

Preparing the Apheresis service for novel cellular therapies (CAR-T): Challenges and Solutions

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Introduction

Mononuclear cell collection via Apheresis is the first step on the pathway for immune effector cell therapies. The most promising of these therapeutic interventions is Chimeric Antigen Receptor T- cell therapy (CAR-T) for the treatment of certain haematological malignancies, and will require patients to complete un-mobilised leukapheresis procedures. In the UK, two CAR-T products are currently licenced and approved for this indication (NHS England, 2018). In addition, numerous clinical trials are providing opportunities for patients to access these novel therapies following unsuccessful conventional treatments.

There is also interest within solid tumours, exploring the mechanism of collecting large numbers of mononuclear cells / T lymphocytes for both diagnostic and therapeutic purposes, widening access of Apheresis services to non-haematological/transplant settings, and therefore potentially increasing pressures on this service.



Methods

The Apheresis unit primarily serves the Haematopoietic Stem Cell Transplant (HSCT) programme at our tertiary referral, JACIE accredited, specialist cancer institution. Data retrospectively reviewed over a 12 month period (January - December 2018) demonstrated a total of 249 Apheresis procedures. **78% were performed for adult autologous HSCT**, 5% for paediatric autologous HSCT, **9% related allogeneic HSCT and Donor Lymphocyte Collections**, and 2% Therapeutic Plasma Exchanges. An additional 6% were diagnostic solid tumour leukapheresis procedures collecting metastatic circulating tumour cells. Interest, opportunities, and clinical trials in Apheresis procedures for cellular therapies is evident and continually expanding, and so it was important to determine feasibility within the existing infrastructure of the service.

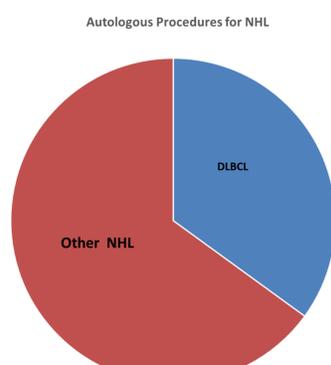
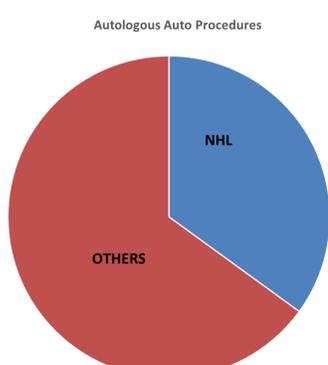
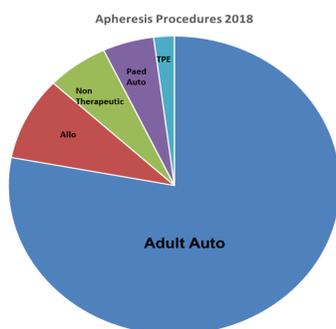
The challenges included:

- space
- capacity
- scheduling
- staffing
- education and competency on aspects of research and good clinical practice (GCP)
- robust standard operating procedures



It remains uncertain how much additional pressure this will create for the current Apheresis service; many patients scheduled for CAR-T therapy would otherwise progress along the autologous HSCT pathway and undergo peripheral blood stem cell collection. For example, per our 2018 data 33% of patients had a diagnosis of Non-Hodgkin Lymphoma, over a third (35%) of these were Diffuse Large B Cell Lymphoma, the primary indication for CAR-T therapy. This accounted for 12% of all autologous Apheresis procedures.

However, we required both the flexibility and the capacity to offer patients Apheresis slots without comprising access to trials and precise cellular therapy manufacturing timelines, or compromising our collection procedures for the HSCT programme.



Results

In response, and to ensure the cancer centre as a whole was capable of delivering CAR-T, a cellular therapy steering group was established with Apheresis personnel a key component. One additional Apheresis chair space was allocated in the research unit to accommodate these procedures. The most significant outcome has been the introduction of a new nursing role which combines Apheresis with Research, and cell collection with cell re-infusion. It is uncertain at this time if this role is primarily one of Apheresis practitioner, Specialist Research Nurse, or a Clinical Nurse Specialist for patients receiving CAR-T and other immune effector cell therapies, or what the best model of care actually is. However, the creation of this post has resulted in SOPs being developed and amended to ensure compliance with JACIE 7th standards for cellular therapy (2018), provided education and training for nurses and health care professionals, and has been the key link between diverse disciplines in preparing our service for CAR-T therapies in the context of clinical trials. In addition, this role has augmented the support available for our first patients, including education, information –giving, psycho-social, and financial, pre and post their leukapheresis.

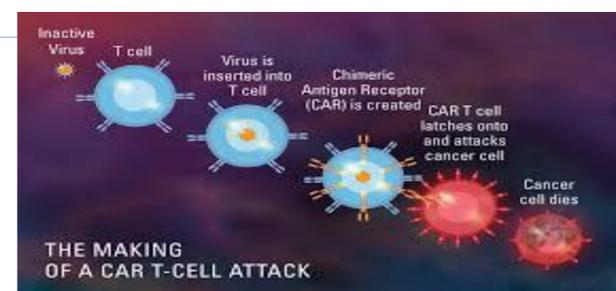
Job Description overview: Specialist Nurse for Cellular Therapy

The post holder is responsible for managing aspects of **apheresis for cellular therapy** in conjunction with **research protocols** for various **clinical research teams** within the trust. To provide a robust service for cellular therapy by reviewing research protocols for feasibility, cost effectiveness and relevance to the trust and conforms to its vision. The post holder will **coordinate the apheresis service for clinical trials** and this will be based at the satellite unit. They will work in conjunction with the Apheresis haematology team and follow their local policy Standard Operating Procedures and guidelines for apheresis.

The post holder will act as a source of information and advice to the patient, family and clinical research teams. This can involve both **inpatient and outpatient care, ensuring the patient has all medical, nursing, physical, psychological and social needs addressed**. The post holder is **skilled in apheresis** and partakes in the clinical rota to ensure a robust service. In addition: s/he participates in education and training for nurses / medical staff and members of the multidisciplinary team pertinent to the role.

Cellular Therapies Steering Group Agenda

- Trials – current and in the pipeline
- Regulatory/governance issues
- Apheresis satellite unit assessment and update
- Trust Cellular therapy policy, including risk assessment
- HTA/GCP training requirements
- Planning for increased activity
- Future resource and capacity planning
- NHS commissioning – update
- Financial
- Other



Conclusion

This indication for Apheresis will continue to expand in the future. We therefore have to adapt our current service in order to contribute to, and participate in, this exciting novel therapeutic intervention. This requires exploring different ways of working and innovative approaches to the delivery of care to patients requiring leukapheresis. Our solutions include multi-disciplinary collaboration, use of satellite areas, and the introduction of a new nursing role: the Apheresis/Cellular Therapy Specialist Nurse. This will provide additional staffing and capacity, and may enhance continuity of care and improved patient experience for this population. It may, however, result in some fragmentation of Apheresis, Research, and Transplant service nursing roles while we navigate the best model of care for these patients and this new treatment modality.

References

NHS England, 2018, CAR-T therapy. Available at: <https://www.england.nhs.uk/cancer/cdf/car-t-therapy/>
JACIE (2018) 7TH standards. Available at: <https://www.ebmt.org/sites/default/files/2018>

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