Quality and Accreditation for Cellular Therapy: A Global Perspective

- Dietger Niederwieser, MD, University of Leipzig
- Alok Srivastava, MD, Centre for Stem Cell Research & Department of Hematology at Christian Medical College, Vellore
- Carlos Bachier, MD, Program Director and Processing Facility Director at Sarah Cannon Transplant and Cellular Therapy Program

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Dietger Niederwieser, MD

Dr. Dietger Niederwieser is a Professor of Medicine at the University of Leipzig. Prof. Niederwieser joined the University Hospital Leipzig in 1998, where he became the Chairman of the Department of Hematology, Oncology, and Hemostaseology. He has authored over 600 publications in peer-reviewed journals and has held a number of society memberships. He was appointed as President of the EBMT in 2006 and as president of the Worldwide Network for Blood and Marrow Transplantation WBMT in 2011. He is currently the chair of the AML Working Party of the OSHO (East German Study Group Hematology and Oncology) and will present evaluations of the AML studies.

Alok Srivastava, MD

Dr. Alok Srivastava is Professor of Medicine at the Christian Medical College in Vellore, India. He is the head of the Centre for Stem Cell Research at the same institute where a major focus is on gene therapy for the common inherited hematological diseases. He is Secretary of the Indian Society for Blood and Marrow Transplantation and co-chair of the Executive Board of the Asia Pacific Blood and Marrow Transplant group.

Carlos Bachier, MD

Dr. Carlos R. Bachier joined Sarah Cannon in 2015 and serves as the director of cellular research. As part of his role, he designs and leads the clinical trial menu for stem cell transplant at the Sarah Cannon Center for Blood Cancer at TriStar Centennial in Nashville.

Dr. Bachier has worked as an inspector for the Foundation for the Accreditation of Cellular Therapy (FACT) since 2003. He is a member of the FACT Cellular Therapy Accreditation and Global Affairs Committees. He serves on the Immune Effector Cell Standards Subcommittee and Immune Effector Cellular Therapy Task force. Dr. Bachier is also a member of the Board of Directors and Executive Committee for FACT.

Establishing an HSCT Program: Essential Requirements

Presnted by: Dietger Niederwieser, MD
University of Leipzig

Worldwide Network for Blood and Marrow Transplantation
NGO in official relations with World Health Organization

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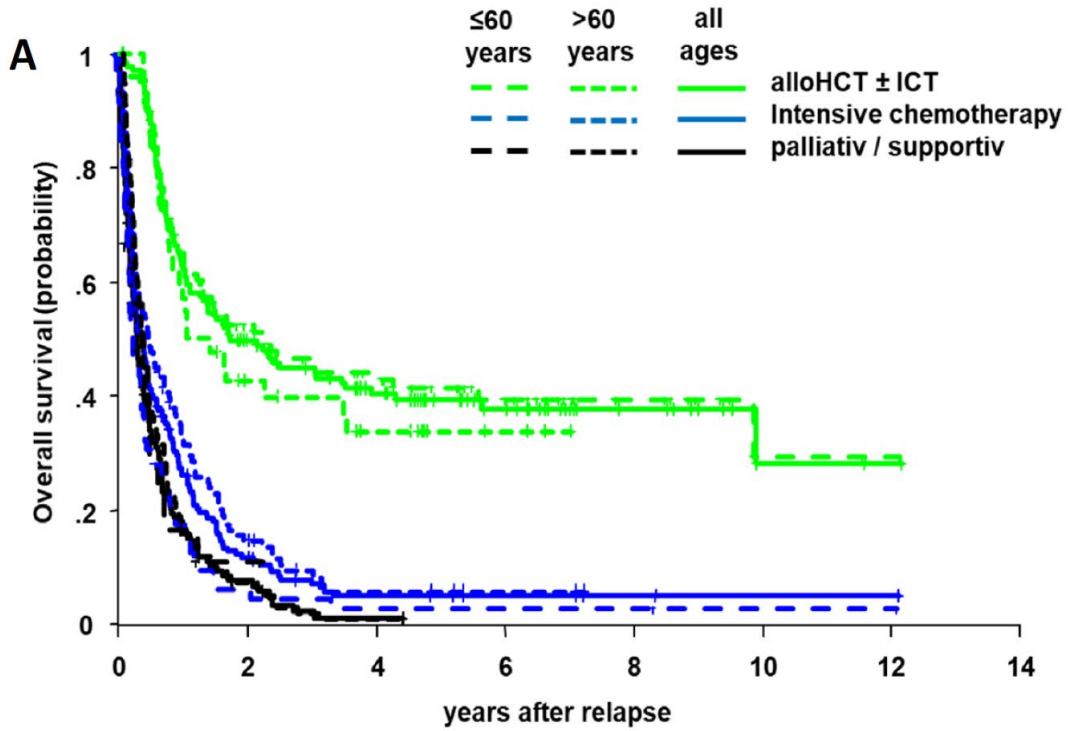
Mission of WBMT

Promote excellence in stem cell transplantation including cellular therapy at a global level

AML Results in First Relapse



	alloHCT ± prior ICT			Intensive chemotheraüy (ICT)			palliativ/supportiv			
	n	OS %	median (months)	n	OS %	median (months)	n	OS %	median (months)	P-value
all ages	151	39.3 (31.8 - 48.6) @5y	20.4	190	5.0 (2.5 - 9.9) @5y	4.8	155	1.2 (.2 - 7.7) @4y	3.6	<.001
age ≤60 years	107	41.6 (32.8 - 52.9) @5y	28,8	71	3.2 (.8 - 12.5) @5y	3.6	21	11.3 (3.1 - 41.3) @2y	4.8	<.001
age >60 years	44	33.8 (21.7 - 52.5) @5y	16.8	119	6.0 (2.7 - 13.2) @5y	6.0	134	1.1 (.2 - 7.3) @4y	3.6	<.001
P-value (≤ vs. > 60 years)		0.3			<0.05			0.9		

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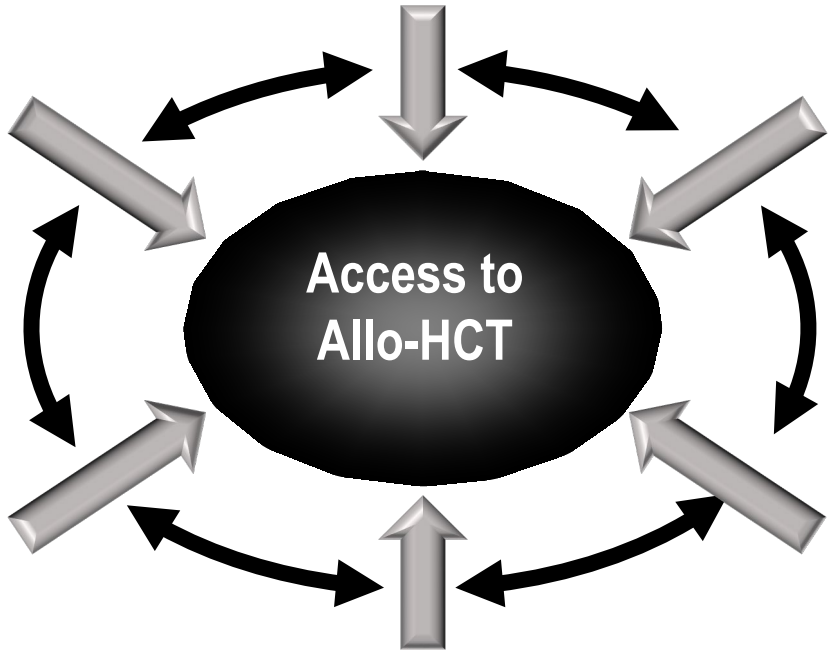

Donor type and stem cell source availability

Related, unrelated donors and cord blood

Patients Demographics

Age, gender, race, language and socio-economic status

Economics

Country of origin
Gross national income per capita
Health expenditure per capita
Human Development Index
Insurance coverage

Social

Geographical distance
Patient/family attitudes
Availability of caregivers

Health care system

Transplant rate
Transplant center density
Infrastructure and complexity
Public and private care
National and International regulations

Provider

Physian referall and indications
Provider attitudes and biases

Increasing access to HCT worldwide

Target	Topic	Actions
Benchmarking activities among countries and regions	Global HCT activity reports	Biannually survey since 2006[4,6,47–50]
Starting new programs	Alerting health authorities and politicians about the need for programs in countries with low HCT activity	Organization of WBMT workshops in cooperation with WHO[51]
	Essential medication	Published previously[52]
	Training of physicians, nurses, technicians, and data manager	Scientific societies; accredited transplant centers
	Infrastructure	Define essential infrastructure[37,53]
	Site visit from experienced physicians	Role of scientific societies
	Financial aspects	Optimize treatment
	Twinning and telemedicine	Supervisory telemedicine[42]
Optimizing existing programs	Outcome registries	Establish outcome registries Analysis of different techniques[54]
	Accreditation	Liaise with JACIE/FACT
	Utilization of HCT worldwide	Analyzing incidence (tumor registries) and HCT activities for each disease in regions and countries[55]
	Establishing alternate donor registry	Describe challenges in developing countries[56]
	Establishing clinical studies	Structures for local registries, non-interventional, interventional studies

Transplant rate (TR) by world region and HCT type (2016)

REGION	Allogeneic HCT	Autologous HCT	Total
USA/Canada	227	334	561
Europe	181	258	439
LABMT	30	47	77
Asia Pacific	34	20	54
Eastern Mediterranean	22	14	36
Africa	5	5	9

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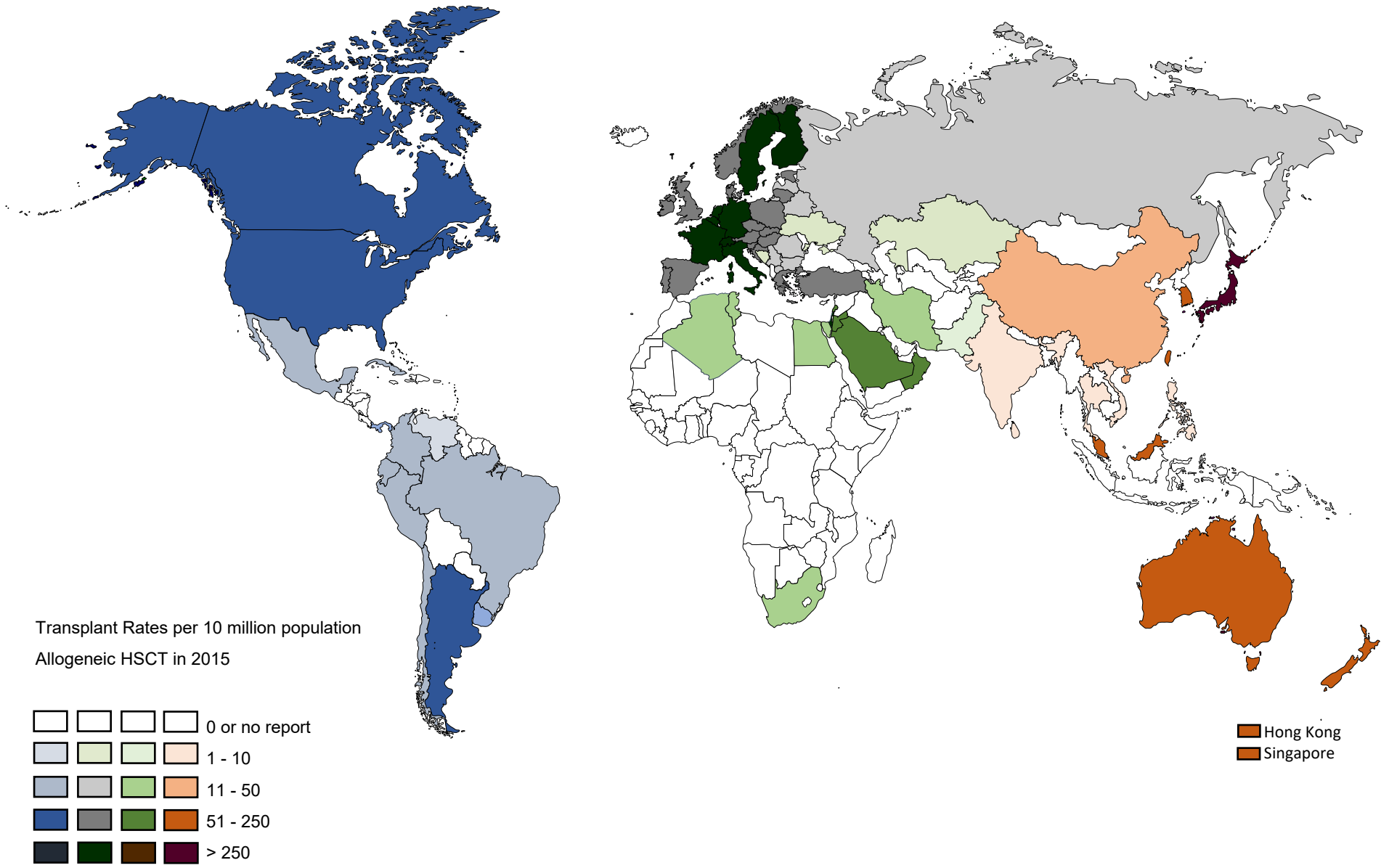
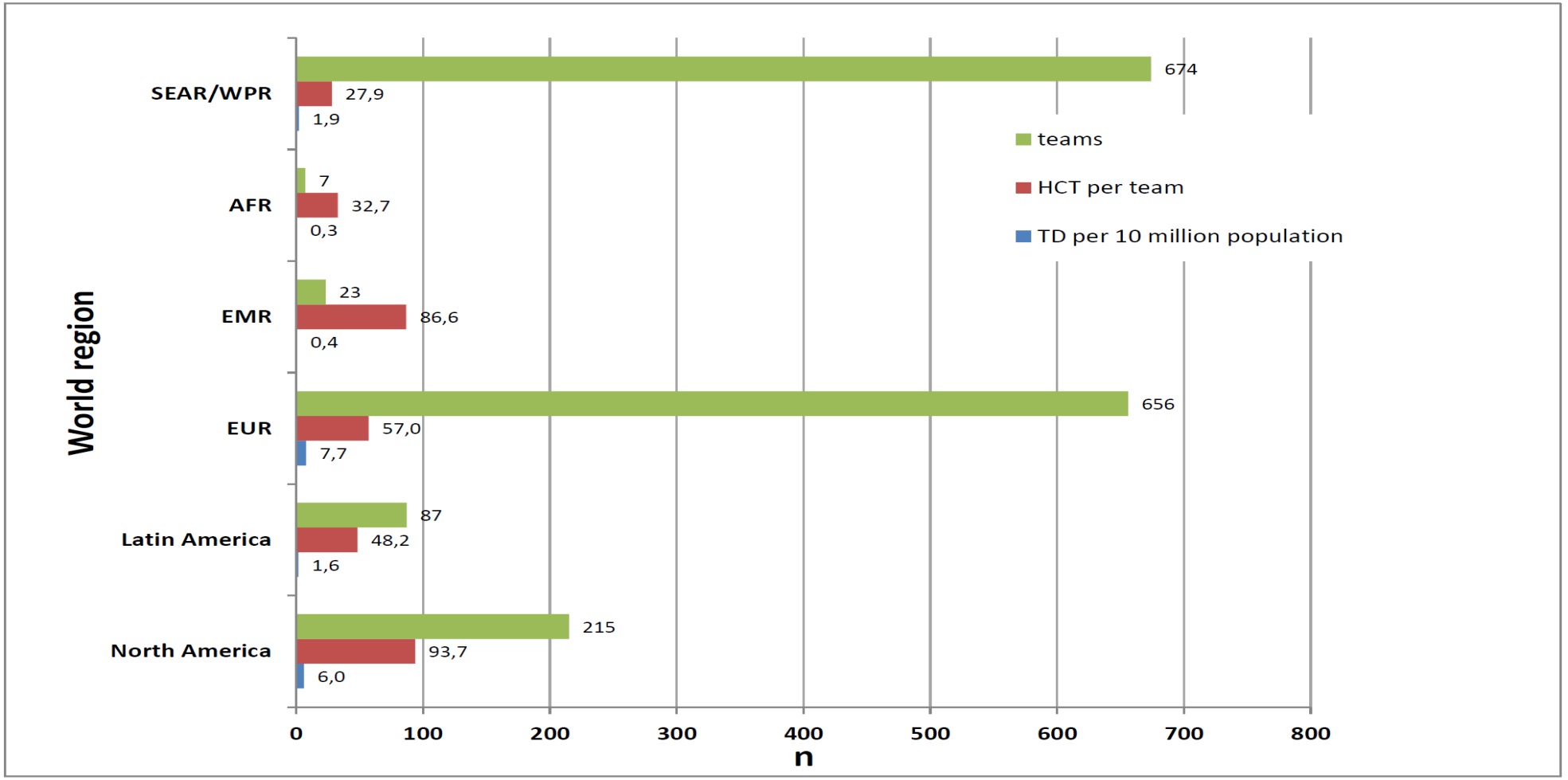
TR, HCT / 10 million population.

WBMT Global Survey 2015



Teams, Teams Density and HCT/Team Worldwide



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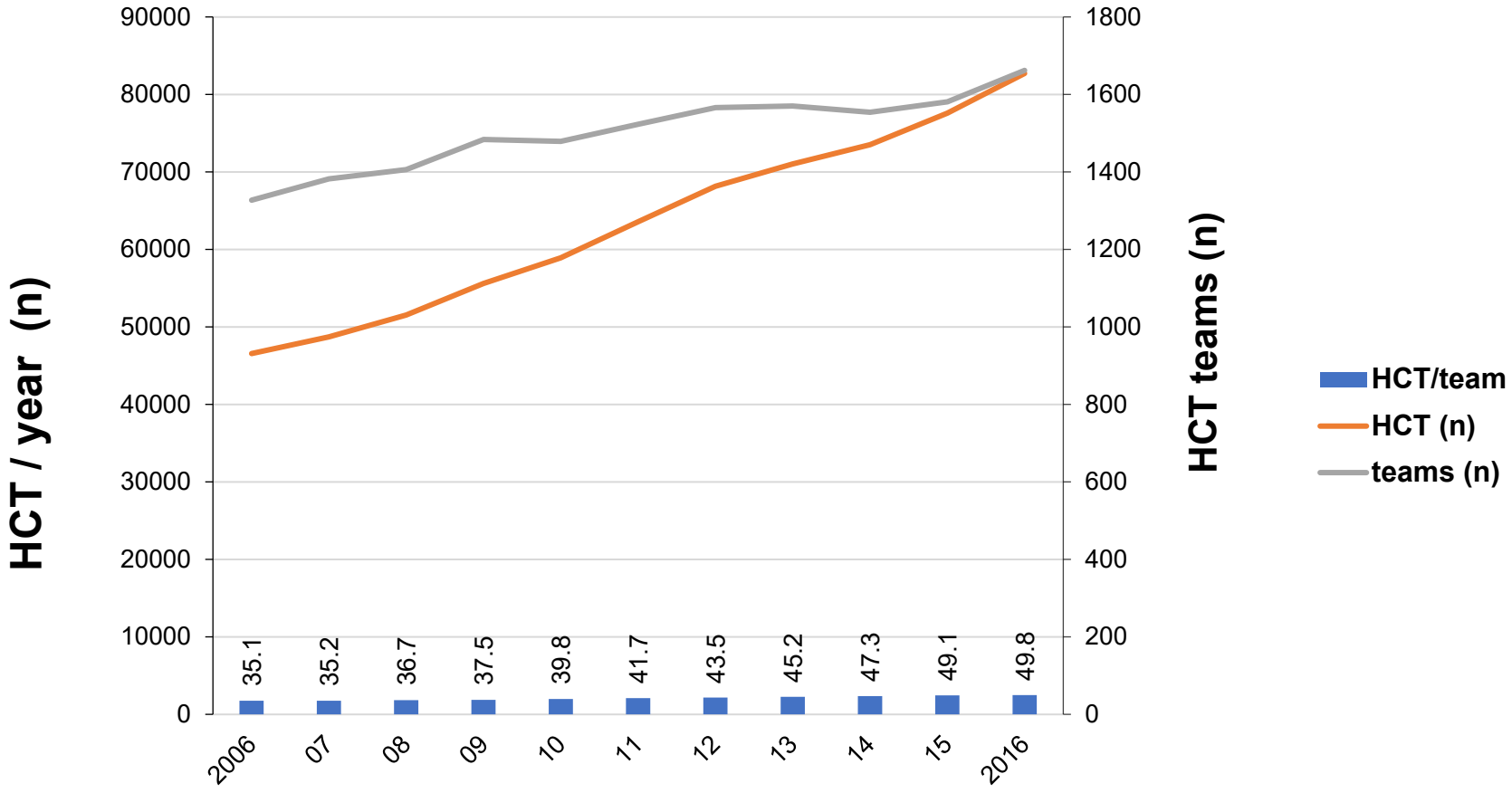
Trends in HCT use and teams



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Recommendations for Establishing a HSCT Program

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Worldwide Network for Blood and Marrow Transplantation (WBMT) recommendations for establishing a hematopoietic cell transplantation program (Part I): Minimum requirements and beyond ☆

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Worldwide Network for Blood and Marrow Transplantation (WBMT) recommendations for establishing a hematopoietic stem cell transplantation program in countries with limited resources (Part II): Clinical, technical and socio-economic considerations ☆

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Aljurf M. et al. BBMT 25 (2019) 2330-2337

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Recommendations for Establishing a HSCT Program

Table 1 Scoring of HCT program required elements.

Score	Description	Category	Level	Comments
1	Absolutely required	Minimum	I	A program cannot be implemented without this element
2	Required			A program needs to have this in place or at least planned in the first year of implementation
3	Important	Preferred	II	Important for further expansion of the program
4	Good			Not necessary but recommended
5	Important but not needed at early implementation	Ideal	III	Ideal element but not critical for the day-to-day operations
6	Might be beneficial in certain situations			Item that could be specific to a patient population or type of transplant
7	Not recommended			Should not be considered as a necessary element

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Recommendations for Establishing a HSCT Program

Minimum Requirements for Development of HCT Program by Transplant Type

Domain	Minimum Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Infrastructure	Institution (or Hospital Leadership) support	1.7 (.67)	1.44 (.71)
	Cell processing laboratory (access to laboratory services for cell count, sterility assessment)	1.5 (.71)	1.67 (1.35)
	Tertiary care center*	2.60 (1.71)	2.11 (1.45)
	Intensive care unit (access to vasopressors, dialysis, positive-pressure or mechanical ventilatory support)	2.0 (1.49)	2.0 (1.84)
	Apheresis services (autologous HCT)	2.60 (1.26)	1.67 (1.14)
Staff	Medical director: hematologist/oncologist or immunologist	1.3 (.48)	1.44 (.82)
	Medical director, licensed hematologist with minimum 6 months training in a BMT unit (recommended: ability to establish relationship with an experienced HCT center)	1.5 (1.08)	1.44 (.82)
	Nurse with hematology-oncology experience or trained in handling chemotherapy and infection control	1.20 (.63)	1.33 (.79)
	Pharmacist with experience in handling chemotherapy	2.00 (1.41)	1.78 (1.03)

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Recommendations for Establishing a HSCT Program

Minimum Requirements for Development of HCT Program by Transplant Type

Domain	Minimum Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Cell processing laboratory	Cryopreservation procedures and storage capability (autologous HCT)	3.30 (1.57)	1.44 (.82)
Blood banking	Availability of blood and platelets	1.10 (.32)	1.11 (.47)
	Availability of leukocyte-reduced (or irradiated) blood products	1.30 (.48)	1.78 (.88)
HLA testing	Access to HLA typing laboratory (allogeneic HCT)	1.40 (.97)	–
Laboratory	Cell counter	1.00 (–)	1.00 (.32)
	Chemistry	1.20 (.63)	1.00 (.32)
	ABO blood typing	1.40 (1.26)	1.00 (.32)
	Immunohistochemistry	2.10 (.88)	1.89 (.95)
	CSA or tacrolimus level (allogeneic HCT)	1.30 (.48)	–
Microbiology	Basic bacterial and fungal cultures	1.30 (.48)	1.11 (.47)
	Serology for hepatitis, HIV, HSV, syphilis, and HTLV-1	1.10 (.32)	1.33 (.79)
Allogeneic HCT	CMV detection (antigenemia or PCR)	1.70 (.67)	2.67 (1.60)

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Recommendations for Establishing a HSCT Program

Minimum Requirements for Development of HCT Program by Transplant Type

Domain	Minimum Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Radiology	X-ray and CT scan	1.10 (.32)	1.33 (.63)
Pharmacy	Access to chemotherapy agents used in the conditioning regimen	1.00 (—)	1.33 (1.03)
	Antiemetics	1.20 (.42)	1.22 (.57)
	Broad-spectrum antibiotics	1.00 (—)	1.00 (.32)
	Antifungal agents for prophylaxis and/or treatment	1.10 (.32)	1.89 (1.06)
Allogeneic HCT	Agents for HSV prophylaxis and viral infection treatment (eg, acyclovir, ganciclovir)	1.10 (.32)	1.89 (1.16)
Allogeneic HCT	Agents for treatment of GVHD	1.40 (.70)	—
Allogeneic HCT	Availability of CNI with or without methotrexate for GVHD prophylaxis	1.10 (.32)	—
Interventional radiology	Placement of central line access	1.90 (1.29)	1.44 (.67)

* Added per recommendation of reviewers.

BMT indicates bone marrow transplantation; CSA, cyclosporine A; HSV, herpes simplex virus; HTLV-1, human T-cell leukemia/lymphoma virus type 1.

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Recommendations for Establishing a HSCT Program

Table 3
Preferred Requirements for Development of an HCT Program

Domain	Preferred Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Infrastructure	Apheresis suite	2.60 (1.26)	1.67 (1.35)
	Cryopreservation cell storage warehouse	3.30 (1.57)	2.78 (2.01)
	Dedicated transplantation unit	2.90 (1.37)	3.78 (1.65)
	Government support for development or registering new programs	2.30 (1.06)	2.89 (1.52)
	HEPA-filtered units	2.90 (1.37)	4.00 (1.79)
	Outpatient clinic for transplantation recipients	2.10 (.88)	3.11 (1.25)
	Operating room with availability for elective bone marrow harvesting (allogeneic HCT)	2.50 (1.08)	4.33 (2.04)
	Private patient rooms	2.20 (1.32)	3.22 (1.03)
	Transplantation rooms in hematology/oncology wards	2.20 (1.40)	2.22 (1.70)
Staff	Additional physicians: hematologist/oncologist	1.70 (.95)	2.44 (1.62)
	BMT program quality management professional (for accreditation)	4.30 (.95)	3.89 (1.65)
	Cell processing lab director, MD/PhD or PhD with HCT laboratory experience	2.00 (.82)	2.33 (1.43)
	Dedicated professional responsible for coordination of care: PBSC pheresis and bone marrow harvest, including training personnel, scheduling, and performing the procedure	2.50 (1.35)	2.56 (1.57)
	Social worker	4.10 (.74)	4.00 (1.84)
	Physician to oversee related donor workup who is not directly involved with the recipient's workup (allogeneic HCT)	3.90 (1.10)	–
Cell processing laboratory	Capabilities for minimum graft manipulation: RBC reduction, $CD34^+$ cell enumeration	2.20 (1.40)	–
	Cryopreservation procedures and storage space	2.00 (1.40)	1.44 (.82)
Blood banking	Accreditation from the AABB or equivalent	3.20 (.79)	3.22 (1.66)
HLA Testing	Access for consultation with immunogenetic professional to assist in donor or cord blood selection (allogeneic HCT)	3.40 (.97)	–
	Access to trained professional in performing unrelated donor searches	3.10 (1.20)	–
	Capabilities to test for anti-HLA antibodies	3.30 (1.64)	–
Laboratory	Immunoglobulin level	2.30 (1.42)	3.44 (2.33)
	Chimerism analysis (allogeneic HCT	2.60 (.97)	–

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Recommendations for Establishing a HSCT Program

Table 3
Preferred Requirements for Development of an HCT Program

Domain	Preferred Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Microbiology	CMV detection (antigenemia or PCR) (autologous HCT)	1.70 (.67)	2.67 (1.60)
	Availability for testing for different viruses, including molecular testing (PCR)	2.80 (1.14)	3.67 (1.40)
Pharmacy	Patient-controlled analgesia	3.30 (1.25)	3.33 (2.31)
	Total parenteral nutrition	2.70 (1.06)	4.00 (1.37)
	Ganciclovir for treatment of viral infection (autologous HCT)	1.30 (.48)	3.33 (1.89)
Pathology	Flow cytometry	2.00 (.94)	2.56 (.95)
	PCR for disease markers (allogeneic HCT)	3.70 (1.49)	4.44 (1.57)
Radiology	Magnetic resonance imaging	2.60 (.84)	2.67 (1.43)
Interventional radiology	Placement of central line and assistance with other procedures, including lumbar puncture, thoracentesis, paracentesis, and image-guided biopsy, among others	2.20 (1.62	2.56 (1.89)
Ancillary services (consults)	Hematopathologists	1.90 (.99)	2.22 (1.41)
	Infectious diseases	2.30 (1.25)	2.78 (1.84)
	Gastroenterology and endoscopies services	2.00 (1.15)	3.89 (2.27)
	Pulmonary and endoscopies services	2.20 (1.03)	3.22 (1.85)
	Critical care services or intensivists	1.70 (.95)	2.22 (1.25)
	Radiation oncology	2.20 (1.03)	3.00 (1.83)
	Ophthalmology (cGVHD) (allogeneic HCT)	2.90 (1.20)	–
	Gynecologist (cGVHD) (allogeneic HCT)	4.00 (1.49)	–
	Neurology (allogeneic HCT)	3.20 (1.23)	–
Quality	Accreditation with local, regional, or international BMT quality entities	3.00 (1.56)	3.22 (1.73)
	Collection of demographic and outcome data according to international standardized forms	3.40 (1.07)	3.44 (1.66)
	Data sharing with local, regional, or international outcomes registries	3.60 (1.51)	3.78 (2.01)
	Development of a quality program	3.40 (1.26)	3.44 (1.85)
	Development of a relationship with an established transplant program for at least the first year of implementation	2.00 (.94)	2.44 (1.55)
	Development of standard operating procedures for the HCT program that are available to the whole team	2.50 (1.51)	2.89 (1.78)
Other	Participation and training program for junior faculty in transplantation	4.00 (1.56)	3.11 (1.55)

cGVHD indicates chronic graft-versus-host disease.

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Recommendations for Establishing a HSCT Program

Table 4
Ideal Requirements for Development of an HCT Program

Domain	Ideal Requirements	Allogeneic HCT Score, mean (SD)	Autologous HCT Score, mean (SD)
Infrastructure	Structure for outpatient transplantation: infusion room open daily with staffing	3.20 (1.87)	3.33 (1.58)
Staff	Access to a donor search coordinator	4.20 (1.48)	–
	Clinical coordinator for organization of pretransplantation testing and scheduling	4.00 (1.25)	5.00 (1.79)
	Data manager responsible to data capture and reporting	4.60 (.84)	4.11 (1.64)
	Dietitian	4.30 (1.34)	4.11 (1.64)
	Financial services professional	4.40 (1.51)	4.67 (2.10)
	Psychologist for pretransplantation evaluation	5.50 (1.18)	5.22 (2.31)
Cell processing laboratory	Capabilities for more than minimum graft manipulation, such as T cell depletion or $CD34^+$ cell selection	4.40 (0.84)	–
Laboratory	Busulfan PK, either local or as a send-out	4.40 (1.71)	–
Microbiology	Galactomannan assay	4.50 (1.90)	4.67 (1.69)
Pharmacy	Access to ATG	4.00 (1.05)	6.89 (.32)
	Defibrotide	4.60 (1.71)	–
Pathology autologous HCT	PCR for disease markers	3.70 (1.49)	4.44 (1.57)
Radiology	Nuclear medicine	4.20 (1.32)	4.33 (1.97)
	PET/CT scan	3.80 (.79)	4.11 (2.00)
Ancillary services	Psychiatrist	4.40 (.97)	–
Other	Access to extracorporeal photopheresis	5.00 (1.63)	–
	Clinical research coordinators for development or participation in clinical trials	5.30 (1.63)	5.11 (2.07)

PK indicates pharmacokinetics; ATG, antithymocyte globulin; PET, positron emission tomography.

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Mission of WBMT

Provide a list of essential medication for stem cell transplantation

Complex system:

I. Price
II. Availability
III. Affordability
IV. R&D
V. Transparency of pricing and prices
VI. Unintended negative consequences
VII. Registration

Essential Medications

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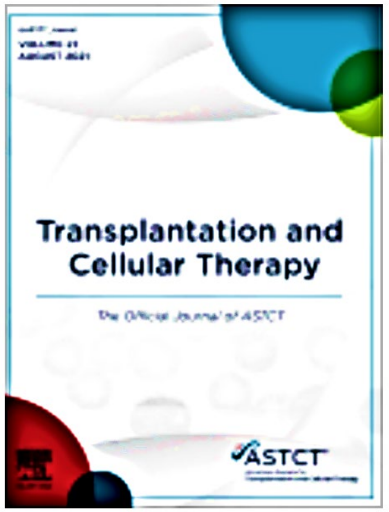

Worldwide Network for Blood and Marrow Transplantation (WBMT) Recommendations Regarding Essential Medications Required To Establish An Early Stage Hematopoietic Cell Transplantation Program

Riad El Fakih[1,*], Hildegard Greinix[2], Mickey Koh[3,4], Bronwen Shaw[5], Mohamad Mohty[6], Mohammad Al Nahedh[7], Wael Saber[5], Mohamed A. Kharfan-Dabaja[8], Miguel-Angel Perales[9,10], Bipin N. Savani[11], Navneet S. Majhail[12], Jakob R. Passweg[13], Anna Sureda[14], Syed Osman Ahmed[1], Eliane Gluckman[15], Marcie Riches[16], Areej El-Jawahri[17], Damiano Rondelli[18], Alok Srivastava[19], Lawrence Faulkner[20], Yoshiko Atsuta[21], Karen K. Ballen[22], Walid Rasheed[1], Shinichiro Okamoto[23], Adriana Seber[24], Nelson Chao[25], Nicolaus Kröger[26], Yoshihisa Kodera[20], Jeff Szer[27], Shahrukh K. Hashmi[1,28], Mary M. Horowitz[5], Daniel Weisdorf[29], Dietger Niederwieser[30], Mahmoud Aljurf[1]

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Stages of Development of HCT Programs

	Stage I	Stage II	Stage III
Types of transplantation performed	■Autologous ■HLA-matched sib donors	Stage I + ■All MSD transplants including MMSD ■Autologous with cryopreserved products	Stage II + ■Haploidentical ■and/or MUD, MMUD ■and/or UCB ■and/or T-cell depleted
Number of HCT	5 Auto-HCT/year 3-5 Allo-HCT/year	10 Auto-HCT/year 5-10 Allo-HCT/year	>10 Auto-HCT/year >10 Allo-HCT/year

MMSD indicates mismatched sibling donor; MSD, matched sibling donor; MMUD, mismatched unrelated donor; MUD, matched unrelated donor; UCB, umbilical cord blood; auto-HCT; autologous hematopoietic cell transplant; allo-HCT, allogeneic hematopoietic cell transplant.

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Essential Medications

Table 4
Medication Score as Voted for by ≥70% of Expert Group

	Required (Score 1 and 2) With Votes Above 70%	Preferred (Score 3 and 4) With Votes Above 70%	Ideal (Score > 4) With Votes Above 70%
Stage I program	Mobilization: -Chemotherapy and filgrastim for autologous PBSCT mobilization -Filgrastim for autologous PBSCT mobilization -Filgrastim for allogeneic PBSCT mobilization Conditioning: -Cyclophosphamide -Cytarabine -Melphalan -Fludarabine Seizures prophylaxis: -Benzodiazepine GvHD prophylaxis: -Cyclosporine -Methotrexate -Methylprednisolone -Prednisone -Dexamethasone Antimicrobials: -Piperacillin/Tazobactam -Cefepime -Ciprofloxacin -Vancomycin -Fluconazole -Acyclovir -Ganciclovir -Bactrim Supportive: -IV narcotics -5-HT3 antagonists	Mobilization: none Conditioning: -Oral busulfan -Intravenous busulfan -Carboplatin -Carmustine -Etoposide Seizures prophylaxis: -Phenytoin -Levetiracetam GvHD prophylaxis: -Tacrolimus -Mycophenolate -Rituximab Antimicrobials: -Carbapenem -Levofloxacin -Tigecycline -Amphotericin B (liposomal) -Echinocandin -Voriconazole -Posaconazole -Valganciclovir -Foscarnet -Valacyclovir -Pentamidine Supportive: -Phenothiazines -Neurokinin antagonists -Ursodiol -IVIG -TPN -PCA	Mobilization: -Plerixafor for autologous PBSCT mobilization Conditioning: -Intravenous busulfan with TDM Seizures prophylaxis: none GvHD prophylaxis: -Antithymocyte globulin rabbit -Budesonide -Sirolimus -Etanercept -Alemtuzumab -Basiliximab -Extracorporeal photopheresis -Infliximab Antimicrobials: -Amphotericin B (conventional) -Isavuconazonium -Cidofovir -Letermovir Supportive: -Defibrotide -Olanzapine

TDM indicates therapeutic drug monitoring.

El Fakih R et al. Transplantation and Cellular Therapy 27 (2021) 267e1-267e5

Cost Reduction Using Biosimilars

Table 1 List of some Biosimilars approved in the United States and the European Union pertaining to HSCT*.

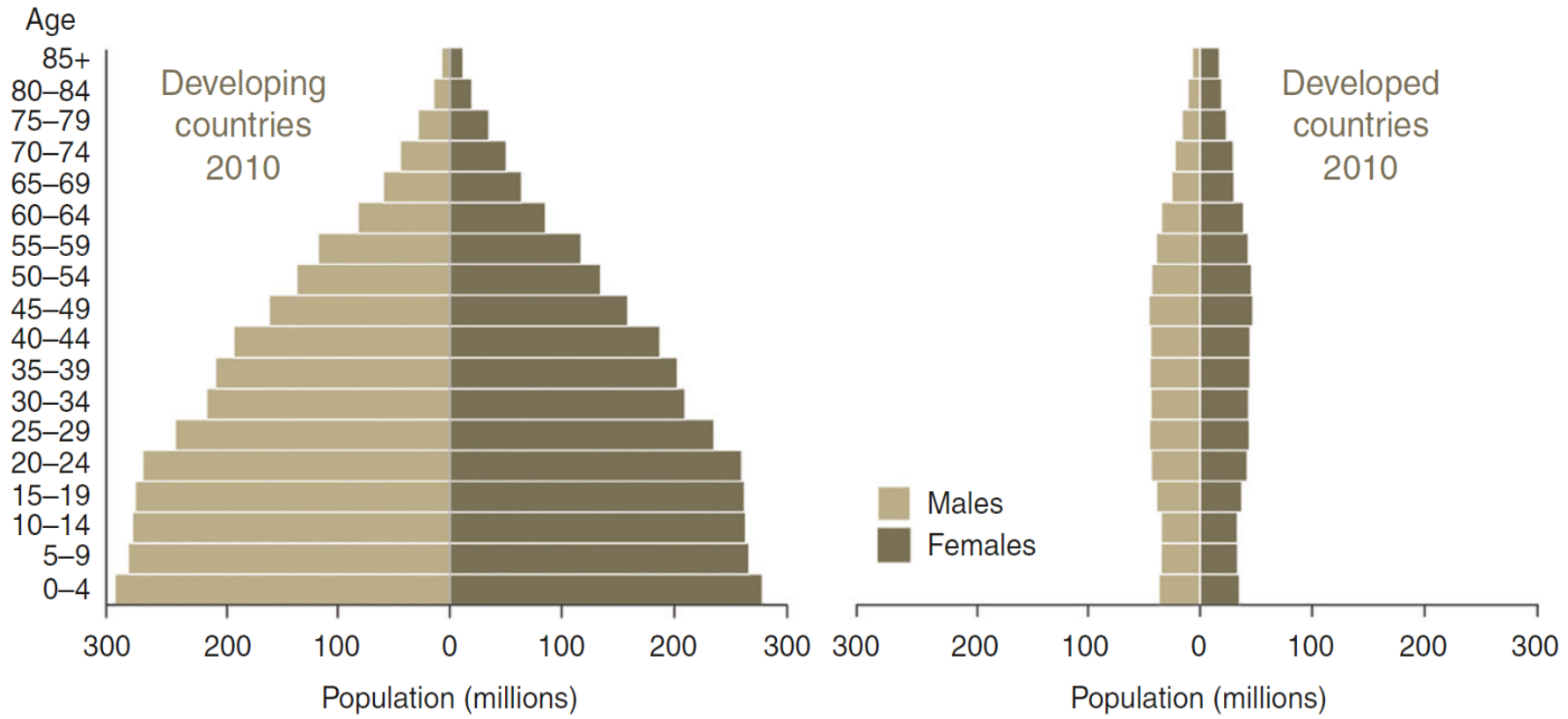
Generic/molecule	Biosimilar	Year approved	Use in HSCT
Filgrastim	Tevagrastim	2008 (EMA)	Mobilization of peripheral stem cells for autologous HSCT
	Ratiograstim	2008 (EMA)	
	Filgrastim Hexal	2009 (EMA)	
	Zarzio	2009 (EMA)	
	Accofil	2014 (EMA)	
	Zarxio	2015 (US-FDA)	
Rituximab	Truxima	2017 (EMA)	Treatment of chronic GVHD
	Rixathon	2017 (EMA)	
	Ritemvia	2017 (EMA)	
Infliximab	Inflectra	2013 (EMA); 2016 (US-FDA)	Treatment of acute GVHD
	Flixabi	2016 (EMA)	
Etanercept	Benepali	2016 (EMA)	Treatment of acute GVHD
	Erelzi	2016 (US-FDA); 2017 (EMA)	Treatment of BOS
			Treatment of IPS
Enoxaparin	Inhixa	2016 (EMA)	DVT prophylaxis
	Thorinane	2016 (EMA)	DVT treatment

EMA: European Medicines Agency; US-FDA: United States Food and Drug Administration; GVHD: Graft-versus-host-disease; BOS: Bronchiolitis obliterans syndrome; IPS: Idiopathic pulmonary syndrome; DVT: Deep venous thrombosis; HSCT: Hematopoietic stem cell transplantation.
*The table list only some of the approved biosimilars and not intended to be inclusive of all approved biosimilars. WBMT is working on a separate publication that will have a complete list of approved biosimilars.

H. Baldomero 3.2013

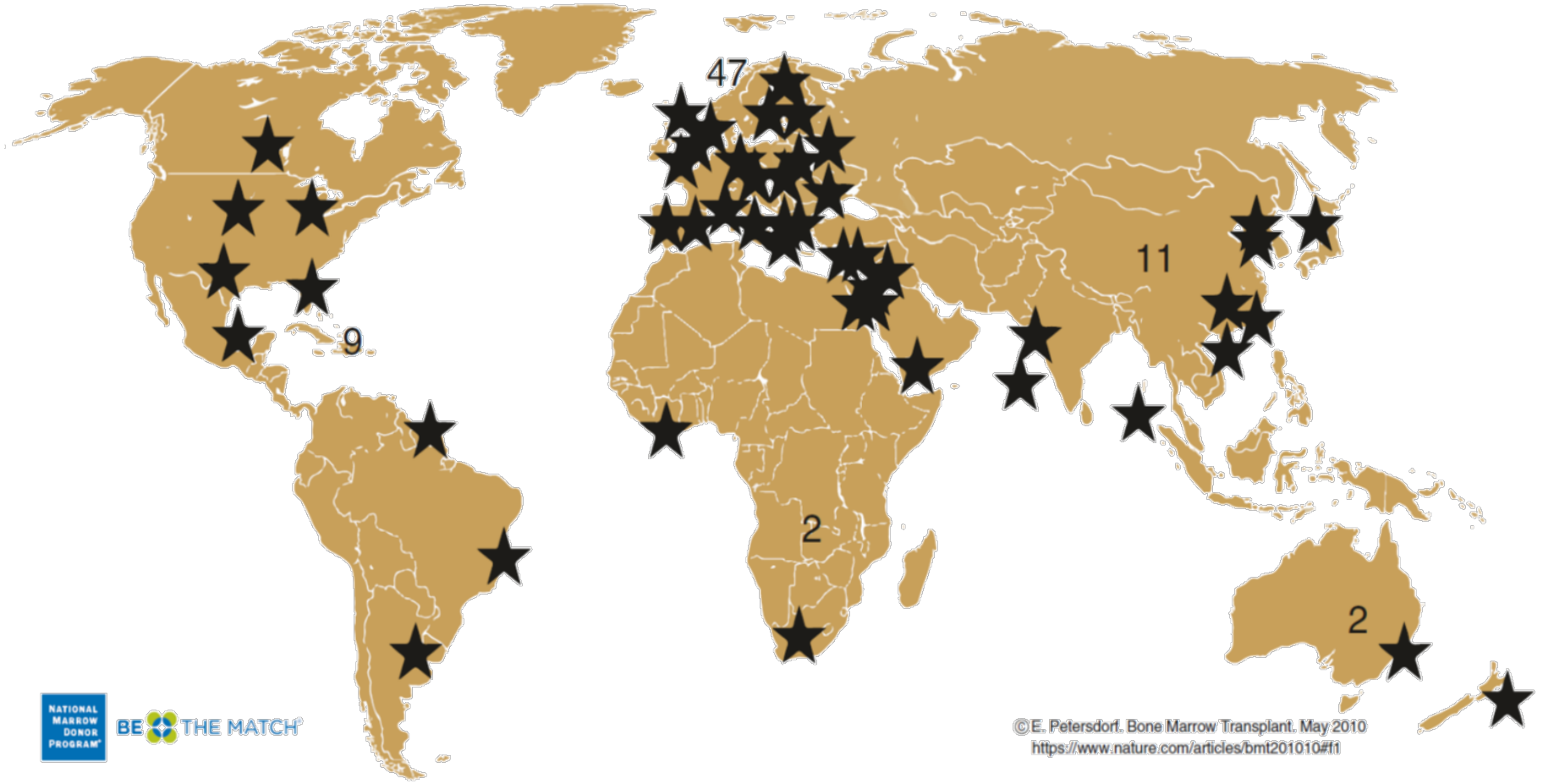
Aljurf et al. BBMT 25 (2019) 2330-2337

Population´s Age in Developing and Developed Countries



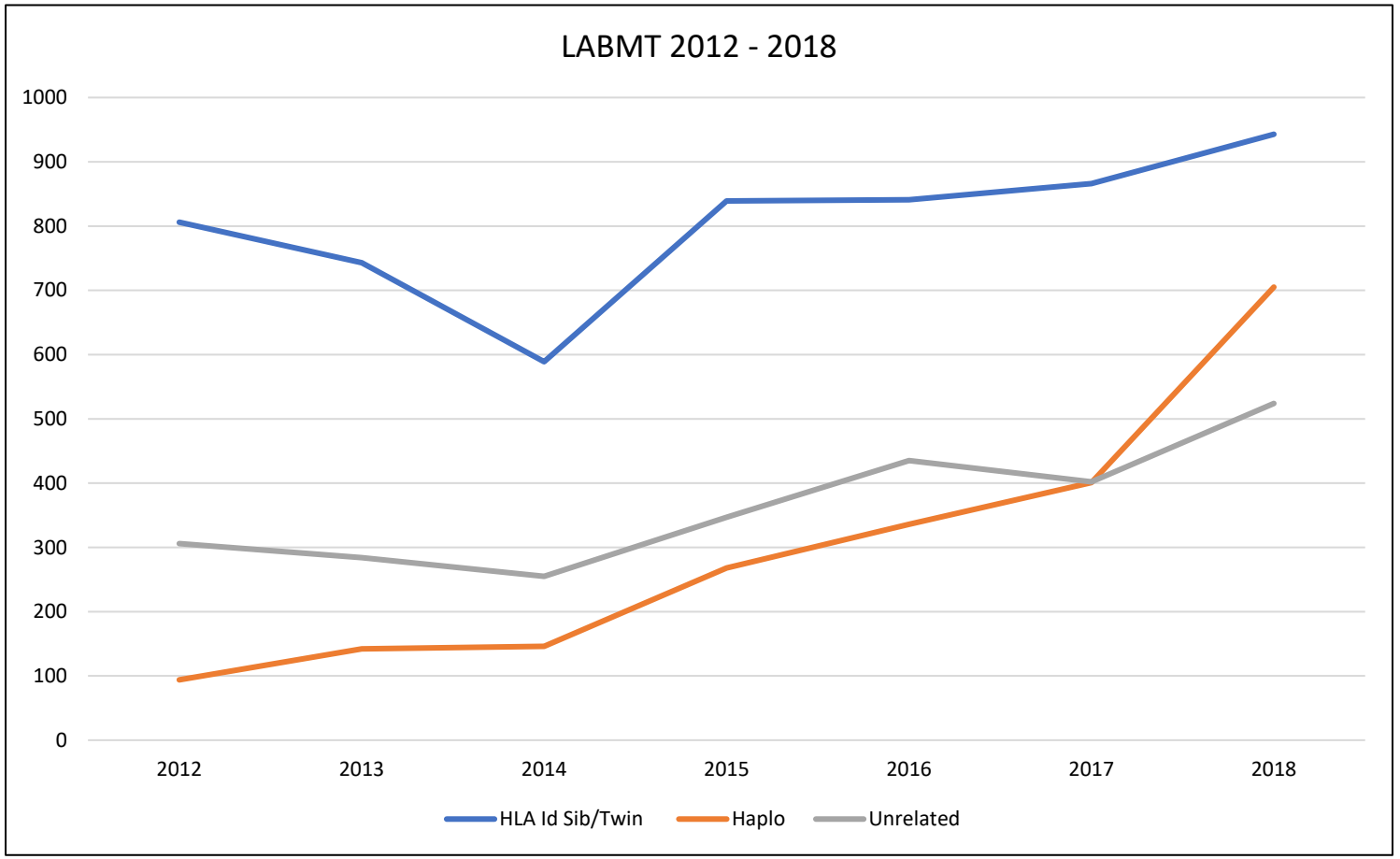
Aljurf M. et al. BMT 54 (2019) 1179-1188

Location of Unrelated Donor Registries

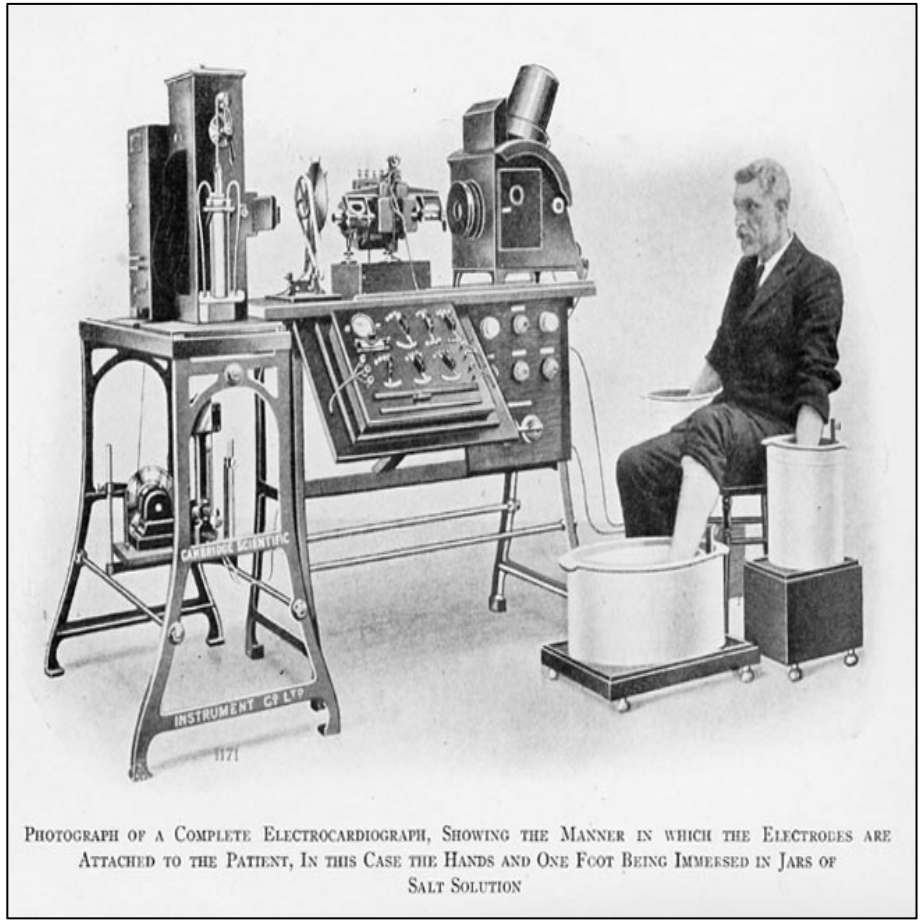


Aljurf M. et al. BMT 54 (2019) 1179-1188

2012-2018 Trends - Donor Source for Allo



Telemedicine History



PHOTOGRAPH OF A COMPLETE ELECTROCARDIOGRAPH, SHOWING THE MANNER IN WHICH THE ELECTRODES ARE ATTACHED TO THE PATIENT, IN THIS CASE THE HANDS AND ONE FOOT BEING IMMERSED IN JARS OF SALT SOLUTION

Einthoven W. Le télécardiogramme [The telecardiogram]. Archives Internationales de Physiologie, 1906, 4:132–164.

Courtesy of D. Vaitiekus

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Telemedicine (TM) program for HSCT

HOSPITAL OF LITHUANIAN UNIVERSITY OF HEALTH SCIENCES
KAUNAS CLINICS

1) Training in a JACIE accreditated HSCT Center (6 months)

2) Establishment of core facilities in Kaunas

3) Site visit to the facilities

4) Selection of local experienced hematological staff

5) Start the program with protocols in place under supervision of experienced director (8/2015)

	n
TRM at 90 days	1,4%
OS @ 1 years	92,6%
OS @ 2 years	88,4%
OS @ 3,5 years	88,4%
PFS 3,5y	63,8%

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Increasing Access to HCT

- Collaboration among international organizations
- Promote quality and safety
- Use of telehealth systems
- Wearable devices
- Use of articifial intelligence
- Research agenda focused on issues affecting resource-constrained populations


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APBMT
Asia-Pacific Blood and Marrow Transplantation Group

Development of a Quality Program in the Asia-Pacific Region

- Presented by: Alok Srivastava, MD
- Centre for Stem Cell Research & Department of Hematology at Christian Medical College, Vellore

inStem

CHRISTIAN MEDICAL COLLEGE VELLORE INDIA
NOT TO BE MINISTERED UNTO BUT TO MINISTER

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Asia Pacific region : ~50-55% of the world population

2 most populous countries : ~40% of the world population

Very high economic & socio-cultural diversity within the region

APBMT SURVEY - 2021

HSCT STANDARDS & ACCREDITATION STATUS

COUNTRY/REGION – *NO. OF HSCT CENTERS –

*The number of HSCT centers printed is data in 2019 and given from APBMT Data Center. If it is not up to date, please correct it.

		YES/NO
1	ARE THERE DEFINED STANDARDS FOR HSCT CENTRES IN YOUR COUNTRY/REGION?	
	IF THE ANSWER ABOVE IS YES, PLEASE ANSWER THE FOLLOWING QUESTIONS	
2	ARE THESE STANDARDS MANDATORY (BY NATIONAL REGULATION) OR VOLUNTARY (OPTIONAL)?	
3**	ARE THESE STANDARDS AS PER INTERNATIONAL NORMS (FACT / JACIE)?	
	ARE THESE STANDARDS AS PER COUNTRY/REGION SPECIFIC NORMS?	
	ARE THESE STANDARDS LEFT TO INSTITUTIONAL / HSCT CENTRE DEFINED NORMS?	
4.	WHAT PERCENTAGE OF CENTERS FOLLOW ANY OF THE DEFINED STANDARDS? <10% 10-25% 25-50% 50-75% >75%	
5.	IS THERE A SYSTEM OF AUDIT OF HSCT CENTERS FOR ASSESSMENT OF MAINTENANCE OF STANDARDS?	

**: More than one option possible.

Christian Medical College, Vellore, India
Hematopoietic Stem Cell Transplantation Program

*Established 1986: Within a multi-specialty university affiliated tertiary care hospital (*established in 1900*)

-Currently with ~2500 beds → Expanding to 3500 beds *(later in 2021)*

-1 bed unit → 3 bed unit → 8 bed unit → 18 bed unit → 30 bed unit *(later in 2021)*

*Annual HSCT number: 275-300 HSCTs (adult & pediatric)

-200-225 allogeneic HSCTs

-75-100 autologous

*Quality program for Hospital: Accredited with National Boards

-NABL / NABH in India

*Quality program for HSCT

-No specific accreditation for HSCT program but all HSCT related processes conducted as per written / reviewed protocols

-Weekly review / audit of deaths / other unexpected adverse outcomes

-Data submitted to CIBMTR (Undergone 2 CIBMTR audits successfully!)

Tata Medical Centre, Kolkata, India
Hematopoietic Stem Cell Transplantation Program

*Established May 16, 2011: Within a multi-specialty tertiary cancer hospital -Currently with ~400 beds

-9 bed HSCT unit (adult & pediatric)

*Annual HSCT number: ~75 (allo & auto together)

*Quality program for Hospital: Accredited with National Boards

-NABL / NABH in India

*Quality program for HSCT

-In the process of FACT accreditation

-Effort on for last ~3 years with one dedicated faculty coordinating

-"Self-assessment tool kit" - 4 sections: Clinical program; BM Collection; Apheresis; Cell Processing

-~700 items each, to understand and standardize policies & documents

-"Still working on the latest FACT Standards (8th Edition) published last month"

→*Very significant resources required for preparing for such accreditation*

Information courtesy – Rizwan Javed / Mammen Chandy, TMC

Quality Programs & HSCT in the Asia – Pacific Region

*Extremely low overall HSCT density

*Many countries / regions within countries lack expertise /infrastructure for HSCT

*Training manpower for HSCT a major requirement

*Significant proportion of HSCT activity in the 'private' healthcare sector in several countries ('user pay system')

*Advocacy for government support for HSCT essential

*Establishment of quality programs impacted by these considerations

→Quality Programs for HSCT – Absolutely essential

-Challenge is making it possible in a practical model applicable in *all HSCT centres all over the world!*


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FACT-JACIE Accreditation in Latin America

Presented by: Carlos Bachier, MD
Program Director and Processing Facility Director
Sarah Cannon Transplant and Cellular Therapy Program

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Background

- FACT-JACIE International Task Force
  - The Latin American Bone Marrow Transplantation Group (LABMT) sought guidance from FACT and JACIE to develop accreditation programs.
  - To provide uniform guidance, a FACT-JACIE International Task Force was developed in 2015 with representation from FACT, JACIE and the LABMT.

Purpose

> The FACT-JACIE International Task Force evaluates and develops a collaborative approach for global accreditation of transplant centers in regions outside of North America, Europe, Australia and New Zealand.

Initial Roster

FACT-JACIE INTERNATIONAL TASK FORCE

CHAIR - FACT
Carlos Bachier, MD
Sarah Cannon Blood and Marrow Transplant Program

CO-CHAIR - JACIE
John Snowden BSc (Hons), MBChB, MD, FRCP, FRCPath
Sheffield Teaching Hospitals
NHS Foundation Trust

Jaap-Jan Boelens, MD, PhD	JACIE	Wilhelmina Children's Hospital	Utrecht, Netherlands
Anna Sureda, MD, PhD	JACIE	Institut Català d'Oncologia, Hospital Duran i Reynals	Barcelona, Spain
Rafael Duarte, MD, PhD	JACIE	University Hospital Puerta de Hierro Majadahonda,	Madrid, Spain
Hugo Fernandez, MD	FACT	Moffitt Malignant Hematology & Cellular Therapy	Pembroke Pines, FL
Phyllis Warkentin, MD	FACT	University of Nebraska Medical Center	Omaha, NE
Edwin Horwitz, MD, PhD	ISCT	Nationwide Children's Hospital	Columbus, OH

Current Task Force and Staff

FACT	JACIE	Staff
Carlos Bachier	Kim Orchard	Magaly Unruh, FACT
Daniel Couriel	Isabel Sanchez-Ortega	Suzanne Birnley, FACT
Phyllis I. Warkentin	John Snowden	Raquel Espada, JACIE
Joan Garcia Lopez	Ángela Ruso	Martha Saldivar, JACIE
Linda Miller, MPA	Eoin McGrath	

International Accreditation Program Development

- Determine cost of accreditation in both developed and emerging or low-to-middle income countries (LMIC) countries.
- Offer traditional full accreditation process at discounted price for advanced programs ready to be inspected.
- For developing centers, determine Stepwise Accreditation Process including length of inspection cycles, inspection team composition, language of inspections (English vs primary language of program), and educational support.
- Develop an action plan and timeline for the International Accreditation Program along with an approach to accreditation in incremental steps.

Stepwise Accreditation Program

Preliminary

Focus on quality systems and ensure operations for patient and donor safety

.

Intermediate

Build on the established foundation to develop a complete quality management program

Accredited

Evaluates the effectiveness of the quality program; ensures reporting to the appropriate regulatory and accrediting agencies; and evaluates clinical outcomes.

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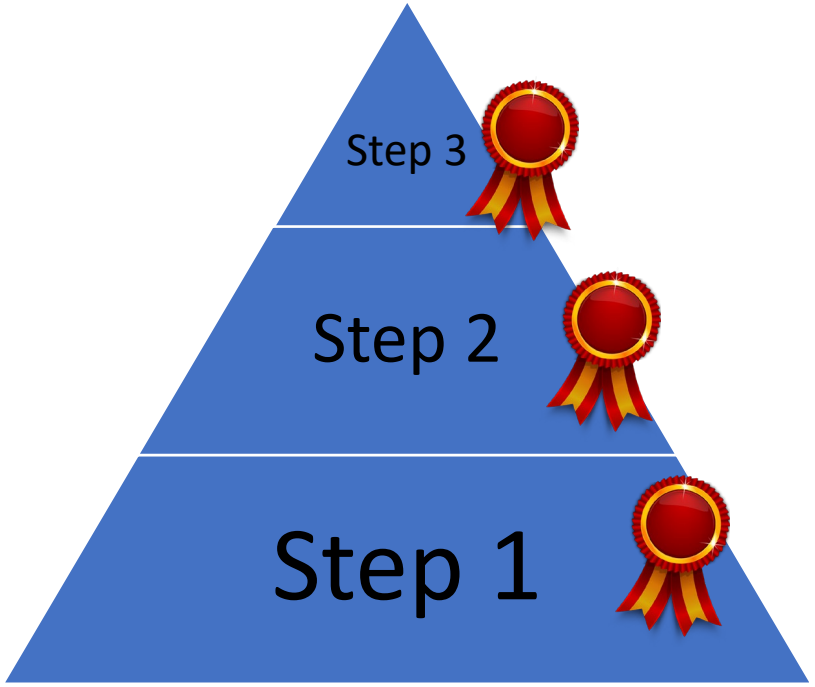
Stepwise Accreditation Program

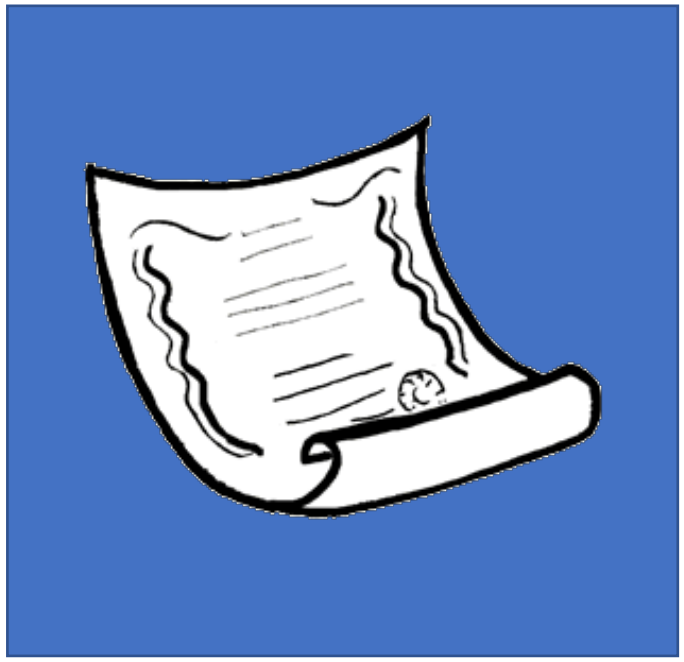
Step 1 = minimal for patient & donor safety STARTER	Step 2 = desirable quality management & efficacious care INTERMEDIATE	Step 3 = prepared for accreditation ADVANCED		
Step 1	Step 2	Step 3	Ref	Standard
			B.01	GENERAL
X			B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).
X			B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.
X			B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.
X			B.01.03	The Clinical Program shall abide by all applicable laws and regulations.
X			B.01.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.
	X		B.01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place for at least twelve (12) months preceding initial accreditation.

International Accreditation Program

Determine international accreditation program structures.



Stepwise Accreditation



Full Accreditation

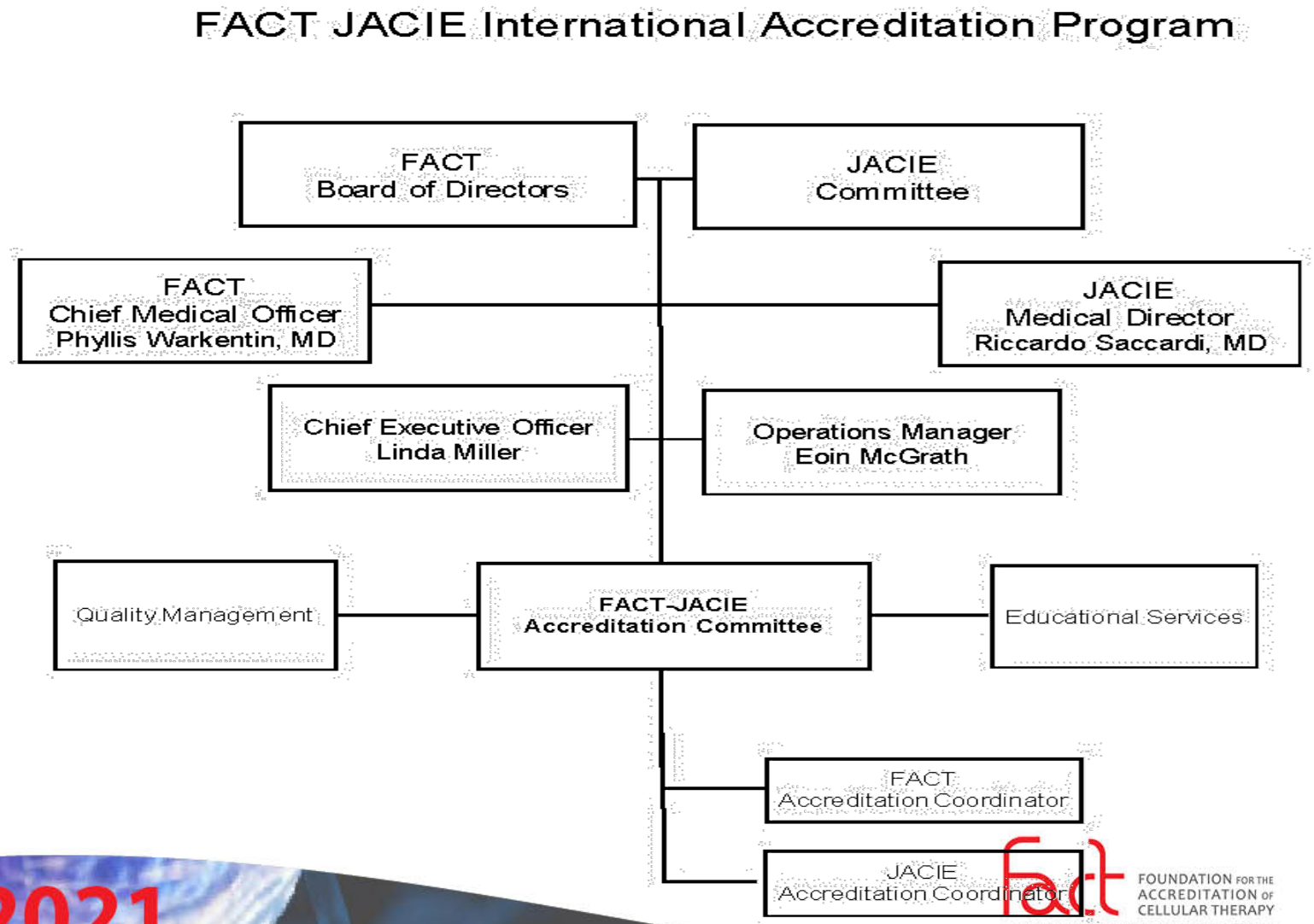
Stepwise Accreditation Program

- Certification cycle = 2 years
- Programs will be permitted a maximum of two years before being required to complete the next step in the process
- Programs will be allowed to remain at the same step for two cycles. However, the program will be required to undergo another onsite inspection for that same step
- By achieving compliance with all three steps, programs will meet FACT requirements and be granted accreditation
- Accreditation will be valid for three years

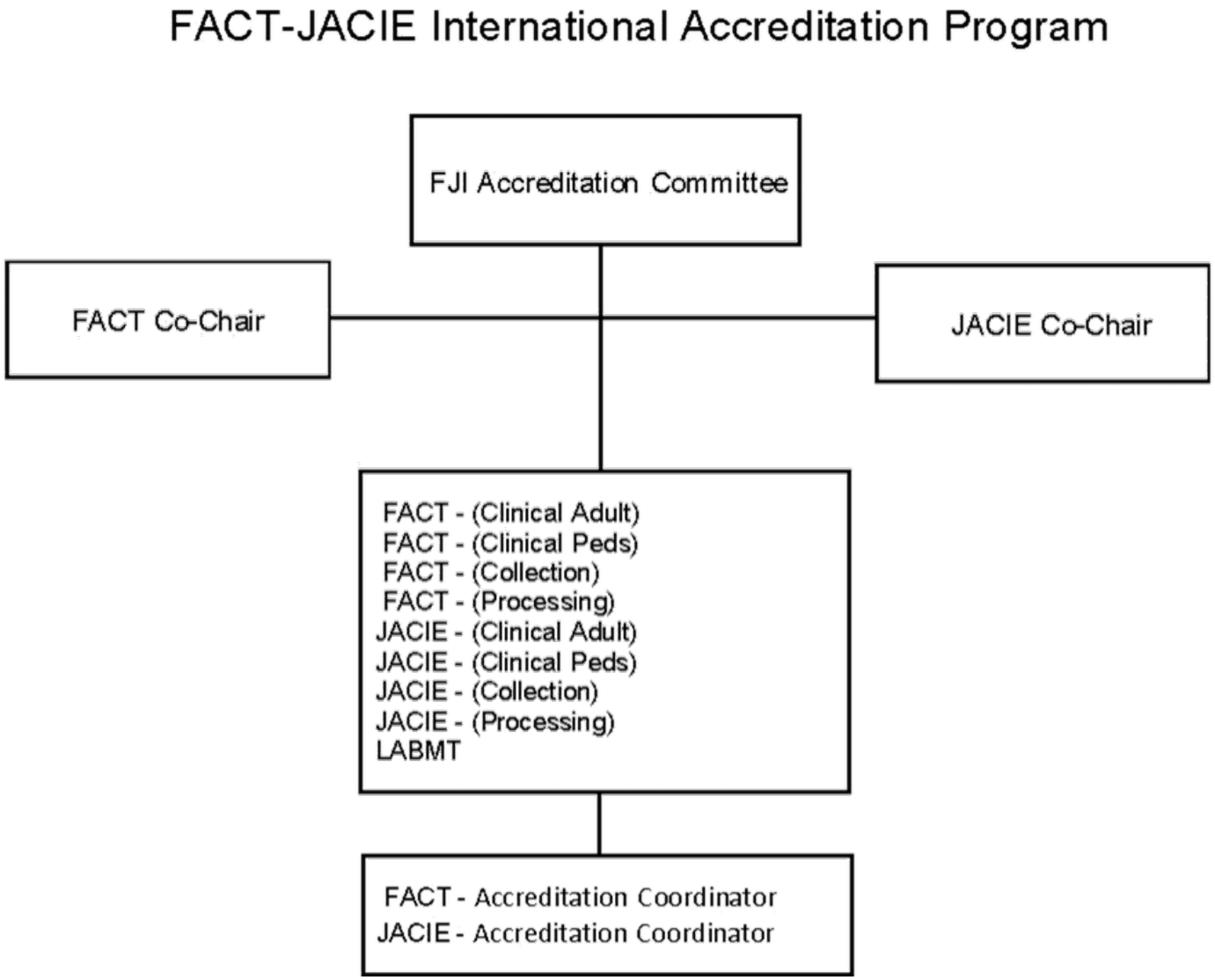
International Accreditation Options

	Full Accreditation	Stepwise Accreditation
Timeframe:	Inspected once every 3 years	Inspected at each step = 2 years
Status:	Accreditation upon successful compliance with all Standards	Certification upon successful compliance with Standards at each step
Cost:	Emerging Economy Discount 30% off full accreditation fees	$3,000/year ($6,000 for 2-year cycle)

FJI Accreditation Program – Organizational Chart



FJI Accreditation Program – Organizational Chart



Activities

01

Pilot Centers

Two initial centers selected for the FJI Stepwise Accreditation Program have undergone inspection. One center certified for step 1.

02

Additional Centers

One program that is preparing for reinspection to complete the first step, two programs are in the process of getting ready for inspection of step one, Seven programs are in the process of completing the compliance and preparing for inspection, and two programs are working on the eligibility application.

03

Standards Translation

The 8th Edition *FACT-JACIE International Standards for Hematopoietic Cellular Therapy* have been translated to Spanish and are now available.

04

On Demand Education

A dedicated web page for the FJI Program is under development and will include access to recorded webinars in Spanish.

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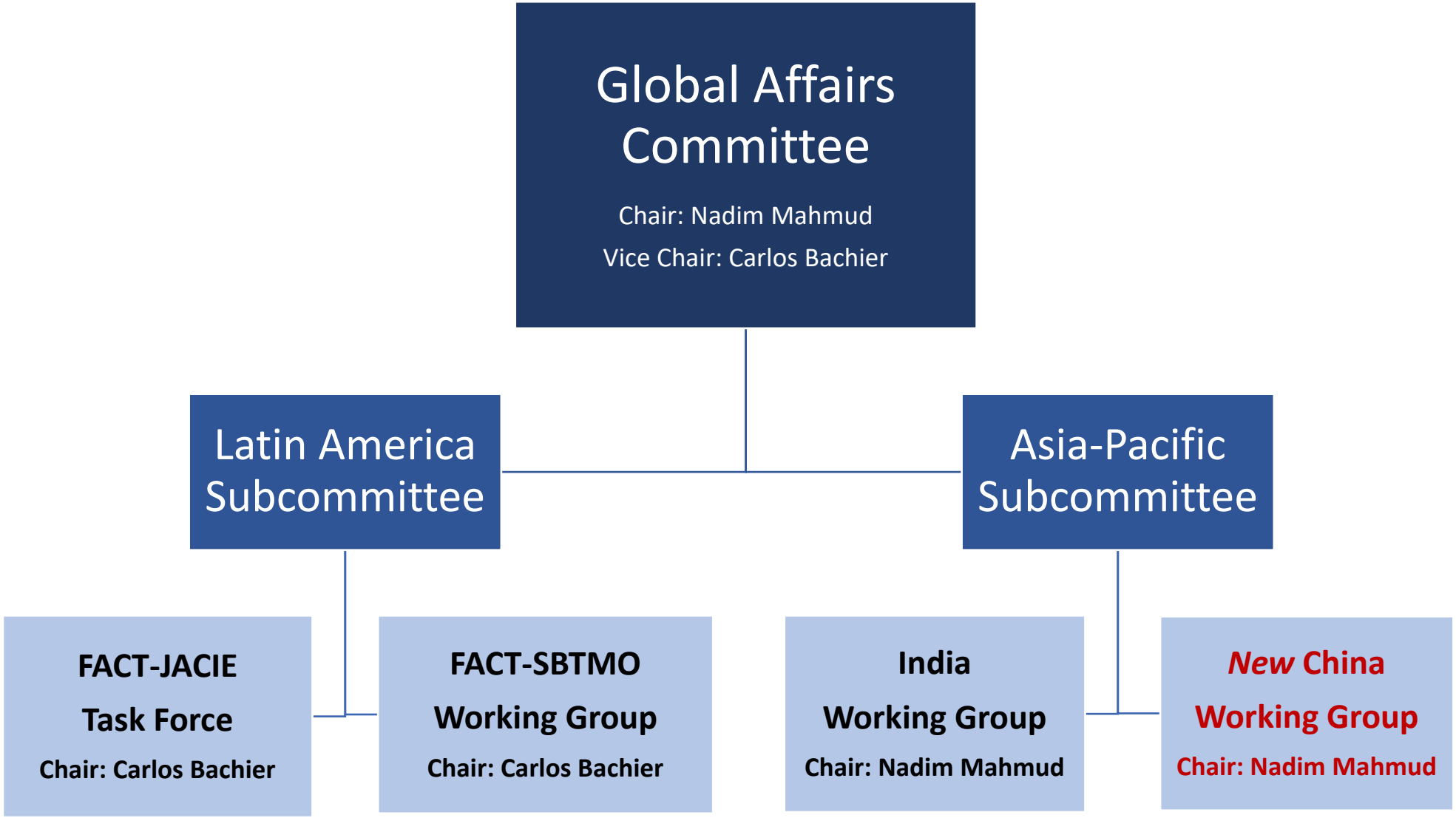

Global Affairs Committee
Chair: Nadim Mahmud
Vice Chair: Carlos Bachier
Latin America Subcommittee
Asia-Pacific Subcommittee
FACT-JACIE Task Force
Chair: Carlos Bachier
FACT-SBTMO Working Group
Chair: Carlos Bachier
India Working Group
Chair: Nadim Mahmud
New China Working Group
Chair: Nadim Mahmud

FACT-SBTMO Joint Accreditation Program in Brazil

FACT-SBTMO TASK FORCE

First meeting of the FACT-SBTMO Task Force to review strategy for joint accreditation in Brazil occurred on October 17, 2018

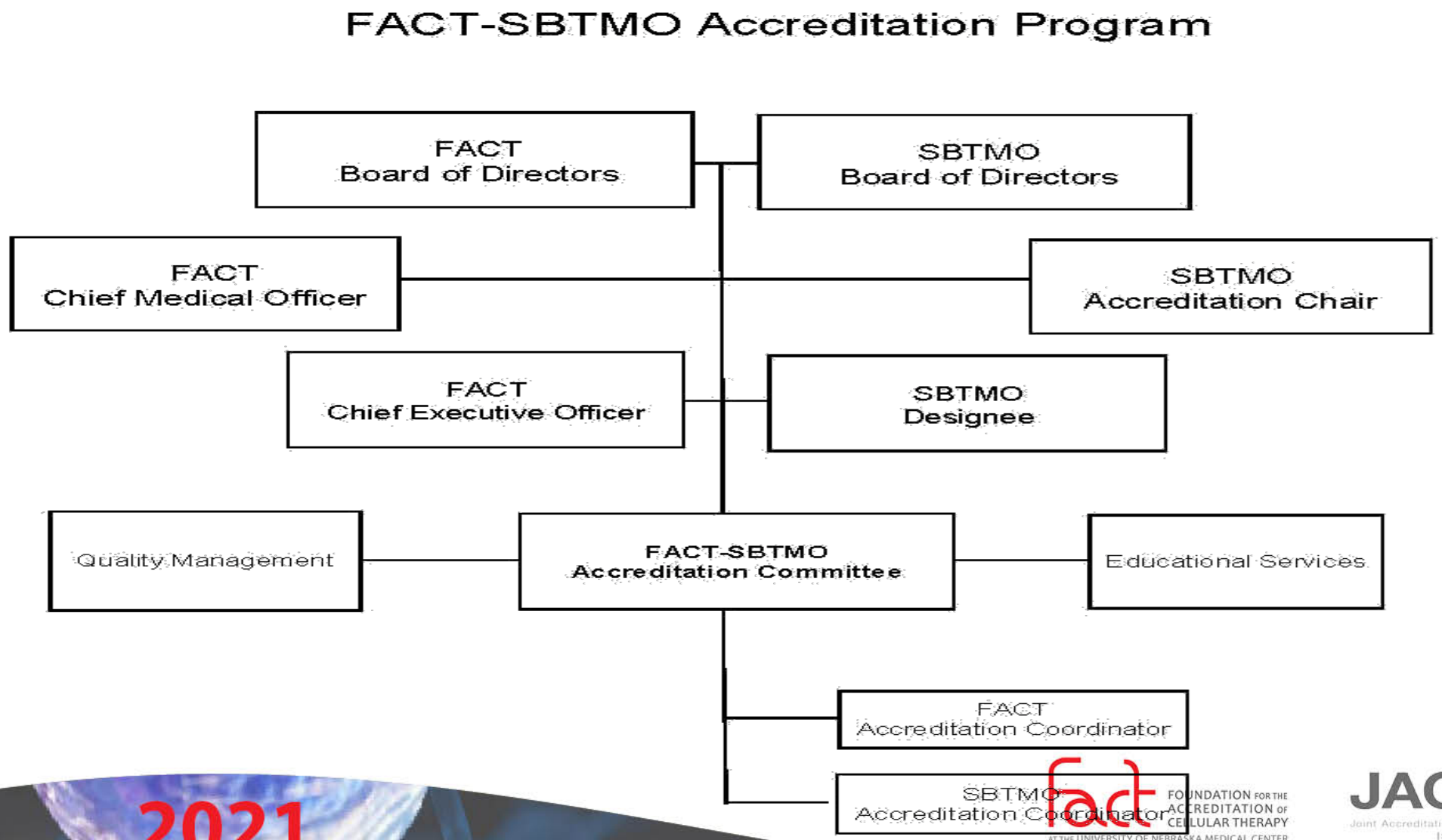
- 7th Edition Cell Therapy Standards translated to Portuguese.
- BMT survey sent to 96 transplant centers in Brazil to assess transplant activity, personnel, facilities, and quality systems.
- 20 transplants centers indicated interest in participating in accreditation process.

FACT-SBTMO Joint Accreditation Program in Brazil

FACT-SBTMO STRATEGY FOR ACCREDITATION

- Effort aims to:
  - Improve quality and patient safety at cellular therapy programs.
  - Increase access for patients to internationally accredited transplant programs in Brazil.
  - Provide an accreditation program at an affordable cost.
- FACT-SBTMO Task Force Meeting on July 31, 2019 to:
  - Define the objectives, services, organizational structure, management, and financial plan to administer the joint accreditation program.

FACT-SBTMO Joint Accreditation Program in Brazil



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Development of Accreditation Program

To facilitate the accreditation program and provide assistance to applicant transplant centers, the following is being developed:

Education

Online webinars

In-person workshops

Regional Inspectors

Affiliated with applicant or accredited program

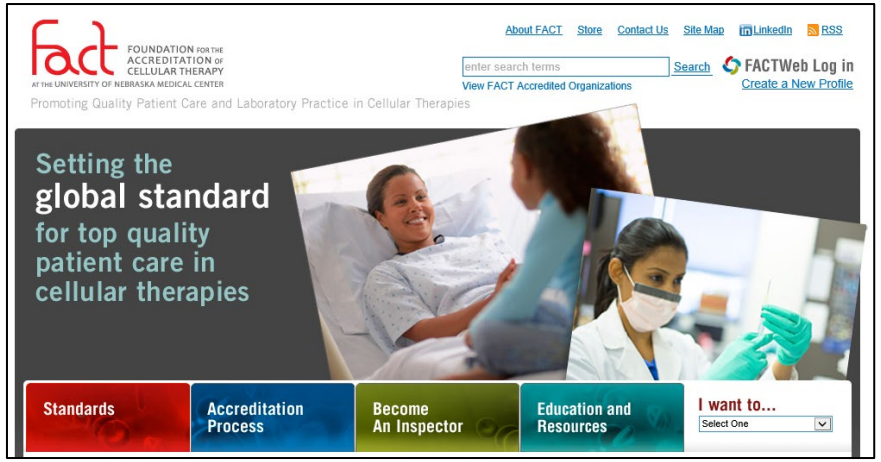
Accreditation Committee

Membership from FACT and SBTMO leadership

International Accreditation Program: Education

Webinars

Workshops



Website: www.factwebsite.org

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Question and Answer Session

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