EBMT

ABSTRACTS COLLECTION

The 48th Annual Meeting of the European Society for Blood and Marrow Transplantation: Quality Management Group – Oral Session (O159-O162)

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Quality management oral session

O159

Development of a nursing education pathway for the introduction of chimeric antigen receptor T cell (CAR T) therapy

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Background: This research presents a case study on the design and development of a bespoke nursing education pathway to meet competency and accreditation standards.

Nurses are at the forefront of introducing new treatments and improving the patient's experience, new interventions require bespoke training so that knowledge can diffuse throughout a unit. However little guidance is given on how to design and develop an end to end bespoke learning pathway for specialist nurses.

St James Hospital Stem Cell Transplant unit commenced delivery of a CAR T cell therapy programme in December 2021. The administration of this therapy and the nursing care of this cohort of patients required specific education and training.

Review of the current haematology nurse training highlighted the need for the development of a tailor made CAR T cell nursing education pathway that would build on the knowledge and skills of nurses already competent in the administration and nursing care of patients receiving allogeneic and autologous transplants.

Methods: A course development team was established to commence a gap analysis of current training. The team collated essential documentation e.g. policies and procedures, nursing competencies, JACIE accreditation requirements.

Using an action research methodology (Coghlan and Brannick 2014) a cooperative inquiry (CI) group was established. This was a collaboration between the clinical skills team of the Department of Nursing and Midwifery, Trinity College Dublin and the clinical nursing team and clinical quality manager from the stem cell transplant unit of St James Hospital, Dublin. The group represented technical, clinical and education skills.

Results: A bespoke end to end education pathway was designed for a specific cohort of nursing staff which included theoretical, simulation and practical components.

Finalising CAR T cell policies and procedures was key to planning and informing the education pathway. Utilising local and international knowledge was required to plan the pathway and identify key learning outcomes for a specific staff cohort.

The development of videos was utilised to impart key learning. Majima et al (2018) note clinical videos capture and transfer expert nursing knowledge. A repository of photographs and videos were produced and utilised as part of the education pathway.

Conclusions: Key learning from the action research method was the importance of agreed hospital policies and procedures to underpin the education process and provided a way to share skills, knowledge and responsibilities.

The development of the CAR T nursing education pathway highlighted areas in policies that required further consideration or clarity. The final approval of all policies prior to script sign off and filming ensured there was full agreement and confidence in the educational material filmed and documented.

Further opportunities for extracting the knowledge learned from this case study and utilising this well-designed education pathway are abundant and have the potential to change the way we plan and deliver bespoke education to specific cohorts of staff.

Disclosure: Not applicable

O160

Implementation of a standardized therapeutic education program for patients who receive an allo-HSCT

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Background: JACIE clinical standards promote high- quality patient care and require a training system for the professionals

in the HSCT ward. Due to the COVID-19 pandemic, we have a more significant rotation of professionals in the staff, which implies the incorporation of junior nurses, and the employment of additional nursing staff with relevant experience from the hospital pool of nurses who do not have experience in the care of transplant patients. On the other hand, allo-HSCT is a complex procedure that involves an extended hospital stay. It is essential to empower the patients and their primary caregivers to maintain adherence to drug treatment and to follow strict measures once at home during the entire period. These facts led us to assess the need for a tool in order to aid nurses to determine what therapeutic education the patient ought to receive precisely at each stage of the allo-HSCT procedure and at the same time increase the quality and continuity of the care received by the patients.

Methods: Design a standardized therapeutic education program (TEP) based on our institution's clinical guidelines and the available scientific evidence, that allow the entire nurses' team in the HSCT ward to access the information and therapeutic education the patient must receive at each moment of the allo-HSCT procedure.

Results: In December 2020, a team of nurses from the HSCT ward, haematologists, and the quality manager began the development of a TEP that finished in April 2021. In May 2021, the TEP was shared by email with the entire nursing team. We held an online session where the TEP was presented and posted on our intranet to be viewed later. A record of the viewing session was made, obtaining that 87.5% of professionals in the unit viewed the session. In June 2021, we began the application of TEP, and 32 patients who received an allo-HSCT have been included. The TEP development has helped us review and update all the documentation given to patients. It has led us to develop a new guide with recommendations for discharged patients who receive an allo-HSCT and their primary caregivers.

Conclusions: TEP's implementation is being evaluated using specific questionnaires for patients and nurses as a tool for improving the quality of patients' care and safety during the process. At the same time, it adds value to the nurse's role in therapeutic education during the transplant procedure.

Disclosure: Nothing to declare

O161

Impact on days to take by changing from fresh to cryopreserved peripheral blood stem cells during the COVID-19 pandemic – a single center study

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Background: On March 13th, 2020 the COVID-19 pandemic changed the complex planning of patient and donor before a hematopoietic stem cell transplantation (HSCT). European Blood and Marrow Transplantation (EBMT) changed in March 2020 its recommendations to:

- Stem cell products from all unrelated donors, changed to peripheral (PBSC), as first priority.
- Fresh PBSC products to be delivered to recipient center and cryopreserved before start of conditioning.
- Request of higher cell count for non-myeloablative HSCT.

Due to the risk of a donor testing Covid-19 positive, we chose to search for three unrelated donors, instead of the usually two.

Purpose

To compare the safety of changing the infusion procedure from fresh to cryopreserved PBSC on the following endpoints:

- number of days to neutrophil take (first of 3 consecutive days with neutrophils ≥ 0.5 Mia/L).
- number of days to platelet take (first of 3 consecutive days with platelets ≥ 20 Mia/L without transfusion)
- cell dose harvested.

Methods: Retrospective data was collected for myeloablative and non-myeloablative patients from our local database. Patients from the age of 18 was included and data was collected within day +100 (+/− 14 days).

Patients received cryopreserved PBSC in the period between March 13th until October 1st, 2020.

We compared data from cryopreserved PBSC to data from the use of fresh PBSC from January 1st to December 31st, 2019.

Mean values were compared by the Mann–Whitney test, p values < 0.05 were considered significant.

Results:

Type BMT	Cryo 2020 $N = 13$ NMA	Control 2019 $N = 56$	Cryo 2020 $N = 16$ MAC	Control 2019 $N = 28$
Days to neutrophil take				
Mean	21.3 (range 11–34)	18.40 (range 0–19)	20 (range 13–33)	20.71 (range 13–29)
Median	25.5	19	24.5	24.5
p	0.968		0.349	
Days to platelet take				
Mean	24.46 (range 0–109)	19 (range 0–70)	21.14 (range 12–20)	23.96 (range 14–92)
Median	16	0	20	23
p	0.107		0.913	
CD34 + x10*6/kg				
Mean	8.51 (range 3.4–1.16)	8.84 (range 2.19–15.66)	7.39 (range 4.1–13.34)	6.38 (range 3.88–8.91)
Median	7.35	7.80	8.72	7.44
p	0.954		0.347	

Conclusions: We observed no statistically significant difference in engraftment by changing the transplant procedure to cryopreserved PBSC.

In our department we usually don't perform a cell count before infusion of fresh cell products and neither did we during the pandemic when infusing the cryopreserved product. Therefore, we can't compare the cell dose harvested to the cell dose infused.

Despite we followed the new EBMT recommendation for requesting a higher cell dose, our experience was that the cell dose harvested during the COVID-19 pandemic was almost the same as before the pandemic.

In conclusion, cryopreservation of PBSC products before HSCT, is a safe procedure without consequences for engraftment.

As an essential point in using cryopreserved PBSC products instead of fresh PBSC, our center had an increased workload. The increased workload applied for all professional groups involved in the transplant procedure.

Disclosure: No conflict of interest

O162

Can regulatory-driven process innovation open the door for cellular therapies to emerging markets?

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Background: Due to their impressive clinical success, cellular therapies are becoming a more mainstream treatment for patients with hematologic malignancies. In order to make this promising form of therapy accessible to patients in need worldwide, a successful scale-up of all parts of this complex supply chain is essential. Already a challenging endeavor in most privileged countries, but a chimerical undertaking in the more logistically challenged regions across the globe.

Methods: Cryopreserving the fresh apheresis material will maintain cell viability through longer hold-times while providing the necessary flexibility in scheduling a manufacturing slot. However, this logistical de-risking comes at a cost. If not designed well, the cryopreservation process can easily be mistaken for a manufacturing step bringing unnecessary regulatory requirements to the cost of this treatment.

Results: Fortunately, regulators have recognized this and provided guidance on what forms of cellular processing are considered non-substantial manipulations (e.g. 2009/120/EC, 1394/2007). We present a minimally manipulating cryopreservation process with risks that can be mitigated under Tissue and Cell legislations (e.g. 2004/23/EC). The simplicity of this fully closed process will also enable peripheral hospitals to perform the cryopreservation locally, without the need for expensive clean-rooms or GMP requirements.

Conclusions: What is then needed for a truly global roll-out of this innovative treatment is that both manufacturers and inspectors embrace this concept and work together on a harmonized implementation of the existing regulatory framework for cellular starting materials. If successful, this will lead to a high-quality product accessible throughout the world, lower cost of goods and minimal regulatory burden.

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