



JACIE
joint accreditation committee
isct ebmt

Applicant and Inspector guide to the JACIE
inspection process

Version 15

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Introduction

This Guide has been compiled to help applicants and inspectors prepare for the JACIE inspection. The document should be read in conjunction with the current FACT-JACIE standards and Accreditation Manual.

While the contents of the guide do not cover every possible scenario, the reader will find information about the inspection process and its different phases. It is also envisaged that this guide will evolve so you are encouraged to check for more recent versions online. If you have any suggestions for what should be included, please contact us at help@jacie.org.

There is also more information available on the JACIE web site at www.jacie.org including Frequently Asked Questions (FAQs).



Help or support: help@jacie.org

CONTACT

In case of doubts or questions, please do not hesitate to contact the JACIE Office:

JACIE Accreditation Office:

EBMT Executive Office

Edifici Dr. Frederic Duran i Jordà

Passeig Taulat, 116, 08005 Barcelona (Spain)

Tel: [+34 93 453 8570](tel:+34934538570) - Fax: [+34 93 451 9583](tel:+34934519583) - www.jacie.org

URGENT CONTACT

If you need assistance during an inspection and **cannot** contact the office at the number above, please contact Eoin McGrath at +34 678 214 832 (mobile).

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Section 1 – Application for Accreditation

Before submitting an application for accreditation, the applicant should ensure that they can clearly demonstrate compliance in **all** areas of the Standards. The key areas are:

1. That the programme functions as a Single Integrated Programme sharing common staff training, protocols, regular meetings and quality management systems.
2. Minimum transplant activity – see the current version of the FACT-JACIE Standards.
3. **EFI.** If the clinical programme carries out allogeneic transplantations, it must use a HLA-typing laboratory accredited by the European Federation for Immunogenetics (EFI).
4. The application form, available on the JACIE web site in the Document Centre, along with the completed Inspection Checklist is sent to the JACIE Office by email or by post. An electronic copy is preferred to allow the information to be copied to our register. The application will be reviewed by the JACIE Office who will contact you shortly after.
5. Possible dates for the inspection will be discussed between the applicant, the JACIE Office and possible inspectors. The applicant should in any case propose dates for the on-site inspection when **ALL KEY PERSONNEL** will be available. At a minimum, this includes the:
 - a. Programme Director
 - b. Collection Facility Director and Medical Director
 - c. Laboratory Director and Medical Director
 - d. Person responsible for quality management in each facility.

In addition, there must be designated personnel available throughout the audit to accompany each of the inspectors and assist as needed, and at least one person familiar with charts and data to assist with chart review.

6. The applicant should be ready for the initial inspection within 12 months from the date of approval of the application. This time period may be extended at the discretion of the JACIE Office subject to a written request from the applicant explaining the circumstances. A new Application Form and Inspection Checklist should be submitted, any new versions of documentation that has changed since the previous submission and any additional fees due to an increase from when the initial application was made may be charged to the applicant.

If you consider that your centre will not be ready within a maximum 12 months, then you should not apply yet.

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Section 2 – Inspection Checklist

1. Review Inspection Checklist: assign someone to complete each section.
2. Make sure you are able to document how you meet each standard, for example by noting a specific SOP, training record, meeting record, etc. These references and other information should be entered into the Inspection Checklist to help the inspector easily find supporting documents and evidence of compliance with the standards. For instance, identify the hospital safety manual, the lab procedure for labelling, the name of the person responsible for quality management etc).

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Section 3 – Pre-inspection document submission

APPLICANT

Before sending in documents

1. Use the pre-formatted folders available for download from the JACIE website..
 - a. Ensure that new protocols or procedures are written or existing protocols/ procedures are revised to demonstrate compliance
2. Organise all procedures / protocols / documents in order of the checklist.
 - b. Assemble ALL required documents according to the document checklist Make a duplicate set for your own records. Be sure you assemble exactly what is requested and submit the documents in the order listed.
 - c. Those documents that are not already available in electronic format should be scanned as Adobe PDF files. Be careful not to produce scanned files that are excessively large in size e.g. more than 1 MB.
3. Avoid using characters such 'é', 'ü' if possible when naming files as this can potentially provoke problems when opening files.
4. Minimum Essential Data (**MED-A**). See p. 19 for detailed instructions.

Centres applying for accreditation are required to submit documentation in advance of the inspection. This documentation is requested so that the inspectors can understand the centre's activity and organisation and also to check compliance with some of the standards before the on-site visit.

The requested documentation includes:

- Selection of key SOPs
- Evidence of staff training and qualifications
- Official facility licences and authorisations
- Quality Management Manual or Handbook
- Basic evidence that the QM system is functioning
- Basic data on recent transplant activity
- Consent forms and related information
- Sample labels
- Plans or maps of the centre
- Sample agreements with third-party service providers

The documents are submitted in a pre-formatted .ZIP file that contains folders for the various types of documents. The file and instructions can be downloaded from the Document Centre under the "Pre-Inspection Documentation" section.

When do I have to send these documents?

Documents should be sent to the JACIE Office within 30 days after sending the accepted Quotation and signed Accreditation Agreement to the JACIE Office. Where an applicant delays more than 30 days in submitting the pre-audit documentation, the accreditation process of the centre will be considered expired and the centre must restart the process

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What about if I send a document and then it is updated in our system?

Any revised documents should be sent to the JACIE Office before the inspection clearly indicating what changes have been made and what document should be replaced.

What does JACIE do with these documents?

Firstly staff at the JACIE Office check the folders contents. Staff do not assess the quality of the documentation, only that a file or document is present. The inspectors assess the contents of the documents. If documents appear to be missing, the JACIE Office will contact the centre to ask for the documents.

After this check, the documents are distributed to the Inspection Team members for their preparations. Inspector may request additional documents in advance of the inspection. The files are also stored electronically by the JACIE Office in the folders created for each centre after application. On occasion, these files may also be consulted by the Inspection Report Assessors when they review the Inspection Reports and by members of the Accreditation Committee. In the rare event of an appeal to the JACIE Committee, the Committee members may also be given access to these files if necessary.

In all cases, anyone given access to the files is reminded of their obligation to keep confidential any information contained therein.

These files are maintained indefinitely.

How does JACIE store and distribute these documents?

JACIE uses a cloud-based service for document storage and distribution: Dropbox. The system is secured using industry-standard encryption combined with other measures to protect data. See below for their full security specifications.

While our strong preference is to use Dropbox to distribute files, there may be technical or other reasons that do not permit us to do so. In these cases, documents may also be distributed via email as attachments or on CD or USB memory sticks via regular postal or messenger services.

Important notice: The centre should consider if there are any documents that require special handling such as the MED-A forms or other files. It is recommended that an internal discussion among the centre team be held before documents are submitted. Unless JACIE is told otherwise, we will assume that all documents can be stored and distributed using the above services. It is the responsibility of the centre to notify the JACIE Office if exceptions to this policy are required. In those cases, alternatives will be considered and discussed with the centre.

Security specifications



<https://www.dropbox.com/privacy#security>.

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Section 4 - Preparing for the Inspection

APPLICANT

Before The On-Site Inspection

1. The inspectors **MUST** visit each site to be included in the accredited programme and talk to key personnel at each of these sites. Schedule the on-site inspection with these personnel, and in particular, make appropriate arrangements with clinical sites (e.g. hospitals) to enable the inspectors to visit on the scheduled date. This may require clearance from an administrator, Director of Nursing, etc.
2. Recommend accommodation to the JACIE Office for the inspection team in a convenient and reasonably-priced hotel (usually a good business class hotel).
3. Provide information for the inspectors on how to get to the facility. It is helpful to make arrangements to pick up the team at their hotel. If this is not possible, provide information for them about available transportation and estimate the time that will be required to reach your facility.
4. Inform the team where you want them to meet you on arrival at your facility e.g. at the main entrance to the hospital.
5. Reserve a room for the inspectors for the duration of the audit for reviewing case notes, procedures, manuals and documents. In addition, reserve a room for the initial meeting and the exit interview that is adequate in size to accommodate the entire inspection team, key programme personnel and others that the team wishes to invite.
6. Arrange to provide a modest business lunch for the inspection team. Most teams will want to utilise the lunch hour at least in part as a working lunch.

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INSPECTOR

1. In general, the structure of the inspection team is as follows:
 - a. There may be two or more inspectors.
 - b. Trainees / Observers may accompany one or more of the inspectors.
 - c. The Team Leader, usually the Clinical Inspector, or the inspector who has participated in most JACIE inspections within the inspection team, is responsible for both, the inspection of one of the areas and leading the inspection team.
 - d. The **Clinical** inspector is responsible for inspection of the **Clinical** and **Bone Marrow Collection** Facilities where they exist.
 - e. **Apheresis** Collection inspectors usually inspect only the **Apheresis** Collection Facility but could be asked to help the other inspectors.
 - f. The **Cell Processing Laboratory** inspector generally has only the **Laboratory** to inspect, but must ensure that the **appropriate communications** exist with the collection facilities and that **transport procedures and policies** are in place.
 - g. The **Quality Management Inspector** will assess these standards for all the units involved. Where no Quality Management Inspector is available, the Clinical Inspector will assess "QM - Part B" and "QM - Part CM", the Collection Inspector will assess "QM - Part C" and the Processing Inspector will assess "QM - Part D" in addition to their corresponding sections according to their area of expertise.
 - h. Inspection team roles:

Tasks	Team Leader	Inspector	Trainee	Observer	Translator/ Facilitator
Timetable	Prepare and approve the Inspection timetable.	Comments and approval of the timetable.			
Pre-audit documentation & printed Inspection Checklist	Provided with the pre-audit documentation in advance and printed Inspection Checklist.	Provided with the pre-audit documentation in advance and printed Inspection Checklist.	Provided with the pre-audit documentation in advance and printed Inspection Checklist.		Provided with pre-audit documentation.

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Tasks	Team Leader	Inspector	Trainee	Observer	Translator/ Facilitator
Pre-audit teleconference	Leads the teleconference call and makes sure that all the Inspection team understands their role and the nature of the programme.	Actively participate in the teleconference.	Actively participate in the teleconference.		Translation and language support for understanding the nature of the programme and verbal description of contents of documentation, if needed.
Introduction meeting	Lead the Introduction meeting.	Actively participate in the Introduction meeting	Observe the Introduction meeting		Observe the introduction meeting and translation support, if
Inspection of Facilities	Inspect the facilities that they are qualified for.	Inspect the facilities that they are qualified for.	Observe the Inspection of the facilities that they are qualified for and assist.	Observe the Inspection but without taking part in it.	Observe the Inspection but without taking part in it. Only language support.
Interviews	Interview the personnel of the facilities that they are qualified for.	Interview the personnel of the facilities that they are qualified for.	Observe the Interview the personnel of the facilities that they are qualified for and assist.	Observe the Interviews without taking part in it.	Verbal translation and language support to the inspection team and centre personnel in
Closure Meeting	Lead the closure meeting	Actively participate in the closure meeting	Observe the closure meeting.	Observe the closure meeting.	Observe the closure meeting and verbal
Completion of the Inspection Checklist	Complete their section of the Inspection Checklist	Complete their section of the Inspection Checklist and send it to the team leader and the JACIE Office.			
Completion of the Summary Report	Complete their inspection part and the part of the team leader of the Summary Report	Complete their inspection <u>part</u> of the Summary Report and send it to the team leader and the JACIE Office.			

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Tasks	Team Leader	Inspector	Trainee	Observer	Translator/ Facilitator
Finalize Summary Report & Inspection Checklist.	Collect all the Summary Reports and Checklist and send it to the JACIE Office.				

2. The JACIE office will contact you to ascertain your availability before an assignment is made. **Travel arrangements should be arranged through the official travel agency by following the instructions provided by the JACIE Office.** Inspectors should note that their task does not start and finish with the inspection. They will need time to prepare the inspection, review the submitted documentation, write their report, respond to any questions from the Inspection Report Assessors and the Accreditation Committee and to review the documentary evidence of corrections submitted by the applicant post-inspection. Where it is decided that a reinspection is necessary, the original inspectors will be asked to carry this out. Inspectors should take these tasks into account when considering their availability to conduct an inspection.

3. As soon as the applicant submits the pre-inspection documentation, you will be notified. The materials will be sent to you in electronic format e.g. Word, PDF with a printed copy of the Inspection Checklist

4. Read all materials as soon as possible; DO NOT save it for the plane or train.
- a. Read instructions from the JACIE office where provided.
 - b. Read the information provided by the facility:
 - i. Application form
 - ii. Completed facility checklist
 - iii. Read the submitted materials.
 - a. Pay special attention to items such as labels and mark any errors in advance of the inspection
 - b. Decide which SOPs you want to see when you arrive for the inspection
 - c. Make a list of the items that are missing
 - d. Request missing documentation via the JACIE Office
 - c. As you review the materials, you may be able to answer some of the questions on the Inspection Checklist.
 - d. Mark the Inspection Checklist with your specific questions and note what you specifically want to see at the on-site inspection. This will help you organise the time on-site.
 - e. Recheck the JACIE Accreditation Document Checklist; make a list of items still missing from your area; be certain you obtain these through the JACIE Accreditation Office or at the inspection. Otherwise list them as deficient.

5. Before you go on the inspection, communicate with the other team members. Your team members' phone numbers and email addresses will be provided by the

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JACIE Accreditation Office.

6. Between two and three weeks before the visit, the JACIE Office will make arrangements for a **teleconference** for the inspectors to discuss the visit.

7. **Reserve your travel plans with the official travel agency** by following the instructions provided by the JACIE Office. Flights and hotels will be arranged through the agency who will invoice JACIE directly. All members of the team should stay at the same hotel to facilitate communication.

a. Be certain to allow travel time before the scheduled inspection, arriving in time for an Inspection Team meeting and document review before the on-site inspection. This may be the afternoon of the first day which is dedicated to record and documentation review or alternatively the night before the on-site visit.

b. Do not plan to leave the site before 5 PM on the second day of the inspection unless this has been discussed and agreed in advance with the JACIE Office and other inspectors.

8. The Inspection Team Leader will prepare a draft of the inspection timetable and this will be communicated to the applicant via the JACIE Office. The applicant will be invited to comment on the timetable and changes to the scheduling can be proposed but the final decision will remain with the Team Leader.

9. The Team Leader should meet before the inspection with the inspection team. Allow about an hour to:

a. Review plans for the inspection (start time and place, how to get there, etc.).

b. Be sure each person knows what she/he has to inspect: which areas, what sites.

c. Be certain that all sites have a scheduled inspector.

d. Where applicable, be certain that trainees know what they should do, with whom they should spend the day, etc. Trainees should be sure to see one area thoroughly.

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Section 5 - The Inspection

APPLICANT

On-Site Inspection

1. The initial interview should include all key personnel of the HPC Programme and members of the Inspection Team.
2. The Programme Director should plan to introduce the members of the applicant HPC transplantation team, and present any other information to the inspection team about the programme that may be helpful, particularly any information that was not required on the checklist or required documents list. It is helpful to review the structure of the programme and the location of the applicant sites, particularly if these issues are complex and/or there are any off-site locations. This presentation should not exceed 10-15 minutes.
3. Each inspection team member should have a knowledgeable member of staff available at all times to answer questions, find documents or procedures, etc. Appropriate individuals would include a quality manager, data manager, collection centre nurse supervisor, and laboratory supervisor.
4. The following documents should be immediately available for the inspectors to review (See appendix for a more detailed description):
 - a. The collected documentation for the 10 or more clinical charts.
 - b. Complete SOP manual for the clinical, collection and laboratory areas.
 - c. Documentation of training and continuing competency of the staff.
 - d. Quality assessment and improvement documents, including internal audits.
 - e. Validation studies.
5. The Inspection Team Leader will provide a schedule for the on-site inspection, see sample on p. 39. If you do not have a detailed schedule one week before the on-site inspection, the Programme Director should contact the Team Leader and/or the JACIE Office to obtain it.
6. The inspectors will need to visit every site to be included in the accreditation of your programme.
7. Be prepared to have someone escort the inspectors to each of the sites. If there are distant sites, be prepared to transport the inspectors there and accompany them at those sites.
8. Inspectors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites. For example, Clinical Programme - head nurse, social worker, pharmacy staff, any additional personnel who are needed to answer specific questions on the checklist.
9. Be prepared to gather additional documentation requested by the team during the time that they are present in your facility. If you try to send it in later, it delays the final report.
10. Assume that the inspectors will want some closed session time during the lunch hour, though they may also wish to use a portion of this time to communicate with the applicant. Be available. Be sure to check with the inspection team for questions or

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concerns related to completing the inspection visit before you leave for your own lunch break.

11. At the end of the inspection, the inspectors may wish to meet privately with the Programme Director and/or designated directors if there are issues to be raised that may be of a sensitive or confidential nature. Be available for this meeting.

12. The purpose of the Exit Interview is to allow the inspectors to summarise their major findings and to outline the remainder of the accreditation process. Remember that the Inspection Report observations are reviewed by the JACIE Accreditation Committee who will assess the applicant centre's current level of compliance and make recommendations for the correction of any deficiencies. The inspectors have specifically been instructed not to speculate on the level of compliance your programme will attain after Accreditation Committee review.

INSPECTOR

1. Initial Interview - things to accomplish:
 - a. Introductions of team members and inspection team.
 - b. Allow the Programme Director to describe the structure or organisation of the programme, location of sites, and/or present any information that may be helpful to the team, particularly items not included on the checklist or required documents list.
 - c. Team leader should present a copy of the planned schedule for the day, including who will inspect which areas.
2. Someone from the inspection team must visit every site to be accredited.
3. Applicants frequently like to give facility tours, especially when they have new or particularly novel space. Remember that someone has to see everything, but everyone does not need to see everything, so pace yourself, skip the tour if you are only inspecting the lab for example.
4. An appropriate, knowledgeable person from the applicant programme should accompany each member of the inspection team (e.g. nurse coordinator, data manager, laboratory supervisor).
5. Be thorough. Ask to see things, for example, "show me your procedure for documentation of dosages in the administration of high dose therapy" and "Show me the records of this patient's chemotherapy verification" (pick a patient at random from the list of ten submitted charts). Rather than "Do you have a procedure for verification of chemotherapy dosages", ask to see specific procedures. Staff members should know where the SOP manual is kept.

Remember that you want to see both the written procedures and the evidence that these procedures are actually being followed.

6. As you go through the inspection and checklist, talk to the applicant about any observations, both positive and negative. If there is an area that you believe is a significant problem, be certain that the person accompanying you and the director/medical director of that area are aware of the issue before the Exit Interview.
7. Take notes. Do not trust your memory. It is acceptable to write notes on the checklist to assist you in preparation of your final report. Record the reasons for observed variances or deficiencies.
8. Complete the checklist or for the area being inspected as you go to ensure

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everything is covered.

9. DO NOT SKIP ANY ITEM ON THE CHECKLIST.

10. The Inspection Checklist is designed so that the correct answer (the one that indicates compliance with a standard) is practically always COMPLIANT (or NOT APPLICABLE). Pay particular attention to any item marked "PARTIALLY COMPLIANT" OR "NON-COMPLIANT" by the applicant facility. Also bear in mind that recommendations for corrections will be based on the Inspection Report, therefore write specific notes next to any items that do not indicate a COMPLIANT by either the applicant or the inspector e.g. if SOP's are missing references, give examples of specific SOP's.

11. Meet up with the rest of the inspection team about mid-day to ensure that you are each getting finished with what needs to be completed and if the remainder of the schedule seems realistic. Determine if additional help is needed in any area - such as chart review - and if any team member will be able to assist. A working lunch is an efficient way to accomplish this communication.

12. Just before the exit interview, reconvene the inspection team to discuss findings, what will be presented at the exit interview, etc.

13. If significant questions arise at any time during the day, call the JACIE office at the details listed on page 5.

APPLICANT AND INSPECTOR

Exit interview

1. Meet privately with Programme/Facility Director(s) as needed, particularly if you believe there are potentially significant problems at the programme.

2. Attendees at the Exit Interview should include: ALL INSPECTORS, Programme Director, Facility Directors and Medical Directors from each area inspected; anyone who accompanied the inspection team during the day; supervisors; and any other facility personnel whom the Applicant Programme Director invites.

3. The Team Leader leads this interview, but all inspectors participate.

4. EACH INSPECTOR should summarise the major findings in the area he/she inspected. Remember that the applicants have worked hard to prepare, they are understandably anxious about the outcome. It is helpful to begin with positive impressions and observations. Be careful to compare the programme to the Standards, not to your own programme.

5. Be careful to be thorough. The impression you leave with the facility should be close to what you write in your report. When the applicant facility personnel receive their initial report detailing any deficiencies, **THERE SHOULD BE NO SURPRISES!**

6. Explain the remainder of the process to the applicants. Explain that you will report your observations; these are reviewed by the JACIE Office and the JACIE Report Assessors and then summarised for the JACIE Accreditation Committee. The JACIE Accreditation Committee makes the final decision on accreditation.

7. Avoid making promises or speculations. Specifically, do not guess about the likelihood of the applicant's "passing" the inspection. The JACIE Accreditation Committee will make this determination. The Inspector should not give specific instructions to the applicant at this point. However, where the changes required are very

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obvious or straightforward, the applicant can take note of these and start to implement corrections immediately following the inspection.

8. If you don't know the answer to a question, say so. Notify the JACIE Office immediately if there are unanswered questions from the applicant that require answers before a final report will be available. You should include applicant questions in your report.

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Section 6 - Data Management

Data Management will be inspected by comparing completed MED-A* records for a sample of transplanted patients with the original patient records in order to assess the accuracy and completeness of patient data.

Instructions to the applicant facility:

1. From the complete patient list for the most recent 12-month period, identify a consecutive selection of patients. The number of patients required to be presented can be determined from Table 1 below.
2. Depending on what accreditation your centre is requesting, the numbers of MED-A forms that should be presented is as follows:
 - a. For programs applying only for allogeneic transplantation, identify ten (10) consecutive patients.
 - b. For programs applying for autologous accreditation only, identify five (5) consecutive autologous patients.
 - c. For programs applying for allogeneic and autologous accreditation, identify fifteen (15) patients of which at least ten (10) should be consecutive allogeneic patients and five (5) consecutive autologous patients.
 - i. If your programme performed less than five (5) autologous transplants in the given period, increase the number of allogeneic patients until the combined total equals fifteen (15) patients.
 - d. For programs with more than one (1) clinical site, include at least five (5) patients from each site.
 - e. If both pediatric and adult patients are treated in a combined program at the same clinical site, include at least five (5) patients in each population.

Table 1

	Single site	Combined program†		Multiple sites	
Allo only	10	<i>adult</i>	5	5 per site	
		<i>paeds.</i>	5		
Auto only	5	<i>adult</i>	5	5 per site	
		<i>paeds.</i>	5		
Allo & Auto <i>Combined total must be 15 patients</i>	10 allo + 5 auto (see 2.c.i más atrás)	<i>adult</i>	5 allo 3 auto	<i>allos</i>	5 per site
		<i>paeds.</i>	5 allo 2 auto	<i>autos</i>	5 per site

3. For each of these patients, complete and submit the applicable Minimum Essential Data-A (MED-A) forms.

* For more information on MED-A forms, see the EBMT web site
<http://www.ebmt.org/Contents/Data-Management/Registrystructure/MED-ABdatacollectionforms/Pages/MED-AB-data-collection-forms.aspx>

† Combined programme means where adults and paediatrics are part of the same transplant programme

4. Using the unique patient identifier, list these patients in the table below. Use additional pages if necessary.
5. **IMPORTANT!** In order to facilitate the work of the inspectors, make sure that in the primary patient record for each data point on the MEDA form, you mark the source documents to facilitate verification by the on-site inspector. For example, the date of diagnosis should be clearly marked with a *Post-it*® or similar type of bookmark in the patient record.
6. The patient records corresponding to the completed MED-A forms should be easily available to the inspector. For instance, the records could be all made available in the data manager's office with a space for the inspector to perform the check. Alternatively, if there is an electronic system in place, someone familiar with the system should be available to assist the inspector.

ALLOGENEIC TRANSPLANT RECIPIENTS			
Unique Pt. ID	Transplant Date	Paediatric or Adult?	Clinical Site of Transplant
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
AUTOLOGOUS TRANSPLANT RECIPIENTS			
Unique Pt. ID	Transplant Date	Paediatric or Adult?	Clinical Site of Transplant
1.			
2.			
3.			
4.			
5.			
Additional AUTOLOGOUS TRANSPLANT RECIPIENTS for multiple sites or populations			
1.			
2.			
3.			
4.			

Instructions to the Inspector:

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- 1) The audit is based on comparing data points (a specific item contained within the MED-A form) with the original patient records.
- 2) The Clinical Program has already selected a list of consecutive transplant patient records for audit and prepared completed MED-A forms for these patients. The exact number of patients is determined using Table 1 above.
- 3) Verify that these are consecutive patients by using the submitted patient list (see list above).
- 4) Verify that the minimum number of patients from each age group (pediatric and adult) and from each clinical site, as applicable, have been included. See Table 1 above.

So now you will have between 5 (if AUTO only) and 15 (if an ALLO & AUTO, Combined or Multiple-site programme) patient records.

What you have to check:

1. You must check a minimum of thirty (30) data points for each type of transplant performed. This means that you should check
 - a. For allogeneic AND autologous transplant = 30 x 2 transplant type = 60 data points in total
 - b. For allogeneic OR autologous transplants, 30 x 1 transplant type = 30 data points in total
 - c. For Combined Programmes, 30 x [number of units AND/OR patient types]
2. On the forms included in the Inspection Checklist, five (5) data points are pre-determined on both the ALLO and AUTO Inspection Report Forms. These are:

<u>Allogeneic</u>	<u>Autologous</u>
<input type="radio"/> Primary disease	<input type="radio"/> Primary disease
<input type="radio"/> Stem cell source	<input type="radio"/> Disease status at transplant
<input type="radio"/> Donor type	<input type="radio"/> Stem cell source
<input type="radio"/> Engraftment date	<input type="radio"/> Engraftment date
<input type="radio"/> Survival status at day 100	<input type="radio"/> Survival status at day 100

3. In addition, there is also space for the data points that you can choose to check at random.
4. You must audit the **five (5)** predetermined items on:
 - a. at least **three (3)** patient records for each type of patient/site = 15 data points
and
 - b. the remaining 15 data points for each type of patient/site to be either
 - i. checked on additional records
or
 - ii. 5 more data points on each of the 3 records already chosen.

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Preparation in advance of the inspection

1. In order to use your time more efficiently, you should decide in advance which records you wish to see on-site.
 - a. You may select at random the specific patient records you will audit.
2. If you are inspecting a COMBINED program (either a program that transplants both adults and children or a program with more than one clinical site utilizing the same data management system and personnel), you must include a representative number of records of pediatric and adult transplant patients or a representative number of records from each clinical site.
3. Complete the Inspection Report Form with the Unique Patient Number before you go to the centre.
4. You should also select any additional data points in advance of the inspection using the documentation submitted by the centre. For instance, this can be done by highlighting on the completed MED-A forms which data points you want to check.

On-site inspection

1. The patient records corresponding to the completed MED-A forms should be easily available to you with the data points marked by the centre in advance. For instance, the records could be all made available in the data manager's office with a space for you to perform the check. Alternatively, if there is an electronic system in place, someone familiar with the system should be available to assist the inspector.
2. Record your audit results on the report forms that follow these instructions. Be certain to record the unique patient identifier for each of the records audited. Verify the items that are listed, and list the additional items that you audited.
3. If you notice a pattern of errors, check additional records for the items where errors have occurred to determine if this is a random transcriptional error, or if there is a systemic problem in data management that results in the same errors being made repeatedly.

During the patient record audit, a knowledgeable member or members of the data management team of the applicant program should be present to assist the inspector. Ask these personnel if you have any questions, any difficulty finding the source data, or in verifying accuracy.

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Section 7 - Post-Inspection

APPLICANT

1. Following the inspection and the submission of the Inspection Report, there is a phase where the report is analysed by the JACIE Accreditation Committee. Clarification may be required from the inspectors of any points not fully understood. The length of this phase is subject to the availability of the inspectors. The Accreditation Committee will then assess the level of compliance and make recommendations for the correction of any deficiencies. The Inspection Report will be reviewed by the Accreditation Committee and will then be forwarded to you. Feel free to contact the JACIE Accreditation Office if you have not received expected communications.

2. The JACIE Office will send you an On-Site Inspection Evaluation form for completion online. The form should be used by the applicant to formally state satisfaction with the performance of the inspection or to raise any issues that may have occurred during the inspection visit. It also gives the applicant an opportunity to give feedback on the process overall. It is important that this form be returned as quickly as possible. The evaluation by the centre will also be sent to the inspectors for their information and response where necessary.

Evidence of Corrections

3. A timeline for implementing the required corrections and submitting documentary evidence will be outlined by the Accreditation Committee with a **maximum period of 9 months** being allowed from when the Summary Report is issued. Once you have received the report you should send a formal response indicating whether you can meet the proposed schedule.

- a. If not, please submit a summary of any issues that may delay or obstruct corrections and estimate the time required for consideration by JACIE.

4. When documentary evidence of corrections is submitted, this will be reviewed by the original inspection team and their comments will be sent to the Accreditation Committee. If this evidence is satisfactory, a final recommendation for accreditation will be made to the JACIE Board.

5. In some cases a reinspection may be required to look at a very specific aspect of the programme or where a wider review is necessary. This will be arranged by the JACIE office on a date that is convenient for the applicant centre and the inspectors but should take place within 1 year of the Inspection Report.

- a. Costs arising from the focussed reinspection will be payable by the centre. These costs will be limited to the inspector's travel, accommodation and subsistence costs. JACIE will invoice the centre for the arising costs.

6. Where an applicant delays in submitting evidence of corrections to the JACIE Office more than 9 months after receiving the Summary Report, accreditation will be awarded starting from the date when the inspectors have confirmed that all deficiencies have been corrected and ending 4 years from the date of inspection, not from when the corrections were approved. This means that the centre will be accredited for a shorter period of time than if the corrections had all been resolved within the 9 month period after receipt of the Summary Report.

7. Where an applicant delays more than 12 months in demonstrating full compliance with the FACT-JACIE Standards after receiving the Summary Report, the accreditation process of the centre will be considered expired and the centre must restart the process. The calculation of 12 months will be made from the date when the Summary Report was emailed from the JACIE Accreditation Office to the

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applicant.

INSPECTOR

After The Inspection

1. Complete your report as soon as possible after the inspection. A delay in preparation of your report has a significant negative impact on the quality of the report and on the inspection process.

While not a requirement, it is **highly recommended** to write a draft of your inspection report while still onsite. While you will probably be tired, it will be far easier to remember key points and will also mean that this task is 'out of the way' of your normal work. In addition, JACIE is happy to reimburse the costs of an additional night's accommodation if this facilitates writing the report.

2. The completed checklist should be given to the Inspection Team Leader at the end of the inspection along with your completed inspection report if possible, or sent to the Team Leader and the JACIE Office **within three days** of completing the inspection.

3. The Team Leader is responsible for collecting the other team member's comments and observations and collating these in the Summary Report before sending it and any other files to the JACIE Office. This final report is expected within **2 weeks** of the actual inspection.

4. The Inspector is required to assist with later phases of the application process. Once the centre has submitted evidence that they have corrected the deficiencies, as an inspector, you will be asked to review this evidence and where necessary conduct a reinspection of the centre.

Report Structure

1. The Inspection Report has two parts
 - a. The Inspection Summary which includes the basic information on the centre, the programme structure, Team Leader summary, overall impression of the inspection
 - b. The completed Excel Inspection Checklist that includes the specific observations on each of the individual items in the checklist.

2. The report should be written to and for the Applicant (see below for advice on report writing). While the report will be reviewed by JACIE, there will be as little change as possible introduced into the text of the report (aside from correction of spelling or grammar where errors occur).

3. Record your observations of everything that does not appear to meet a standard in your area. List the number of the standard with your comments.

- a. Submit all reports to the Team Leader
- b. **Report submission:**

The report summary must be submitted in the standard Word template which the JACIE office will provide to all inspectors and the individual observations completed in the Excel Inspection Checklist.

- c. Be certain to retain a copy for your own records until the inspection process has been completed for that applicant programme.

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4. Return **EVERYTHING** to the Team Leader or directly to the JACIE Office: the **completed Inspection Checklist**, printed or electronic report and all printed documentation that you received at the inspection and/or after you received the initial inspection assignment. Be sure to include any of the following items or documents you may have used or acquired during the inspection: documentation, data sheets, forms, and labels.

5. Be sure to include every page from the checklist for the area you were assigned to inspect. **Make sure that each box is marked with your answer.** This will avoid having to return the checklist to you for completion.

6. Remember that all observations, findings, and deliberations of the inspection team are strictly confidential. None of this information may be discussed with other colleagues or personnel.

7. Differences between an inspector's and the Accreditation Committee's interpretation:

Infrequently, the Accreditation Committee finds that it must amend an inspector's comment(s) where it is considered incorrect or where it could lead to misunderstandings. Inspectors will be notified when an inspector's finding is changed by the Accreditation Committee. This notification will be sent before sending the report to the centre and will give the inspector the opportunity to respond. However the final decision will lie with the Accreditation Committee. The inspector will have a 7 days to respond before the report is sent to the centre. In the event that the inspector doesn't answer, the report will be sent to the centre in order to avoid delays in the submission of reports.

The aim is to respect the inspector's effort and outline the reasons for the change or different interpretation as part of the inspector's ongoing education and training.

Five Steps When Writing a Narrative Report

Step 1 - Plan

A good inspector begins to plan his/her report the day the inspection begins. By thinking about how the facts must be reported ahead of time, the inspector can improve both the quality of the inspection report as well as the inspection itself.

Step 2 - Organize the material

All information gathered during the inspection must be collected and reviewed, including inspection report forms and checklists, for relevance and completeness. The inspection checklists are useful tools for developing the narrative report, but cannot replace a narrative report. The material must then be organized in the order it will be presented in the report.

Step 3 - Write

While writing the inspection report, keep the following in mind:

- Write to express, not to impress. Only relevant facts and evidence necessary to prove the compliance or deficiencies of the site being inspected must be included in the inspection report.
- State complicated matters in simple direct terms.
- Keep the reader in mind. When preparing an inspection report, assume that the reader knows nothing about the case except what is in the report. The report must construct a complete and accurate picture of the entire inspection, step by step.

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Step 4 - Evaluate

After the report has been written, review the report from the viewpoint of the reviewer and answer the following questions:

- What is the report trying to communicate?
- Has the report fulfilled the purpose of the inspection visit?
- Can supervisors and reviewers make correct decisions based on this report?
- Does it answer the questions - who, what, when, where, why, and how?
- Are any further inquiries necessary?
- Is it readable?
- Is it fair, concise, complete, accurate, and logical?
- Is any part ambiguous?

Proofread the report to check for inconsistencies, unnecessary repetition, tone, omissions, and typographical errors.

Step 5 - Rewrite

Correct those portions of the narrative that were identified as needing improvement.

Essential of Good Reports

Fairness

The reports must be entirely objective, impartial, unbiased and unemotional. Convey facts so they speak for themselves. Rumours, gossip, offensive remarks or language should be avoided. To test for fairness, read the material aloud to ensure the report is conveying the proper tone for the reader and the purpose of the report.

Accuracy

The information must be stated precisely and accurately in plain language. The inspection report must not, under any circumstances, include the inspector's conclusions regarding compliance or non-compliance. The goal is to present the facts so clearly that there will be no need for conclusions. If the inspector wants to communicate certain findings or observations to the reviewer, these opinions must be contained in a memorandum separate from the inspection report. In addition, the inspector may have been wrong about a deficiency.

Completeness

Include all information that is relevant. Completeness implies that all known facts have been reported either in the text or as an attachment, so that no further explanation is needed. The report must be tested to ensure that it answers the questions "who, what, how, when, where, and why."

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Conciseness

Conciseness is never omitting facts, details or necessary explanation, but the removal of all that is elaborate or non-essential. Conciseness is not what is said, but how it is said. Use short sentences with active verbs and paragraphs whenever possible.

Clarity and Logical Presentation

The report must be written clearly in order to avoid misinterpretations. Writing takes time and effort. Order thoughts; select those most useful to the reader; arrange them logically; and select the words that will best convey the thoughts to the reader.

Confidentiality Considerations

The information that an inspector may encounter during an inspection is considered confidential.

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Potential Inspection Outcomes

The below levels are indicators that are stated on the Accreditation Committees Initial report to the applicant centre. This level is an outcome of the inspection and **not an accreditation level**. The applicant must fully comply with all applicable standards in order to be accredited.

Description
No deficiencies or variances observed at the onsite inspection or in submitted materials. Full accreditation for four years awarded effective from the date of the JACIE Board decision with provision for an interim audit at the end of the second year of accreditation.
Few minor deficiencies noted at the onsite inspection and/or in submitted materials. Full accreditation can be awarded upon written documentation by the Programme Director of correction of all deficiencies and a satisfactory response to all recommendations. The JACIE Accreditation Committee will determine the adequacy of the facility's response and make appropriate recommendation to the JACIE Board.
Significant deficiency or deficiencies documented at the site inspection. Full accreditation requires Programme Director's documented correction of all deficiencies and satisfactory response to recommendations. The JACIE Accreditation Committee will determine the adequacy of the facility's response and make appropriate recommendation to the JACIE Board.
Significant deficiency or deficiencies observed at the site inspection. Full accreditation requires that all deficiencies be corrected and that a satisfactory response to all recommendations be provided by the Programme Director. Documentation of correction of deficiencies also requires that a focussed reinspection of one or more areas of the facility operation be conducted. Unless specifically requested by the facility, the same inspector(s) will be responsible for conducting the focussed reinspection. The JACIE Accreditation Committee will review the results of the reinspection and make appropriate recommendation to the JACIE Board.
Significant deficiencies observed during the site inspection requiring a full reinspection of the applicant facility to document correction of all deficiencies. Satisfactory responses to all recommendations must be provided. The JACIE Accreditation Committee will review the results of the reinspection and make appropriate recommendation to the JACIE Board.
Non-accreditation. Reapplication and submission of documents required.

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Section 8– Interim audit

Introduction

The change of the duration of the accreditation cycle from 3 to 4 years was the result of a proposal by the JACIE Board on 30 March 2008 and adopted on 10 October 2008. The 4-year accreditation cycle was introduced with effect from 1 January.

There are no changes to the procedure for requesting and preparing for accreditation/reaccreditation and the inspection process will remain as it is.

Focus

The interim audit focuses primarily on the **quality management system**. JACIE reserves the right to examine any issues identified in the previous inspection report.

Process

At the end of the 2nd year of accreditation, the centre will receive a request for documentation by the JACIE Office 3 months before the second year of accreditation ends.

The interim audit will be based on these documents and assessed by the same inspectors that participated in the previous full Inspection. Where an inspector is no longer available, a substitute will be appointed.

The audit does not introduce any new requirements or questions not already addressed by the Standards.

Scope

The audit will be based on a condensed version of the JACIE Inspection Checklist. It is available for download from the Document Centre on the JACIE web site at www.jacie.org.

The audit will focus on the functioning of the quality system. The auditor will assess:

- Evidence of continuous educational and training activity
- Quarterly reports on quality management activities and/or minutes of meetings where these activities were reported
- Internal annual reports on the performance of the quality management system
- Evidence of regular review and approval of SOPs and other documentation
- Evidence of internal audits
- Evidence of regular meetings e.g. minutes, agenda
- Reports of Serious Adverse Events (SAEs), their review and evidence of corrective actions
- Evidence of review of donor records
- Evidence of outcome analysis
- Current status of licence/authorisation by the regulatory authorities.
- Evidence of validation of procedures or equipment
- Evidence of environmental monitoring
-

The auditor will receive a copy of the most recent Inspection Report and Annual Report for the centre. JACIE reserves the right to examine any issues identified in the previous inspection report.

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Format

Desk-based review of documentation. There is no dedicated on-site visit the facilities unless this is determined to be necessary from the document review. JACIE also reserves the right to perform an onsite visit at any time.

Consequences

The audit is a *check-up* on the operation of the quality management system. The audit will lead to an assessment of the actual state of quality management in the programme and may identify deficiencies or highlight areas that require attention.

If deficiencies are reported, the centre should submit corrective actions within a time period not exceeding 6 months from receipt of the Interim Audit Checklist completed by the auditor(s). Failure to correct deficiencies within this time period may result in suspension of accreditation.

Centres are still required to submit annual reports at the end of Year 1, Year 2 and Year 3 of the accreditation period.

Section 9 – Reaccreditation

1. It is recommended that reaccreditation applicants make a note of the accreditation timeline on p.6.
2. It is recommended that proceedings for reaccreditation are initiated **one** year prior to expiry in order to minimize the possibility of lapses between accreditation expiry and reaccreditation. Please bear in mind that such lapses are subject to the timing of document submission, availability of inspectors, the findings of the inspection and the applicant's submission of documentary evidence of corrections.
3. The JACIE office will contact accredited units in their final year of accreditation to initiate and assist with the reaccreditation process. If you have any queries, please do not hesitate to contact the JACIE office (see contact details on p. 5).

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Section 10 – Specific Issues

Bone Marrow Collection - Guidance for Clinical Programmes

The 6th Edition of the FACT-JACIE Standards requires the following minimum collection activity for bone marrow harvests :

CM1.5 A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period immediately preceding facility accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within the accreditation cycle.

Scenarios

1. Programmes that regularly[‡] use Bone Marrow

Clinical programmes must use collection facilities that meet JACIE standards, which in practice means that collection facilities must be inspected and accredited. This applies to bone marrow (HPC-Marrow) collection as well as collection of HPC-Apheresis. This is made explicit in the 6th edition of the FACT-JACIE standards:

B3.6.2 The Clinical Program shall have access to licensed physicians who are trained and competent in marrow collection and utilize a marrow collection facility that meets these Standards.

Inspection Checklist: Fully completed Part CM checklist must be submitted

Note: A programme meeting these criteria and satisfying all of the requirements in Part CM of the standards will be accredited for Bone Marrow Collection.

2. Programmes that only occasionally use Bone Marrow

If a centre does collect bone marrow but less frequently than the minimum number of procedures established in the Standards, then the programme **cannot** be accredited as a Bone Marrow Collection Facility, even if all the other standards in part C are satisfied.

In these circumstances standard B3.6.2 above will be interpreted as requiring the clinical programme to have in place the following:

- a. Access to licensed physicians who are trained and competent in bone marrow harvesting appropriate physical facilities for bone marrow harvest[§].
- b. SOPs for bone marrow harvesting, labelling and transport
- c. Incorporation of bone marrow harvest activity into quality management programme (adverse event reporting, audit, analysis of time to engraftment data, etc.)

[‡] Defined as meeting the minimum activity requirements established in the Standards to apply for accreditation for bone marrow collection.

[§] Physical facilities should be inspected if part of the same programme but if in a different institution, it would mean time out of an inspection to look at a distant facility. The programme should be able to demonstrate evidence of support from the department responsible for surgery and operating theatres.

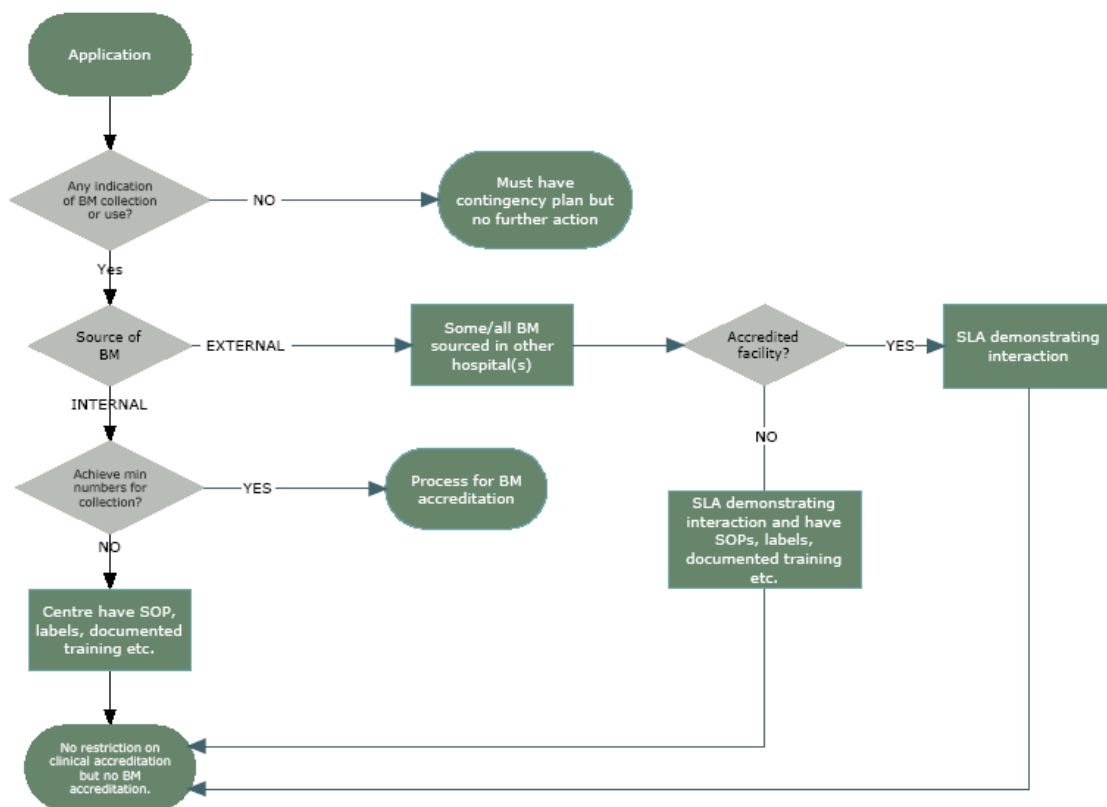
Inspection Checklist: Part CM checklist for Bone Marrow not required to be completed

Alternatively, the centre may have arrangements in place for bone marrow harvesting to be done by an **accredited** bone marrow collection facility elsewhere. These arrangements should be covered by a third party agreement in the form of a contract or service level agreement. The applicant centre should be able to demonstrate that the criteria are complied with e.g. evidence of training, copies of SOPs.

3. Programmes that do not use Bone Marrow

If a programme never uses bone marrow as a source of stem cells then the above requirements do not apply, but there should be a specific policy stating that bone marrow stem cells are not used, e.g. even where harvesting of HPC is inadequate.

Procedural Flowchart: Bone Marrow Collection



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Physical alterations and moves to new facilities/buildings

Where an accredited centre makes substantial changes to existing facilities and/or moves to new facilities/buildings

Context:

Large-scale improvements to an existing facility or a move to a new building or facility represent substantive changes to an accredited programme. It is reasonable to expect that new or refurbished facilities represent improvements in service. However, JACIE must be satisfied that the centre continues to be compliant with the standards following the change.

Note: If a centre is considering accreditation for the first time and anticipates physical changes to the facilities being introduced shortly before or after inspection, it is recommended that the applicant centre waits 3-6 months from the start of operations in the new facilities before being inspected.

Requirements:

1. A centre must notify JACIE of any changes to facilities as soon as they are completed and in use.
2. The centre must submit the required documentation (see below) to JACIE within 3 months of completion of the move. If at the end of 3 months following this notification all documentation has not been received, accreditation of the affected part of the programme may be suspended.
3. JACIE will review the submitted documentation and may decide that no further steps are required in order to maintain accreditation. The original inspectors may be consulted.
4. Any arising actions will depend on how much time has lapsed since a centre has been awarded accreditation:
 - a. If a move occurs within the first year of accreditation or reaccreditation, the centre must demonstrate that the new facility is compliant with the relevant standards. A focused revisit may be scheduled subject to the review of the submitted documentation.
 - b. If a change occurs in the second year of accreditation, this will be examined during the interim audit which is automatically scheduled for this period for all accredited centres.
 - c. If a change occurs in the third year of accreditation, then the conditions under point (4) above apply.
 - d. If a change occurs in the fourth year of accreditation, this will be examined as part of the reaccreditation inspection.
5. JACIE reserves the right to schedule a focussed inspection of the new facilities at any point, subject to the documentation review.
6. Required documentation:
 - a. Evidence of the effective date of the move e.g. confirmation from hospital management

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- b. Short description of the changed or new facility(s) and their impact on the working of the programme e.g. if paediatric patients are now also treated, changes in staffing, etc.
 - c. Evidence of validation of facility(s) including environmental checks and monitoring. This includes patient areas e.g. installation of HEPA filters, as well as laboratory facilities e.g. air quality in LAF cabinets.
 - d. Plan or map of the new facility(s)
 - e. Organigramme, if amended
 - f. Revised Quality Management Plan highlighting the points reflecting the change, if amended
 - g. Emergency and disaster plan, including the Facility response.
7. Costs arising from the focussed inspection will be payable by the centre. These costs will be limited to the inspector's travel, accommodation and subsistence costs. JACIE will invoice the centre for the arising costs.
8. The dates of accreditation will remain the same.

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Recommendations for provision of ICU services

Background

The 6th edition of the Standards includes the requirement:

B2.13 There shall be an intensive care unit or equivalent coverage available.

B2.6 There shall be written guidelines for communication, patient monitoring, and prompt transfer of patients to an intensive care unit or equivalent when appropriate..

The standard doesn't define "institution" which leaves it open to interpretation. However, the Guidance has been expanded in edition 6.0 of the Accreditation Manual (p.26) to read as follows:

The Clinical Program must have documentation that there is ready access to an ICU or equivalent coverage in an immediate fashion for its patients when appropriate. This requires the ability to provide multisystem support including assisted respiration. Ordinarily, this would be within the institution but contractual arrangements with another institution may be considered if transfer procedures are in place to ensure prompt service and patient safety.

Outpatient facilities must document a plan for immediate transfer to an ICU, emergency department (ED), or inpatient unit if clinically warranted. The outpatient plan for providing inpatient care if needed should be discussed with the patient regardless of the type of outpatient setting (e.g., home, day unit, hotel, etc.). The outpatient plan should address specific needs of transplant recipients, such as the need for isolation protocols for immunocompromised patients, transfer to transplant designated units related to clinical indications, and transplant-specific discharge plans.

Clinical Programs must have written guidelines for the transfer of patients to an intensive care unit or equivalent coverage. The purpose of this standard is to facilitate clear communication between the program and any other departments and health care professionals, and the prompt transfer and ongoing monitoring of appropriate patients. It is not the intent to dictate which patients require transfer, to set criteria for patient transfer, nor to define the amount of intensive care that can or should be provided on a transplant unit. Facility guidelines may allow flexibility depending on patient characteristics. There should be quality parameters regarding the transfer, such as how quickly the patient is transferred..

Issues

The intent of the standard is obviously to assure speedy access to ICU. It is clear that lack of ICU access is a potential risk to patient safety given the general level of illness of transplant patients and the relatively fast rate at which a patient may deteriorate. Additionally, intensive care medicine is moving towards referring to IC (intensivists) experts at an early point so that care may potentially be given at the bed-side without having to move the patient. This early intervention requires close collaboration with intensivists which is obviously greatly facilitated where services are separated by only short distances.

Interpretation of standard B2.6 & B2.13

1. That an ICU on the same site represents the standard of care and that any deviations from this will be carefully reviewed
 - a. Centres with on-site access should have a contingency for when the on-site unit is full or unavailable

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2. That 'equivalent coverage' is able to provide multisystem support including assisted respiration on-site for patients who will then be transferred to another hospital (in or outside the same health care provider) for more 'formal' ICU management
3. That access to ICU in terms of response time and time-in-transit is very carefully monitored and documentation is available at inspection
4. That the impact of transferring patients to another facility that is not in the same hospital is monitored and that this data is used to assess whether or not the clinical programme meets JACIE requirements.
5. Additional information:
 - a. A concise description of access to ICU is included among the pre-inspection documentation e.g. SOPs describing the process for accessing ICU services
 - b. Inspectors would be instructed to meet with ICU staff during the on-site inspection and/or for an intensivist to attend the opening meeting of the inspection

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Accreditation of units that are dependent on separate cell collection or processing facilities for accreditation

Introduction

The FACT-JACIE Standards require that cell collection and processing facilities meet the requirements of the FACT-JACIE Standards (B1.2, CM1.2, C1.2). In practice these requirements are interpreted to mean that the collection and processing facilities shall be JACIE-accredited.

Many cell collection and processing facilities commonly serve more than one transplant programme. This is especially the case where the services are part of a national organisation e.g. NHSBT (UK), DRK (Germany), Sanquin (The Netherlands).

Issue

In some transplant programmes, collection or processing facilities are not under the direct control of a clinical and/or collection units. On occasions, either the collection unit and/or laboratory have not progressed as quickly to accreditation and are lagging behind the clinical units or alternatively, they proceeded ahead of the other services, achieved accreditation and this has subsequently expired. This can lead to situations where a clinical and/or collection unit has already passed through its inspection and is compliant in all aspects except for complying with B1.2, CM1.2 and/or C1.2. Currently in these cases, the centre enters a *limbo* period while they wait for the other services to achieve accreditation. In some cases this period can exceed 12 months which has repercussions for these *limbo* centres.

Response

Rather than allow these almost fully compliant clinical and/or collection units to enter into *limbo* as compliant but unaccredited while they wait for their external cell collection or laboratory services to be accredited or reaccredited, it is proposed to acknowledge the efforts of the clinical and/or collection teams while accommodating external services outside of their direct control once the following conditions have been met:

- a) The cell collection and/or laboratory facilities shall have been accredited at least once before by JACIE
- b) For these cell collection and/or laboratory facilities, their latest accreditation expiry date must fall within 12 months of the clinical and/or collection units being considered compliant in all other aspects
- c) The cell collection and/or processing facilities must have applied for reaccreditation on or before the date of the inspectors' approval.
- d) If these facilities' application for reaccreditation is received later, this later date will be the effective date of accreditation of the clinical and/or collection units.
- e) Valid and current authorisation by the relevant regulatory authority must be demonstrated

It should be noted that this is an exceptional decision to be made after full consideration of the individual programme by the JACIE Accreditation Committee, and will be audited at the time of the interim audit and future full inspections.

This accreditation will be termed *Conditional Accreditation*, issued for 12 months. When the laboratory has been accredited, this *Conditional Accreditation* would be converted to *Accreditation* for 4 years from the date when it was first awarded.

If at the end of the 12 month period the collection and/or processing facilities have still not advanced towards accreditation (excluding delays within the accreditation process that lie within

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the responsibility of JACIE e.g. difficulty in finding inspectors), then the clinical and/or collection units' accreditation will not be extended until the cell collection and/or processing facilities are accredited. The resulting accreditation will be for the period starting with the cell collection and/or processing facilities' accreditation and ending 3 years after the *Conditional Accreditation* expired.

Example

A clinical and collection combined unit, following inspection and submission of corrections, is considered by the inspectors on 1 June 2012 to meet all of the standards. However the processing laboratory, an external service accredited once before by JACIE allowed this accreditation to lapse.

Taking into account the following:

The laboratory service's last accreditation expired on 19 September 2011

AND

the laboratory has applied for reaccreditation on 15 May 2012

AND

the laboratory demonstrated that it is currently authorised to operate by the relevant competent authority,

The clinical and collection units would be awarded Conditional Accreditation for 12 months from 1 June 2012.

For dependent Clinical Programs	For dependent Collection Facilities
<ul style="list-style-type: none"> ○ The cell collection <u>and</u> laboratory facilities shall have been accredited <u>at least once</u> before by JACIE 	<ul style="list-style-type: none"> ○ The laboratory facilities shall have been accredited <u>at least once</u> before by JACIE
<ul style="list-style-type: none"> ○ For the cell collection and/or laboratory facilities , the latest accreditation <u>expiry date falls within 12 months</u> of the clinical and/or collection units being considered compliant in all other aspects 	<ul style="list-style-type: none"> ○ For the cell collection and/or laboratory facilities , the latest accreditation <u>expiry date falls within 12 months</u> of the clinical and/or collection units being considered compliant in all other aspects
<ul style="list-style-type: none"> ○ The cell collection and processing facilities have <u>applied</u> for reaccreditation on or before the date of the inspectors' approval. 	<ul style="list-style-type: none"> ○ The processing facilities have <u>applied</u> for reaccreditation on or before the date of the inspectors' approval.
<ul style="list-style-type: none"> ○ If these facilities' application for reaccreditation is received later, this later date will be the effective date of accreditation of the clinical and/or collection units. 	<ul style="list-style-type: none"> ○ If these facilities' application for reaccreditation is received later, this later date will be the effective date of accreditation of the clinical and/or collection units.
<ul style="list-style-type: none"> ○ Valid and current authorisation by regulatory authority must be demonstrated 	<ul style="list-style-type: none"> ○ Valid and current authorisation by regulatory authority must be demonstrated

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Appendix

This section contains the following documents:

1. Sample inspection timetable for 1.5 day inspection
2. Documentation & Information to be facilitated by the applicant on the day of the audit

All documents relevant to the JACIE Accreditation process can be found on JACIE online www.jacie.org in the Document Centre. Direct Link: <http://www.jacie.org/document-centre>

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Sample inspection timetable

The timetable presented below is based on periods of half-days that can be combined either as 1.5 days starting on the afternoon of the first day and finishing on the evening of the second day or, starting on the morning of the first day and finishing on the afternoon of the second day.

Suggestion I

From Inspection Team Leader to Programme Director:

1st Half-Day Period

As agreed we would like to start with your brief presentation/overview and an introduction to the team. The rest of the period is really for reviewing documentation, prior to on-site inspection of the clinical areas/collection facilities/laboratory areas the next day.

From the clinical point of view, I would like to have all the notes referred to in the submitted Med A forms available for inspection. Hard copies of all the submitted documents inc. Quality Manual and SOPs for all areas to be inspected.

(Clinical/collection/lab) documentation should also be available for the inspectors to review. The Processing Inspector will be liaising with the Laboratory Director as to where this should take place for the laboratory documentation

2nd & 3rd Half-Day periods

We would like to be able to interview the following:

<i>Clinical</i>	<ul style="list-style-type: none"> • Programme Director • A transplant physician • The quality manager • Senior Nurse • Nurse responsible for training • BMT unit nurses • Pharmacist
<p>On the Friday I would wish to visit all clinical areas and can conduct some of the above interviews as I move from area to area. Clearly some personnel may be added or subtracted from this list depending on our initial document review.</p>	
<i>Cell Collection</i>	<ul style="list-style-type: none"> • Collection facility director • Collection facility medical director • All staff involved in collection of cells
<i>Laboratory</i>	<ol style="list-style-type: none"> 1. Laboratory Director 2. Laboratory Medical Director 3. Laboratory Quality Manager 4. Laboratory Processing Lead 5. Laboratory Quality Manager 6. Laboratory Trainee(s) (as appropriate)

Suggestion II

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1st Half-day Period

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

2- MEDA/B data audit and initial review of documentation

- *MED A, hard copies of all submitted document for entire programme (10 consecutive allos 5 consecutive autos **whole** programme). **N.B. DATA MANAGER AND NOTES FROM ALL SITES MUST BE PRESENT THROUGHOUT FOR ASSISTANCE***
- *Quality Manual & SOPs and documentation*

2nd Half-day Period

1- Tour around facilities demonstrating links between facilities.

2- 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 Quality Manager
- Laboratory Processing Lead
- Laboratory Quality Manager
- Laboratory Trainee(s) (as appropriate)

**Inspectors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites. For example, Clinical Programme - head nurse, social worker, pharmacy staff, any additional personnel who are needed to answer specific questions on the checklist.*

3rd Half-day Period

1- Continue tour around facilities, interviews and review of remaining documentation


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- 2- Exit Meeting with Programme Director.
- 3- Closing Meeting

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Documents & Information to be facilitated by the applicant on the day of the audit

1. A selection of Donor Notes must be made available for review during the onsite inspection.
2. Evidence of current licensure to practice in the jurisdiction of the transplant programme as well as a written description of responsibilities with description of supervision should be presented.
3. The written copy or electronic version of the SOPs should be readily identifiable to the inspector.
4. The SOPs should be organised in such a manner for the inspector to ascertain that the SOPs are comprehensive, defining all aspects of the transplant programme.
5. The fully and correctly completed orders, worksheets, reports, label and forms should become part of each SOP. The purpose of this standard is to ensure that not only are these documents easily accessible to a reader of the SOP but also provides guidance as to how they should be used.
6. During the chart audit, a knowledgeable member or members of the Data Management Team of the applicant Programme should be present to assist you.
7. The applicant facility and the inspector should complete in its entirety the inspection checklist section or sections that are applicable to the services of the applicant facility. If an entire section of this checklist is not applicable, this fact should be noted at the beginning of that section.
8. There should be a consistent mechanism for conducting the studies, analysing the data, drawing conclusions and making final recommendations. Reports of these activities should be complete, legible and organised for review.
9. Validation may be performed by the Processing Facility or the manufacturer. In the case of manufacturer validation, the certificate of analysis should be available in the facility.
10. The Collection Facility should provide examples of collection errors or products that failed to meet specifications so the inspector can determine how the situation was resolved
11. The manual should be organised in such a manner for the inspector to ascertain that the policies and procedures are comprehensive and define all aspects of the Collection Facility.
12. Documentation of review, validation, if deemed necessary, and/or training should be readily available
13. At least the most recently archived versions of the procedures should be available on-site for review. However, if not feasible, archived procedures may be stored in an easily accessible alternate site.
14. The inspector may ask to review the personnel list and dated training or competency records for a specific individual.
15. Likewise, the inspector may ask to see the records of validation of the aphaeresis instruments
16. Patient files should be examined to verify that these procedures are in effect as described in the SOP. The Processing Laboratory should be prepared to provide examples of processing errors or products that failed to meet specifications so the inspector can determine how the situation was resolved
17. The manual should be organised in such a manner for the inspector to ascertain that the

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- policies and procedures are comprehensive and define all aspects of the Processing Facility.
18. The inspector may ask about the process for review of protocols, ask which IRB is used by the programme, and examine the IRB regulatory binder for a specific study.
 19. The inspector could also ask to see a signed consent form in one of the patient charts and cross check with IRB approval dates