Introducing An Education Programme To Ensure CRF Readiness For ATMP Clinical Trials

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Aim/Purpose
The Christie Hospital is the lead organisation for one of three Advanced Therapy Treatment Centres (ATTCs) funded by Innovate UK. The iMATCH (Innovate Manchester Advanced Therapy Centre Hub) consortium aims to facilitate the scale up of delivery of Advance Therapy Medicinal Products (ATMPs) by making complex ATMP trials as easy to deliver as standard drug trials. Staff education and training form an integral part of achieving these objectives.

Methodology
The Christie CRF has some early experience in delivering ATMP studies, however activity was sporadic therefore maintaining staff competence was challenging. With a growing ATMP trial portfolio, the appointment of an ATMP senior practice educator was seen as critical. This has facilitated the development of a comprehensive education programme which includes didactic and experiential learning.

Implementation has been over 4 months, releasing 2-3 nursing staff every week for a series of lectures. Moreover, the programme includes specialist clinical placements with specific learning objectives and competencies using a self-directed workbook.

Results and Conclusion
While the ATMP education programme is in its infancy, early feedback indicates staff feel supported in the management of this complex group of patients. Evaluation is ongoing at weekly management meetings and through formal audit. The programme and results are shared monthly through the consortium to other CRF establishments and at national ATMP meetings.

Priority Training for CRF Staff

- An Overview of Cellular Therapy
- Cytokine Release Syndrome
- Immune Effector Cell-Associated Neurotoxicity Syndrome
- Inpatient management of patients receiving immune effector cells
- Administration of preparative regimens including growth factors
- Prophylaxis and antifungals management
- Infusion of Cellular Products
- Emergency T-Cell Administration Training

Contribution of CRF
Improved improvements to clinical and theoretical knowledge are evident from staff feedback. Specifically, initiating Patient Group Directions for IV antibiotics, blood products, emergency training and in-depth awareness of ATMP toxicities have improved staff confidence levels.

Improvement: Clinical and Theoretical Knowledge

- Improved skills in handling ATMPs
- Enhanced understanding of potential adverse effects
- Increased confidence in patient management

Priority Training:

- 25% Emergency Scenario Training
- 75% Priority Training

Sepsis and Intravenous PGD Antibiotics Training

- 25% Sepsis and Intravenous PGD Antibiotics Training
- 75% Priority Training

Emergency Scenario Training

- 25% Emergency Scenario Training
- 75% Priority Training

Cell Product being remove from dry shipping container

The NIHR Manchester Clinical Research Facility comprises four dedicated experimental medicine research units at The Christie NHS Foundation Trust, Manchester Royal Infirmary, Royal Manchester Children’s Hospital and Wythenshawe Hospital.