Pre-inspection documentation

Introduction 1
Language 1
Pre-formatted folder structure 2
When do I have to send these document? 2
What does JACIE do with these documents? 2
How does JACIE store and distribute these documents? 3
Contact details 3
Document checklist 5

Introduction

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

See below for full details.

Language

Document should be in the language of the centre since JACIE would expect to assign inspectors that speak and understand the language. However, there may be exceptions to this:

- Centre is located in a country where no inspectors are available
- JACIE may not have inspectors anywhere that speak the centre’s language
- The transplant community in a given country has requested that only external inspectors be assigned to avoid conflicts of interest

In these cases we must resort to other inspectors to perform the inspection. For these inspectors, one of the key parts of their preparation is reading documents made available in advance. Without this it is very difficult for them to arrive on-site adequately prepared and this would clearly affect the quality of the inspection.

In such cases, JACIE will ask the centre to translate a selection of the documents provided to the inspectors in advance of the inspection and will request the centre to provide local experts to facilitate interviews and understanding of documentation.
Please contact the Accreditations Coordinator at jacie@ebmt.org if you have any doubts about this aspect.

Pre-formatted folder structure

The documents are submitted in a pre-formatted .ZIP file (Pre-audit documentation folders.zip) 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.
The zip file is organised into a series of folders and sub-folders relevant to each part of the standards: Clinical, Collection –Bone Marrow and Apheresis- and Processing.
By following the folder layout, you will be able to group and classify your documents in such a way that the inspectors can easily identify the document and its purpose.

See the graphic below to understand how the folders are organised.

Please note that you might have to save the same document into more than one folder. This could be because:

1. The document is relevant to two different sections e.g. labelling for collection and for processing
2. A single document might cover several different areas e.g. donor and patient consent
3. Different inspectors will assess different areas e.g. the clinical inspector will also look at bone marrow while the collection inspector will only look at apheresis

By copying the document to the relevant files, you will make it easier for the inspectors to find the document relevant to their part of the inspection.

Once you have the files gathered together into their relevant folders, you can send them to the JACIE Office.

When do I have to send these documents?

Documents should be sent to the JACIE Office within 30 days after formal approval of the application form. Failure to provide the documents in a timely manner could result in the inspection date being postponed.

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. 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, this 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

Dropbox

The Dropbox security specification can be read at https://www.dropbox.com/privacy#security.

Instructions:

- Download the .zip file to your PC.
- Double-click on the file to open
- Extract the folder to your PC where you can work with the folders and files
- When complete, compress the file again and send to the JACIE Office via one of the channels indicated above.

Contact details

JACIE Accreditation Office
EBMT Secretariat,
Edifici Dr. Frederic Duran i Jordà
Passeig Taulat, 116, 08005 Barcelona (Spain)
Tel: +34 93 453 8570
Fax: +34 93 451 9583
Email: jacie@ebmt.org
www.jacie.org

Illustrative view of the folder structure. For definitive list, see below.

Name of Document: G-002-09-Pre-inspection documentation guide Approved by: Eoin McGrath Responsible: Iris Bargalló Entry: Pre-Inspection documentation list	Creation date: 08/05/2013 Effective date: 22/07/2013 Review date: 14/03/2018 Modification: Adapt references to version 7.0 of the JACIE Standards	

Document checklist

Instructions

- Copies of the following items are required prior to the on-site inspection, and should be submitted in **electronic** format (Word or PDF) with the Inspection Checklist (Excel file) in advance of the onsite visit.
- Please do not use patient names on the documents submitted
- If your facility utilises electronic records, hard copies of the primary source data must be assembled, flagged, and ready for inspector review before the inspection
- Those items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency
- For additional information, see the Standard referenced and/or the guidance in the Accreditation Manual related to that Standard
- Contact the JACIE Office.

Documentation available on the day of the inspection

- A selection of Donor Notes must be made available for review during the onsite inspection.
- Copies of the documents listed below

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	General				
1.	Health authorities licence/certification of facilities, where applicable	B1.3.1, CM1.3.1,C1.3.1, D1.2.1	□	□	□
2.	Programme organizational chart that includes key personnel (position and name)		□	□	□
	Quality Manual, Policies and Procedures:				
3.	Quality Management: Complete copy of the facility's Quality Management Plan/Manual	B4, CM4,C4, D4	□	□	□
4.	Four (4) quarterly reports from previous 12 months	B4.2.2, C4.2.2, D4.2.2	□	□	□
5.	Annual report of QM activities	B4.1.2, C4.1.1, D4.1.1	□	□	□
6.	List of SOPs including Title, version number and date of last		□	□	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	revision for each applicable facility				
7.	SOP describing the process of writing SOPs		□	□	□
8.	SOP for Training	B4.4, C4.4, D4.4	□	□	□
9.	**Validation:** The validation or qualification protocol and an example of one completed validation or qualification study performed by the collection or processing facility staff. An example may be of the validation or qualification of a process, piece of equipment, reagent(s), or supplies used in the Collection or Processing Facility.	C4.14, D4.14	□	□	-
10.	**Cryopreservation:** SOP(s) for each cryopreservation procedure performed in the Processing Facility.	D5.1.7	-	□	-
	Patients				
11.	Complete patient list for the past twelve (12) month period ending approximately 100 days before submission of pre-inspection documentation and checklist. Do not include any direct identifiers including patient names. For programs that transplant both adult and pediatric patients, indicate on the log which patients are pediatric and which are adult. Include in the table: ○ unique patient identifier number (UPN) ○ date of transplant ○ diagnosis ○ source of cells (marrow, peripheral blood, cord blood) ○ type of transplant (autologous; allogeneic).	B1.5	-	-	□
12.	Minimum Essential Data (MED-A) forms. Please do not include any direct identifiers including patient names. Select the applicable consecutive records from the complete patient log for the most recent year (B1.3) for audit, and list these patients by unique patient identifier below. Use additional pages if necessary. • For programs applying for allogeneic accreditation,	B1.5, B9.1	-	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	submit ten consecutive allogeneic records, and five consecutive autologous records. • For programs applying for autologous accreditation only, submit five consecutive autologous records. • For programs with more than 1 clinical site, include at least five patients from each site. • If both paediatric and adult patients are treated in a combined program at the same clinical site include at least five patients in each population. There are two options for preparing the MED-A forms: 1. Data reported to the EBMT Registry can be extracted and presented in the MED-A format in PDFs by following the instructions on the EBMT > Registry website at http://www.ebmt.org/Contents/Data-Management/Dataretrieval/Pages/Data-retrieval.aspx under the section "**MED-A paper form merging**". 2. Alternatively, blank forms can be downloaded from the same web page, completed manually and scanned as PDFs. If you need any assistance with preparing these forms, please contact the Registry Office directly: EBMT Central Registry Office Phone: +44-207-188-8408 Fax: +44-207-188-8411 Email: registryhelpdesk@kcl.ac.uk				
	Consent				
13.	Unsigned consent forms for consent to be a cellular therapy product donor, including the form and any information give to the donor.	B6.2, CM6.2, C6.2	□ (if not the exclusive responsibility of the	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
			clinical unit)		
14.	Unsigned allogeneic and/or autologous consent forms for the cellular therapy product collection procedure (if not previously submitted with the Clinical Program documentation).	B6.2.1, CM6.2.1,C6.2.1	□ (if not the exclusive responsibility of the clinical unit)	-	-
15.	Agreement between donor and storage facility on the storage duration. (It can be included in a more general consent form to be signed before the product collection)	D12.1.1	□ (if not the exclusive responsibility of the clinical unit)	□ (if not the exclusive responsibility of the clinical unit)	□
	Labelling & Product Information				
	Labelling SOP	C5.1.8, D5.1.6	□	□	-
	Completed example of each label used by the processing facility NOTE: Use unique patient identifiers; do not use patient names.	C7, D7			
16.	Primary collection container label, applied at the completion of collection of cells for allogeneic use	Appendix II	□	-	-
17.	Primary collection container label applied at the completion of collection of cells for autologous use	Appendix II	□	-	-
18.	Label applied at completion of processing of allogeneic cells.	Appendix II	-	□	-
19.	Label applied at completion of processing of autologous cells.	Appendix II	-	□	-
20.	Labels attached prior to distribution.	Appendix II	-	□	-
21.	Biohazard and warning labels and method of notifying Clinical staff of biohazard if not written on label.	Appendix III	□	□	-
22.	Labels applied prior to transport of cellular therapy products, including inner and outer shipping labels, if applicable.	Appendix II and III	□	□	-
23.	Documentation that accompanies product at distribution , if applicable	Appendix IV	□	□	-
	Listing of all labels that are applied to each of the following cellular therapy product types:				

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
24.	Autologous cellular therapy product from a fully eligible donor at distribution for administration		-	□	-
25.	Autologous cellular therapy product from a donor with a positive infectious disease marker at distribution for administration		-	□	-
26.	Allogeneic cellular therapy product from a fully eligible donor at distribution for administration		-	□	-
27.	Allogeneic cellular therapy product from a donor with a positive infectious disease marker at distribution for administration		-	□	-
28.	Allogeneic cellular therapy product from a donor with a positive history for infectious disease risk but with negative testing at distribution for administration		-	□	-
29.	Allogeneic cellular therapy product from a donor not tested within 30 days at the time of distribution for administration		-	□	-
30.	Copy of current circular of information in use at your facility.	D11.1.4	-	□	-
	Electronic Records If an electronic record system is used, documentation of validation of the system must be available onsite as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following FACT-JACIE Standards:				
31.	Validated procedures for and documentation of:	D13.2.6			
32.	Systems development	D13.2.6.1	-	□	-
33.	Numerical designation of system versions if applicable	D13.2.6.2	-	□	-
34.	Prospective validation of system including hardware, software, and databases	D13.2.6.3	-	□	-
35.	Installation of the system	D13.2.6.4	-	□	-
36.	Training and continuing competency of personnel in the	D13.2.6.5	-	□	-

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	use of the system				
37.	Monitoring of data integrity	D13.2.6.6	-	□	-
38.	Back-up of the electronic records system on a regular schedule	D13.2.6.7	-	□	-
39.	System maintenance and operations	D13.2.6.8	-	□	-
40.	System assignment of unique identifiers	D13.2.6.9	-	□	-
	Audits				
41.	A list of audits performed in the 12 months prior to document submission including scope of the audit and date	B4.8.1, C4.8.1, D4.8.1	□	□	□
42.	A calendar of audits to be performed and their scope	B4.8.1, C4.8.1, D4.8.1	□	□	□
	Site plans & maps				
43.	General physical floor plan of all Programme facilities. If facilities are not located in the same building, include a map showing locations of all sites.		□	□	□
44.	Description of each of the following services including their location relative to the clinical program site(s):		-	-	-
45.	Radiation Oncology		-	-	□
46.	Emergency Department		-	-	□
47.	Blood Bank or transfusion service		-	-	□
48.	Intensive Care Unit(s),		-	-	□
49.	Pharmacy		-	-	□
50.	Investigational Drug Pharmacy		-	-	□
	Third Party Agreements				
51.	Description of any service(s) (i.e., collection or processing) that is performed for the Clinical Program by another facility under a contract.		-	-	□
52.	Description of any service(s) (i.e., collection or processing) that the applicant program provides for other facilities by contract.		□	□	-
53.	Sample Service Level Agreement (SLA) or contract with an external service provider e.g. microbiology testing laboratory	B4.6, C4.6, D4.6	□	□	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
54.	HLA laboratory: For allogeneic transplant programmes, a copy of the HLA laboratory's current ASHI or EFI accreditation certificate	B2.14	-	-	□
	Personnel				
	Director or Heads of Service (Clinical/Collection/Processing)	B3.1			
55.	Copy of current Medical License for Medical Directors	B3.1.1, C3.1.1, D3.2.1	□	□	□
56.	Curriculum vitae, if not previously submitted, of all directors.	B3.3, C3.4, D3.4	□	□	□
57.	Documented experience including the size and complexity of the program as well as the approximated number of transplant patients the person has managed and photocopies of five (5) representative publications from the field of hematopoietic progenitor cell transplantation extending over ten (10) years.	B3.1.1, C3.1.1, D3.1.1	-	-	□
58.	Written documentation of one (1) year of specific clinical training as defined by Standard B3.3 *or* Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.1.2.	B3.3, C3.1.4 B3.1.2	-	-	□
59.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity: ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.1.6, C3.1.5 , D3.1.3	□	□	□
	All Other Attending Physicians (specify adult and paediatric	B3.2			

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	programmes if applicable):				
60.	Copy(s) of current certificate(s) of higher specialist training	B3.2.1			
61.	Copy of documentation of completion of requisite residency and fellowship	B3.2.1	-	-	□
62.	Copy of current medical license.	B3.2.1	-	-	□
63.	Written documentation of one (1) year of specific clinical training as defined by Standard B3.2 *or* Written documentation of at least two (2) years experience as an attending physician as defined in Standard B3.2.1	B3.4 B3.2.1	-	-	□
64.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity:B3.2.2 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity		-	-	□
	Physician Training for Clinical Programme Directors and Attending Physicians	B3.3			
65.	Written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.3 for each attending physician including Programme Director.	B3.3	-	-	□
66.	For Programmes requesting allogeneic transplantation accreditation, written documentation of specific training and competency in each of the cognitive skills listed in Standard B3.3.4.	B3.3.4, B3.2.2	-	-	□
67.	Written documentation of knowledge in the procedural skills listed in Standard B3.3.5.	B3.3	-	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners, certified nurse midwives, and clinical nurse specialists.	B3.5			
68.	Copies of national certification/license to practice as required by the jurisdiction of the Programme.	B3.5.1	-	-	□
69.	Documentation of training and competency in transplant related cognitive and procedural skills they routinely practice, including but not limited to skills listed in Standards B3.5.2-B3.5.5	B3.5.2	-	-	□
70.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity:B3.5.3.1 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B3.5.3.1	-	-	□
	Consulting Specialists	B3.9			
71.	Documentation of appropriate credentialing of the consulting specialists and/or specialist groups. Clinical Programs are not	B3.9.1, B3.9.2	-	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	required to submit documentation for individual consultants unless requested by the inspector.				
72.	Surgery	B3.9.1.1	-	-	□
73.	Pulmonary Medicine	B3.9.1.2	-	-	□
74.	Intensive Care	B3.9.1.3	-	-	□
75.	Gastroenterology	B3.9.1.4	-	-	□
76.	Nephrology	B3.9.1.5	-	-	□
77.	Infectious Diseases	B3.9.1.6	-	-	□
78.	Cardiology	B3.9.1.7	-	-	□
79.	Pathology	B3.9.1.8	-	-	□
80.	Psychiatry	B3.9.1.9	-	-	□
81.	Radiology	B3.9.1.10	-	-	□
82.	Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.	B3.9.1.11	-	-	□
83.	Transfusion medicine	B3.9.1.12	-	-	□
84.	Neurology.	B3.9.1.13	-	-	□
85.	Ophthalmology	B3.9.1.14	-	-	□
86.	Obstetrics/Gynecology	B3.9.1.15	-	-	□
87.	Dermatology	B3.9.1.16	-	-	□
88.	Palliative and end of life care	B3.9.1.17	-	-	□
	Nurses	B3.7			
89.	Document describing the following: ○ Number of nurses per patient ○ Number of permanent staff / rotational staff ○ Employment of relief nurses ○ Number of nurses with specialist qualifications in oncology and/or haematology	B3.7	-	-	□
	Pharmacists	B3.8			
90.	Copy of current license.	B3.8.1	-	-	□
91.	Written documentation of regular participation in	B.3.8.4	-	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
	educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity B3.8.4.1 ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity				
	Quality Manager	B3.10			
92.	Written documentation of regular participation in educational activities related to the field of hematopoietic progenitor cell transplantation, including the minimum information for each activity ○ Title of activity ○ Type of activity (for example, webinar, meeting, grand round, etc.) ○ Topic of activity (for example, hematology, cell transplantation, etc.) ○ Date of activity ○ Approximate number of hours of activity	B.3.10.2	-	-	□
	Support Services Staff	B3.11			
	Documentation of appropriate credentialing of the support services staff. Clinical Programs are not required to submit documentation for individual consultants unless requested by the inspector.		-	-	□
93.	Dietary staff capable of providing dietary consultation regarding the nutritional needs of the recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.	B3.11.1.1	-	-	□
94.	Social Services staff.	B3.11.1.2	-	-	□

	DOCUMENTATION	STANDARD	COLLECTION	PROCESSING	CLINICAL
95.	Psychology Services staff.	B3.11.1.3	-	-	□
96.	Physical Therapy staff.	B3.11.1.4	-	-	□
97.	Data Management staff sufficient to comply with B9.	B3.11.1.2	-	-	□