Committee: World Health Organization (WHO)

Topic: The question of using bone marrow in scientific research

Student Officer: Shichang (Sissi) Zhang

Position: Deputy President

Personal Introduction

My name is Sissi Zhang and I am an IB1 student at CGS. It is my utmost honor and pleasure to be serving as deputy president of WHO in CSMUN 2022. My hobbies include playing tennis, drawing, and watching sunsets. I am going to pursue an interdisciplinary career in the future including neuroscience and media. Speaking about MUN has offered me the intriguing and wonderful experience of being a delegate, ambassador, or chair. The biggest harvest from my previous MUN experience was the powerful mindset I developed in the conferences; it refreshed my world outlook and my self-recognition.

World Health Organization (WHO) is a committee that concentrates on the improvement of health, keeping the world safe, and helping the vulnerable. The committee's goal is to ensure that more people have universal health coverage, protect more people from health emergencies, and provide them with better health and well-being.[1] This study guide discusses the issue "The question of using bone marrow in scientific research". In this study guide, I analyze the topic by providing you with background information such as the process and the details of the most known bone marrow related medical treatment—bone marrow transplant, bone marrow donation together with its relevant legal issues including the sale of bone marrow, ethical issues such as the donors right, and children as donors, the challenges the rising bone marrow registries face,etc. Furthermore, this study guide also offers you

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[1] "What We Do." World Health Organization, World Health Organization, https://www.who.int/about/what-we-do.

past involvements and treaties such as Legal regulations to protect under-aged donors issued by E.U. Member Countries,etc. In the end, one can find the suggested solutions to this issue, in which a range of factors have been considered.

Although this study guide will provide and serve as a strong foundation for your understanding and research of this topic, it should not be regarded as the only source of information throughout your research. Having said that, it is strongly recommended that you do extensive research on your delegation's policy and other related issues. If you have any inquiries, feel free to contact me through email.

With that being said, I wish you good luck with your study and research of the issue, stay healthy and see you at Campion School!

Yours truly,

Sissi Zhang shichangzhang0710@gmail.com

Topic Introduction

Bone Marrow has always been the center of medicine. From its discovery to the first successful bone marrow transplant in 1956, bone marrow has successfully saved millions of lives due to its transplantable and reproducible properties. Until today, in the field of medicine and science, research related to bone marrow is still developing to further improve the effectiveness of bone marrow transplants and decrease the side effects.

Bone marrow transplant (BMT) technologies help patients with hematological cancers such as leukemias and aplastic anemia. A bone marrow transplant can be used to replace diseased, non functioning bone marrow of patients to regenerate a stronger immune system; fight existing cancers; or prevent genetic diseases. For every BMT, there is a transplant team in which groups of professionals are involved in the transplant process and the patient's health care. At first, an extensive evaluation of the patient is completed by the bone marrow transplant team[2], including aspects such as age, overall health, the extent of disease, personal preferences, and so on. After that, bone marrow donors are evaluated for their potential and availability.[3] Once a donor and a recipient are matched, they both undergo additional tests to move to the next step bone marrow transplant procedures.

Scientists have been conducting deep research to seek the scope for improvement in this field. Technologies that involve the use of bone marrow have evolved and turned out to be more and more mature and advanced during these years. But as BMT technologies appear more and more in the public's sight, a lot of donors, ethical and legal issues arose. For instance, in the past years, efforts have been made to make bone marrow donors aware of their full rights because before there were cases in which donors were deceived as they didn't know the true purpose of their donation.

Technology regarding bone marrow can raise a huge conversation of controversy by itself. On one hand, it can't be denied that thousands of lives and families have been saved thanks to it. On the other hand, there are still issues awaiting to be considered, evaluated, and solved in fair, humanitarian, and scientific manners.

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[2] "The First Bone Marrow Transplantation in 1956 Changed Cancer Treatment." Home.cancerresearch, 17 Jan. 2017, https://home.cancerresearch/1956-the-first-successful-bone-marrow-transplantation/.

[3] "Bone Marrow Transplantation." Johns Hopkins Medicine, 8 Aug. 2021, www.hopkinsmedicine.org/health/treatment-tests-and-therapies/bone-marrow-transplantation.

Definition of key terms

Bone marrow transplant (BMT)

A bone marrow transplant is a medical treatment that replaces your bone marrow with healthy cells. The replacement cells can either come from your own body or from a donor.[4]

Bone marrow

The soft, spongy tissue that is found in the center of most bones.[5]

Stem cells

Stem cells mostly live in the bone marrow, they divide to make new blood cells. Stem cells make red blood cells, white blood cells, and platelets. We need all of these types of blood cells to keep us alive.[6]

Bone Marrow Harvest

The bone marrow is harvested and removed while the donor is under general anesthesia. A large needle is put through the skin on the lower back and into the back of the hip bone. The thick liquid marrow is pulled out through the needle. This is repeated until enough marrow has been taken out.[7]

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[4] "What Is a Bone Marrow Transplant (Stem Cell Transplant)?" *Cancer.Net*, 23 June 2021, https://www.cancer.net/navigating-cancer-care/how-cancer-treated/bone-marrowstem-cell-transplantation/what-bone-marrow-transplant-stem-cell-transplant.

[5] "NCI Dictionary of Cancer Terms." *National Cancer Institute*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bone-marrow.

[6] "Answers to Your Questions about Stem Cell Research." *Mayo Clinic*, Mayo Foundation for Medical Education and Research, 19 Mar. 2022, https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117.

[7] "What Are Stem Cells?: Where Do Stem Cells Come from?" *American Cancer Society*, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/stem-cell-transplant/why-stem-cell-transplants-are-used.html.

Haematological (blood cell) cancers

Cancer that begins in blood-forming tissue, such as the bone marrow, or in the cells of the immune system. Examples of hematologic cancer are leukemia, lymphoma, and multiple myeloma. Also called blood cancer.[8]

Chemotherapy

Chemotherapy (and sometimes radiotherapy) is used to kill cancer cells. With the demonstration of successful bone marrow transplantation, doctors were able to use effective doses of chemotherapy and radiation. The higher doses also kill normal bone marrow cells, but now these cells can be replaced with donor cells.[9]

Donor

A person or animal that gives something, for example, an organ or blood.

Recipient

A person or animal that receives something, for example an organ or blood.

Engraftment

Engraftment of the stem cells happens when the donated cells make their way to the marrow and begin making new blood cells.[10]

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[8] "NCI Dictionary of Cancer Terms." *National Cancer Institute*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/hematologic-cancer.

[9] "The First Bone Marrow Transplantation in 1956 Changed Cancer Treatment." *Home.cancer research*, 17 Jan. 2017, https://home.cancerresearch/1956-the-first-successful-bone-marrow-transplantation/.

[10] Raymaakers, Karen. "Discover the Ways Engraftment Shows a Successful Stem Cell Transplant." *Verywell Health*, Verywell Health, 12 Mar. 2022, https://www.verywellhealth.com/what-is-engraftment-2252116.

HLA typing

Human leukocyte antigen (HLA) typing is used to match patients and donors for bone marrow or cord blood transplants.[11]

Donor attrition rate

Donor attrition rate is the rate at which donors do not renew their gifts each year, expressed as a percentage of all active donors in a given year. [12]

Next-generation sequencing (NGS)

Next-generation sequencing (NGS) is a massively parallel sequencing technology that offers ultra-high throughput, scalability, and speed. The technology is used to determine the order of nucleotides in entire genomes or targeted regions of DNA or RNA. [13]

Haploidentical donor

A haploidentical, or half-matched, donor is usually the recipient's parents or child.[14]

Background Information

Bone marrow and Stem cells

There are two kinds of bone marrow: red and yellow. Red bone marrow contains blood stem cells which will become red blood cells, white blood cells, or

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[11] BeTheMatch.org. “HLA Typing Definition.” *Human Leukocyte Antigen (HLA) Typing and Matching | Be The Match*, https://bethematch.org/transplant-basics/matching-patients-with-donors/how-donors-and-patients-are-matched/hla-basics/.

[12] “Donor Attrition Rate.” *Harvey McKinnon Associates*, https://harveymckinnon.com/do-you-know-your-donor-attrition-rate/.

[13] “Next-Generation Sequencing (NGS).” *Next-Generation Sequencing (NGS) | Explore the Technology*, https://www.illumina.com/science/technology/next-generation-sequencing.html.

[14] Wasta, Vanessa. “Haploidentical Transplant: Johns Hopkins Kimmel Cancer Center.” *Haploidentical Transplant: Johns Hopkins Kimmel Cancer Center*, 23 Feb. 2022, https://www.hopkinsmedicine.org/kimmel_cancer_center/cancers_we_treat/bone_marrow_transplant/haploidentical_transplantation.html.

platelets. Bone marrow stem cells are different from other blood cells thanks to their properties which are ability to renew, to breed another cell identical to them; their ability to differentiate, to make into other forms of cells. In a bone marrow transplant, it is the stem cells from the red blood cells that are needed. Relatively, the hematopoietic stem cell transplantation (HSCT) activity refers to the transplantation of stem cells, usually derived from bone marrow, peripheral blood, or umbilical cord blood. But in the case of bone marrow transplant (BMT), physicians only extract stem cells from bone marrow.

The procedure and complications of bone marrow transplant

The first ever successful bone marrow transplant was performed by Dr E. Donnall Thomas in the U.S.A. in 1956. This milestone like transplantation involved a pair of twins. With the extraction of bone marrow from the healthy twin, and given to the other, who had leukemia, the first bone marrow transplant broke the glass ceiling in the field of medicine. Bone marrow transplant (BMT) is a special therapy for patients with certain cancers or other hematological diseases. A bone marrow transplant engages in extracting cells that are originally found in the bone marrow, filtering those cells, and giving them back either to the donor or to another patient who is in need. To date, bone marrow transplant has been used successfully to cure diseases such as leukemias, severe aplastic anemia, lymphomas, multiple myeloma, immune deficiency disorders and some solid-tumor cancers under uncommon circumstances.

Historically, before the appearance of the leading bone marrow transplantation, high doses of chemotherapy, enough to kill all the cancer cells, could not be used, due to the fact that they also killed the functional cells in the bone marrow. However, as there are more and more successful bone marrow transplantation cases, doctors were able to use higher and more effective doses of chemotherapy and radiation. These higher doses kill normal bone marrow cells, but now these cells can be replaced with donor cells thanks to BMT technologies. Apart from that, a bone marrow transplant can be used to renew an immune system that will fight the residual leukemia or other cancer cells which are not killed by the chemotherapy or radiation, to replace unhealthy bone marrow with genetically well-functioning bone marrow to avoid more damage from a genetic disease. Bone marrow harvesting means collecting stem cells by placing a needle into the soft center of the bone, the marrow. The hip bones and the sternum are the most common bone marrow harvesting location. The procedure takes place in the operating room and as the donor will be anesthetized during the harvest, the needle won't be felt.

There are complications and side effects of BMT. On one hand, bone marrow donors may experience fatigue, soreness and bruising where the needle was inserted after donating. These side effects last for from a few days to several weeks in the most cases. On the other hand, bone marrow recipients, during infusion of bone marrow, may experience pain, chills, fever, hives, chest pain. After infusion, the patients could also be liable to infection, they may experience excessive bleeding and need blood transfusions or to lean on medicine to forestall graft if the transplant was allogeneic. The transplanted new cells tend to attack the patient's tissues, whether or not the donor could be a relative. Consequently, the patient may experience nausea, vomiting, diarrhea, mouth sores, temporary mental confusion and emotional or psychological distress.

According to the research, from 1957-2016 a total of 1,298,897 Hematopoietic Stem Cell Transplants (HSCT) (57.1% autologous) procedures were collected. By the end of 2016, hematopoietic stem cell transplantation (HSCT) activity was reported from 87 of the 195 WHO member states. A total of 89,070 HSCT from 1662 centers were reported in 2016. [15]

Although there are many successful cases in the field of BMT and HSCT, technical issues are still brought up to the public such as physical side effects such as infections, low platelets; low red blood cells and organ damage that may happen in the transplantation process. Ethical issues include, for instance, concerns about the rights of donors, and the allocation of resources.

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[15] Niederwieser, Dietger, et al. "One and Half Million Hematopoietic Stem Cell Transplants (HSCT). Dissemination, Trends and Potential to Improve Activity by Telemedicine from the Worldwide Network for Blood and Marrow Transplantation (WBMT)." *Blood*, vol. 134, no. Supplement_1, 2019, pp. 2035–2035., https://doi.org/10.1182/blood-2019-125232.

Donor-recipient match process

To be a donor one needs to have stem cells that match the patient they are donating to. Matching is associated with typing human leukocyte antigen (HLA) tissue. The antigens on the surface of these special white blood cells determine the genetic makeup of a person's immune system.[16] The laboratory staff take the samples of HLA of the potential donor and recipient to compare the surface of these blood cells. The more antigens that match, the better the donated marrow engraft in the recipient's body. There are different types of BMT, which include the autologous bone marrow transplant, in this case, the donor is the patient themselves. Stem cells are taken from the patient by bone marrow harvest, filtering, frozen, and then given back to the patient after intensive treatment. Another type of BMT is allogeneic bone marrow transplant, stem cells are taken by bone marrow harvest from a matched donor who has high bone marrow compatibility with the patient, and then given to the patient in need. In most cases, the donor in the allogeneic bone marrow is a related donor, which mean a sibling of the recipient, since the patient only has two of each chromosome, one they received from each of parents, a full sibling of a patient in need of a transplant has a 1 in 4 chance of having gotten the same set of chromosomes and being a "full match" for transplantation.[17] Other donors for allogeneic bone marrow transplants may include a parent or unrelated bone marrow transplants (UBMT or MUD for matched unrelated donors).

Funding of registry in developing countries

Maintaining a well functional registry costs a lot of money. Each step requires financial expenses, the cost includes the donor recruitment, education events for the public, HLA typing, other ancillary tests, laboratory maintenance, wages, donor collection facilities, software, etc. Besides that, the costs of maintaining contact with

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[16] Choo, Sung Yoon. "The HLA System: Genetics, Immunology, Clinical Testing, and Clinical Implications." *Yonsei Medical Journal*, vol. 48, no. 1, 2007, p. 11., https://doi.org/10.3349/ymj.2007.48.1.11.

[17] "Bone Marrow Transplantation." *Johns Hopkins Medicine*, 8 Aug. 2021, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/bone-marrow-transplantation.

and communication with potential donors represent an important financial problem for developing countries. This has led to the preferential and broad use of hematopoietic cell transplantation (HCT) by high-income countries but appears to be unaffordable for a lot of lower income countries in Asia, Africa and so on. Funding of a new regional or country registry is the main financial burden especially in the first steps of establishing the registry and before the registry is functional in providing donors resources and allocating them. Usually, the funding is followed by two pathways, government funding and charity, either from private companies or patient support organizations.

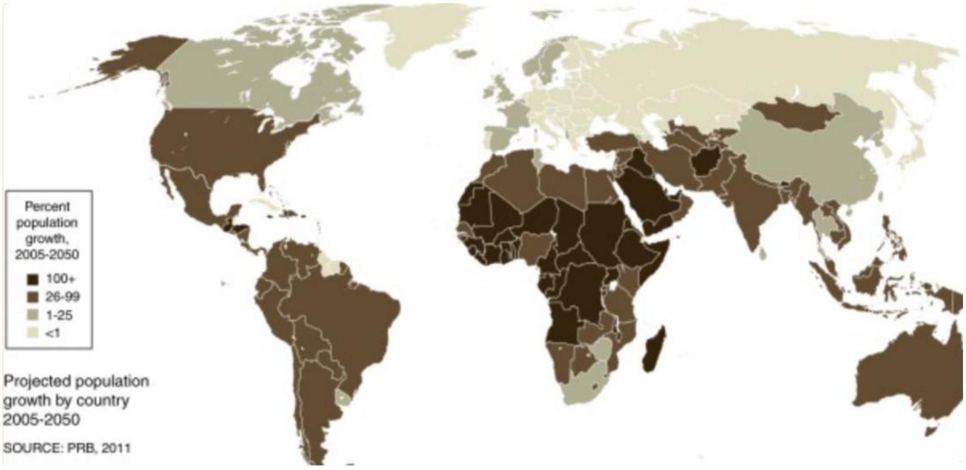
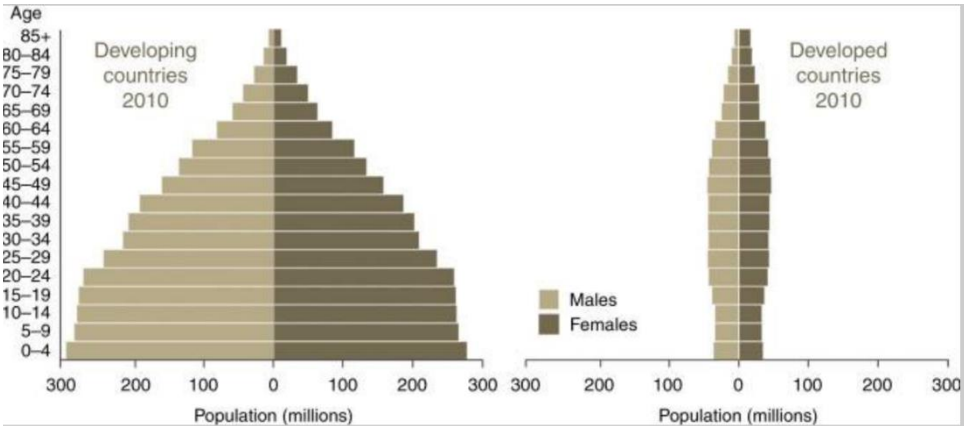


Fig. 1: shows that population growth that will occur in developing countries from 2005 to 2050 is higher than developed countries. [18]



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[18] “Projected Population Growth by Country 2005–2050.” Https://Www.ncbi.nlm.nih.gov/Pmc/Articles/PMC6760540/, 18 Feb. 2019.

Fig. 2: shows the growing population in developing countries are mainly younger people , which will accelerate the fast population growth and increase the demand on medical needs as compared with other developed countries. [19]

©E. Petersdorf. Bone Marrow Transplant. May 2010
https://www.nature.com/articles/bmt201010#f1

Fig. 3: shows the location and the numbers of unrelated bone marrow donor registries globally and highlights the limited number of registries in developing countries outside North America, Europe, and East Asia. [20]

Decreased donor availability

Existing registries aim to improve donor availability for the country or region with its unique HLA phenotype spectrum. The appropriate registry size relies on different factors including target population size, homogeneity of the population, and haplotype frequency distribution.[21] HLA haplotype frequencies are also a helpful tool to determine the most appropriate composition and optimal size for an effective registry to function well. The mixing and ethnic diversity of a population extends the frequency of novel haplotypes and thus making the search process for a suitable donor complicated. For example, in comparison with the rest of the world, more than 1/3 of

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[19] "Age Distribution in Developing versus Developed Countries." *Https://Www.ncbi.nlm.nih.gov/*, 18 Feb. 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760540/figure/Fig3/.

[20] "Location of Unrelated Donor Registries Worldwide." *Https://Www.ncbi.nlm.nih.gov/*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760540/figure/Fig4/.

[21] Aljurf, Mahmoud, et al. "'Worldwide Network for Blood & Marrow Transplantation (WBMT) Special Article, Challenges Facing Emerging Alternate Donor Registries.'" *Bone Marrow Transplantation*, Nature Publishing Group UK, Aug. 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760540/.

HLA types within the Indian population are unique and peculiar.[22] Differently, in Saudi Arabia, a more homogeneous country, the chance of finding a 10/10 matched unrelated donor (MUD)is projected to be ~50% with a registry size of one million donors. Another homogenous country is Japan where 8/8 HLA-matched donors are found for 96% of the patients.[23] In conclusion, the more heterogeneous the indigenous make-up of a country or of a region, the larger the registry size needed to assure donor availability and registry cost-effectiveness. In conclusion, the more heterogeneous the indigenous make-up of a country or of a region, the larger the registry size needed to ensure donor availability and registry cost-effectiveness. Gathering a large number of voluntary donors and minimizing donor attrition rates is challenging for multiple reasons, such as the lack of awareness, ethnic, religious, and other factors such as prevalence of infectious diseases in certain populations and BMI higher than 40 all belong to relative exclusion criterion for donation. A US study once stated that people from the white population have 30% higher possibilities to donate compared with other racial groups.[24] On the other hand, many minorities give objections to donation and report less trust in stem cell transplantation due to their ethical and religious beliefs.

HLA typing

HLA typing by PCR testing was firstly introduced by biochemists Mullis and Faloona in the 1980s in the U.S. Scientists discovered that the method of sample collection for HLA typing, namely through blood, finger stick or buccal swab, etc. can have an impact on the amount of DNA collected for testing and as such affect the failure rate of the test. Several PCR techniques are currently available, including DNA amplification with sequence-specific primers (SSP), single-strand conformation

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[22] Jangi S. Problems of creating bone marrow donor registries in emerging economies. BMJ. 2013;346(may10 1):f2976–f2976. doi: 10.1136/bmj.f2976.

[23] Al-Awwami Moheeb, Aljurf Mahmoud, Al-Humidan Hind, El-Solh Hassan, Almeshari Khalid, Al-Seraihy Amal, Ayas Mouhab, Aldawsari Ghuzayel, Al-Dayel Fouad, Freeman John, Madbouly Abeer, Maiers Martin, Gragert Loren. 85-P. Human Immunology. 2012;73:106. doi: 10.1016/j.humimm.2012.07.211.

[24] witzer Galen E., Bruce Jessica G., Myaskovsky Larissa, DiMartini Andrea, Shellmer Diana, Confer Dennis L., Abress Linda K., King Roberta J., Harnaha Allyson G., Ohngemach Sibylle, Dew Mary Amanda. Race and ethnicity in decisions about unrelated hematopoietic stem cell donation. Blood. 2013;121(8):1469–1476. doi: 10.1182/blood-2012-06-437343. [

polymorphism (SSCP), sequence-specific oligonucleotide probes (SSO), sequence-based typing (SBT), DNA chip technology, and next-generation sequencing (NGS).[25] These techniques provide the lab staff with better certainty and are more reliable than the traditional serologic methods, and definitely help to standardize and regulate HLA-typing methods. Today, accelerated progress in NGS technology has led to revolutionary advances in genomics. The use of NGS technology for HLA typing results in high-throughput and high-resolution capabilities as compared with traditional PCR-based techniques. Until now, several high-throughput HLA-typing methods using NGS have been developed. Consequently, it will be more feasible and efficient for a new established registry to adopt NGS-based typing, and probably it can be more advantageous to outsource HLA typing to applicable and specialized laboratories to achieve more cost-effective pricing and proper standardized testing outcomes.

Information technology in rising registries

In this case, information technology (IT) is an essential tool to conduct donor searches, to analyze HLA-haplotype frequencies, to predict the possibilities of finding a donor for each patient and to allocate resources fairly. In the past, most of the sizable international registries developed their own software with internal and external IT staff or companies to process the searching and matching process for a start. These internal software programs are usually complicated and tightly eligible to the regional needs. However, they are not applicable commercially and thus not available for rising registries.

In fact, establishing an in-house program is costly, time-consuming and it needs a high level of expertise, which is an especially burdensome process for small and medium-sized local registries. However, acquiring a home-grown software means an independent and tailored solution for local needs. Such implications appear in Be The Match, France Greffe de Moelle (FGM), etc.

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[25] Aljurf, Mahmoud, et al. "'Worldwide Network for Blood & Marrow Transplantation (WBMT) Special Article, Challenges Facing Emerging Alternate Donor Registries.'" Bone Marrow Transplantation, Nature Publishing Group UK, Aug. 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760540/.

Recently, some software packages for donor registries are now available commercially in the market. The existing pricing differs from ~35 dollars per month to ~1400 dollars for installation depending on multiple factors like the marketing segments, languages supported, software categories and so on. This method offers Clear customer–vendor relationship which facilitates effective implementation of changes, timely updates, etc. However, there is a limited number of vendors and the prices may be unaffordable if the registry has limited budget. Examples of registries which use a commercial system are registries in Belgium, Finland, Sweden, South Africa, the UK and so on.

Except for the establishment of a brand new one software, partnering with an existing registry that has already developed an IT system is another way to acquire software. It is inexpensive and handy since potential difficulties might have been faced by the partner. But the disadvantages include the limited control of the software system such as that partner registry may always prefer their own interests and their own requests for change. Registries which use such implications are The New Zealand Bone Marrow Donor Registry, Singapore Bone Marrow Donor Program, Thai Stem Cell Donor Registry, the Australian Bone Marrow Donor Registry software system and so on.

No matter which way of acquiring a registry software is used, the modal software should cover all key business processes of the registry such as donor and patient data management, export information and data to Bone Marrow Donors Worldwide (WMDA)[26], international donor search, management of requests, finances, cases records and donor/patient situation follow-up.

Sale of bone marrow

The sale of organs has been a serious phenomenon that has caused attention in the society for the past years. If people were allowed to sell their organs, it would result in the apparent exploitation of the vulnerable groups in the society such as the poor, college students, children, elders, etc. Bone marrow, despite being a

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[26] *WMDA*, 25 July 2022, https://wmda.info/.

replenishable organ, the National Organ Transplant Act of U.S.A banned its sale in commerce in 1984. The penalty for one who buys or sells bone marrow includes a fine of not more than 50000 dollars or imprisonment for not more than five years or both.[27]

Minors as donors

In the case of a minor who is going to be a donor for their sibling, for example the kidney, it is conventional to ask for a court order to grant the donation. Based on the concept that the donor child gets benefit from the continued life of the sick sibling, nearly all courts have approved these orders. Thus, the courts' basic criterion for granting is that a child gains more from a complete home and the lifelong sibling relationship than they would from growing up with two kidneys. Other courts have discarded this concept of “happy home outweighs individual choice” and have simply allowed the parents to make a decision about the donation from one of their healthy children to a sick child based on the familial cost-benefit analysis. A special case was that the Louisiana courts in the U.S.A once denied to grant a child with cerebral palsy, whose ability to create and enjoy a relationship is minimal even at his best, to donate a kidney for his adult sister. The Louisiana court explained that it would make very little difference to the boy if his sister was alive or dead since his capability to benefit from the relationship with his sister is marginal. Court orders have to be requested due to the fact that parents who are traumatized by making decisions between a severely ill child and one healthy child are not at an objective position to decide logically and fairly. In the case of allogeneic bone marrow transplantation, it is obligatory to acquire both the consent of the donor and the consent of parents of the recipient. Information of the transplantation and possible side effects to parents of both children must be detailed.

Organ donation has risky factors, especially for minors, the process of kidney removal involves risk, there are also some risks internal in the donor's growing up process with only one kidney. In the case of bone marrow, although it regenerates, the long-term risks are totally different from the issues present in kidney donations by

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[27] Holder, A R. “Legal Issues in Bone Marrow Transplantation.” *The Yale Journal of Biology and Medicine*, Yale Journal of Biology and Medicine, 1990, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2589369/?page=2.

minors. In fact, there are approximately no risks for the child donor and, if any, they are related to the general anesthesia. For a minor who is old enough to discuss and understand the donation procedure but who refuses to be a donor is not coerced to follow the next steps of donation. Because a teenager, even though younger kids, may understand the procedure, the beneficial and risky factors involved in this kind of donation, but as persons under 18 years old are as a group, they can't give a legally valid consent. If the child is too young to understand the procedure and give voluntary consent, the parents would have to request the authorities to consent.

The medical care personnel who care for children with hematological diseases are often faced with ethical and legal issues. Hospitals hosting a BMT Unit must reach several demands to guarantee the best results when faced with the unexpected events such as possible complications and complexity, difficulties and challenges in transplantation, the requirements are such as a sufficient blood bank, a well-functional infectious diseases department, available consultants, playworkers, teachers, psychologists, and social workers, etc.

Ethical issues

There are several cases which dealt with adults who have tried to coerce their relatives to be tested for bone marrow compatibility. According to the federal regulations for human subject research, the informed consent requirement states that no matter which procedure is being conducted, the prospective subject has the right to refuse to participate without loss of benefits to which they are otherwise permitted. Thus, no court and no one has the authority to compel such participation. If adults cannot be coerced by courts to be donors, it is even less likely that a parent's refusal to permit his child to be a donor would ever be overridden by a court. Theoretically, the courts held that the word "donation" means "gift" and court orders are forbidden to use to compel “gifts”. There is one law that regulates that no one's body can be used compulsorily for the benefit of another.

In one famous case from Iowa in the U.S.A, a man who was critically ill to nearly death and could not find a bone marrow donor discovered from an employee at the University of Iowa Registry that, according to their data, somewhere there was a woman who would be a perfect match for the transplantation. She had been typed before because her son once needed bone marrow. When the Registry contacted her two times to ask if she would be willing to be a donor for this unrelated patient, she declined. The man then sued to enforce the registry to release her name and address so that he could contact her directly and beg for her help. In the end, the trial judge and the Supreme Court of Iowa both considered that release of a donor's name and address without her consent would be an invasion of her privacy, and thus the patient had no right to this information.

Major countries and organizations involved

United States of America

Since 1990, when The Nobel Prize was awarded to Americans Dr Joseph Murray and Dr E Donnall Thomas for their pioneering work in kidney and bone marrow transplantation, the United States deeply contributed to understanding the field of bone marrow transplants and accordingly developed advanced technologies. It was one of the countries which initially organized national and international organizations and programs to provide resources to those in need of bone marrow. Some of the programs established were National Marrow Donor Program (NMDP) and BE THE MATCH.

India

The number of bone marrow transplants is on a consistent rise in India, with about 2,500 transplants being performed yearly.[28] In India, there are five organizations listing donors for international recipients: BMST India as an intermediary of DKMS Registry (21,695 donors), Be the Cure Registry-Jeevan Foundation (6449 donors), Datri Blood Stem Cells Registry (367,561 donors), GeneBandhu (7,991 donors), and

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[28] Bureau, EH News. "How India Can Steer Availability of Bone Marrow Transplant Meeting a Range of Blood Therapy Needs." Express Healthcare, 2 Jan. 2022, www.expresshealthcare.in/news/how-india-can-steer-availability-of-bone-marrow-transplant-meeting-a-range-of-blood-therapy-needs/432778/.

the Marrow Donor Registry India (MDRI) (35,768 donors).[29] According to a local report, though the number of BMT centers is increasing, it satisfies less than 10% of the actual requirement in India. An INR 500-1000 (about 6 dollars to 12 dollars) per injection is affordable for any middle-class family in India. The whole therapy should not be over INR 5 lakh (about 6255 dollars), if affordable for local people, whereas a patient is always billed with INR 18-38 lakh (about 22512 dollars to 47525 dollars). Even today, 90-95 per cent of the population cannot afford it. Moreover, the chance of finding a matched unrelated donor at 10/10 low resolution level is only 19% due to its high ethnic variety, the chances of finding a donor at high-resolution 10/10 level is even less in India.[30]

The generic drug therapy in India is much lower than the rest of the world such as North America, Australia or Europe besides a low consultation fee and hospital charges. The fact that the BMT treatment in India costs only 1/10 of the costs of BMT in the rest of the world attracts international medical tourists who can afford the costs of BMT in India more than they could in their own countries.

Brazil

In 1979, Hematopoietic stem cell transplantation (HSCT) first began in Brazil. However, although there are about 70 transplant centers in Brazil now, the HSCT data reporting (DR) for a local database has not been made feasible yet, which makes the scientific and international access to the database very difficult. Efforts have been implemented to encourage Brazilian centers to improve the registration of transplants in International Research Blood and Marrow Transplant Research (CIBMTR) such as presentation meeting to introduce CIBMTR and sensitize the transplant center teams to the impact of data registry on the researches, collaborating with the global scientific community to HSCT advances. Other challenges include understanding the data flow and identifying the data to be reported, not being able to take part in online training

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[29] "Total Number of Donors and Cord Blood Units." WMDA Total Number of Donors and Cord Blood Units, statistics.wmda.info/.

[30] Dedhia Leenam, Parekh Sunil. Challenges faced by bone marrow registries in India. Indian Journal of Transplantation.

because all of them are offered in English language, the setting up of the Doctorate of Medicine (DM) team and implementing a process to help data collection. Some solutions proposed are the creation of an exclusive email to receive exams and other information about the patients involved in the project, the participation of the DM nurses in the weekly professional meeting and in the daily medical visit to the inpatients and the participation in local and international events addressed to DMs to share and exchange knowledge and experience with other DMs in other transplant centers and to value the data registry as an opportunity to check and detail information. Despite the above strategies, the lack of infrastructure and personnel dedicated to the collection and systematic recording of data and the fact that DMs are not full time dedicated to the project are still issues in Brazil.

The Federal Republic of Germany

Germany now has the second largest blood stem cell and bone marrow donor register worldwide which has access to over 10 million donors. These donors are maintained in around 30 different files from all regions of Germany. A significant proportion of the previously recorded 2.8 million blood stem cell donors in Germany are recorded in the files. [31]

There are currently about 32,000 blood stem cell donors in their files and registered in the “Central Bone Marrow Donor Registry for Germany " (ZKRD) [32] The operational system of ZKRD is worth noting. ZKRD has 8 respective departments focusing on the fields of Search and Transplantation Service, Transport Product Service, Finance and Billing Service, Information Technology (IT), Quality Management, Human Resources (HR), Office Management and Public Relations (PR).

Search and Transplantation Service aims at coordinating the entire process from search request to stem cell transplantation, including searching for unrelated

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[31] Co., deltacity.NET GmbH &. “German Red Crossblood Donor Service North-East.” Bone Marrow Donors, en.blutspende-nordost.de/bone-marrow-donors/.

[32] “Central Bone Marrow Donor Registry for Germany" (ZKRD)., www.zkrd.de/?lang=en.

blood stem cell donors and responding to requests for suitable donors from search centers and transplant centers in Germany and abroad, ensuring compliance with safety standards and coordinating the preparations for blood stem cell collection. Transport Product Service organizes and ensures that the transportation of stem cell products from peripheral blood or bone marrow from unrelated donors is reliable and safe by coordinating with stem cell couriers with the customs office and airport security. Finance and Billing Service works on clarifying the question of costs regarding the different transplant program, it also handles the payment and billing of all patient-related services, from donor search to transplantation.

The IT team is responsible for maintaining the information and communication software, supporting employees internally with any hardware or software issues at the ZKRD but also enhancing and/or newly developing its components. At ZKRD, they have specialized in home software named Opti Match matching software, which benefits smooth operations, national and international data exchange. The Quality Management team at the ZKRD works for the establishment of an environment and processes that guarantee the quality of the products and services supplied to patients and serve to protect donors nationally and internationally. HR teams manage the recruitment of staff with various qualifications and expertise needed to reach the requirements of coping diverse and complex tasks involved in searching for a stem cell donor, apart from that, HR team pursues personal development such as trainee support, continuing professional development for internal employees. Office management team works for handling administrative tasks for their colleagues in other departments such as answering calls, email from inquiries from patients, donors, doctors or potential partners. The PR team is responsible for issuing regular press releases, talking with journalists preparing informational brochures, annual reports and articles to give adequate information about all aspects of the donor search for interested parties.

Europe

The following two sets of statistics describe the stem cell transplantation data comparison from countries in Europe. It is an obvious tendency that the most developed countries in the medical field conducted more stem cell transplantation cases than the countries with less advanced medical Infrastructure.

According to the data from 2017, over 30 000 patients in the European Union (EU) underwent the stem cell transplantation to replace the destroyed stem cells from healthy ones. Germany hit the highest number of stem cell transplants with 7700 cases, France with 5500 cases, Italy with 5100 cases, the United Kingdom with 3800 cases and Spain with 3100 cases. The absolute numbers of stem cell transplants across Member States have been adjusted to the size of the national population in order to make comparison between countries clearer. Thus, with 9.3 stem cell transplants per 100 000 inhabitants, Germany registered the highest rate among the EU Member States in 2017. It was followed by Italy (8.5), France (8.3), Sweden (8.1) and Lithuania (8.0). At the opposite end of the scale, with no stem cell transplants in 2017, the lowest rates were recorded in Malta and Slovenia, followed by Romania (1.6), Bulgaria (2.0) and Cyprus (2.3). [33]

Data from 2018 demonstrates that with 9.6 stem cell transplants per 100 000 inhabitants, Germany registered the highest rate among the EU Member States in 2018, followed by Italy (9.4), France (8.6), Belgium (8.4), the Netherlands (8.4) and Sweden (8.2). On the other hand, if recognized oppositely, it shows Malta with no stem cell transplants per 100 000 inhabitants, followed by Cyprus (1.2), Romania (1.8), Bulgaria (2.3) and Poland (3.7). [34]

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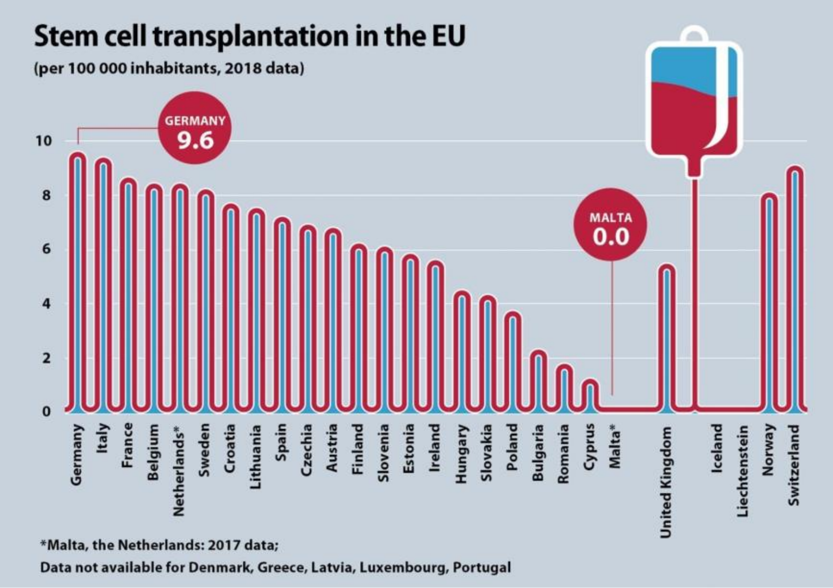
[33] “Stem Cell Transplantation in the EU.” Stem Cell Transplantation in the EU - Products Eurostat News - Eurostat, ec.europa.eu/eurostat/web/products-eurostat-news/-/EDN-20191011-1.

[34] “Stem Cell Transplantation in the EU.” *Stem Cell Transplantation in the EU - Products Eurostat News - Eurostat*, ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20201010-1.

*The Netherlands: 2014 data; ** Spain, Portugal: 2015 data.
Data not available for Denmark, Greece, Latvia and Luxembourg.

ec.europa.eu/eurostat

Fig.3 shows the absolute numbers of stem cell transplants which have been adjusted to the size of the national population across EU Member States in 2017[35]



*Malta, the Netherlands: 2017 data;
Data not available for Denmark, Greece, Latvia, Luxembourg, Portugal

ec.europa.eu/eurostat

Fig4. shows the absolute numbers of stem cell transplants which have been adjusted to the size of the national population across EU Member States in 2018[36]

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[35] Stem Cell Transplantation in the EU in 2017. ec.europa.eu/eurostat/documents/4187653/9451024/Stem+cell+transplantation+2017/74c97f7b-68f9-7baa-0a4c-732457639a9b?t=1570724010973.

[36] Stem Cell Transplantation in the EU in 2018. ec.europa.eu/eurostat/documents/4187653/10321620/Stem+cells+transplants.jpg.

The Center for International Blood and Marrow Transplant Research(CIBMTR)[37]

The Center for International Blood and Marrow Transplant Research (CIBMTR)is a research collaboration between the National Marrow Donor Program (NMDP)/Be The Match and the Medical College of Wisconsin (MCW).

The CIBMTR collaborates with the global scientific community to lead and conduct studies to advance the BMT technologies worldwide to increase survival and enrich quality of life for patients. CIBMTR collects, maintains and provides access to outcomes data from the transplant centers from all over the world. It also provides access to research repository samples, statistical expertise to researchers.

Worldwide Marrow Donor Association (WMDA)38

Based in Leiden, Netherlands, World Marrow Donor Association (WMDA) is an organization which coordinates the collection of the HLA phenotypes and other relevant data of volunteer stem cell donors across the globe. WMDA aims at promoting global collaboration to share the best practices and potential donor data between its members for the benefit of donors and patients.

National Marrow Donor Program (NMDP)

Established in 1988 in Saint Paul, Minnesota, U.S. The National Marrow Donor Program (NMDP) is a non-profit organization dedicated to establishing a system that provides transplants of bone marrow and other hematopoietic cells from volunteers, unrelated donors for individuals with leukemia and other life-threatening blood diseases.[39] Its registry maintains almost 3 million marrow donors worldwide and there are a few hundred donor centers collection centers, transplant centers, and several

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[37] "The Center for International Blood and Marrow Transplant Research (CIBMTR)." *Cibmtr.org*, www.cibmtr.org/Pages/index.aspx.

[38] *WMDA*, 25 July 2022, https://wmda.info/.

[39] Sencen, Lisa. "National Marrow Donor Program." NORD (National Organization for Rare Disorders), 3 Aug. 2020, www.rarediseases.org/organizations/national-marrow-donor-program/.

recruitment centers under its network inside the U.S., some countries in Europe and Asia. Be The Match[40] is one of the most well-known organizations operated by NMDP. It is a nonprofit organization that engages in helping every patient get the transplant they need by providing the ground-breaking research, innovative technologies, patient support and education. To date, Be The Match have conducted more than 111,000 blood stem cell transplants.

Timeline of events

Early 1900s	Doctors make the first ever attempt to treat patients with a donor's bone marrow. However, this treatment is unsuccessful, as the bone marrow is given by mouth.
1956	The first successful bone marrow transplant between related donors was performed by Dr. E Donnall Thomas in New York.
1958	French immunologist Dr Jean Dausset identified human leukocyte antigens (HLA)
1973	First bone marrow transplant between unrelated patients. A 5-year-old patient in New York with severe combined immune deficiency (SCID) is treated with multiple infusions of bone marrow from a donor in Denmark.
1978 May 29th	The European Council declared the principles concerning organ transplantation for the Member Countries
1988	The worldwide register of bone marrow donors – World Marrow Donor Association (WMDA) is established.
1990	The Nobel Prize is awarded to Americans Dr Joseph Murray and Dr E Donnall Thomas for their pioneering work in kidney and bone marrow transplantation, respectively.

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[40] BeTheMatch.org. "About Us." Donate Marrow or Blood Stem Cells, www.bethematch.org/.

2007	The number of donors and cord blood units registered on the Bone Marrow Donors Worldwide (WMDA) database passes 11 million.
2014	World Marrow Donor Day (WMDD) is established, it is celebrated all over the world every 3rd Saturday of September.
2020 July 17th	Mrs. Vardinoyannis is declared to be one of the two laureates of the United Nations 2020 Nelson Rolihlahla Mandela Prize.

Previous attempts to solve the issue

Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) [41]

This Convention is the first legally promissory international text aimed to sustain human dignity, rights and freedoms, through guidelines, principles and prohibitions against the misuse of biological and medical technologies. The principles include aspects of bioethics, medical research, consent, rights to private life and information, organ transplantation, public debate etc. According to the treaty, the treatment of persons unable to grant their consent, such as children and vulnerable people, may be carried out only if it could offer real and direct benefit to their health. The Convention constrains the removal of organs and other tissues which are not replenishable in the human body. The only exception is in the case of regenerative tissue, especially bone marrow, between siblings under certain conditions.

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[41] “Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.” Treaty Office, www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164.

This convention had signatures not followed by ratifications from 7 countries and ratifications /accessions from 29 countries.[42]

Legal regulations to protect under-aged donors issued by E.U. Member Countries. [43]

Allogeneic bone marrow transplantation in the E.U. is a conventional treatment, thus, specific legal procedures are required to protect under-aged donors. As the International Convention on children's rights stated that the minor has the right to give their opinion, which must be taken into consideration. The European Council declared the principles concerning organ transplantation for the Member Countries on 29th May 1978.[44] These guidelines decreed obtaining written consent from the donor or their guardian.

In France, an ethics committee must inform the minor about the consequences of the procedure, respect their own will and obtain consent from them. In Luxembourg, the Department of Health grants the operation only if written consent as well as authorization can be permitted by three experts, including two physicians. In Spain, an ethics committee must obtain the minor's consent and then be approved by a government authority and signed by a physician. In the UK, an N.H.S. directive (1st Aug. 1993) states that children over 16 years old must give consent by themselves to decide to be a donor or not.[45] In Germany minors over 14 years old are allowed to give consent on their own. In Belgium minors between 15 and 18 must witness the written consent process, counter-signed beside the guardian and approved by a

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[42] "Full List." Treaty Office, www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164.

[43] L;, Massimo L;Manfredini. "[Legal Regulations to Protect under-Aged Donors Issued by E.U. Member Countries. Analysis of the Present Situation and Proposals]." Minerva Pediatrica, U.S. National Library of Medicine, www.pubmed.ncbi.nlm.nih.gov/11309544/.

[44] European Parliament. Organ Donation and Transplantation, www.europarl.europa.eu/RegData/etudes/BRIE/2020/649363/EPRS_BRI(2020)649363_EN.pdf.

[45] "Children and Young People -Consent to Treatment." *NHS Choices*, NHS, www.nhs.uk/conditions/consent-to-treatment/children/.

physician. In Portugal a verbal consent by the minor and the guardian is acceptable. In Denmark the guardian's written consent is needed no matter what.

In conclusion, most of the E.U. countries have applied certain legal procedures to protect the rights of under-aged donors from being exploited.

Relevant UN Resolutions, Events, Treaties and Legislation

United Nations 2020 Nelson Rolihlahla Mandela Prize to Marianna V. Vardinoyannis

Mrs. Marianna V. Vardinoyannis is a Greek philanthropist and advocate for human rights, children welfare, and healthy infrastructure improvement for over 30 years. She created the first Bone Marrow Transplant Unit in Greece which is called "ELPIDA", meaning "hope" in 1993 which helped 1200 children from Greece, the Mediterranean and Balkans to receive bone marrow transplants without the need of paying. In 2010, the creation of the first Pediatric Oncology Hospital in Greece was under her name; to date, 150,000 hospitalizations of children have been recorded. In 2014, her establishment of the Bone Marrow Donor Registry which provides transplants for children and adults from all over the world. In 2020, she set up the first ever Cell and Gene Therapy Center in Greece.

On 17 July 2020, the President of the 74th Session of the UN General Assembly, Mr. Tijjani Muhammad-Bande, announced Mrs. Vardinoyannis as one of the two laureates of the United Nations 2020 Nelson Rolihlahla Mandela Prize. This prize recognizes those who dedicate their lives to the service of humanity while honoring Nelson Mandela's extraordinary life and legacy of reconciliation, political transition, and social transformation.[46] For the past 30 years, Marianna V. Vardinoyannis fought not just cancer but also the prejudice towards cancer patients by promoting the purpose and principles of the United Nations.

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[46] "'It Is Worth Fighting for Even One Child's Life' | Africa Renewal." *United Nations*, United Nations, www.un.org/africarenewal/magazine/july-2020/it-worth-fighting-even-one-childs-life.

Possible solutions

Increasing awareness

Conducting awareness campaigns and counseling parties or groups of people who carry doubts about BMT are great chances to assist overcome fears and myths, thus increasing the number of recruitments, and donor commitment, and minimizing attrition. Moreover, educating the general public regarding various conditions that can be cured by transplantation may attract more volunteers to be engaged, diffusing the mission of the alternate donor registry and expanding registry size. Recruiting regular platelets and blood donors is useful as these donors are usually motivated to donate and already familiar with the bone marrow harvest procedure, so it is more likely for them to contribute more than once. Reaching out intently to key influencers and public figures in the society, collaborating with schools and organizations, using vaccination campaigns strategies, new educational tools, and platforms such as conducting social media campaigns, educational programs, and speeches to educate people about bone marrow donation and its benefit, breaking down the stereotypes and fears for it. Including relevant bone marrow information and content in school textbooks and school biology classes. Universities, medical centers, and the government make posters in reality or through media to advocate bone marrow donation.

Funding to build more registries in developing countries

Funding from the world bank, international monetary fund, government funding, NGOs, and charity, either from private companies or patient support organizations to build more bone marrow match centers in the region in need. A reward-based approach from the government also can lead to more BMT centers that are equipped with trained medical faculties in a sterile environment. Moreover, funding is also an urgent need for scientific research regarding bone marrow. Assembling a group of experts on researching further improving the effectiveness of a bone marrow transplant and decreasing the side effects during or after the operation.

Increasing matching efficiency for allogeneic bone marrow transplant

Mapping haplotype frequencies to regions within the country has allowed the modeling of future donor registry size. Thus, each country/region is suggested to model its own registry's financial needs, size, the number of personnel, and donor availability based on factors including homogeneity of the population, haplotype frequency distribution, and target size of the population. Merging registries at the country level or merging registries that have a similar haplotype frequency distribution might offer greater efficiency.

IT

Each country/region is encouraged to decide on the software that they rely on for the entire process from search requests to the conduction of operation by considering the aspects including budgets, the internal IT team's availability, and ability, the average workload in the registry, the amount of information needed to process, the size of the target population. Furthermore, regarding the HLA typing process, the use of NGS technology for HLA typing results in high-throughput and high-resolution capabilities as compared with traditional PCR-based techniques. To date, several high-throughput HLA-typing methods using NGS have been developed. Consequently, it will be more feasible and efficient for a newly established registry to adopt NGS-based typing, and probably it can be more advantageous to outsource HLA typing to applicable and specialized laboratories to achieve more cost-effective pricing and proper standardized testing outcomes.

Making BMT more affordable

The disproportionately limited number of donor registries in the developing countries doesn't mean that future growth and demand in those countries will be low. Bearing in mind the cases of India and Brazil, it is obvious that the urgent need is to meet the demand with viable costs. However, the responsibility is not only on the government and the hospitals but also on companies that determine the costs of the equipment and life-saving drugs. The utilization of generic drugs could be a solution. Apart from that, insurance and public health schemes that cover the required BMT costs are recommended to apply to patients with low income. Medical centers that provide free BMT to those below the poverty line are needed as well.

Establishing a framework that carries legal implications

If official procedures for a BMT and/or research regarding bone marrow are not followed, there should be a protocol to support the donor's and the recipient's rights and to apply a penalty to the perpetrators. It is a good way to avoid phenomena such as exploitation of minors, private information leakage, sale of bone marrow, compelled donation, and other unethical and illegal events.

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