EBMT

ABSTRACTS COLLECTION

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Data Management Group Poster Session

31 - Data Management

P725

MYELOMATRIAGE: AN INTERACTIVE WEB-BASED TOOL TO IMPROVE THE STRATEGY OF MULTIPLE MYELOMA TREATMENT PATIENTS USING R-SHINY AND NETWORK META-ANALYSIS

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Background: Multiple myeloma (MM) is one of the most common hematologic malignancies in the world. Today, many interventions are available, including cell therapy, and hundreds of drug combinations. MM treatment regimens are often difficult to compare directly due to the cost and time requirements of additional clinical trials. Based on statistical and mathematical methods, we created a web-based tool for decision support in selection of MM therapy for the best response.

Methods: Data about treatment options, response rates, number of patients, and other parameters were collected from clinical trial reports and real-world practice in the management of patients with MM. As outcomes, we used a very good partial response (VGPR) and better. In real-world practice, it is an easy parameter to assess and the one of predictors of progressive-free survival. Several complementary approaches are used in our tool: (1) we calculated inverse percentages of VGPR for each clinical study and treatment method, (2) we added all the inverse percentages for a given treatment method to get the average rate, and (3) the VGPR rates for the two treatment options were compared using the Odds Ratio in Bayesian and Frequentist Network Meta-analysis (NMA). Furthermore, we used a Monte-Carlo summation to model the confidence interval (CI) of VGPR for each option and the ranking of therapies by formula: P^2/CI, P - VGPR or better. All statistical analyses were done using R version 4.1.0. and the "shiny", "epiR", "gemtc", "netmeta" packages.

Results: A literature review identified 120 publications and 108 treatment options for 18911 patients with MM. As new publications become available, the database can be expanded. An interactive web app was developed to visualize the data gathered from this corpus of publications. We used three complementary methods. The first is Monte-Carlo simulation - the CI of VGPR is plotted as a ranking plot for treatment options after 1000 iterations with data replacement. The others are Bayesian and Frequentist NMA, that allow evaluation of multiple interventions that may, or may not, have been directly compared in trials and is represented as a forest plot diagram. The Bayesian NMA uses the comparative effects model and a Markov chain Monte-Carlo (MCMC) process to obtain the posterior distributions of the log odds ratios for the basic parameters. Also, we use ranking strategy, including the surface under the cumulative ranking (SUCRA) curve method. The app contains an intuitive "point and click" interface that includes some settings to select a patient profile and type of scientific publications. The current version of the web app provides an additional reference point for deciding about the treatment strategy for MM patients. The tool facilitates estimating the efficacy of one therapy in relation to another. The app is available at https://luchinin.shinyapps.io/MyelomaTRIAGE.

Conclusions: The aim of this project was to develop an interactive digital tool to help hematologists choose the right treatment strategy for MM. Our analysis was based on existing statistical methods and some innovative solutions, along with freely available software. This approach could be extended and integrated into hematology clinical decision-support systems in the future.

Disclosure: Nothing to declare

31 - Data Management

P726

WORLD MARROW DONOR ASSOCIATION SEARCH, MATCH & CONNECT, A GLOBAL ENVIRONMENT TO FACILITATE THE BEST MATCH FOR YOUR PATIENT

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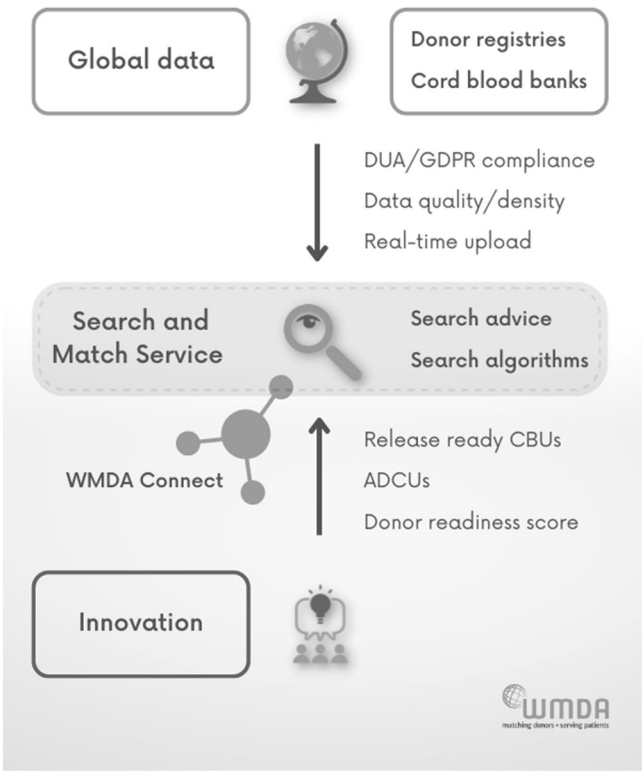
Background: In 2017 World Marrow Donor Association (WMDA) acquired the global database of unrelated donor (UD) and cord blood unit (CBU) records and aimed for a global "Search, Match & Connect" environment facilitating the best possible match between UDs/CBUs and transplant patients.

Methods: In collaboration with its membership and after independent review by industry leaders, WMDA centralised the global database in a secure cloud environment and launched a series of information and communication technology (ICT) projects to achieve this goal.

Results: To ensure donor and patient's anonymity and organisations complying with European General Data Protection Regulation (GDPR), WMDA implemented a twofold data transfer and user agreement (DUA), between WMDA and member organisations listing UD/CBU records in WSMC and for inter-organisation communication.

An overview of WMDA Search, Match & Connect (WSMC) ICT projects are listed in Figure 1.



Currently, 137 donor registries (DRs) and cord blood banks (CBBs) in 55 different countries are listed in WSMC, representing UDs/CBUs with a wide variety of HLA genotypes. Number of UD/CBU records increased 27.4% compared to 2017. Furthermore, efforts were made to improve quality/density of data in WSMC. Records with unknown sex and age both decreased 2%, while UDs/CBUs HLA typed for ABDR increased 2.3%. Young donors now make up 39.2% of all UDs compared to 29.5% in 2017. Furthermore, frequency of data uploads have increased 4-fold since 2017 and 76.7% of all records are updated at least weekly (Table 1).

WSMC statistics	December 2017	December 2022	% Difference
Records			
Unrelated donors + cord blood units	31,890,614	40,630,676	27.4%
Unrelated donors	31,145,172	39,826,434	27.9%
Cord blood units	744,902	804,242	8.0%
Quality/density			
Sex unknown	1,909,540	1,644,381	−13.9%
% sex unknown	6.1%	4.1%	−2.0%
Age unknown	1,819,230	1,538,793	−15.4%
% age unknown	5.8%	3.9%	−2.0%
Donor age 18–35 years	9,202,344	15,622,072	69.8%
% young donors	29.5%	39.2%	9.7%
HLA-AB typed	1,616,263	855,821	−47.0%
% HLA-AB typed	5.1%	2.1%	−3.0%
HLA-ABDR typed	30,274,351	39,491,783	30.4%
% HLA-ABDR typed	94.9%	97.2%	2.3%
Real-time upload			
Data uploads per week	41	197	380.5%
Records uploaded (at least) weekly	13,992,006	31,146,693	122.6%
% records uploaded(at least) weekly	43.9%	76.6%	32.8%

Sophisticated HLA matching algorithms are developed, which undergo extensive validation to ensure accuracy and performance. They are driven by geographically specific haplotype frequency sets and provide information on match grade as a percentage for overall match and locus-specific match probability. If potential UDs/CBUs are limited, assistance from an immunogenetics specialist can be leveraged to develop a search strategy and/or provide UD/CBU selection recommendations. WMDA has a team of expert search consultants who can assist with difficult cases which may be requested by any organisation using WSMC.

Improving patient outcomes can be achieved by reducing time to transplant, WMDA has therefore developed a series of connectors (APIs) for search coordinators to search in WSMC from their local system and submit donor-related requests via the same connectors. These APIs will vastly improve search, match and communication capabilities.

Future innovations include donor readiness score project improving prediction of donor availability by inputting specific data into an algorithm currently undergoing validation. Next, the WSMC CBU report will flag "release ready" CBUs, meaning HLA verification typing and post thaw testing have been performed and results meet release criteria. Finally, adult donor cryopreserved units (ADCUs), a new type of off the shelf product, can be listed in early 2023 as a third stem cell source.

Conclusions: By leveraging ICT, WMDA improved the quality of WSMC data and by widening global communication through open standards, data exchange has been made more efficient yet secure. Therefore, WMDA is democratising UD/CBU search and provides, especially through the APIs and real-time data, the means to identify the most suitable stem cell source for patients in need.

Disclosure: Nothing to declare

31 - Data Management

P727

EDUCATIONAL AUDIT PROCESS FOR HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) REPORTS

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Background: External audits are widely used tools to validate internal processes and identify errors that would go undetected by quality programs, it verifies the veracity and ensures the accuracy of the information generated. Audits are a common and mandatory practice in the US and Europe. There is no mandatory HSCT data report in Brazil, nor a systematized audit for this area. AMEO (Bone Marrow Association) promoted a 2nd edition of Training for Data Managers (DM) in HSCT, which aimed to train transplant center (TC) professionals to correctly enter the data in the HSCT records and analyze the data itself. All participating TCs agreed to undergo an Educational Audit (EA).

The proposal is to present the results obtained during the EA process of the AMEO's training for DM.

Methods: An excel spreadsheet was prepared in two models: a reduced one (22 variables – autologous / 29 – allogeneic) and an extended one (74 variables – autologous / 109 – allogeneic), representing respectively the variables requested by the AMEO HSCT Map and by the essential data common to most international registries (CIBMTR and EBMT) (Table 1). Five medical records (2 extended and 3 reduced) of patients submitted to transplants performed in the year 2022 from each participating CT were selected. The audit was conducted virtually. All data entered in the spreadsheet sent by the students were compared with the documents and records contained in the medical record. The audited variables were classified as "compliance" and "non-compliance". The "non-compliance" items were subclassified into: (1) Missing data in the medical record; (2) Spreadsheet data differs from the medical record; (3) Existing data not transcribed; (4) Incorrect data in the medical record. Audit results were sent to each participating CTs.

Table 1: List of audited variables

REDUCED SPREADSHEET VARIABLES		**EXPANDED SPREADSHEET VARIABLES**					
Transplant Type *	Date of Death	Research Consent*	Platelet engraftment Date >20,000**	ALL - Classification	**Prior fungal infection****	Non-Hodgkin's Lymphoma (NHL)*	Result Chimerism-3
ALLOGENIC subtype	Primary Cause of Death*	Consent Date*	Platelet engraftment >50,000 (yes/no)*	Mono (MO)*	**VOD****	MM - Classification*	Date Chimerism-4
Current HCT number	Cause of Death*	Patient Blood Type*	Platelet engraftment Date >50,000**	CD34+ (CTP)*	MRD pre*	MM - light chain	% Chimerism-4 Donor Cells
Previous HCT type*	Relapse or Recurrence*	Race**	GVHD prophylaxis 1*	Nucleates (blood cord)	% positive MRD*	MM - Durie & Salmon	Result Chimerism-4
Gender*	Date of Relapse	Origin*	GVHD prophylaxis 2*	Cell Viability***	AML – Classification*	MM – ISS*	Date Chimerism-5
Birth date*	Donor Gender*	State or Country*	GVHD prophylaxis 3*	Graft failure	ALL - Classification	Other Malignancies*	% Chimerism-5 Donor Cells
Education***	Donor Age*	Pre HCT condition**	GVHD prophylaxis 4*	Graft failure date	Other Leukemia - Classification	Date Chimerism-1	Result Chimerism-5
Diagnosis*	Donor Blood Type*	**Karnofsky/ Lansky******	Acute GVHD *	New neoplasm	SAA – Transfusions	% Chimerism-1 Donor Cells*	2nd HCT done after
HCT indication date**	Relationship*	Conditioning Protocol*	Acute GVHD date*	New neoplasm date	CML - Response Level	Result Chimerism-1*	Date 2nd HCT
Date of Diagnosis**	Match HLA***	**Conditioning Classification******	MAXIMUM Acute GVHD Grade*	New neoplasm diagnosis	CML - Current BCR	Date Chimerism-2*	Date 3rd HCT
HCT date (day, month, year)*	Admission date*	Neutrophil engraftment (yes/no)	MAXIMUM GVHD-Acute Grade date*	**HCT-CI Index*******	CML - Current Cytogenetics	% Chimerism-2 Donor Cells	Diagnosis Cytogenetics*
Cell Source*	Discharge date**	Neutrophil engraftment Date*	Chronic GVHD*	Pre-HCT Patient CMV**	Diagnostic MDS (WHO)*	Result Chimerism-2	Cytogenetics date*
Follow-up date*	Health insurance or public health service	Platelet engraftment >20,000 (yes/no)*	Chronic GVHD date	Pre-HCT Donor CMV *	MDS risk group*	Date Chimerism-3	
Current status*		Platelet engraftment Date >20,000**	Chronic GVHD grade*	**Previous OTI history*******	Hodgkin	% Chimerism-3 Donor Cells	

*1 to 10 "non-compliance" medical records for this variable
**11 to 20 "non-compliance" medical records for this variable
***21 to 30 "non-compliance" medical records for this variable
****31 to 40 "non-compliance" medical records for this variable
*****Over 40 "non-compliance" medical records for this variable

Results: 31 centers and 153 medical records were audited, totaling 4759 fields, of which 619 were scored as "non-compliance". The number of "non-compliance" items ranged from 4 to 40 among the TCs. The average of "non-compliance" in the medical records was 13%. The most frequent type of "non-compliance" was "Missing data in medical records" with 71%. The variables that appeared more than 30 times as "non-compliance" were: HCT-CI Index (42), OTI History (42), Conditioning Rating (38), Previous Fungal Infection (36), VOD (36) and Karnofsky /Lansky (32). There was a statistically significant difference between the means of "non-compliance" for the TC who had already participated in the 1st training and those who are beginning in the 2nd training ($t = -3.87$, $p = 0.002$).

Conclusions: The EA showed that the highest frequency of "non-compliances" occurs due to the lack of recording information in the medical record. Standardization and implementation of a template with mandatory fields can help transplant teams systematically record missing data. We observed that the centers that participated in the first training had better quality in data reporting. The EA can provide support to CT programs to improve the quality of their database.

Disclosure: No conflicts of interest

31 - Data Management

P728

CRYOSTEM NETWORK FUELING EXCELLENCE IN TRANSLATIONAL RESEARCH ON HEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) COMPLICATIONS

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Background: Limited knowledge in HSCT complications has justified in 2010 the promotion of the CRYOSTEM project by the Francophone Society for Stem Cell Transplantation and Cell Therapy (SFGM-TC). The goal was to speed up biomarker discovery, development of adequate treatments, and to improve transplanted patients healthcare, by setting up a dedicated biological resources collection.

Methods: CRYOSTEM has established a network bringing together all the French transplant units and 28 biological resource centers (BRCs). Transplant units are responsible for the blood sampling, treated by the BRCs and derived in the different types of samples, according to harmonized procedures and protocols. Moreover, CRYOSTEM network has been certified ISO 9001 since 2015, thus guaranteeing collection quality and focus on users expectations and satisfaction, along with a greater international collaboration.

Results: In the last 10 years, CRYOSTEM network has operated the first and unique European standardized collection of biological resources from almost 2500 donors and 6000 transplanted patients, with nearly 200,000 aliquots available for research, processed from systematic blood samplings pre- and post-HSCT and at GvHD occurrence. Since 2015, CRYOSTEM has been taking part actively in translational research on HSCT complications. Indeed, 17 French and international major research projects have been granted with almost 9000 samples, leading to 7 publications in major journals, based on CRYOSTEM samples use, such as Nature communication, Science translational medicine and Blood.

Moreover, since 2018, thanks to its biobanking expertise, CRYOSTEM network sustains translational research in HSCT-related fields by implementing prospective biological resources collections in order to enrich epidemiological cohorts and/or clinical protocols by ancillary studies. Currently, 9 academic and private promoters have relied on CRYOSTEM biobank network expertise to generate biological samples and clinical data answering specifically to their medical and research issues. As of November 2022, 2600 patients have been included in the different prospective protocols managed by CRYOSTEM network from whom different types of samples are performed: blood, bone marrow, skin biopsies, stools.

Conclusions: Thanks to its unique network in Europe, CRYOSTEM is providing the national and international scientific community with its high-quality biological resources to improve HSCT medical knowledge and patient care. Currently, beyond the retrospective supply, CRYOSTEM network supports academic or private investigators with biological resources collections tailored to the needs of projects of excellence in order to address issues in a more relevant and dedicated manner in the field of hematology and cell therapy.

Disclosure: No disclosure

31 - Data Management

P729

BMT BRAZILIAN MAP: COMPARISON OF BMT MAP WITH EBMT ACTIVITY SURVEY AND ACTIVITY REPORT CIBMTR

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Background: Introduction: Brazil has a large and consolidated Hematopoietic Stem Cell Transplantation (HCT) program with 126 transplant public and private centers registered at the Ministry of Health. The country has an extensive territory, the regions have their particularities with unequal socio-economic conditions that are reflected in some way in the transplant program. It is very important to access transplant outcomes in the country and in its regions to seek public policies that favor equity.

Objective: Built up a website for the public, health care providers and patients to access Brazilian HCT results, observe internal results and compare with international data. The platform called "Bone Marrow Transplantation Map (BMTMap)" (https://ameo.org.br/mapa-do-transplante-de-medula-ossea/) brings a view of transplantation in Brazil with data presentation of approximately 50% of transplants in the country, and portrays the regions with their particularities.

Methods: The platform BMTMap was designed in 2020. The centers received training and underwent educational auditing for the correct completion of HCT data, the reports are uploaded and

updated twice a year, outcomes were checked using Business Intelligence tools.

Using the available tools in the BMTMap, we selected allogeneic transplant data performed in Brazil, and compared indication data by diagnosis, type of transplant and cell source with publications of EBMT Activity Survey and The Transplant Activity Report from CIBMTR regarding the year of 2020.

Results: In 2020, 716 allogeneic transplants were recorded on the BMTMap with the participation of 30 brazilian transplant centers, in the European registry, 18,796 allogeneic transplants were registered from 690 participating centers in 50 countries and 9026 transplants performed in the United States were registered in the CIBMTR.

On the BMTMap, the main indications for transplantation were ordered in AML, ALL and MDS/MPN; while in EBMT and CIBMTR the order was AML, MDS/MPN and ALL.

The main source of cells used both in our data and in international records was PBC, with a higher predominance in the record of EBMT 83.1% and CIBMTR 78.6% while it was 55.0% in the BMT Map (Table1).

Table 1. Data of HSCT from BMTMap, EBMT and CIBMTR, 2020

	Map of BMT	EBMT Activity Survey	CIBMTR Activity Report
Transplants	**716**	**18,796**	**9026**
Main indications			
Acute myeloid leukemia (AML)	230 (32.1%)	7330 (38.9%)	3373 (37.4%)
Acute lymphoblastic leukemia (ALL)	189 (26.4%)	3195 (16.9%)	1411 (15.6%)
Myelodysplastic diseases (MDS)/Myeloproliferative (MPN)	84 (11.7%)	3383 (17.9%)	1696 (18.7%)
Stem cell source			
Bone Marrow	305 (42.6%)	2811 (15.0%)	1507 (16.7%)
Peripheral Blood	394 (55.0%)	15,616 (83.1%)	7097 (78.6%)
Cord Blood	6 (0.8%)	345 (1.8%)	422 (4.7%)
Bone Marrow + Peripheral Blood	7 (1.0%)	-	-
Unknown	4 (0.6%)	24 (0.1%)	-
Donor type			
HLA-id sibling	283 (39.5%)	5592 (29.7%)	1846 (20.5%)
Haploidentical	281 (39.2%)	3790 (20.2%)	2338 (25.9%)
Unrelated	152 (21.2%)	9414 (50.1%)	4842 (53.6%)

Conclusions: The BMTMap is a tool that gathers national data and provides information on various aspects of HSCT. The layout of the platform, with several filters, allows the user to choose the information and customize their research, enabling the use of the tool to compare the profile of transplants performed in the country with data from international records. We were able to observe several differences in indications, in the use of donors and in the source of cells. Several hypotheses arise to explain these differences, but we need observation over time to find out if these are real differences or if there will be a tendency to approach international standards.

Acknowledgments: The Bone Marrow Transplantation Map platform was developed by AMEO through a project approved by PRONON (2019–2020), the maintenance of the project was done by AMEO, with the support of Astellas, Zurick-Santander and Pfizer.

We want to thank hospitals, that voluntarily provide their data to contribute to the knowledge about the transplant program in Brazil.

Disclosure: Nothing to declare

31 - Data Management

P730

CEDACE DONOR PANEL OPTIMIZED MANAGEMENT

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Background: CEDACE (Portuguese Bone Marrow Donor Registry) data shows that the increase in the number of registered bone marrow donor candidates does not correlate into a proportional increase in their genetic variability. Awareness campaigns, organised either by donors groups or private citizens, mobilise a high number of donor candidates, without taking into account the particularities and real needs of the CEDACE genetic panel.

LabX - Center for Innovation in the Public Sector is an organic unit integrated in the Agency for Administrative Modernization (AMA, I.P.). LabX's mission is to contribute to the innovation ecosystem in the Public Administration, promoting the renewal of public services, appropriate to the real needs of citizens and businesses.

So the aim of this work is to present the project developed to validate a methodology to increase the adherence of young people and ethnic minorities to the Portuguese Registry of Bone Marrow Donors (CEDACE).

Methods: We planned and carried out three sequential phases:

Research Phase - It took place between February and July 2021 and "allowed to define the real problem", confirming the need to prioritise addressing ethnic minorities and young people to address the shortcomings of CEDACE.

Co-creation Phase – It ran from September 2021 to May 2022 and consisted of "Find the most appropriate solutions working in co-creation with ethnic minorities and young people". In order to overcome the barriers identified in the research phase and recruit these candidates for bone marrow donation, sessions were held to promote trust and rapport between the participants and IPST, IP. staff and to facilitate the generation of ideas.

Results: The methodology applied enabled IPST,IP to establish networks with ethnic communities and student associations, having acquired and applied a set of lessons that made possible:

- Establish bridges for recruiting young donor candidates and with genetic characteristics with little representation in the Registries;
- Identify messages and channels with ethnic minorities to contribute to the optimal management of CEDACE;
- Use the identified channels to improve literacy about CEDACE to the identified actors;

The trial sessions resulted in the collection of almost fifty blood samples with enrolment of about 87% of potential donors from different ethnic groups, until now with low representability in the registry.

Conclusions: The methodology defined and the networks established will allow IPST, IP to attract donor candidates to fill the CEDACE genetic panel, in a sustained and continuous manner, and will enable young donors to be enrolled and remain in the global database.

The replication of this methodology may be applied in other areas of IPST, IP intervention.

Disclosure: Nothing to declare

31 - Data Management

P731

AUTOLOGOUS STEM CELL TRANSPLANTATIONS ($ASCT_S$) IN YEARS 1993-2022 – 1 CENTRE EXPERIENCE OF EBMT REPORTS PROCESSING

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Background: It's been 30 years since the first ASCT was performed at our center. This is the opportunity to analyze the amount of required data management work with EBMT reports. We also want to compare the numbers requested by EBMT with the actual reports sent.

Methods: Retrospective analysis of consecutive patients after ASCT between 1993–2022 in our centre.

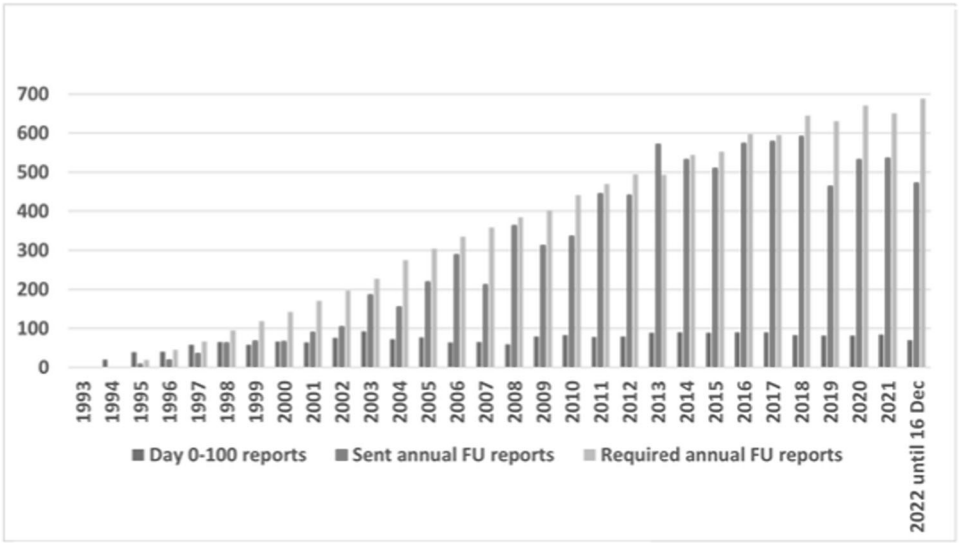
According to EBMT instructions, every transplant should be reported on day 0 (D0) after ASCT and day+100 (D + 100). These two reports are calculated as one because historically it has been.Follow up (FU) reports are requested: every year if patient was transplanted <10 years ago, every 2 years between 10–20 years ago,every 5 years if patient was transplanted >20 years ago.

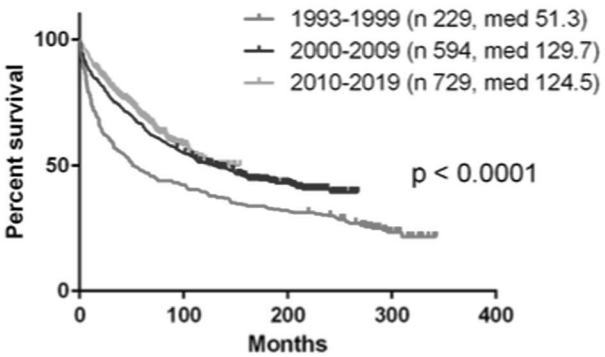
We calculated in each year the number of transplants, figured out the living patients number since previous periods, calculated the number of reports which had to be sent and compared to the really sent FU reports. The real number of FU reports sent were calculated from the EBMT DB export.

The covid-19 period was reflected.

We analysed overall survival (OS) and compared three time periods: 1993–1999, 2000–2009 and 2010–2019, by using Kaplan–Meier curves and log-rank test.

Results: The first ASCT was performed on 10 December 1993. Until 16.12.2022, a total of 2089 ASCTs were performed in 1733 patients. The cohort consists of 984 men (57%) and 749 women (43%) with median age of 54 years (18–73). The main ASCT indications were m.myeloma (MM 674.39%) and lymphoma (906.52%) corresponding to European figures. The number of ASCTs gradually increased, since 2009 has stabilised at 80–90/year. The Covid-19 period has had no impact on ASCT except the year 2022 when we are expecting the number <80 (fig.1). OS probability of patients was significantly ($p < 0.0001$) increased in 2000+ periods compared to 1993–1999 period, but there is no statistically significant improvement in 2010–19 vs 2000–09 period





(fig. 2). Whereas in 1993 we had to fill out 1 report and 125 reports in 1997, since 2014 we have to fill out approx. 600–750 reports/year (fig. 1), (D0 and D + 100 reports are counted as one – see methods). There is yearly increased number by 20 (the mean) since 2015. We observed decreased reports number in COVID-19 years (2020–2022), but it was already noted in the pre-COVID-19 year 2019. The reason is technical, not linked to COVID-19 epidemy. During the whole transplant period we should have sent 2089 first reports (D0-D + 100) and 10612 FU reports (12701 in total). The real number of reports sent: 2089 first reports (100%), 8809 FUR (69%), 10898 (86%) reports in total.Thereby we have to handle 63 reports/month (approx. 7 D0-D + 100 and 56 FU reports) currently.

Conclusions: Transplant reports still take a lot of time, depending on the quality of source documentation, cooperation with the team and other centres. The amount of work is increasing with more required time and financial support need. It is going to be more important in the era of CAR T-cell reporting, not discussed here. These challenges have to be taken into account when changes in reporting are planned.

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Disclosure: Nothing to declare

31 - Data Management

P732

ISAVUCONAZOLE OFF LABEL USE IN CHILDREN AND ADOLESCENTS: A SINGLE TERTIARY-PEDIATRIC-CARE CENTER EXPERIENCE REVIEW

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Background: Invasive fungal disease (IFD) is a main complication in immunocompromised patients, especially in patients who undergo hematopoietic stem cell transplantation (HSCT). Isavuconazole (ISA) is a new generation broad-spectrum triazole with a promising role in IFD since its use/approval in adults in 2015. However, its pediatric use is still off-label. The aim of our study is sharing our experience as a tertiary-pediatric hospital.

Methods: We retrospectively describe ISA prescription at our center, related to HSCT recipients and IFDs characteristics, ISA indication and posology, Isavuconazole plasma concentration (IPC), adverse events and outcomes. Data from patients who had received ISA from June/2020 to june/2022 were collected from electronic records. IPC was quantified at our reference lab and a target range of 2.5–5mg/L was set according to safety and efficacy evidence published previously.

Results: ISA – use was registered in 12 patients who underwent HSCT with a median age of 11.5 y.o. (IQR 6–15.4) as second or third line treatment. Isavuconazole was administered for treatment (83.3%) or profilaxys (16.7%) because of previous treatment failure (70.6%) or previous treatment toxicity (29.4%). Isavuconazole plasma concentration (IPC) was available in 10 patients. Only two patients reached the targeted range (2.5–5 mg/L) in the first IPC quantification (despite the loading regimen). ISA dose adjustment was carried in 7/10 cases (maximum dose of ISA: median 15.07 mg/kg/day; IQR 8.08–21.65 mg/kg/day). Four patients presented adverse events related to ISA (nausea, neutropenia).

Conclusions: Despite our limited experience, we verified the safety of ISA-use in pediatric patients. Most of the patients needed dose increment over standard recommendations, to reach the IPC therapeutic range. Therefore, we recommend IPC periodical monitoring in paediatric patients, since pharmacokinetics and weight-adjusted doses might vary from adult-use.

Disclosure: Nothing to declare

31 - Data Management

P733

ACTIONS AND ACHIEVEMENTS FOR THE HEMATOPOIETIC STEM CELL TRANSPLANTATION BRAZILIAN REGISTRY ESTABLISHMENT, USING *CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH* INFRASTRUCTURE

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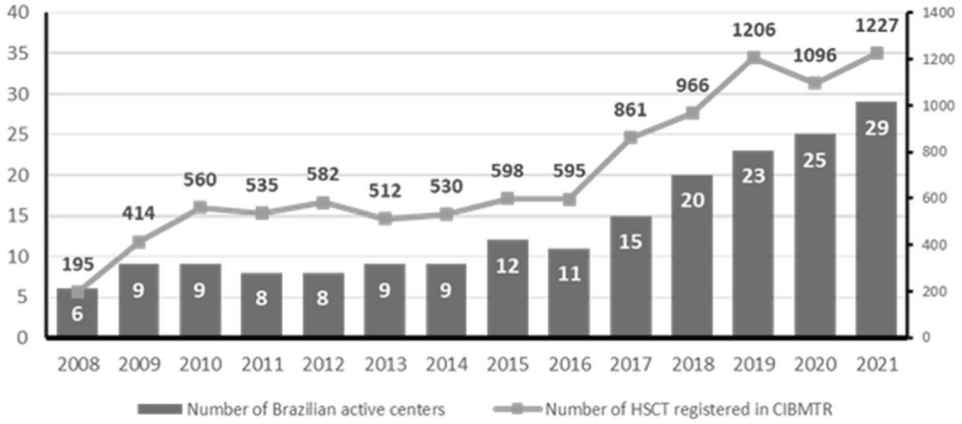
Background: Since 2016, efforts have been made to consolidate the Hematopoietic Stem Cell Transplantation Brazilian Registry (HSCTBR), aiming to better understand national transplant activities and outcomes. Through the collaboration between the Brazilian Society of Bone Marrow Transplantation and Cellular Therapy (SBTMO) and the Center for International Blood and Marrow Transplant Research (CIBMTR), the HSCTBR was created in 2019.

Methods: Bibliographical and historical review of the actions that helped to establish the HSCTBR by the Data Managers Working Group (DMWG) of SBTMO.

Results: The first affiliation of a Brazilian Hematopoietic Stem Cell Transplantation (HSCT) center to the CIBMTR happened in the 80s. In 2017, a multicenter HSCT study was approved and regularized to report the national data to the CIBMTR following Brazilian laws. The partnership between SBTMO and CIBMTR was officialized in 2019, resulting in the national dashboard with information from the Data Back to Center (DBtC). From 2016 to 2021, the number of active centers in the CIBMTR increased 164% (11 to 29) and the transplants annually registered 106% (595 to 1227) (Graphic 1). Currently, 61% (78/128) of the country's HSCT services joined the study and 34% (533/1547) of the national allogeneic HSCT were registered in the CIBMTR in 2021. The approval of the multicenter HSCT study and regularization of reporting national data to the CIBMTR allowed the development of the first Brazilian Summary Slides published in 2021. The recognition of the HSCTBR by the National Transplant System and



Graphic 1: Number of Brazilian active centers at the CIBMTR, and HSCT registered (2008 to 2021)

the certification by the SBTMO issued to each participant HSCT service reporting their data were necessary steps to develop the Brazilian HSCT registry. In 2022, the Brazilian Summary Slides was updated with data from transplants performed between 2012–2021 (including 31 services and analysis of 7982 HSCT). Due to the increased interest in Brazilian HSCT data, a data requesting flow was created, supported by the GVHD and Late Effects Working Group (GEDECO) of the SBTMO. Until now, 26 requests for DBtC data analysis have been made. In 2022, through the voluntary collaboration of 42 professionals, the DMWG developed the DM educational training, free of charge, composed of 7 modules and 60 video lessons complementary areas of HSCT knowledge (Table 1). The objective of the course is to enable data managers to send quality data to the CIBMTR.

Table 1: Brazilian educational training for data managers

	Subject	Number of speakers ($N = 42$)	Number of video lessons ($N = 60$)	Workload (minutes) ($N = 1135$ min)
Module 1	HEMATOPOIETIC STEM CELL TRANSPLANTATION BRAZILIAN REGISTRY OF THE BRAZILIAN SOCIETY OF BONE MARROW TRANSPLANTATION AND CELLULAR THERAPY (SBTMO)	14	14	90
Module 2	CELL THERAPY AND ACCREDITATION BASIC CONCEPTS	10	10	245
Module 3	CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH (CIBMTR) BASIC CONCEPTS	2	6	133
Module 4	BASIC CONCEPTS OF FILLING IN CIBMTR DATA FORMS – AUTOLOGOUS BONE MARROW TRANSPLANTATION – MULTIPLE MYELOMA	4	9	179
Module 5	FILLING IN CIBMTR DATA FORMS - MYELODYSPLASTIC SYNDROME CLINICAL CASE	2	3	72
Module 6	FILLING IN CIBMTR DATA FORMS –POST-TRANSPLANT COMPLICATIONS	6	9	205
Module 7	BASIC, INTERMEDIATE AND ADVANCED STATISTICS FOR CELL THERAPY	4	9	211

Published on the following platforms - SBTMO (https://sbtmo.org.br/registro-multicentrico-tcth/); CIBMTR (https://portal.cibmtr.org); Academia digital (https://academiadigital.einstein.br) and Hematolog (https://hematolog.app/)

Conclusions: The creation of the HSCTBR required not only collaboration between the SBTMO and the CIBMTR, but implementation of a national protocol. In addition, the increased interest, and publications of multicenter studies in Brazil have played an important role engaging the HSCT community to report their data. The HSCTBR contributed to a broader view of the Brazilian patterns of transplants, activities, and outcomes. This valuable information has solidified and developed new projects to further advance treatments, longevity, and quality of life for patients.

Disclosure: Nothing to declare

31 - Data Management

P734

COMPREHENSIVE MANAGEMENT SYSTEM FOR THE IMPLEMENTATION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) IN THE CLINICAL PRACTICE IN MADRID AND ITS RESULTS

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Background: Chimeric antigen receptor T (CAR-T) cell therapies are Advanced Therapy Medicinal Products (ATMP), one of the greatest success achieved in the treatment of oncological diseases where there is a high-unmet medical need. However, they are also one of the most complex therapies to manage.

In Spain, a positive decision from a CAR-T experts Group is required to have access to treatments. From the economical point of view, to face data uncertainty and affordability challenges, payment of CAR-T follows an outcomes-based staged scheme in two installments, linking the second one to achievement of individual patient outcomes after 18 months of infusion. Data registries are essential in the payment for performance, a responsibility of each Autonomous Region, where a regional follow-up Committee for CAR-T payment verifies the fulfillment of individual patient outcomes.

Methods: The Healthcare Office (*Consejería de Sanidad*) of the Region of Madrid, aware of these challenges established a regional strategy for a comprehensive management of ATMP so-called the *Estrategia Regional de Terapias Avanzadas* (ERTA) with the goal to grant equitable patients' access to these therapies.

In the frame of the ERTA, a management plan for each ATMP is elaborated with a multidisciplinary approach in collaboration with clinical experts from Madrid's *Net of Advanced Therapies a*nd the coordination of the *Unit of Advanced Therapies* (UTA). Each plan includes a Patients' Register Database.

Madrid CAR-T Patients' Register Database contains information from the first treatment application received at the UTA on December 2018 up to date for either diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) or B-cell acute lymphoblastic leukaemia (ALL). The information gathered is represented in a dynamic dashboard and includes data from the 18 months follow-up period after patient infusion unless they died earlier or they receive chemotherapy or autologous haematopoietic stem cell transplantation.

Results: 219 CAR-T treatment applications have been received at the UTA. 60.3% were male ($n = 132$). The majority of patients ($n = 161$; 73.5%) had DLBCL, with a median age of 61.5 years; 22.4% ($n = 49$) had ALL (16.5 years) and 4.1% ($n = 9$) PMBCL (31.5 years).

63.5% cases ($n = 139$) received CAR-T infusion and 48.9% ($n = 68$) patients have achieved 18 months follow-up after infusion: 17 achieved complete remission, 22 received chemotherapy/transplantation and 29 exitus. Main causes of non-infusion were disease progression ($n = 32$); manufacture failure ($n = 9$) or negative opinion from the CAR-T experts Group ($n = 5$). Twelve cases are pending infusion at the time of this report.

The median time from CAR-T experts Group positive opinion to the date of infusion was 53.5 days. In addition, the median time from request reception at the UTA to infusion was 56.0 days. The median time from apheresis to infusion is 42.0 days.

Conclusions: ERTA Management plans for ATMPS are an innovative methodology that helps facing the challenges of these complex therapies. Madrid CAR-T Patients' Register Database helps to manage patients' access in an efficient manner through the design of a dynamic dashboard.

Disclosure: Nothing to declare

31 - Data Management

P735

COMPLETION OF THE PILOT PROJECT EVALUATING THE BENEFIT OF ADDITIONAL SUPPORT IN HCT RESEARCH DATA MANAGEMENT ON BEHALF OF ANTHONY NOLAN AND BSBMTCT

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Background: Anthony Nolan's Patient/Donor project carries out retrospective research to determine the best donor for a patient undergoing unrelated donor Haematopoietic Cell Transplantation (HCT). Previously we reported the interim results of a Research Data Manager (RDM) pilot project that aimed to show the benefit of additional resources on patient outcome data completion and quality. Here, we provide the results after the completion of the pilot project.

Methods: HCT dates ranged from 1996–2020, with a similar sized cohort in both centres. This longitudinal study posed specific challenges. Both centres had data stored as a combination of digital and paper records. One centre stored data in multiple digital sources, with a legacy system being unavailable. The other centre stored most data in a single system, however not all paper records for earlier patients had been retained prior to its introduction. Training was required for current and legacy local systems and specific centre working practices. The RDM benefited from existing knowledge of the EBMT Registry system and data variables.

The RDM used NHS-Digital tools to trace patients who were no longer attending follow-up appointments at the centres. Towards the end of the pilot, London Care Records became available in both centres' systems, facilitating follow-up for some London based patients.

Results: For 1 year, the RDM collected and validated MED-AB data on 420 patients overall. This enables both centres to benefit further if these patients are selected in future studies. In addition to the specific RDM project aims, the RDM was also able to contribute to data collection for an additional research study, ensuring rapid completion of the data request, assisted with missing data reports related to audits, and assisted in the completion of cytogenetics data for outcome reports. The RDM also provided support and further education to centre Data Managers on novel areas of data management/handling.

Variability in data availability was seen, depending on the time-period and prior studies. Patients in the Centre 2 cohort had more up-to-date MED-A (essential data) and follow-up, but less MED-B (study data) recorded in the EBMT Registry database than Centre 1. The table below shows an example of key items where data completion improved:

Data Item	Number of Transplants with missing data				Unknown/Not Evaluated	
	Centre 1		Centre 2		Centre 1	Centre 2
	Start	End	Start	End	Start	End
Patient Blood Group	63	0	22	0	0	0
Donor Blood Group	68	0	29	0	0	0
aGvHD date onset	50	12	62	1	3	18
Conditioning doses	16	4	64	2	0	1
Comorbidity at HSCT	21	0	127	0	5	30
	12	0	17	0	3	0

Data Item	Number of Transplants with missing data				Unknown/Not Evaluated	
	Centre 1		Centre 2		Centre 1	Centre 2
Disease status at transplant						
Infections by day 100 (Y/N)	122	0	205	0	4	22
Other complications day 100 (Y/N)	113	0	234	0	0	60
Infections post day 100 (Y/N)	150	0	200	0	15	34
Other complications post day 100	151	0	207	0	18	60
Other cell therapy/DLI (Y/N)	18	0	67	0	1	8
Relapse at last assessment (Y/N)	20	0	60	0	8	17
Secondary malignancy (Y/N)	26	0	86	0	9	24
Patients Lost to Follow-Up	28	9	22	3	0	0

Conclusions: Two main challenges included: the variety of patient data sources and legacy records in longitudinal studies; the availability of follow-up for long-discharged patients. Centre 2 runs a Late Effects clinic which facilitates long-term follow-up reporting. Recent advances in NHS-Digital made it possible to trace most historical patients and the number of lost to follow-up patients decreased in both centres. The results of this pilot project clearly demonstrate the benefits of additional data management resources, providing much needed support to existing Data Management teams, and helping to improve patient outcomes by facilitating detailed research studies. The previously acquired expertise in handling HCT patient data and the EBMT Registry system was hugely beneficial. The RDM was able to ensure complete, accurate, and up-to-date patient outcome data was available on this cohort of individuals, making the long-term goal of improving patient outcome data a reality.

Disclosure: Nothing to declare

31 - Data Management

P736

STEM CELL TRANSPLANT DATA REGISTRIES: ROLE AND FUTURE IN SAUDI ARABIA

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Background: Stem cell transplant is the mainstay of treatment for a vast majority of malignant, non-malignant hematological and immune disorders. Over the last few decades, there has been a significant increase in the number of transplants in Saudi Arabia. This continuous increase in the number of stem cell transplants would mean more data would be extracted, reported and translated into clinical research and therefore impose more challenges on the existing stem cell data registries facing a dearth of trained and qualified data managers. This report intends to summarize our experience at the Department of Pediatric Hematology/Oncology, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia, for transplants performed, between 1993 to 2021.

Methods: All 2866 transplants performed, between 1993 to 2021, were analyzed in relation to abstraction and reporting to an in house database and international registries of Center for International Blood and Marrow Transplant Research (CIBMTR) and European Group for Blood and Marrow Transplantation (EBMT). An impact of having trained and qualified data managers on the accuracy and timeliness of data reported was also assessed based on national and international data reporting guidelines.

Results: Between 1993 to 2021, a total of 2866 transplants were performed on 2756 patients. 2609 (91%) were allogeneic and 257 (9%) autologous transplants. The average number of transplants rose from 92 per year between 2000–2010 to a staggering 140 transplants per year between 2011 to 2021. Among the allogeneic group, HLA type was dominated by full matched transplants 1870 (71.6%), followed by cord blood transplants 371 (14.2%), Haplo-identical transplants 227 (8.7%), related one antigen mismatched transplants 88 (3.4%), matched unrelated donor transplants 40 (1.5%) and related two antigens mismatched transplants 13(0.5%) respectively. There was a surge in haplo-identical and matched unrelated transplants in the last 10 years, requiring more complex data to be reported. Hiring additional trained and qualified data managers helped us in successfully passing our CIBMTR audit and in maintaining an overall good standing with CIBMTR and EBMT as well as JACIE accreditation during these years. The quality of data was found to be consistently above the CIBMTR / EBMT bench marks as evidenced by annual MED A (minimum essential data) audits performed by an independent auditor. The number of queries in CIBMTR query reports dropped whereas our center's participation in EBMT studies improved significantly. In addition we were able to publish more scientific papers emanating from our data registry.

Table 1. Pediatrics Hematology/Oncology Stem Cell Transplant Data Registry

Planning of new research proposals by providing data for hypothesis generation and potential subjects enrolment
Helping the Physicians by providing data on patient care and evaluation of treatment efforts and hence in decision making
Provision of data for scientific papers for presentations in conferences and publications in various journals, more than 70% of the department's publications are from the stem cell transplant.
Abstraction and reporting of data to CIBMTR and EBMT for participation in international/multi center studies
Abstraction and collation of data to an in house data registry, from 1993 to date.
CAR T Cell therapy, maintenance of data and help in evolution of data reporting mechanisms to CIBMTR & EBMT
Helps in an internal third party audit and international CIBMTR audit
Satisfying the data requests from hospital administration and quality management

Conclusions: Data registries are cardinal components of any stem cell transplant program for data collection, analysis and to vanguard clinical research. Due to its clinically proven efficacy, increased awareness and acceptance in the general population and opening of new stem cell transplant centers across Saudi Arabia, more data is expected to be added to the existing pool. We envisage that there will be a need to establish more stem cell data registries and train more data

managers, for stem cell transplant patient care and research in Saudi Arabia.

Disclosure: Nothing to declare.

31 - Data Management

P737

CURRENT SITUATION AND DEVELOPMENT OF HEMATOPOIETIC CELL TRANSPLANTATION CENTERS: A NATIONWIDE SURVEY IN CHINA

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Background: The number of hematopoietic cell transplantation (HCT) is increasing rapidly in China along with the development of haplo-identical (haplo-) HCT, but no data focusing on HCT centers in China has been reported. It is necessary to recognize the situations of HCT centers in China for the further development.

Methods: A nationwide survey of HCT centers in China was conducted, which was designed by the National Clinical Research Center for Hematologic Diseases supported by the First Affiliated Hospital of Soochow University, and EBMT China Office. The survey was administered through the web-based questionnaire system. Totally 93 HCT centers were invited. The information of transplant activities, human resources, treatment and follow-up models for HCT recipients, and support resources in 2020 were collected in this survey.

Results: The valid response rate was 89.2%. The enrolled 83 HCT centers distributed in 23 provincial regions, covering 67.6% of provincial regions but 84.3% of population in mainland China. All the enrolled centers possessed 1159 HCT units and conducted a total of 6904 transplants in 2020. They were divided into four levels which contained 24 (≤25 transplants per year), 15 (26–50 transplants per year), 23 (51–100 transplants per year) and 21 centers (>100 transplants per year), respectively. Among the big centers, 90.5% were located in municipalities or provincial capital cities ($P = 0.029$), 95.2% were affiliated to hospitals with ≥2000 beds ($P = 0.009$), and 100% possessed an independent HCT department. 89.2% HCT centers conducted both auto-HCT and allo-HCT, and 94.9% allo-HCT centers could conduct haplo-HCT. The median number of HCT per bed and per physician was 5.8(3.3–9.1), 6.4(3.1–10.3), and an increasing HCT efficiency was observed with the HCT number of centers ($P < 0.001$). Preferred flows of HCT recipients were quite different between auto- and allo-HCT after discharging from HCT units ($P < 0.001$). The first choice for auto- and allo-HCT were back to home directly ($n = 38$, 45.8%) and transfer to normal hematological ward ($n = 44$, 53.0%), respectively. During the follow-up of post-HCT, most centers recommended recipients to be followed up by their HCT physicians regardless of auto-HCT ($n = 60$, 72.3%) or allo-HCT ($n = 75$, 90.4%). Logistic regression models showed that more beds in hematological department (OR = 6.540, $P = 0.035$) and higher HCT efficiency per bed (OR = 6.457, $P = 0.021$) were positively related to the a big autologous HCT center, and more beds in hematological department (OR = 19.838, $P = 0.031$), higher HCT efficiency per unit (OR = 18.610, $P = 0.017$), higher HCT efficiency per physician (OR = 132.747, $P = 0.025$), location in big cities (OR = 115.532, $P = 0.031$), and the prospective collecting programs for HCT bio-sample (OR = 11.665, $P = 0.044$) were positively related to a big allogeneic HCT center.

Table 1: Multivariate logistic analysis for big auto-HCT and allo-HCT centers

	Variables	*P* value	OR (95% CI)
Auto-HCT	Number of hospital beds, ≤2500 vs >2500	0.719	1.393(0.229–8.462)
	History of auto-HCT, ≤15 vs >15	0.520	1.749(0.319–9.605)
	Number of beds in hematological department, ≤100 vs >100	0.035*	6.540(1.142–37.456)
	Auto-HCT per bed, <3 vs ≥3	0.021*	6.457(1.329–31.356)
	Auto-HCT per physician, <3 vs ≥3	0.096	3.692(0.792–17.217)
	Auto-HCT per nurse, <2 vs ≥2	0.839	1.187(0.227–6.206)
	Subspecialty of HCT, no vs yes	0.176	2.957(0.615–14.220)
Allo-HCT	Location in provincial capital cities/ municipalities, no vs yes	0.031*	115.532(1.525–8753.317)
	Number of beds in hematological department, ≤100 vs >100	0.031*	19.838(1.315–299.308)
	Allo-HCT per bed, <5 vs ≥5	0.017*	18.610(1.694–204.454)
	Allo-HCT per physician, <4 vs ≥4	0.025*	132.747(1.842–9568.521)
	Allo-HCT per nurse, <2 vs ≥2	0.828	0.714(0.034–15.004)
	Allo-HCT/HCT, <0.65 vs ≥0.65	0.345	3.532(0.257–48.515)
	Subspecialty of HCT, no vs yes	0.358	2.972(0.291–30.363)
	Prospective bio-sample collecting programs, no vs yes	0.044*	11.665(1.065–127.754)

Conclusions: Through this first nationwide survey on HCT centers, we outlined the landscape and challenge of HCT centers in China which may be beneficial for policy-makers as well as the development of individual centers.

Disclosure: Nothing to declare

31 - Data Management

P738

FINDING OUT THE REGULATORY REQUIREMENTS FOR THE DEVELOPMENT OF GENE AND CELL THERAPY PRODUCTS WITH THE EUROGCT RESEARCH PATHWAYS

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Background: Communicating information on the regulatory framework applicable to gene and cell therapies, at every stage of development and towards every actor involved, is a challenge. Therapy development needs to comply with several regulatory requirements mostly to ensure products' and patients' safety, the complexity comes from the diversity of the regulatory frameworks. Some requirements are binding, others are guidance only. Most aspects are governed by European Union law, but some remain regulated on a national scale. The regulatory landscape is a combination of general and specific rules and guidances depending on competent institutions (e.g. EU and Member States regulatory agencies or health technology assessment bodies), types of products, and steps of their developments.

Methods: The European Consortium for Communicating Gene and Cell Therapy Information (EuroGCT) is building an online tool

to provide research pathways' information. Therefore, communicating clear, precise, and accurate information in the form of a database. It will allow professionals of the field as well as patients to be informed on all regulatory aspects of the development of a Gene and Cell therapy product.

Results: Depending on the legal classification of these therapies different regulatory pathways appear, which are shown on the EuroGCT website. Becoming a "one-stop shop" for accurate legal information on the legal classification of Gene and Cell therapies from lab to patient.

Conclusions: The tool will facilitate better decision-making at key points in development of new therapies and thus enable improved product development, by providing the research community and regulatory and healthcare authorities with an information source on the practical steps needed for cell and gene therapy development.

Disclosure: Nothing to declare

31 - Data Management

P739

UPDATING DONOR REGISTRIES ON THE GOOD, THE BAD AND THE UGLY. A BSBMTCT REGISTRY ANALYSIS OF PATIENT FOLLOW-UP REPORTS COMPLETED FOR DONOR REGISTRIES WORLDWIDE (2012-2022)

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Background: The British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT) completes patient follow-up reports (PFURs) for donor registries worldwide. The number of PFURs completed over the past decade for donor registries was of interest as this is a service provided outside of the core workstream.

Methods: Since May 2012 completion dates of PFURs have been logged as free text within the comments section of the EBMT ProMISe database. Comments, along with additional Med-A data, were exported to Excel for allograft transplants to identify patients and transplants with completed PFURs. A significant amount of manual checking was required as logs, made by different staff, varied in written format and could contain typographical errors. The initial export contained 36,656 transplants which was reduced to 4221 relevant cases. Some patients had repeat PFURs (due to different transplants and/or the initial PFUR getting 'lost' in transmission), so a tally of PFURs against each transplant was made. The exported Med-A HSCT data allowed identification of the donor centre.

Results: The first log in ProMISe for PFURs was 26/05/2012 and the last log (up to the point of data export) was 18/11/2022. In total 4754 PFURs were logged and sent to donor registries worldwide.

Thirty-seven countries received PFURs. The top 5 countries for PFURs are: Germany (2907, 61.1%); UK (854, 18.0%); Poland (306, 6.4%), USA (131, 2.8%) and Israel (126, 2.7%). Six countries only had one PFUR each: Chile, China, Ireland, New Zealand, Slovakia and Slovenia.

The number of PFURs completed each year have generally increased over the last decade. In 2013 (first full year) 415 (8.7%) were completed and in 2021 (most recent full year) this increased to 771 (16.2%). The number for 2022 so far is lower than expected at 472 (9.9%) but this is because staff shortages and Covid-19 lockdowns had a knock-on effect.

Table 1 shows the top 5 and 10 donor registries for PFURs. DKMS gGmbH (Germany) came top and received 49% (2329) of all PFURs. Anthony Nolan received 9.4% (449) of all PFURs and were second placed. The top five registries combined had 74.9% (3562) of all completed PFURs, while the top 10 had 84.7% (4029).

The DKMS donor registry is German in origin but today is international with additional registries in Chile, Poland, USA, Africa, UK and India. Looking at the combined DKMS registries, they had 61.3% (2915) of all PFURs.

Table 1: Top 5 and 10 donor registries for patient follow-up reports (2012–2022)

	ION Code	Name of Donor Registry	Country	Number of Completed Patient Follow-up Reports (2012-2022)		Total	
1	4596	DKMS gemeinnützige GmbH - HUB DR (DE-DKM)	Germany	2329	49.0%	3562	74.9%
2	6354	Anthony Nolan (AN)	UK	449	9.4%		
3	7414	Fundacja DKMS (PL-DKMS)	Poland	301	6.3%		
4	9968	DKMS United Kingdom (GB-DKMS) Aka Delete Blood Cancer	UK	282	5.9%		
5	6939	Stefan-Morsch Stiftung (DE-SMS)	Germany	201	4.2%		
6	4987	Ezer Mizion (EM)	Israel	124	2.6%		
7	6939	Bayerische Stammzellbank gGmbH (DE-AKB)	Germany	114	2.4%		
8	2731	British Bone Marrow Registry/NHS Blood and Transplant (BBMR)	UK	100	2.1%		
9	3553	National Marrow Donor Program (NMDP)	USA	73	1.5%		
10	8139	Matchis Foundation (MATCHIS) Previously known as Europdonor Foundation (prior to 2016)	The Netherlands	56	1.2%		
Total				4029	84.7%		

Conclusions: DKMS gGmbH in Germany received, by far, the most PFURs from the BSBMTCT (49.0% of all PFURs). No other registry or country had nearly as much PFURs completed for them. The DKMS collective of international registries is also comparable to Germany in terms of the number of PFURs completed, 2915 (61.3%) and 2907 (61.1%) respectively.

Disclosure: Nothing to declare

31 - Data Management

P740

DEVELOPMENT OF DISTANCE CONTINUING EDUCATION FOR DATA MANAGERS, USING THE DESIGN THINKING METHODOLOGY

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Background: Actions to consolidate the Brazilian registry of hematopoietic stem cell transplantation (BRHSCT), using the infrastructure of the Center for International Blood and Marrow Transplant Research (CIBMTR) were executed by the Brazilian Society of Cell Therapy and Bone Marrow Transplantation (SBTMO), CIBMTR and Data Managers Working Group (DMWG). From 2016 to 2021 there was an increase of 127% of active centers (11 to 25) and 92% of registered transplants in CIBMTR (595 to 1141), reinforcing the need to train data managers (DM) to ensure accuracy of the data sent to the CIBMTR. In 2017, the 1st national, free distance learning (DL) tutorial was developed. To maintain the continuing education of DM, in Dec/2021, the 2nd version of the course started with the Design Thinking (DT) methodology (concept of Rolf Fast (Stanford teacher) and David Kelley, in the 70´s).

Methods: The DT method promotes creative, empathetic, and collaborative solutions to solve problems through 5 steps, which were consolidated and resulted in the creation of the course from Dec/2021 to Apr/2022.

Results: There were 42 professionals mobilized to teach in the course voluntarily from 16 institutions (13 national and 3 international), with 41% (16) of them being specialists from several areas. The course was structured in 7 modules, containing 60 video lectures, 13 support testimonials and 9 knowledge areas. When comparing the 1st and 2nd courses, there was an increase of 740% (5 to 42) in the number of instructors. Both were distance-learning, the first was a tutorial, containing 2 modules with 0.75h of videoclasses duration, and the second had a total duration of 18.9h. There was an increase of 250% (2 to 7) of modules and 2420% (0.75h to 18.9h) of workload. The courses were published on the CIBMTR and Hospital Israelita Albert Einstein digital platforms, and the 2nd course also in Hematolog.

Table 1: Brazilian educational training for data managers

	Subject	Number of speakers ($N = 42$)	Number of video lessons ($N = 60$)
Module 1	HEMATOPOIETIC STEM CELL TRANSPLANTATION BRAZILIAN REGISTRY OF THE BRAZILIAN SOCIETY OF BONE MARROW TRANSPLANTATION AND CELLULAR THERAPY (SBTMO) https://academiadigital.einste% (16) of them being specialists from several areas. The course was structured in 7 modules, containing 60 video lectures (Table 1), 13 support testimonials and 9 knowledge areas. When comparing the 1st and 2nd courses, there was an increase of 740% (5 to 42) in the number of instructors. Both were distance-learning, the first was a tutorial, containing 2 modules with 0.75h of videoclasses duration, and the second had a total duration of 18.9 h. There was an increase of 250% (2 to 7) of modules and 2420% (0.75h to 18.9h) of workload. The courses were published on the CIBMTR and Hospital Israelita Albert Einstein digital platforms, and the 2nd course also in Hematolog. in.br/oe/1040/video	14	14
Module 2	CELL THERAPY AND ACCREDITATION BASIC CONCEPTS https://academiadigital.einstein.br/oe/1078/video	10	10
Module 3	CENTER FOR INTERNATIONAL BLOOD AND MARROW TRANSPLANT RESEARCH (CIBMTR) BASIC CONCEPTS https://academiadigital.einstein.br/oe/1104/video	2	6
Module 4	BASIC CONCEPTS OF FILLING IN CIBMTR DATA FORMS – AUTOLOGOUS BONE MARROW TRANSPLANTATION – MULTIPLE MYELOMA https://academiadigital.einstein.br/oe/1123/video	4	9
Module 5	FILLING IN CIBMTR DATA FORMS - MYELODYSPLASTIC SYNDROME CLINICAL CASE https://academiadigital.einstein.br/oe/1132/video	2	3
Module 6	FILLING IN CIBMTR DATA FORMS – POST-TRANSPLANT COMPLICATIONS https://academiadigital.einstein.br/oe/1158/video	6	9
Module 7	BASIC, INTERMEDIATE AND ADVANCED STATISTICS FOR CELL THERAPY https://academiadigital.einstein.br/oe/1211/video	4	9

Conclusions: We concluded that the DT method facilitated the development of the educational content, by allowing for easy identification of main issues so that timely adjustments could be made to improve DM's education. There was a national and international effort to maintain strategies to provide continuing education for DM and improve the accuracy of data in the

RBHSCT. The course serves as an important continued education tool for data managers working with HSCT data, as seen by the large number of enrolled students.

Disclosure: Nothing to declare

31 - Data Management

P741

A SUSTAINABLE PIPELINE TO STAFF A DIVERSE RESEARCH DATA MANAGEMENT TEAM

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Background: In response to the absence of an established pipeline for diverse and inclusive hiring and to address staff retention challenges such as staff leaving for Industry positions or medical school, we designed an Intern-to-Full Time Employee (FTE) pipeline as a sustainability tool for staffing and to ensure diverse hiring within our research data management team.

Methods: In response to recognition of barriers imposed by systemic racism, we prioritized building a more diverse research data management team. We partnered with Dana-Farber Cancer Institute's Workforce Development Office (WFD) to host student interns for academic-year and summer cycles. WFD partners with underrepresented and historically marginalized communities in the Boston area to ensure youth and adults can develop skills and have access to resources needed to pursue healthcare careers. Through their student training program, WFD places interns in departments across Dana-Farber. WFD provides interns with college and career readiness and skills training, which allows our clinical trials staff to focus on clinical research and data management activities with the interns. Each intern is assigned to a dedicated supervisor to allow for guidance and mentorship simultaneously providing the supervisor with leadership opportunities. Standardized intern responsibilities include required training, pre-specified project work and delegated tasks. Interns are integrated into daily activities through job-shadowing with team members ranging from research coordinators to physicians. Once a new intern is onboarded and acclimated to team operations and the pre-specified tasks, they join additional projects based on team need and intern interest. We ensure each intern feels their importance within our team through assigning responsibilities, consistent communication and providing opportunities for growth within the team.

Results: With the Intern-to-FTE pipeline we have hosted five WFD interns and hired three WFD interns into full-time positions. We expanded the number of interns we can host during a given intern cycle through process-improvement and streamlining efforts. The makeup of our team is more diverse, allowing us to better represent the patient populations we serve. This pipeline helped us establish a culture that accepts interns as valuable contributors to our program, whether they go on to FTE positions within our team or not.

Conclusions: Our results suggest that partnering with underrepresented and underserved community groups can impact the dynamics of a growing team by increasing diversity, creating a culture of collaboration and mentorship and overall engagement in the work by interns and FTEs alike. Through this effort, we ensure we build teams with diverse voices that prioritize inclusion and collaboration. Full time staff hired through this pipeline require less onboarding and training due to their intern experience, creating efficiencies in the growth of our team. By hosting student interns, we are introducing and providing exposure to a specific sector of healthcare that may establish sustained interest in research and healthcare careers in the future.

Disclosure: Nothing to declare