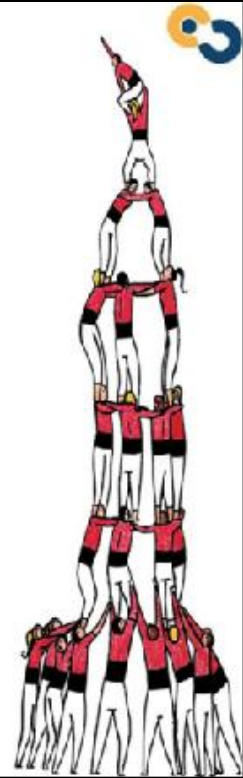


The JACIE Accreditation Process

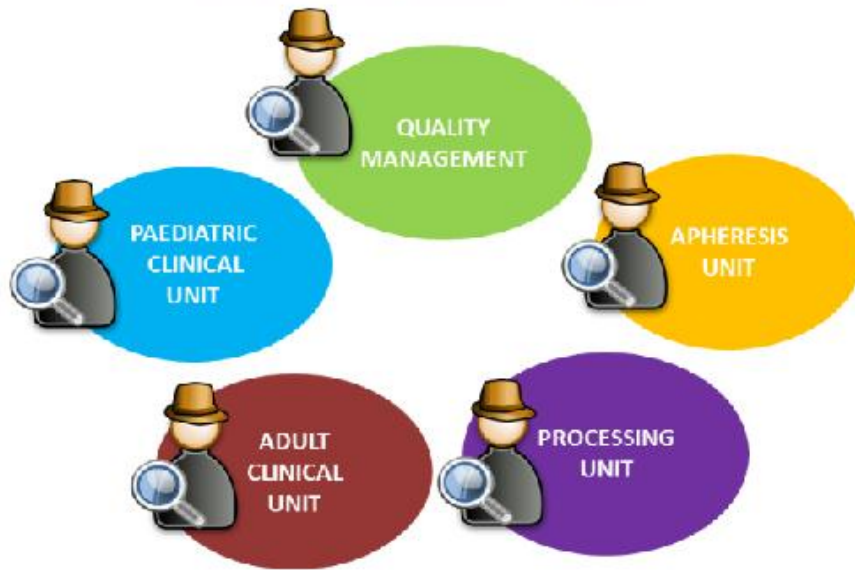
JACIE Office,
Barcelona, Spain



Accreditation Process



Current Inspection Team



Quality Management Inspectors



CURRENT INSPECTOR POOL (October 2016) = 52

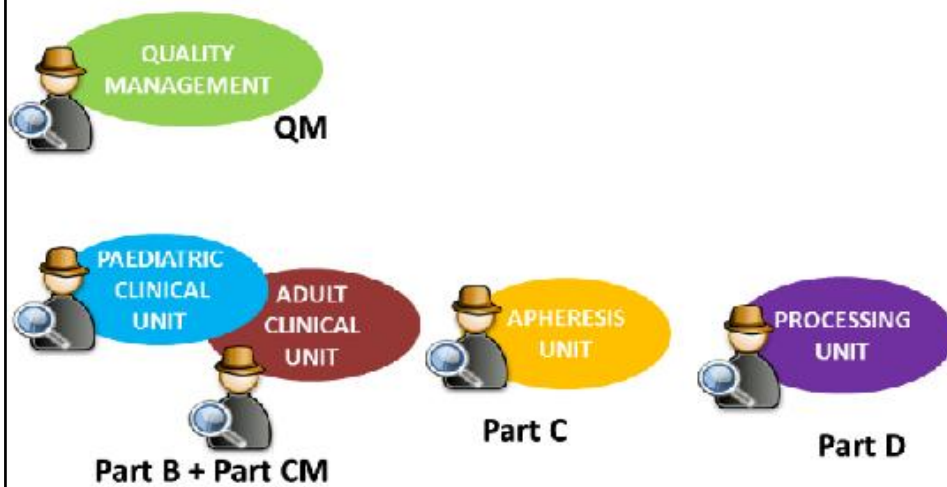
October 2016

ESTIMATED INSPECTOR POOL (December 2016) = 55 - 60

QMI

Belgium, Czech Republic,
Denmark, Germany, Greece,
Ireland, Italy, Macedonia,
Netherlands, Nigeria, Saudi
Arabia, Spain, Sweden,
Switzerland, Turkey, UK

Distribution of Standards to be Inspected



Distribution of Standards to be Inspected

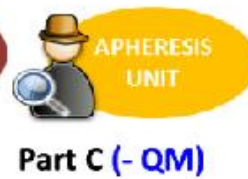
Part B/CM/C/D 4 QM excluding:

- Outcome analysis
- Tracking & traceability/labeling requirements
- Qualification
- Validation

Parts B/CM/C/D 5 Policies & Procedures



Part B + Part CM (- QM)

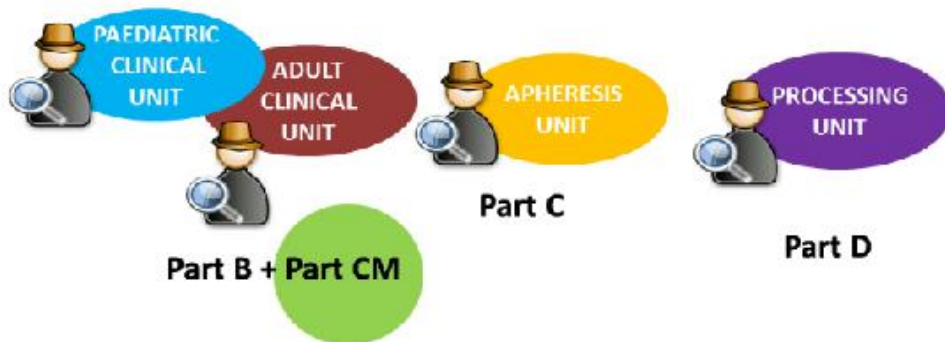


Part C (- QM)



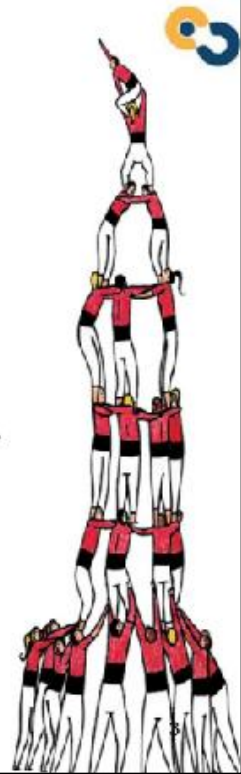
Part D (- QM)

Distribution of Standards to be Inspected



Inspection timetable

- Proposal made by the Team Leader
- Reviewed by the center who can insist on reasonable changes if necessary
- Usually 1.5 days



Sample timetable

1st Half-day Period

Inspectors' arrival to the site, introduction & presentation of overall clinical programme by Programme Director

MEDA/B data audit and initial review of documentation

Quality Manual & SOPs and documentation

2nd Half-day Period

Tour around facilities demonstrating links between facilities.

Interviews**

Clinical

Programme Director

A transplant physician

The quality manager

Senior Nurse

Nurse responsible for training

BMT unit nurses

Pharmacist



Cell Collection

Collection facility director

Collection facility medical director

Potentially any staff involved in collection of cells

Laboratory

Laboratory Director

Laboratory Medical Director

Laboratory Processing Lead

Laboratory Quality Manager

Laboratory Trainee(s) (as appropriate)

3rd Half-day Period

Continue tour around facilities, interviews and review of remaining documentation

Exit Meeting with Programme Director.

Closing Meeting



Inspection

- Thorough examination of all aspects of the programme.
- Verification of the applicant's completed checklist



At the end of the inspection

- The exit interview
 - Inspector will discuss any sensitive issues with facility head and/or **Programme Director** in private **BEFORE** exit interview
 - The inspectors discuss their visit and inform the Programme Director and staff of what they found
 - Inspectors **do not** comment on possible outcome



The Inspector

- Inspectors return Completed Inspection Checklist, any notes and documents to the Team Leader (TL) or directly to JACIE Office



Item	Yes	No	Not Applicable
1. The institution has a written policy regarding the selection and appointment of the inspector.			
2. The institution has a written policy regarding the independence of the inspector.			
3. The institution has a written policy regarding the confidentiality of the inspector's report.			
4. The institution has a written policy regarding the impartiality of the inspector.			
5. The institution has a written policy regarding the integrity of the inspector.			
6. The institution has a written policy regarding the honesty of the inspector.			
7. The institution has a written policy regarding the objectivity of the inspector.			
8. The institution has a written policy regarding the fairness of the inspector.			
9. The institution has a written policy regarding the transparency of the inspector.			
10. The institution has a written policy regarding the accountability of the inspector.			



Inspection Report

Inspector: _____

Team Leader: _____

Inspected: _____

Reported: _____

Findings: _____

Recommendations: _____

Comments: _____



Report

- Fundamental part of the Accreditation Process
- All decisions are made based on the report.
- Based on completed Inspection Checklist



Applicant / Inspectors

- Complete and return the Onsite Evaluation form for JACIE Office
 - Opportunity to raise concerns (or give praise!) about anything involving the on-site inspection



Post-inspection evaluation



JACIE ON-SITE INSPECTION EVALUATION (Applicant)

This survey should be completed by centres that have recently undergone a JACIE inspection. The information collected in this survey is confidential. Please use the survey to report your satisfaction or dissatisfaction with any aspects of the inspection or application process. If you have any questions, please contact the JACIE Office at +31-63 453 8711 or jac@jaciebent.org.

1. Surname and family name of person completing the survey

2. Position or role of person completing the survey

☐ Service Director☐ Quality Manager☐ Nurse☐ Data Manager☐ Other

Other, please specify

3. Name of applicant centre/programme

4. City

5. Country

6. Contact information

BN / MM / YYYY



**Applicants Feedback + Inspectors Feedback =
Improvement of the accreditation process**

JACIE Survey - 2016



INSPECTOR'S SATISFACTION

Overall, how satisfied are you with the onsite inspection process (preparation phase and onsite inspection)?

Answered: 32 Skipped: 4

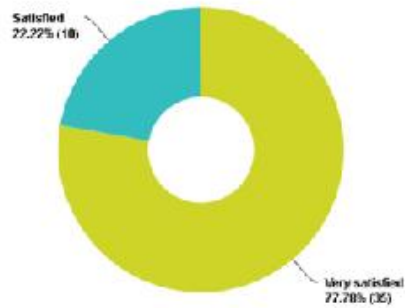


CENTER'S SATISFACTION



Overall, how satisfied are you with the onsite inspection process (preparation phase and onsite inspection)?

Answered: 46 Skipped: 1



The report pathway

4.
Report sent to
Centre with
recommendations

1.
Inspector sends
report
to JACIE Office

3.
Report Assessors
Present report to
**Accreditation
Committee**

2.
Report reviewed
by
**Report
Assessors**



Accreditation Committee



Accreditation Committee

- Discusses each individual report and make recommendations
- Source of expert opinion



- Monthly teleconference



Accreditation Committee

Chair: Maria Vittoria Gazzola (Italy)

Clinical

Riccardo Saccardi (Italy)
Kim Orchard (UK)
Hellmut Ottinger (Germany)
Lucien Noens (Belgium)
Andreas Humpe (Germany)
Almudena de la Iglesia (Spain)

Paediatric

Christiane Vermylen (Belgium)
Justyna Kanold (France)

QM members

Collection

Kim Orchard (UK)
Kristina Hölig (Germany)
Justyna Kanold (France)
Lucien Noens (Belgium)
Tuula Rintala (UK)
Lynn Manson (UK)
Andreas Humpe (Germany)
Valerie Lapierre-France (France)

Processing

Dominique Latinne (Belgium)
Monique Grommé (Netherlands)
Maria Vittoria Gazzola (Italy)
Valerie Lapierre (France)
Ender Altıok (Turkey)
Dania Arabi (Saudi Arabia)



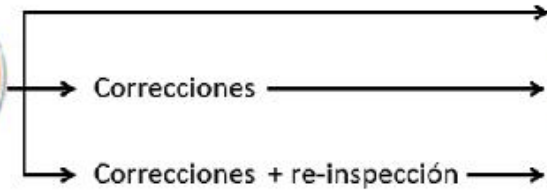
Post-inspection



Accreditation Process



Possible Outcomes





Corrections

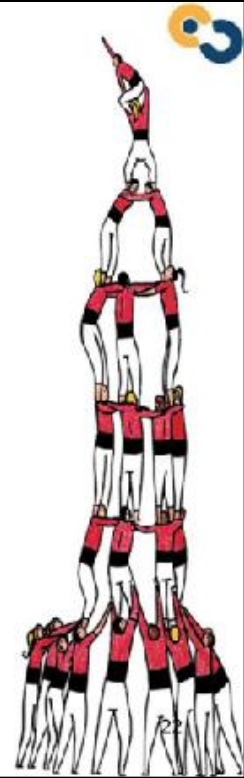
"Well, nobody's perfect":

Osgood Fielding III
Some Like It Hot (1959)



Corrections

- “99.99%” of 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



Review of corrections and/or need for revisit



Review of corrections and/or revisit

- The same inspectors assess evidence of corrections
- In certain cases, a revisit to the site may be required.
 - extensive failures in the quality management system,
 - new construction since inspection



Accreditation

- Accreditation awarded when inspectors are satisfied that all points have been resolved + the JAC do not have further comments



- Certificate and letter issued to the centre



Accreditation

- Accreditation for 4 years from date of award
 - If a centre takes more than 9 months to resolve deficiencies, JACIE may award accreditation from date of inspection
- Annual report – short summary of activity and changes
- Interim review at end of year 2 of accreditation



Interim audit

- At end of year 2 of accreditation
- Documentation review will focus on how the quality management system is functioning
 - Evidence of audits
 - QM meetings
 - SOP review
 - Etc.
- Based on standards i.e. no new requirements
- May result in on-site visit



Fees - effective April 3rd 2016

Registration Fee (non-refundable):

€3,850 on application (*applicable to all applications, both first-time and reaccreditation, and non-refundable*)

Inspection Fees:

€2,310 charged per area to be inspected

Supplementary Fee

€1,100 per each additional site

Applications from centers whose staff members have participated in an inspection event(s) in the 4 years preceding submission of the new application will qualify for a discount of 10% per event up to a maximum of 20%.



Time

Pre-audit documentation: 11.5 hr

Teleconference: 0.5 - 1 hr

Inspection: 1.5 days



Inspection Report

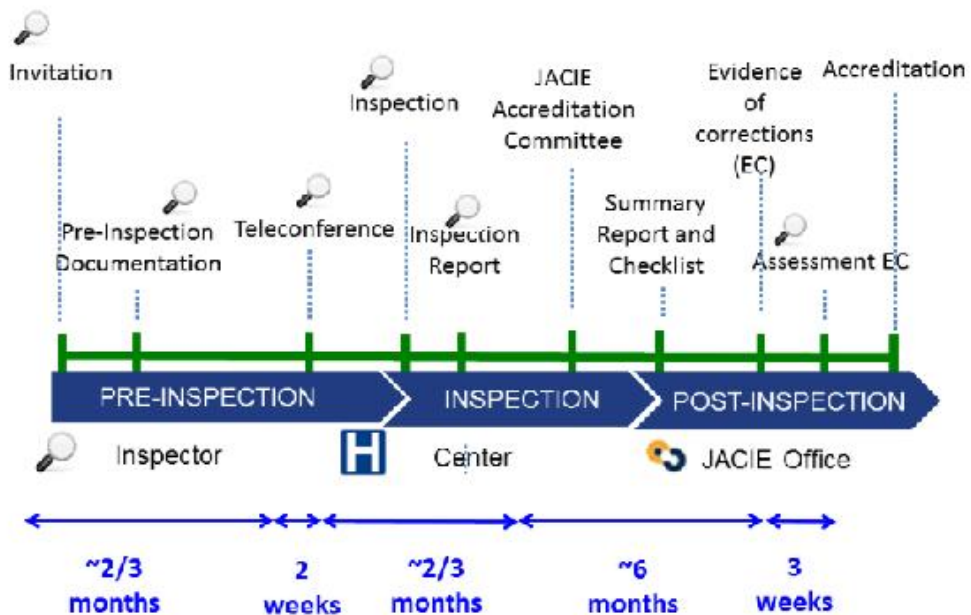
Evidence of corrections

Interim Audit

JACIE Inspector



Timing



- Thank you for listening
- Any questions?

