Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK

22. Haemopoietic progenitor cells

Last updated on 4 September 2023

22.1. Introduction

Cellular therapy is now covered by a variety of legislation.

The EU Directive on Tissues and Cells (2004/23/EC) and its associated Commission Directives (2006/17/EC and 2006/86/EC) have been transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations 2007 as amended.

The Human Tissue Act 2004, Human Tissue (Scotland) Act 2006 and Directions or Codes of Practice issued by the Human Tissue Authority (HTA) also apply.

In addition, there are a number of key international standards for haemopoietic stem cells, notably the FACT-JACIE and NetCord-FACT Standards and the WMDA standards. The lists of publications in 22.1.1 and 22.1.2 below have been grouped according to their origins.

The guideline references in this chapter apply to the donation, collection, testing, processing, cryopreservation, storage and distribution of haemopoietic progenitor cells (HPC) and mononuclear cells (MNC) within the UK. These guidelines are applicable to stem cell donor registries and to bone marrow, peripheral blood and cord blood collection and processing facilities, and importing facilities, hereafter mentioned as establishments.

22.1.1. UK Regulation/Guidelines

1. Statutory Instrument 2007 No. 1523 The Human Tissue (Quality and Safety for Human Application) Regulations 2007 and subsequent amendments
2. HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment
3. Human Tissue Act 2004 (except Scotland)
4. Human Tissue (Scotland) Act 2006
5. Human Tissue Authority Codes of Practice
    a. Guiding principles and the fundamental principle of consent (Code A)
    b. Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation (Code G).
6. Human Tissue Authority Guidance document for establishments working with Umbilical cord blood
7. Data Protection Act 2018
8. BSHI guidelines for HLA matching and donor selection for haematopoietic progenitor cell transplantation
9. JPAC Donor Selection Guidelines
    a. Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines
    b. Cord Blood Donor Selection Guidelines
10. JPAC Geographical Disease Risk Index (GDRI)

11. Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Microbiological safety guidelines

22.1.2. European & International Directives/Guidelines

1. EDQM Guide to the quality and safety of tissues and cells for human application
2. EC Guidelines to Good Manufacturing Practice (Eudralex) Manufacture of Sterile Medicinal Products
3. International Standards for Cellular Therapy Product Collection, Processing, and Administration from the Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee of ISCT-Europe and EBMT (JACIE)
4. International Standards for Cellular Therapy Product Collection, Processing, and Administration Accreditation Manual
5. NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration
6. NetCord-FACT Cord Blood Accreditation Manual
7. World Marrow Donor Association (WMDA) International Standards for Unrelated Hematopoietic Stem Cell Donor Registries
8. European Federation for Immunogenetics (EFI) Standards for histocompatibility testing
9. National Marrow Donor Program (USA) Standards
10. WMDA Donor Medical Suitability Recommendations

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22.2. **Terminology**

This chapter aligns with the terminology described at FACT-JACIE International Standards for Haemopoietic Cellular Therapy, Product Collection, Processing, and Administration.

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22.3. Policy and procedure requirements and safety

22.3.1. HTA licensing and requirements

The procurement and testing of human tissues or cells in UK should only be carried out by establishments holding an appropriate Human Tissue Authority (HTA) licence or by individuals or organisations working under the authority of a third-party agreement with an establishment holding an appropriate HTA licence.

The requirements described in the HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment apply to the establishments and third parties which carry out the procurement, testing, processing, distribution, or export of tissues and cells for human application, and for licensed establishments which store or import tissues and cells for human application.

22.3.2. FACT-JACIE and NetCord-FACT standards

The FACT-JACIE and NetCord-FACT standards are available for the clinical and laboratory facilities who wish to conform to the FACT-JACIE and NetCord-FACT Standards as appropriate.

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22.4. Adverse events and reactions

22.4.1. HTA Guide for the management of serious adverse events (SAEs) and reactions (SARs)

All licensed establishments must have a system in place for reporting, investigating, registering and recording information about serious adverse events (SAEs) and serious adverse reactions (SARs) which may influence the quality and safety of tissues and cells, and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

Further details can be found in the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment.

22.4.2. 22.4.2: WMDA reporting system

The World Marrow Donor Association (WMDA) maintains a voluntary central global reporting system to report Serious (Product) Events and Adverse Reactions (SPEARs).

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22.5. Donor selection, consent and testing

Establishments must have detailed policies and procedures for the testing and assessment of donors of stem cells. These must be in accordance with the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), UK-JPAC standards as detailed in the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines, FACT-JACIE Standards and the WMDA standards.

Anonymity must be maintained between donors and recipients in accordance with the requirements of EU Directive 2004/23/EC (Northern Ireland) and the UK information governance regulations.

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22.6. Collection, processing and storage

Stem cells and therapeutic cells should only be collected in a hospital facility or Blood Service apheresis unit with appropriate experience (see chapter 5.8) and which meets the standards required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), FACT-JACIE Standards and NetCord-FACT Standards as appropriate.

For more information, see the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment and FACT-JACIE Standards Parts CM, C and D.

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22.7. Testing of haemopoietic progenitor cell donors and components

Infectious disease marker testing, ABO and RhD typing and clonogenic assays must be done in accordance with the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment (updated on January 2021), and SaBTO guidance.

Additional information and guidance available with FACT-JACIE, WMDA and NetCord-FACT standards.

The minimum current requirements for mandatory and additional microbiology testing (serology and/or NAT) are described in chapter 9.

Annex 7 indicates the requirements for the timing of testing for each type of HPC.

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22.8. Requirements for the timing of testing

Please see annex 7 for guidance relating to the timing of testing for different categories of HPC.

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22.9. Labelling, packaging, transportation and release

The mandatory requirements for these are described in the Human Tissue Authority (HTA) Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment.

The FACT-JACIE Standards and NetCord-FACT Standards will also apply as appropriate.

The requirement for an EU Single European Code (SEC) still applies in Northern Ireland.

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22.10. Disposal of haemopoietic progenitor cells

Disposal of cellular therapy products shall meet the EMBT guideline requirements in the JACIE Standards (Chapter D12: Disposal).

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22.11. Record maintenance

All patient records and results should be maintained to comply the requirements of the UK General Data Protection Regulation (UK GDPR).

Establishments must comply with advice on record keeping and maintenance in the Microbiological safety guidelines produced by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

The requirements for these are described in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), FACT-JACIE Standards, NetCord-FACT Standards and WMDA standards.