

# JACIE Accreditation: Overview and context

Mr. Eoin McGrath  
JACIE Operations Manager  
EBMT

# VUCA

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Volatility | Uncertainty | Complexity | Ambiguity

# VUCA

## VOLATILITY

- Increasing rate of change

## UNCERTAINTY

- Less clarity about the future

## COMPLEXITY

- Multiplicity of decision factors

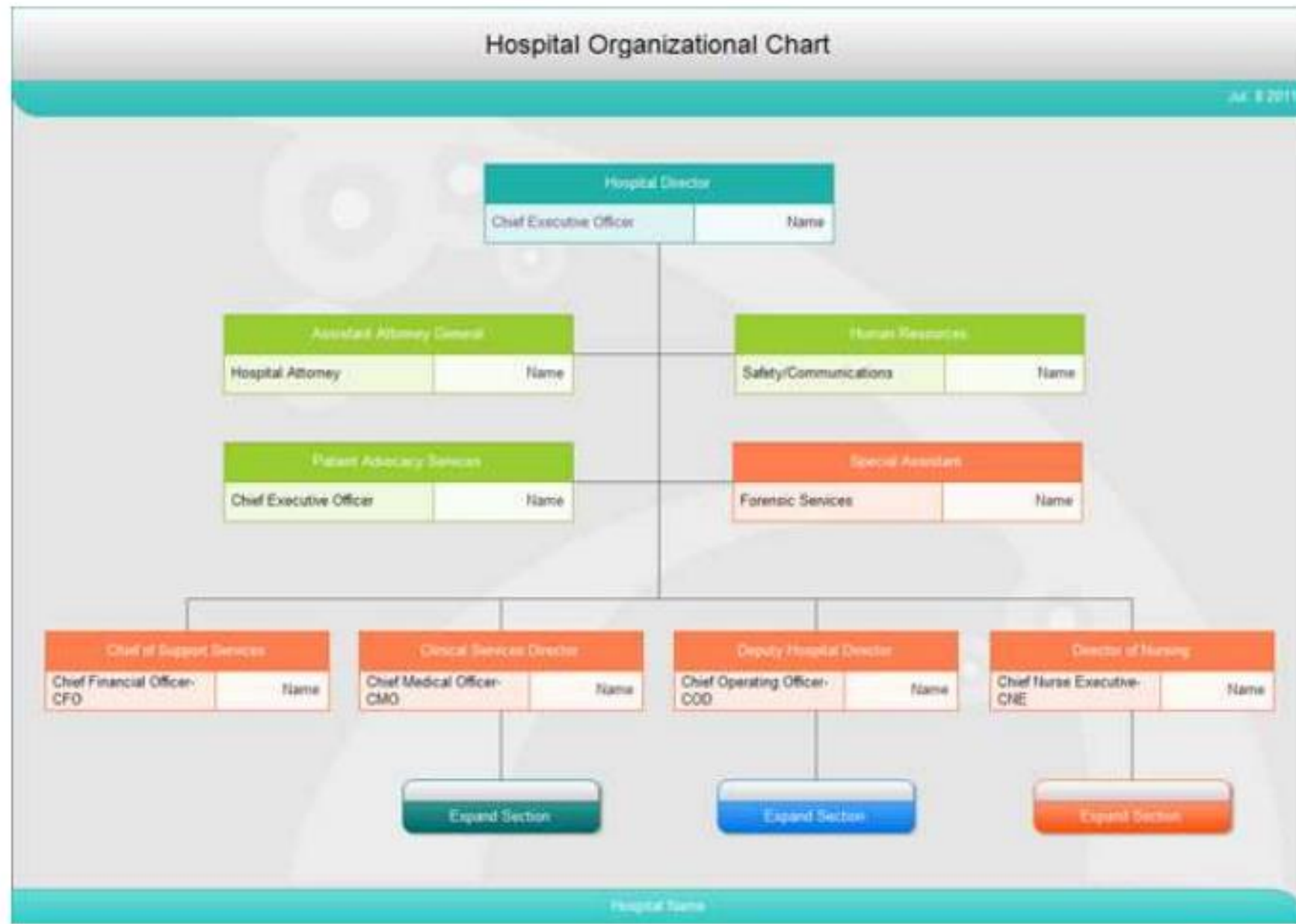
## AMBIGUITY

- Unlikely to be a single “correct” answer

What we think  
healthcare looks  
like

Jeffrey Braithwaite, PhD  
Robyn Clay-Williams, PhD

Presentation to the Resilient Healthcare Net Conference  
Middlefart, University of Southern Denmark  
12 August 2014



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

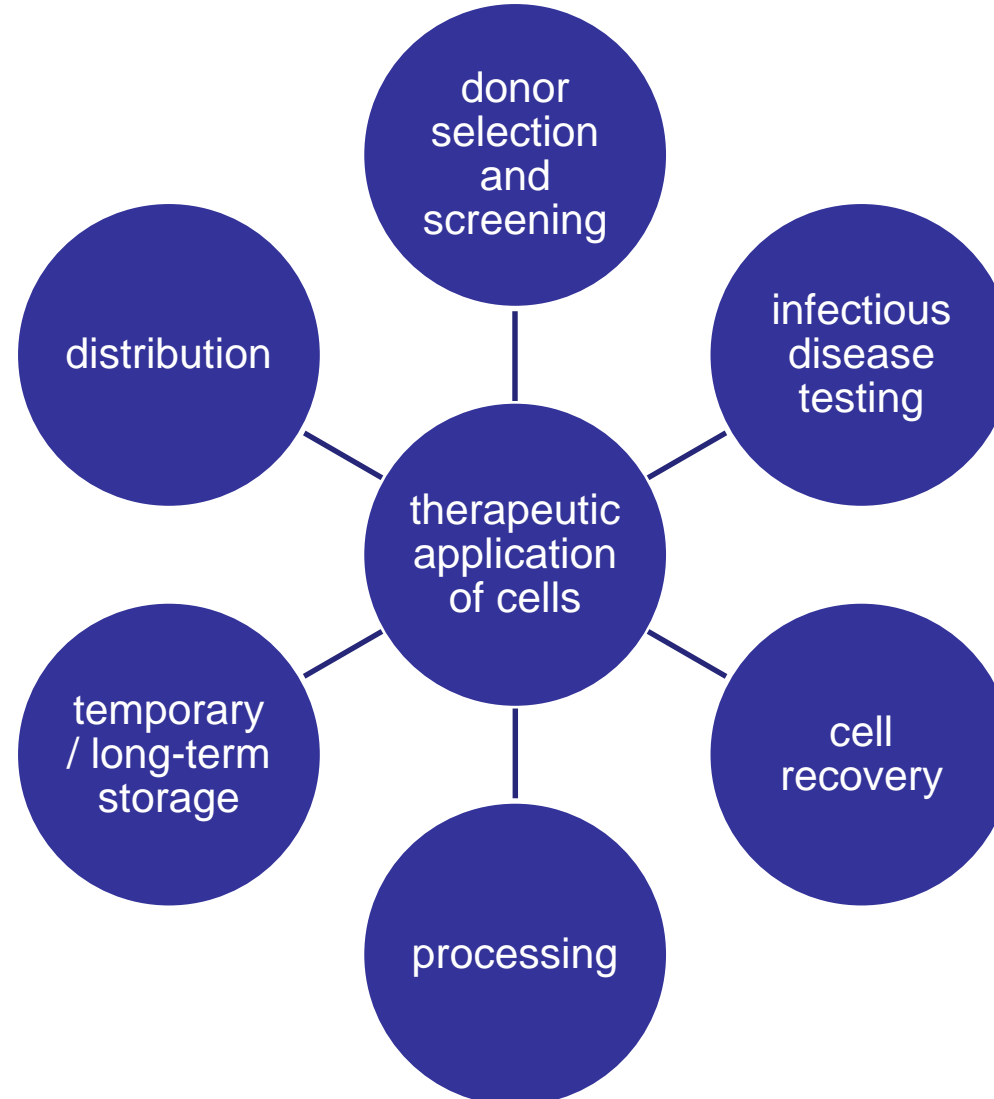
[illegible]

Presentation to the Resilient Healthcare Net Conference  
Middlefart, University of Southern Denmark  
12 August 2014

@JACIE\_EBMT



# Bone Marrow Transplantation is an especially 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.

# International context

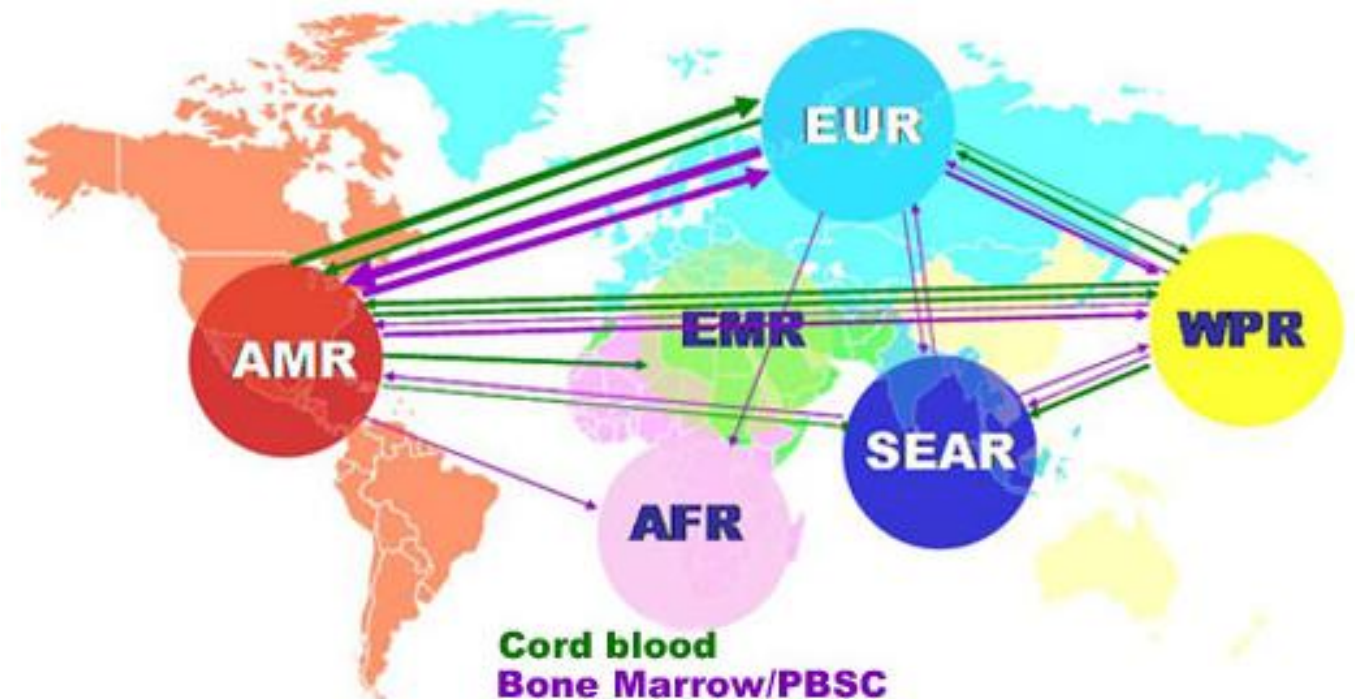
Hwang, W. Y. K., & Foeken, L. M. (2014). Blood stem cell donation: A model for worldwide cooperation in transplantation. *Annals of the Academy of Medicine Singapore*, 43(6), 294–295.

- “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)



# Changes in BMT

## Accreditation and regulations in cell therapy

C. Chabannon,<sup>1,2,3</sup> O. Caunday-Rigot,<sup>4</sup> C. Faucher,<sup>1</sup> I. Slaper-Cortenbach,<sup>5</sup> B. Calmels,<sup>1,3</sup> C. Lemarie,<sup>1,3</sup> A. Mahalatchimy,<sup>6</sup>  
E. McGrath<sup>7</sup> & E. Rial-Sebbag<sup>8,9</sup>

### Donors

- Unrelated donors outnumber related donors

### Older patients

- Need for decreased toxicity in order to offer HSCT

### Society

- Increasing demands for safer treatments

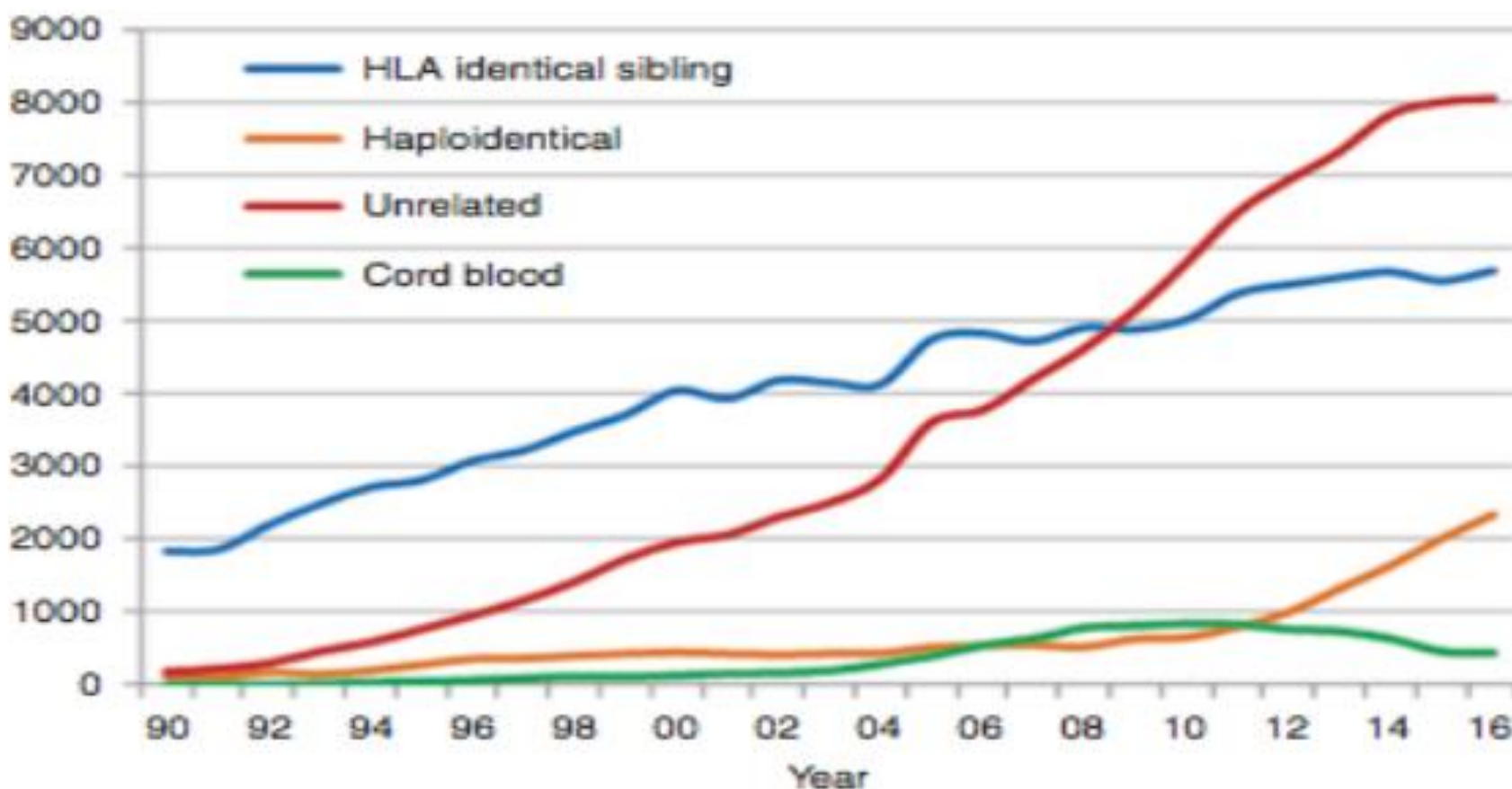


# EVOLUTION: HSCT & JACIE

Is the use of unrelated donor transplantation leveling off in Europe?  
The 2016 European Society for Blood and Marrow Transplant  
activity survey report

Jakob R Passweg<sup>1</sup> · Helen Baldomero<sup>1</sup> · Peter Bader<sup>2</sup> · Grzegorz W. Basak<sup>3</sup> · Chiara Bonini<sup>4</sup> · Rafael Duarte<sup>5</sup>  
Carlo Dufour<sup>6</sup> · Nicolaus Kröger<sup>7</sup> · Jürgen Kuball<sup>8</sup> · Arjan Lankester<sup>3</sup> · Silvia Montoto<sup>10</sup> · Arnon Nagler<sup>11</sup> ·  
John A. Snowden<sup>12</sup> · Jan Styczynski<sup>13</sup> · Mohamad Mohty<sup>14</sup> for the European Society for Blood and Marrow  
Transplantation (EBMT)

Received: 14 December 2017 / Revised: 30 January 2018 / Accepted: 7 February 2018  
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# Ethical issues

- Donors' and recipients' priorities may conflict - personal ethical values, beliefs and religiosity of the potential donors
- Risk to donor of procedure
- Risk to patient of treatment – benefits v effects
- Professionals conflicts of interest
- Consent – particularly when minors concerned
  - e.g. pregnancy assessment of minors of childbearing age

Hindawi  
Stem Cells International  
Volume 2017, Article ID 1286246, 11 pages  
<https://doi.org/10.1155/2017/1286246>



## *Review Article*

### **Hematopoietic Stem Cell Transplantation: A Bioethical Lens**

Arcangelo Liso,<sup>1</sup> Margherita Neri,<sup>2</sup> Francesca Maglietta,<sup>3</sup> Raffaele La Russa,<sup>4,5</sup> and Emanuela Turillazzi<sup>3</sup>

## Values at stake

- Protection of confidentiality
- Voluntary unpaid donation (Informed consent, respect of autonomy)

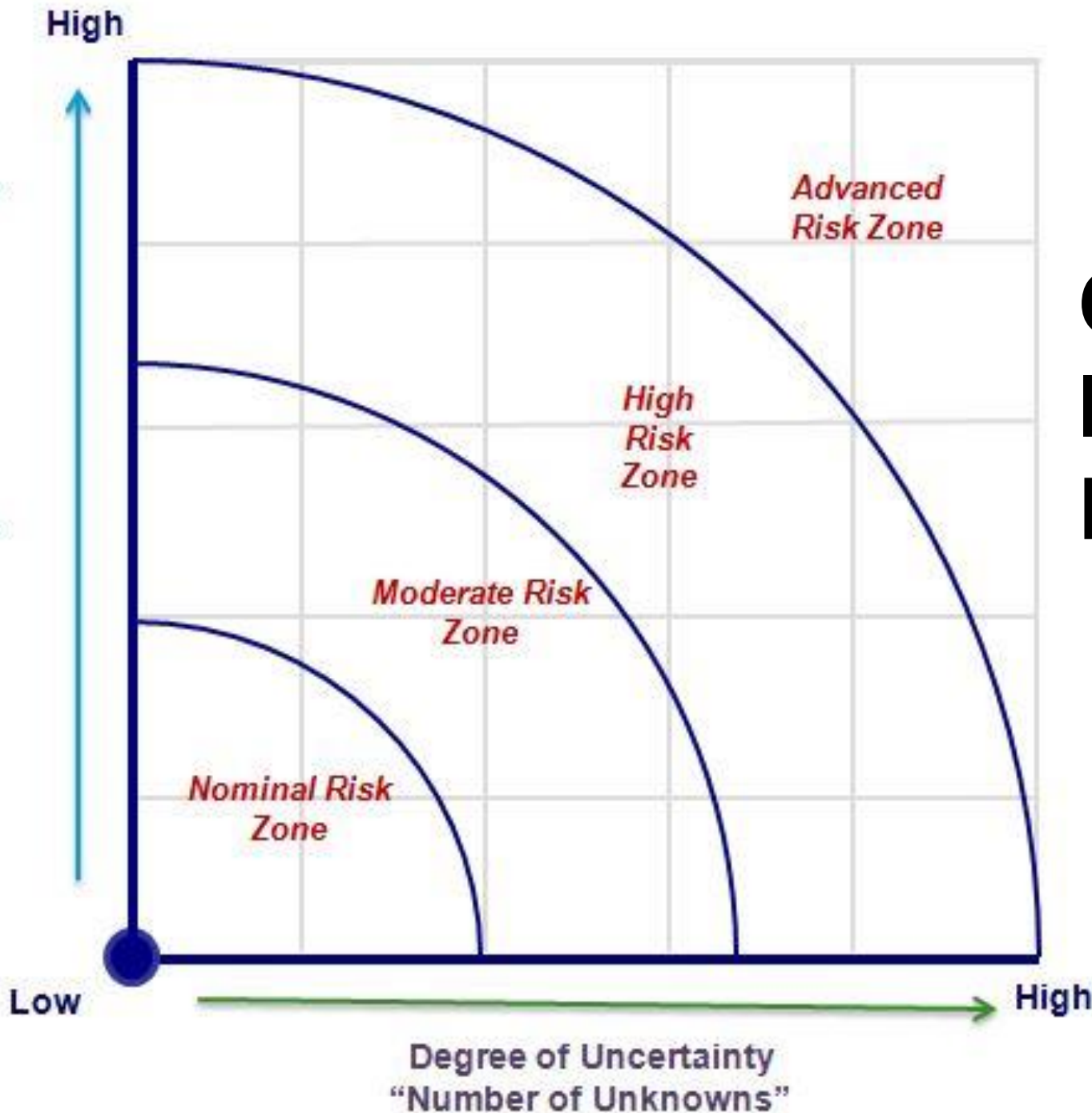
## Future

- New safety and production models
- Public-private partnerships
  - Intellectual property rights?
- Changing regulations

E. Rial-Sebbag EBMT Valencia,  
April 2016



Degree of Complexity  
“Number of Inter-Dependant Relationships”



**COMPLEXITY  
INCREASES  
RISK**

## Medication Errors Among Adults and Children With Cancer in the Outpatient Setting

Kathleen E. Walsh, Katherine S. Dodd, Kala Seetharaman, Douglas W. Roblin, Lisa J. Herrinton, Ann Von Worley, G. Naheed Usmani, David Baer and Jerry H. Gurwitz

**EUROPEAN JOURNAL OF HOSPITAL PHARMACY**

Helping hospital pharmacists to provide better patient care

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Online First | Current Issue | Archive | Supplements | eLetters | Topic collections

Home > Volume 19, Issue 2 > Article

Eur J Hosp Pharm 2012;19:126-127 doi:10.1136/ehjpharm-2012-000074.110

**Abstracts**

General and Risk Management, Patient Safety (including: medication errors quality control)

**Development of a pharmaceutical care programme in a bone marrow transplantation unit**

A. Asensio, G. Lizeaga, I. Fernandez, P. Pascual, P. Carmona, J. Barral, B. Irastorza, K. Andueza, E. Eneola, O. Velhuela

## THE IRISH TIMES

Mon, Mar 9, 2015, 10:10

A bone marrow transplant patient died from a virus after a "transcription error" resulted in failing to monitor her for it, an inquest has heard.

A verdict of medical misadventure was returned at the inquest into the death of a woman after Dublin Coroner's Court heard a transplant co-ordinator mistakenly marked her down as negative for cytomegalovirus (CMV). A common virus which can lie dormant, CMV can be reactivated and become dangerous when someone is immunosuppressed post-transplant.



« Previous | Next Article »  
Table of Contents

### This Article

Published online before print  
December 29, 2008, doi:  
10.1200/JCO.2008.18.6072  
JCO February 20, 2009 vol. 27  
no. 6 891-896

» Abstract  
Full Text

### Study of Medication Errors on a Community Hospital Oncology Ward

By Clyde D. Ford, MD, Julie Killebrew, MS, RN, Penelope Fugitt, RN, Janet Jacobsen, RPh, and Elizabeth M. Prytas, MD

Intermountain Blood and Marrow Transplant Program and Departments of Nursing, Pharmacy, and Medicine, LDS Hospital, Salt Lake City, UT

Am J Health Syst Pharm. 2004 Sep 15;61(18):1908-16.

### Nature and causes of clinically significant medication errors in a tertiary care hospital.

Winterstein AG<sup>1</sup>, Johns TE, Rosenberg EI, Hatton RC, Gonzalez-Rothi R, Kanjanarat P.

A bone marrow cancer patient has called on ..... hospitals to carry out closer checks when dispensing prescriptions - after he was handed doses of several medicines intended for someone else.

Published on the

23 July  
2013  
10:24

**theguardian**  
Winner of the Pulitzer prize 2014

## stem cell freezing problem may have led to girl's death

Coroner rules that deaths of three other children at hospital were not connected to difficulties with medical procedure

NEWS

NEWS | OPINION | NATIONAL AFFAIRS | BUSINESS | AUS IT | HIGHER ED | MEDIA | SPORT

BREAKING NEWS | THE NATION | THE WORLD | FEATURES | IN-DEPTH | GALLERIES | INVESTIGATIVE

NEWS

Tweet 0

Recommend

## Cancer tests mix-up denies Lisa Beckwith the chance for more children

October 15, 2012 1:00AM



Committee  
EBMT



## Hospitals

# Great Ormond Street deaths caused by stem cell lab failures, inquest told

**Bone marrow transplants did not work, leading to calls to review the storage of stem cells across the UK**

**Denis Campbell** *and Alice Hutton*

Fri 21 Nov 2014 19.36 GMT

Four children have died after failings in how stem cells used in life-saving

Bone Marrow Transplantation (2017) **52**, 922–925

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

### LETTER TO THE EDITOR

Developing quality assurance for pediatric autologous stem cell transplants in England: results of a 3-year national audit of activity and engraftment by treatment centre

“However, without a robust system for the data collection, real-time analysis and benchmarking against other centres these issues with delayed engraftment had not been appreciated”

# 2 Adverse Events



# **RESPONSE BY HEALTHCARE PROFESSIONALS TO THESE CHALLENGES**



## Strategy 1

- Apply Quality Management concepts to healthcare

## Strategy 2

- Accreditation/Certification

# QUALITY TIME

IT MAY NOT BE SEXY, BUT QUALITY ASSURANCE  
IS BECOMING A CRUCIAL PART OF LAB LIFE.

BY MONYA BAKER

**R**ebbecca Davies remembers a time when quality assurance terrified her. In 2007, she had been asked to lead accreditation efforts at the University of Minnesota's Veterinary Diagnostic Laboratory in Saint Paul. The lab needed to ensure that the tens of thousands of tests it conducts to monitor disease in pets, poultry, livestock and wildlife were watertight. "It was a huge task. I felt sick to my stomach," recalls Davies, an endocrinologist at the university's College of Veterinary Medicine.

She nevertheless accepted the challenge, and soon found herself hooked on finding — and fixing — problems in the research process. She and her team tracked recurring tissue-contamination issues to how containers were being filled and stored; they traced an assay's erratic performance to whether technicians let an enzyme warm to room temperature; and they established systems to eliminate spotty data collection, malfunctioning equipment and neglected controls. Her efforts were crucial to keeping the diagnostic lab in business, but they also forced her to realize how much researchers' work could improve. "That is the beauty of quality assurance," Davies says. "That is what we were missing out on as scientists."



# Popular improvement strategies

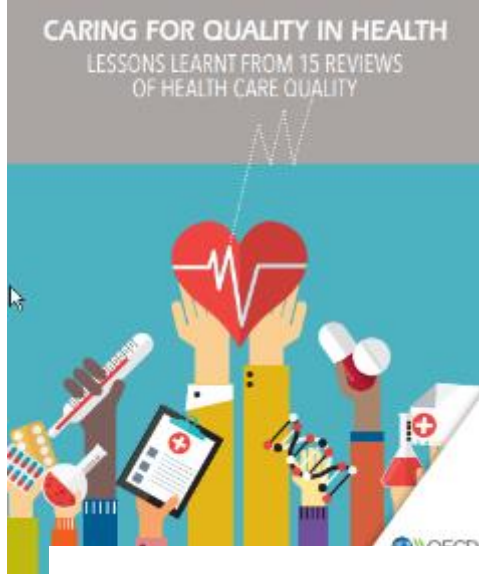
Table 14.2 Popular improvement strategies

Category	Examples
<b>1. Philosophical, conceptual</b>	<ul style="list-style-type: none"> <li>• Accounts of causation</li> <li>• Theoretical domains framework</li> <li>• Quality improvement conceptual frame</li> </ul>
<b>2. Patient journey</b>	<ul style="list-style-type: none"> <li>• Clinical practice guidelines</li> <li>• Care pathways</li> <li>• Chronic disease management</li> <li>• System re-engineering (or redesign)</li> <li>• Lean production cycles</li> </ul>
<b>3. Education, development</b>	<ul style="list-style-type: none"> <li>• Educational outreach</li> <li>• Continuing medical education</li> <li>• Professional development and self-directed learning</li> <li>• Extended professional roles</li> <li>• Specialty outreach programs</li> <li>• Continuous quality improvement programs</li> </ul>
<b>4. Specific tools</b>	<ul style="list-style-type: none"> <li>• Clinical governance</li> <li>• Audit and feedback</li> <li>• Risk and safety management</li> <li>• SBAR communication</li> <li>• Severity assessment systems</li> <li>• Causation analysis</li> <li>• Forcing functions</li> <li>• Failure modes and effects analysis</li> <li>• Functional resonance analysis method</li> <li>• Six Sigma</li> <li>• Plan-Do-Study-Act cycles (PDSA)</li> <li>• Managerial walkarounds</li> <li>• Checklists</li> <li>• Clinical decision support systems</li> <li>• Adjuvant models of care</li> <li>• Evidence-based medicine</li> </ul>
<b>5. Natural systems characteristics</b>	<ul style="list-style-type: none"> <li>• Local opinion leaders and champions</li> <li>• Physician practice profiling</li> <li>• Culture change</li> <li>• Political reframing</li> <li>• Peer case reviews</li> <li>• Realistic evaluation</li> <li>• Formative and summative evaluation approaches</li> <li>• Clinical audit</li> </ul>
<b>6. Teamwork, collaboration</b>	<ul style="list-style-type: none"> <li>• Interdisciplinary collaboration and teamwork</li> <li>• Multi-site quality improvement collaborations</li> <li>• Clinical service networks</li> <li>• Influencing organizational culture</li> <li>• Social campaigns</li> </ul>
<b>7. Patient-led</b>	<ul style="list-style-type: none"> <li>• Patient-mediated quality improvement strategies</li> <li>• Patient reported outcomes measures</li> <li>• Patient-centered or patient-focused care</li> </ul>
<b>8. External stimulus, reporting</b>	<ul style="list-style-type: none"> <li>• Public scorecards and performance reporting</li> <li>• Pay for performance schemes</li> <li>• External accreditation and standards</li> <li>• Incident reporting</li> <li>• Market-based control mechanisms</li> </ul>

**External accreditation and standards**

Adapted from: Scott (2009); Braithwaite and Coiera (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



## OECD 2017 “Caring for quality in health: Lessons learnt from 15 reviews of health care quality”



Accreditation of  
health care  
organisations

Table 0.1 **Key policies and institutions that influence health care quality**

Policy	Examples
Health system design	Accountability of actors, allocation of responsibilities, legislation
Health system inputs (professionals, organisations, technologies)	Professional licensing, accreditation of health care organisations, quality assurance of drugs and medical devices
Health system monitoring and standardisation of practice	Measurement of quality of care, national standards and guidelines, national audit studies and reports on performance
Improvement (national programmes, hospital programmes and incentives)	National programme on quality and safety, pay for performance in hospital care, examples of improvement programmes within institutions

<https://www.oecd.org/els/health-systems/Caring-for-Quality-in-Health-Final-report.pdf>

# Regulation v. Accreditation



**Table 1 Contrasting accreditation and regulation**

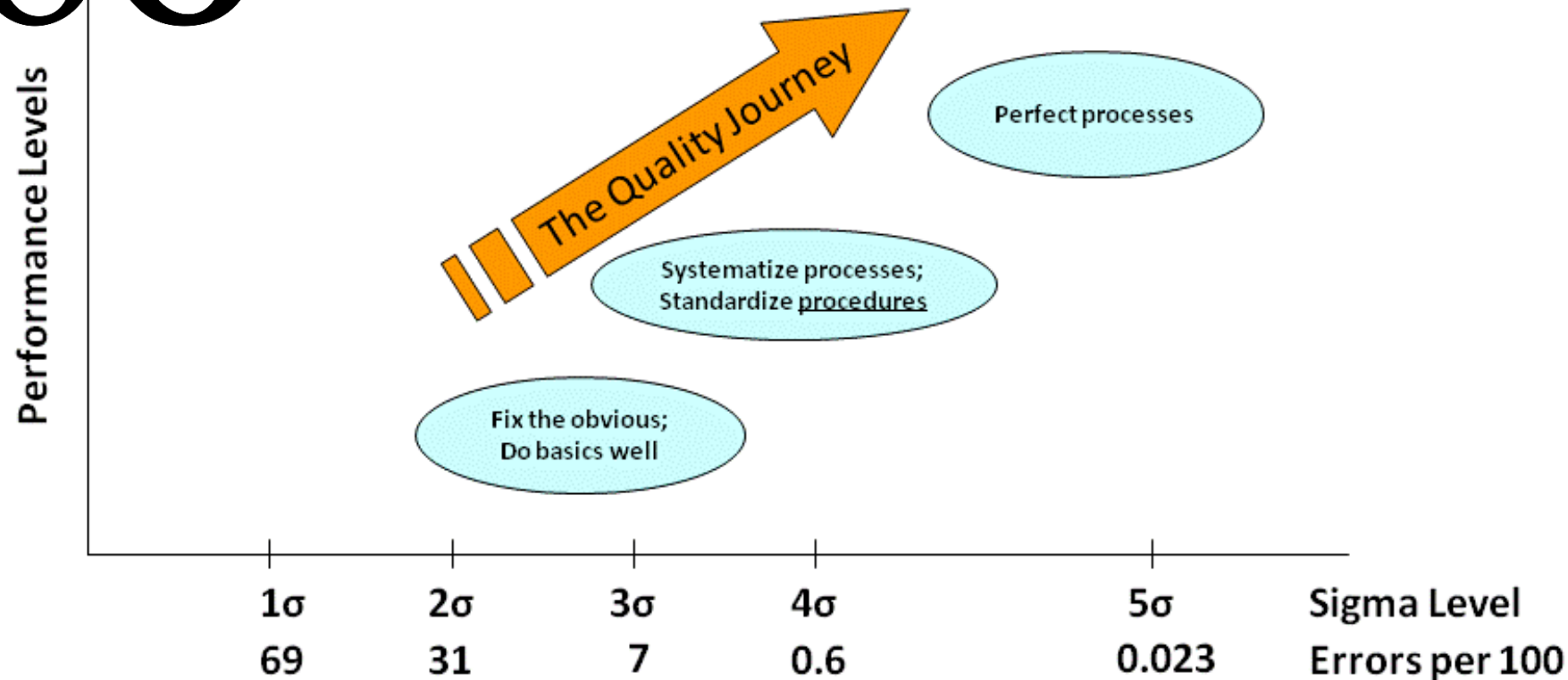
	Regulation	Accreditation
Standards	Minimal	Optimal
Aim	Compliance	Development
Facilitation	No	Yes
Self-assessment	No	Yes
Assessors	Inspectors	Peers
Staff engagement	Low	High

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



# Journey to Quality: Minimize Variability

# 6σ



[http://www.lifetime-reliability.com/cms/tutorials/reliability-engineering/human\\_error\\_rate\\_table\\_insights/](http://www.lifetime-reliability.com/cms/tutorials/reliability-engineering/human_error_rate_table_insights/)

Sources: David Burns, SIRF Roundtables Ltd, Melbourne, Australia  
 George. Mike et al, 'What is Lean Six Sigma', McGraw-Hill, 2004

# Patient Mortality During Unannounced Accreditation Surveys at US Hospitals

Michael L. Barnett, MD; Andrew R. Olenski, BS; Anupam B. Jena, MD, PhD

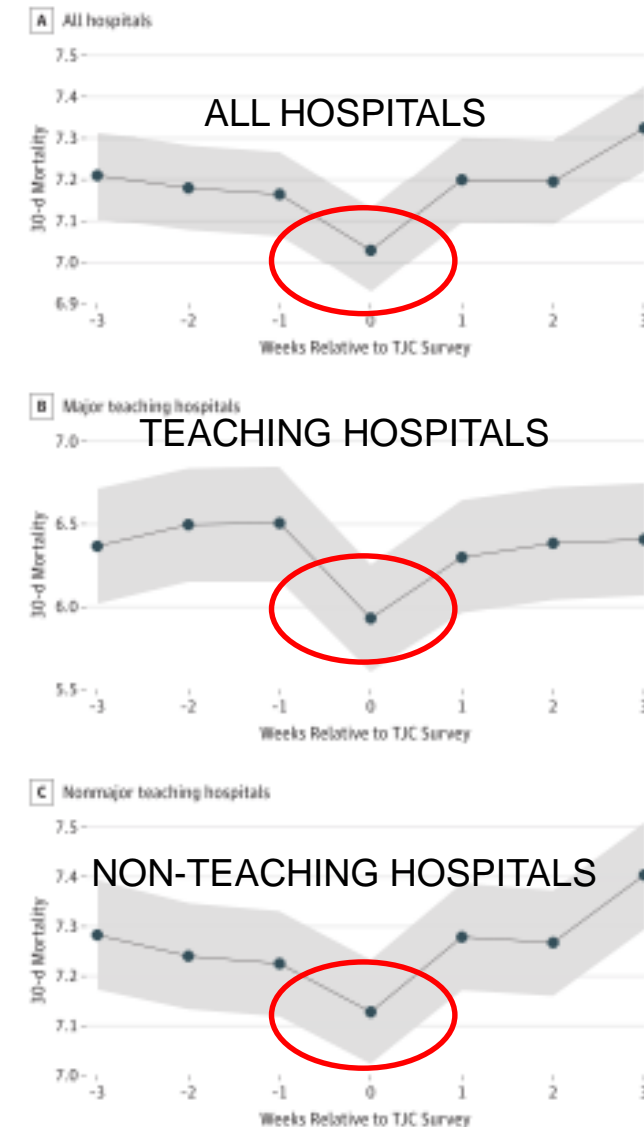
## Key Points

**Question** What is the effect of heightened vigilance during unannounced hospital accreditation surveys on the quality and safety of inpatient care?

**Findings** In an observational analysis of 1984 unannounced hospital surveys by The Joint Commission, patients admitted during the week of a survey had significantly lower 30-day mortality than did patients admitted in the 3 weeks before or after the survey. This change was particularly pronounced among major teaching hospitals; no change in secondary safety outcomes was observed.

**Meaning** Changes in practice occurring during periods of surveyor observation may meaningfully improve quality of care.

Figure 2. Unadjusted 30-Day Mortality by Week of Admission Relative to The Joint Commission Survey Visit



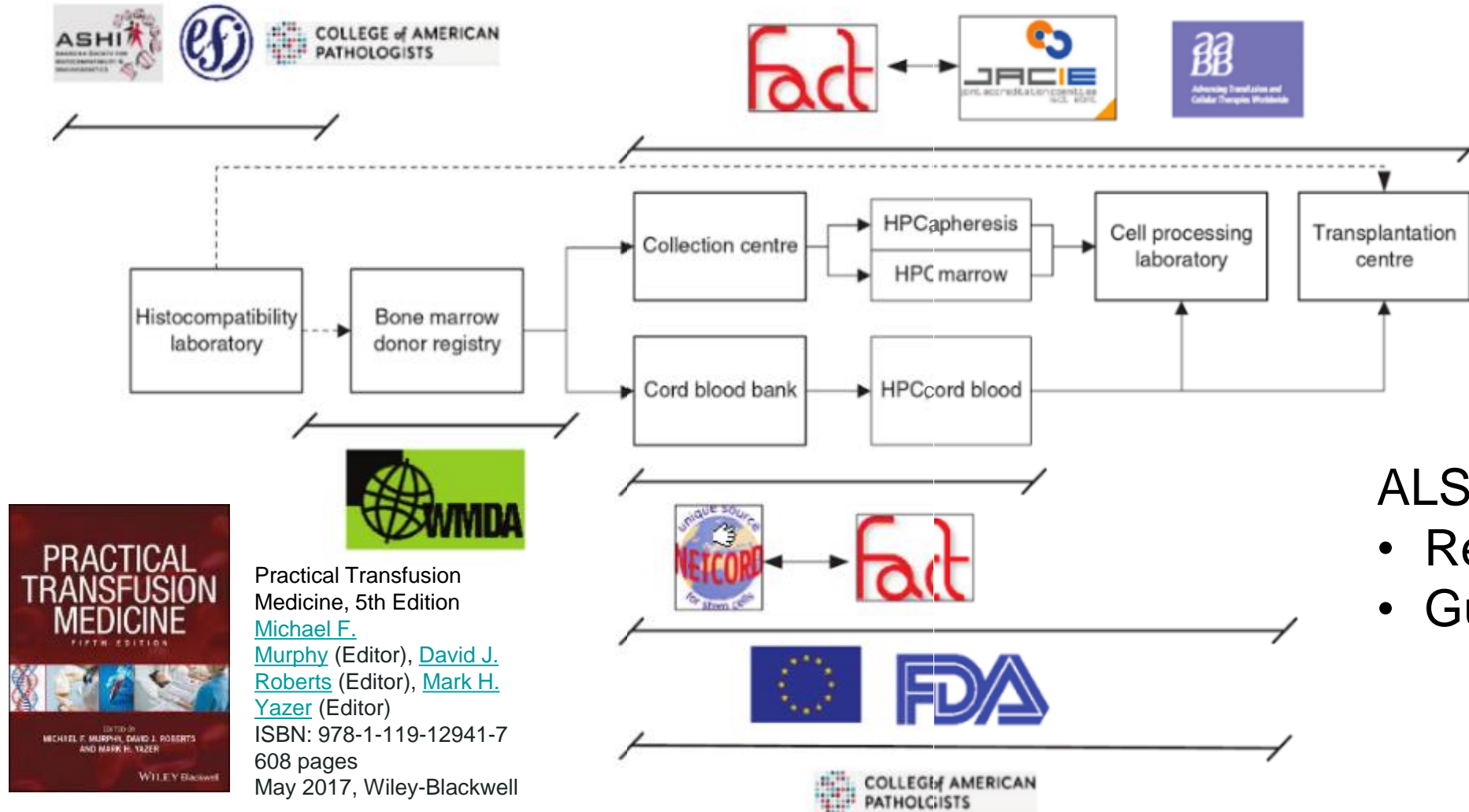
Trends for 30-day mortality in week-long intervals relative to on-site surveys for all hospitals (A), major teaching hospitals alone (B), and nonmajor teaching hospitals (C). Shaded 95% CIs are shown for all unadjusted estimates, assuming a normal distribution of rates given the large sample size of admissions.



Guidelines, Regulations & Standards

# **SO WHAT HAPPENED IN BMT?**

# Standards



- ALSO
- Regulations
  - Guidelines

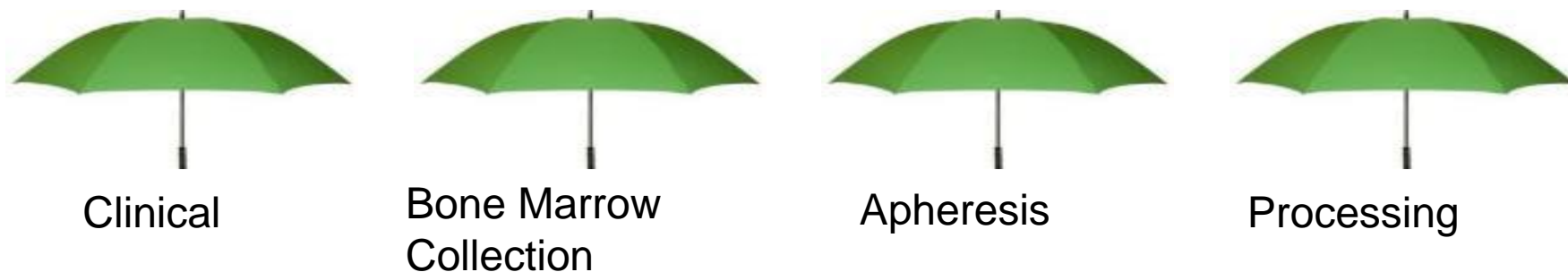
**Figure 38.3** Regulatory environment for haematopoietic stem cell transplantation. Note that this figure does not reflect all potential regulatory reporting requirements for transplantation centres.

# JACIE 20

20<sup>TH</sup> ANNIVERSARY



## “Classic” view



## FACT-JACIE view





## FACT-JACIE Standards

- International standards
- Renewed every 3 years
- Complement regulations
- Based on consensus





# FACT-JACIE Hematopoietic Cellular Therapy Standards 7<sup>th</sup> edition

1 March 2018

FACT-JACIE International Standards  
for **HEMATOPOIETIC  
CELLULAR THERAPY**  
Product Collection, Processing, and Administration  
SEVENTH EDITION 7.0

PART B CLINICAL	PART CM MARROW	PART C APHERESIS	PART D 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 Standard Operating Procedures	CM5 Policies and Standard Operating Procedures	C5 Policies and Standard Operating Procedures	D5 Policies and Standard Operating 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
	CM8 Process Controls	C8 Process Controls	D8 Process Controls
	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
B8 Clinical Research			D11 Distribution and Receipt
B9 Data Management			D12 Disposal
B10 Records	CM11 Records	C11 Records	D13 Records
	CM12 Direct Distribution to Clinical Program	C12 Direct Distribution to Clinical Program	

# New therapies

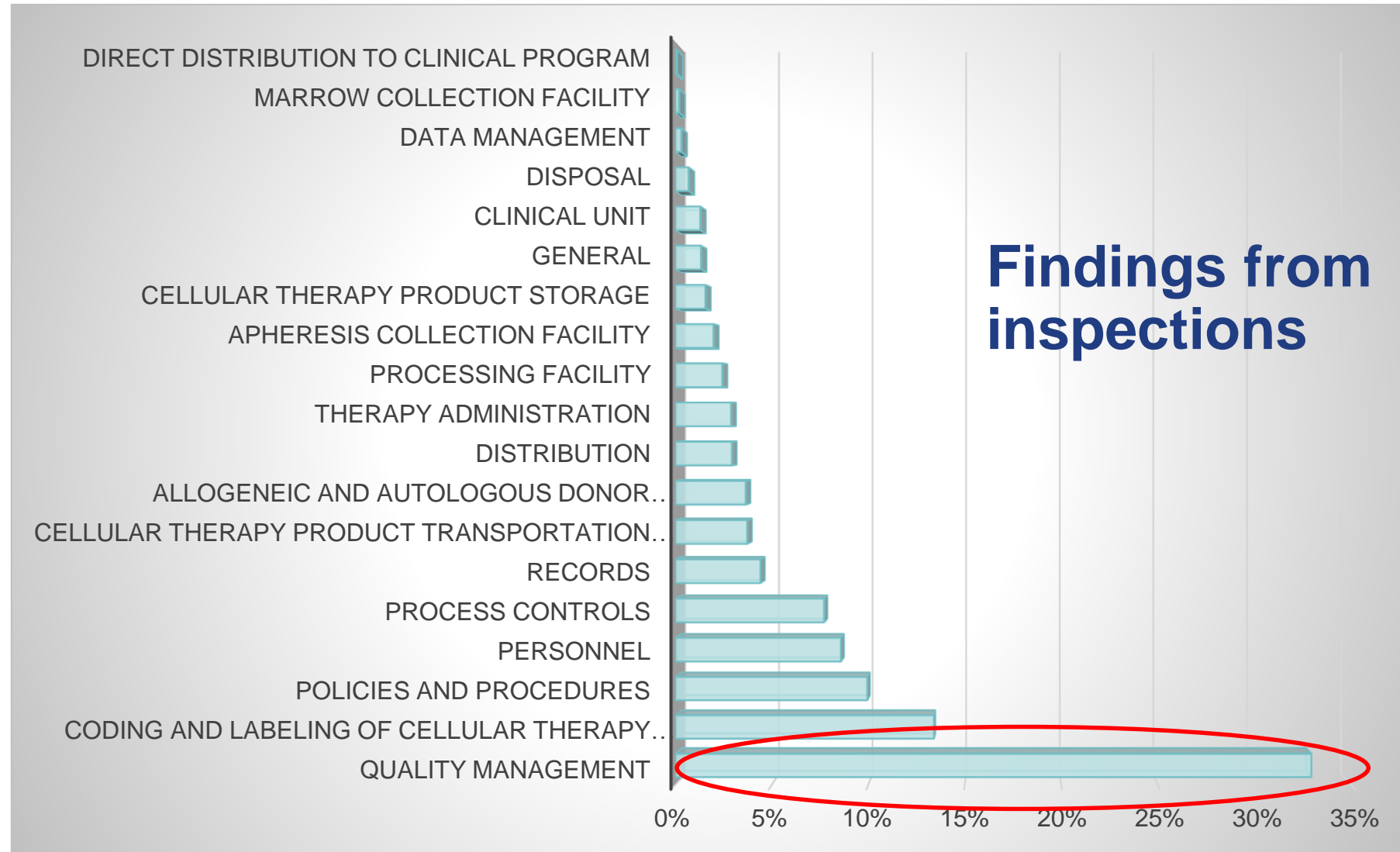
- Standards now also include administration of immune effector cells
  - Excludes the production of these cells



The screenshot shows the JACIE website header with logos for JACIE, EBMT, and ISCT. A search bar is present on the right. The left sidebar contains navigation links: Home, About JACIE (Annual Activity Reports, Partners, Regulations & guidelines, Related publications, Collaborations), and Events (Training, Webinars, Slides and documents). The main content area features a news article titled "New interim standards to cover administration of immune effector cell products in bone marrow transplantation programmes" posted on 2 Feb 2017 by Eoin McGrath. The article text states: "FACT and JACIE have published interim standards for the sixth edition FACT-JACIE International Standards for Hematopoietic Cellular Therapy Collection, Processing, and Administration. The interim standards are intended to promote quality in administration of immune effector cell products, such as chimeric antigen receptor T cells (CAR-T cells), natural killer cells, virus-specific T cells, therapeutic cellular vaccines, and others. The requirements primarily highlight unique aspects of administration and toxicities of immune effector cells."

# Benefits of working to Standards

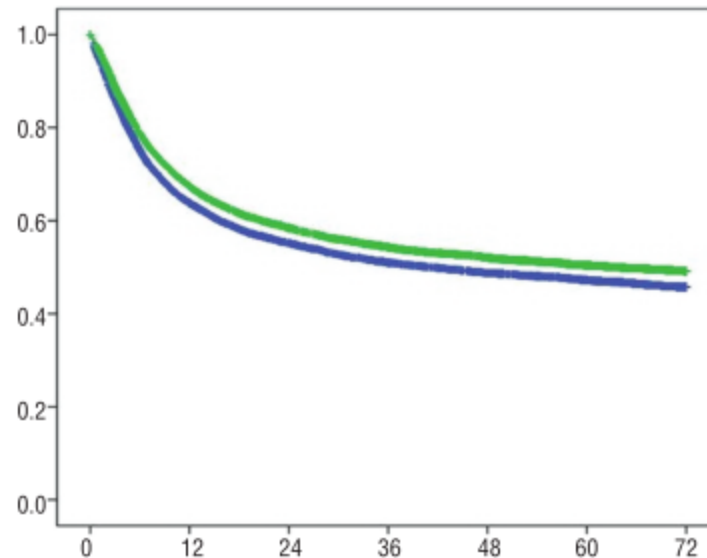
- Helps to establish consensus on
  - **WHAT** you are doing
  - **WHY** you are doing it
  - **HOW** you are doing it
- Reduces inconsistency
- Increases repeatability
- Facilitates training
- Identifies opportunities for improvement
- Creates team spirit
- Gives confidence to patients and payers





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

Alois Gratwohl,<sup>1</sup> Ronald Brand,<sup>2</sup> Eoin McGrath,<sup>3</sup> Anja van Biezen,<sup>2</sup> Anna Sureda,<sup>4</sup> Per Ljungman,<sup>5</sup> Helen Baldomero,<sup>6</sup> Christian Chabannon,<sup>7</sup> and Jane Apperley,<sup>8</sup> for the Joint Accreditation Committee (JACIE) of the International Society for Cellular Therapy and the European Group for Blood and Marrow Transplantation, and the European Leukemia Net



haematologica | 2014; 99(5)

**Figure 2.** “JACIE” accreditation status of the transplant team by November 2012 and outcome of patients transplanted between 1999 and 2006. (A) Kaplan-Meier estimates of overall survival of 17,655 patients with an allogeneic HSCT, transplanted in the years 2004-2006 in a center accredited (green line; n=8,983) or not (blue line; n=8,672) by 2012. The respective hazard ratios are presented in Table 2A. (B) Overall survival (OS) and non-relapse mortality (NRM) at 72 months by EBMT risk score for 17,243 patients transplanted with an allogeneic HSCT in a large center accredited by November 2012 (blue line) or not (red line). (C) Overall survival and non-relapse mortality at 72 months by EBMT risk score for 28,052 patients transplanted with an autologous HSCT in a large center accredited by November 2012 (blue line) or not (red line).

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

## Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation

Alois Gratwohl, Ronald Brand, Dietger Niederwieser, Helen Baldomero, Christian Chabannon, Jan Cornelissen, Theo de Witte, Per Ljungman, Fiona McDonald, Eoin McGrath, Jakob Passweg, Christina Peters, Vanderson Rocha, Ineke Slaper-Cortenbach, Anna Sureda, Andre Tichelli, and Jane Apperley

Gratwohl A, Brand R, Niederwieser D, Baldomero H, Chabannon C, Cornelissen J, et al. Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation. *J Clin Oncol*. 2011;29:JCO.2010.30.4121-

From the European Group for Blood and Marrow Transplantation (EBMT) Activity Survey Office, University Hospital, Basel; University Hospital, Geneva, Switzerland;

## European Group for Blood and Marrow Transplantation Centers with FACT-JACIE Accreditation Have Significantly Better Compliance with Related Donor Care Standards



Chloe Anthias<sup>1,\*</sup>, Paul V. O'Donnell<sup>2</sup>, Deidre M. Kiefer<sup>3</sup>, Jean Yared<sup>4</sup>, Maxim Norkin<sup>5</sup>,  
Paolo Anderlini<sup>6</sup>, Bipin N. Savani<sup>7</sup>, Miguel A. Diaz<sup>8</sup>, Menachem Bitan<sup>9</sup>, Joerg P. Halter<sup>10</sup>,  
Brent R. Logan<sup>11,12</sup>, Galen E. Switzer<sup>13</sup>, Michael A. Pulsipher<sup>14</sup>, Dennis L. Confer<sup>15</sup>,  
Bronwen E. Shaw<sup>11</sup>

“Our results show that practice in accredited centers was much closer to recommended standards as compared with nonaccredited centers.

Specifically, a **higher** percentage of accredited centers use **eligibility criteria** to assess RDs (93% versus 78%;  $P = 1/4.02$ ), and a **lower** percentage have a **single physician simultaneously responsible** for an RD and their recipient (14% versus 35%;  $P = 1/4.008$ ).”

**Twenty years of unrestricted hematopoietic stem cell collection and storage: impact of Joint Accreditation Committee International Society for Cellular Therapy Europe standards implementation on stem cell storage policy and resource utilization**

NICOLA PICCIRILLO<sup>1</sup>, GIUSEPPE AUSONI<sup>1</sup>, PATRIZIA CHIUSOLO<sup>1</sup>,  
FEDERICA SORÀ<sup>1</sup>, ROSSANA PUTZULU<sup>1</sup>, MARIA BIANCHI<sup>1</sup>,  
MADDALENA MARESCA<sup>1</sup>, ALBERTO FIORE<sup>2</sup>, PAOLO OPPEDISANO<sup>2</sup>, SIMONA SICA<sup>1</sup>,  
GINA ZINI<sup>1</sup> & GIUSEPPE LEONE<sup>1</sup>

<sup>1</sup>Istituto di Ematologia, Università Cattolica Del Sacro Cuore, Rome, Italy, and <sup>2</sup>Unità di valutazione delle tecnologie, Università Cattolica Del Sacro Cuore, Rome, Italy

- **Reduction** in the number of leukaphereses per patient
  - result of a strict selection of patients requiring more than 1 cell dose and to the definition of stem cell dose.
- Statistically significant **decrease** in the number of bags Collected for patients *never* transplanted,
- **Well-defined policy** for CSC disposal after 10 years and included informed consent describing terms and conditions for storage and disposal

# WHERE ARE WE NOW

# Overall (since 2000)

First-time applications:

• 405

Total completed  
inspections:

• 611

Accreditation awards


• 324

Countries:


• 30



# Take-up ALLO

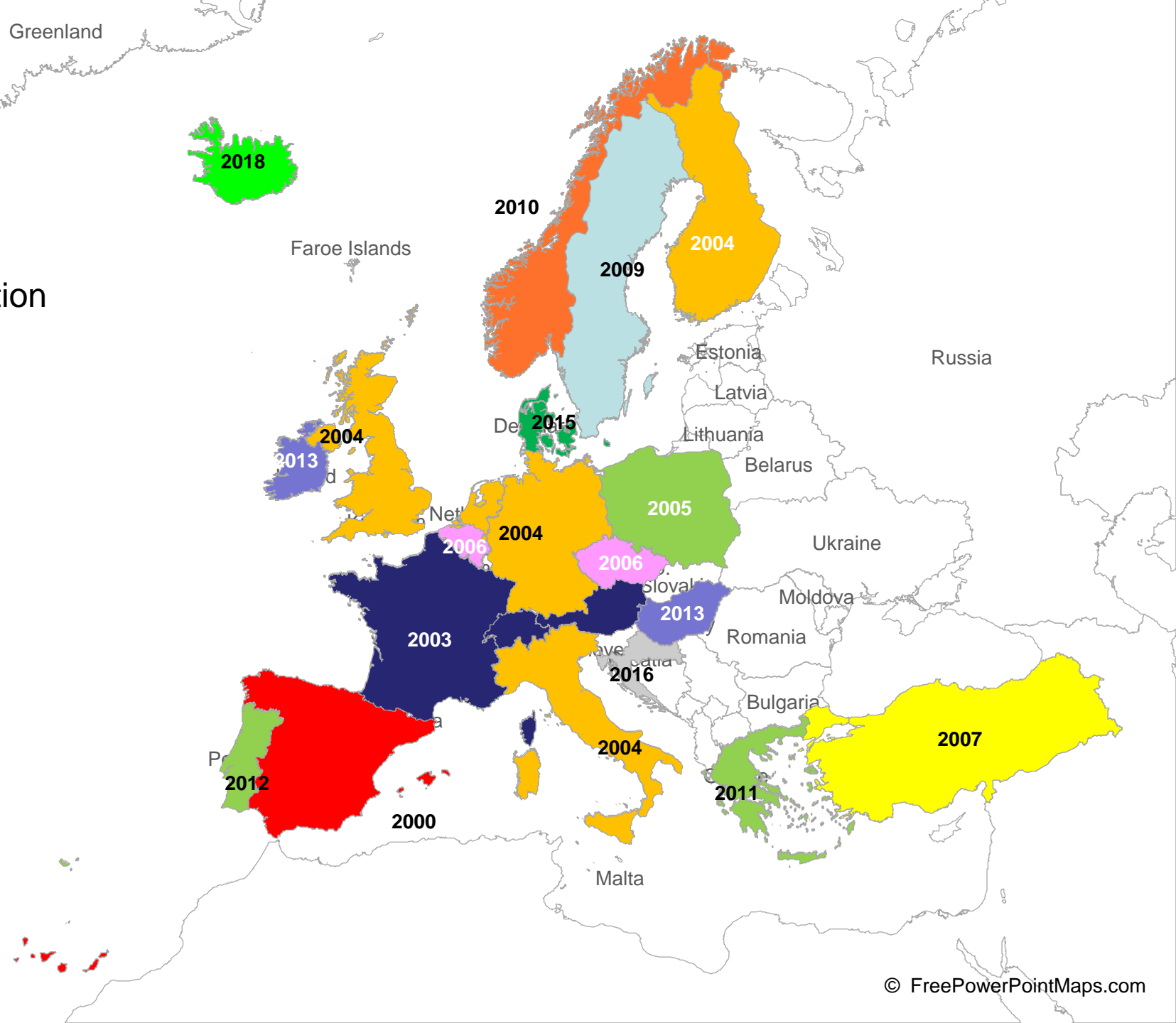
Country		No	Yes
Austria		40%	60%
Belgium		0%	100%
Croatia		0%	100%
Czech Republic		67%	33%
Denmark		0%	100%
Finland		0%	100%
France		11%	89%
Germany		31%	69%
Greece		20%	80%
Hungary		100%	0%
Ireland		50%	50%
Israel		71%	29%
Italy		11%	89%
Lebanon		0%	100%
Netherlands		0%	100%
Norway		0%	100%
Poland		86%	14%
Portugal		67%	33%
Saudi Arabia		60%	40%
South Africa		67%	33%
Spain		33%	67%
Sweden		17%	83%
Switzerland		0%	100%
Turkey		94%	6%
United Kingdom		3%	97%
<b>Total general</b>		<b>32%</b>	<b>68%</b>

# Take-up AUTO

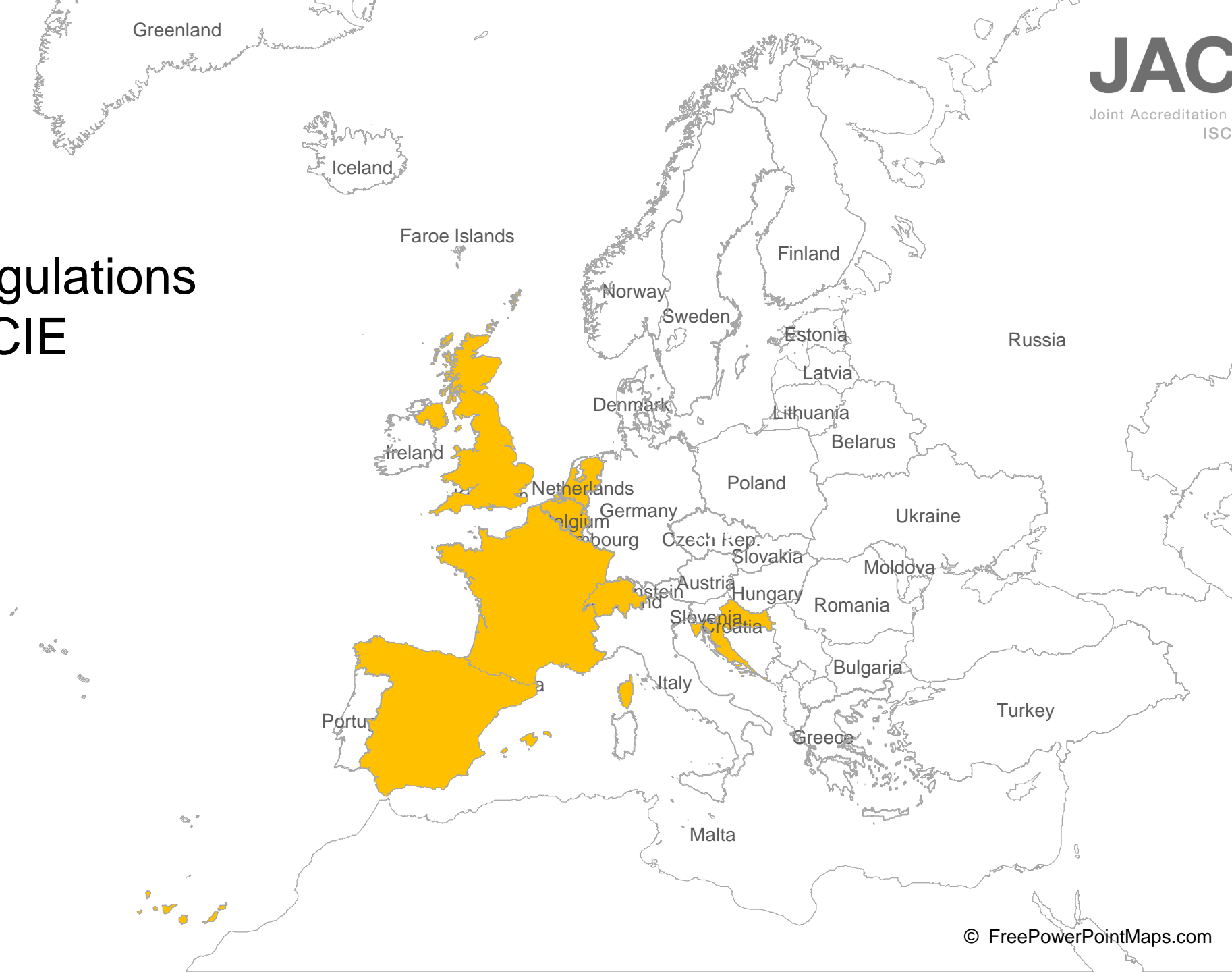
Country		No	Yes
Austria		100%	0%
Belgium		50%	50%
Croatia		100%	0%
Czech Republic		100%	0%
Denmark		100%	0%
Finland		100%	0%
France		82%	18%
Germany		94%	6%
Greece		100%	0%
Hungary		50%	50%
Ireland		100%	0%
Israel		100%	0%
Italy		45%	55%
Netherlands		0%	100%
Norway		100%	0%
Poland		100%	0%
Portugal		100%	0%
South Africa		100%	0%
Spain		92%	8%
Sweden		100%	0%
Switzerland		0%	100%
Turkey		100%	0%
United Kingdom		19%	81%
<b>Total general</b>		<b>72%</b>	<b>28%</b>

## Year of first application by country

Lebanon	2015
Saudi Arabia	2008
Israel	2009
South Africa	2012
Singapore	2012
Mexico	2017
Argentina	2017



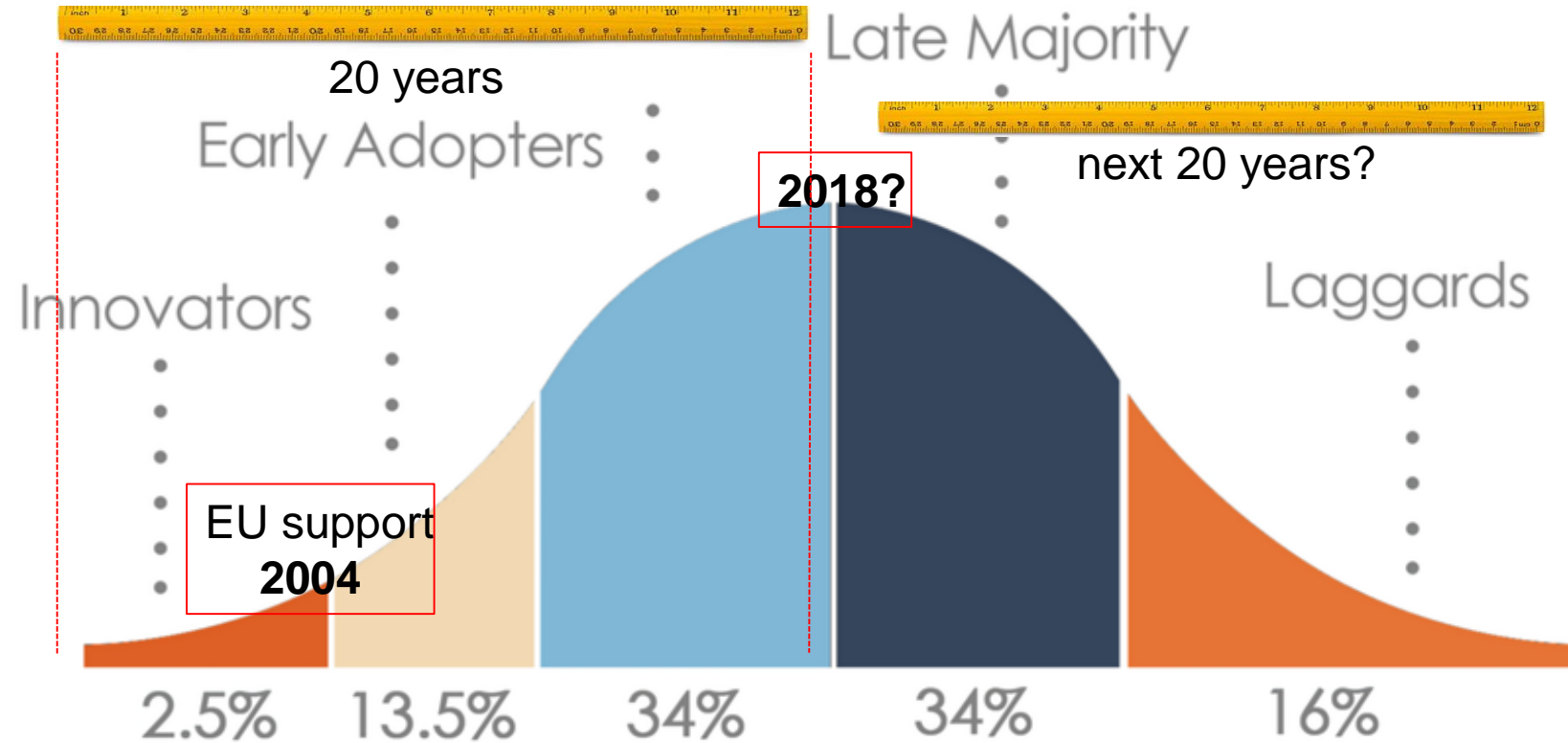
# National regulations & JACIE



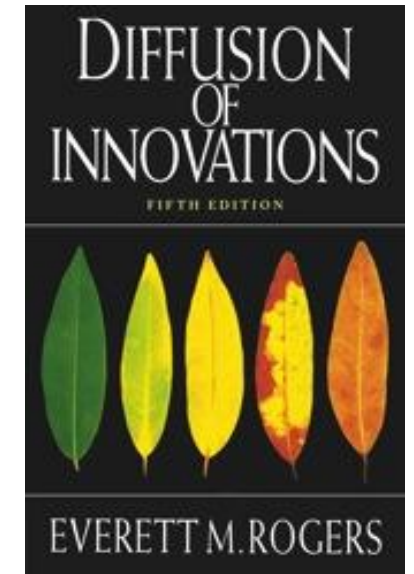


# Take-up of JACIE

Early Majority



Rogers Diffusion Of Innovation Bell





# WHAT'S NEXT?

# BENCHMARKING OF OUTCOMES

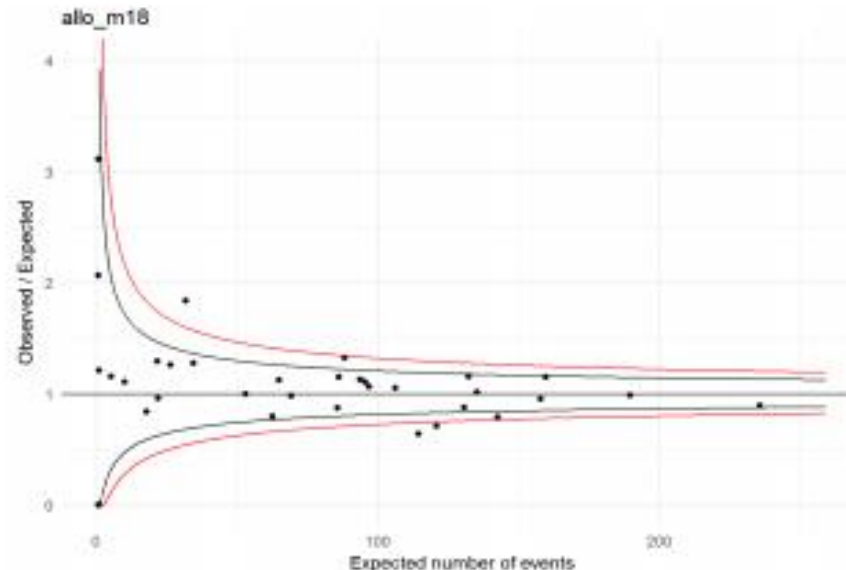
**STANDARD:**  
B4.7.5

*The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.*

**B4.7.5.1** *If expected one-year survival outcome is not met, the Clinical Program shall implement a corrective action plan that meets FACT or JACIE requirements.*

- Introduced in 6th edition, developed in 7th edition
- High interest from external bodies e.g. regulators, payors, patients...
- EBMT's 'Project 2020' Registry Upgrade will include benchmarking component

Risk adjusted  
analysis by  
Leiden model

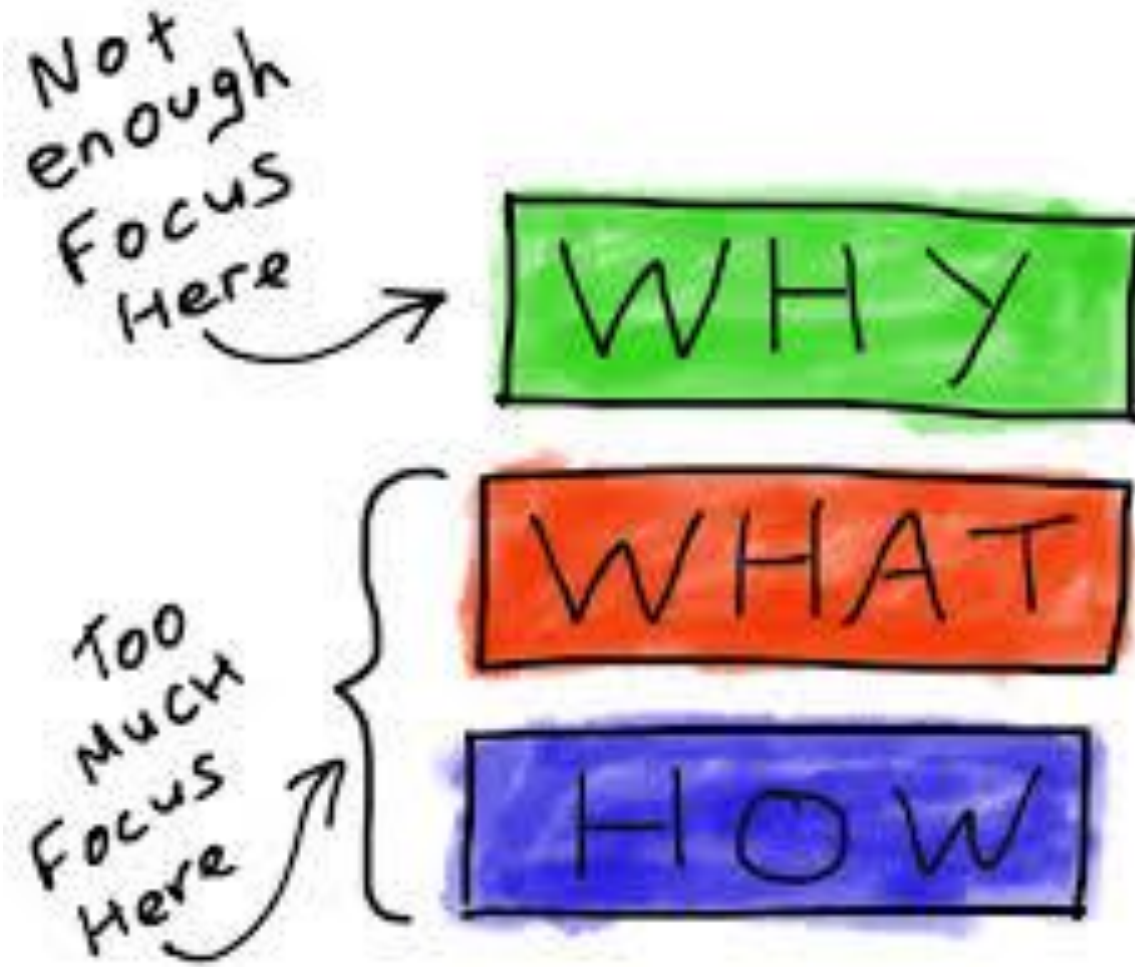


# ‘First step’ or Stepwise certification

- Based on condensed part of Standards emphasising quality management
- Designed for centres to ‘get on to the accreditation ladder’
- Objective – full accreditation but over longer period
  - Not a lower level requirement



# “Always Communicate the Why”



# CONCLUSION

**Lots of hard work**

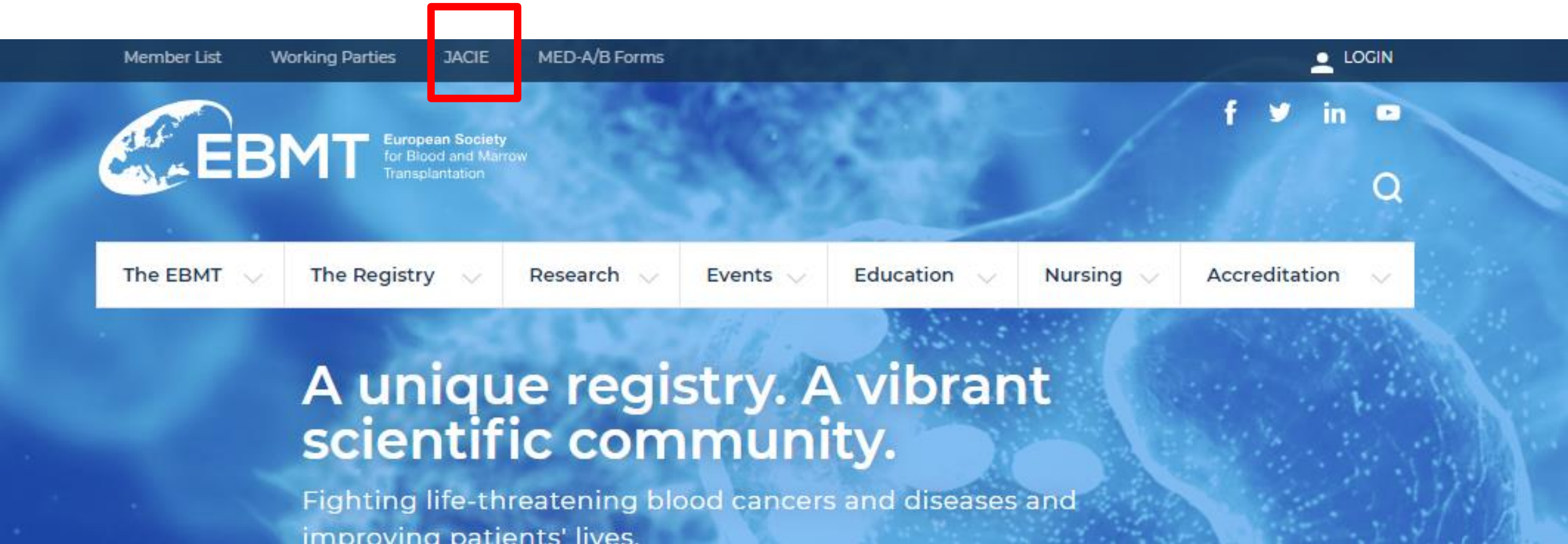
**Improves:**  
- outcomes  
- donor management  
- organisation

**Improvement never  
ends**

**Take part!**



For more information  
[www.ebmt.org/jacie-accreditation](http://www.ebmt.org/jacie-accreditation)



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- Training courses
  - November 8-9, London, UK
  - November 22-23 – Barcelona, Spain

