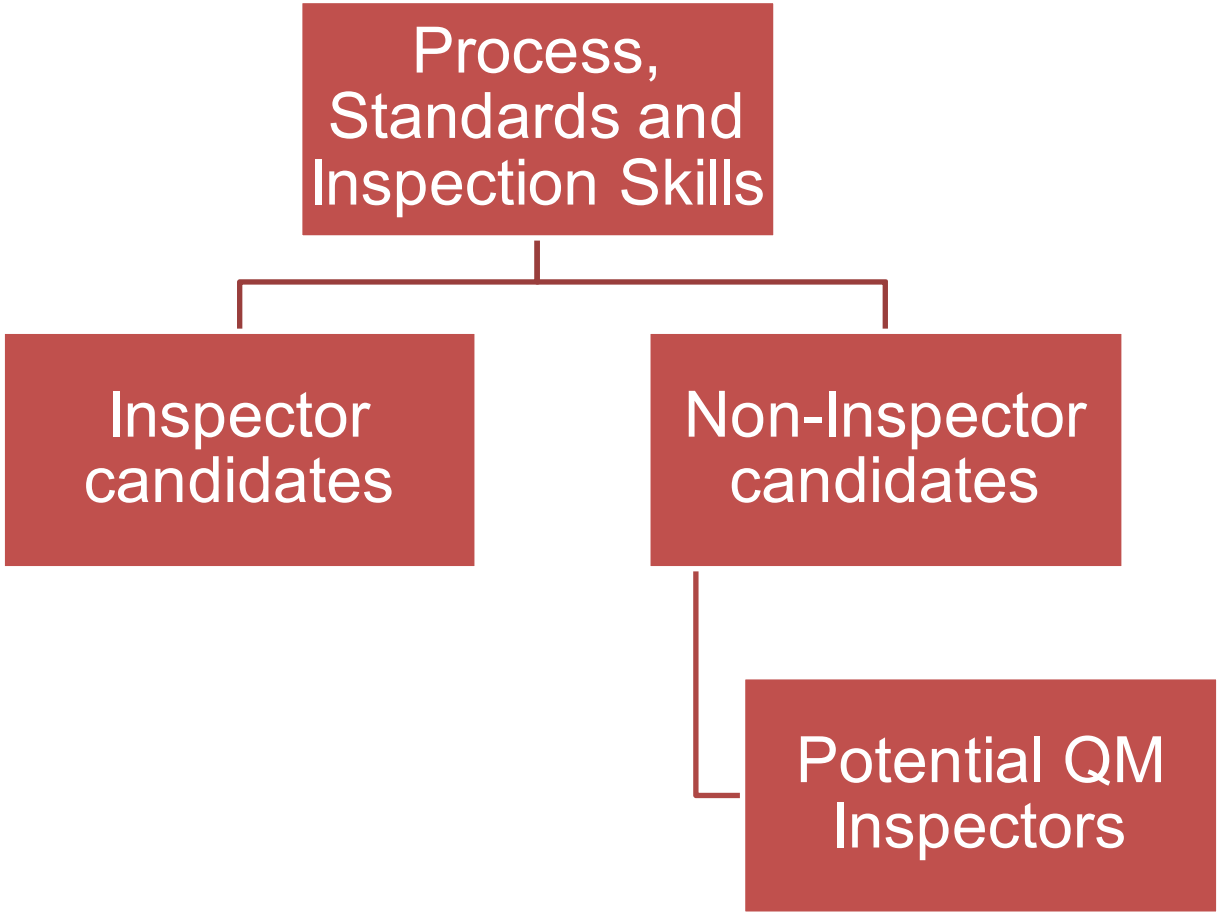
28th JACIE Training Course

Manchester, UK

Course objectives



Trainers

- Eoin McGrath
- Operations Manager
- Since 2002

- Iris Bargalló
- Accreditations Coordinator
- Since 2010

- Raquel Espada
- Accreditations Coordinator
- Since June 2014

Contributors

- John Snowden
- Kim Orchard
- Robert Wynn

‘Housekeeping’

- Emergency
- Bathrooms
- Wifi
- Breaks / Lunch
- Dinner

JACIE joint accreditation committee
EBMT European Society for Blood and Marrow Transplantation
International Society for Cellular Therapy ISCT

Thanks!

EUSAPharma

Therakos

JACIE
joint accreditation committee
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European Society for Blood and Marrow Transplantation
International Society for Cellular Therapy
ISCT

EHA CME

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USB sticks/pen drive

Will be updated shortly

Pre-inspect doc 6th	29/06/2015 9:53	Carpeta de archivos	
CH-001-07-Inspection Checklist	22/06/2015 15:08	Microsoft Excel W...	679 KB
Comparison table 5th to 6th 2015-03-01	17/04/2015 17:35	Foxit PhantomPD...	604 KB
F-001-08-Application Form	18/06/2015 11:08	Microsoft Word D...	80 KB
G-001-08-Inspection guide 5th edition	29/04/2014 16:18	Foxit PhantomPD...	2.748 KB
JACIE_Welcome_Guide_2014	11/12/2014 16:32	Foxit PhantomPD...	1.297 KB
Manual 6.00 ed	02/03/2015 9:59	Foxit PhantomPD...	3.002 KB
Standards 6.00 ed	02/03/2015 9:54	Foxit PhantomPD...	879 KB
Summary of 6th ed changes	25/02/2015 12:13	Foxit PhantomPD...	201 KB
WHO Lab QMS Manual_eng	01/10/2014 9:46	Foxit PhantomPD...	6.047 KB

JACIE & Quality Management in HSCT

- JACIE Operations Manager
- From Ireland
- Live in Barcelona since 2002
- Working for EBMT/JACIE since 2002

Press release

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

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The Unexpected

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South Korea hospital fire kills 21

Blaze believed set by an 81-year-old dementia patient

The Associated Press | Posted: May 27, 2014 9:23 PM ET | Last Updated: May 28, 2014 7:43 AM ET

Helicopter Crash on Grand Rapids Hospital

May 24th, 2011 | Author: Murdoc

Luckily, it was a training flight and the crew escaped unharmed

GRAND RAPIDS, Mich. (AP) — A helicopter whose pilot was practicing approaches crashed on the roof of a hospital Thursday, sending fire members after the two people on board escaped unharmed, a fire official said.

No patients were aboard the helicopter when the crash around 11 a.m. at Spectrum Health Butterworth Hospital, Fire Chief John VanSickerna said. The chopper landed on its side and caught fire, he said.

The crash sent thick black smoke over downtown and forced the evacuation of patients from the building.

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Last Updated: Wednesday, 2 January 2008, 20:26 GMT

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Fire forces hospital's evacuation

Patients and staff were forced to flee onto the streets as a major fire swept through a leading cancer hospital.

The fire broke out at the Royal Marsden Hospital in Chelsea, west London, at 1320 GMT but is now under control.

Much of the roof was destroyed

The fire has destroyed much of the top floor

pt

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TRENDING Saeed Ajmal suspended for illegal action - 2 hours ago

Kolkata hospital fire kills 89

Foreign DECEMBER 10, 2011 BY AFP

JACIE | EBMT | ISCT International Society for Cellular Therapy

SunSentinel.com

Related Articles

Cancer Center Admits Fatal Chemotherapy Error

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

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

NEWS

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

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

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

A verdict of medical misadventure was returned at the inquest into the death of Barbara Kozyra 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

Tuesday 25 November 2014 19.33 GMT

Great Ormond Street 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

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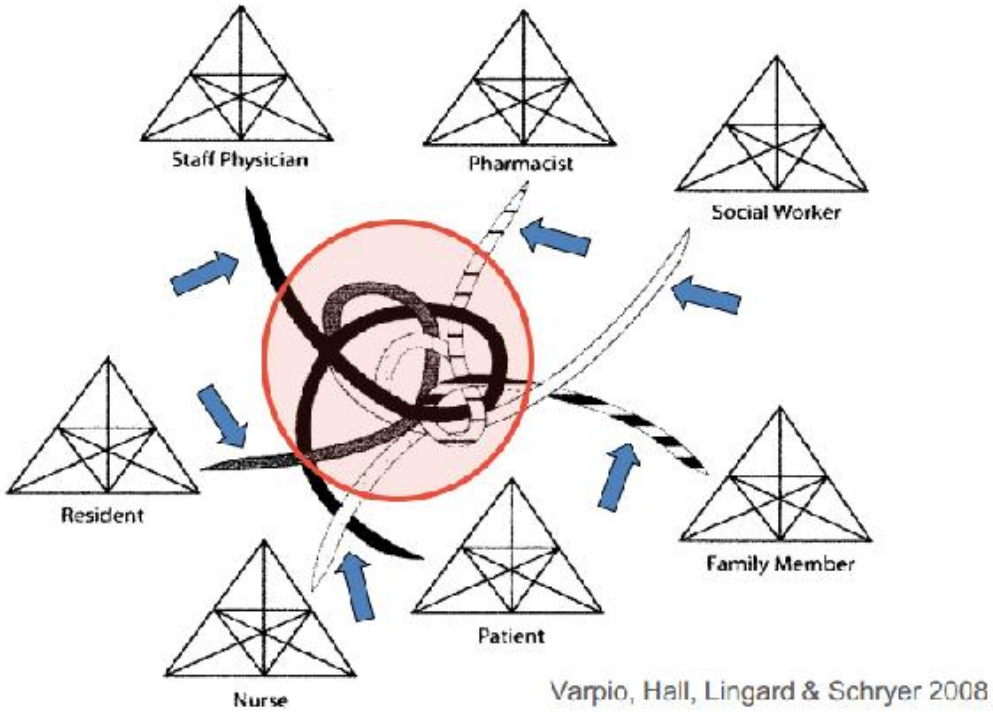
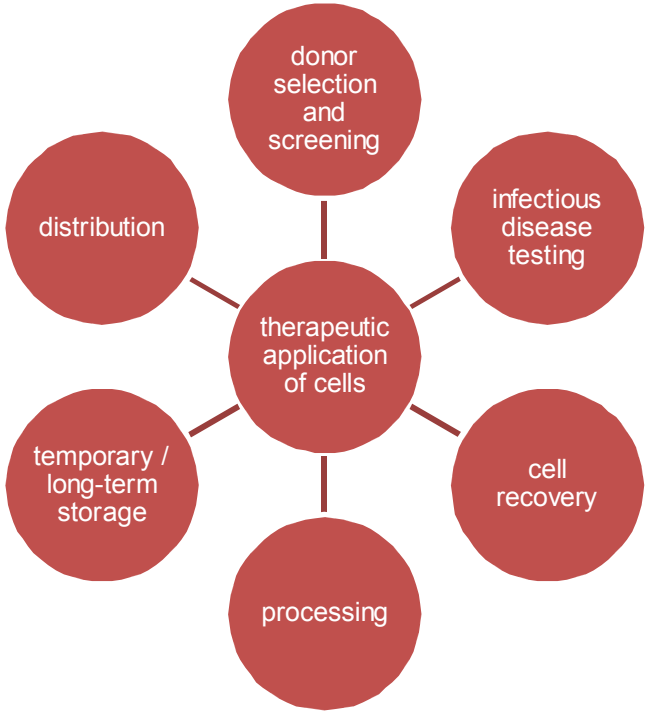
Teams in healthcare are dynamic and complex



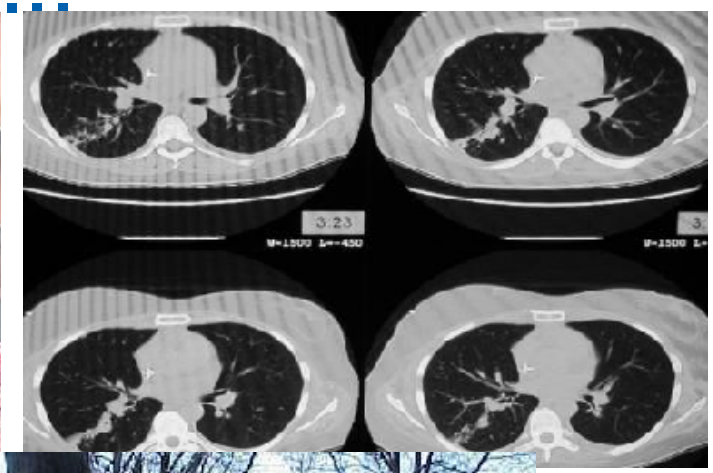
http://www.nvz-ziekenhuizen.nl/_library/10852/Erik

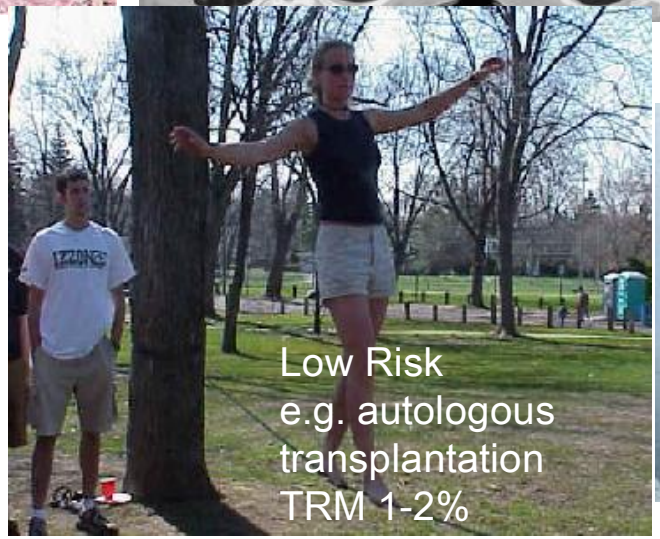
BMT is a complex process…

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

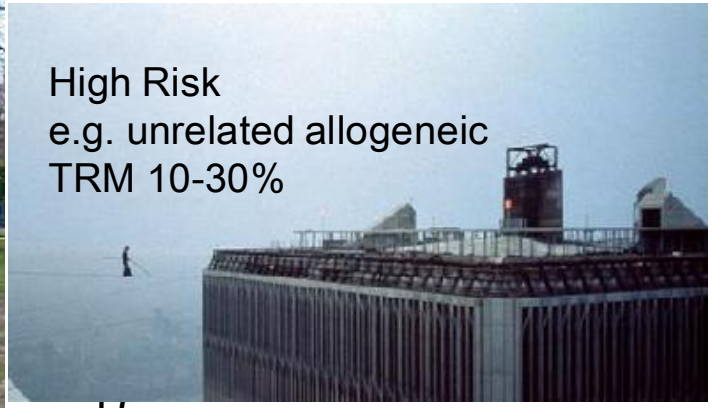


.....and TOXIC.....





… with RISK..



Donation is not without morbidity and risk

- 5 donor fatalities
- 37 severe adverse events
- 20 hematologic malignancies

haematologica
the Hematology Journal
Open Access Publication

Severe events in donors after allogeneic hematopoietic stem cell donation

Joerg Halter[1], Yoshihisa Kodera[2], Alvaro Urbano Ispizua[3], Hildegard T. Greinix[4], Norbert Schmitz[5], Geneviève Favre[1], Helen Baldomero[6], Dietger Niederwieser[7], Jane F. Apperley[8] and Alois Gratwohl[1] for the European Group for Blood and Marrow Transplantation (EBMT) activity survey office

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This Article

Published online before print December 4, 2008, doi: 10.3324/haematol.13668
haematol January 1, 2009 vol. 94 no. 1 94-101

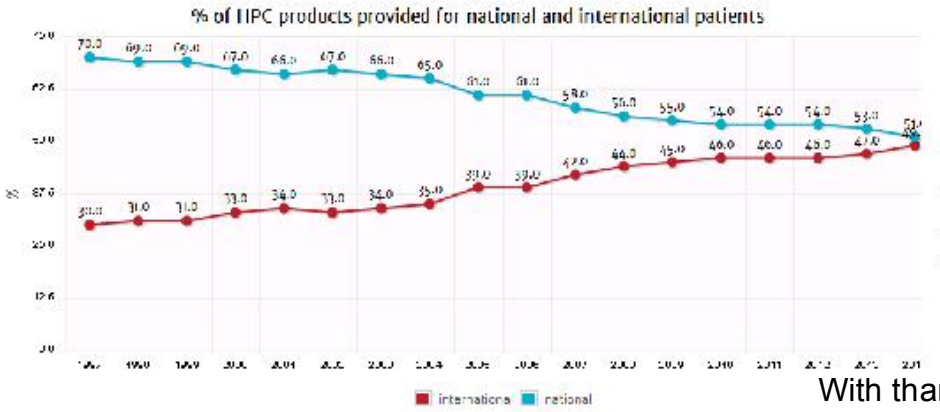
» Abstract
Full Text
Full Text (PDF)

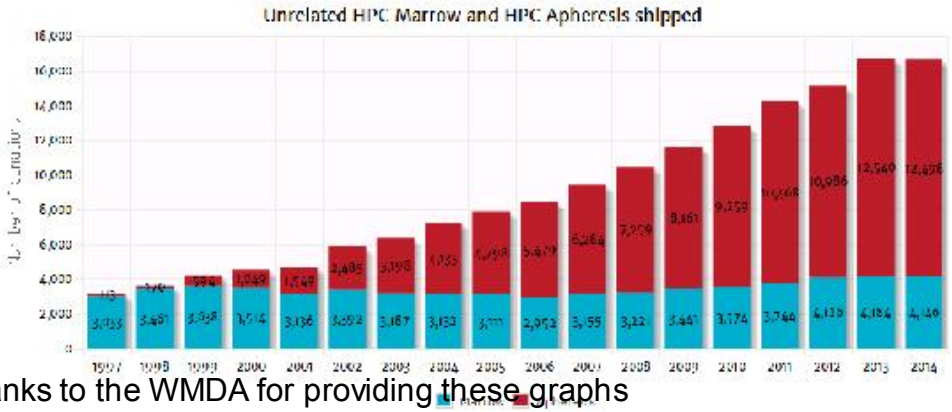
About the Jo
Editorial Bo
Policies and
Information
Information Reviewers

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





With thanks to the WMDA for providing these graphs

RESPONSE BY THE PROFESSIONALS TO THESE CHALLENGES

SunSentinel.com

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Aiding Breast Cancer Research
October 14, 2002

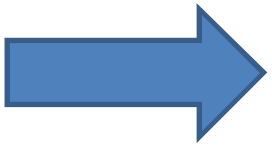
Breast Cancer Research: The Quest For Funds
January 24, 1991

Walk Aims To Pick Up Pace In Battling Breast Cancer

Cancer Center Admits Fatal Chemotherapy Error

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

BOSTON — When a woman died in December at the Dana-Farber C
gruelling three-month treatment for breast cancer, it seemed a tragic r
right states cancer care.



Foundation for the Accreditation of Cellular Therapy

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.

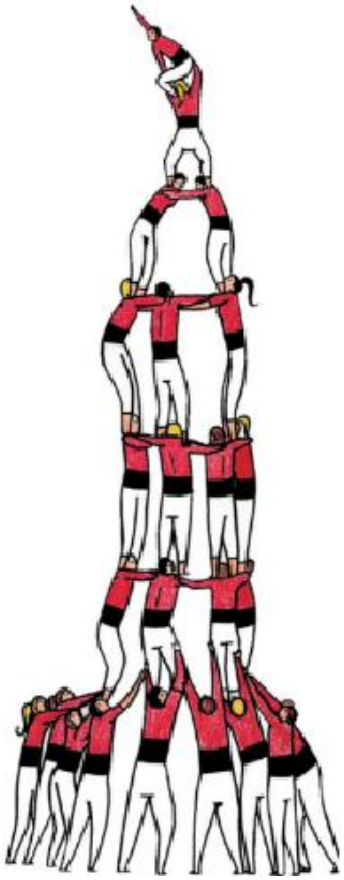
….

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)

WHAT IS JACIE?

JACIE: A Standards-setting & Accreditation organisation



What is JACIE?

- International
- Standards setting and accreditation organisation
- Focussed on cellular therapy
- Independent of the regulators - established by the practitioners themselves
- Compatible with EU regulations (2004/23/EC etc.) & US (FDA)

Relationship with FACT

- JACIE inspired by FACT's model in the USA
- Close partnership in standards development
  - International standards

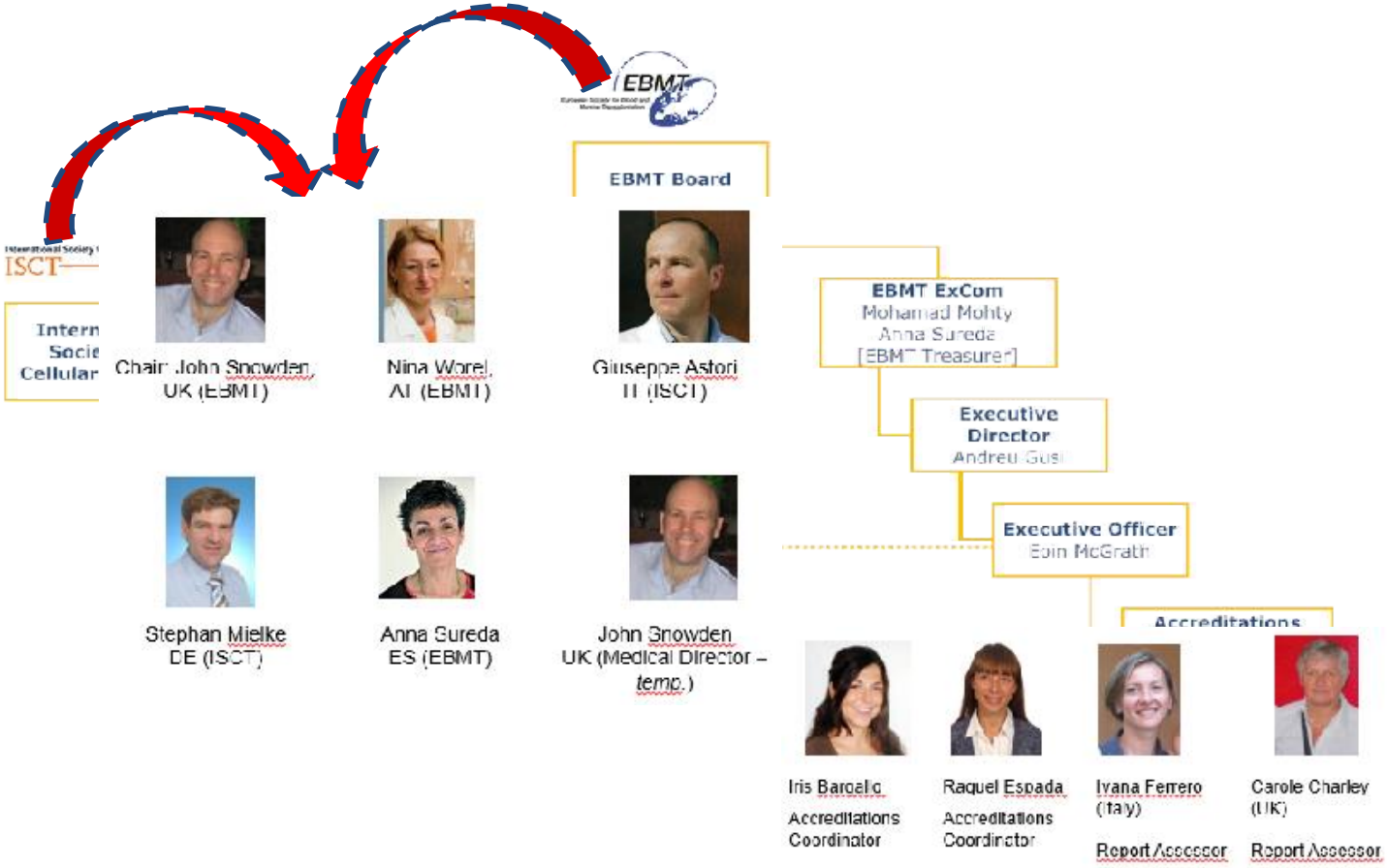
Regulation v. Accreditation

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.

Structure & Reporting lines



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ISCT International Society for Cellular Therapy

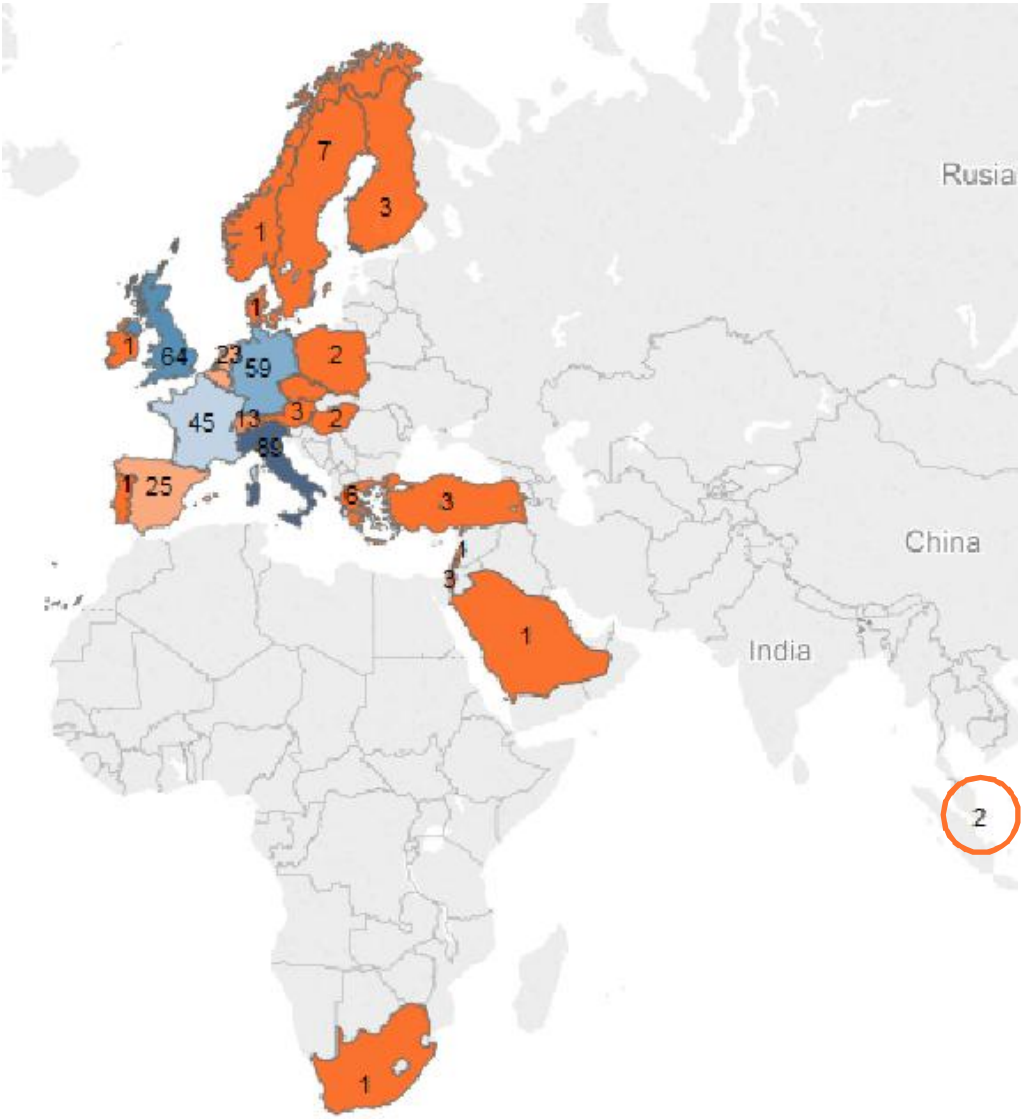
Clinical	Collection Marrow	Collection Apheresis	Processing
B1 General	CM1 General	C1 General	D1 General
B2 Clinical Unit	CM2 Marrow Collection Facility	C2 Apheresis Facility	D2 Processing Facility
B3 Personnel	CM3 Personnel	C3 Personnel	D3 Personnel
B4 Quality Management	CM4 Quality Management	C4 Quality 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	

Acknowledgements

JACIE Sponsors
EBMT
ISCT
JACIE Founders
Alois Gratwohl
Günnar Kvalheim
JACIE Board Chairs
Alvaro-Urbano-Ispizua
Ineke Slaper-Cortenbach
Jane Apperley
Christian Chabannon
Alessandro Rambaldi

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

Total Initial Applications by Country since 2000



International language developing around quality in transplantation

Take-up among transplant centres*

- % of transplanting centres reporting to 2013 EBMT Activity Survey that have applied, been inspected or been accredited since 2000

- ~ 40% of all those reporting centres are/have been in some part of the JACIE process
  - ~ 55% of allogeneic centres
  - ~ 17% of autologous centres

*Provisional data

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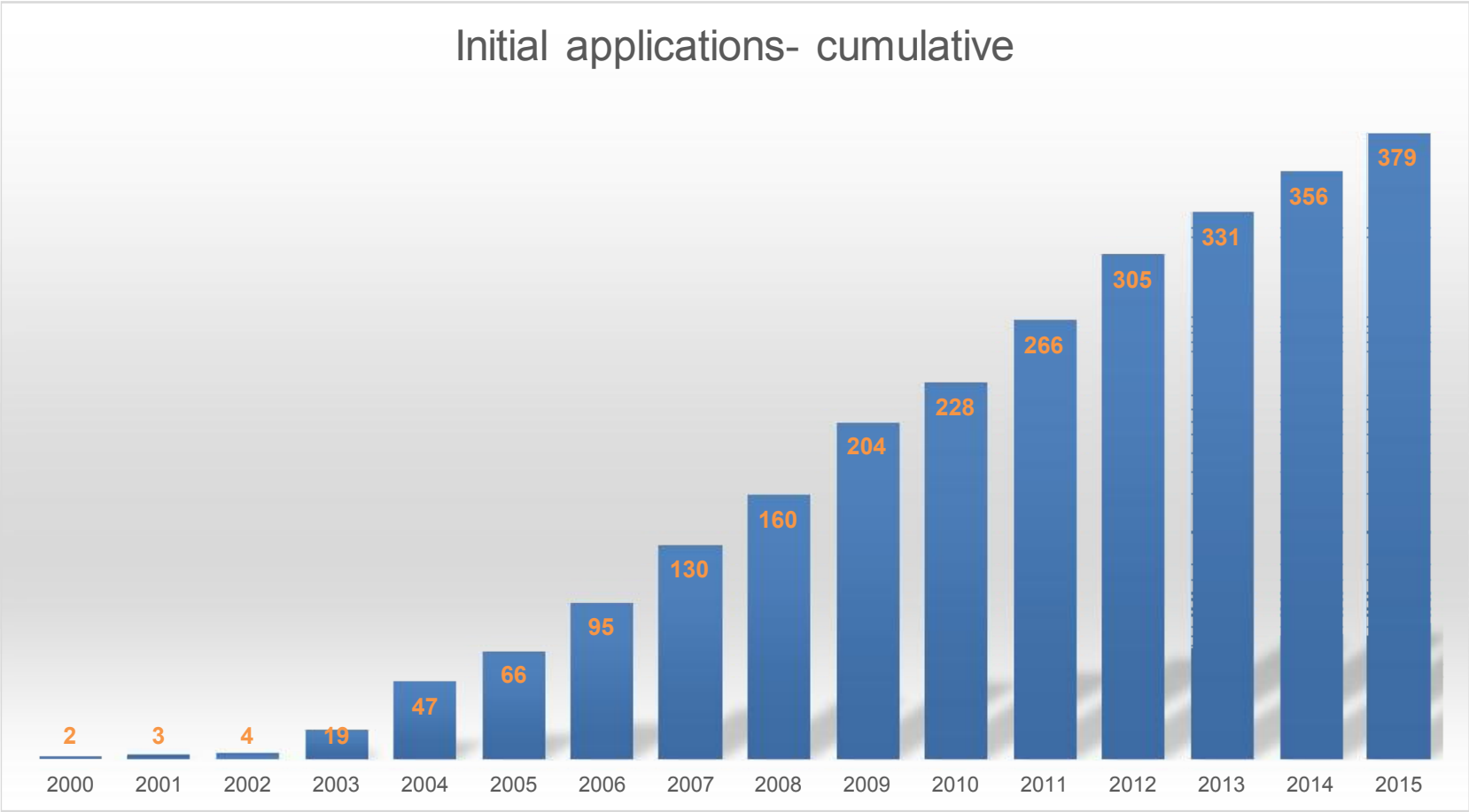
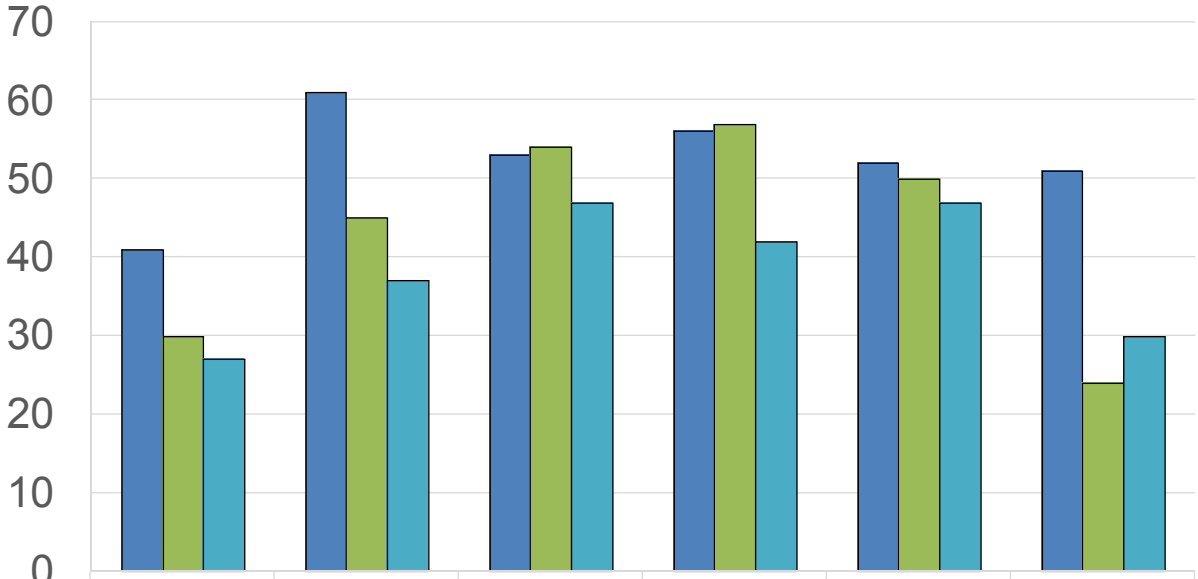
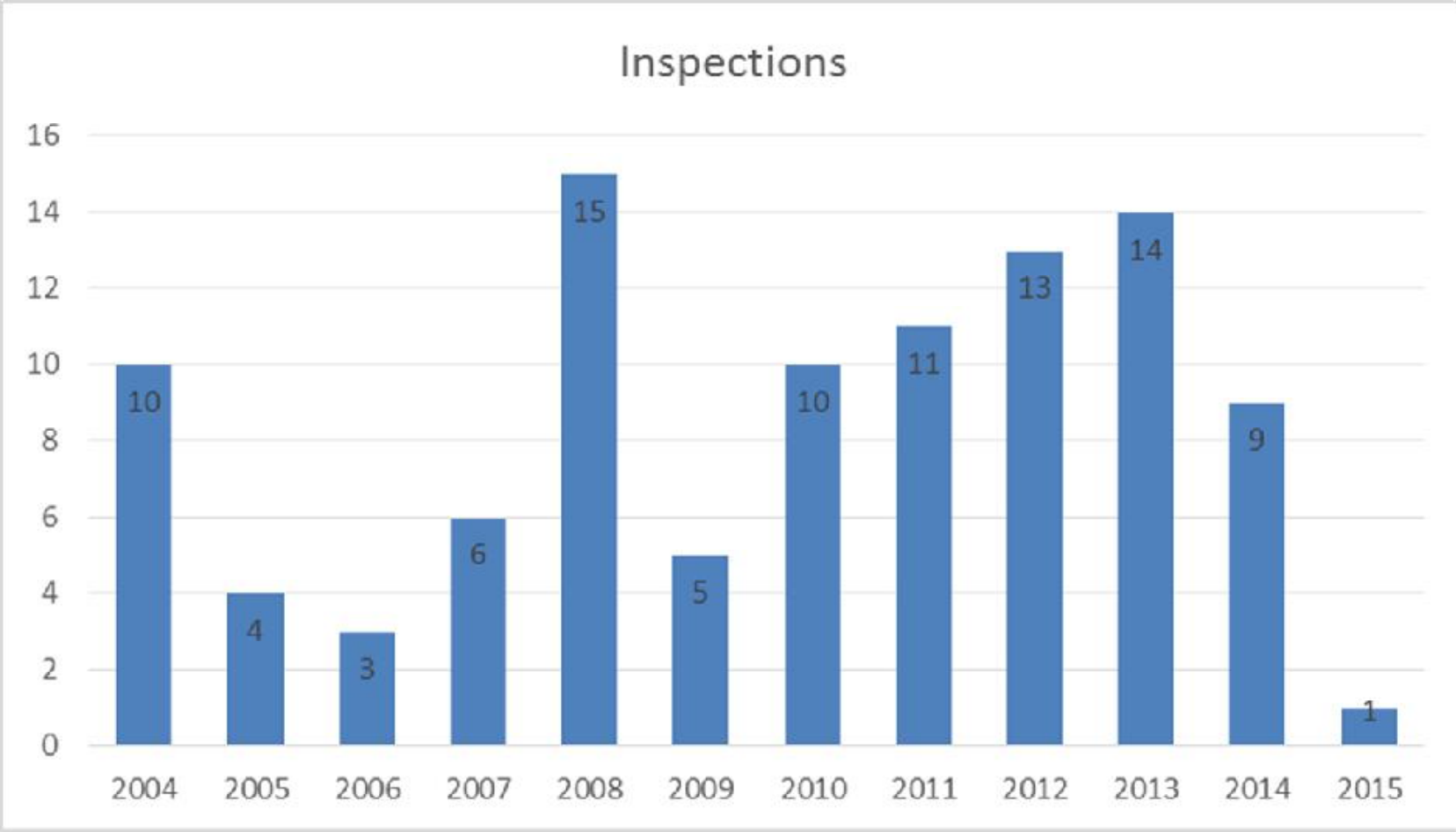

Initial applications- cumulative
2
3
4
19
47
66
95
130
160
204
228
266
305
331
356
379
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015

ACTIVITY

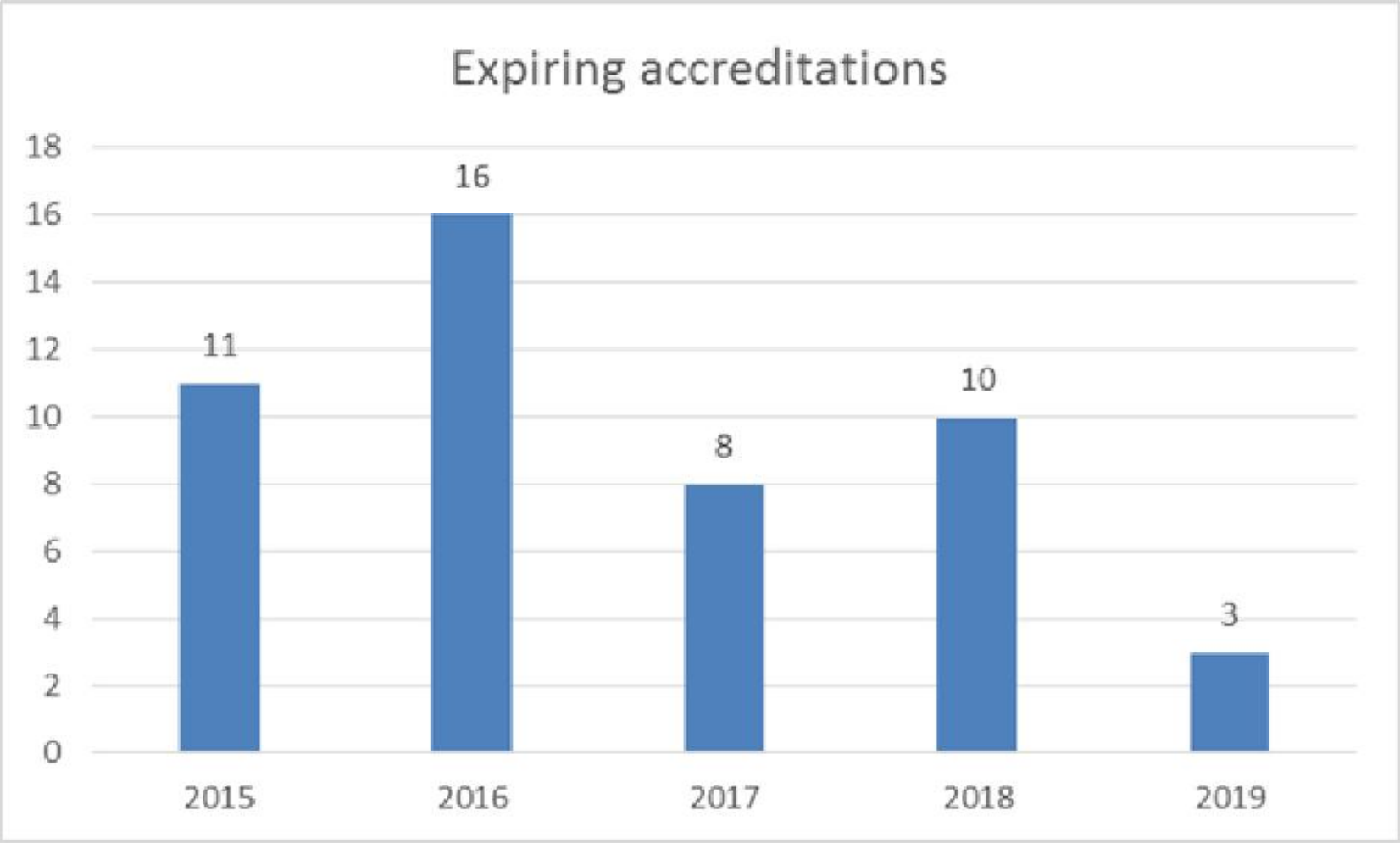


	2010	2011	2012	2013	2014	2015
Applications	41	61	53	56	52	51
Inspections-completed	30	45	54	57	50	24
Accreditations	27	37	47	42	47	30

Inspections - UK



Expiring accreditations - UK



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Why JACIE?

- Professional pride

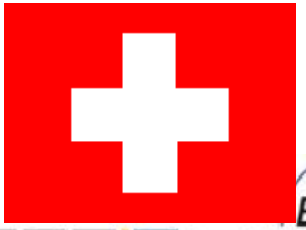
- Competition with other centres?

- Improved outcome for patients

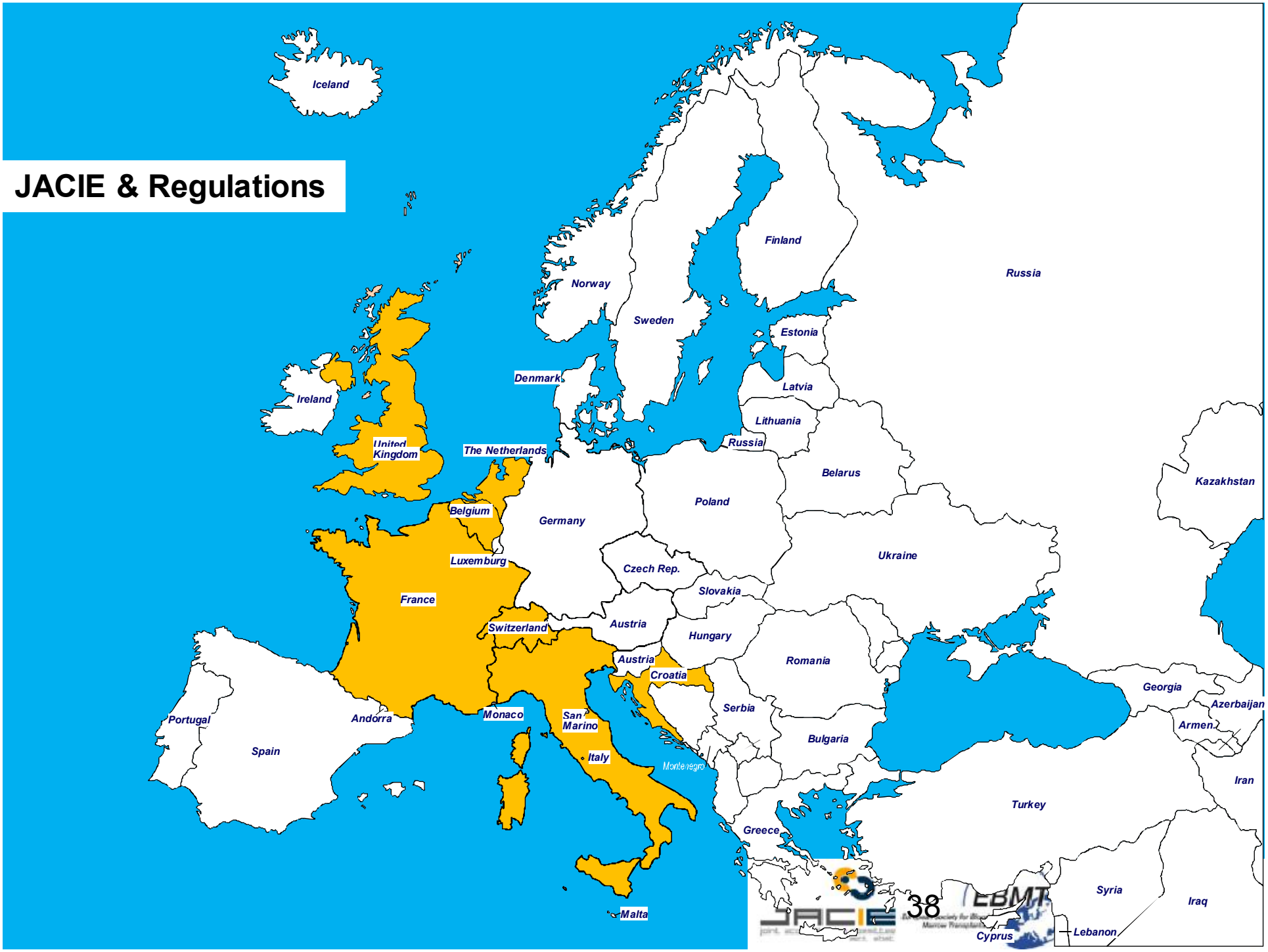
Why JACIE?

- Legal requirement in some countries

- Health insurance companies may require it
- Social insurance systems may require it -



JACIE & Regulations



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Regulations & guidelines

Regulations

- **France** Engagement with JACIE a requirement for allogeneic transplant centres according to Arrêté du 3 avril 2009 relatif au contenu du document d'évaluation des activités de greffes d'organes et de greffes de cellules hématopoïétiques
- **Belgium** JACIE accreditation will be a legal requirement for transplantation centers (doing autologous and/or allogeneic transplantations) in Belgium for reimbursement by the social security according to *C-2012/22474 Arrêté royal modifiant l'article 20, § 1er, a), de l'annexe à l'arrêté royal du 14 septembre 1984* published 21-12-2012.
- **NEW Croatia** Ordinance *Pravilnik o uvjetima u pogledu prostora, stručnih radnika, medicinsko-tehničke opreme i sustava kvalitete za obavljanje djelatnosti prikupljanja, uzimarja, testiranja, obrade, očuvanja, pohrane i raspodjele ljudskih tkiva i stanicahaematopoietic.* Art 35 (2) "progenitor cells bank must be accredited according to the JACIE standards".
- **Switzerland** Accreditation required to receive reimbursement from Social Insurance for treatments. *Ordonnance du DFI sur les prestations dans l'assurance obligatoire des soins en cas de maladie (Ordonnance sur les prestations de l'assurance des soins, OPAS)*
- **Italy** Decreto Legislativo 25 gennaio 2010, n.16 implementing the European Directives on Tissues and Cells cites a 2003 agreement recognising JACIE
- **The Netherlands** Accreditation required to receive authorisation to transplant from Ministry of Health

Guidelines

- **Belgium** Reference to JACIE standards in specific standards of the Superior Health Council "*Standards de qualité pour les tissus et cellules reproducteurs / Kwaliteitsnormen voor reproductieve weefsels en cellen*" 5 August 2009.
- **European Directorate for the Quality of Medicines & HealthCare**
  - Guide to the quality & safety of tissues and cells for human application, 1st edition (2013)
  - Guide to the Safety and quality assurance for the transplantation of organs, tissues and cells, 4th edition (2010)
- **EU-BIS - European Blood Inspection System** - Common European Standards and Criteria for the Inspection of Blood Establishments. Audit / Inspection – Training Guide. Ed. 1.0.
- **Germany** Zentrales Knochenmarkspender-Register Deutschland (ZKRD) German Standards for Unrelated Blood Stem Cell Donations Version 8 2012-06-20
- **Italy** Piano Oncologico Nazionale 2010-2012 cites JACIE accreditation
- **Philippines** The Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell-Based or Cellular Therapies in the Philippines cite the FACT-JACIE Standards.
- **United Kingdom**
  - JACIE cited in National Institute for Health and Clinical Excellence (NICE) guidelines
    - Manual for Cancer Services Haemato-oncology Cancer Measures Version 1.0 (2013)
    - Improving Outcomes in Children and Young People with Cancer (2005)
    - Improving Outcomes in Haematological Cancers (2003)
  - The Future of Unrelated Donor Stem Cell Transplantation in the UK. A Report from the UK Stem Cell Strategic Forum (July 2010). NHSBT
  - JACIE cited in Specialised Services National Definitions Set (3rd edition) SSNDS Definition No.2, Specialised Services for Blood and Marrow Transplantation (all ages)

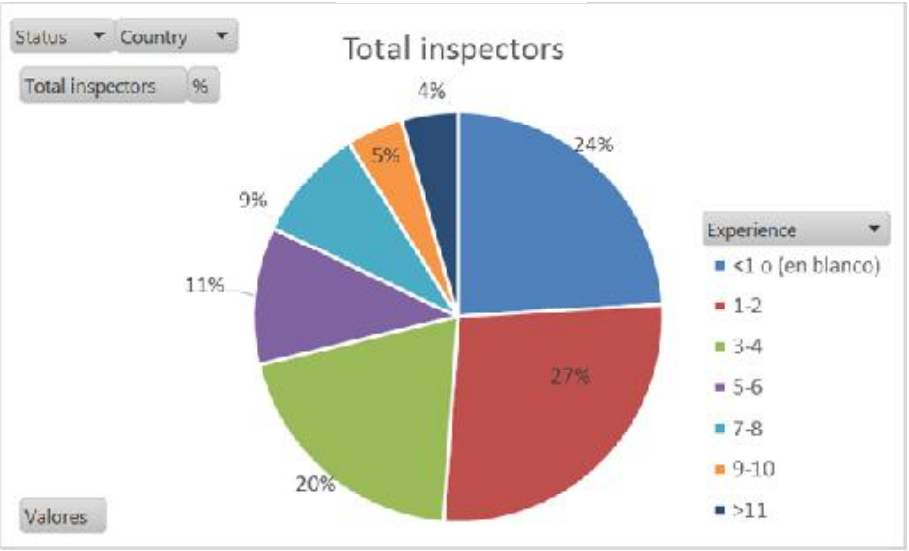
Inspectors

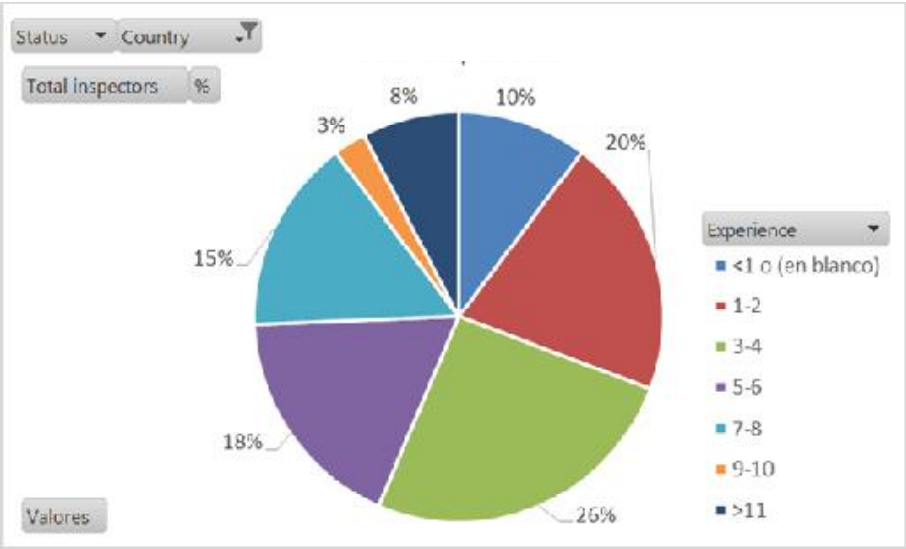
Inspectors

- 300+ cellular therapy professionals on the JACIE register
- <u>Volunteers</u>
- Receive only expenses and *per diem*
- Excellent supporters of JACIE
- Fundamental to the process

Comparison of accumulated experience

- All countries
- UK

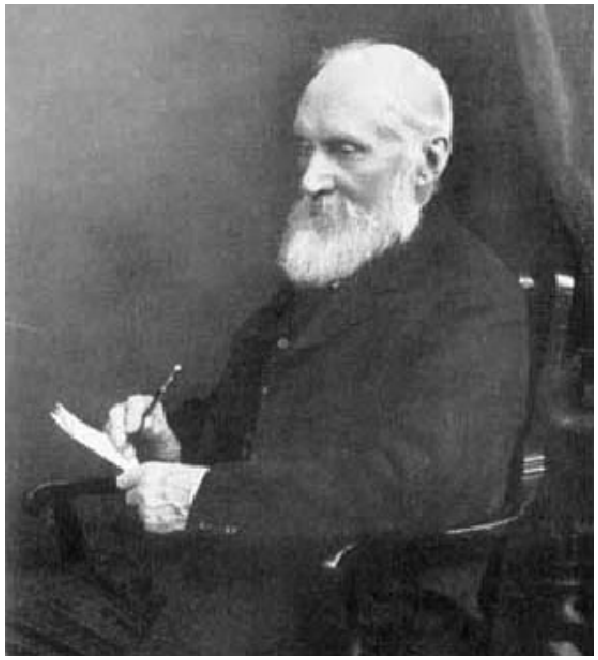




Graph shows experience of inspectors as percentage of total inspectors e.g. 26% of all UK inspectors have performed 3-4 inspections

“To measure is to know”

- “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**

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.

EBMT 40 Anniversary

Paradigm of Care: Ego- or Eco-system?

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
- Self-critique
- Lifelong learning
- Reflective Practice

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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 Petersen, Vanderson Rocha, Ineke Slaper Cortenbach, Anna Sureda, Andre Tichelli and Jane Apperley

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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

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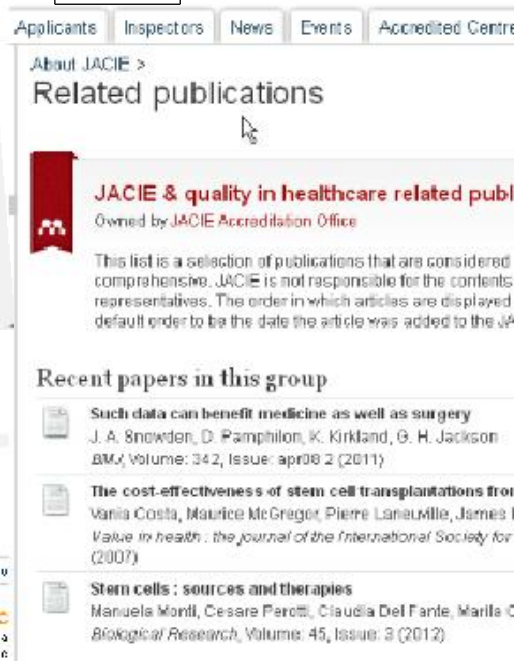
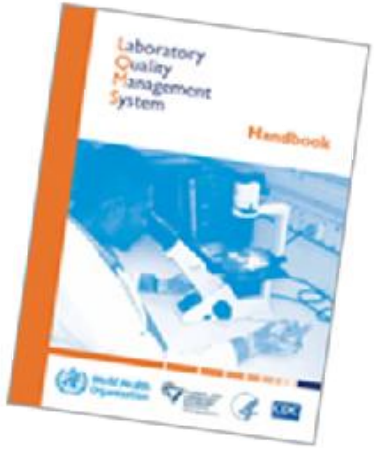
Overall mortality of the entire cohort of 107,904 patients with a transplant (41,623 allogeneic, 39%; 66,281 autologous, 61%) between 1999 and 2006 decreased over the 14 years observation period by a factor of 0.63 per 10 years (HR: 0.63; 0.58-0.69). This improvement was significantly faster with approx. 5.3% per year for the 49,459 patients transplanted in "JACIE" accredited centers, defined as programs having achieved accreditation the latest by November 2012, than the approx. 3.5% per year for the 58,445 patients in non accredited centers (HR: 0.83; 0.71-0.97). As a result, relapse free (HR 0.85; 0.75-0.95) and overall survival (HR 0.86; 0.76-0.98) were significantly higher at 72 months for those patients transplanted in the 162 "JACIE" accredited centers. No significant effects were observed after autologous transplants (HR 1.06; 0.99-1.13). Hence, working towards implementation of a quality management system triggers a dynamic process associated with a steeper reduction in mortality over the years and a significantly improved survival after allogeneic stem cell transplantation. Our data support the use of a quality management system for complex medical procedures.

JACIE joint accreditation committee
EBMT European Society for Blood and Marrow Transplantation
International Society for Cellular Therapy ISCT

No se puede mostrar la imagen en este momento.

@JACIE_EBMT





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

Other resources

- AHCTA
- 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.

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