The JACIE Accreditation Process

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Goals

• To introduce the principle concepts of JACIE accreditation
• To describe the accreditation process
• To answer questions and clarify doubts
What is JACIE?

• Standards setting and accreditation organisation

• Introduces quality management into clinical practice

• International
What is JACIE?

- Focused on cellular therapy
- Independent of the regulators
- Established by the practitioners themselves
What is JACIE?

Classic view

- Clinical
- Bone Marrow Collection
- Apheresis
- Processing

FACT-JACIE view

- Clinical
- Bone Marrow Collection
- Apheresis
- Processing
Why JACIE?

- Professional pride
- Competition with other centres?
- Improved outcome for patients
Impact on survival


Why JACIE?

• Legal requirement in some countries

• Health insurance companies may require it

• Social insurance systems may require it -
Why JACIE?

- Increasing use of unrelated donors with international exchanges of cellular products
- Collaboration between departments/service is critical
“To measure is to know”

- “If you cannot measure it, you cannot improve it.”

- William Thomson (Lord Kelvin) 1824 – 1907
- Determined the correct value of absolute zero as approximately -273.15 Celsius
Initial Applications by Country since 2000
Accredited centres
JACIE Inspection Process
Support and help centres achieve & maintain quality in transplant
Process

Decision to work according to the Standards
Process

Preparations, working with quality

Decision to work according to the Standards
Preparation by the centre
Process

- Request inspection
- Preparations, working with quality
- Decision to work according to the Standards
Application Form
Inspection Checklist

• Based on Traffic Light system
  – Compliant
  – Partially Compliant
  – Non-compliant
  – Not Applicable (N/A)

• IMPORTANT: Include additional information, explanations, references to documents, etc
<table>
<thead>
<tr>
<th>Ref</th>
<th>Standard</th>
<th>Applicant's Self-assessment</th>
<th>Applicant's Comments (support your answers with additional information)</th>
<th>Inspector's Assessment</th>
<th>Inspector's Comments (support your answers with additional information)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B01</td>
<td>GEHERAL</td>
<td>Compliant</td>
<td>Compliant</td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.01</td>
<td>The Clinical Program consists of an integrated medical team housed in geographically contiguous or proximate space with a Clinical Program Director(s) and common staff training, programs, protocols, and quality management systems.</td>
<td>Compliant</td>
<td></td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.01.01</td>
<td>Clinical Programs that include non-contiguous institutions shall demonstrate common protocols, procedures, quality management systems, and review of clinical results and evidence of regular interaction.</td>
<td>Compliant</td>
<td></td>
<td>Compliant</td>
<td></td>
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<tr>
<td>B01.02</td>
<td>The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.</td>
<td>Part of this application</td>
<td></td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.03</td>
<td>The Clinical Program shall abide by all applicable laws and regulations.</td>
<td>Compliant</td>
<td></td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.03.01</td>
<td>The Clinical Program shall be licensed, registered, and/or accredited as required by the appropriate governmental authorities for the activities performed.</td>
<td>Partially</td>
<td>Please indicate the relevant issues, authorisations etc.</td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.04</td>
<td>For initial accreditation, a dedicated transplant team including a Clinical Program Director(s) and at least one other physician trained and/or experienced in cell therapy and/or HPC transplantation shall have been in place for at least twelve (12) months preceding accreditation.</td>
<td>Non-compliant</td>
<td></td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.05</td>
<td>If the Clinical Program requests accreditation for allogeneic HPC transplantation, a minimum of ten (10) new allogeneic patients shall have been transplanted during the twelve (12) month period immediately preceding program accreditation and a minimum average of ten (10) new allogeneic patients shall be transplanted per year within the accreditation cycle. A Clinical Program that is accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation.</td>
<td>Not applicable</td>
<td></td>
<td>Compliant</td>
<td></td>
</tr>
<tr>
<td>B01.05.01</td>
<td>For Clinical Programs utilizing more than one clinical site and requesting accreditation for allogeneic HPC transplantation, a minimum of five (5) new allogeneic patients shall have been transplanted at each site performing allogeneic transplants during the twelve (12) month period immediately preceding accreditation and a minimum average of five (5) new allogeneic patients shall be transplanted at each site performing allogeneic transplants</td>
<td></td>
<td></td>
<td>JACIE Office: The following examples illustrate the criteria used to determine if a given recipient would be considered to be a &quot;new patient&quot;: • A patient on a tandem study (planned sequential transplants) who received two autologous transplants two months apart would count as one new autologous</td>
<td></td>
</tr>
</tbody>
</table>
Submit documentation before inspection

- 3 months to submit documentation
- Labels
- Quality Manual
- List of SOPs
- Donor / patient consent information
- Evidence of qualifications
- Evidence of audits performed….
Process

- Inspection
- Request inspection
- Preparations, working with quality
- Decision to work according to the Standards
Inspection Team

- PAEDIATRIC CLINICAL UNIT
- APHERESIS UNIT
- CLINICAL UNIT
- APHERESIS UNIT
- PROCESSING UNIT
Inspection

• 1 – 2 Days
• Thorough examination of all aspects of the programme.
• Verification of the applicant’s completed checklist
Report

• Fundamental part of the Accreditation Process!!!
• All decisions are made based on the report.
• Based on completed Inspection Checklist
The report pathway
Accreditation Committee

• Discusses each individual report and make recommendations

• Source of expert opinion

• Monthly teleconference
Process

- Corrections
- Inspection
- Request inspection
- Preparations, working with quality
- Decision to work according to the Standards
Corrections

• Almost all inspections reveal deficiencies

• Great variety in seriousness of deficiencies
  – Vary from missing references in SOPs to dangerous storage areas

• Most cases, evidence of corrections is submitted electronically and reviewed by inspectors

• 6 to 9 months to send corrections to JACIE
Process

- Accreditation
- Corrections
- Inspection
- Request inspection
- Preparations, working with quality
- Decision to work according to the Standards
Accreditation

• Accreditation awarded when inspectors are satisfied that all points have been resolved

• Certificate and letter issued to the centre
• Accreditation for 4 years from date of award

• Interim audit at end of year 2 of accreditation
• Subscribe to our mailing list

http://www.jacie.org/subscribe

  – Subscribers will receive periodical JACIE updates and news items. All subscribers can easily update their details or unsubscribe from the list at any time.
  – If the address is already in our system, you will see a message "[your email] is already subscribed to list [list name]".
Fees – new from 1 Jan 2015

- **Registration Fee (non-refundable):**
  €3,500 on application *(applicable to all applications, both first-time and reaccreditation, and non-refundable)*

- **Inspection Fees:**
  - €2,100 charged per area to be inspected. Areas are considered to be
    - one (1) adult OR one (1) pediatric clinical site/unit
    - one (1) collection site for marrow*
    - one (1) for peripheral blood progenitor cells
    - one (1) cell-processing laboratory

- **Supplementary Fee**
  €1,000 per each additional site
Training

JACIE Inspector Training Course, Manchester, UK, 2-3 July 2015

Cuándo
Comienza: 02 Jul 2015 - 10:00AM
Termina: 03 Jul 2015 - 4:00PM

Dónde
Chancellors Hotel
Chancellors Way, Moseley Road
Fallowfield, Manchester M14 6ZT
United Kingdom

Inscríbete

JACIE Inspector Training Course, Barcelona 1-2 October 2015

Cuándo
Comienza: 01 Oct 2015 - 10:00AM
Termina: 02 Oct 2015 - 4:00PM

Dónde
Hotel Zenit Borrell
C/ Comte Borrell, 208 (8029),
Barcelona, Spain

Inscríbete

https://ebmt.stagehq.com/
Related publications

