EBMT

ABSTRACTS COLLECTION

The 48th Annual Meeting of the European Society for Blood and Marrow Transplantation: Data Management Group – Poster Session (P601- P606)

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Data Management Group Poster Session

P601

Optimizing teamwork leads to a high quality data collection

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Background: The primary objective of a Clinical Data Manager is to provide high quality data by keeping the number of errors and missing data as low as possible. In 2010, at Duran i Reynals hospital, the paper-based medical record was replaced by a digital one. Made life much easier but what if we could make the most out of this tool? And for that, a simple but optimal method for essential data collection for our transplant unit is, worked out together with the IT team to improve the use of our Software tool. Instead of getting all the date from a written text which takes a lot of time, we asked that templates be added to the tool, to be filled by our Physicians and Nurses meanwhile visiting the patient.

Methods: Our transplant team is asked to provide, the essential data they need during the different visits they have with the patient and, together with the data requested from the different national and international databases and CRFs we work with, we created a template in which we ask the IT team to add as a drop-down in the patients electronic health record. Tabs are designed exclusively for our Physicians and nurses of our transplant unit. At each visit they have with the patient, they fill in the templates directly. Once the grids are completed, they are saved. Once saved, the information is automatically reflected in text at the digital patient's medical records and available in excel for the Data manager.

We have specific templates for AUTO, ALLO and Cell Therapy transplantation. They are classified in such a way that the information is collected from the first pre-transplant visit to the day the patient is discharged.The diferente templates are:

- Nurse: (Figure 1)
  First ALLO/AUTO pre-HSCT visit
  Family Typing
  First Visit Donor
  First mobilization visit
  Post discharge telephone visit 48h
  On-site visit upon discharge
  First mobilization visit
- Physician: (Figure 2)
  First ALLO/AUTO/pre-HSCT visit
  Post-transplant visits (100 days, 3 months, 6 months, 9 months, 1 year & 2 Years).

Results: This method has saved us a lot of time both in the patient consultation as in completing databases and CRFs of different studies. We can keep our databases up to date. The information is clear and direct from the medical staff. The fact that the information is collected in situ reduces the margin of error and makes it possible to obtain more reliable and valid data.

Conclusions: In order to optimize the use of resources, synergy with the team and other departments, can make you save a lot of time and work in a more efficient way. Thanks to this method, which makes us collect quality data more quickly, accelerates the availability of the data.

Disclosure: Nothing to declare

P602

A pilot project to evaluate the benefit of additional support in HCT research data management on behalf of Anthony Nolan and BSBMTCT

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Background: Anthony Nolan carries out retrospective research to determine the best possible donor for a patient undergoing

Haematopoietic Cell Transplantation (HCT) using an unrelated donor. Factors studied include the use of both HLA and non-HLA genetic markers as well as clinical factors.

Transplant centres are submitting clinical outcomes data to the EBMT Registry database, where national registries have a shared access. Consecutive BSBMTCT data management surveys have reported of centres' data managers growing workload, with capacity and resourcing frequently cited as impediments to fully participating in retrospective studies.

Methods: A Research Data Manager (RDM) was recruited in June 2021, embedded within two large UK BMT centres, working alongside Data Managers (DMs) to provide additional resourcing.

The first Centre is a multi-disciplinary centre performing approximately 120 allografts per year, and the placement continued successfully, despite COVID-19 mitigations. HCT dates for the first centre cohort of 209 patients ranged from 1996-2020, posing specific challenges such as needing to access up to eight different data sources (from paper records to diagnostic reports; drug schedules; legacy systems and a new Electronic Health Record (EHR) system). One legacy system was no longer accessible, making it impossible to verify any data still available in the EHR system.

Training was required for the current and legacy local systems and specific centre working practices. The RDM benefited from existing knowledge of the EBMT Registry system and working knowledge of BMT data variables. The RDM began work on a mix of historical and recent patients, to become familiar with different data sources and estimate the time required for patients transplanted in earlier time points, before prioritising recent patients over historical paper records.

Results: In five months, the RDM has so far collected and validated MED-B data on 176 of 209 patients in the first centre. The MED-B includes MED-A (essential) items, plus optional data questions for studies, such as chimerism and transplant complications. In this way, the centre can benefit further if these patients are selected in future studies. The RDM was also able to contribute to another study due to overlapping patients.

Variability in data availability was seen, depending on the time-period and prior studies. The table below shows an example of key items where data completion improved:

Missing Data Items	Jun 2021	Nov 2021
Ethnicity specified	209	62
Overall chimerism	123	15
Infections by day 100	124	13

Conclusions: Two main challenges included: the variety of patient data sources and legacy systems in longitudinal studies; the availability of follow up for long-discharged patients. Advances in digital healthcare made it possible to trace some historical patients, however there is scope for follow up improvement. The results demonstrate the benefit of increased data completion with additional resourcing, along with a significant increase in patients now included in this project.

Disclosure: Nothing to declare

P603

Adapting interactive pre-stem cell transplant screening and clearance dashboard for pediatric non-malignant blood disorder patients: experience from a tertiary care center during the COVID-19 pandemic

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Background: Stem Cell Transplantation (SCT) requires coordinated pre-transplant care involving vital clinical investigations and evaluations for screening and clearance prior to SCT procedure, necessitating active coordination and follow-up. Pediatric Hematology/Oncology department at King Faisal Specialist Hospital & Research Centre, Riyadh,Saudi Arabia is the national referral center for Inherited Non-Malignant Blood Disorders (NMBD) cases indicative of SCT

Methods: Pre-BMT Screening and Clearance module on REDCap software was developed in January'2016, as part of the institutional performance improvement initiative to streamline pre-SCT clearance. The electronic software was adapted into an interactive dashboard during the course of COVID-19 pandemic (March 2020 to October 2021) to prioritize and facilitate the clearance process and virtual clinic follow-up for continuity of care.

Results: A total of 139 cases were referred for SCT during the course of pandemic, 81% (112/139) with Hemoglobinopathies (sickle cell disease, 67% (75); thalassemia, 25% (28); sickle cell-thalassemia, 8% (9)) and 19% (27/139) Bone Marrow failures (severe aplastic anemia 67% (18), Fanconi anemia 11% (3), Diamond blackfan anemia 11% (3), congenital neutropenia 11% (3)). Patients were categorized in to reports based on their HLA typing, pre-SCT workup and clearance status: A total of 62% (86/139) patients had fully-matched donor of which 58 (67%) on follow-up for further investigations and 20 (33%) cleared for SCT, while 38% (53/139) had No-Matched Donor available. Patients from the follow-up report reviewed weekly by the clearance team to facilitate investigations through virtual clinic appointments every two weeks, while an alternate donor search conducted periodically for patients from the No-Matched donor list. From the cleared patients, 80% (20) of the transplanted patients were with bone marrow failures requiring urgent transplant.

Conclusions: User-friendly feature of the system enabled interactive dashboard for disease-specific work-up plans, identification of early-scheduling areas through virtual clinic follow-up during the pandemic. In our experience, incorporating the interactive machine-learning model with telemedicine was found capable of maintaining continuity of care, demonstrating an unexpected prospect in the face of adversity.

Clinical Trial Registry: Not Applicable

Disclosure: None to declare

P604

The role of the UK transplant trials network impact in delivering the Amadeus study during the COVID-19 pandemic

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Background: Improving survival for patients with acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS) is reliant on the success of clinical trials which underpin advances in routine patient care. The COVID-19 pandemic has significantly impacted cancer services and negatively affected the ability of centres to run clinical trials.

Despite the challenges of the pandemic, patients with AML and high-risk MDS continue to be offered curative treatment with allogeneic stem cell transplantation (allo-SCT). Relapse risk post-transplant remains high, reported in up to 40–70% of patients, and therefore studies with a focus on reducing relapse are essential to improve outcomes.

Methods: Here we describe the critical importance of a network of transplant centres in the United Kingdom (UK) to support the delivery of essential transplant clinical trials throughout the COVID-19 pandemic. The IMPACT network in the UK is composed of 11 funded and 11 affiliate (unfunded) centres. Funding supports a clinical trials research nurse at each funded centre. The network is focused on prompt set up and delivery of primarily investigator led transplant studies, one of which is the AMADEUS study (NCT04173533). AMADEUS is the first multicentre, prospective, two arm, double blind, randomised phase III clinical trial comparing the efficacy and safety of oral azacitidine (CC-486) versus placebo in subjects with AML or high risk MDS following allo-SCT.

Results: The AMADEUS study plans to recruit 324 patients over 3 years. The trial opened in 19 IMPACT centres and the first patient was enrolled in June 2019. Despite recruitment being briefly halted for 3 months at the start of the pandemic, the essential support provided by the IMPACT trials team, ongoing engagement with the chief investigator and regular communication with principal investigators and study site staff, meant the trial was able to re-open by July 2020. 84% of AMADEUS patients enrolled to date have been recruited since March 2020. The study has now recruited more than 57% of its target sample size with 226 patients having been screened and 187 patients randomised.

A key focus for the IMPACT network is to obtain high quality data and ensure study protocols are inclusive and acceptable for patients. As such, amendments were made to collect COVID-19 data remotely, to permit telephone consultations and to perform defined protocol assessments locally. Such amendments ensured safe delivery of the study whilst reducing the burden of travel and hospital visits for patients and supporting patients to remain on study, particularly those living in rural communities.

Furthermore, sample collection for translational research has exceeded target with a return of 89.7%, providing an important source of material for future studies.

Conclusions: Recruitment to clinical trials continues to be a challenge during the COVID-19 pandemic and threatens therapeutic advances for patients with blood cancers. A national model of integrated transplant centres (IMPACT) focused on the delivery of clinical studies ensures resilience in trial recruitment, provides a platform for the sharing of clinical experience, enables sites to learn from best practice and most importantly facilitates nationwide patient access to novel agents.

Clinical Trial Registry: ClinicalTrials.gov number: NCT04173533

Disclosure: Ingram, Wendy - Advisory Board/Honoraria - Novartis, Takeda, SOBI, Alexion.

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Chakraverty, RonJon - Speaking honoraria from Neovii and Mallinckrodt Pharmaceuticals (Therakos (UK) Ltd); Consultancy fees from Novartis.

P605

A cost analysis for the cellular therapies supply chain: Identifying the low-hanging fruits to optimize cost control

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Background: Chimeric Antigen Receptor (CAR)-T cell therapies represent one of the most promising cancer treatments in recent years. In contrast to traditional oncology drugs, this form of personalized medicine typically involves autologous donation, labor-intensive manufacturing and a complex supply chain. Robust cost control is increasingly important to enable future patient access globally.

Methods: Resulting from an in-depth cost and market analysis, we identify key cost drivers in the cell procurement process. The cell procurement includes all costs associated with autologous donation, cryopreservation and logistics of the cellular starting material.

Results: Based on the most significant cost drivers, cost reduction opportunities were identified and analyzed for their feasibility in the heavily regulated landscape of cell therapies.

Conclusions: We show how cost control is an essential next step in the future success of cellular therapies, where a lower Cost of Goods enables further global deployment serving those patients in need.

Disclosure: Nothing to declare

P606

Observational trends in GvHD data submissions: Do centres have a data collection process and is this responsible for submission improvements?

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Background: The Graft versus Host Disease (GvHD) data submission allows the collection of data variables like those relating to its prevention, onset, staging, conditioning intensity and site of disease. The grading and submission of these have been one of the challenges faced by Data Managers over the years.

Methods: We wanted to know if all our Allogeneic Transplant centres had documented processes supporting their GvHD data collection and submissions, and if Data Managers were confident interpreting the clinical data required for GvHD data variable fields on the ProMISe database. We ran data reports from ProMISe and sent out a poll to the centres to know if they had processes for GvHD data collection and submission, and to further buttress our research on data submission improvements since 2004.

Results: Our data revealed a total of 33,023 allogeneic transplants were performed between 1974 and 2020. Between 2004 and 2020, submission had improved and missing data for aGvHD reduced from 10% (2638/14148) to 4% (878/2350), while that of cGvHD showed a reduction from 15% (6971/26,576) to 10% (1997/19,259).

The proportion of missing GvHD data for most centres had also reduced as shown in our comparison graph below (Fig. 1).

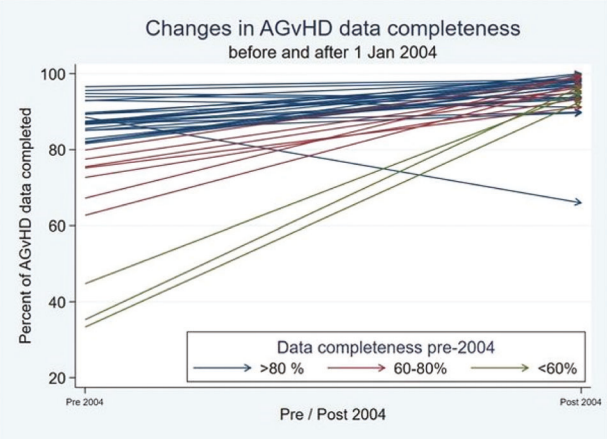

Figure 1: Differences between GvHD data submission completeness for centres before and after 2004.

Some other patterns observed in the reported data included the highest proportional occurrence of aGvHD being amongst the 31–40-year old, age at Transplant. Our survey and report data comparison report is summarised below (Table 1).

Overall centre			**% of GvHD Data submission completeness**	**Familiarity**			**Median GvHD completeness**
					DM is Familiar with Process	16	
	Responded	19	98%		DM is not Familiar	2	98%
	Did not Respond	13	96%		Clinical staff provides Data	1	97%
	p-value		**0.13**		**p-value**		**0.88**
			Median GvHD completeness	**Confidence**	Yes	13	**Median GvHD completeness**
Process	Yes	14	97%		No	5	98%
	No	5	98%		Not Applicable	1	94%
	p-value		**0.56**		**p-value**		**0.63**

Table 1: Comparison between report and poll data for 19 Allograft performing centres that responded to poll.

Of the 19 centres that responded, we compared their survey and reporting data. Though the percentage of completeness for each group was quite good; it was over 90% in all the groups, the p-values were not lower than our overall significant level of 0.05 for any of the questions.

Conclusions:

1. 74% our Allogeneic Transplant centres that responded to our poll, had established data collection processes massively supporting GvHd data submissions.
2. The proportion of missing data by centres shows improvement. Interestingly, factors such as having data collection and submission processes, familiarity with the process and confidence with reporting the data collected, does improve reporting. However, from our research these factors are not statistically significant.
3. Improved data submission can give Clinical teams some insight into planning for better care of GvHD patients.

Disclosure: Nothing to declare