



# CONTEXT

## Health MEPs propose blueprint for safer healthcare

Public health - 14-04-2015 - 17:01

Committee : Environment, Public Health and Food Safety



- **MEPs note that between 8 and 12% of patients admitted to hospitals in the EU suffer adverse events such as healthcare-related infections, which place a heavy burden on limited health service budgets.**

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bIM-PRESS%2b20150414IPR41844%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>



Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire at least one health care-associated infection.

### **Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis**

THE LANCET

*Benedetta Allegranzi, Sepideh Bagheri Nejad, Christophe Combescure, Wilco Graafmans, Homa Attar, Liam Donaldson, Didier Pittet*

#### Summary

**Lancet 2013; 377: 228–41**  
Published Online  
December 10, 2010  
ISSN 0950-2688

**Background** Health-care-associated infection is the most frequent result of unsafe patient care worldwide, but few data are available from the developing world. We aimed to assess the epidemiology of endemic health-care-associated infection in developing countries.



© 2009 by American Society of Clinical Oncology

## 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

« 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

# NEWS

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NEWS

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

#OPHIEELWORTH | The Courier-Mail | October 15, 2012 1:00AM

### EUROPEAN JOURNAL OF HOSPITAL PHARMACY

Helping hospital pharmacists to provide better patient care

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

European Volume 18, Issue 2, Article

Cur J Hosp Pharm 2012 18:125-127 doi:10.1106/ejpharm-2012-000074.110

#### Abstracts

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

#### Development of a pharmaceutical care program in a bone marrow transplantation unit

A. Asenalo, C. Lizeaga, I. Fernandez, R. Pascual, R. Carrion, J. Derral, D. Inatorza, K. Andueza, E. Esnaola, O. Valbuena

### 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. Prystis, MD

Intermountain Blood and Marrow Transplant Program and Departments of Nursing, Pharmacy, and Medicine, LDS Hospital

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 Sheffield 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

# THE IRISH TIMES

Mon Mar 9, 2015, 18:10

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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.

# 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

# 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)





Figure 1. Patient care system at the University of Michigan Health System. The diagram illustrates the flow of patients through various stages of care, from primary care to hospital admission, treatment, and discharge. Key components include:

- Primary Care:** Patients enter the system through primary care, with flows for "FP referrals to day medicine", "FP referrals to ED", and "FP referrals to consultants or clinics".
- Emergency Department (ED):** Patients enter the ED from primary care or walk-in. Flows include "ED priority for ED and lab services", "ED discharge after consult to outpatient care", "ED discharge after consult to home", and "ED discharge without consult to outpatient care".
- Outpatient Clinics:** Patients are referred to outpatient clinics or seeing consultants. Flows include "Consultant referrals to day medicine", "Outpatient clinic capacity in operation", and "Outpatient discharge".
- Hospital Wards:** Patients are admitted to hospital wards. Flows include "Patients waiting for hospital ward bed", "Hospital admitting", "Wards discharge to ALC", "Wards discharge to home", and "Wards discharge to day medicine for final therapy".
- Discharge:** Patients are discharged to day medicine, home, or to an alternative level of care (ALC). Flows include "Discharge planning effectiveness", "Discharge to day medicine for final therapy", and "Discharge to ALC".

The diagram is annotated with various parameters and constraints, such as "FP referrals to day medicine", "ED priority for ED and lab services", "Consultant referrals to day medicine", "Patients waiting for clinic or consultant", "Patients on hospital waiting list", "Patients in surgery and recovery", "Patients in hospital wards", and "Discharge to day medicine for final therapy". The diagram is color-coded with red and blue arrows to highlight different aspects of the system. The diagram is titled "Figure 1. Patient care system at the University of Michigan Health System".

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

newmedia/

 **JACIE**  
joint accreditation council  
joint accreditation council

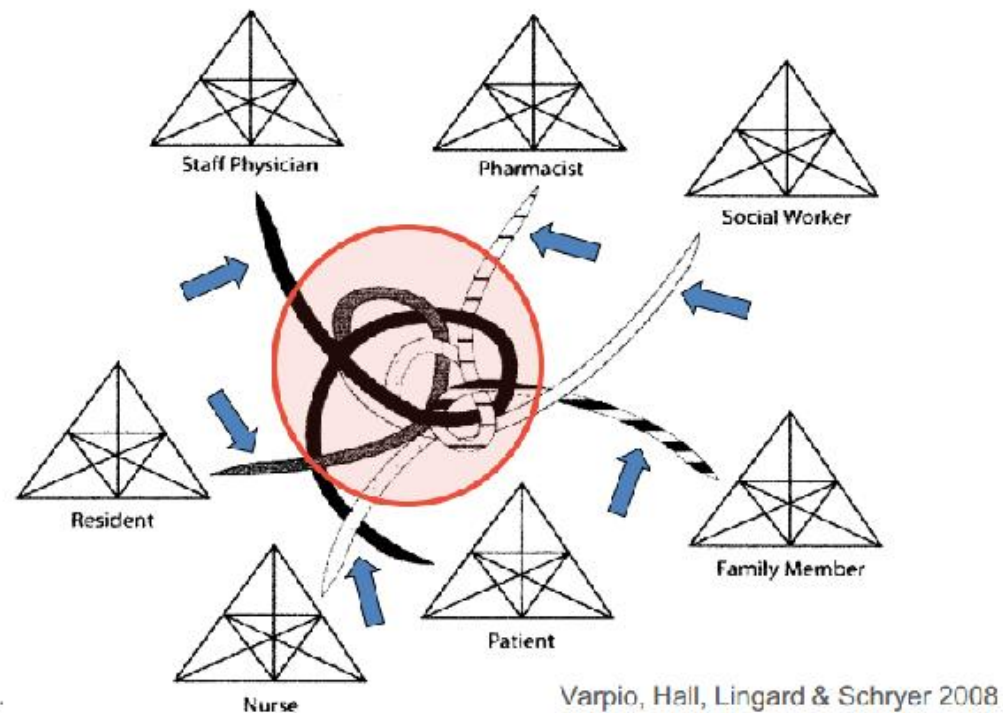
 **EBMT**  
European Society for Blood and Marrow Transplantation

 **ISCT**  
International Society for Cellular Therapy

5



## Teams in healthcare are dynamic and complex



[http://www.nvz-ziekenhuizen.nl/\\_library/10852/Erik](http://www.nvz-ziekenhuizen.nl/_library/10852/Erik)



## QUESTION

- HOW MANY PEOPLE WORK ON DELIVERING TRANSPLANTATION IN YOUR CENTRE?



**MANY HANDS**





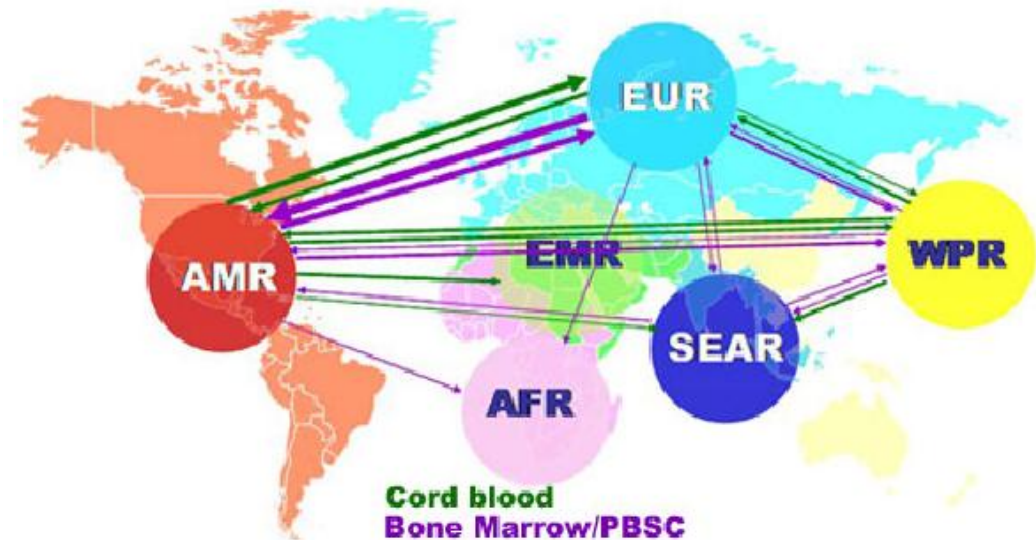
## International context

- “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



**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 business process 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</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> </ul>
<b>6. Reviews, evaluations</b>	<ul style="list-style-type: none"> <li>• Peer case reviews</li> <li>• Realistic evaluation</li> <li>• Formative and summative evaluation approaches</li> <li>• Clinical audit</li> </ul>
<b>7. 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>• 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>
<b>8. External stimulus, reporting</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>

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



# 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.





# SO WHAT HAPPENED IN BMT?

#### Related Articles

Aging Breast Cancer Research  
 October 14, 2002

Breast Cancer Research: The Quest For Funds  
 January 24, 1999

Wakins To Pick Up Pace In Battling Breast Cancer  
 January 24, 1999

### Cancer Center Admits Fatal Chemotherapy Error

March 27, 1995 | BY RICHARD A. KNIX The Boston Globe

DOSTICK - — When a woman died in December at the Dana-Farber Cancer Institute after a grueling three-month treatment for breast cancer, it seemed a tragic error. It might have been avoided.

1996



Experts at the hospital, as well as outside consultants, recognized that many factors contributed to this tragedy (Conway and Weingart, 2005).

System issues included

- minimal double-checks
- orders written by fellows without attending MD signoff
- unclear protocols that were not current and not easily available to RNs and pharmacists.

Some dosages were written in total dose and some in daily dose formats, often in the same protocol.

Maximum dose checking was not a feature of the pharmacy computer system.

....

When reporting did occur, it did not move up the organization in a timely fashion.

From *Preventing Medication Errors: Quality Chasm Series*

Committee on Identifying and Preventing Medication Errors, Philip Aspden, Julie Wolcott, J. Lyle Bootman, Linda R. Cronenwett, Editors. ISBN: 0-309-65856-X, 480 pages, 6 x 9, (2007)

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 Selection, 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	





## “Classic” view



Clinical



Bone Marrow  
Collection



Apheresis



Processing

## FACT-JACIE view



Clinical

Bone Marrow  
Collection

Apheresis

Processing

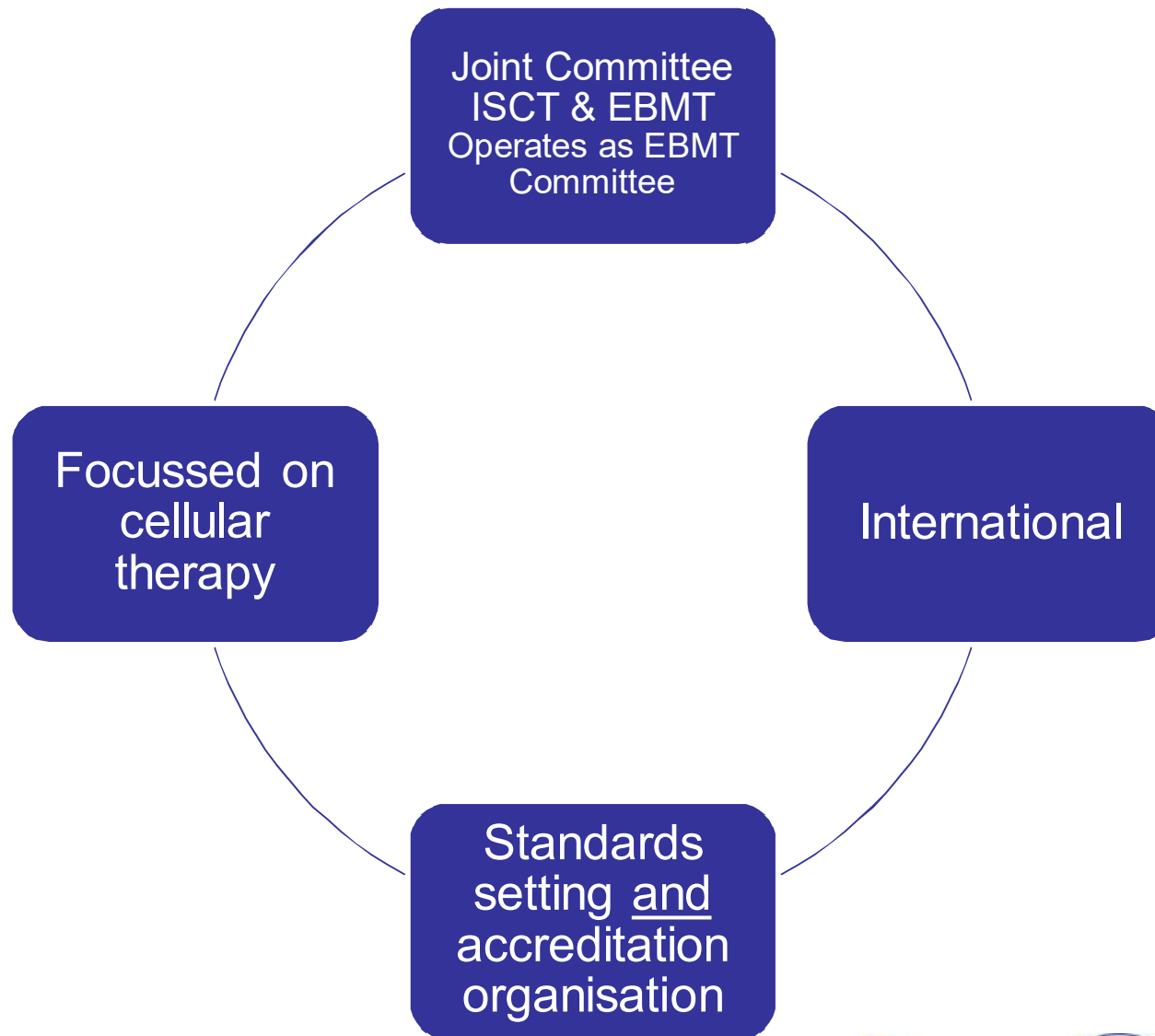




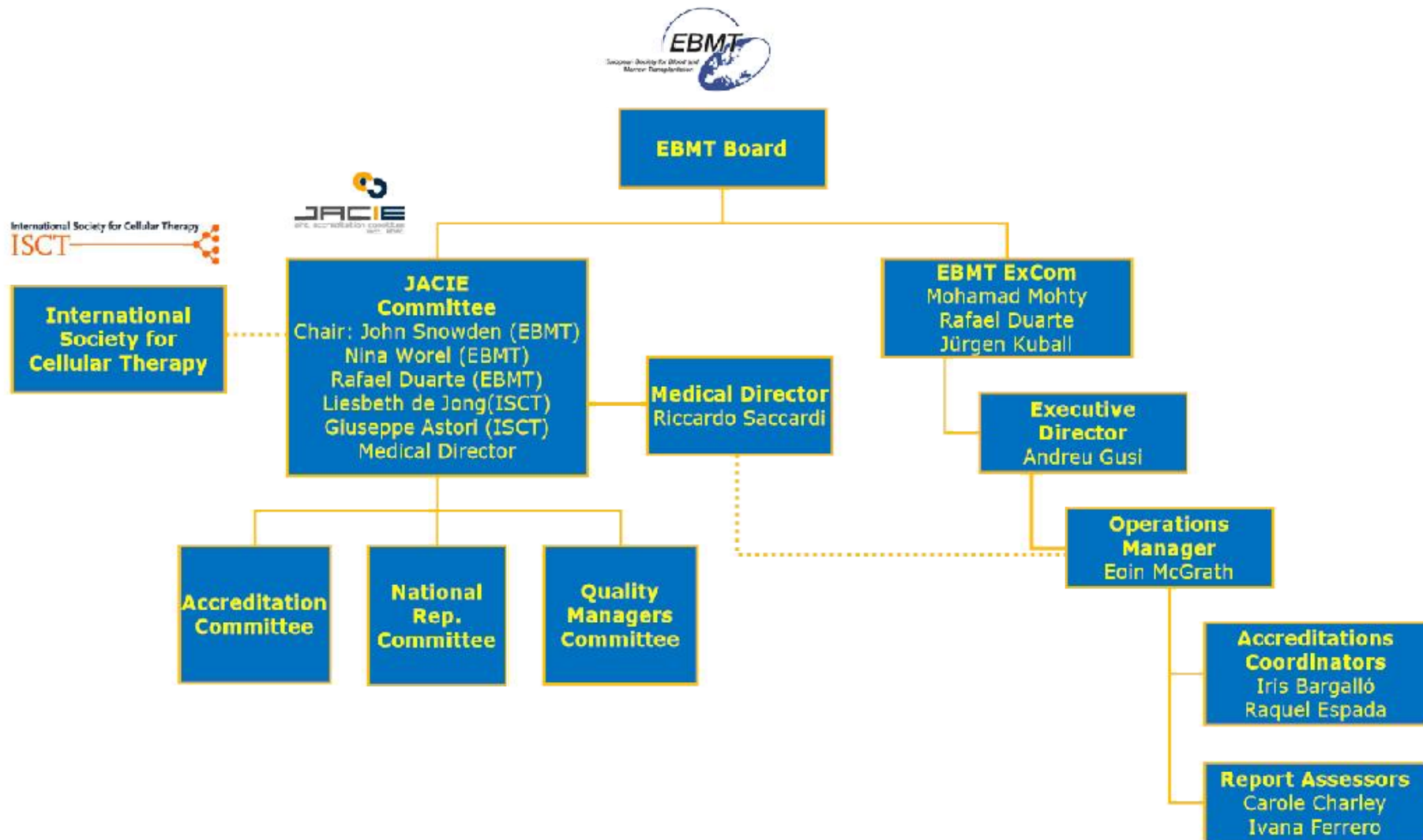
# WHAT IS JACIE?



# What is JACIE?



# Structure & Reporting lines





# WHAT WE DO WANT TO BE

## An initiative that impacts on patient survival



### 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

EBioMedicine 3 (2015) 2161–2166



Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.elsevier.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>g</sup>, Mohammad Mohty<sup>h</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>, Dieter Niederwieser<sup>n</sup>, Theo Stijuen<sup>o</sup>, Ronald Brand<sup>a</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>21</sub>

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

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





# WHERE ARE WE TODAY?



## Among the pioneers in Europe

2004  
The  
Netherlands

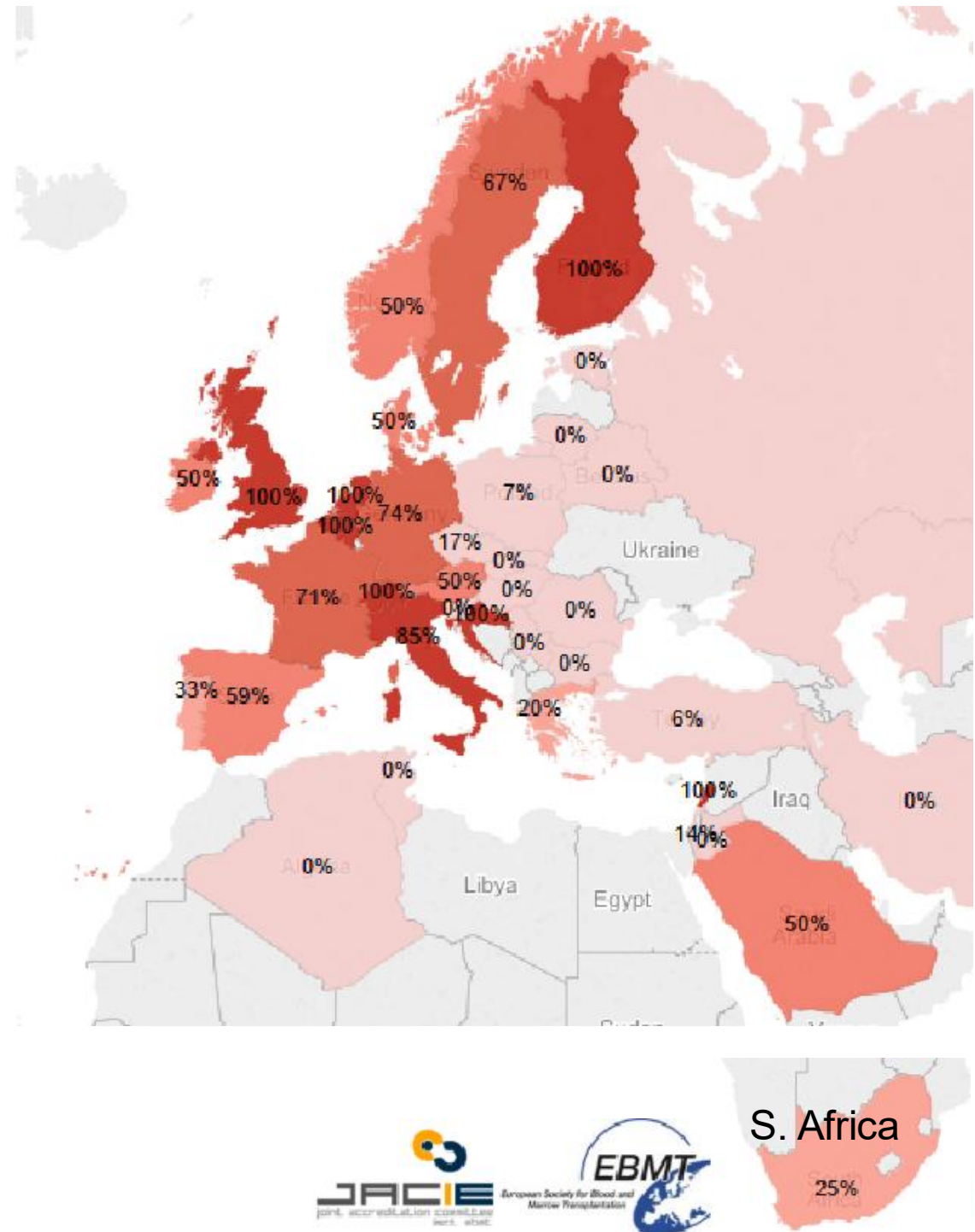




@JACIE\_EBMT

Take-up of JACIE  
among **allo**-  
transplanting  
centres –

Centres that have  
applied as  
percentage of  
total centres  
reporting  
transplants to  
2014 EBMT  
Activity Survey





## Take-up among transplant centres\*

- Percentage of transplanting centres reporting to the 2014 EBMT Activity Survey\* that have at least applied for accreditation since 2000

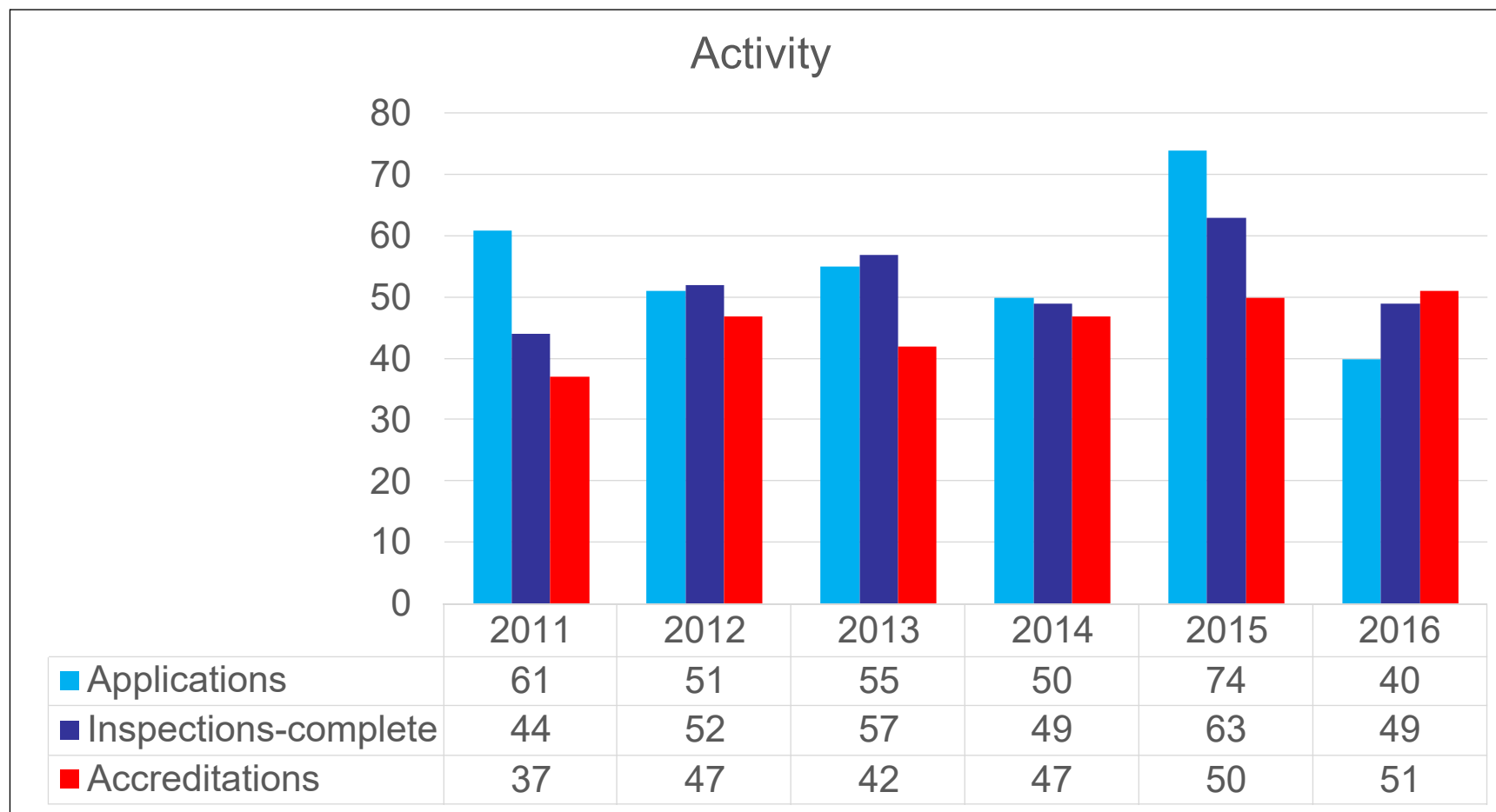
Transplants	Global	Netherlands	UK	Italy	Germany	France
All types	42%	93%	88%	65%	47%	43%
Auto	21%	83%	88%	24%	9%	14%
Allo	59%	100%	100%	85%	74%	71%
Total respondents	657	15	51	95	109	76

\* Passweg JR, Baldomero H, Bader P, Bonini C, Cesaro S, Dreger P, et al. Hematopoietic stem cell transplantation in Europe 2014: more than 40 000 transplants annually. Bone Marrow Transplant [Internet]. 2016 Feb 22;(January):1–7. Available from: <http://www.nature.com/doifinder/10.1038/bmt.2016.20>

\*data May 2016



# Activity



\* 2016 – 12 inspections scheduled up to Dec.

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## JACIE & Regulations



@JACIE\_EBMT

## JACIE & Regulations & Take-up of accreditation





# Other EBMT/JACIE interactions with European Union



- EU Commission
  - DG SANTÉ
    - Invitation to contribute to upcoming stakeholders consultation on Tissue & Cell Directives revision assessment
  - Projects / Joint Actions
    - EuroGTP II
    - ARTHIQS
    - VISISTART



# INSPECTORS





## Inspectors

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



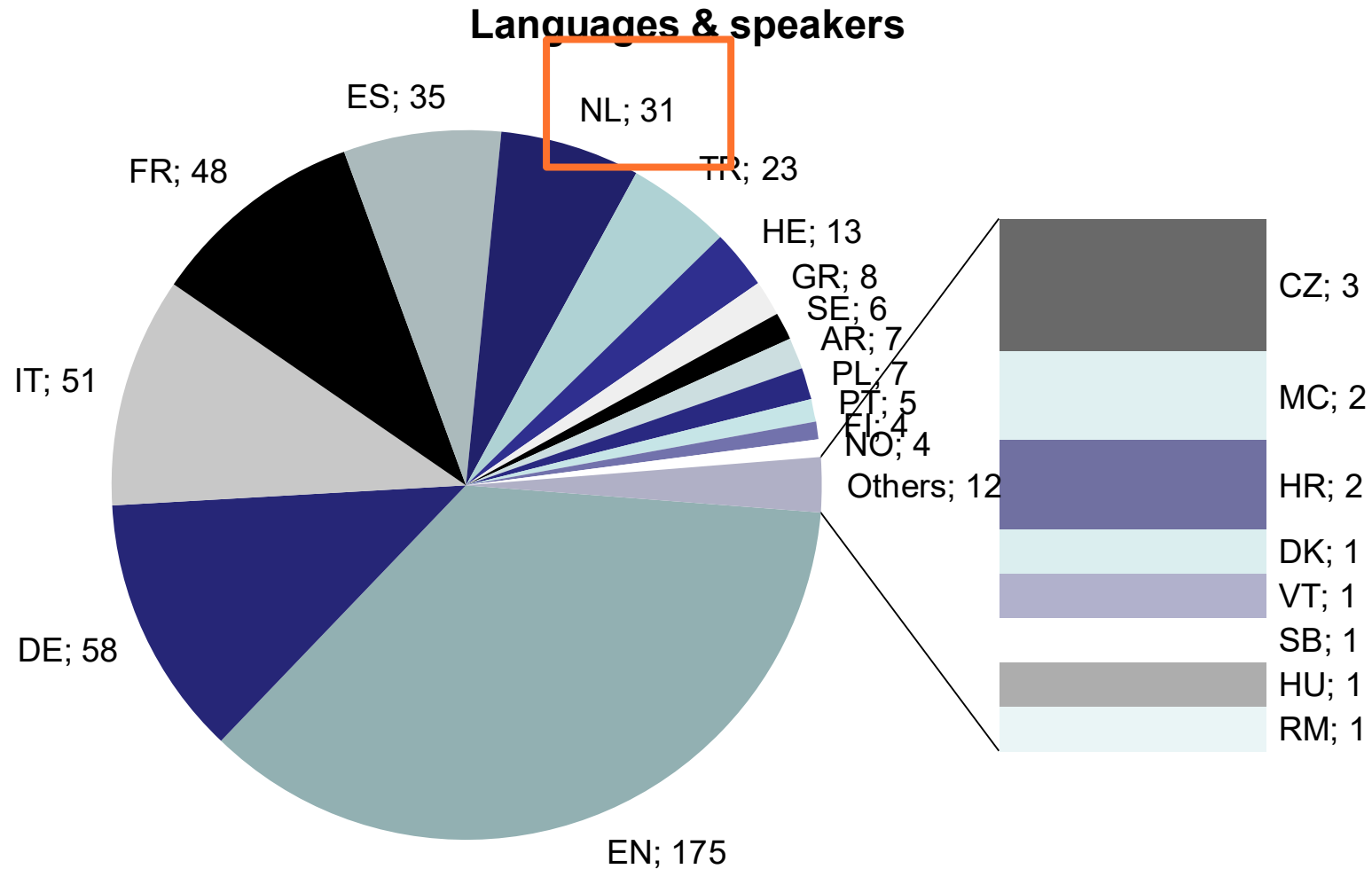


## Criteria for inspectors

- 5 years professional experience in their BMT field
  - Membership of professional society
  - Attend JACIE Training Course
  - Pass online exam on standards and process
  - Level B1 in English (at least writing)
- 
- Coming soon – interviews of new candidates before acceptance by JACIE



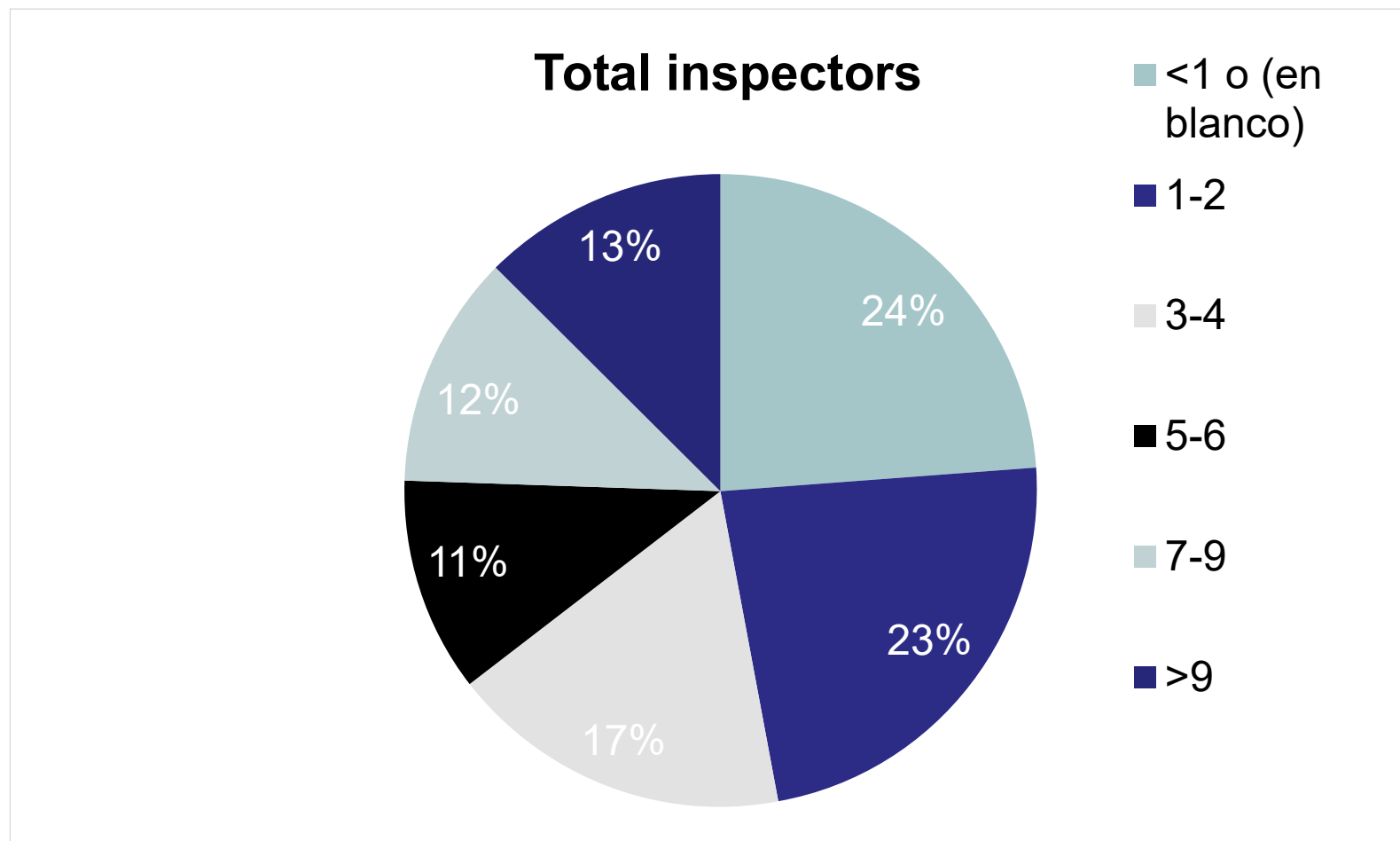
# Languages & inspectors







## Experience among inspector pool



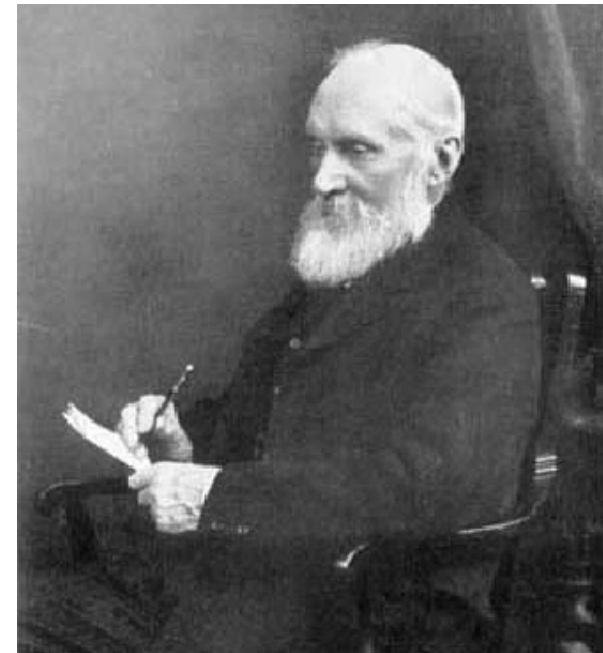
# Quality Management Inspectors

- Initiative from late 2015
- Further details with Raquel Espada



- **“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

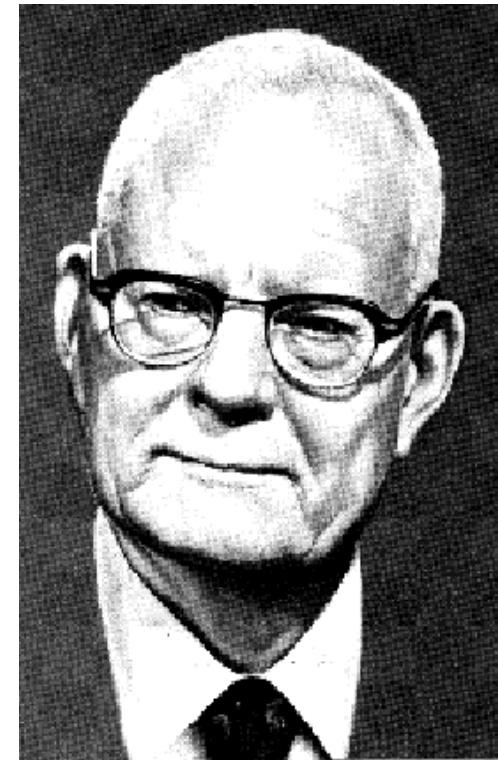




- **“Without data, you’re just another person with an opinion”**

**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)





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## Related publications

### JACIE & quality in healthcare related publi

Owned by JACIE Accreditation Office

This list is a selection of publications that are considered comprehensive. JACIE is not responsible for the contents representatives. The order in which articles are displayed default order to be the date the article was added to the JACIE

### Recent papers in this group



#### Such data can benefit medicine as well as surgery

J. A. Snowden, D. Pamphilon, K. Kirkland, G. H. Jackson  
BMJ, Volume: 342, Issue: apr08 2 (2011)



#### The cost-effectiveness of stem cell transplantations from Vania Costa, Maurice McGregor, Pierre Lemaire, James I. Value in health: the journal of the International Society for (2007)



#### Stem cells: sources and therapies

Manuela Mondil, Cesare Perotti, Claudia Del Fante, Maria C. Biological Research, Volumes: 45, Issue: 3 (2012)



<http://tots.edqm.eu/entry.htm>



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The Joint Accreditation Committee (JACIE) & EBMT is a non-profit organisation established for the purpose of assessing and accrediting centres in the field of the transplantation of all HSCs to hospitals and to other primary and secondary health care providers. The JACIE & EBMT is a partnership between the European Society for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT). The JACIE & EBMT is a non-profit organisation established for the purpose of assessing and accrediting centres in the field of the transplantation of all HSCs to hospitals and to other primary and secondary health care providers. The JACIE & EBMT is a partnership between the European Society for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT).

JACIE

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ISCT

EBMT

ISCT

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European Society for Blood and Marrow Transplantation



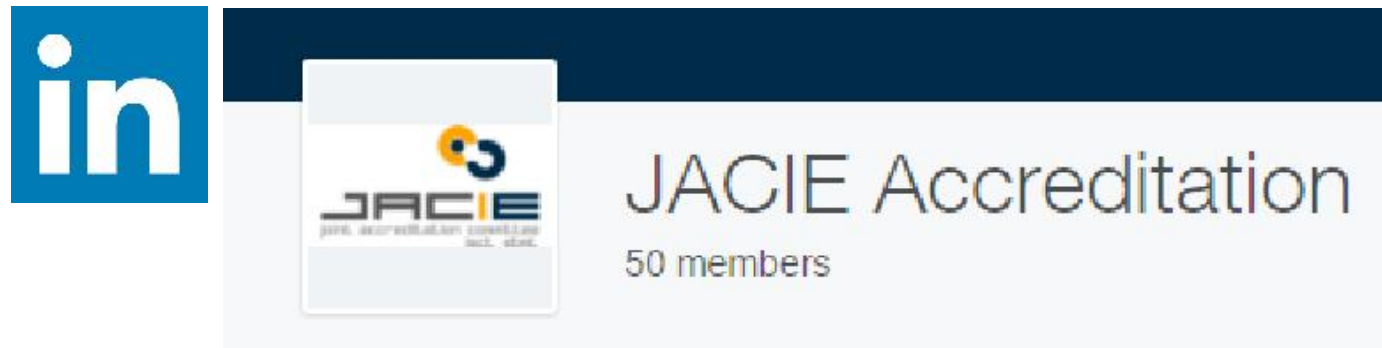
International Society for Cellular Therapy







## LinkedIn Group



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



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# Acknowledgements

## **JACIE Patrons**

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Alois Gratwohl  
Gönnar Kvalheim

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Alvaro-Urbano-Ispizua  
Ineke Slaper-Cortenbach  
Jane Apperley  
Christian Chabannon  
Alessandro Rambaldi  
John Snowden

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- JACIE Accreditation Committee
- JACIE QM Committee
- JACIE National Representatives
- **JACIE Inspectors**
  - **27 countries**