70th World Health Assembly
Side Event on Agenda Item 14.2

SAFEGUARDING BLOOD SAFETY FOR MULTI-TRANSFUSED PATIENTS

Friday, 26 May 2017 | **18:00-19:30**
Palais des Nations Building (Room IX)

SPONSORS

THALASSAEMIA INTERNATIONAL FEDERATION

International Alliance of Patients' Organizations
A global voice for patients

WFH
WORLD FEDERATION OF HEMOPHILIA
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ISBT

WBMT

Achieving Blood Safety and Hematopoietic Stem cell Transplantation Excellence access with Universal Access on a global level

Prof. Dietger Niederwieser / Dr. Mickey Koh
Worldwide Network for Blood and Stem Cell Transplantation (WBMT)

The Worldwide Network for Blood and Marrow Transplantation (WBMT) was formally created in 2007 by leaders from major hematopoietic stem cell transplantation (HSCT) societies and donor registries across the world. With the strong support of the World Health Organization (WHO), the mutual vision of combining efforts towards improving access to and standardization in HSCT, cellular therapy and related fields was achieved. The WBMT is today a global network of 24 international societies representing more than 1500 transplant centers in 78 countries and an NGO in working relations with the WHO. WBMT and WHO would like to further improve HSCT worldwide by supporting every aspect of human HSCT including stem cell donation, advanced cellular therapies and helping to support/provide know-how on all continents.

HSCT is a complex therapy successfully used in increasing numbers for patients with life-threatening disorders. After decades of experience (since 1957), discoveries, and international cooperation through registries and regional societies, HSCT is now accepted as the only curative treatment for many malignant and non-malignant diseases (e.g. Thalassemia). Data provided by WBMT suggest that the 1 millionth HSCT occurred in 2012 and there are now >70,000 procedures annually, with no evidence of a plateau in growth. However, use of HSCT varies considerably among world regions and the types of diseases transplanted. In Thalassemia for example, there are still countries without any activity in the field, other countries with only low transplant activity despite the cost effectiveness of the procedure. The same applies to sickle cell disease.

Experienced, multidisciplinary teams, adequate infrastructure for supportive care, including safety of blood supply and anti-infectives, as well as the ability to collect and share data are required for successful outcomes to ensure access and safety of this life saving modality. WBMT offers HSCT as a paradigm for how an essential therapeutic modality can be successfully deployed on a global scale with benefits for people and nations with diverse economic resources. Biennial global surveys, workshops in low activity countries, consultations with politicians and health authorities are showing first results. WBMT is instrumental in helping to establish safety of blood components as an essential prerequisite for HSCT by educating and twining with evolving countries, by standardization and accreditation of programs around the world.

Through all these activities, WBMT identifies great needs worldwide. The WBMT message to this respectful forum is that we need to encourage governments to include this curative treatment in their national health programs to ensure equity in access and safety around the world. This can be obtained by adapting national legislation, fostering donor registries, linking/establishing outcome registries worldwide, by increased twining with established centers and by developing specialized programs to cure congenital hematopoietic diseases like thalassemia worldwide. WBMT is also looking into the complex issue of advanced cell therapy and the increasing use of stem cells in the treatment of a wide variety of diseases. Some of this treatment remains unproven and should be conducted in formal clinical trials with the appropriate regulatory frameworks.

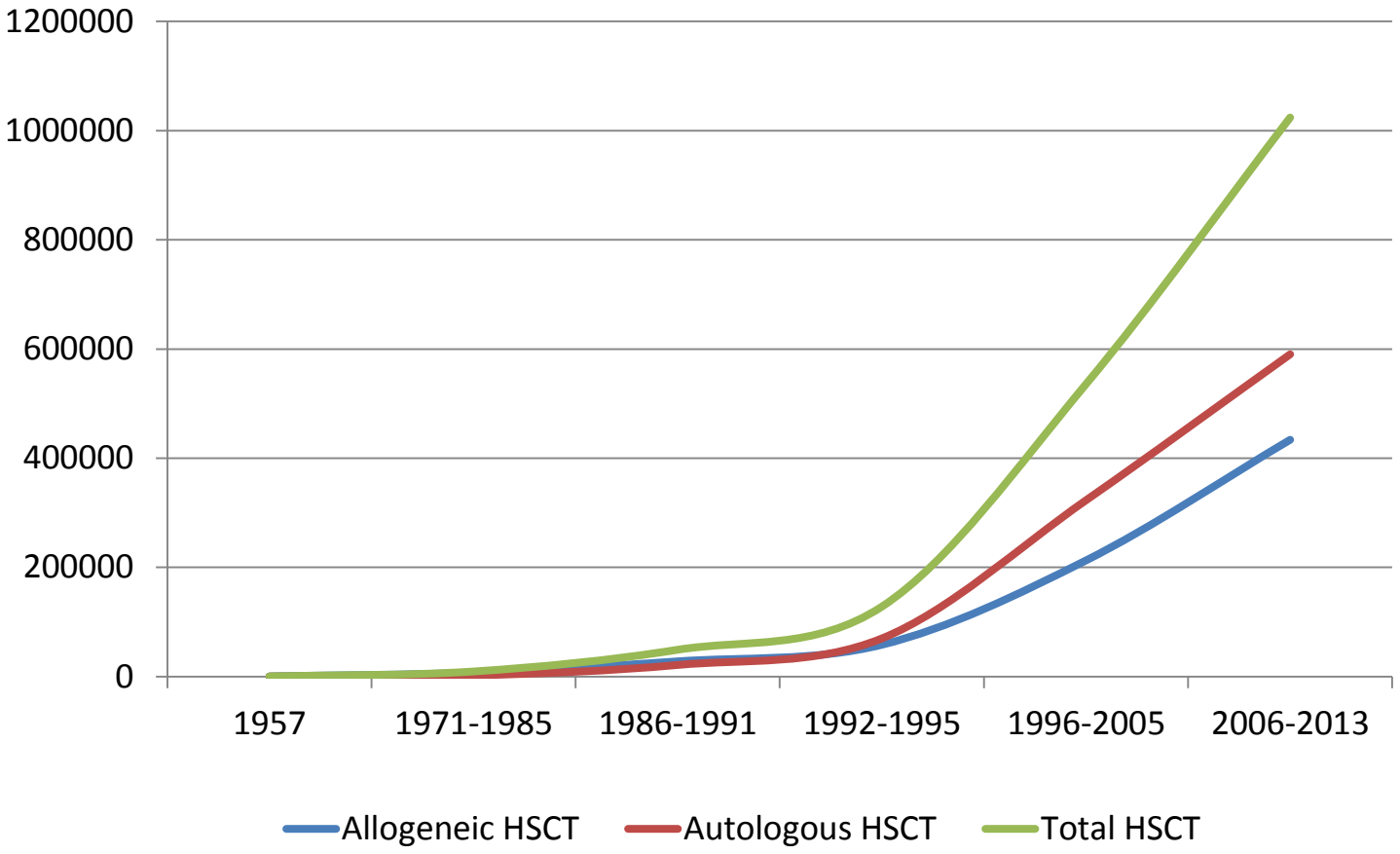
Achieving Blood Safety and HSC - Transplantation Excellence with universal access on a global level

Dietger Niederwieser
Mickey Koh

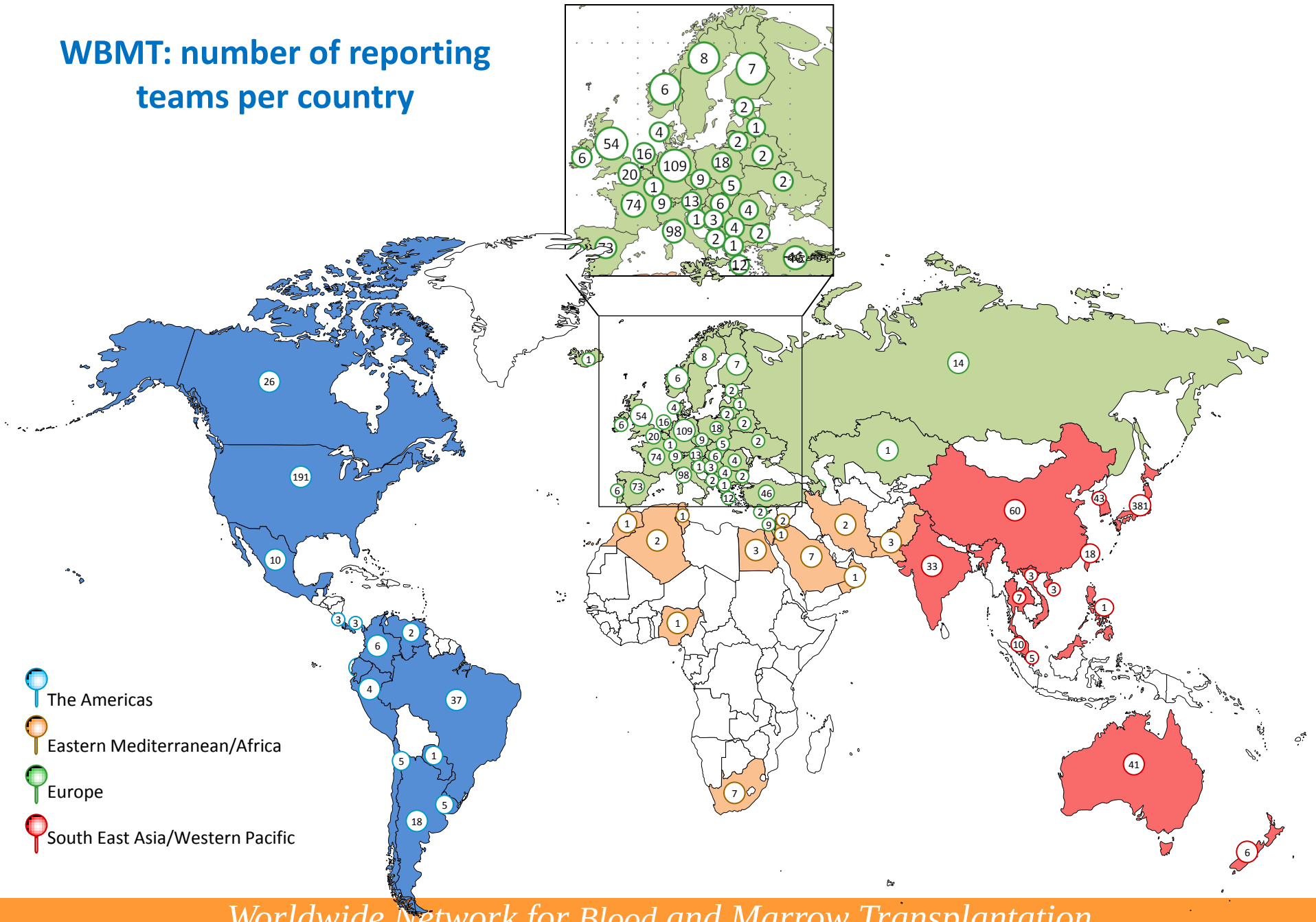
Geneva 2017

Networking – WBMT Federation

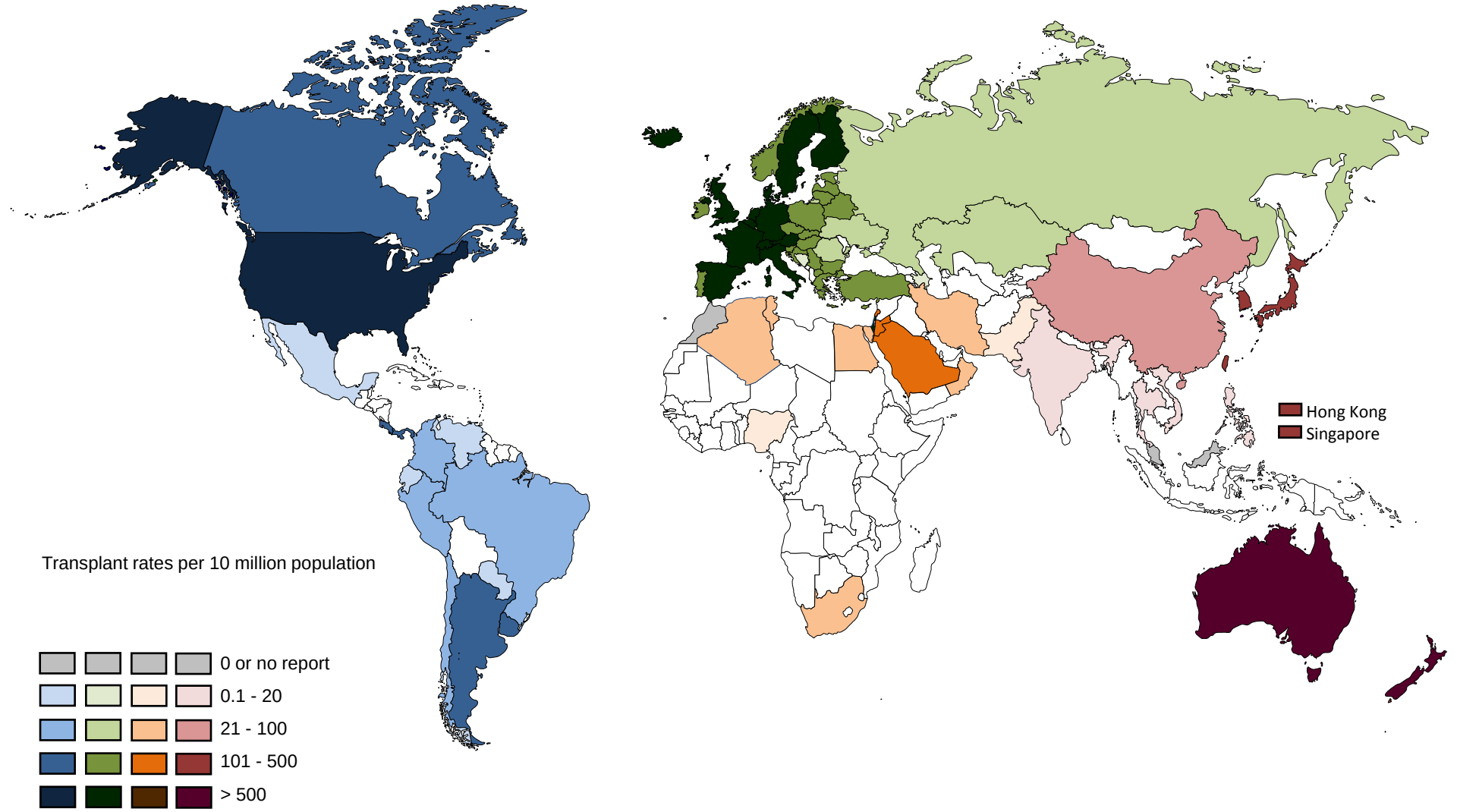
WBMT Global Survey



WBMT: number of reporting teams per country



WBMT Global Survey: Transplant Rates/ Country



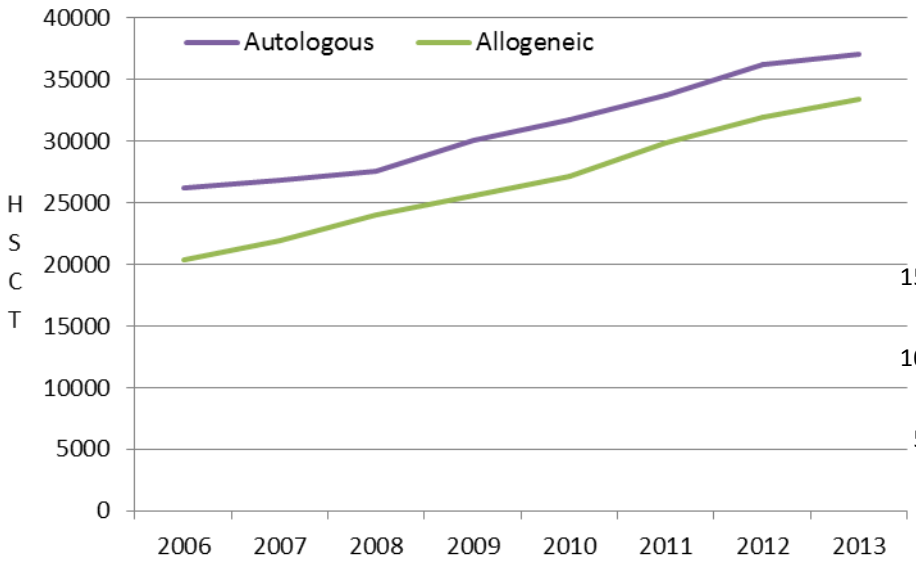
D. Niederwieser et al, BMT 2016

Global Activity Survey: 2006 – 2013

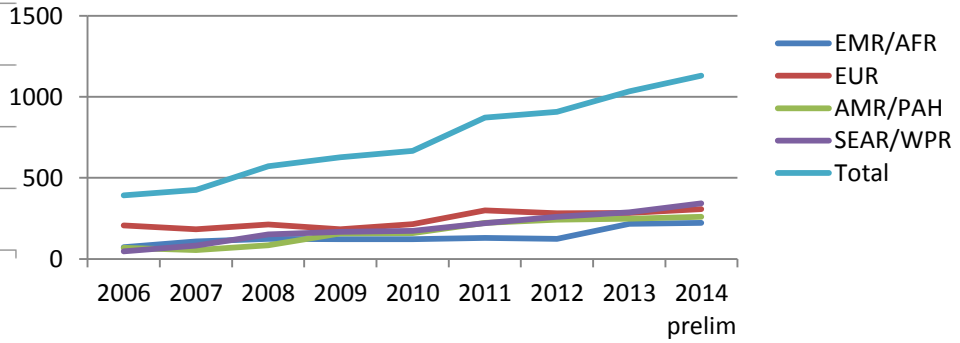
Allogeneic	2006	2012	2013	Δ% (2012-13)
Acute Leuk/other leuk/MDS/MPS	12 502	21 362	22215	+4
Chronic Leuk	1 890	1 874	1815	-3
Lymphoproliferative disorders	3 219	4 322	4531	+5
Solid Tumors	150	130	130	
Non Malignant disorders	2 360	4 068	4364	+7
BMF	*1 292*	*1 979*	2071	+5
Others	212	170	144	-15
Total	20 333	31 926	33441	+5
Autologous				
Leukemias	1 726	1 044	832	-20
PCD	10 675	17 590	18512	+5
Lymphomas	10 980	14331	14461	+1
Solid Tumors	2 560	2 884	2769	-4
Non Malignant disorders	193	330	275	-17
Others	96	41	38	-7
Total	26 230	36 220	36998	+2
Total	**46 563**	**68 146**	**70439**	+3

WBMT Global Survey 2006-2013

numbers of overall HSCT



numbers of HSCT for Hemoglobinopathies



Allogeneic	Americas	Asias	Europe	EMRO/Africa	Total
Leukemias	73,4	74,7	72,3	53,2	72,5
Lymphoproliferative disorders	14,7	10,5	15,9	4,4	13,7
Solid Tumors	0,1	0,6	0,4	0,0	0,4
Non Malignant disorders	11,6	13,9	10,7	42,0	13,0
Others	0,1	0,3	0,7	0,4	0,4
Total	100%	100%	100%	100%	100%

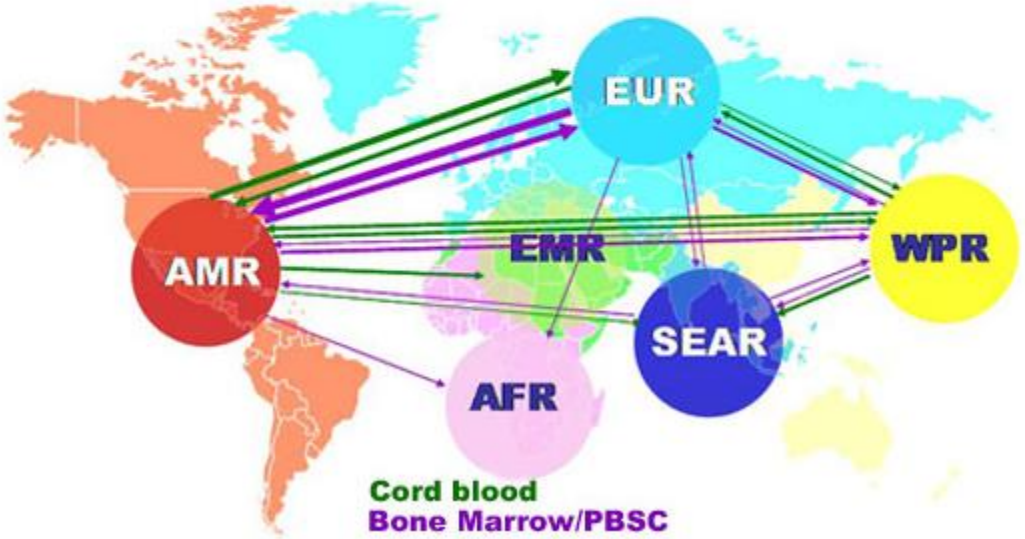
International context

- “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

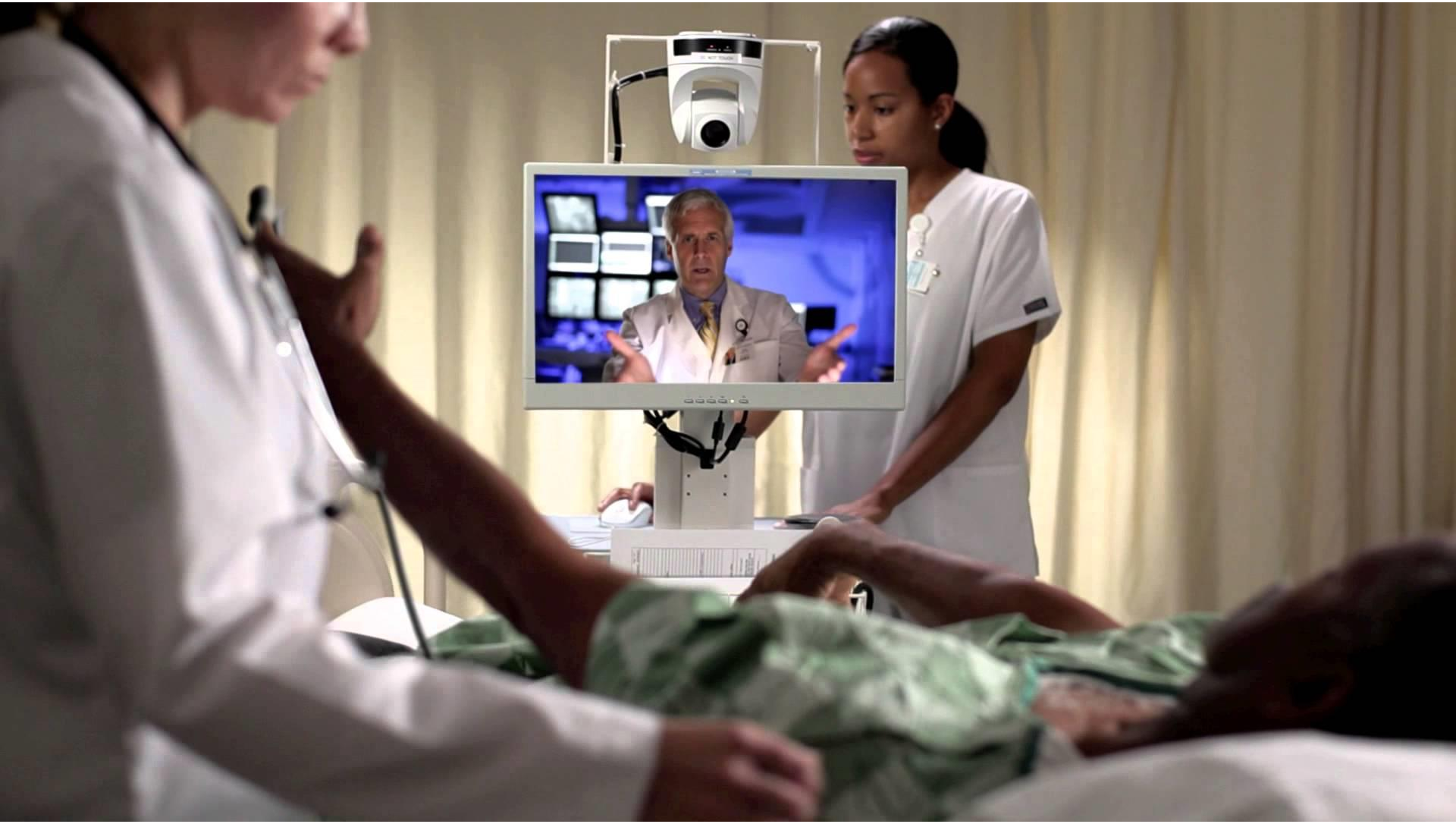
Stem cells are daily circulating around the World

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)



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.



Global Governance

- ✓ Increasing access to the appropriate therapy

Global Governance

- ✓ Increasing access to the appropriate therapy


Bologna Initiative
for Global Vigilance and Surveillance
BIG V&S

Centro Nazionale Trapianti

T NOTIFY LIBRARY
The Global Vigilance and Surveillance Database for Transplantation and Assisted Reproduction

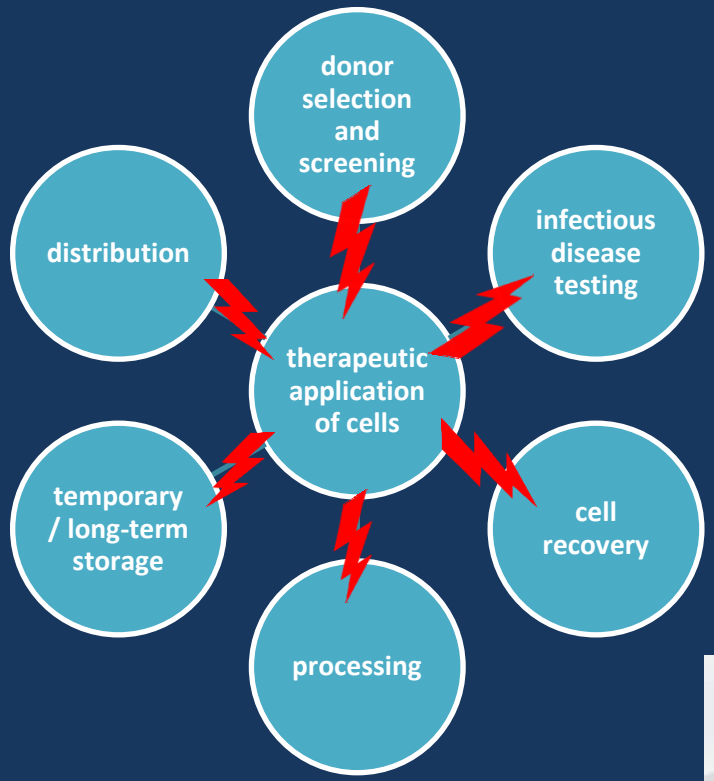
World Health Organization

Objective: communicating vigilance information as widely as possible in the interests of improving the safety of MPHO worldwide

- More than 900 documented case types can be searched in a structured way by organ, tissue or cell type and/or incident type
  - associated bibliographic references and expert analyses.
- Reactions
  - Infectious transmissions of all types, malignancy transmissions, and genetic transmissions to transplant recipients and to the offspring of children born from donated gametes.
- Events
  - caused by process failures and reactions in living donors
- Site and search tools publicly available (without username and password)
- Language specific interface in Regions.

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

complex process…



- Standards & Quality managment help:
  - Reduce risk
  - More consistent care
  - Improve communications
  - Continous improvement
  - Benchmarking

BETTER RESULT FOR PATIENT + DONOR

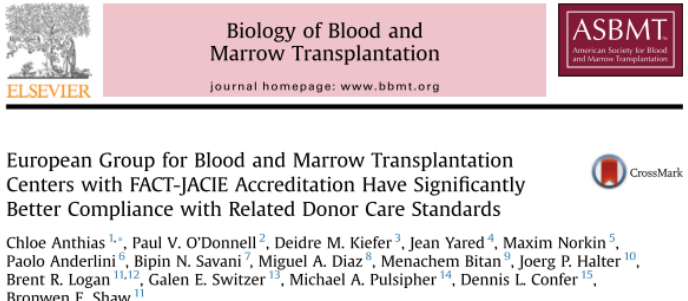

haematologica
Journal of the European Hematology Association

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

by Alois Gratwohl, Ronald Brand, Eoin McGrath, Anja van Biezen, Anna
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,
Chabannon C, and Apperley J. Use of the quality management system "JACIE" and
hematopoietic stem cell transplantation. Haematologica. 2014; 99:xxx
doi:10.3324/haematol.2013.096461


ELSEVIER

Biology of Blood and Marrow Transplantation

journal homepage: www.bbmt.org

ASBMT

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

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

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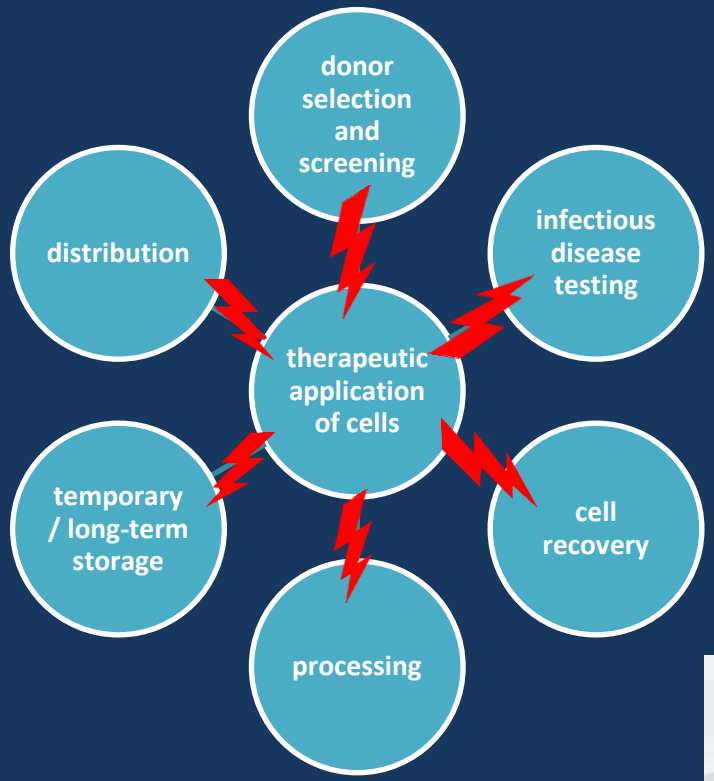
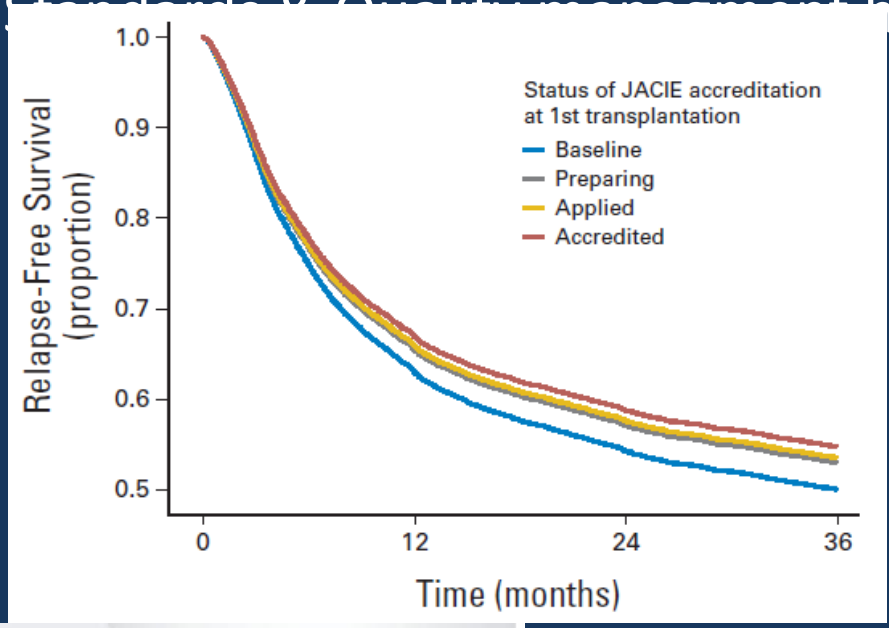
comp

- Standards & Quality management help:



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



haematologica

Journal of the European Hematology Association

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distribution

/ long-term storage

Includes comercial and non-comercial HSCT and CBB organisations

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JACIE & National Regulations
Iceland
Finland
Russia
Norway
Sweden
Estonia
Denmark
Latvia
Ireland
Lithuania
United Kingdom
The Netherlands
Russia
Belarus
Kazakhstan
Belgium
Germany
Poland
Ukraine
Czech Rep.
France
Slovakia
Switzerland
Austria
Hungary
Austria
Romania
Croatia
Georgia
Azerbaijan
Portugal
Serbia
Armen.
Spain
Bulgaria
Italy
Montenegro
Iran
Turkey
Greece
Syria
Iraq
Malta
Cyprus
Lebanon

Conclusions

- Safe blood supply is critical to any HSCT program
- Adapting national legislation
- Fostering donor registries
- Linking and establishing outcome registries worldwide
- Increase twinning with established centers
- Programs for congenital haematopoetic disorders
- Advanced cell therapies should be conducted in clinical trials