2022 WBMT

Nongovernmental Organisation in official relations with the World Health Organization (WHO)









Worldwide Network for Blood and Marrow Transplantation

(WBMT)

Progress Report

Calendar Year 2022

wbmt.org

Headquarters: Waldeggstrasse 51, CH-3097 Liebefeld, Switzerland



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1.0 INTRODUCTION

The Worldwide Network for Blood and Marrow Transplantation (WBMT) was formally created in 2007 by leaders from major hematopoietic cell transplantation (HCT) societies and donor registries across the world, culminating in consensus on Bylaws and an organizational structure in 2009. With the interest and strong support of the World Health Organization (WHO), these leaders shared a mutual vision of combining efforts towards improving standardization in the global application of HCT, cellular therapy, and related fields as well as broadening the scope of data sharing. This "Federation of Societies" began with 17 international organizations now numbering 21, all with substantial interest in HCT (Appendix A). In October 2021, WBMT member society American Association of Blood Banks changed its organizational name into Association for the Advancement of Blood & Biotherapies. The abbreviation remains AABB. Additionally, the Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) became the Australia and New Zealand Transplant and Cellular Therapies Ltd (ANZTCT) in 2022. The WBMT was incorporated as a non-profit organization for educational, scientific, and philanthropic purposes under the laws of Switzerland with headquarters in Liebefeld (formerly located in Bern, but moved office in 2022). Funding support has been solicited from relevant industry plus income from educational activities. Description of the earliest years of WBMT activity is available in previous Progress Reports available on the WBMT website (wbmt.org). They contain information on how WBMT developed, its structure and charter, its notable achievements, and its future aims and goals. This report focuses on the accomplishments of WBMT during the calendar year 2022. After two consecutive years (2020 and 2021) of dealing with the COVID-19 pandemic and its restrictions, WBMT was thrilled to be able to organize the 8th Workshop & Symposium in Rawalpindi, Pakistan. The tremendous amount of work performed by the WBMT Education & Dissemination Committee and the local organizing committee (lead by Prof. Dr. Q. Chaudhry) assured that the workshop became an enormous success! Additionally, the relationship with the WHO was reinforced by establishing the WHO Liaison Standing Committee, several papers were published and well received and an important webinar on Management of Viral Infections in Hematopoietic Stem-Cell Transplant took place in June 2022.

1.1 Early Development

The four founding Member Societies of the WBMT are the Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Center for International Blood and Marrow Transplant Research (CIBMTR), European Society for Blood and Marrow Transplantation (EBMT), and World Marrow Donor Association (WMDA). Representatives organized themselves in 2007 to help identify goals and to communicate them to all other interested societies in HCT or related fields. They recognized:

- HCT is a global endeavor.
- More could be accomplished if the different societies active in this field collaborated.
- An international organization could support and even influence thoughtful, local policy and legislation from a global perspective.

It was concluded that the WBMT required a unique organizational structure to fulfill its goal of coordinating HCT, stem cell donor, and cellular therapy activities worldwide. It was also important not to duplicate decades of successful efforts by other established organizations in the field; the result was the current and continuing Federation of Societies structure.



1.2 Current Status with the WHO

The WHO played a critical role in the WBMT from its inception by providing substantial interest in and support of this new initiative. The collaborative relationship with the WHO led to the current status as non-government organization (NGO) in official relations, approved in January 2013. The WHO Executive Board reviewed the report of the relations and collaboration at its 144th session in January 2019 and confirmed that WBMT will remain in official relations with the WHO. In January 2022 the WHO Executive Board at its 150th session decided to maintain WBMT in official relations with WHO based on our achievements during the last years and the working plan for the period of 2022 to 2024. The WHO strongly supported the WBMT's early collaborative and unifying efforts. WHO representatives continue to attend meetings as observers, assist in planning activities, and participate as forum presenters on a variety of relevant topics. Since acquiring *NGO in official relations* status, the WBMT provides a set of collaborative projects to the WHO in pursuit of its educational, scientific, and philanthropic mission (**Section 4**).

2.0 COMMITTEE STRUCTURE

2.1 Board

The WBMT Board leads decision-making for all WBMT activities. The Board includes elected Executive Committee officials (Section 2.2 and Appendix B) as well as Co-Chairs of the Standing Committees (Sections 2.3 and 3.0). Each committee is permitted a single vote. The WBMT Board includes a primary and alternate representative from each Member Society. Each Member Society is permitted a single vote, either by the primary or the alternate representative. Find below an overview of the member society representatives.

WBMT Board: Primary and A	Alternate repr	esentatives			
Primary Representative	AABB	David	McKenna	July 1, 2025	End of second term
Alternate Representative	AABB	Christina	Celuzzi	July 1, 2024	End of first term
Primary Representative	ANZTCT	Nada	Hamad	July 1, 2024	End of first term
Alternate Representative	ANZTCT	Duncan	Purtill	July 1, 2025	End of second term
Primary Representative	AfBMT	Alaa	Elhaddad	July 1, 2025	End of second term
Alternate Representative	AfBMT	Bazuaye	Nosa	July 1, 2025	End of second term
Primary Representative	APBMT	Shinichiro	Okamoto	July 1, 2025	End of second term
Alternate Representative	APBMT	Alok	Srivastava	July 1, 2025	End of second term
Primary Representative	ASTCT	Damiano	Rondelli	July 1, 2024	End of first term
Alternate Representative	ASTCT	Corey	Cutler	July 1, 2025	End of second term
Primary Representative	ASFA	Laura	Connelly-Smith	July 1, 2024	End of first term
Alternate Representative	ASFA	Joseph (Yossi)	Schwartz	July 1, 2024	End of first term
Primary Representative	ASHI	Medhat	Askar	July 1, 2024	End of first term
Alternate Representative	ASHI	E. Victoria	Turner	July 1, 2025	End of second term
Primary Representative	CIBMTR	Wael	Saber	July 1, 2024	End of first term
Alternate Representative	CIBMTR	Marcelo	Pasquini	July 1, 2024	End of first term
Primary Representative	EBMT	Anna	Sureda	July 1, 2024	End of first term
Alternate Representative	EBMT	John	Snowden	July 1, 2025	End of second term
Primary Representative	EFI	Steven	Marsh	July 1, 2025	End of second term
Alternate Representative	EFI	Mats	Bengtsson	July 1, 2025	End of second term
Primary Representative	ELN	Rüdiger	Hehlmann	July 1, 2025	End of second term
Alternate Representative	ELN	Dietger	Niederwieser	July 1, 2025	End of second term
Primary Representative	EMBMT	Amir Ali	Hamidieh	July 1, 2025	End of second term
Alternate Representative	EMBMT	Syed Osman	Ahmed	July 1, 2025	End of second term



Primary Representative	ESH	Ghyslaine	le Bougault	July 1, 2024	End of first term
Alternate Representative	ESH	Clotilde	Magistry	July 1, 2025	End of first term
Primary Representative	Eurocord	Annalisa	Ruggeri	July 1, 2024	End of first term
Alternate Representative	Eurocord	Vanderson	Rocha	July 1, 2025	End of second term
Primary Representative	FACT	Paul	Eldridge	July 1, 2025	End of second term
Alternate Representative	FACT	Phyllis	Warkentin	July 1, 2025	End of second term
Primary Representative	ICCBBA	Eoin	McGrath	July 1, 2024	End of first term
Alternate Representative	ICCBBA	Karen	Moniz	July 1, 2024	End of first term
Primary Representative	ISBT	Mickey	Koh	July 1, 2025	End of second term
Alternate Representative	ISBT	Peter	Horn	July 1, 2025	End of second term
Primary Representative	ISCT	Fermin	Sanchez-Guijo	July 1, 2024	End of first term
Alternate Representative	ISCT	Dominique	Farge	July 1, 2024	End of first term
Primary Representative	JACIE	John	Snowden	July 1, 2025	End of second term
Alternate Representative	JACIE	Nina	Worel	July 1, 2024	End of first term
Primary Representative	LABMT	Gregorio	Jaimovich	July 1, 2025	End of second term
Alternate Representative	LABMT	Carmem	Bonfim	July 1, 2024	End of first term
Primary Representative	WMDA	Jeff	Szer	July 1, 2025	End of second term
Alternate Representative	WMDA	Lydia	Foeken	July 1, 2025	End of second term

At the end of 2022, WBMT had 21 Member Societies. Each Member Society reviewed and confirmed the individuals serving as their representatives on the Board on an annual basis. The Board meets annually in person, alternating between the February Transplantation and Cellular Therapy Meetings in the US and the March - April European Society of Blood and Marrow Transplantation Meeting in Europe. The Board generally holds additional teleconferences, (Appendix E), to remain informed and to handle issues arising between the in-person sessions. Email communication is utilized as necessary between these meetings. Meeting minutes are posted on a password-protected section of the WBMT collaboration website and are available on request. Due to the COVID-19 pandemic no in-person WBMT Board meetings were possible in 2022. All meetings were video conferences. Therefore, the Bylaws of WBMT have been adjusted to accommodate video conferences.

2.2 Executive Committee

The Executive Committee informs the WBMT Board while managing business matters between Board meetings. Membership includes the elected President, Vice President, Treasurer, Secretary, Past President and WBMT Representative to the WHO. The final role, WBMT Representative to the WHO, was added to the Executive Committee in 2016 and is filled by the Past President. As noted above, appointed Co-Chairs of the now eight Standing Committees (Sections 2.3 and 3.0) serve on the Executive Committee conducts monthly hour-long teleconferences, and minutes of these meetings are also posted on a password-protected section of the WBMT collaboration website.

WBMT

WBMT Progress Report 2022

Following existing Nomination and Election House Rules (which were reviewed and revised through 2016-2022), and with input from Board members, an ad hoc Nominating Committee, including one representative from each WHO region, convenes as necessary. In 2021, the Nominating Committee was activated to fill the President and Treasurer position. Vice President Mahmoud Aljurf was elected President in December 2021. He took office on April 1st 2022, and his term will expire on April 1st 2024. Annalisa Ruggeri was elected Treasurer; this term will expire on April 1st 2024. In January 2022, a new ballot was sent out to avoid vacancies in the positions of elected officers. In February 2022 Mickey Koh was elected Vice President and Sebastian Galeano Secretary. The elected officers took office on April 1st 2022, and their terms will expire on April 1st 2024.

WBMT ELECTED OFFICERS - SERVE ON EXECUTIVE COMMITTEE AND BOARD 2022											
President	Mahmoud	Aljurf	April 1, 2024	End of term							
Past President and WHO representative	Hildegard	Greinix	April 1, 2025	End of term							
Vice President	Mickey	Koh	April 1, 2024	End of first term							
Secretary	Sebastian	Galeano	April 1, 2024	End of first term							
Treasurer	Annalisa	Ruggeri	April 1, 2024	End of first term							

Appendix B displays photos and contact information for all current, elected officers of WBMT.

2.3 Standing Committees

Eight Standing Committees (**Section 3.0**) focus on areas of prime importance to the mission of the WBMT, as identified by the Executive Committee. Most of these committees were created in 2008, however, in 2022 the WBMT WHO Liaison Standing Committee was established. Committee leadership positions were reviewed annually at the beginning of the respective year. The majority of WBMT project work is accomplished by these Standing Committees:

- Accreditation [the international Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA) serves in this capacity] (Section 3.1)
- Donor Issues (Section 3.2)
- Education and Dissemination (Section 3.3)
- Graft Processing and Cellular Therapy (Section 3.4)
- Global Emergencies / Nuclear Accident Management (Section 3.5)
- Patient Advocacy / Advisory (Section 3.6)
- Transplant Center / Recipient Issues (Section 3.7)
- WHO Liaison (Section 3.8)

Two or rarely three Co-Chairs lead each committee. These Co-Chairs also participate in the ongoing work and decisions of the Executive Committee as noted above. Syed Osman Ahmed was newly appointed by the WBMT Board in April 2021 to become Co-Chair of the Graft Processing and Cellular Therapy



Committee. His first term started on July 1st 2022, and should have officially ended on July 1st 2024. However, due to a busy work schedule Syed Osman Syed decided to step down on 31st December 2022. His role will be taken over by Ibrahim Yakoud-Agha from 1st January 2023 onwards.

By July 2022, some of the terms of operational Co-Chairs expired or Co-Chairs decided stepped down;

- Donor Issues Committee: Chloe Anthias (stepped down)
- Education and Dissemination Committee: Sebastian Galeano (became WBMT's Secretary)
- Graft Processing and Cellular Therapy Committee: Paul Eldridge (term expired)
- Patient Advocacy / Advisory Committee: Menachem Bitan (term expired)
- Global Emergencies / Nuclear Accident Management Committee: David Ma (term expired)

Consequently, approval was granted by the WBMT Board for appointment of new Co-Chairs, whose names can be found in the below table.

In 2016, the Board revised the WBMT Bylaws related to the Standing Committee Co-Chairs. There is now greater emphasis on committee leader expectations and reporting committee activities. Any interested individual belonging to any (one or more) of the Member Societies is eligible to join these committees; membership is solicited and refreshed periodically.

Because all WBMT committees are project driven, they meet with varying frequency, usually by teleconference due to international participation. WBMT committees also take advantage of relevant, international HCT meetings for in-person dialog as they are attended by many of their members; these international meetings are conducted in both the US (February) and the EU (March - April) annually.



STANDING COMMITTEE CHAIRS - SERVE ON EXECUTIVE COMMITTEE AND BOARD										
Accreditation (AHCTA)	Joseph (Yossi)	Schwartz	July 1, 2023	End of second term						
Donor Issues Committee	Nina	Worel	July 1, 2024	End of second term						
Donor Issues Committee	Thilo	Mengling	July 1, 2025	End of first term						
Donor Issues Committee	Jörg	Halter	July 1, 2025	End of first term						
Education and Dissemination Committee	Yoshihisa	Kodera	July 1, 2023	End of second term						
Education and Dissemination Committee	Adriana	Seber	July 1, 2025	End of first term						
Education and Dissemination Committee	Damiano	Rondelli	July 1, 2025	End of first term						
Graft Processing and Cellular Therapy Committee	Syed	Osman Ahmed	December 31, 2022	End of term						
Graft Processing and Cellular Therapy Committee	Christian	Chabannon	July 1, 2025	End of first term						
Patient Advocacy / Advisory Committee	Cristóbal	Frutos	July 1, 2023	End of first term						
Patient Advocacy / Advisory Committee	Carmem	Bonfim	July 1, 2025	End of first term						
Transplant Center / Recipient Issues Committee	Yoshiko	Atsuta	July 1, 2023	End of second term						
Transplant Center / Recipient Issues Committee	Dietger	Niederwieser	July 1, 2023	End of second term						
Transplant Center / Recipient Issues Committee	Laurent	Garderet	July 1, 2025	End of first term						
Global Emergencies / Nuclear Accident Management Committee	Ray	Powles	July 1, 2024	End of second term						
Global Emergencies / Nuclear Accident Management Committee	Shahrukh	Hashmi	July 1, 2023	End of first term						
Global Emergencies / Nuclear Accident Management Committee	Nada	Hamad	July 1, 2025	End of first term						
WHO Liaison Committee	Hildegard	Greinix	July 1, 2025	End of term						



3.0 STANDING COMMITTEE ANNUAL REPORTS AND ACCOMPLISHMENTS IN 2022

3.1 Accreditation Committee formerly known as AHCTA

Committee Mission

The mission of the Accreditation Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to regulatory matters, practices, and codes with both national and international implications. This involves procedures related to all activities of the other Standing Committees. In its vigilance to avoid duplication of efforts, WBMT members agreed in 2009 that AHCTA would fulfil the role of the WBMT Accreditation Committee.

Leadership

The Chair of this committee is:

• Joseph Schwartz (Member Society, ASFA)

Meetings / Teleconferences

The Accreditation Committee meets by videoconference at least quarterly and in person once or twice per year, as international conference attendance permits. In 2022, this committee had two committee calls and no in person meetings due to the pandemic.

Completed Projects

• Webinar: "FACT-JACIE & WBMT: Quality and Accreditation for Cellular Therapy: A Global Perspective": click on the <u>link</u> for further details

Future Plans

In 2023 the Accreditation Committee plans:

- A new Co-Chair has been identified; from 1st January 2023 onwards, Dr. Amal Alseraihy Alharbi will take on this role;
- Education effort regarding different cell therapy accreditation pathways existing world wide to include FACT, JACIE, AABB, Cord Blood Banks;
- Education effort in areas which seem to be an obstacle to achieve accreditation e.g. quality programs and different quality programs in different areas of the world;
 - Webinar in conjunction with the Education and Dissemination Committee is in planning stages.

Publications

Alseraihy A, McGrath E, Niederwieser D, Chabannon C, Szer J, Mohty M, Kharfan-Dabaja MA, Orchard K, **Schwartz J**, Rasheed W, Koh M, Kröger N, Kodera Y, Fakih RE, Worel N, Manson L, Rintala T, Tabakhi A, Savani B, Gergis U, Sureda A, Eldridge PW, Yakoub-Agha I, Hamadani M, Weisdorf D, Greinix H, Aljurf M. WBMT Special Article on Key Elements in Quality and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy. Transplant Cell Ther. 2022;28 (8) :455-462. PMID: 35413459.



3.2 Donor Issues Committee

Committee Mission

The mission of the Donor Issues Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the identification of stem cell donors (bone marrow, peripheral blood, unstimulated leukocytes, and cord blood), harvesting procedures, product transportation, donor safety practices, and outcomes / long term follow-up within a member collection center; this includes the conduct of individuals and processes related to these procedures and practices.

Leadership

The Co-Chairs of this committee are:

- Nina Worel (Member Society, EBMT)
- Thilo Mengling (Member Society, WMDA)
- Jörg Halter (Member Society, EBMT)

Meetings / Teleconferences

The Donor Issues Committee did not meet in person in 2022 due to the pandemic. One videoconference took place for this committee.

Completed Projects

During 2022, the Donor Issues Committee completed the following projects:

Publications

- Worel N, Aljurf M, Anthias C, Buser AS, Cody M, Fechter M, Galeano S, Greinix HT, Kisch AM, Koh MBC, Mengling T, Nicoloso G, Niederwieser D, Pulsipher MA, Seber A, Shaw BE, Stefanski HE, Switzer GE, Szer J, van Walraven SM, Yang H, Halter JP. Suitability of haematopoietic cell donors: updated consensus recommendations from the WBMT standing committee on donor issues. Lancet Haematol. 2022 Aug;9(8):e605-e614. doi: 10.1016/S2352-3026(22)00184-3. PMID: 35901845
- Koh MBC, Halter JP, Greinix HT, Aljurf M, Worel N. Prioritising health equity alongside donation safety - Authors' reply. Lancet Haematol. 2022 Nov;9(11):e803-e804. doi: 10.1016/S2352-3026(22)00302-7. Epub 2022 Sep 22. PMID: 36156201

Ongoing Projects

Brainstorming with committee members to define specific needs for teams in emerging countries.

Future Plans

The Donor Issues Committee identified the following projects for initiation during 2023:

- designing educational material (booklet) for staff members / operators working in the field of medical clearance of stem cell donors and apheresis procedures.
- Preparation for publication of a book about all aspects of stem cell donors.



3.3 Education and Dissemination Committee

Committee Mission

The mission of the Education and Dissemination Committee is to recommend to the Executive Committee policies, programs, actions and materials pertaining to the development or design of resources prepared for the express purpose of educating the populace about HCT. This committee collaborates with all partners within the WBMT and assists in preparation of opinion or advisory materials for the WBMT and/or WHO. It plays an important role in Workshop program design.

Leadership

The Co-Chairs of this committee are:

- Yoshihisa Kodera (Member Society APBMT)
- Damiano Rondelli (Member Society ASTCT)
- Adriana Seber (Member Society LABMT)

Meetings / Teleconferences

The Education and Dissemination Committee continues to participate actively in various projects including workshops, webinars and printed materials related to HCT.

Completed Projects

1) The slides, flyers and recordings of the webinars are available at the WBMT webpage: https://www.wbmt.org/past-events/

In 2022, the Education and Dissemination Committee has developed the educational webinar 'Management of Viral Infections in Hematopoietic Stem-Cell Transplant in collaboration with the Indian Society for Blood and Marrow Transplantation (ISBMT)' organized to summarize practical aspects for the management of viral diseases in HCT recipients.

Moderators: Alok Srivastava - Christian Medical College, Vellore, India and Sebastian Galeano -Hospital Británico, Montevideo, Uruguay

Program and Speakers:

- o BK virus and Epstein-Barr virus Simone Cesaro Ospedale Donna Bambino, Verona, Italy
- o Reemergent viral diseases: measles, yellow fever, dengue, zika, chikungunya Clarisse Machado - Institute of Tropical Medicine, Universidade de Sao Paulo, Sao Paulo, Brazil
- o Cytomegalovirus and varicella-zoster virus Genovefa Papanicolaou Memorial Sloan Kettering Cancer Center, New York, USA



The talk is available in YouTube: https://youtu.be/sYxogusvOSE

2) The 8th WBMT Workshop in Rawalpindi, Pakistan was successfully held on September 22-14, 2022, as a hybrid event. The platform was accessible at <u>https://wbmt2022pakistan.com/</u> Find all details in **Section 4.2.2.8**.



Future Plans

The Education and Dissemination Committee identified the following projects for 2023:

- Organization of regular educational webinars;
- Organization of training activities for nurses in HCT;
- Continue to organize Workshop/Scientific Symposia annually or as appropriate. Call for the next WBMT Workshop planned for September 2024;
- Discuss financial support for future WBMT Workshops;
- Develop online training programs directed to low-middle income countries in cooperation with regional transplant organizations;
- Develop online nursing training programs in cooperation with the Nurses Committees of the regional/international transplant organizations;
- Establish contacts and identify obstacles for setting up new transplant centers in emerging and underdeveloped countries;
- Assess long-term outcomes of previous Workshops for organizers and participants.

Publications

 Niederwieser D, Baldomero H, Bazuaye N, Bupp C, Chaudhri N, Corbacioglu S, Elhaddad A, Frutos C, Galeano S, Hamad N, Hamidieh AA, Hashmi S, Ho A, Horowitz MM, Iida M, Jaimovich G, Karduss A, Kodera Y, Kröger N, Péffault de Latour R, Lee JW, Martínez-Rolón J, Pasquini MC, Passweg J, Paulson K, Seber A, Snowden JA, Srivastava A, Szer J, Weisdorf D, Worel N, Koh MBC, Aljurf M, Greinix H, Atsuta Y, Saber W. One and a half million hematopoietic stem cell transplants: continuous and differential improvement in worldwide access with the use of non-identical family donors. Haematologica. 2022



May 1;107(5):1045-1053. doi:10.3324/haematol.2021.279189. PMID: 34382386; PMCID: PMC9052915.

- Worel N, Aljurf M, Anthias C, Buser AS, Cody M, Fechter M, Galeano S, Greinix HT, Kisch AM, Koh MBC, Mengling T, Nicoloso G, Niederwieser D, Pulsipher MA, Seber A, Shaw BE, Stefanski HE, Switzer GE, Szer J, van Walraven SM, Yang H, Halter JP. Suitability of haematopoietic cell donors: updated consensus recommendations from the WBMT standing committee on donor issues. Lancet Haematol. 2022 Aug;9(8):e605-e614. doi: 10.1016/S2352-3026(22)00184-3. PMID:35901845.
- Correa C, Gonzalez-Ramella O, Baldomero H, Basquiera AL, Baena R, Arcuri L, Puga B, Rosales C, Chávez M, Hernández C, Maldonado B, Gómez-De León A, Mendoza N, Frutos C, Aranda L, Díaz L, Hernández M, Seber A, Karduss A, Jaimovich G, Martínez-Rolon J, Bonfim C, Greinix H, Koh MBC, Aljurf M, Iida M, Saber W, Niederwieser D, Atsuta Y, Galeano S; Latin American Bone Marrow Transplantation Group (LABMT); Worldwide Network for Blood and Marrow Transplantation (WBMT). Increasing access to hematopoietic cell transplantation in Latin America: results of the 2018 LABMT activity survey and trends since 2012. Bone Marrow Transplant. 2022 Jun;57(6):881-888. doi: 10.1038/s41409-022-01630-9. Epub 2022 Mar 28. PMID: 35347244.
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3.4 Graft Processing and Cellular Therapy Committee

Committee Mission

The mission of the Graft Processing and Cellular Therapies Committee is to recommend policies, programs, and actions pertaining to the handling of a harvested product, including: storage, preparation and manipulation, equipment, product transportation, and documentation within a cell processing center. This includes the conduct of individuals and processes related to these practices. The committee also focuses on cellular therapy, which is increasingly important in haemato-oncology, transplantation, and regenerative medicine, in relation to cellular product source, processing, and in the coming years, in relation to advanced therapeutic medicinal products.

Leadership

The Co-Chairs of this committee are:

- Christian Chabannon
- Ibrahim Yakoub-Agha (Member Society, EMBMT)

Meetings / Teleconferences

During 2022, the Graft Processing and Cellular Therapy Committee did not meet in person. The committee had 3 videoconferences in 2022, mainly discussing tasks related to the ongoing project on the use of non-cryopreserved autologous HCT products.

Ongoing Projects

This committee continues to work on the following projects:

- Partner with the International Society of Cellular Therapy (ISCT) on the *ISCT Presidential Task* Force on the Use of Unproven Cellular Therapies.
- Survey of laboratory practices related to the use of non-cryopreserved autologous HCT products.



• The committee also helped with the planning of the 2022 WBMT workshop and symposium in Pakistan.

Future Plans

The Graft Processing and Cellular Therapy Committee identified the following projects for action in 2023:

- Create a list and map of cell processing laboratory facilities worldwide.
- Collaborate with the EBMT Cellular Therapies Working Party and other organizations on a parallel project of clinical outcome of non-cryopreserved autologous HCT transplants.
- Coordinate with FACT and the Joint Accreditation Committee of ISCT and EBMT (JACIE) and AHCTA Committee to introduce stepwise accreditation for laboratories (and transplant programs) in emerging regions under a joint International Accreditation Program.

3.5 Global Emergencies / Nuclear Accident Management Committee

The creation of this committee was first suggested in 2014 under the name Nuclear Accident Management Committee. Initial meetings and sessions took place in 2015. In the fourth quarter of 2015, the committee leaders gave presentations during the WBMT session at the APBMT annual scientific meeting. Highlights of this session focused on the number and types of radiologic response exercises being conducted worldwide; all emphasized the need to engage and educate the HCT community of their potential involvement in a nuclear disaster and to continue these practice exercises. In 2020 the mission and name of the committee were reviewed and updated, resulting in the current name which has continued until now.

Committee Mission

The mission of the Global Emergencies / Nuclear Accident Management Committee is to promote worldwide awareness of public health emergencies, (including pandemics), radiation or other disasters that may impact global HCT practice or there could be a role of HCT and cell therapy in the management of these emergencies. Committee objectives include the following:

1. Increase preparedness in WBMT members, teams, organizations, and member countries to provide assistance in the event of a massive radiation incident, pandemic, or a public health emergency.

2. Develop international consensus guidelines for triage and treatment of casualties that require hematopoietic support.

3. Establish coalitions within member countries to share information following radiation or other types of incidents or relevant global emergencies.

Leadership

The Co-Chairs of this committee are:

- Ray Powles (Member Society, EBMT)
- Shahrukh Hashmi (Member Society, ASTCT)
- Nada Hamad (Member Society, ANZTCT)



Meetings / Teleconferences

In 2022, the Global Emergencies / Nuclear Accident Management Committee had 3 video conferences related to the COVID-19 pandemic and the Ukraine disaster.

Ongoing Projects

During 2022:

- Continue partnerships with EBMT, ASTCT, APBMT, AABB, disaster task force, and other appropriate organizations.
- WBMT's preparedness in Ukraine crises with respect to HCT was published by this committee.

Future Plans

- The Global Emergencies / Nuclear Accident Management Committee plans to review the model for how this committee operates.
- Gain recognition as a formal/affiliated member of the WHO's global emergencies team. A WHO-WBMT meeting is scheduled for this.
- Write a consensus paper on the role of WBMT in public health aspects will be proposed at GENA's annual meeting during the April EBMT's annual meeting in 2023, Paris, France.

3.6 Patient Advocacy / Advisory Committee

The first in-person session of this committee was held in December 2015. The committee addressed activities regarding: "How do we define patient advocacy? Is it personal advocacy navigating one patient through the HCT process or is it the broader concept of social and governmental advocacy towards larger numbers of patients – or both".

Committee Mission

The mission of the Patient Advocacy / Advisory Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the establishment and / or support of international patient advocacy groups and activities. This includes projects in collaboration with international disease or treatment specific organizations that are related to HCT (pre-and post-transplantation issues) particularly those with emphasis on patient, donor, family, and / or caregiver related topics. There will be mentorship and harmonization in the development and distribution of patient / public educational materials.

Leadership

The Co-Chairs of this committee are:

- Cristóbal Frutos (Member Society, LABMT)
- Carmem Bonfim (Member Society, LABMT)

Meetings / Teleconferences

During 2022, this committee had 3 video conferences.

Completed Projects

During 2022, the Patient Advocacy / Advisory Committee completed the following projects:

- Participate in the cGVHD NIH group;
- Present at the ASTCT/WBMT Session at the Tandem Meetings;
- Present at the WBMT Workshop in Pakistan.

Ongoing Projects

This committee continues to work on the following projects:

- Participate in GVHD Day (organized by GVHD Alliance);
- Continue to expand the committee's global network of patient's groups and seek relevant partnerships;
- Organize Patient Days at national or international HCT conferences;
- Work on an application for patients on their mobile device.

Future Plans

The Patient Advocacy / Advisory Committee identified the following projects for the future:

- Participate in patient activities during the ASTCT (formerly Tandem) Meeting and EBMT Annual Meeting, such as the Patient's Day at the EBMT Annual Meeting with an effort to make the sessions more educational and broadly informative.
- Participate in future WBMT sponsored workshops with advocacy position papers created as appropriate.
- Take part in the international group on Chronic GVHD that has been established and will also cover aspects on patients' point of views and accessibility to immunosuppressants.
- Develop a PAAC site within the WBMT website. It will include information regarding diseases and steps of transplantation. We already received information from BMT Infonet.
- Engage more patients in video meetings.
- Organize paper on "How to" build a patient advocacy organization.
- Survey on who funds transplantation in different countries.

3.7 Transplant Center / Recipient Issues Committee

Committee Mission

The mission of the Transplant Center / Recipient Issues Committee is to recommend to the Executive Committee policies, programs, or actions pertaining to the performance of hematologic transplantation and other cellular therapies / procedures within a member transplant center; this includes recording recipient outcomes, maintenance of records, and the conduct of individuals and processes carrying out these procedures and practices. As of 2006, this committee also administers biennial activities related to

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the global transplant activity (GTA) reports and GTA data use proposal reviews / deliberations (**Section 4.1**).

Leadership

The Co-Chairs of this Standing Committee are:

- Yoshiko Atsuta (Japanese Data Center for HCT, and Member Society, APBMT)
- Dietger Niederwieser (Member Society, ELN)
- Laurent Garderet

Meetings / Teleconferences

During 2022, this Standing Committee maintained regular video conferences every 2 months throughout the year, particularly related to the GTA, utilization and activity of autologous HCT in myeloma worldwide and in acute leukemias. Several videoconferences were held in addition for the WBMT project Autologous Stem Cell Transplantation in MM (WAUSTIM) project and for consultation and preparation of the new program for the Global activity survey with Daniel Neumann, Ronald Brand and Helen Baldomero. An algorithm for authorship on survey publications has been developed with our member societies.

Several requests on brand mark registration of the WBMT of the WIPO (Japan, Switzerland, Australia) were answered and obtained.

Completed Projects

During 2022, this Standing Committee completed the following projects:

• Revision of the WBMT Research Guidelines, the guiding principles of collection, presentation, dissemination and sharing of the Global Activity Survey data. In the Global Transplant Activity Guiding Principle #3, a paragraph was added to provide the WBMT policies of the authorship for publications by using the GTA. To respond to growing interest to GTA data use, WBMT Operation Manual for GTA Use was formulated as an appendix (*Appendix E*) along with the Letter of Commitment (*Appendix F*). The revisions of the WBMT Research Guidelines were approved by the Board in September 2021.

Ongoing Projects

This Standing Committee continues to work on the following projects:

- Continue to lead the Research Data Activities Task Force, including overseeing review of incoming proposals for use of GTA data.
- Letter of intent for funding the project by the Leukemia Society has been submitted. Agreement between the societies has been presented to the EC and protocol finalized.
- Reviewed and approved a study request for use of GTA data to describe the global state of HCT for multiple myeloma including outcome (WAUSTIM project).
- Transplants of acute myeloid leukemia worldwide and utilization of autologous and allogeneic HCT in this indication.
- Review paper on rare infections among the recipients of HCT.



- Encourage use and further analyses of GTA data more broadly.
- Intervention for drug shortage in Latin America by Pierre Fabre together with WHO.
- Development of an internet based database (GTR) for transplant centers to submit their transplantation data.
- Analysis on HSCT in CML worldwide possibly with outcome.
- Registrations of cellular therapies outside stem cell transplantation.
- Write manuscripts on the Waustim project.

Future Plans

This Standing Committee has identified the following projects for the future:

- Implementation of an internet based database (GTR) for TC's to submit their transplantation data.
- Develop an annual report from the GTA in the form of a slide set to be available to all member societies on the WBMT website.
- Earlier publication of the GTA data with the use of the new database.

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3.8 WHO Liaison Standing Committee

Committee Mission

The mission of the WHO Liaison Committee is to recommend to the Executive Committee policies, programs, and actions pertaining to the continuation of collaborative projects with the WHO in pursuit of WBMT's educational, scientific and philanthropic mission. This includes projects to promote global access to hematopoietic cell donation and transplantation as well as administration of other cellular therapies, technical and scientific input on safety and quality of HCT and cellular therapies and consultation services with emphasis on HCT and cellular therapies.

Leadership

The Co-Chairs of this Standing Committee are:

- Hildegard Greinix (Immediate Past President and WHO representative WBMT)
- Daniel Weisdorf (Past President WBMT)

Meetings / Teleconferences

The group meets annually in person and by telephone conferences throughout the year every 2 months.

Completed Projects

Annual Report to WHO about WHO WBMT collaborative projects.

Ongoing Projects

- Report on the WBMT Pakistan Workshop together with the Education & Dissemination Committee and local organizers.
- Support for Ukrainian HCT teams.
- Worldwide survey on current use of cell and gene therapies and future needs, including mapping of how practices are regulated together with the Graft Processing and Cellular Therapy Committee.

Future Plans

- Safety standards, quality management systems and accreditation processes currently available for the development of gene and cell therapies together with Accreditation Committee (AHCTA);
- Minimum requirements for establishing an advanced cellular therapy and gene therapy facility together with Education & Dissemination Committee, Accreditation Committee (AHCTA) and Graft Processing and Cellular Therapy Committee;
- Work with the WHO on Global Action Framework in Stem Cell Donation and Transplantation.

4.0 WBMT ACTIVITIES AND ACCOMPLISHMENTS IN 2022

The WBMT engages in a variety of activities including:

- An annual global survey of HCT activity (Section 4.1);
- Establishing an internet-based program for data collection on a global level
- Conducting scientific and educational conferences (Section 4.2);
- Developing consensus guidelines for optimum delivery of HCT services and accreditation of HCT facilities (Section 4.3);
- Collaborating and consulting with the WHO to promote excellence in HCT, stem cell donation, and cellular therapy (Section 4.4);
- Supporting other global HCT activities (Section 4.5);
- Maintaining a Website for broad communication (Section 4.6);
- Establishing research guidelines within this global HCT community, particularly as related to use of the Global transplant activity data (Section 4.7).

4.1 Annual Global Survey

WBMT leaders agreed in early formative years that a first initiative should be to conduct annual global surveys of HCT activity performed by transplant centers (**Appendices C1 and C2**); a minimal yet essential level of activity information is requested of participating centers. The annual survey displays volume of, and main indications for, allogeneic (related, unrelated, and graft source information) and autologous HCT activity. Disease indications for HCT include main- and sub-class categories.

The WBMT survey reporting sheet is available on the WBMT website; it is accompanied by the disease indications classification codes to assist in completing the survey. This will continue during transition from the hard copy manual entry to the internet based reporting system. In countries lacking internet connection, the data will still be reported by hard copy/fax to the regional office and entered there directly.

The WBMT continues to promote the annual survey by publishing findings biannually in scientific journals and presenting results at least once annually at international meetings (**Appendix F**). The WBMT encourages other, growing and developing groups (e.g., LABMT and AfBMT) to form their own registries to participate in the survey, and a WBMT representative presents at each Workshop and Symposium (**Section 4.2.2**), describing the activity data, including the collection process, and encouraging all teams to report their activity data.

Data for the Global Transplant Activity (GTA) survey are currently being collected from our member societies APBMT, EBMT and CIBMTR for their regions and, for all other regions of the world from each center on hard copies. The activity of these centers is reported directly to the WBMT office and the information entered there by hand. Worldwide we have around 1700 transplant centers reporting now more than 90.000 HCT/year. Global activity data are then returned to the regional societies to allow analysis on developments of regional or national registries. These data do not represent an outcome registry, but the GTA survey is a mechanism by which each country's annual

data can be registered with the WBMT and can also be used by the reporting organization. In addition, GTA survey is allowing comparisons between countries and detect gaps between developed or raising countries. The procedure is time consuming and the data are available with a considerable time delay (in 2022 data were published until 2016).

Furthermore, the EBMT, that reported the data for whole Europe using the Promise system, will stop using this program and has been working on alternatives. In order to maintain and improve reporting, WBMT decided to develop an internet-based reporting system using the actual sheet. This is not trivial considering the different levels of the GTA survey, security and the need of highest data quality and safety. Information can be entered at transplant center, country and region level (at the moment a considerable proportion is entered at a global level) and should avoid duplicates, inappropriate use and is restricted to a limited number of persons of each center (data manager and Head of Department). The connection with the server has to be encrypted. Using this security tools, we are now planning to go online in 2022 with the GTR starting in Latin America. Every transplant center will enter its activities and have an overview of its own data only. Selected persons have access to country level data and the central WBMT office to the regional data. All the calculations will be performed by the program including additions, percentages and correlations. This will allow to have yearly real time data at the latest in March of the following year. A manual is in development to explain data entering. These activity data can be used at the team level for those countries / societies that do not have an existing data collection system (e.g. LABMT, AfBMT). If a new regional or national registry were to be developed, it could potentially use the GTA data to identify the activity in those countries that are outside other data collection systems, providing a mechanism for followup reporting.

In the near future reports of second HCT and cellular therapy worldwide is planned. The GTA survey will be essential for obtaining actual data for the WHO, for publications and for understanding the development and trends in the field.

The WBMT has guidelines for research using these data, which have been renewed during 2021 (**Appendix D1**). Member Societies can request use of these data for research purposes with signed Data Transmission Agreements (**Appendix D2**). Proposals for the use of these data are reviewed and approved by the Transplant Center / Recipient Issues Committee (**Section 3.7**).

During a previous annual meeting of the American Society of Hematology Vanderson Rocha gave an exciting oral presentation on the topic of increasing access to allogeneic HCT on an international level. He showed data from WBMT's global transplant survey focusing on donor sources, different world regions and main indications. He discussed factors associated with access to allogeneic HCT including donor type and stem cell source availability, patient demographics, economical and social issues, provider and health care system impact. Finally, V. Rocha discussed strategies for expanding allogeneic HCT activity in resource-constrained areas, such as use of telehealth systems, wearable devices, use of artificial intelligence, and collaboration among international organizations.

4.2 Scientific and Educational Conferences

4.2.1 Joint Scientific / International Symposia

Scientific conferences are an important activity of the WBMT for communicating with other clinicians and researchers. WBMT conducts an annual 90-minute Scientific / International Symposium at one or two major HCT conferences. The Symposium is most often presented during the US-based Transplantation

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and Cellular Therapy Meetings [sponsored by the CIBMTR and the American Society for Transplantation and Cellular Therapy (ASTCT)] each February. Additionally, the WBMT presents a similar or modified program at the annual EBMT meeting in March – April. The focus during the WBMT presentations is on topics of global interest. **Appendix F** lists annual Symposia programs since WBMT began coordinating them in 2009.

Due to the COVID-19 pandemic all international scientific meetings had to be virtual ones. In February 2021 WBMT organized a scientific symposium during the TCT meeting focusing on challenges of HCT during a worldwide crisis. Speakers from Latin America, China and the Eastern Mediterranean area shared their experience with a worldwide audience and presented solutions for safe conduct of stem cell donation and transplantation.

In March 2021 WBMT participated in a joined session at the EBMT annual meeting discussing COVID-19 vaccination in HCT. Speakers from Germany, Sweden and the US presented informative and exciting data on development of COVID-19 vaccines, its use in HCT recipients and global access to COVID-19 vaccines, respectively.

In October 2021 Hildegard Greinix presented at the virtual annual meeting of the APBMT on behalf of WBMT. She described the aims of WBMT, their member societies, main scientific and educational activities and the future development of WBMT.

4.2.2 WBMT Workshops and Scientific Symposia

The WBMT sponsors Workshops and Scientific Symposia in various world regions; often those with constrained resources to encourage expansion of existing transplant programs or establishing new programs. The WBMT leverages the skills and expertise of its member Societies along with the Education and Dissemination Committee and all other Standing Committees in planning these programs. Since 2011, the WBMT conducted eight Workshops and Symposia: in Hanoi, Vietnam, in 2011 (Section 4.2.2.1); Salvador, Brazil, in 2013 (Section 4.2.2.2); Cape Town, South Africa, in 2014 (Section 4.2.2.3), Riyadh, Saudi Arabia, in 2017 (Section 4.2.2.4); Casablanca, Morocco, in 2018 (Section 4.2.2.5) Beijing, China, in 2018 (Section 4.2.2.6); Asuncion, Paraguay (Section 4.2.2.7) and Rawalpindi, Pakistan (Section 4.2.2.8).

4.2.2.1 2011 Hanoi, Vietnam

In late 2011, the WBMT conducted its first two-day Workshop and associated one-day Scientific Symposium in Hanoi, Vietnam, in cooperation with the WHO and in partnership with the APBMT and a local Vietnamese Organizing Committee.

The Hanoi Workshop concluded that WBMT should conduct training programs for physicians who lead transplant programs abroad. Since then, several teaching fellowships materialized during 2013 and increased in number through 2015. Trainees included practitioners from Vietnam (Hanoi and Ho-Chi-Minh City), Mongolia, Qatar, the Philippines, and Cambodia cross-training in Japan, Korea, Belgium, and Germany. This Workshop also enhanced networking across the globe. For instance, representatives from Myanmar, Indonesia, and Bangladesh established an HCT program under the guidance of WBMT 2011 Workshop participants.

4.2.2.2 2013 Salvador, Brazil

With a commitment by the WBMT Board to support the LABMT, a new WBMT Member Society in 2013, and strong interest from a local organizing committee, the WBMT hosted a two-day Workshop and one-day Scientific Symposium in late 2013 in Salvador da Bahia, Brazil. Participants indicated this was a



successful and valuable collaborative venture, but the most visible measurement of success has been the high level of regional organization and productivity since the Workshop.

The LABMT now holds regular monthly and annual meetings and continues to actively develop standing committees modelled after WBMT committees. Within two years of the Workshop, LABMT investigators published in peer-reviewed journals and presented oral abstracts at the prestigious American Society of Hematology (ASH) meetings.

4.2.2.3 2014 Cape Town, South Africa

The WBMT held its third Workshop and Scientific Symposium in November, 2014, in Cape Town, South Africa, in collaboration with the WHO, the African Society of Blood Transfusion and a local, South African planning committee. With the largest audience yet, attendees represented 34 countries, 20 of which were African. More than 200 individuals registered for the Workshop, and providing primarily positive responses and sound suggestions for improvements to future Workshop programs.

The WBMT customized the scientific program to address blood transfusion safety, a special problem on the continent, and included more open dialog time than in previous Workshops.

As was true for both previous Workshops, a broad spectrum of expert planners and presenters were from Europe, the Far East, Mediterranean region, and the US, augmenting a cadre of regional speakers.

Similar to the LABMT and the Workshop in Salvador, Brazil, the WBMT encouraged and strongly supported a more formal structure and activity level of the AFBMT. The WBMT received and approved a formal application for status as a WBMT Member Society in February 2015, and the AFBMT hosted a business meeting with newly elected officers in Istanbul in March 2015.

4.2.2.4 2017 Riyadh, Saudi Arabia

The fourth Workshop and Symposium, this one co-organized with the EMBMT, took place in Riyadh, Saudi Arabia, in January 2017. WBMT Officers and Standing Committee Co-Chairs participated along with the Riyadh-based Planning Organization. An extended program included longer, open discussion periods, as suggested on prior program evaluation forms. More than 1,000 individuals from 34 countries participated in the Workshop. Representatives from 12 different countries provided regional presentations. A summary of the presentations was published (**Appendix G**).

4.2.2.5 2018 Casablanca, Morocco

In April 2018, the WBMT and AFBMT hosted a Workshop in Casablanca, Morocco, in association with the Moroccan Society of Hematology. The scientific program focused on setting up and enhancing HCT programs in Africa, including adapted conditioning regimens and focusing on diseases affecting regional populations. JACIE offered a workshop regarding establishing an accreditation program in low-middle income countries. A summary of this meeting was published.

4.2.2.6 2018 Beijing, China

The 5th Annual WBMT / WHO Workshop and Scientific Symposium in collaboration with the Chinese Hematopoietic Stem Cell Transplantation Committee and the Chinese Medical Association was held at Beijing Kuntai Hotel, Beijing, China from September 19-21, 2018, focusing on the development of a HCT global outcome registry and advanced technology for HCT in emerging countries. The attendees were approximately 500 and most of the domestic attendees were relatively young physicians and other medical professionals. They concluded that it was a successful workshop and that they learned that different regions and differing

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times require different approaches to the challenges of HCT internationally. The scientific, social and organizational parts were outstanding. Following the pattern of the other meetings of the WBMT; we developed some new scientific aspects of importance.

Congratulations were offered for the extremely well-arranged 5th WBMT workshop. Most important was the very high-quality program and lectures and the large number of local and international speakers. This is in addition to the exceptional arrangements of logistics including venue, lecture room, audiovisuals, exhibit, registration, meals and many others. It was encouraging to note that the Central Administrative Office, WBMT and the Local Administrative Office communicated well each other. This was a model for the preparation of future workshop/scientific symposia sponsored with the WBMT.

4.2.2.7 2019 Asuncion, Paraguay

The 6th WBMT Workshop and Symposium was held September 2-4, 2019 in Asuncion, Paraguay. With the participation of 13 countries from Latin America sharing the current situation of HCT from the key players to an audience of 20 different countries as well as the Paraguayan Minister of Health, representatives from PAHO and WHO. Debate and discussion was vigorous. Everyone wanted to share what they were doing, express their weaknesses, ask how other countries had gotten through common barriers including access to medication and funding for HCT.

With over 300 colleagues, a list of essential medication was brought forth by the WBMT, discussed by all those present, and a commitment was secured by WHO representatives to make every effort possible to ensure easy access to these drugs.

The first day of the Workshop closed on a high note with the official launch of the Paraguayan Donor Registry and the presence of the Orchestra Band of Cateura, a local band composed of children from Asuncion that make their instruments out of the salvaged garbage -- a true testament of their resilience.

Day 2 began with meet the experts session followed by a Pediatrics HCT round table that finished with the commitment of all Heads of Services of Pediatric Centers to work together towards harmonizing treatments and sharing facilities. Common HCT debates included discussion of cryopreserved vs refrigerated grafts for autologous HCT; matched unrelated donor vs Haploidentical donor; and bone marrow vs cord blood with detailed presentations.

Patients emphasized the challenges of living after HCT. They formed a patient association and came to give their thanks to the WBMT for their assistance in the development of the HCT Program in Paraguay.

During the Gala Dinner that was held the second day of the meeting the President of the National Social Security Insurance assured those present he would expedite processes to have a HCT Center built with international standards by seeking the help of the WBMT.

Parallel to these events, the first JACIE-FACT Workshop was held on the 1st of September, a Nurses Satellite meeting took place coordinated by the Nurses Group of the LABMT and EBMT and the LABMT held an assembly where officers were elected, charges were distributed and work was outlined for the next two years. Follow-up to the success of the workshop led to expressions of thanks to the WBMT. It was stated that the meeting "truly shattered all our expectations".



4.2.2.8 2022 Rawalpindi, Pakistan

From September 22 to 24, 2022 the 8th WBMT Workshop, organized together with Armed Forces Bone Marrow Transplant Centre/National Institute of Blood and Marrow Transplant (AFBMTC/NIBMT) in collaboration with WHO, took place as a hybrid meeting in Rawalpindi, Pakistan. This workshop was attended by 2845 individuals from 52 countries including delegates from the Eastern Mediterranean region, North America, South America, Asia Pacific, Europe and Africa. The program consisted of sessions on minimum essential requirements for establishing or expanding a transplant program in emerging countries, transplant indications for starting programs, training and dissemination of knowledge, donor selection and donor safety, transfusion services for transplant centers, cell collection and processing, quality assurance in transplant centers, and patient/donor registration and outcome database. Short presentations were followed by moderated panel discussions with local and regional representatives discussing all important topics in detail.

In the inaugural session attended also by Lt. Gen. Nigar Johar, the Surgeon General/DGMS of the Pakistan Army and Minister of Health, Dr. Efstratios Chatzixiros presented the WHO global perspective of HCT followed by reports about regional transplant activities.

Dr. Qamar Un Nisa Chaudhry mentioned the fragmented and under-developed health care system, the under-developed diagnostic and transfusion services, the low number of transplant centers, the lack of trained human resource, the non-availability and costs of chemotherapeutic agents and monoclonal antibodies, the lack of national disease and transplant data and the lack of awareness and prevention programs for genetic diseases like beta thalassemia as challenges for HCT in Pakistan. In Pakistan, the first allogeneic HCT was performed by the Armed Forces Bone Marrow Transplant Centre on 19 July 2001. Meantime, the country has 12 transplant centers and a total number of 3,380 HCT including 2,704 allogeneic and 676 autologous HCT have been performed. The first cellular culture facility was established at the AFBMTC in 2015. This facility performed clinical trials on the use of mesenchymal stromal cells in spinal cord injuries, graft-versus-host disease, COVID-19 pneumonia and studies in autoimmune disorders and diabetic nephropathy are currently ongoing. The AFBMTC plans to establish an in-house CAR-T-cell program that has been approved. Currently, infrastructure including procurement of equipment and training of staff is ongoing. Future plans include in-house production of cytotoxic T-cells and gene therapy. Additionally, reports on transplant activities in Saudi Arabia, Oman, Iran, Qatar, United Arab Emirates, Nepal and Bangladesh were presented. A parallel Nursing Session took place on 23 September 2022.

4.2.2.9 Future Workshops and Symposia

In March 2024, an international conference on Global CAR-T and advanced cellular therapy will be held in Riyadh, Saudi Arabia. Additionally, WBMT recently started the organisation of the next Workshop, to take place in September 2024, of which details will be shared in due time.

4.3 Consensus and Guideline Initiatives

The primary purpose of the WBMT is to serve as a collective venue and voice – at a global level – for HCT and related issues. With the support of its Board, the WBMT publishes its findings on critical matters or burning issues on its website and collaborates with other scientific organizations. Previously, WBMT positions were published on standardized product labelling, and rejection of financial reimbursement for donation of cellular products in peer review journals as can be seen on the WBMT website.



More recently, current and previous Standing Committees authored substantial work, either independently or collaboratively, on standardization of practice topics (minimal requirements for a HCT program, training best practices and other topics) (Section 3.0 and Appendix G). In 2017 and 2018 the Transplant Center / Recipient Committee created a table of minimal requirements for establishing a new HCT program. All elements were rated, then reviewed by committee volunteers and later published. This fundamental information was used, in part, by a WBMT group who visited Ethiopia in December 2015 to assess their existing situation and to document what might be required for their five-year HCT plan. A final report was provided in the second quarter of 2016. Unfortunately, there is current considerable political instability in Ethiopia which has meant that the current project has been put on hold as the local team and government are unable to focus on this project currently. We will pick this up when the political situation improves.

In 2021 a statement on changes in HCT practices in response to COVID-19 based on an international survey was published under the leadership of the WBMT Donor Issues Standing Committee.

4.4 Collaboration with the WHO

As noted previously, a WHO representative has been involved with WBMT activities since the earliest development meetings. The WBMT maintained a working relationship with the WHO for almost four years before being officially invited to apply for *NGO in official relations* status with the WHO. The WHO approved the WBMT's initial application as of January 2013 and approved this continued status in January 2019. This status provides the WBMT with the opportunity to continue its work in partnership with the WHO in promoting global excellence in HCT, stem cell donation, and cellular therapy. This partnership brings with it additional responsibilities, including participation in other WHO initiatives, in pursuit of mutual educational, scientific, and philanthropic missions. Because of the importance of this collaboration, the WBMT created in 2016 an Executive Committee position, generally the Past President, specifically designated to represent the WBMT within the WHO.

In 2022 the WBMT Board approved a new standing committee, called the WHO Liaison Standing Committee chaired by the Past President to acknowledge the increasing activities important for fulfilling the collaboration plan with WHO.

4.4.1 Platform for WBMT Collaborative Projects

The NGO status of the WBMT is in relation to activities that form the foundation of WBMT's continued work consisting of:

- Technical input and relevant data that may inform WHO's work on raising awareness and addressing the burden of diseases/conditions that are amenable to HCT
 - Assess access to HCT over time on a global level (WBMT Global Activity Survey)
 - Assess access to HCT over time in different regions of the world (WBMT Global Activity Survey)
 - Organization and conduct of 8th WBMT workshop in Pakistan assessing regional HCT activities, HCT infrastructure and teams as well as challenges for HCT access
 - WBMT member activities to support HCT programs in different world regions
 - Impact of COVID-19 on global HCT activities



- Support of Ukraine during ongoing war
- Technical input that may inform WHO's work towards developing guidance materials for establishing hematopoietic stem cell transplantation programs at country-level
- Under WHO's guidance, support WHO's work towards the development of knowledge resources to build capacity in low and low-middle income countries selected by WHO and in agreement with national authorities for starting or strengthening HCT programs, in line with WHO's guiding principles (WBMT/WHO Workshop in Pakistan)
- Technical input that may inform WHO in assessing access to cell and gene therapies worldwide in line with current WHO frameworks and guidelines
- Technical input that may inform WHO's work in the development of resources and tools for strengthening the oversight capacity at global and national level, in line with WHO's principles
- Technical input that may inform WHO's work on development of quality and safety guidance for gene and cell therapies, in line with relevant WHO regulatory frameworks and guidelines

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4.5 Supporting Other HCT Global Activities

4.5.1 Ethiopia – A New HCT Center

The WBMT assists in establishing new HCT programs of high quality. In November 2014 representatives from Ethiopia (a Minister of Health office representative, individuals representing blood banks, hematologists, and others) met with WBMT leaders and requested support and technical assistance in establishing an HCT program in their country. These preliminary discussions led the WBMT to create a task force of interested parties to assess and assist in this venture. As at that time Co-Chair of the WBMT Graft Processing and Cellular Therapies Committee, Mickey Koh, was identified as the WBMT Project Leader and he maintained frequent communication with the Ethiopian team throughout 2015. Planning became more focused in the second half of 2015, and a comprehensive onsite visit by four WBMT HCT clinicians (some with substantial blood transfusion expertise) followed in December 2015. In the first part of 2016, the team prepared a full report, which was approved by the WBMT Executive Committee and distributed to the Ethiopian clinician team as well as the Dean of the adjacent medical school and the Minister of Health. Throughout the year, Mickey Koh conducted regular discussions via email with the Ethiopian team, and this project continued in 2018. Though challenges exist (recent political instability), the WBMT is impressed with the eagerness and engagement of local planners who are strongly supported by their current government.

Since then, Mickey Koh has continued with regular teleconference calls to assess the progress of this initiative all though 2016 and 2017. There were encouraging signs of continuing governmental support and concrete plans were being drawn up for building works. There was also planning done for training of Ethiopian staff in HCT. Unfortunately, the domestic and political situation changed in Ethiopia about 2018 and there has been little progress since. The political situation has worsened with fighting in the country and Covid-19 has put further strain on the country and its resources.

This project is currently on hold. Mickey Koh intends to touch base with the Ethiopian team sometime in 2022 if the Covid and political situation improves.

4.5.2 Ukraine

In November 2021 the ELN and WBMT were asked to help to develop allogeneic stem cell transplantation (HCT) in Ukraine. While allogeneic HCT was performed in children, no activity was reported for a

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population of 44 million inhabitants. Since WBMT has already a considerable experience in supervisory telemedicine in Paraguay and Lithuania, an inspection of two autologous programs on site took place in November 2021. With the beginning of the war in February 2022, HUP was founded as a network of worldwide leading scientific non-profit societies for Ukrainian patients with hematological diseases. Members of this unique network are the American Society of Hematology (ASH), the American Society for Transplantation and Cellular Therapy (ASTCT), the European Society for Blood and Marrow Transplantation (EBMT), the German Society of Hematology and Oncology (DGHO), the Lymphoma Coalition, the European Cancer Coalition, the European LeukemiaNet (ELN) and the WBMT, with its working relation with the World Health Organization (WHO). The HUP, in cooperation with the City of Leipzig, was extremely successful in delivering substantial amounts of drugs, diagnostic reagents and medical devices not available in the country. Intellectual support was provided by weekly (daily for the Kyiv BMT center) videoconferences and by establishing the first European Tumor Board for Ukrainian patients (EBMT). Recently, the most modern hematology diagnostics provided by the laboratory MLL in Munich, Germany became available free of charge for all patients admitted to Ukrainian Hospitals. The care and outcome of patients with hematological diseases in the Ukraine are now comparable with the majority of European countries representing an essential step forward in comparison to the pre-war situation, where patients were sent abroad (e.g. Turkey) at the expense of the Ukrainian government. In 2022, 223 Hematopoietic Stem Cell Transplantation (HSCT) procedures, the only curative approach for many hematological and non-hematological diseases, were performed in the Ukraine (Table attached). Most importantly and for the first time, 45 allogeneic HSCT from related and unrelated donors were performed in adult patients. The 2022 activities in HSCT/population, although being lower than the median activity in other European countries, represent today a sustainable and important step forward in difficult periods and beyond for a European country like Ukraine.

The majority of these autologous and allogeneic HSCT (n=58) and the specialized care of patients returning from the treatment abroad to Ukraine were performed at the Kyiv BMT Center. Using daily supervisory telemedicine, all modern type of HSCT including those from related identical, related non-identical and unrelated donors were performed in the center on a routine basis. This was possible only through the modern infrastructure of the center (lamina air flow rooms, laboratories, stem cell harvest facilities) and the experienced team of physicians and nurses based on more than 1000 HSCT from patient's own stem cells (autologous HSCT). More importantly, the Kyiv BMT center has excellent and expensive up-to date sterile rooms with HEPA filtration, which are essential to decrease or avoid life threatening infections during the period of aplasia (no defense against infection). The infection rates of the patients transplanted in the center are similar to the one in the bigger European and non-European centers and the overall treatment related mortality is below 5%. It is not surprising that the head of the unit was honored 2 weeks ago for life achievement from the ASTCT, and the oral presentation in Orlando, USA, was scored best abstract. The HUP continues his work by videoconferencing every week (more than 43 meetings were held up to now) and is open to all interested people.



	2021									2022								
	adults pediatric						adults				pedatric							
	Auto	MRD	M(M)UD	Haplo	Auto	MRD	M(M)UD	Haplo	Total	Auto	MRD	M(M)UD	Haplo	Auto	MRD	M(M)UD	Haplo	Total
Kylv BMT Center	80	2	0	0					82	41	6	6	5					58
Blood pathology and transfusion Lviv	15	0	0	0					15	21	0	D	0					21
National Cancer Institute	48	0	0	0					48	31	0	0	0	6				37
Children Hospital "Ohmatdyt"	0	0	0	0	11	12	14	16	53	0	2	9	6	2	4	12	1	36
Cherkasy regional Hospital	30	2	2	0					34	34	з	5	З					45
Kylv Regional Hospital	16	0	0	0					16	12	0	0	0					12
Feofania Hospital										11	0	0	0					11
Ukrainian Children's, Lviv										0				3				З
Children's Hospital, Dnipro	0	0	0	0				0	0					0	0	0	0	0
Total	189	4	2	0	11	12	14	16	248	150	11	20	14	11	4	12	1	223
Total	189		6		11		42		248	150		45		11		17		223

Table: Hematopoietic Stem Cell Transplantation in the Ukraine during 2021 and 2022

4.5.3 Regional HCT Societies

As previously mentioned, (**Section 4.2.2.2**) the WBMT has been instrumental in supporting the development of the now highly successful LABMT. The LABMT first met as an integrated group in 2013; now it has a Board and bylaws, and it holds regular monthly and annual meetings. The WBMT continues to support this organization, and the LABMT continues to actively develop, including creating standing committees modelled after WBMT committees.

Similarly, the WBMT was very supportive of establishing the AfBMT (**Section 4.2.2.3**). A small, interim Executive Committee existed early in the building process; elected officers are now in place. The WBMT approved the AfBMT's formal application for Member Society status in February 2015 and continues to place high focus and expectations on this organization; it represents the single remaining continent that has not uniformly reported transplant activity or outcome data. In April 2018, the WBMT and AfBMT hosted a Workshop in Casablanca, Morocco, in association with the Moroccan Society of Hematology (**Section 4.2.2.5**). The AfBMT under the current leadership of Dr. Alaa Elhaddad has regular meetings discussing important topics of HCT and stem cell donation.

Both of these groups are encouraged to commit to participation in the WBMT annual global survey of HCT activity (**Section 4.1**). After the Workshop in Latin America, several new transplant centers started providing activity data to this survey. This is an important step forward in addressing the current gap in acquisition of data from these regions.

4.6 Website

The first WBMT website was launched in 2010. Identifying itself via the internet was an important first step in the evolution of WBMT branding. In 2020 a new version of the website was launched: <u>wbmt.org.</u> Substantial effort is continually placed on posting current documents, information regarding Workshops and Symposia programs, and important newsworthy items (e.g., joint statement on crisis in Ukraine, latest versions of the Bylaws and House Rules, etc.).

4.7 Research Data Task Force

The WBMT Board mandated development of a Task Force in 2013 for the purpose of developing guidelines for management and use of the WBMT GTA data as well as guidelines for how research should be managed with collaboration amongst WBMT Member Societies. These documents (**Appendices D1 and D2**) were
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approved in 2015, and all Member Societies signed data transmission agreements in early 2016. Since 2015, the Transplant Center / Recipient Issues Committee (**Section 3.7**) administers all activities related to the GTA survey, including providing reports and reviewing proposals for use of these data. During 2021, this Task Force completed the revision of the WBMT Research Guidelines, the guiding principles of collection, presentation, dissemination and sharing of the Global Activity Survey data.

4.8 Administrative support

Administrative support is outsourced to the World Marrow Donor Association (WMDA) that took on this responsibility per July 2019.

4.9 Updated Bylaws and House Rules

In 2022 the WBMT <u>Bylaws</u> and <u>House Rules</u> were updated. The most recent versions are available on the WBMT website (by clicking the links).



5.0 FUTURE AIMS

The WBMT continues to evolve and available resources and time from the Society leaders and committee members constrain the selection of projects for its portfolio. In addition to the plans identified by each Standing Committee, the Executive Committee regularly assesses priority activities.

They are to:

- Establish a more durable mechanism for soliciting and sustaining high level financial support. Over the past few years, WBMT member societies have been asked to contribute via a voluntary fee. The personalized letter stating this request has been added (**Appendix J**).
- Continue the close collaboration with the WHO on global projects relevant to HCT and stem cell donation and fulfilling WBMT responsibilities as an NGO in official relations with the WHO (Section 4). The WHO Liaison Standing Committee has been created (Section 3.8) to follow up on projects with the WHO.
- Continue to offer Workshops and Scientific Symposia in regions with constrained resources and willing to establish new or expand existing HCT programs.
- Integrate regional registries to the WBMT registry.
- Continue working on improvement of collection and analyses of global activity data by the new and user friendly database and its publication.
- Integrate subcommittee functions with regional registries.
- Additional focus on advanced cell therapy and access to these advanced therapies by LMIC.



APPENDIX A: MEMBER SOCIETIES

Member Society	Description
Association for the Advancement of Blood & Biotherapies (AABB) <u>aabb.org</u>	AABB (Association for the Advancement of Blood & Biotherapies) is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association works collaboratively to advance the field through the development and delivery of standards, accreditation and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.
African Blood and Marrow Transplantation Group (AfBMT) <u>https://www.wbmt.org/member-</u> <u>societies-of-wbmt/AfBMT/</u>	In order to encourage activity in the medical and scientific field of blood and marrow transplantation in Africa, AfBMT has been established with the support of the WBMT. The main objectives are to improve awareness among health workers, to improve the skills of healthcare teams through sharing experiences and adapt the knowledge and potential of HCT therapy to local resources and needs.
American Society for Apheresis (ASFA) apheresis.org	ASFA is the premier organization of physicians, scientists, and allied health professionals whose mission is to advance apheresis medicine for patients, donors, and practitioners through education, evidence-based practice, research, and advocacy. ASFA creates guidelines for the appropriate use of apheresis techniques, provides education for apheresis practitioners, and promotes research in apheresis medicine, as well as information for patients regarding apheresis procedures.
American Society of Transplantation and Cellular Therapy (ASTCT) <u>https://www.astct.org/home</u>	ASTCT is an international professional membership association of more than 2,200 physicians, investigators and other health care professionals from more than 45 countries. It is dedicated to improving the application and success of stem cell transplantation and related cellular therapies. It strives to be the leading organization promoting research, education and clinical practice in the field.
American Society for Histocompatibility and Immunogenetics (ASHI) <u>ashi-hla.org</u>	ASHI is a not-for-profit association of clinical and research professionals including immunologists, geneticists, molecular biologists, transplant physicians and surgeons, pathologists and technologists. As a professional society involved in histocompatibility, immunogenetics and transplantation, ASHI is dedicated to advancing the science and application of histocompatibility and immunogenetics; providing a forum for the exchange of information; and advocating the highest



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	standards of laboratory testing in the interest of optimal patient care.
Asia Pacific Blood and Marrow Transplantation (APBMT) <u>apbmt.org</u>	APBMT is an international organization which is involved in hematological stem cell transplantation, sharing their information and cooperating with basic and clinical research in Asia-Pacific countries. APBMT is comprised of 22 countries/regions (Australia, Bangladesh, Cambodia, China, Hong Kong, India, Indonesia, Iran, Japan, Korea, Malaysia, Mongolia, Myanmar, Nepal, New Zealand, Pakistan, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam) and is expanding its activities through the annual congresses, registration systems and working groups under the collaboration with the member societies of WBMT.
Australia and New Zealand Transplant and Cellular Therapies Ltd (ANZTCT) <u>anztct.org.au</u>	The Australia and New Zealand Transplant and Cellular Therapies Ltd (ANZTCT) is a society consisting of medical graduates and scientists involved in the clinical or laboratory management of patients undergoing blood or marrow stem cell transplantation or with an interest in the field of blood or marrow stem cell transplantation research.
Center for International Blood and Marrow Transplant Research (CIBMTR) <u>cibmtr.org</u>	CIBMTR [®] is a research collaboration between the National Marrow Donor Program [®] (NMDP)/Be The Match [®] and the Medical College of Wisconsin (MCW). CIBMTR collaborates with the global scientific community to advance hematopoietic cell transplantation and cellular therapy worldwide to increase survival and enrich quality of life for patients. CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of transplant centers, and a unique and extensive clinical outcomes database.
Eastern Mediterranean Blood and Marrow Transplantation (EMBMT) <u>embmt.org</u>	EMBMT was established in 2008 as a cooperative platform for physicians, scientists and healthcare workers from institutions in the WHO designated Eastern Mediterranean area with the goal of sharing experience, initiation of cooperative trials and establish common strategy to achieve optimization in the field of HCT. The group's aim is to promote all aspects of patient care, academic and research activities associated with HCT in the region which includes knowledge of the trends, patterns and status of HCT in Eastern Mediterranean countries.
Eurocord eurocord.org	EUROCORD is a non-profit organization affiliated to the University Paris Diderot and to the Assistance Publique des Hopitaux de Paris (APHP). It has strong links with the University Institute of Hematology (IUH) at the Saint-Louis hospital, and the French Agence de la biomédecine. Located within the campus of Saint Louis hospital in Paris, EUROCORD is a clinical 40



	research group dedicated to study cord blood transplantation and innovative therapy in both malignant and non-malignant diseases, and to develop new indications for stem cell therapy.
European Federation for Immunogenetics (EFI) <u>efi-web.org</u>	EFI is a European society of workers in the field of immunogenetics, histocompatibility testing and transplantation. EFI supports the development in Europe as a discipline in medicine and promotes research and training in this field.
European Society for Blood and Marrow Transplantation (EBMT) <u>ebmt.org</u>	EBMT is a collaborative peer network of professionals working in centres and as individuals in the field of clinical stem cell transplantation and cellular therapy. Members contribute to and benefit from the collective knowledge that the EBMT has accrued, with the ultimate goal of saving the lives of patients with blood cancers and other life-threatening diseases.
European Leukemia Network (ELN) <u>www.leukemia-net.org</u>	The objective of the ELN is to integrate the leading leukemia trial groups (CML, AML, ALL, CLL, MDS, CMPD), their interdisciplinary partners (diagnostics, treatment research, registry, guidelines), industry and SMEs across Europe to form a cooperative network for advancements in leukemia-related research and health care and cure.
European School of Hematology (ESH) <u>esh.org</u>	ESH is a non-profit institution for continuing education that promotes and facilitates access to research in hematology and related disciplines in Europe, North America, North Africa, and the Middle East. ESH also develops tools for continuing education produced in collaboration with international experts in the field.
Foundation for the Accreditation of Cellular Therapy (FACT) <u>factwebsite.org</u>	FACT is a non-profit organization that establishes standards for high-quality medical and laboratory practices in cellular therapies for the purposes of voluntary inspection.



International Council for Commonality in Blood Banking Automation (ICCBBA) <u>iccbba.org</u>	ICCBBA is a not-for-profit, tax exempt, NGO responsible for management of the ISBT 128 Information Standard for Blood and Transplantation, a global standard for the terminology, identification, labeling, and information transfer of human blood, cell, tissue, and organ products across international borders and disparate health care systems. It ensures the highest levels of accuracy, safety, and efficiency for the benefit of donors, patients, and ISBT 128 licensed facilities worldwide. The system features a unique, highly flexible, and comprehensive coding method for every collected product and provides international consistency to support the transfer, transfusion, or transplantation of blood, cells, tissues and organs.					
International Society of Blood Transfusion (ISBT) <u>isbtweb.org</u>	ISBT is an international professional society that facilitates knowledge about transfusion and transplantation science and medicine.					
International Society of Cellular Therapy (ISCT) <u>isctglobal.org</u>	ISCT is a global association that promotes cellular therapies research by fostering international translational research, driving commercialization strategies, and providing education.					
Joint Accreditation Committee – ISCT (Europe) & EBMT (JACIE) jacie.org	JACIE is a non-profit organization that assesses and provide accreditation in the field of HCT. Its primary aim is to promot high-quality patient care and laboratory performance i hematopoietic stem cell collection, processing an transplantation through an internationally recognized system of accreditation. It partners with EBMT, ISCT, and FACT.					
Latin American Bone Marrow Transplantation group (LABMT) <u>https://www.wbmt.org/member-</u> <u>societies-of-wbmt/labmt/</u>	The purpose of this group is to provide a mechanism through which Latin American Blood and Marrow Transplant and Hematology groups can collaborate and engage in scientific and educational activities and endeavours to promote excellence in stem cell transplantation, stem cell donation, cellular therapy and hematologic practices. Activities include data collection and sharing outcome information.					



World Marrow Donor Association	WMDA is a global association whose mission is to assure that
	high-quality stem cell products are available for all patients in
(WMDA)	need, while maintaining the health and safety of volunteer
<u>wmda.info</u>	donors. WMDA now incorporates all functions previously
	undertaken by Bone Marrow Donors Worldwide and Netcord.

APPENDIX B: EXECUTIVE COMMITTEE ELECTED OFFICERS



President Mahmoud Aljurf, MD, MPH King Faisal Specialist Hospital & Research Center P.O. Box 3354 Riyadh 11211 Saudi Arabia maljurf@kfshrc.edu.sa



Immediate Past-President and WHO Representative Hildegard Greinix, MD Medizinische Universitaet Graz Division of Hematology Auenbruggerplatz 38, 8036, Graz Austria hildegard.greinix@medunigraz.at



Vice President Mickey Koh, MD, FRCP, FRCPath, PhD St George's Hospital and Medical School Jenner Wing Corridor 6 Blackshaw Road London W 17 0QT, UK <u>Mickey.koh@stgeorges.nhs.uk</u>





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Treasurer



Past President Daniel Weisdorf, MD Blood & Marrow Transplant Program, University of Minnesota, MMC 480, Minneapolis, MN 55455, USA weisd001@umn.edu



Past President Jeff Szer Department of Clinical Haematology & BMT Service, The Royal Melbourne Hospital, Melbourne, Australia jeff.szer@mh.org.au



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Founding President

Dietger Niederwieser, MD Division of Hematology and Medical Oncology, Univ. of Leipzig Johannisallee 32A, 04103 Leipzig, Germany <u>dietger@medizin.uni-leipzig.de</u>



APPENDIX C1: CENTER SITES THAT CONTRIBUTE DATA TO THE ACTIVITY SURVEY

WBMT: maximum number of reporting teams per country: 1890



APPENDIX C2: COUNTRIES THAT HAVE CONTRIBUTED DATA

Region	WHO Region	Country	Max. N Teams
			in any survey year
3	EMR/AFR (AFBMT)	Algeria	2
1	AMR/PAH	Argentina	24
2	EUR	Armenia	1
4	SEAR/WPR	Australia	42
2	EUR	Austria	13
2	EUR	Azerbaijan	1
4	SEAR/WPR	Bangladesh	4
2	EUR	Belarus	2
2	EUR	Belgium	20
1	AMR/PAH	Bolivia	3
2	EUR	Bosnia and Herzegovina	2
1	AMR/PAH	Brazil	45
2	EUR	Bulgaria	2
1	AMR/PAH	Canada	26
1	AMR/PAH	Chile	5
4	SEAR/WPR	China	149
1	AMR/PAH	Colombia	6
1	AMR/PAH	Costa Rica	3
2	EUR	Croatia	3
1	AMR/PAH	Cuba	5
2	EUR	Cyprus	2
2	EUR	Czech Republic	9
2	EUR	Denmark	4
1	AMR/PAH	Ecuador	3
3	EMR/AFR (AFBMT)	Egypt	3
2	EUR	Estonia	2

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2	EUR	Finland	7			
2	EUR	France	75			
2	EUR	Georgia	1			
2	EUR	Germany	116			
2	EUR	Greece	14			
4	SEAR/WPR	Hong Kong	3			
2	EUR	Hungary	6			
2	EUR	Iceland	1			
4	SEAR/WPR	India	81			
	SEAR/WPR	Indonesia	3			
3	EMR/AFR (EMRO)	Iran	5			
3	EMR/AFR (EMRO)	Iraq	1			
2	EUR	Ireland	6			
2	EUR	Israel	10			
2	EUR	Italy	100			
4	SEAR/WPR	Japan	381			
3	EMR/AFR (EMRO)	Jordan	2			
2	EUR	Kazakhstan	1			
3	EMR/AFR (EMRO)	Kuwait	1			
2	EUR	Latvia	1			
3	EMR/AFR (EMRO)	Lebanon	2			
2	EUR	Lithuania	3			
2	EUR	Luxembourg	1			
2	EUR	Macedonia, FYR	1			
4	SEAR/WPR	Malaysia	15			
1	AMR/PAH	Mexico	31			
4	SEAR/WPR	Mongolia	1			
3	EMR/AFR (AFBMT)	Morocco	2			
4	SEAR/WPR	Myanmar	2			

4	SEAR/WPR	Nepal	1
2	EUR	Netherlands	16
4	SEAR/WPR	New Zealand	6
3	EMR/AFR (AFBMT)	Nigeria	1
2	EUR	Norway	6
3	EMR/AFR (EMRO)	Oman	2
3	EMR/AFR (EMRO)	Pakistan	3
1	AMR/PAH	Panama	3
1	AMR/PAH	Paraguay	2
1	AMR/PAH	Peru	5
4	SEAR/WPR	Philippines	6
2	EUR	Poland	18
2	EUR	Portugal	6
3	EMR/AFR (EMRO)	Qatar	1
2	EUR	Romania	5
2	EUR	Russian Federation	17
3	EMR/AFR (EMRO)	Saudi Arabia	7
2	EUR	Serbia	4
4	SEAR/WPR	Singapore	5
2	EUR	Slovak Republic	5
2	EUR	Slovenia	1
3	EMR/AFR (AFBMT)	South Africa	9
4	SEAR/WPR	South Korea	45
2	EUR	Spain	73
4	SEAR/WPR	Sri Lanka	4
2	EUR	Sweden	8
2	EUR	Switzerland	10
3	EMR/AFR (EMRO)	Syria	0
4	SEAR/WPR	Taiwan	18

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4	SEAR/WPR	Thailand	12				
3	EMR/AFR (AFBMT)	Tunisia	1				
2	EUR	Turkey	73				
2	EUR	Ukraine	4				
2	EUR	United Kingdom	54				
1	AMR/PAH	USA	203				
1	AMR/PAH	Uruguay	5				
1	AMR/PAH	Venezuela	2				
4	SEAR/WPR	Vietnam	3				
		93	1898				

APPENDIX D1: WBMT RESEARCH GUIDELINES

WBMT RESEARCH GUIDELINES

(Original proposal for submission to WBMT Board – November 2014)

(Renewed version September 2021)

This document* is developed by the Worldwide Network for Blood and Marrow Transplantation (WBMT) and outlines the guiding principles of research performed directly by this entity through the global survey data or indirectly by fostering collaboration among member societies with the intent of dissemination of information for advancement of the hematopoietic cell transplantation field.

BACKGROUND:

The idea of creating guidelines for research endeavors generated by WBMT Member Societies laterally, or on behalf of the parent organization (WBMT), was first presented during the 2013 annual, in-person Board meeting in Salt Lake City, USA. The Board agreed that guiding principles for the conduct of research by or within the WBMT was an important topic to be explored and formed a Research Activity Task Force to 1) develop a guidelines document on developing, conducting and disseminating results of studies involving data and/or investigators from multiple Member Societies and, 2) to promote collaboration among the WBMT Member Societies/registries through the establishment of a framework for the conduct of research.

During the deliberations of the Research Activity Task Force it was decided to cover this topic of research in two different fronts, first to develop the guiding principles of collection, presentation, dissemination and sharing of the Global Activity Survey data, herein defined as Global Transplant Activity data. Second, the Research Activity Task force would develop guiding principles to provide general guidelines for the conduct of international collaborative research (Appendix D), with the intent to serve as reference for research procedures and for fostering collaboration among member societies.

OVERARCHING WBMT GUIDING PRINCIPLES OF RESEARCH

Overarching Guiding Principle #1

The Worldwide Network for Blood and Marrow Transplantation (WBMT) has the responsibility to collect, store, disseminate information related to global hematopoietic cell transplantation activity. This is done through the annual global activity survey. WBMT will be responsible for safe keeping of this data and oversight of its utilization.

Overarching Guiding Principle #2

The WBMT shall not duplicate or compete with research actively being conducted by its Member Societies and/or registries. Each WBMT Member Society conducts research in its unique manner, independent from the WBMT.

Overarching Guiding Principle #3

The WBMT will foster collaboration through its member societies for the development of collaborative research to address global questions in transplantation, encourage the analysis of regional differences and offer a global perspective on transplantation. Furthermore, this collaborative research shall fulfill the WBMT mission including increase global awareness of the importance of transplantation, improve access to transplant, optimize safety for patients and donors, and improve the quality of all activities associated with hematopoietic cell transplantation

GLOBAL TRANSPLANT ACTIVITY (GTA)

Global Transplant Activity Guiding Principle #1

The WBMT is required to survey transplant activity globally in an annual basis to maintain its Non-Government Organization (NGO) status with the World Health Organization (WHO).

Commentary on GTA Guiding Principle #1

Since the January 2013 award of NGO status by the WHO, there are important and continuing obligations for the WBMT. One such criterion is referred to as "Global Database on Donation and Transplantation". WHO, along with the Spanish National Transplant Organization established the Global Observatory on Donation and Transplantation and one of several goals is the development of a global database on donation and transplantation. WBMT has facilitated access to its global survey data for input into this Observatory database since 2006 and remains an ongoing project.

The current process for collecting these Global Activity data is performed by the WBMT Global Transplant Activity Survey Officer. All GTA related communication (e.g., requests to centers and registries) is managed by this individual. The data is collected through a survey and represents the number of first transplants performed by a center during a calendar year. Data for a particular year activity is collected from November of the subsequent year through February. For example, submission related to the activity for 2013 will be due starting November 2014 through February 2015. This data will be compiled and released to the WHO and to the public by fall of 2015.

Any transplant center is eligible to provide data to the WBMT through its Member Society. The only requirement for participation is that each member society has a standing agreement with the WBMT to share transplant activity data. (Appendix A) WBMT will have the autonomy in using this data according to its mission and share with third parties for specific projects (Guiding Principles #2 and #3).

One important exception in the relationship between the WBMT and a member society involves transplant activity data from regions were the regional member society is still in development. In these instances, direct communication from a transplant center and the WBMT is allowed, condition upon having a standing agreement in place. The transplant center is required to include in the survey whether it has an active affiliation (i.e. data reporting) with an outcomes registry (APBMT, CIBMTR or EBMT) or not. Additionally, the regional member society in question needs to be aware of this direct relationship between its transplant center and the WBMT. In case of data being shared from a transplant center directly with the WBMT, the WBMT will share this activity information with the regional member society.

WBMT Global Transplant Activity data reports (Appendix B) capture disease indications (malignant and nonmalignant) for allogeneic (related and unrelated) and autologous stem cell transplantation, donor type and stem cell sources. They do not include outcome data. Data are provided to the WBMT by transplant program sites, national societies and/or outcome registries.

The data from a WBMT member society with registry (APBMT, CIBMTR, EBMT, EMBMT, ABMTRR, and in future, LABMT and AFBMT) that is shared with the WBMT can be utilized by the same member society for other uses without restrictions.

Collection forms are available on the www.wbmt.org website and may be submitted in paper format or electronic mail.

Global Transplant Activity Guiding Principle #2

The WBMT will be responsible for the dissemination of the Global Transplant Activity report.

Commentary on GTA Guiding Principle #2

The responsibilities with the GTA include report annually to the WHO and share the activity with member societies. A summary slide set, updated annually outlying annual and cumulative activity will be uploaded in the WBMT website for public use. Activity reports in form of manuscript for publication are included among the dissemination of global transplant activity and will be done in a minimum schedule of one every other year.

Global Transplant Activity Guiding Principle #3

The WBMT has ownership of the GTA data and any use needs to be approved by the WBMT. This includes data requests and proposal for scientific studies that seek to utilize this data for analysis.

Commentary on GTA Guiding Principle #3

The GTA comprises of center level data on the number of transplant recipients including indications, donor and stem cell sources. These data, in aggregate, demonstrate important information of trends in activities and practices globally. Additional uses of this data are possible by any WBMT member societies. In addition to annual reports of global activities, any individual on behalf of the member societies can request specific information by contacting the WBMT Global Transplant Activity Survey Officer. If the use is for research purposes, the proponent is required to complete a proposal form (Appendix C) which needs to be approved by his or her Member Society Representative before it can be submitted to the WBMT. This proposal will then be reviewed by the Transplant Center and Recipient Standing Committee before it can be released. When a proposed study is approved, any Member Society that provided data to be used for that study will be notified by the approval committee. For data requests outside the member societies, GTA data can only be released with approval from the WBMT board or the Executive Committee according defined operation. In these situations, charges may apply, if these are requests from for-profit entities, according to the WBMT corporate program guidelines.

The data from a member society that is shared with the WBMT can be utilized by the same member society (which also has ownership of its data) without restrictions.

Uses of GTA data to fulfill the non-governmental organization (NGO) with WHO will also be overseen by the Transplant Center and Recipient Issues Standing Committee. These analyses include periodic reports (annual or biennial) on practices and trends related to transplantation. The Transplant and Recipient Standing Committee will develop and maintain a tracking document with the status of all projects that utilized the GTA. This tracking document will be available to the Board and Executive Committee and the status of these studies or projects will be presented to these committees periodically.

Authorship of publication of studies using the GTA data will follow the authorship recommendations of the International Committee of Medical Journal Editors (ICMJE), which include the following criteria:

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

Drafting the work or revising it critically for important intellectual content; AND

Final approval of the version to be published; AND

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authorship is carefully decided considering contributions of the study as well as the collection and the analyses of the GTA data of the WBMT. Authors lists consist of primary investigators who proposed the study, representatives from the WBMT member societies with registry, which submit GTA data, and the members and co-chairs of the Transplant Center and Recipients Issues Standing Committee, the WBMT Global Transplant Activity Survey Officer as well as representatives of the Executive Committee of the WBMT. The number of authors from each member society with registry will be agreed in advance among the co-chairs of the Transplant Center and Recipient Standing Committee (see Appendix E). The member societies that submitted data are then requested to select authors. The final authors list is overseen by the Transplant Center and Recipient Issues Standing Committee.

The specific procedures of the use of GTA data for research purposes are defined in the Appendix E (the WBMT Operation Manual for Global Transplant Activity Data Use) along with the Appendix F (the Letter of Commitment).

Insertion site for APPENDIX A (Data Transmission Agreement; DTA)

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					Fa	mily					ι	Jnrelate	d							-
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	MPS																			
Ī	CLL incl. PLL																			
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	Total Plasma Cell Disorder						-													-
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9	PCD - other																			_
	Total Lymphoma																			
	HD																			
	NHL																			
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	Ewing																			
	Other solid tumor																			
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- noN	Inherited Dis of Metabolism																			
	Auto Immune Disease						[_						[
	Other Non Malignant Disease													1						
-	Other																			-
																				+
	TOTAL PATIENTS (1st. HSCT)																			
TOTAL NUMBER OF TRANSPLANTS PERFORMED THIS YEAR: includes 1							udes 1st, 2nd, 3rd. etc. ALLO:					1	AUTO:			TOTAL:				

Appendix C

GTA Study Form

Global Transplant Activity (GTA) Study Proposal Form

Prepare a brief description of the proposed study as you envision it. This should be no more than three pages, using standard 8½" X 11" paper with 1" margins. Use the outline below and send your description to (H. Baldomero or WBMT site)

Study Title

Include the name(s) and institution(s) and WBMT Member Society of the individual(s) proposing the study.

Specific Aims

State the primary purpose(s) of the study as concisely and clearly as possible. A reader should have a clear idea of the purpose for which the data will be analyzed.

Scientific Justification

Summarize the rationale of the study, citing relevant previous work. This should convey the importance of the intended study.

IV. Study Design (Scientific Plan)

Describe how the specific aims would be addressed using information from the WBMT. It should include the specific statistical methodology planned, with discussion of limitations, if relevant.

Appendix D

COLLABORATIVE INTERNATIONAL RESEARCH IN HEMATOPOIETIC CELL TRANSPLANTATION WBMT Reference Document -

General Research Guiding Principle #1

Any collaborative research is required to follow all basic principles for ethical conduct of research in addition of being inclusive to all participating parties, being fair, minimize bias, avoid conflicts of interest and strictly adheres to the WHO guiding principles on cell, tissue and organ transplantation.

Commentary on General Research Guiding Principle #1

International collaborative research is herein defined as biomedical research that includes sharing of data or biologic specimens ("biospecimens") among different organizations or groups that are located in separate countries.

The rules and guiding principles for collaborative research are no different from any biomedical research, as the majority of biomedical research requires some level of collaboration. This guiding principle mostly apply to complex collaborative, involving different organizations situated in different countries that abide to similar but not equal rules and regulations towards the practice of research. This first guiding principle is broad and applies to biomedical research involving human subjects. The ethical principles of conduct of research are derived from the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) and include respect for persons, beneficence and justice. The inclusiveness to all participating parties is an essential component for the conduct of international collaborative parties are large complex organizations or when the number of collaborative parties is large. Fairness applies to all levels of research, development, conduct, interpretation and dissemination. Additionally, this guiding principle is referring to fairness among the collaborative parties. Bias is inherent in research, and minimize bias strengthens research. Finally, conflict of interest at any level, from commercial to self-promotion is deleterious for research as it clouds the conduct and manipulates the message or conclusion of a project.

International collaborative research in hematopoietic cell transplantation is the main responsible for the success of this field. The guiding principles are meant to be a general reference document for the conduct of research and assist investigators to promote the betterment of the practice of transplantation, advance the field by improving access and outcomes of patients and safeguard the health of volunteer donors.

General Research Guiding Principle #2

The process of international collaborative biomedical research requires several steps to ensure its efficiency and fairness at the same time safeguarding the patients' data.

Commentary on General Research Guiding Principle #2

Biomedical research process applied to specific collaborative projects can be stratified into several phases: concept development, project development, data sharing, analysis, results interpretation, dissemination and conclusion. In general these phases can be distinct or combined depending on the project, however consideration of each of these steps are relevant in order to organize the procedures and requirements.

This guiding principle proposes general procedure in each phase of a collaborative project that could be considered.

Concept Development

The inception of a project starts with the concept or idea. The concept often focuses on the hypotheses of interest to be tested in the project. This step can be part of the project development. However, often in the collaborative international research, the concept or proposal is often a necessary step for recruiting collaborators, obtain approval or to better describe a project that is intended. Understanding the availability of data already in existence or procurement of such data can also be considered in the step of the research process.

<u>Project Development</u>

The development of the project requires detail information on the objectives, background, population and requirement of informed consent, data sources and analyses being done. This a priori exercise sediment the proposed activities and anticipates all potential pitfalls. The most common procedure in this phase is the development of a protocol that includes all the components of the project. The development of the protocol should be a collaborative effort that ensures that all participating parties are aware of the project details.

Additionally, this phase of the project development needs to address the safeguard of the data, the protection human subjects, funding information, shared responsibilities plan and authorship guidelines, results review process and dissemination plan. Each of these components might not apply to all projects, but if presented upfront might help avoid delays during the life cycle of the project.

The section below outlines each component with proposed format and content.

- Protocol Document: Describes in detail all the proposed scientific activities to be done with in the project. The protocol document should include the objectives of the project in a succinct and direct language; background that justifies the study and or hypotheses; description of the population of interest and the sources of data; description of the outcomes being tested; detailed of the proposed statistical analysis; relevant references and any additional information that is relevant for the understanding of the project (i.e. demographic table, surveys, etc). If the study involves additional informed consent of recipients, this document would be to be referenced or added to the protocol document.
- 2. <u>Safeguard of the data</u>: This description could be incorporated in the protocol or in a separate document. However a safeguard plan would requirement agreements between parties if data are being exchanged. The important components for the safeguard plan include description of the data needed in the study, the expected transferring plan, who will be the responsible parties to oversee this exchange or transfer and how the transferred data will be stored, including security details, for how long and the procedures that will take place once the project is completed. In case of data, a description on whether personal health information (PHI, i.e. date of birth, gender, social security or other unique identification number among others) is required for the study and the type of PHI needs to be included. Also, if the project requires data from different databases to be merged, a description of this data merger should include the variables used for the merger, identification of an honest broker in case of datasets with PHI, storage or plans for data destruction once the project is completed.
- 3. <u>Protection of Human Subjects</u>: any biomedical research that utilizes data requires appropriate informed consent, which authorizes the utilization of data for a particular use or research in general. Ethical committee oversight is a vital component of biomedical research to assure that human subjects are not being harmed. The rules of ethical committee engagement vary in different countries which makes a protection of human subjects document important in collaboration international research. The components of this document should include, the type of data being utilized in the project, whether the patients or individuals who consented for the specific project in question. In case of sharing dataset that include PHI, additional oversight might be required to overview that the process is appropriately set to avoid data breeches or losses. For studies that required additional informed consent, the document should include how the consent procedure will take place.
- 4. <u>Funding Sources:</u> studies that are done as parted of funded projects may require a document that outlines any restriction that the funding agent might impose on the project. Additionally, the funding plan might require multiple sources which should be outlined accordingly.
- 5. <u>Shared Responsibilities</u>: It is important to develop a leadership plan that outlines the responsibility of each member of the project and that all members are in agreement with this plan. This document should also include authorship guidelines for any publication that results from this project. The authorship guidelines might be a detailed list of each member of the project and their position in a manuscript or general rules that will be considered to choose authors and their respective position on any manuscript from this project.
- 6. <u>Results review and Dissemination Plan:</u> some of the components of this section can be included in the protocol document. A detailed plan for how the results will be reviewed and disseminated might be necessary in studies that involve different outcomes databases or research groups. This includes timeline for completion of the analysis, presentation in conferences or meetings and other public dissemination.

<u>Project Analysis</u>

Once the project is developed with documentation and agreements approved, data can be transferred. If the project requires separate informed consent, enrollment of participants may be initiated.

Prior to analyses, verification of the data for errors, outliers and follow up is important to avoid misinterpretation of results. Analyses results when completed should follow the results review and dissemination plan outline above.

Completion of the Project

Once the study is completed, which in some instances might be upon the publication of results or otherwise determined procedures for returning, destroying shared data or left over samples, or indefinitely storage should take place. Additional studies that include any data used in the original project need to be discussed among the original owners of the data before proceeding. This will initiate another project cycle and some of the steps described above may apply.

*This document will be prominently posted at <u>www.wbmt.org</u>.

Appendix E

WBMT Operation Manual for Global Transplant Activity Data Use

This manual provides specific procedures of the use of Global Transplant Activity (GTA) data for research purposes. The GTA data is collected and managed in accordance to the WBMT Research Guidelines.

- 1. Research proposals
- Activity reports in form of manuscript for publication are included among the dissemination of global transplant activity and will be done in a minimum schedule of one every other year. These reports are planned under the responsibility of the co-Chairs of the Transplant Center / Recipient Issues Standing Committee.
- Additional uses of this data are possible by any WBMT member societies. If the use is for research purposes, the proponent is required to complete a proposal form (Appendix C of the WBMT Research Guidelines) which needs to be approved by his or her Member Society Representative before it can be submitted to the Transplant Center / Recipient Issues Standing Committee of the WBMT.
- 2. Review and approval of research proposals
- A new study proposal by using the proposal form will be reviewed by the Transplant Center / Recipient Issues (TCRI) Standing Committee during the committee meeting. Study proposal and its approval will be recorded in the minutes of the TCRI Standing Committee meeting. When a proposed study is approved, any Member Society that provided data to be used for that study will be notified by the approval committee.

- 3. Dataset provision
- If the study proposal is approved, a study protocol will be created by the principal investigators (PI) of the proposal. After the study protocol has been approved by the TCRI Standing Committee, the dataset for conducting the study will be provided by the WBMT Global Transplant Activity Survey Officer. The PI must submit a Letter of Commitment (Appendix F of the WBMT Research Guidelines) to the co-Chairs of the TCRI Standing Committee. Whether or not it can be provided by the WBMT Global Transplant Activity Survey Officer will be determined by the TCRI Standing Committee co-chairs.
- 4. Responsibilities of Principal Investigators

The PI must:

- Properly carry out research based on the content certified in the Letter of Commitment
- Report on research progress at the TCRI Standing Committee web meeting
- When the analysis results are finalized, prepare a manuscript in a timely manner.
- Manuscripts must be confirmed by all co-authors prior to submission

5. Authorship

The final authors list is overseen by the co-Chairs of the TCRI Standing Committee. Generally, the authors may include the following individuals.

- PIs that proposed and carried out the study
- Representatives from the registries contributing activities. At least one author from the registries needs to be included. The number of subsequent authors from each registry is determined by the volume of data submission (one author every 5000 patients included in the manuscript). Member societies contributing are requested to select authors.
- WBMT Global Transplant Activity Survey Officer
- Members of the TCRI Standing Committee who participated in the discussion of the proposal, analyses, and interpretation of the results of the study
- Co-chairs of the TCRI Standing Committee
- WBMT officers
- 6. Publication

All publications or presentations of these data shall acknowledge the WBMT and the member societies that contributed data as the data source.

Publications that do not use GTA data are not included in the scope of this manual.

Appendix F

The Letter of Commitment

To the Co-chairs of the Transplant Center and Recipient Issues Standing Committee of the WBMT

I promise to uphold the following commitments.

1. Global Transplant Activity data are not to be used for any purpose other than the study whose protocol approved by Transplant Center and Recipient Issues Standing Committee of the WBMT

2. Data are to be managed under the responsibility of the applicant, and are not to be made available for viewing by, or transferred to, a third party. Viewing by co-researchers or co-authors is to be restricted to an absolute minimum, and such persons are to observe these provisions.

4. The content of data provided by the WBMT Data Center are not to be altered without permission.

5. The final authors list is overseen by the Transplant Center and Recipient Issues Standing Committee. The Transplant Center and Recipient Issues Standing Committee notifies and invites member societies which submit data to the WBMT to recommend study participants, i.e. co-authors for the study.

7. When publishing the results of the research, it is to be made clear that WBMT GTA data were used.

8. The applicant is to inform the Transplant Center and Recipient Issues Standing Committee without delay in the event of any of the following,

(1) discontinuation of use of the data,

(2) changes to the details given in the application to use data.

9. Any infringement of these provisions will result in the cancellation of the data use application approval. In that event, the applicant shall promptly return any data to the WBMT Data Center, and destroy all copied or processed data.

I certify that I have read this document and commit to fulfilling the responsibilities described herein.

Study Title

Date

Institute

Name

APPENDIX D2: WBMT MEMBER SOCIETY REGISTRY DATA

WBMT MEMBER SOCIETY REGISTRY DATA TRANSMISSION AGREEMENT

This Data Transmission Agreement ("Agreement"), effective[Date], is entered into by and

between the Worldwide Blood and Marrow Transplant Network ("WBMT"), a non-government organization with the World Health Organization and ______("WBMT Member Society"), each a "Party" and collectively, the "Parties".

The purpose of this Agreement is to set forth terms by which the WBMT will facilitate its member societies in data submission related to the Global Transplant Activity ("**GTA**") for public dissemination and research purposes.

First and foremost, and following WBMT Guiding Principle #3, "The WBMT has ownership of the GTA data and any use needs to be approved by the WBMT. This includes data requests and

proposal for scientific studies that seek to utilize these data for analysis" and "The data from a Member Society that is shared with the WBMT can be utilized by the same Member Society (which also has ownership of its own data) without restrictions."

Section 1. Data Collection and Records

- <u>Global Transplant Activity Data</u>: The WBMT member society shall submit information related to transplant activity from the transplant centers that are within the region of the member society or has an established relationship with the member society to provide this data. Transplant activity data collected in the Global Activity Survey Form ("**GAS**") includes the volume of first transplants per patients performed at a transplant center in one year with accompanied information related to the indication, graftsource and donor type.
- <u>Data Collection</u>. The WBMT Member Society shall compile all annual transplant activity data from their participating transplant centers and provide to WBMT with GAS compiled for the specific region as requested by the WBMT within the time frames and in the manner specified by the WBMT. The timeline for submission of the compiled regional GAS is from November to February in reference to the activity of the prior year. The GAS should be submitted directly to the WBMT offices during this specified period.

Section 2. Informed Consent

• The GAS does not include any patient specific identifiers. It represents the number of transplants performed at a given transplant center. The volume per center is not provided to the WBMT, the GAT includes the number of active centers in a particular region and the number of transplants performed annually. Informed consent is not required for collection or submission to WBMT.

Section 3. Term

• This Agreement shall commence on its effective date referenced in the first paragraph above and shall continue in force until terminated by either Party at any time, with or without cause, upon thirty (30) days written notice to the other Party. During the thirty

(30) day period after such notice is sent, the Parties shall continue to act toward each other in good faith.

Section 4. Miscellaneous

- <u>Compliance with Laws and Regulations</u>. The WBMT Member Society shall comply with all applicable statutes and regulations specific to that country, including, but not limited to, those regarding the safeguarding of donor and patient records, privacy regulations and human subjects protection.
- <u>Assignment and Subcontracting.</u> The WBMT Member Society may not assign this Agreement or any of their respective rights and responsibilities under this Agreement, without the WBMT's prior written consent. No responsibilities under this Agreement may be subcontracted without the prior written approval of the Parties.
- <u>Amendment.</u> Except as otherwise provided for in this Agreement, this Agreement may not be amended except by written instrument duly signed and delivered by the WBMT and the WBMT Member Society.
- <u>Non-Assumption of Liabilities</u>. Neither the WBMT nor the WBMT Member Society shall be liable for any of the prior existing or future obligations, liabilities or debts of the other Party.
- <u>Governing Law.</u> This Agreement and all transactions contemplated by this Agreement shall be governed, construed and enforced in accordance with the laws of Switzerland.
- <u>Independent Contractors</u>. Nothing in this Agreement is intended to create an employment or agency relationship between the Parties. Neither Party shall be deemed or construed to be an employee or agent of the other.
- <u>Notice</u>. Any notice required to be given by this Agreement shall be in writing and sent by:
 1) mail, registered or certified, as evidenced by a delivery receipt; 2) with a private delivery

service as evidenced by a shipping receipt; or 3) by electronic mail return receipt requested.

- <u>Prior Agreement.</u> This Agreement constitutes and contains the entire Agreement between the Parties with respect to the subject matter hereof, including but not limited to the terms and conditions relating to the maintenance and transmission of data, and supersedes any prior oral or written agreements.
- <u>Force Majeure</u>. Neither Party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the Party failing to perform, except that the WBMT Member Society shall not be excused from strict compliance with this Agreement under this clause due to errors, omissions or failures by its independent contractors or lowertier subcontractors.
- <u>Successors.</u> This Agreement shall be binding on and will inure to the benefit of the Parties and their respective successors and assigns.

This Agreement is executed by individuals who are duly authorized to enter into the Agreement and legally binds their respective parties to be effective on the date stated in the first paragraph above. "Duly authorized" includes the WBMT President, a registry leadership representative or a center representative as is designated by that center.

Ву:	WBMT	Ву:	[Registry WBMT Member Society]
Ву: _		Ву:	
			Authorized Signature
		-	(Typed/Printed Name)
Title:	Current WBMT President	Title:	
Date:		Date:	

APPENDIX E: HISTORY OF MAJOR MEETINGS AND INTERNATIONAL WORKSHOPS

WBMT Board Business Meetings	WBMT Participant Meetings
2022	
Video conference (October)	
	WBMT Workshop & Symposium Rawalpindi, Pakistan (September)
Video conference (March)	
2021	
Video conference (September)	
Video conference (April)	
2020	
Video conference (June)	
Video conference (March)	
2019	
Houston, US (February)	
	Asuncion, Paraguay (September)
	Busan, Korea (September)
2018	
Teleconference (December)	
Teleconference (July)	
	Casablanca, Morocco (April)
	Beijing, China (September)
Lisbon , France (March)	
	Taipei, Province of China (November)
2017	

Teleconference (December)	
Teleconference (July)	
	Regensburg, Germany – Sickle Cell Disease Cure and Prevention Consortium (June)
	Geneva, Switzerland – WHO (May)
Orlando, FL, US (February)	
2016	
Teleconference (December)	
Teleconference (July)	
	Geneva, Switzerland – WHO (May)
Valencia, Spain (April)	
2015	
Teleconference (December)	Addis Ababa, Ethiopia – On-site visit by select WBMT representatives (December)
	Okinawa, Japan – Nuclear Accident Management Committee (October)
Teleconference (July)	
	Regensburg, Germany – Sickle Cell Disease Cure and Prevention Consortium (June)
San Diego, CA, US (February)	
2014	
Teleconference (December)	
	Geneva, Switzerland – MPHO NGO meeting (September)
Teleconference (July)	
Milan, Italy (March)	
2013	

	Brasilia, Brazil – WBMT / NOFITY (December)
Teleconference (November)	
Teleconference (July)	
	Geneva, Switzerland – WHO (May)
	London, UK – Standing Committees (April)
Salt Lake City, UT, US (February)	
2012	
	Atlanta, GA, USA – WBMT / LABMT (December)
	Rome, Italy – WBMT / NOTIFY (November)
Teleconference (October)	Hyderabad, India – APBMT (October)
	St. Petersburg, Russia – WBMT / Russia (September)
	Lagos, Nigeria – WBMT / AFBMT (September)
	Manila, Philippines – WBMT / Philippine Society of Hematology (August)
Teleconference (June)	
Geneva, Switzerland (April)	
	San Diego, CA, US – WBMT / LABMT (February)
2011	
Teleconference (December)	
Teleconference (September)	
	Rio de Janeiro, Brazil – SBTMO / LABMT (August)
Teleconference (June)	
Teleconference (April)	
	Paris, France – Standing Committees (March)
Honolulu, HI, US* (February)	

2010	
	Phuket, Thailand – APBMT (November)
Vienna, Austria (March)	
	Brussels, Belgium – WHO (February)
2009	·
Minneapolis, MN, US (November)	
	New York, NY, US – UN (October)
Nagoya, Japan (April)	
Goteborg, Sweden (March)	
2008	
Minneapolis, MN, US (October)	Geneva, Switzerland – WHO (October)
Firenze / Florence, Italy (March)	
	Tampa, FL (February)
2007	
Minneapolis, MN, US (October)	
Lyon, France (March)	

*1st elected Board meeting

APPENDIX F: HISTORY OF INTERNATIONAL SCIENTIFIC SYMPOSIA

2022

December, ASH (poster)

- International Differences in Baseline Characteristics and Practice Patterns in Patients with Newly Diagnosed Multiple Myeloma Undergoing Upfront Autologous Stem Cell Transplantation *Laurent Garderet et al.*
- Worldwide Network for Blood and Marrow Transplantation (WBMT) Global Study on Baseline Characteristics and Clinical Outcomes in NEWLY Diagnosed Multiple Myeloma Patients Undergoing Upfront Autologous STEM Cell Transplantation, a Study Off 61,725 Patients from 629 Centers *Laurent Garderet et al.*

October, APBMT

• Global Trends in Cellular Therapy and its integration with HSCT- WBMT Perspective *Dietger Niederwieser et al.*

<u>April, TCT</u>

Broad Access to HCT Worldwide: How has the WBMT Advanced Worldwide Equity in 15 years?

- Barriers to Reaching Equity in HCT and Cellular Therapy *Mickey Koh*
- What Allows Us to Deliver Affordable and Available HCTs? *Cristóbal Frutos*
- WBMT Achievements and Future Goals *Yoshiko Atsuta*

March, EBMT, video conference

JS04 Joint session EBMT-WBMT: Maintaining safe access to stem cell transplantation during the pandemic

- JS04-01 Adapting inpatient and outpatient clinical care: comparing experiences from transplant centres worldwide Adriana Seber (Brazil)
- JS04-02 Challenges in donor selection and stem cell collection *Nina Worel (Austria)*
- JS04-03 Global perspective on achieving quality for cellular therapy *Yossi Schwartz (United States)*

2021

October, APBMT, video conference

• Design the future of HCT Societies, WBMT perspective Hildegard Greinix, President of WBMT, Medical University Graz, Austria

March, EBMT, video conference

JS05 Joint session WBMT: COVID-19 vaccination in HSCT

- JS5-1 Translating science into survival; mRNA vaccines for cancer and infectious disease Christopher huber (Germany)
- JS5-2 COVID-19 vaccination in HSCT

Per Ljungman (Sweden)

• JS5-3 Global access to COVID-19 vaccines

Susan Brown (United States)

February, TCT, video conference

S-C2 - WBMT Concurrent: Transplantation During a Worldwide Crisis: Lessons Learned Across the World

- The Latin American Bone Marrow Transplantation Group (LABMT) Experience Adriana Seber, MD, Hospital Samaritano, Sao Paulo, Brazil
- HSCT Challenges and Solutions Under COVID-19: The Experience from China
 Xiao-Jun Huang, MD, Institute of Hematology, Peking University People's Hospital, Beijing, China
- The Eastern Mediterranean Blood and Marrow Transplantation (EMBMT) Group Experience
 - Riad El Fakih, Oncology Center, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia

2020

<u>August, EBMT, video conference</u> International access to HCT drugs: Impact on transplant practice and patients

• Chair: D Weisdorf (United States)

Causes of drug shortages

Chair: G Stemer (Austria)

How can pharmacists help the HCT team in drug shortages and cost of medications

• Chair: H Greinix

Successful models of cooperation to offer essential drugs in the care of HCT patients: Role of WBMT

February, ASTCT, video conference

• Chair: Emily Thakur Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions

- Chair: Zahra Mahmoudjafari Drug Shortages: The Role of the Pharmacist on the HCT Team
- Chair: H Greinix

Successful Models of Cooperation to Offer Essential Drugs for the Care of HCT Patients: WBMT

2019

March, EBMT Frankfurt

Efficiency and Effectiveness of New Models for Transplant Care Delivery

Chair: D Weisdorf (United States)

- Remote health development, consultation from a distance in Nepal (D. Rondelli, Nepal)
- Choosing wisely for haematopoietic cell transplantation (D Weisdorf, United States)
- Telemedicine for Remote Consultations (D Niederwieser, Germany)

February, BMT Tandem Meetings (Houston)

Efficiency and Effectiveness of New Models for Transplant Care Delivery

Chair: D Weisdorf (United States)

- Home Delivery Model of Video Conferencing with Patients (J Nelson, United States)
- Remote Health Strategies in Development of Global BMT (D. Rondelli, Nepal)
- The Cure2Children-Sankalp India Foundation Experience in Affordable Bone Marrow Transplantation for Children with Severe Thalassemia in India (L Faulkner, Italy)
- Telemedicine for Remote Consultations (D Niederwieser, Germany)

2018

February, BMT Tandem Meetings (Utah)

How the best donor can improve transplant outcomes?

Chair: D Weisdorf (United States)

- Introduction and recent trends (J Szer, Australia)
- Assessing donor suitability beyond HLA (H Yang, Australia)
- How regional haplotype frequencies influence the success of finding the best unrelated UCB or volunteer donors (L Bouzas, Brazil)
- Cost and morbility consequences of different donor choices (M Pasquini, United States)
2017

February, BMT Tandem Meetings (Orlando)

Do stem cell transplants need to be so expensive? What is really necessary?

Co-Chairs: Y Kodera (Japan) and J Szer (Australia)

- WBMT introduction (J Szer, Australia)
- Introduction to the topic of cost (D Weisdorf, US)
- The Mexican experience (D Gomez-Almaguer, Mexico)
- The Indian experience (A Srivastava, India)

2016

April, EBMT Meeting (Valencia)

Global Challenges in Transplantation

Co-Chairs: Y Kodera (Japan) and J Kuball (Netherlands)

- Economic stresses in transplantation: How are these challenging existing and new programs? (D Weisdorf, US)
- Quality measures: How to incorporate quality into existing and new sites? (HGreinix, Austria)

• EBMT-JACIE accreditation: 10 years of success (J Snowden, United Kingdom) February, **BMT Tandem Meetings** (Honolulu)

Haploidentical HCT – A Global Overview: Comparing Asia, EU, and US

Co-Chairs: Y Kodera (Japan) and J Szer (Australia)

- Introduction
 - WBMT Global Activity Survey (D Niederwieser, Germany)
 - Trends in Haplo HCT (J Apperley, United Kingdom)
- The Asian Experience (X-J Huang, China)
- The EU Experience (A Nagler, Israel)
- The US Experience (E Fuchs, US)

2015

April, EBMT Meeting (Istanbul)*

*During these meetings, the WBMT participated in a plenary session in lieu of a traditional Joint Session. PLENARY: Access to Stem Cell Transplantation in the 21st Century: An EBMT-WBMT Joint Session

Co-Chairs: Y Kodera (Japan) and T Damirer (Turkey)

- Lessons after one million transplants (A Gratwohl, Switzerland)
- Which AML patient should not be transplanted in 2015? (F Appelbaum, US)

February, BMT Tandem Meetings (San Diego)

Global Donor Selection Challenges: Clinical efficacy and cost performance

Co-Chairs: Y Kodera (Japan) and D Weisdorf (US)

- Introduction (Y Kodera, Japan, and D Weisdorf, US)
- Medical Products of Human Origin / World Health Organization (MPHO / WHO WBMT

/ TTS / ISBT / ICCBBA) Project: Regulatory recommendations for MPHO (J Nunez, Switzerland)

- Haplo-HCT without T-cell depletion vs. unrelated vs. related (post-transplant cyclophosphamide) for developing countries (D Niederwieser, Germany)
- Regional cost differences of matched, haploidentical, and cord blood HCT (S Giebel, Poland)
- Report from regional group LABMT (A Seber, Brazil)

2014

April, EBMT Meeting (Milan)

Hematopoietic Stem Cell Transplantation: Access and Affordability

Co-Chairs: D Niederwieser, Y Kodera, D Confer, D Weisdorf, H Greinix

- Non-Government Organization (NGO): Status significance and opportunities of an NGO (J Nunez)
- Cost of non-transplant therapy for hematologic malignancies (J Apperley)
- Alternative donor selection
 - Haploidentical donor (L Luznik)
 - Cord blood stem cell transplantation (M Eapen)

February, BMT Tandem Meetings (Dallas)

Hematopoietic Stem Cell Transplantation: Access and Affordability

Co-Chairs: D Niederwieser, Y Kodera, D Confer, D Weisdorf, H Greinix

- Non-Government Organization (NGO): Status significance and opportunities of NGO (J Nunez)
- Cost of non-transplant therapy for hematologic malignancies (J Apperley)
- Alternative donor selection

- Haploidentical donor (X-J Huang)
- Cord blood stem cell transplantation (D Weisdorf)

2013

April, EBMT Meeting

The Legacy of E. Donnall Thomas: One Million Hematopoietic Stem Cell Transplants

Co-Chairs: D Niederwieser, Y Kodera, D Confer, H Greinix

- E. Donnall Thomas: From Cooperstown to Global (R Storb)
- Challenges to Future Growth: The Transplant Center Perspective
 - Europe (M Mohty)
 - Eastern Mediterranean (M Aljurf)
 - Africa (N Novitzky)
- Challenges to Future Growth: The Donor Registry Perspective (D Confer)
- Challenges to Future Growth: The WHO Perspective (L Noël)
- Improving Research Collaborations to Move Forward (M Horowitz)

February, BMT Tandem Meetings

The Legacy of E. Donnall Thomas: One Million Hematopoietic Stem Cell Transplants

Co-Chairs: D Niederwieser, Y Kodera, D Confer, H Greinix

- E. Donnall Thomas: From Cooperstown to Global (F Appelbaum)
- Challenges to Future Growth: The Transplant Center Perspective
 - North America (R Champlin)
 - Central / South America (C Bonfim)
 - Asia-Pacific (A Srivastava)
- Challenges to Future Growth: The Donor Registry Perspective (D Confer)
- Challenges to Future Growth: The WHO Perspective (L Noël)
- Improving Research Collaborations to Move Forward (J Apperley)

2012

WBMT Scientific Session Chair: D Niederwieser

- WBMT Update (D Niederwieser)
- The Macroeconomics of Hematopoietic Stem Cell Transplantation (A Gratwohl)
- A Global View of Cord Blood Transplantation (V Rocha)
- The Fukushima Nuclear Accident The Transplant Team Experience (S Taniguchi)

2011

WHO and WBMT: A Model for Optimal Collaboration Between Scientists and Health Institutions Co-Chairs: D Confer, Y Kodera, D Niederwieser

- Update on WBMT Activity (D Niederwieser)
- Global HCT Activity Survey 2007-2008 (H Baldomero)
- Report from the APBMT Congress: HCT Activity and Plans for a Vietnam Meeting (Y Kodera)
- Harmonizing Standards in BMT Improving Outcomes on a Global Scale (K Loper)
- WHO and WBMT a Model for Optimal Collaboration Between Scientists and Health Institutions (L Noël)

2010

<u>Worldwide Network for Blood and Marrow Transplantation (WBMT) Session</u> Co-Chairs: D Niederwieser, M Horowitz

- Update on Progress of WBMT (D Niederwieser)
- Challenges in Establishing HCT Outcomes Registries in Developing Countries Asia- Pacific BMT Group (Y Atsuta)
- Eastern Mediterranean BMT Group (M Aljurf)
- Ethical Issues in Donation of Hematopoietic Stem Cells (A Capron)

2009

<u>WBMT International Session (Supported by THERAKOS, Inc.)</u> Co-Chairs: D Niederwieser, S Davies, Y Kodera, M Oudshoorn

• Overview of Unrelated Adult and Cord Blood Donation: the WMDA Annual Survey (M Oudshoorn)

- Unrelated Donor Outcomes and Plans for Assessing Related Donor Outcomes: A Report from the NMDP / CIBMTR (D Confer)
- Related Donor Outcomes from the Japanese Registry: The Importance of Preregistration (Y Kodera)
- Proposal for an EBMT Donor Outcome Registry (J Halter)

APPENDIX G: PUBLICATIONS LIST

WBN	WBMT Publications		
#	Citation	Credited to	
Publi	ished in 2022		
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APPENDIX H: WBMT PRESIDENTS

2007-2009: Founder and chair of initial working party – Dietger Niederwieser

President	Year
Dietger Niederwieser	2010-2014
Yoshihisa Kodera	2014-2016
Jeff Szer	2016-2018
Daniel Weisdorf	2018-2020
Hildegard Greinix	2020-2022
Mahmoud Aljurf	2023-2024

APPENDIX I: TERMS AND ABBREVIATIONS

Term / Abbreviation	Definition
AABB	Association for the Advancement of Blood & Biotherapies
AFBMT	African Blood and Marrow Transplant Group
АНСТА	Alliance for the Harmonization of Cellular Therapy Accreditation
ANZTCT	Australia and New Zealand Transplant and Cellular Therapies Ltd
APBMT	Asia-Pacific Blood and Marrow Transplantation Group
ASTCT	American Society for Transplantation and Cellular Therapy
ASH	American Society of Hematology
BIG V&S SARE	Bologna Initiative for Global Vigilance and Surveillance of Adverse Reactions and Events
BMT	Blood and marrow transplantation
CIBMTR	Center for International Blood and Marrow Transplant Research
CME	Continuing medical education
EBMT	European Society for Blood and Marrow Transplantation
ECDC	European Centre for Disease Prevention and Control
ELN	European Leukemia Network
ESH	European School of Hematology
FACT	Foundation for Accreditation of Cellular Therapy
GTA	Global transplant activity
НСТ	Hematopoietic stem cell transplantation
ІССВВА	International Council for Commonality in Blood Banking Automation
ISBT	International Society of Blood Transfusion
ISCT	International Society of Cellular Therapy
LABMT	Latin American Blood and Marrow Transplant Society
МРНО	Medical products of human origin
NGO	Non-government organization
NMDP	National Marrow Donor Program

WBMT Progress Report 2022

RITN	Radiation Injury Treatment Network
SOHO V&S	Vigilance and Surveillance of Substances of Human Origin
TAS	Transplant Activity Survey
TTS	The Transplant Society
UK	United Kingdom
UN	United Nations
WBMT	Worldwide Network for Blood and Marrow Transplantation
WHO	World Health Organization
WMDA	World Marrow Donor Association

APPENDIX J: LETTER VOLUNTARY FEE WBMT MEMBER SOCIETIES

Worldwide Network for Blood and Marrow
Transplantation

WBMT Voluntary Fee 2022

September 2022

Dear XXX,

I would like to start by thanking you and your organization for your continued support to the WBMT.

With your continued commitment our organization conducted several activities which impacted the diffusion and knowledge of hematopoietic stem cell donation and transplantation at a global level.

Our standing committees organized several well-attended webinars, focusing on multiple topics of global interest and of great impact on hematopoietic stem cell donation and transplantation, but also on other important educational topics in cooperation with various member organizations of WBMT. Traditionally our webinars have well selected topics of global interest and presentations delivered by renowned speakers. Most of our webinar activities were attended by multi-hundred to thousands of participants around the globe from more than 50 countries.

Our WBMT standing committees had very successful and well-attended committee meetings and started new projects such as global analysis of outcome data in myeloma and acute myeloid leukemia, rare infections in hematopoietic stem cell transplantation, important consensus document about HSCT donor and the impact of cryopreservation of hematopoietic stem cells just to mention some. In addition, we have been working closely with WHO on several projects including WHO listing of essential medications, unproven cell therapies and regulatory issues related to HSCT and ATMP.

Our planned workshop in Pakistan end of this month will have more than 20 distinguished international speakers and will help in facilitation the diffusion of HSCT practice in the near east counties and many countries with restricted resources.

To speed up the global survey, a new database has been implemented that will support all providing transplant data and will allow timely publication of our results.

During the last months, important publications from our standing committees have been accepted in high impact factor journals including our publication about Key Elements in Quality Management in HSCT demonstrating the excellent scientific work performed by our members.



Worldwide Network for Blood and Marrow Transplantation

I would like to take this opportunity to thank for your contributions. To further contribute to our core activities, namely educational and scientific activities, and to cover our annual costs (administrative support, global survey, IT support and website), we would also like to ask this year for the annual membership fee of EUR 2,500.00 to be paid before end of November to support important WBMT activities. We very much appreciate your support and we are open to negotiations in case the current situation does not allow you to transfer this fee.

Thank you all for your generous support and looking forward to talking to you during our next Board Meeting.

With best regards,

SlahmondAl

Mahmoud Aljurf, MD, MPH President, WBMT