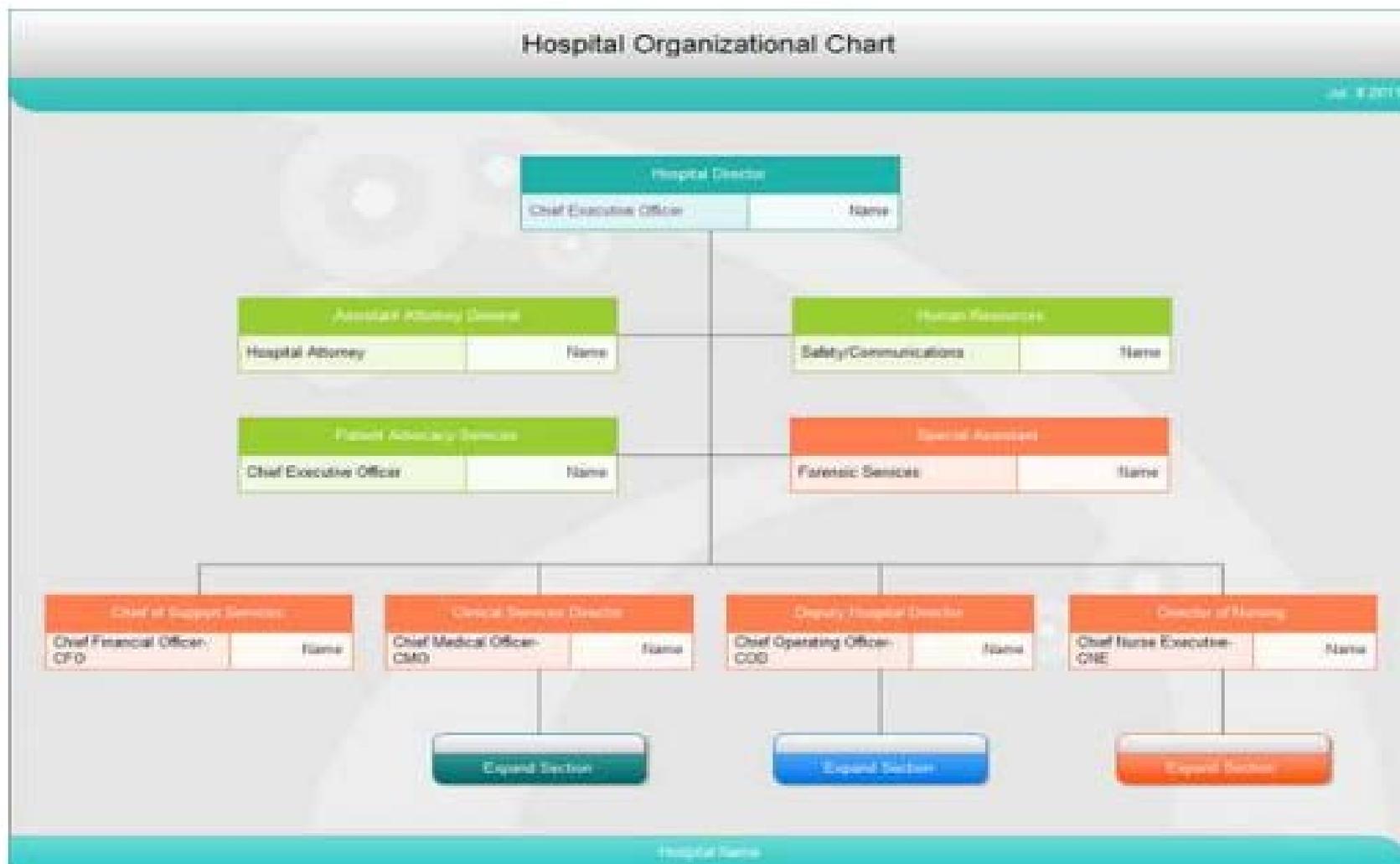
# Creating a Quality System that Works

## Overview of standards & accreditation in HSCT





# What we think healthcare looks like



Jeffrey Braithwaite, PhD  
Robyn Clay-Williams, PhD

[http://resilienthealthcare.net/onewebmedia/Braithwaite\\_Clay-Williams.pdf](http://resilienthealthcare.net/onewebmedia/Braithwaite_Clay-Williams.pdf)







# Why Do We Work on Teams?

- **Quality and safety problems are interprofessional in origin**  
**70% of medical errors due to poor teamwork & communication.**
- **High functioning teams have greater QI success.**

Goetz-Goldberg, Beeson, et al. (2013). Population Health Mang.  
McAllister, et al. (2013). Annals of Family Medicine.  
1Mills & Weeks (2004). Joint Commission Journal  
Sallas & Rosen (2013). BMJ. Building High Reliability Teams  
Vachon, Desorcy et al. (2013). BMC Health Services Research

[www.coursera.org](http://www.coursera.org)



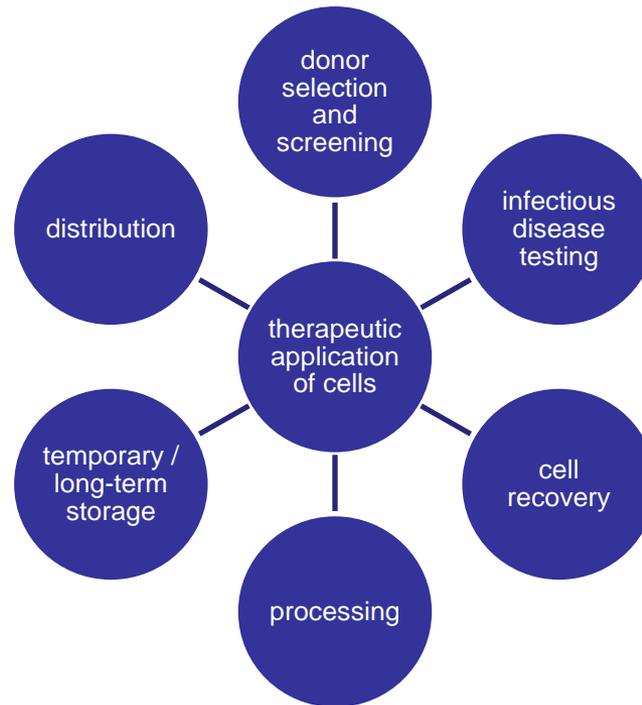
**Mary A. Dolansky, PhD, RN**  
Associate Professor and QSEN Institute Director  
Case Western Reserve University





# BMT is a complex process...

Adapted from  
Tissue and Cell  
Processing: An  
Essential Guide.  
Edited by Deirdre  
Fehily, Scott A.  
Brubaker, John N.  
Kearney, and  
Lloyd  
Wolfenbarger. ©  
2012 Blackwell  
Publishing Ltd.





Hwang, W. Y. K., & Foeken, L. M. (2014). Blood stem cell donation: A model for worldwide cooperation in transplantation. *Annals of the Academy of Medicine Singapore*, 43(6), 294–295.

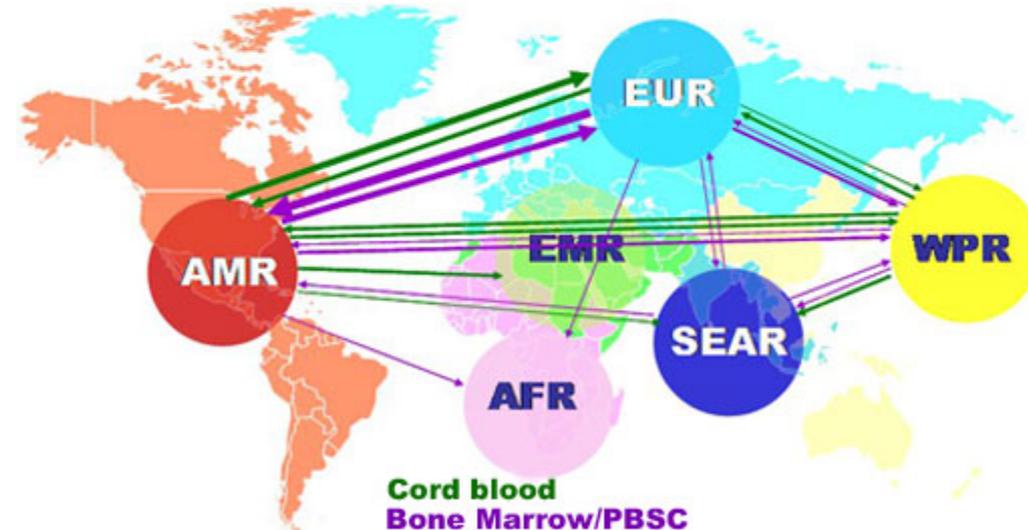
## International context

- “there are now around 33 stem cell products being transported every day across the world to facilitate transplants in another country”
- 12,000+ HSCT products exchanged across borders every year

### Stem cells are daily circulating around the World

In order to find a match, over 40% of the unrelated stem cell transplants involve a donor in a country different from that of the patient, illustrating the unity of humanity beyond national boundaries. Therefore international collaboration is crucial.

International Circulation of Haematopoietic Stem Cells among the six WHO Regions. Unrelated Cord Blood, Bone Marrow and Peripheral Blood Stem Cells. (Source WBMT/WMDA 2009)





# RESPONSE BY HEALTHCARE PROFESSIONALS TO THESE CHALLENGES

# Popular improvement strategies



Table 14.2 Popular improvement strategies

| Category                     |
|------------------------------|
| 1. Philosophical, conceptual |
| 2. Patient journey           |
| 3. Education, development    |
| 4. Specific tools            |

- CLINICAL PRACTICE GUIDELINES
- EDUCATIONAL OUTREACH
- CONTINUING MEDICAL EDUCATION
- RISK & SAFETY EDUCATION
- CHECKLISTS
- EXTERNAL ACCREDITATION & STANDARDS

- Six Sigma
- Plan-Do-Study-Act cycles (PDSA)
- Managerial walkarounds
- Checklists
- Clinical decision support systems
- Adjuvant models of care
- Evidence-based medicine

Adapted from: Scott (2009), Braithwaite and Colera (2010), Hughes (2008); Frankel et al. (2003)

The Oxford Handbook of Health Care Management.  
Ewan Ferlie, Kathleen Montgomery, Anne Reff Pedersen.  
Oxford University Press, 7 abr. 2016 - 504 pp. ISBN  
0191015202, 9780191015205



# Regulation v. Accreditation

**Table 1 Contrasting accreditation and regulation**

|                  | Regulation  | Accreditation  |
|------------------|---|--|
| Standards        |  |  |
| Aim              |   |  |
| Facilitation     |   |  |
| Self-assessment  |   |  |
| Assessors        |   |  |
| Staff engagement |   |  |

Shaw, C. (2015). Accreditation is not a stand-alone solution. *Eastern Mediterranean Health Journal*, 21(3), 226–231.



# SO WHAT HAPPENED IN HSCT?



Advancing Transfusion and Cellular Therapies Worldwide





# “Classic” view



Clinical



Bone Marrow  
Collection

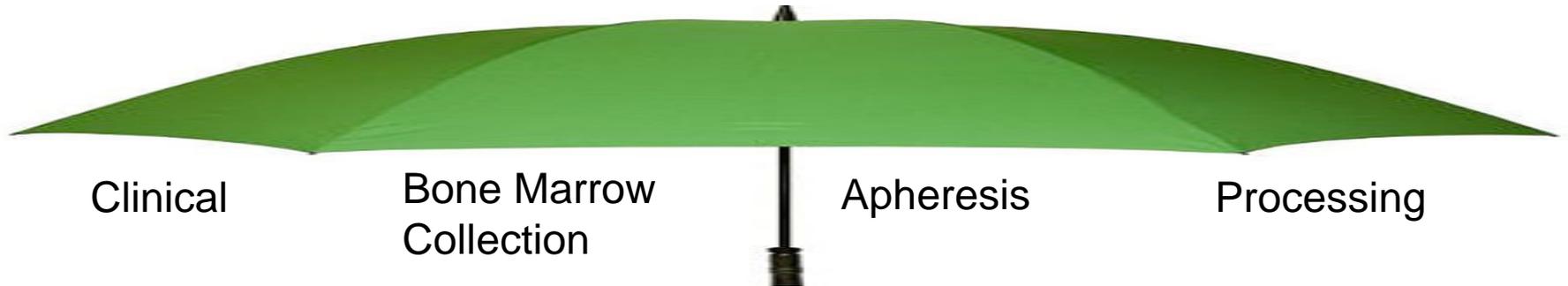


Apheresis



Processing

# Accreditation view



Clinical

Bone Marrow  
Collection

Apheresis

Processing

# Countries with HSCT centres and/or cord-blood banks accredited by one or more of JACIE, FACT, AABB



Includes commercial and non-commercial HSCT and CBB organisations

StreetMap contributors



# Compare requirements



## Comparison of Objectives, Scope, Definitions

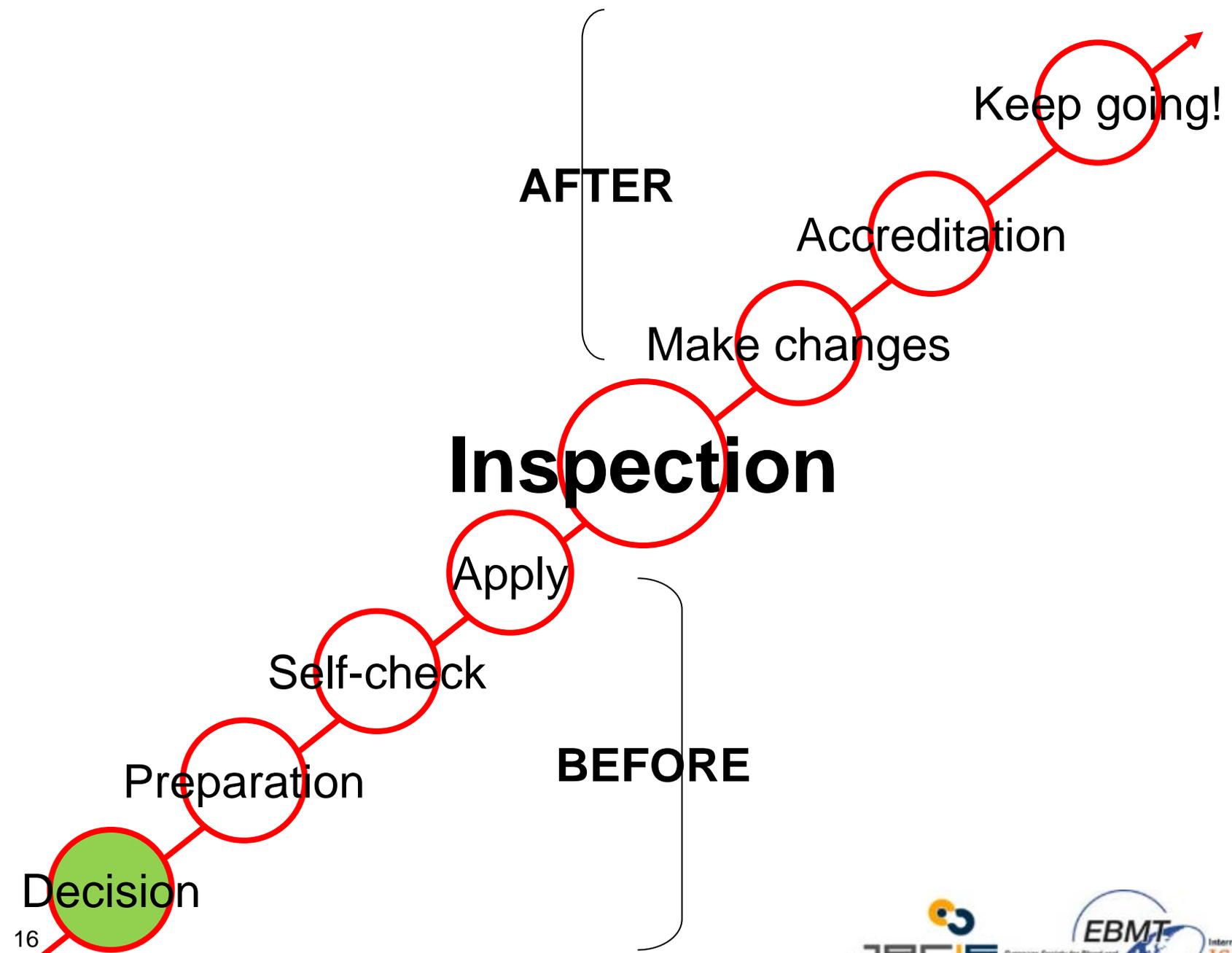
The tables are populated with data from the FACT-JACIE, Netcord-FACT, WMDA and AABB Standards

| Definitions   | Abbreviation       |
|---|--------------------|
| WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries Version January 2014  | <b>W</b>           |
| FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration 6 <sup>th</sup> Edition | <b>F-J</b>         |
| Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 6 <sup>th</sup> Edition                  | <b>NC-F</b>        |
| AABB Standards for Cellular Therapy Services 6 <sup>th</sup> Edition  | <b>AA</b>          |
| Specific definition not addressed in the standards  | <b>Not defined</b> |

Definitions are meant to clarify how terms that may not be in common usage are used to understand the standards

|                  | <b>W</b>   | <b>F-J</b>   | <b>NC-F</b>   | <b>AA</b>   |
|------------------|--|--|---|---|
| <b>OBJECTIVE</b> | These standards are aimed at enhancing the quality of Registries assisting the grafting physician responsible for patient treatment in the international search for an unrelated donor for their patient | To promote quality medical and laboratory practice in hematopoietic progenitor cell transplantation and other therapies using cellular products. | To promote quality medical and laboratory practices throughout all phases of cord blood collection, banking, and release for administration to achieve consistent production of high quality placental and umbilical cord blood units for administration. | The goal of the <i>CT Standards</i> is to maintain and enhance the quality and safety of procurement, processing, storage, and administration of cellular therapy products. |
| <b>SCOPE</b>     | These standards promote the quality of procedures  | FACT-JACIE Standards are now called FACT-JACIE   | The scope of the Standards includes only the use of cord  | Uses a quality systems framework to address overall   |

<http://www.ahcta.org/documents.html>





# STANDARDS

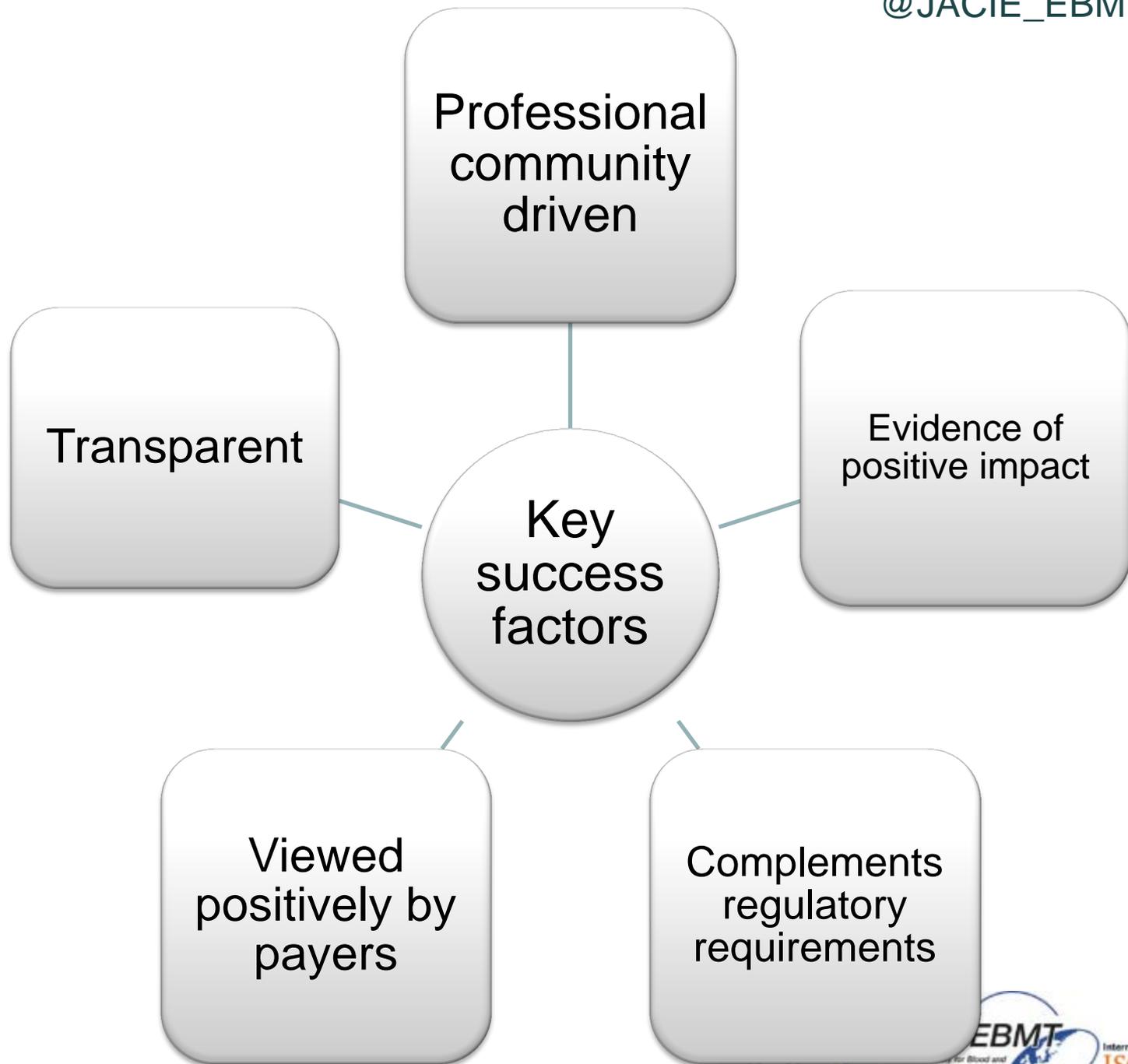
- Developed by professionals working day-to-day in HSCT
- Evidence-based as much as possible
  - where this is not feasible, consensus is reached on the most appropriate approach.
- More generic standards - installations, staff education and skills, quality management, patient and donor management and care
- More technical requirements - specific aspects of the process e.g. stem cell storage, transportation, administration of the product
- Reviewed regularly e.g. 3 years



**S T A N D A R D S**

**FACT-JACIE  
International  
Standards, 6th ed.**

| Clinical   | Collection Marrow   | Collection Apheresis   | Processing  |
|--|---|--|---|
| B1 General   | CM1 General   | C1 General   | D1 General  |
| B2 Clinical Unit   | CM2 Marrow Collection Facility                                | C2 Apheresis 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 <u>Selection</u> , Evaluation, and Management | CM6 Allogeneic and Autologous Donor Evaluation and Management | C6 Allogeneic and Autologous Donor Evaluation and Management | D6 Process Controls                                 |
| B7 Therapy Administration  | 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 Distribution                                     |
| B9 Data Management   | CM9 Cellular Therapy Product Storage                          | C9 Cellular Therapy Product Storage                          | D9 Storage  |
|  | CM10 Cellular Therapy Product Transportation and Shipping     | C10 Cellular Therapy Product Transportation and Shipping     | D10 Transportation, Shipping, and Receipt           |
|  |   |  | D11 Disposal  |
| B10 Records  | CM11 Records  | C11 Records  | D12 Records   |
|  | CM12 Direct Distribution to Clinical Program                  | C12 Direct Distribution to Clinical Program                  |   |





# External organisations

- FACT (USA) – increasingly required for patient care reimbursement from many government agencies and health insurance companies
- AABB - granted deemed status by the Centers for Medicare and Medicaid Services
- Clinical trials
  - FACT for programs that participate in the Cancer Trials Support Unit of the National Cancer, the Children's Oncology Group, the Eastern Cooperating Oncology Group, and the Southwestern Oncology Group centres in
  - Indications that centres in CART trials being asked to have accreditation
- EU Regulations – accreditation required for authorisation/licensing

# JACIE & National Regulations





# IMPACT



# WHAT WE DO WANT TO BE

## An initiative that impacts on patient survival

Bone Marrow Transplantation (2015) 50, 87–94  
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www.nature.com/bmt



### Use of the quality management system "JACIE" and outcome after hematopoietic stem cell transplantation

by Alois Gratwohl, Ronald Brand, Eoin McGrath, Anja van Biezen, Anna Sureda, Per Ljungman, Helen Baldomero, Christian Chabannon, and Jane Apperley

Haematologica 2013 [Epub ahead of print]

Citation: Gratwohl A, Brand R, McGrath E, van Biezen A, Sureda A, Ljungman P, Baldomero H, Chabannon C, and Apperley J. Use of the quality management system "JACIE" and outcome after hematopoietic stem cell transplantation. *Haematologica*. 2014; 99:xxx  
doi:10.3324/haematol.2013.096461

#### ORIGINAL ARTICLE

### The impact of center accreditation on hematopoietic cell transplantation (HCT)

S Marmor<sup>1</sup>, JW Begun<sup>2</sup>, J Abraham<sup>2</sup> and BA Virnig<sup>2</sup>

There are two voluntary center-accrediting organizations in the USA, the Foundation for the Accreditation of Cellular Therapy (FACT) and core Clinical Trial Network (CTN) certification, that are thought to improve and ensure hematopoietic cell transplantation (HCT) center quality care and certify clinical excellence. We sought to observe whether there are differences in outcomes between HLA-matched and -mismatched HCT by CTN and FACT status. Using the 2008–2010 Center for International Blood & Marrow Transplant Research data we created three center categories: non-FACT centers (24 centers), FACT-only certified centers (106 centers) and FACT and core clinical trial network (FACT/CTN) certified centers (32 centers). We identified patient characteristics within these centers and the relationship between FACT certification and survival. Our cohort consisted of 12 993 transplants conducted in 162 centers. After adjusting for patient and center characteristics we found that FACT/CTN centers had consistently superior results relative to non-FACT and FACT-only centers ( $P < 0.05$ ) especially for more complex HCT. However, non-FACT centers were comparable to FACT-only centers for matched related and unrelated patients. Although FACT status is an important standard of quality control that begins to define improved OS, our results indicate that FACT status alone is not an indicator for superior outcomes.

Bone Marrow Transplantation (2015) 50, 87–94; doi:10.1038/bmt.2014.219; published online 10 November 2014



ELSEVIER

Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com



#### Research Article

### Economics and Outcome After Hematopoietic Stem Cell Transplantation: A Retrospective Cohort Study



Alois Gratwohl<sup>a,\*</sup>, Anna Sureda<sup>b</sup>, Helen Baldomero<sup>a</sup>, Michael Gratwohl<sup>c</sup>, Peter Dreger<sup>d</sup>, Nicolaus Kröger<sup>e</sup>, Per Ljungman<sup>f</sup>, Eoin McGrath<sup>b</sup>, Mohamad Mohty<sup>g</sup>, Arnon Nagler<sup>h</sup>, Alessandro Rambaldi<sup>i</sup>, Carmen Ruiz de Elvira<sup>j</sup>, John A. Snowden<sup>k,l</sup>, Jakob Passweg<sup>a</sup>, Jane Apperley<sup>m</sup>, Dietger Niederwieser<sup>n</sup>, Theo Stijnen<sup>o</sup>, Ronald Brand<sup>o</sup>, for the Joint Accreditation Committee (JACIE) of the International Society for Cellular Therapy (ISCT) and the European Society for Blood and Marrow Transplantation (EBMT) and the European Leukemia Net (ELN)



# WHAT WE **DO** WANT TO BE

## An initiative that impacts on donor safety

Bone Marrow Transplantation (2014), 1–4  
© 2014 Macmillan Publishers Limited All rights reserved 0268-3369/14  
[www.nature.com/bmt](http://www.nature.com/bmt)



### ORIGINAL ARTICLE

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

C Anthias<sup>1,2</sup>, ME Ethell<sup>3</sup>, MN Potter<sup>3</sup>, A Madrigal<sup>1,2</sup> and BE Shaw<sup>1,2,3</sup>

“Following the introduction of JACIE standards addressing donor care, new Standard Operating Procedures were written, leading to significant improvements in donor consenting procedures and donor follow-up”

|   | Before change | After change      |
|---|---------------|-------------------|
| Same doctor consented both the RD and their recipient | 20%           | 0%                |
| Donors offered a choice of donation route             | 33%           | 80%               |
| Donor follow-up beyond 1 week post donation           | 37%           | 58% <sub>24</sub> |



# WHAT WE DO **NOT** WANT TO BE

Bone Marrow Transplantation (2004) 34, 835–838

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[www.nature.com/bmt](http://www.nature.com/bmt)

## Editorial

### Just Another Cost Increasing Exercise (JACIE)?

# WHAT WE DO NOT WANT TO BE

- “Tick-box exercise”
- Stop health professionals thinking for themselves!





# INSPECTORS





# Inspectors

- 260+ cellular therapy professionals on the JACIE register
- Volunteers
- Receive only expenses and *per diem*
- Fundamental to the process





Atul Gawande cited by Erik Heineman, 1 April 2014, EBMT, Milan  
*Atul Gawande is an Indian American surgeon and journalist.  
He is widely known as an expert on optimizing modern healthcare systems.*

• Reflective Practice

Paradigm of Care: Ego- or Eco-system

• Self-critique

What is needed on **an individual level** for  
**Clinical Governance?**

➤ **'Humility'**: 'a commitment to self-reflection, self-critique, lifelong learning, and reflective practice'

➤ **'Discipline'**

➤ **'Teamwork'**

Ajul Gawande

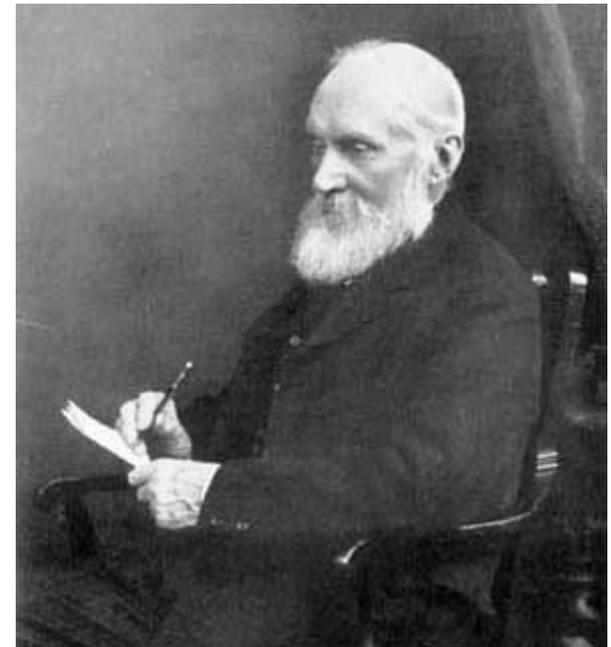
• Self-reflection

• Lifelong learning



- **“If you cannot measure it, you can not improve it”**

William Thomson (Lord Kelvin) 1824 – 1907  
Determined the correct value of absolute zero  
as approximately -273.15 Celsius

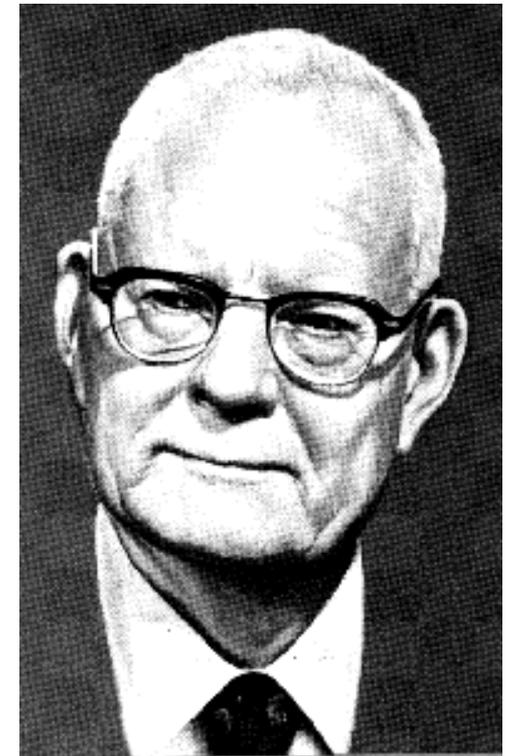




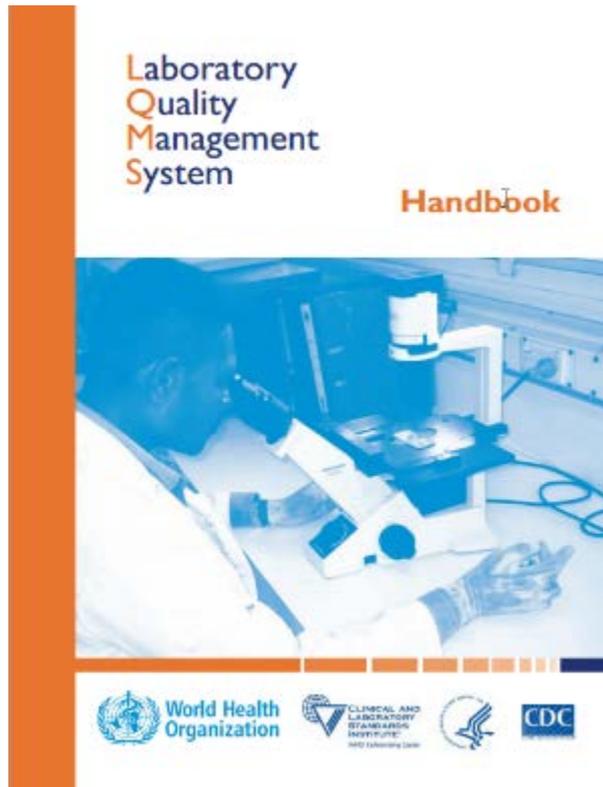
- **“Without data, you’re just another person with an opinion”**

**William Edwards Deming** (October 14, 1900 – December 20, 1993) was an American engineer, statistician, professor, author, lecturer, and management consultant.

[https://en.wikipedia.org/wiki/W.\\_Edwards\\_Deming](https://en.wikipedia.org/wiki/W._Edwards_Deming)



# Laboratory quality management system handbook



- Comprehensive reference on Laboratory quality management
- Covers topics that are essential for quality management of a public health or clinical laboratory.
- Based on both ISO 15189 and CLSI GP26-A3 documents

<http://www.who.int/ihr/publications/lqms/en/#>



## Other resources

- AHCTA
- [www.ahcta.org](http://www.ahcta.org)



**ahcta**

**alliance for harmonisation of  
cellular therapy accreditation**

### **SURVEY November 2013**

The Alliance for Harmonisation of Cellular Therapy Accreditation (AHCTA) requests processing facilities to complete a survey to assist with developing recommendations for cell processing laboratory staff qualifications, training and competency. Please limit your responses to just those staff responsible for the processing of minimally manipulated products like hematopoietic progenitor cells (HPC) for stem cell transplantation and therapeutic cells (TC)- T cells. Only a single response from each processing facility is required.

## Technical Report

*Bone Marrow Transplantation* , (16 June 2014) | doi:10.1038/bmt.2014.104

### Essential requirements for setting up a stem cell processing laboratory

T Leemhuis, D Padley, C Keever-Taylor, D Niederwieser, T Teshima, F Lanza, C Chabannon, P Szabolcs, A Bazarbachi, M B C Koh and on behalf of the Graft Processing Subcommittee of the Worldwide Network for Blood and Bone Marrow Transplantation (WBMT)

**The Graft Processing subcommittee of the Worldwide Network for Blood and Marrow Transplantation wrote this guideline to assist physicians and laboratory technologists with the setting up of a cell processing laboratory (CPL) to support a hematopoietic stem cell transplant program, thereby facilitating the start-up of a transplant program in a new location and improving patient access to transplantation worldwide. This guideline describes the minimal essential features of designing such a laboratory and provides a list of equipment and supply needs and staffing recommendations. It describes the typical scope of services that a CPL is expected to perform, including product testing services, and discusses the basic principles behind the most frequent procedures. Quality management (QM) principles specific to a CPL are also discussed. References to additional guidance documents that are available**

#### ARTICLE TOOLS

- Send to a friend
-  Export citation
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#### SEARCH PUBMED FOR

- ▶ T Leemhuis
- ▶ D Padley
- ▶ C Keever-Taylor
- ▶ D Niederwieser
- ▶ T Teshima
- ▶ F Lanza
- ▶ [more authors of this article](#)





# LinkedIn Group



JACIE Accreditation

50 members

<https://www.linkedin.com/groups/5027189>



@JACIE\_EBMT



# Acknowledgements

## JACIE Patrons

EBMT  
ISCT

## JACIE Founders

Alois Gratwohl  
Gönnar Kvalheim

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- **JACIE Inspectors**
  - **27 countries**