



# Workshop Session

## JACIE Inspection Process

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# Reflections on Advanced Therapy in NHS – Role of JACIE

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# Introduction

- What is JACIE?
- Immune effector cells [IEC]
- IEC and JACIE



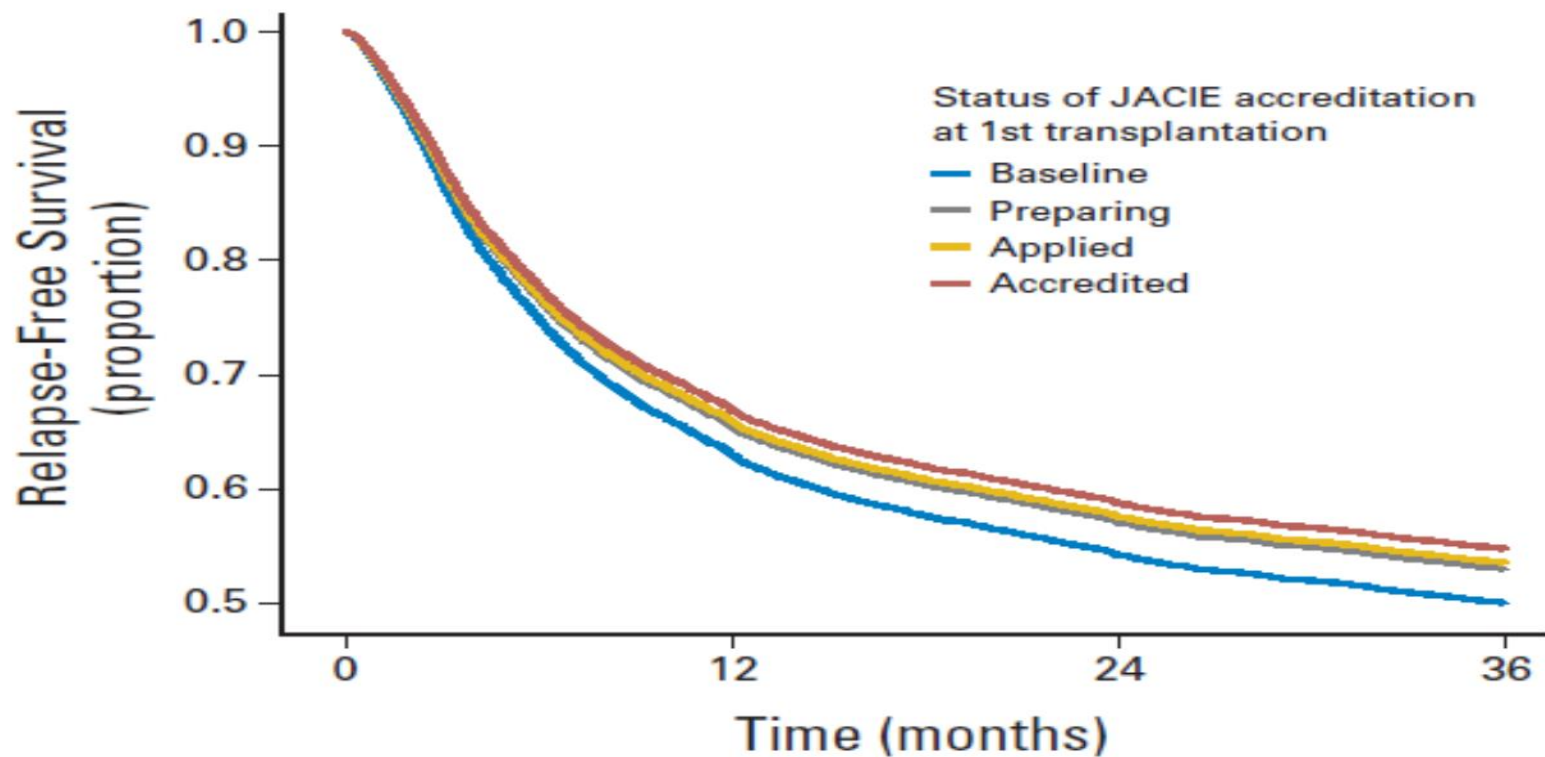
- Joint Accreditation Committee for ISCT and EBMT
  - Internationally agreed standards of care for bone marrow transplantation
    - Clinical
    - Collection
    - Processing
- 4 yearly cycle
- Peer review
- No legal authority

# Who Cares?

# Who cares?

- Demonstrates best practice
- Improves patient outcomes
- Demonstrates quality service
  - Patients
  - Researchers
  - Pharma
  - Commissioners





# Demonstrating JACIE compliance

- Quality Management system
  - What should we do?
  - Do we do what we said we would?
  - Are we keeping practice up to date?





# Demonstrating JACIE standards

- Quality Management system
  - What should we do?
    - Policies and procedures
    - Q pulse
  - Do we do what we said we would?
    - Patient outcome
    - Audits
    - Deviations
    - DATIX
    - M+M meetings
  - Are we keeping practice up to date
    - Review all policies every 2 years
    - National policy changes
    - Clinical trials



# JACIE and IEC

- Version 6.01 first standards to include IEC
- Currently version 7 standards

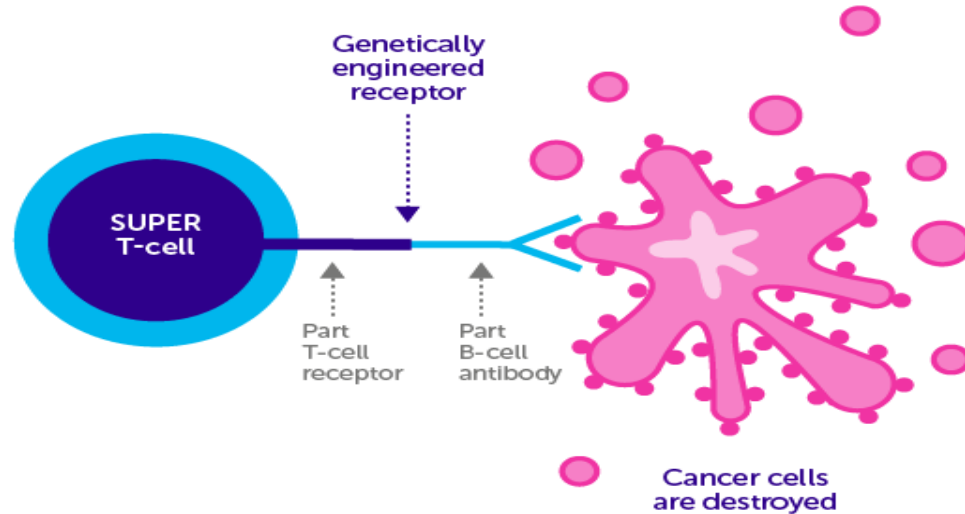
# Immune effector cells

- Any cellular therapy product used to modulate an immune response for therapeutic intent
  - dendritic cells
  - natural killer cells
  - B cells
  - T cells
    - Donor lymphocyte infusions
    - Viral specific T cells e.g. EBV
    - Chimeric antigen receptor T cells (CAR-T cells)



# Chimeric Antigen receptor (CAR)-T cells

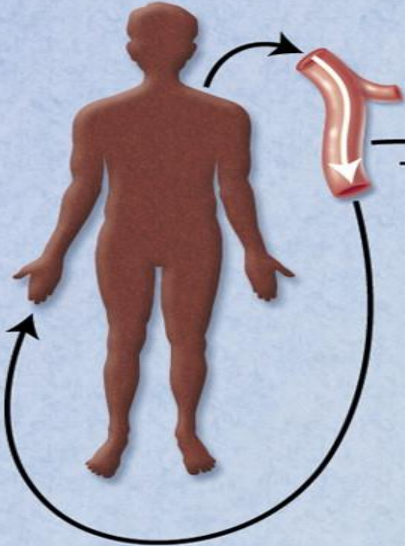
## SUPER T-CELL KILLING MACHINES



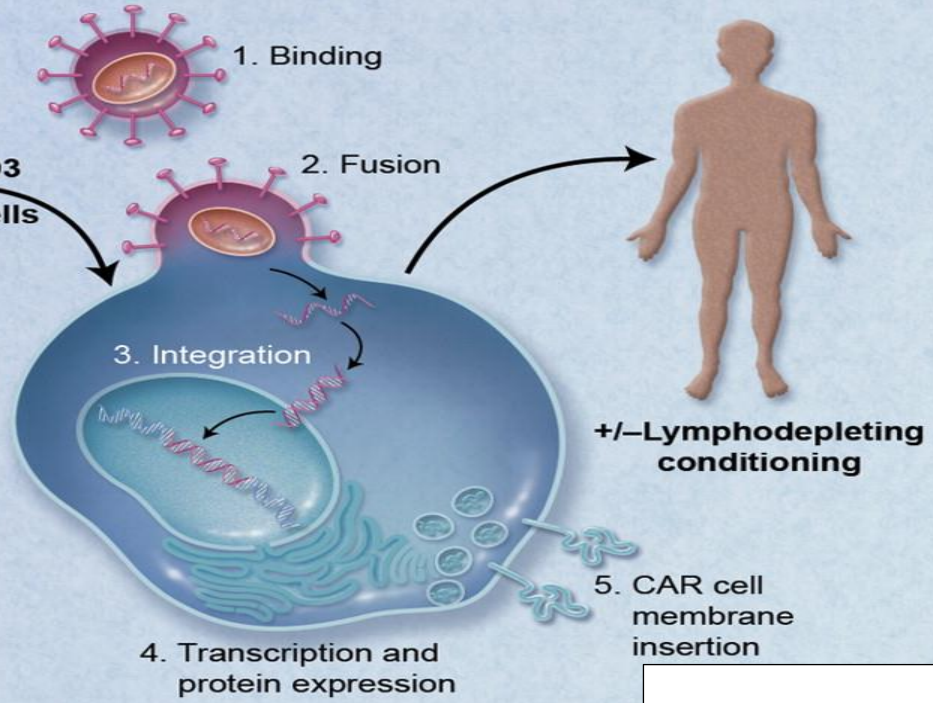
<https://scienceblog.cancerresearchuk.org/2016/01/19/engineering-a-cancer-fighting-immune-super-soldier/>



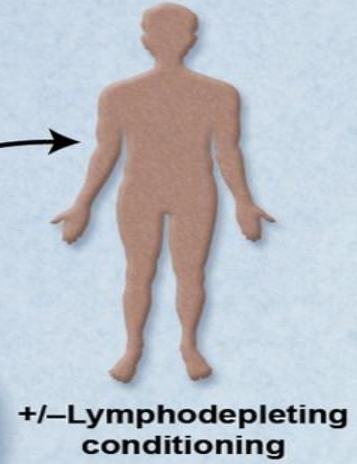
### 1) T Cell Collection



### 2) T Cell Transfection



### 3) T Cell Adoptive Transfer



### 4) Patient Monitoring

- a) Disease response
  - CT scans
  - Bone marrow biopsies
  - Peripheral blood flow cytometry
- b) CAR-T Cell persistence
  - Immunohistochemistry of bone marrow biopsy
  - RT-PCR and flow cytometry of blood and bone marrow aspirate

JACIE

JACIE



# JACIE IEC standards

- 43 specific IEC standards
  - Chain of custody
  - Toxicity management
    - Clinical network
    - SOPs
    - Staff training
  - Quality management system
  - Outcome follow up and reporting



# NCCC JACIE experience

- 43 specific IEC standards
  - Chain of custody
  - Toxicity management
    - Clinical network
    - SOPs
    - Staff training
  - Quality management system
  - Outcome follow up and reporting



# Clinical network

**Consultant  
Haematologists**

**Regional / national  
colleagues**

**MDT**

**Middle grade and  
junior doctors**

**Consultant  
Neurologist**

**Apheresis  
team**

**ITU nurses**

**Consultant  
intensivists**

**Haematology  
nurses**

**Stem cell Lab**

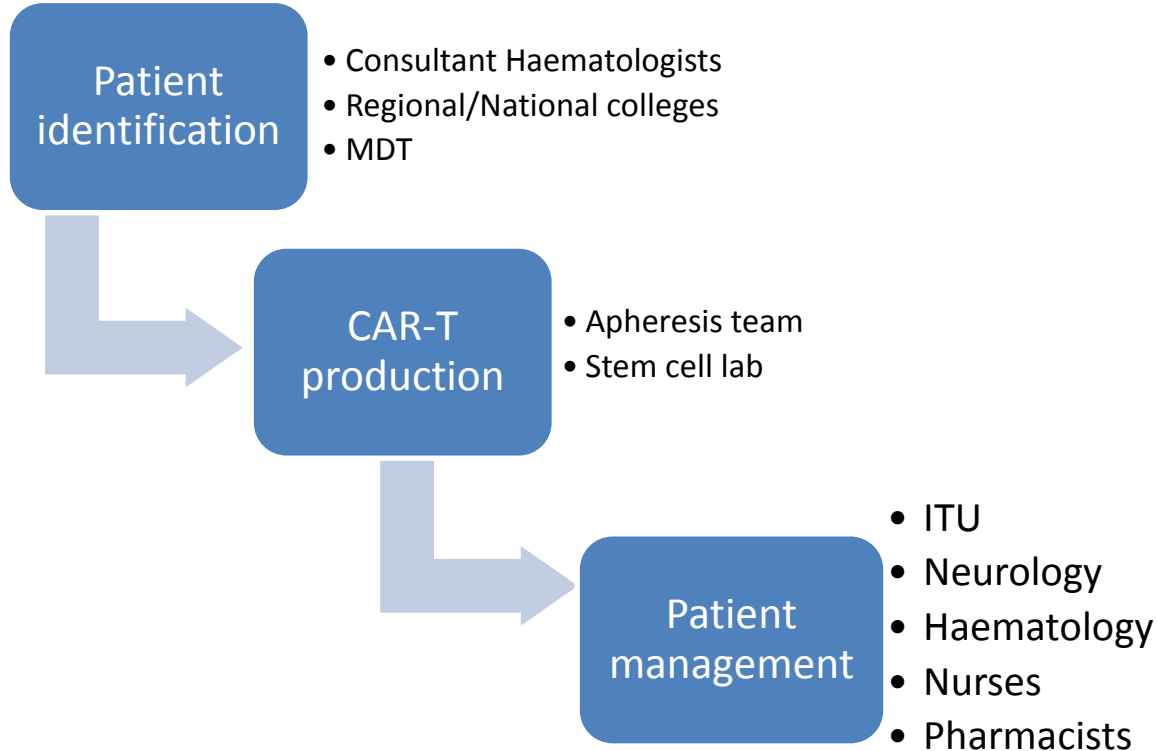
*Quality  
manager*

**Pharmacists**





# Clinical network



# NCCC JACIE experience

- SOPs
  - ~ 20 new policies for adult clinical team alone
- Training
- Training
- Training



# Standard example

- The Clinical program shall establish and maintain policies relating to the management of toxicities of immune effector cellular therapies, including cytokine release syndrome and central nervous system complications.



# Evidence

- CRS and CRES management policy
- CRS assessment tool
- CRES assessment tool
- Patient information leaflet
- ITU transfer policy
- ITU and neurology communication pathway
- Pharmacy policy for Tocilizumab administration
- Education session slides
- Electronic policy acknowledgement



# JACIE Summary

- Internationally agreed set of standards relating to cellular therapy products
- Standards 6.01 first to include immune effector cells [IEC] e.g. CAR-T cells
- In the UK all CAR-T centres must be compliant with the JACIE 6.01 standards
- Demonstrating compliance requires a quality management system and team approach
  - specific policies outlining how the standards are met
  - robust evidence to ensure these policies are followed

