



JACIE in Europe and Belgium

Ivan Van Riet

National Jacie representative

ivan.vanriet@uzbrussel.be

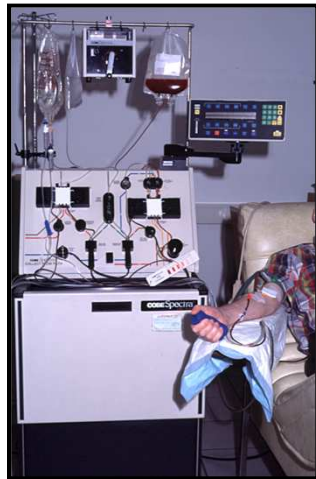
National JACIE meeting day
25 November 2011



What is JACIE ?

- Joint Accreditation Committee of the International Society of Cellular Therapy (ISCT) and European Group for Blood and Marrow transplantation (EBMT)
- Non-profit organisation, founded in 1998 to promote high quality in patient care and laboratory activities in the domain of hematopoietic stem cell transplantation (HSCT) through an international accreditation system.
- Accreditation after “inspection” and “screening” based on “standards of excellence” to European stem cell transplantation centers.

Stamceltransplantatieprogramma



Collection



Processing



Transplantation

Autologous and/or allogeneic

Adult and/or pediatric patients

Stand alone facility or integrated programme



JACIE standards

- Initially established by FACT (Foundation for the accreditation of cellular therapy), review in collaboration with JACIE
- Three domains: collection, processing and transplantation of hematopoietic stem cells
- 4 versions (5^e version release in 2012)
- Compliant with EU directives 2004/23/EC en 2006/17/EC

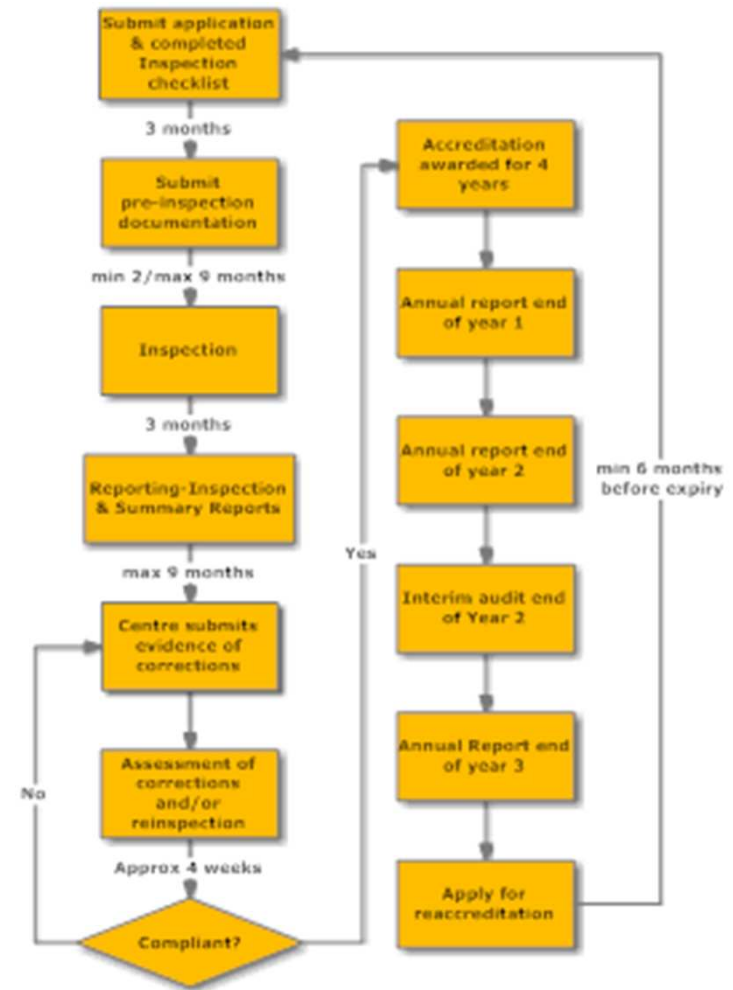


JACIE standards

- Facilities
- Personell
- Quality mamagement
- Policy and procedures (SOP's)
- Reports
- Donor management
- Collection
- Processing
- Labels
- Storage
- Release and distribution
- Transport
- Therapy adminstration
- Data management and clinical research
- Communication

JACIE inspection process

- Accreditation application
- Pre-inspection documentation
- Inspection team + on-site visit
- Inspection report
- Evaluation by accreditation committee
- Corrections
- Accreditation (4 year; interim audit after 2 years)





JACIE inspectors

- Experts; actively involved in domain; sufficient experience
- JACIE training and evaluation
- International exchange
- JACIE inspections
- on-site visit
- interviews
- documents / software



JACIE in Belgium

- Support for implementation en accreditation process by the Belgian Hematological Society (BHS)
- Training JACIE inspectors
- Accreditation subcommittee
- Organisation “centre preparation courses” and “internal auditor trainings”
- National JACIE day

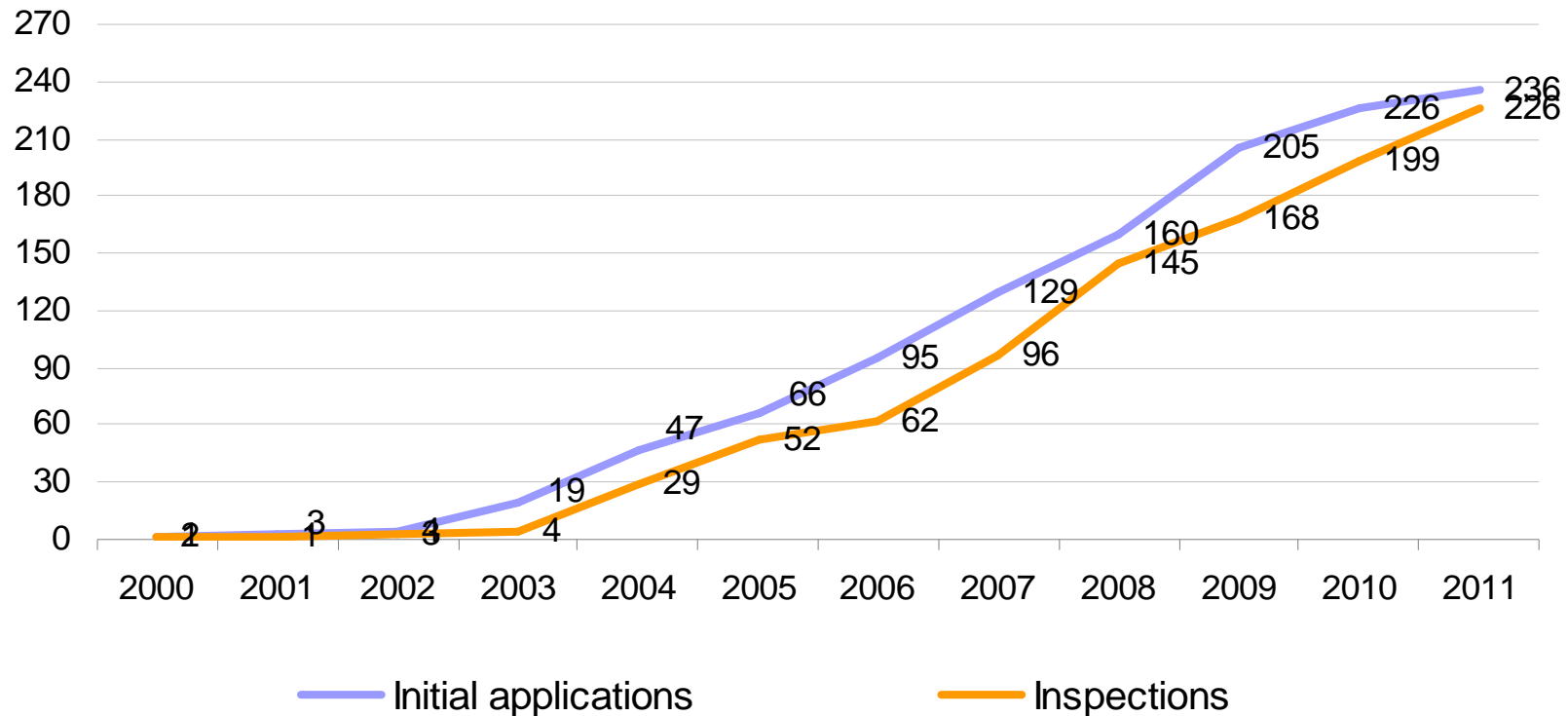
National JACIE meeting day
25 November 2011



Belgian JACIE inspectors in international inspection teams

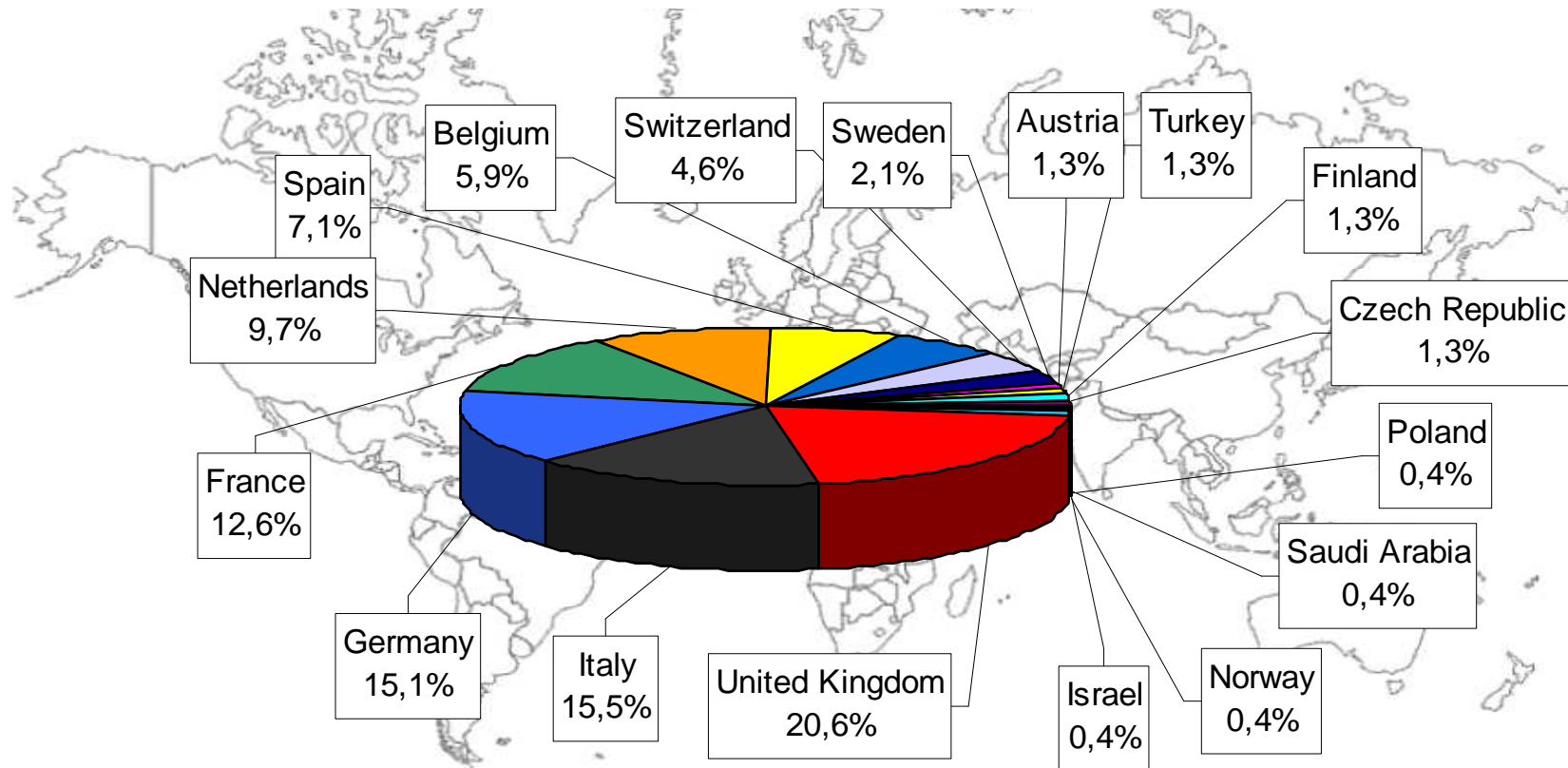
- 15 Inspectors
- participation to 51 JACIE inspections:
 - > France
 - > The Netherlands
 - > Belgium
 - > UK
 - > Switzerland
 - > Israel
 - > Saudi Arabia

Cumulative initial applications & all inspections

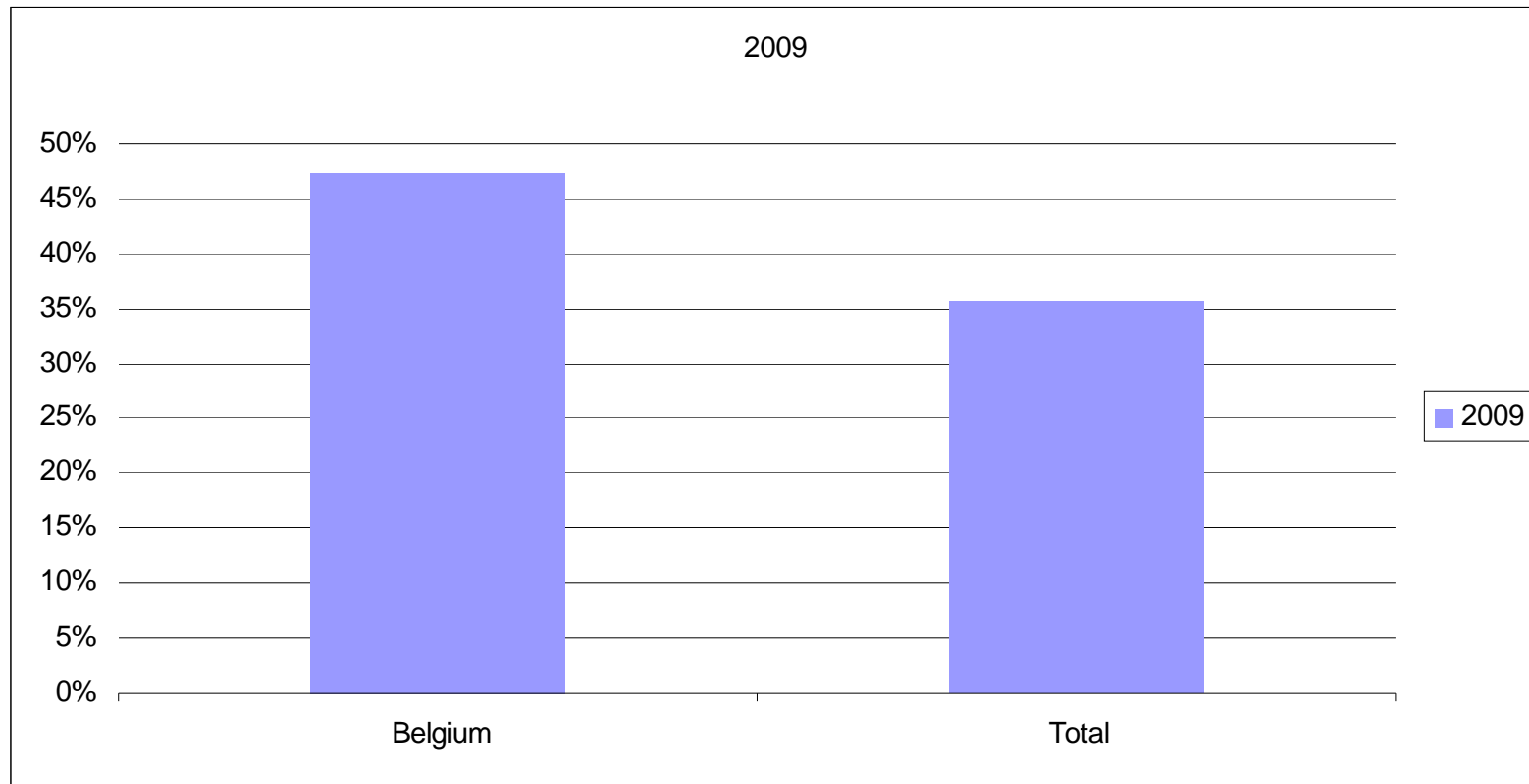


National JACIE meeting day
25 November 2011

% distribution of total initial applications by country



National JACIE meeting day
25 November 2011



Comparison of percentage of Belgian and total centres reporting data to the 2009 EBMT Activity Survey that are also registered with JACIE



JACIE and European SCT centers

- Registered centers : 244 (88% auto+allo SCT centers)
- Inspections in preparation (inclusive re-accreditations):51
- Completed Inspections:234
- Accredited centers and “stand-alone” facilities:103
- Countries:17



JACIE and Belgian SCT centers

- 17 centers eligible for JACIE accreditation
- 11 centers applied for JACIE accreditation (+1 for re-accreditation)
- 6 centers accredited
- 1 center post-inspection
- 4 centers pre-inspection (+1 for re-accreditation)

Accredited centers:

- UZ Leuven (complete programma)
- UCL hospital Brussels (complete programma)
- Bordet institute (+Reine Fabiola hospital) Brussels (complete programme)
- Jessa ziekenhuis Hasselt (autologous SCT/adults)
- UZ Brussel (processing laboratory)*

- Red Cross – BTC Gent (processing laboratory)
- Red Cross – DC Jette (apheresis unit)*

* joined application

JACIE and national regulations

INTERNATIONAL

- JACIE accreditation criterium for national licence as SCT center in the Netherlands
- JACIE accreditation required for reimbursement by social security in Switzerland
- JACIE accreditation (or active implementation) required for Allo SCT centers in France
- JACIE accreditation required for licence by national registry in Germany

NATIONAL

- JACIE accreditation on voluntary basis
- Solid basis for obtaining national tissue bank licence (FAGG/AFMPS)
- Reference to JACIE standards in specific standards of the Superior Health Council
- RIZIV/INAMI reimbursement linked to EBMT accreditation

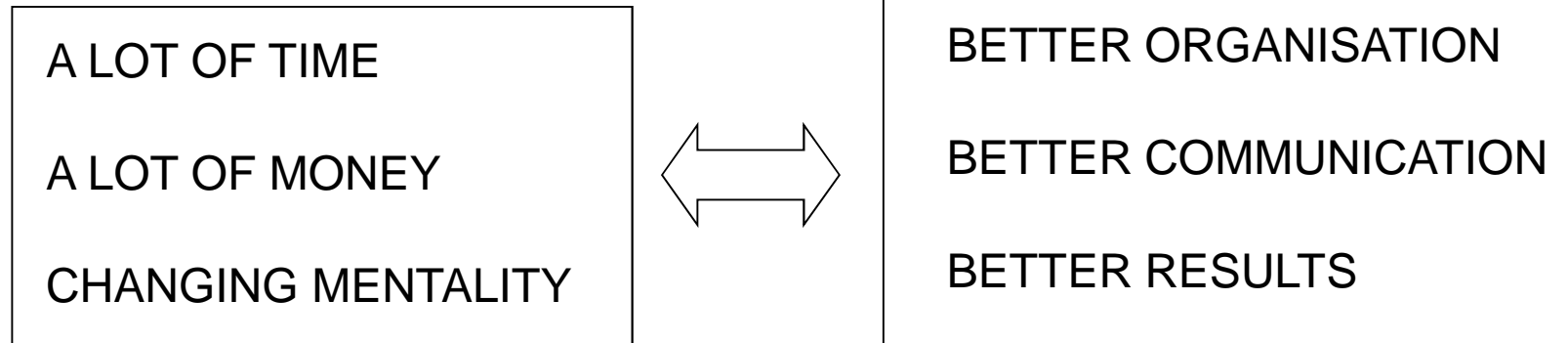


JACIE : why (not) ?

Just another cost increasing exercise (JACIE)?

Apperley J.

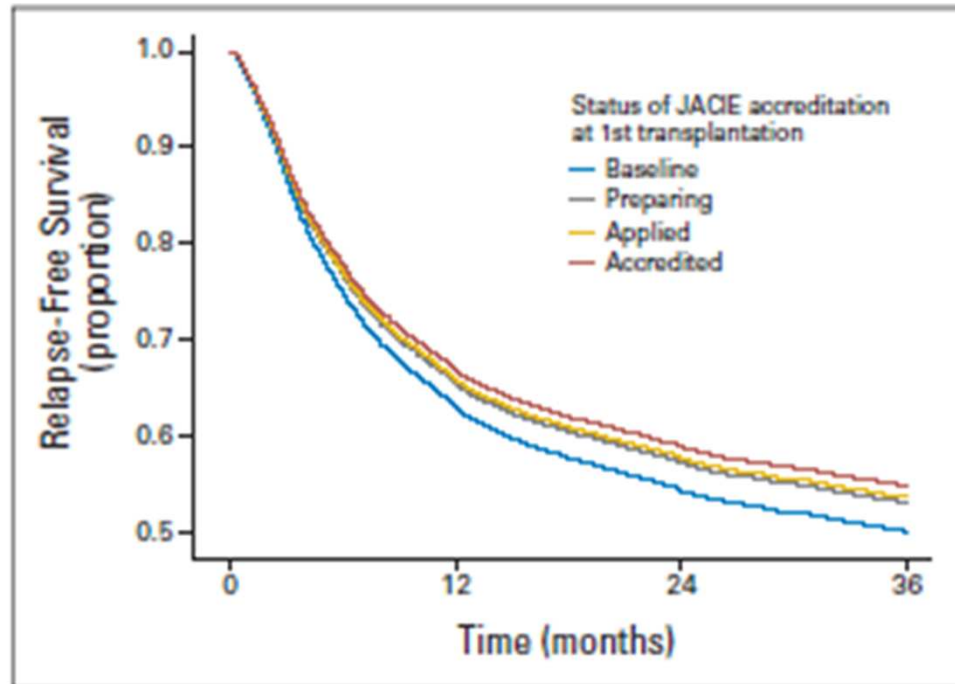
Bone Marrow Transplant. 2004 Nov;34(10):835-8.





Implementation of JACIE standards in SCT centers has positive impact on survival

421 EBMT teams
41.623 allo SCT
66.281 auto SCT



Gratwohl, A. et al. *Introduction of a Quality Management System and Outcome After Hematopoietic Stem-Cell Transplantation*. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 1-7(2011).doi:10.1200/JCO.2010.30.4121

National JACIE meeting day
25 November 2011